CLINICAL STUDY REPORT

A POST MARKETING STUDY OF THE SAFETY, TOLERABILITY, AND PHARMACOKINETICS OF TPOXX® IN ADULT SUBJECTS WEIGHING MORE THAN 120 KG

PROTOCOL NO. SIGA-246-022

Name of Drug:	TPOXX®
Study Design:	Multiple-dose, open-label, safety, tolerability, and PK study in adult subjects weighing more than 120 kg
Sponsor:	SIGA Technologies, Inc. 4575 SW Research Way, Suite 110 Corvallis, OR 97333
Name of Sponsor Signatory:	Dennis E. Hruby, PhD Chief Scientific Officer Telephone: 541-753-2000
Drug Development Phase:	4
Study Initiation Date:	First Subject First Visit: 19 July 2019
Study Completion Date:	Last Subject Last Visit: 05 December 2019
Principal Investigator:	[redacted]
Report Date:	30 March 2020

This study was conducted according to the International Council for Harmonisation Guideline E6(R2): Good Clinical Practice, including the archiving of essential documents at:

[redacted]

CONFIDENTIAL

SIGNATURE PAGE

STUDY TITLE: A Post Marketing Study of the Safety, Tolerability, and Pharmacokinetics of TPOXX® in Adult Subjects Weighing More Than 120 kg

PROTOCOL NUMBER: SIGA-246-022

I have read this report and confirm that to the best of my knowledge it accurately describes the conduct and results of the study.

[redacted]

[redacted]

31 Mar 2020

[redacted]

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[redacted]

SIGNATURE PAGE

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APPROVED BY:

[redacted]

Dennis E. Hruby, PhD
Chief Scientific Officer
SIGA Technologies, Inc.

31 May 2020
Date

2. SYNOPSIS

STUDY TITLE: A Post Marketing Study of the Safety, Tolerability, and Pharmacokinetics of TPOXX® in Adult Subjects Weighing More Than 120 kg

INVESTIGATOR: [redacted]

STUDY SITE: [redacted]

PUBLICATION (REFERENCE): None

STUDY PERIOD:
First Subject First Visit: 19 July 2019

Last Subject Last Visit: 05 December 2019

PHASE OF DEVELOPMENT: 4

OBJECTIVES:
The primary objective of this study was to determine the pharmacokinetic (PK) profile of 600 mg oral TPOXX (3 × 200-mg capsules) administered twice daily (BID) for 7 days in adult subjects weighing more than 120 kg to determine if a change in TPOXX dosing regimen would be needed in these patients.

The secondary objective of this study was to evaluate the safety and tolerability of 600 mg oral TPOXX administered BID for 7 days in adult subjects weighing more than 120 kg.

METHODOLOGY:
This was an open-label, multiple-dose study to assess the safety, tolerability, and PK of TPOXX 600 mg BID when administered orally for 7 days to adult subjects weighing more than 120 kg. A total of 34 subjects, aged 20 to 50 years, inclusive, were enrolled. The study consisted of a screening period (Day –28 to –2), a treatment and confinement period (Days –1 to 9), a follow-up telephone call or visit (Day 14 [+2 days]), and a follow-up telephone call (Day 37 [+2 days]).

Subjects underwent screening evaluations to determine eligibility within 28 days before study drug administration. Subjects were admitted to the study site on Day –1 to complete baseline assessments, the results of which were reviewed by the investigator before dosing. Starting on the morning of Day 1, subjects received 600 mg oral TPOXX BID for 7 days (Days 1 through 7).

All subjects were provided meals (consisting of approximately 600 calories and 25 g fat) 30 minutes prior to study drug administration, and subjects fasted for 2 hours after taking study drug. Subjects ate this meal within 30 minutes or less of taking study drug. Study drug and meals were taken with water only, and no other beverage except water was ingested within 3 hours before and 3 hours after study drug administration.

Subjects remained confined to the study site for collection of PK samples and were carefully monitored for safety and tolerability until discharge on Day 9. Subjects who had abnormal physical examination findings or an ongoing adverse event (AE)/serious AE (SAE) on Day 9 that was deemed related to study drug or per investigator or SIGA discretion, returned to the study site on Day 14 (+2 days) for a follow-up visit. All other subjects had their Day 14 (+2 days) follow-up via a telephone call. All subjects had a follow-up telephone call 30 days

after administration of the last dose of study drug (Day 37 [+2 days]) to report any SAEs. At the time of discharge from the study site, subjects were instructed to notify the investigator of any SAEs that occurred within 30 days after administration of the last dose of study drug. Serious AEs were followed until the SAE was stable or until resolution, as determined by the investigator and/or medical monitor.

Number of subjects:
Up to 36 subjects were planned for this study to allow at least 32 enrolled subjects to complete. Thirty-four subjects were enrolled and completed the study.

Diagnosis and main criteria for inclusion:
Male and female subjects between 18 and 50 years of age, inclusive; who weighed more than 120 kg at screening, at check-in on Day –1, and prior to dosing on Day 1; and who were assessed by the investigator to be in good general health as determined by medical history, clinical laboratory results, vital sign measurements, 12-lead electrocardiogram (ECG) results, and physical examination findings at screening.

Test product, dose, and mode of administration, lot number:
TPOXX 600 mg (3 × 200-mg capsules) oral BID on Days 1 to 7, [redacted].

Reference therapy, dose, and mode of administration, lot number:
Not applicable.

Duration of treatment:
The total duration of the study for each subject, including the screening period, treatment and confinement period, and the Day 37 (+2 days) follow-up telephone call, was approximately 65 days.

CRITERIA FOR EVALUATION:
Pharmacokinetics:
Blood samples for the PK analysis of TPOXX were collected from all subjects on Day 1 before study drug administration (0 hour), at 0.5, 1, 2, 4, 6, 8, 12 (before the PM dose), 14, 16, 18, 20, and 24 hours (before the AM dose on Day 2), on Day 6 (before the AM dose and 4 hours after the AM dose), on Day 7 before the AM dose (0 hour), at 0.5, 1, 2, 4, 6, 8, 12 (before the PM dose), 14, 16, 18, 20, and 24 hours (Day 8, 24 hours after the AM dose on Day 7), and on Day 9 (48 hours after the AM dose on Day 7).

The individual plasma concentration versus actual time data for TPOXX were used to derive the PK parameters:

- Area under the plasma concentration versus time curve (AUC) from time 0 to the last quantifiable measurement (AUC_{0-t}).
- AUC from time 0 to 24 hours postdose (AUC_{0-24}).
- AUC during the first dosing interval (AUC_{0-tau}; tau = 12 hours).
- AUC from time 0 extrapolated to infinity (AUC_{0-inf}).
- Percentage of AUC_{0-inf} extrapolated from the last quantifiable measurement to infinity ($\%AUC_{extrap}$).

- Maximum observed plasma drug concentration (C_{max}).
- Time to reach C_{max} (T_{max}).
- Terminal elimination rate constant (λ_z).
- Terminal elimination half-life ($t_{1/2}$).
- Apparent total body clearance (CL/F).
- Apparent volume of distribution (V_d/F).
- Concentration observed prior to the next dose administration (C_{trough}).

Safety:
Safety and tolerability were assessed by monitoring and recording of AEs, clinical laboratory test results (hematology, serum chemistry, and urinalysis), vital sign measurements (systolic and diastolic blood pressures, heart rate, respiratory rate, and body temperature), 12-lead ECG results, and physical examination findings.

STATISTICAL METHODS:
Pharmacokinetics:
Individual plasma concentrations, actual time, and deviation from the scheduled time are presented in a data listing by subject, study day, and nominal time point. Plasma concentration data are summarized by day and time point using the following descriptive statistics: sample size (n), arithmetic mean, geometric mean, SD, geometric SD, coefficient of variation (CV), geometric CV (calculated as sqrt [exp [variance for log transformed data] – 1] × 100), median, minimum, and maximum.

Individual, mean (±SD), and trough (±SD) plasma TPOXX concentration versus time profiles are presented in figures on both linear and semilogarithmic scales. Mean plasma concentration versus time profiles are presented using nominal time and individual plasma concentration versus time profiles are presented using actual time.

Actual sampling times, rather than scheduled sampling times, are used in the computation of PK parameters. However, for ease of presentation, scheduled sampling times are used to present results in summary tables. The individual PK parameters of TPOXX are presented in a data listing. The PK parameters are summarized by day using the following descriptive statistics: n, arithmetic mean, geometric mean, SD, CV, geometric SD, geometric CV, median, minimum, and maximum. For T_{max}, only n, median, minimum, and maximum are included in descriptive statistics. Geometric mean, geometric SD, and geometric CV are included for the AUCs and C_{max}.

No formal statistical analysis of PK data was performed for this study.

Safety:
Adverse events were coded by preferred term (PT) and system organ class (SOC) using the Medical Dictionary for Regulatory Activities (MedDRA, Version 22.0).

An overall summary of all AEs is presented. The number and percentage of subjects, as well as the number of AEs are presented for each of the following categories: any AE; any Grade 2, Grade 3, Grade 4, and Grade 5 AE; any treatment-related AE (TRAE); any Grade 2,

Grade 3, Grade 4, and Grade 5 TRAE; any SAE; any serious TRAE, and any AE leading to discontinuation of study drug. In addition, the table includes a summary of the time to first AE and the time to first AE of Grade 3 or higher. Adverse events are summarized by SOC and PT and by PT alone, including the total number of AEs and the number and percentage of subjects with at least one AE.

Summaries of AEs by relationship to study drug and severity are presented in tables by incidence of occurrence. Treatment-related AEs are presented in a data listing. All AEs and SAEs are presented in a data listing. All AEs leading to study drug discontinuation are presented in a data listing.

Observed values and changes from baseline are summarized for hematology, serum chemistry, and urinalysis laboratory tests with numeric values for subjects in the safety population. Changes from baseline to each scheduled postbaseline visit are presented. Changes in low, normal, high, and abnormal classifications are summarized in shift tables comparing the results at each scheduled postbaseline visit with those at the baseline visit. Shift tables are presented for subjects in the safety population. Where possible, abnormal clinical laboratory values were graded for severity according to the Division of Acquired Immune Deficiency Syndrome (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse Events. The maximum increase in DAIDS grade postbaseline (including both scheduled and unscheduled visits) is summarized and presented.

Observed values and changes from baseline are summarized for vital sign data and 12-lead ECG parameters for subjects in the safety population. Changes from baseline to each scheduled postbaseline visit are presented.

All clinical laboratory test results, vital sign measurements, 12-lead ECG data, and physical examination findings are presented in data listings.

RESULTS:

Pharmacokinetic Results:

Following BID oral administration of TPOXX 600 mg, plasma concentrations of TPOXX were detected immediately after dosing and reached peak levels around 4 hours after dosing. Steady state was achieved by Day 6 following administration of TPOXX for 7 days.

On Day 1, mean plasma exposure values for C_{max}, AUC_{0-24}, and AUC_{0-tau} were 847 ng/mL, 11900 ng*h/mL, and 5130 ng*h/mL, respectively. Mean plasma trough concentration, calculated prior to the third dose, was 517 ng/mL and median T_{max} was 4 hours after dosing. The mean $t_{1/2}$ was 8.46 hours (note that this could only be calculated in 32% of the total subjects due to having insufficient data in the terminal phase).

On Day 7, steady-state mean plasma exposure values for C_{max}, AUC_{0-24}, and AUC from time 0 to 12 hours postdose (AUC_{0-12}) were 1350 ng/mL, 20000 ng*h/mL, and 9830 ng*h/mL, respectively. The mean steady-state $t_{1/2}$ and CL/F values were 12.9 hours and 64.8 L/h, respectively. Mean plasma steady-state trough concentration, calculated prior to the second dose on Day 7, was 617 ng/mL. Median T_{max} was 4 hours after dosing at steady state.

The ratio (Day 7/Day 1) of mean plasma exposure C_{max}, AUC_{0-24}, and AUC_{0-tau} ranged from 1.6 to 1.9, suggesting plasma accumulation of TPOXX at steady-state.

Safety Results:
A total of 9 of 34 subjects (26.5%) reported 12 AEs during the study. A total of 2 of 34 subjects (5.9%) reported 2 TRAEs. The most commonly reported AEs were in the SOCs of gastrointestinal disorders (3 subjects, 8.8%) and nervous system disorders (2 subjects, 5.9%). The most commonly reported AEs were nausea and headache (2 subjects, 5.9% each). All other AEs were reported by 1 subject (2.9%) each. No AEs above Grade 1 (mild; 9 subjects) were reported in this study. All AEs were reported as recovered/resolved by the end of the study. There were no SAEs, serious TRAEs, or AEs leading to study drug or study discontinuation during the study. There were no notable safety signals in results from safety assessments.

Mean clinical laboratory test results (hematology, serum chemistry, and urinalysis), vital sign measurements, physical examination findings, and 12-lead ECG values after dosing were generally similar to baseline values. No individual clinical laboratory test result, vital sign measurement, physical examination finding, or 12-lead ECG value was associated with an AE or considered clinically significant by the investigator. All clinical laboratory test results with toxicity grades were no higher than DAIDS Grade 1 or 2.

CONCLUSIONS:
Pharmacokinetics:

- Following BID oral administration of TPOXX 600 mg, plasma concentrations of TPOXX were detected immediately after dosing and reached peak levels around 4 hours after dosing.
- Steady state was achieved by Day 6 following administration of TPOXX for 7 days.
- On Day 1, mean plasma exposure values for C_{max}, AUC_{0-24}, and AUC_{0-tau} were 847 ng/mL, 11900 ng*h/mL, and 5130 ng*h/mL, respectively. Mean plasma trough concentration, calculated prior to the third dose, was 517 ng/mL and median T_{max} was 4 hours after dosing. The mean $t_{1/2}$ was 8.46 hours (note that this could only be calculated in 32% of the total subjects due to having insufficient data in the terminal phase).
- On Day 7, steady-state mean plasma exposure values for C_{max}, AUC_{0-24}, and AUC_{0-12} were 1350 ng/mL, 20000 ng*h/mL, and 9830 ng*h/mL, respectively. The mean steady-state $t_{1/2}$ and CL/F values were 12.9 hours and 64.8 L/h, respectively. Mean plasma steady-state trough concentration, calculated prior to the second dose on Day 7, was 617 ng/mL. Median T_{max} was 4 hours after dosing at steady state.
- The ratio (Day 7/Day 1) of mean plasma exposure C_{max}, AUC_{0-24}, and AUC_{0-tau} ranged from 1.6 to 1.9, suggesting plasma accumulation of TPOXX at steady-state.
- SIGA will incorporate the PK data for the 34 subjects enrolled in this study into a population PK model which is being developed outside of this clinical study to inform if a change in dosing regimen would be needed in these patients.

Safety:
TPOXX was considered safe and generally well tolerated when administered orally at a dose of 600 mg BID for 7 days in adult subjects weighing more than 120 kg.

DATE OF REPORT: 30 March 2020

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4. LIST OF ABBREVIATIONS AND DEFINITION OF TERMS

ABBREVIATION	TERM
AE	adverse event
AUC_{0-12}	area under the plasma concentration versus time curve from time 0 to 12 hours postdose
AUC_{0-24}	area under the plasma concentration versus time curve from time 0 to 24 hours postdose
AUC_{0-inf}	area under the plasma concentration versus time curve from time 0 extrapolated to infinity
AUC_{0-t}	area under the plasma concentration versus time curve from time 0 to the last quantifiable measurement
AUC_{0-tau}	area under the plasma concentration versus time curve during the first dosing interval
BCRP	breast cancer resistance protein
BID	twice daily
BLQ	below the limit of quantification
CFR	Code of Federal Regulations
CL/F	apparent total body clearance
C_{max}	maximum observed plasma drug concentration
C_{trough}	concentration observed prior to the next dose administration
CV	coefficient of variation
CYP	cytochrome P450
DAIDS	Division of Acquired Immune Deficiency Syndrome
ECG	electrocardiogram
eCRF	electronic case report form
ED	early discontinuation
FDA	Food and Drug Administration
FSH	follicle-stimulating hormone
HBsAg	hepatitis B surface antigen
HCV	hepatitis C virus
HIV	human immunodeficiency virus
ICF	informed consent form
ICH	International Council for Harmonisation
IRB	institutional review board
ISM	independent safety monitor
MedDRA	Medical Dictionary for Regulatory Activities
NDA	New Drug Application
PK	pharmacokinetic(s)
PT	preferred term
QTcB	QT interval corrected using Bazett's formula

ABBREVIATION	TERM
QTcF	QT interval corrected using Fridericia's formula
SAE	serious adverse event
SOC	system organ class
$t_{1/2}$	terminal elimination half-life
T_{max}	time to reach C_{max}
TRAE	treatment-related adverse event
US	United States
V_d/F	apparent volume of distribution

5. ETHICS

5.1 INSTITUTIONAL REVIEW BOARD

The original study protocol, dated 19 February 2019, Amendment 1, dated 27 June 2019, and Amendment 2, dated 02 August 2019, were submitted to the institutional review board (IRB; ADVARRA) for ethical review. Approval was obtained in writing before the study began. All changes to the protocol were approved by the IRB before implementation.

The original protocol and Amendments 1 and 2 are presented in Appendix 16.1.1. A sample electronic case report form (eCRF) is presented in Appendix 16.1.2. The IRB information is presented in Appendix 16.1.3.

5.2 ETHICAL CONDUCT OF THE STUDY

The investigator agreed to conduct the study according to the principles of the International Council for Harmonisation (ICH) harmonised tripartite guideline E6(R2): Good Clinical Practice. The investigator performed all aspects of this study in accordance with the ethical principles that have their origin in the Declaration of Helsinki, the protocol, and all national, state, and local laws or regulations.

5.3 SUBJECT INFORMATION AND CONSENT

A written informed consent in compliance with United States (US) Title 21 Code of Federal Regulations (CFR) Part 50 was obtained from each subject before entering the study and before any study-related assessment or procedure was performed. The informed consent form (ICF) was submitted by the investigator to the IRB for review and approval before the start of the study.

Subjects that enrolled and completed the study before 23 Sep 2019, signed the original ICF, dated 13 Jun 2019 and a second version of the ICF, dated 23 Jul 2019. Subjects that were enrolled in the study prior to 23 Sep 2019 but were still actively participating in the study on 23 Sep 2019, signed the second version of the ICF, dated 23 Jul 2019, and also signed the new ICF, dated 23 Sep 2019. Subjects that were enrolled in the study on or after 23 Sep 2019 only signed the new ICF, dated 23 Sep 2019.

Before recruitment and enrollment, each prospective subject was given a full explanation of the study and was required to read the approved ICF. Once the investigator was assured that the subject understood the implications of participating in the study, the subject was asked to give consent to participate in the study by signing the ICF and received a signed and dated copy. A copy of the ICF is provided in Appendix 16.1.3.

6. INVESTIGATORS AND STUDY ADMINISTRATIVE STRUCTURE

This was a single-center study conducted by the principal investigator, [redacted] The investigator's curriculum vitae is presented in Appendix 16.1.4.

The following laboratories were used:

Clinical Laboratory:

PPD Central Laboratory
7551 Metro Center Drive, Suite 200
Austin, TX 78744.

Bioanalytical Laboratory:

Alturas Analytics, Inc.
1324 Alturas Drive
Moscow, ID 83843.

PPD served as the contract research organization for this study and was responsible for program and project management, clinical and pharmacovigilance for safety reporting, clinical monitoring, medical monitoring, medical writing, clinical data management, pharmacokinetic (PK) and biostatistical plan and analysis, and final reporting. The individuals involved either in coordination of the study or in analysis and reporting of results are presented in Table 6-1.

Table 6-1 Individuals Responsible for Study Conduct

Name	Title	Duties
[redacted]	Principal Investigator	Responsible for study conduct and supervision of study staff and subjects
[redacted]	Medical Monitor	Medical monitoring
[redacted]	Senior Project Manager	Overall management of the study
[redacted]	Project Manager	Management of the study conduct and liaison with biostatistics, medical writing, and clinical laboratory personnel
[redacted]	Biostatistician	Development of statistical analysis plan and analysis of statistical data
[redacted]	Pharmacokineticist	Analysis of pharmacokinetic data
[redacted]	Clinical Data Manager	Responsible for data management
[redacted]	Senior Clinical Research Associate	Responsible for clinical research associate and monitoring activities
[redacted]	Medical Writer	Preparation of clinical study protocol
[redacted]	Medical Writer	Preparation of clinical study report

7. INTRODUCTION

Historically, variola virus (VARV), the etiologic agent of smallpox, has been one of the more important human pathogens. Smallpox is highly communicable and carries exceptionally high morbidity. Secondary attack rates from 30% to 80% have been reported among unvaccinated members of households.[1] Mortality rates range from 1% for variola minor to 30% for variola major.[1] With the advent of biowarfare as an instrument of terrorism, smallpox can no longer be thought of as a disease only of historic impact.

In July 2018, the US Food and Drug Administration (FDA) approved the oral formulation of TPOXX for the treatment of patients with smallpox disease caused by VARV.

This study was conducted as an FDA post marketing commitment to the approved New Drug Application (NDA) for TPOXX (NDA 208,627). SIGA was required to conduct a study to determine the PK profile of TPOXX in subjects with a body weight greater than 120 kg to determine if a change in TPOXX dosing regimen would be needed in these patients.

8. STUDY OBJECTIVES

8.1 PRIMARY OBJECTIVE

The primary objective of this study was to determine the PK profile of 600 mg oral TPOXX (3 × 200-mg capsules) administered twice daily (BID) for 7 days in adult subjects weighing more than 120 kg to determine if a change in TPOXX dosing regimen would be needed in these patients.

8.2 SECONDARY OBJECTIVE

The secondary objective of this study was to evaluate the safety and tolerability of 600 mg oral TPOXX administered BID for 7 days in adult subjects weighing more than 120 kg.

9. INVESTIGATIONAL PLAN

9.1 OVERALL STUDY DESIGN AND PLAN

This was an open-label, multiple-dose study to assess the safety, tolerability, and PK of TPOXX 600 mg BID when administered orally for 7 days to adult subjects weighing more than 120 kg. A total of 34 subjects, aged 20 to 50 years, inclusive, were enrolled. The study consisted of a screening period (Day –28 to –2), a treatment and confinement period (Days –1 to 9), a follow-up telephone call or visit (Day 14 [+2 days]), and a follow-up telephone call (Day 37 [+2 days]).

Subjects underwent screening evaluations to determine eligibility within 28 days before study drug administration. Subjects were admitted to the study site on Day –1 to complete baseline assessments, the results of which were reviewed by the investigator before dosing. Starting on the morning of Day 1, subjects received 600 mg oral TPOXX BID for 7 days (Days 1 through 7).

All subjects were provided meals (consisting of approximately 600 calories and 25 g fat) 30 minutes prior to study drug administration, and subjects fasted for 2 hours after taking study drug. Subjects ate this meal within 30 minutes or less of taking study drug. Study drug and meals were taken with water only, and no other beverage except water was ingested within 3 hours before and 3 hours after study drug administration.

Subjects remained confined to the study site for collection of PK samples and were carefully monitored for safety and tolerability until discharge on Day 9. Subjects who had abnormal physical examination findings or an ongoing adverse event (AE)/serious AE (SAE) on Day 9 that was deemed related to study drug or per investigator or SIGA discretion, returned to the study site on Day 14 (+2 days) for a follow-up visit. All other subjects had their Day 14 (+2 days) follow-up via a telephone call. All subjects had a follow-up telephone call 30 days after administration of the last dose of study drug (Day 37 [+2 days]) to report any SAEs. At the time of discharge from the study site, subjects were instructed to notify the investigator of any SAEs that occurred within 30 days after administration of the last dose of study drug. Serious AEs were followed until the SAE was stable or until resolution, as determined by the investigator and/or medical monitor.

The total duration of the study for each subject, including the screening period, treatment and confinement period, and the Day 37 (+2 days) follow-up telephone call, was approximately 65 days.

9.2 DISCUSSION OF STUDY DESIGN, INCLUDING THE CHOICE OF CONTROL GROUPS

This study included the recognized elements of a well-controlled nonrandomized clinical study.

This study was being conducted as an FDA post marketing commitment to the approved NDA for TPOXX (NDA 208, 627). SIGA was required to conduct a study to determine the PK profile of TPOXX in subjects with a body weight greater than 120 kg to determine if a change in TPOXX dosing regimen would be needed in these patients.

9.3 SELECTION OF STUDY POPULATION

9.3.1 Inclusion Criteria

For inclusion in the study, each subject was required to meet all of the following criteria:

1. Subject was male or female between 18 and 50 years of age, inclusive.
2. Subject had a body weight >120 kg at screening, at check-in on Day –1, and prior to dosing on Day 1.
3. Women of childbearing potential had a negative β human chorionic gonadotropin pregnancy test (serum) at the screening visit and a confirmatory negative serum pregnancy test on Day –1 before receipt of study drug, and met at least 1 of the following criteria:
    a. The subject and their partner had undergone surgical sterilization.
    b. The subject was postmenopausal, defined as 12 consecutive months with no menses without an alternative medical cause and had a documented plasma follicle-stimulating hormone (FSH) level >40 IU/mL.
    c. The subject agreed to be abstinent (i.e., heterosexually inactive or women in a religious order).
    d. The subject agreed to consistently use 1 of the following methods of contraception from the beginning of screening (which they had been consistently using for at least 30 days before the first dose of study drug) through 30 days after the last dose of study drug:
        i. Condoms, male or female, with a spermicide.

            NOTE: For male subjects, condoms must have been used for 90 days after the last dose of study drug.

        ii. Diaphragm or cervical cap with spermicide.
        iii. Intrauterine device with spermicide.
        iv. Oral contraceptives or other hormonal methods.

            NOTE: Subject must have agreed to use an additional nonhormonal method of contraception in conjunction with oral contraceptives.

        v. Male sexual partner who had undergone a vasectomy at least 3 months before screening.

4. If male, subject agreed not to donate sperm from the first dose of study drug through 90 days after the last dose of study drug.
5. Subject was considered by the investigator to be in good general health as determined by medical history (no hospitalizations for chronic medical conditions in the previous 2 years), clinical laboratory results, vital sign measurements, 12-lead electrocardiogram (ECG) results, and physical examination findings at screening.
6. Subject agreed to comply with all protocol requirements.
7. Subject was able to provide written informed consent.
8. Subject agreed to comply with the dietary requirements.
9. Subject did not intend to lose weight (diet or weight loss) from the screening visit and throughout the study.

9.3.2 Exclusion Criteria

Any of the following was regarded as a criterion for exclusion of a subject from the study:

1. Subject was a female who was pregnant or breastfeeding or planning to become pregnant within 3 months after the last dose of study drug.
2. Subject had a history of any clinically significant conditions including:
    - Asthma treated with oral systemic steroids within the past 6 months.
    - Diabetes mellitus (type 1 or 2), with the exception of gestational diabetes.
    - Thyroidectomy or thyroid disease that required medication within the past 12 months.
    - Serious angioedema episodes within the previous 3 years or required medication in the previous 2 years.
    - Head trauma resulting in a diagnosis of traumatic brain injury other than concussion.
    - Frequent episodes of headache.
3. Subject had received treatment in another clinical study of an investigational drug (or medical device) within 30 days or 5 half-lives (whichever was longer) before the first dose of study drug.
4. Subject had been previously enrolled in any clinical study involving TPOXX (tecovirimat).
5. Subject had a history of relevant drug and/or food allergies (i.e., allergy to tecovirimat or excipients, or any significant food allergy that could have precluded a standard diet at the study site).

6. Subject had any condition that could have possibly affected drug absorption (e.g., previous surgery on the gastrointestinal tract, including removal of parts of the stomach, bowel, liver, gallbladder, or pancreas, with the exception of appendectomy).
7. Subject had evidence or history of clinically significant allergic (except for untreated, asymptomatic, seasonal allergies at the time of the first dose of study drug) hematological, endocrine, pulmonary, gastrointestinal, cardiovascular, hepatic, psychiatric, or neurological disease. An exception to this criterion (e.g., stable, mild joint disease unassociated with collagen vascular disease) could have been made following discussions with the medical monitor.
8. Subject had a history of cardiac disease, symptomatic or asymptomatic arrhythmias, syncopal episodes, or risk factors for torsades de pointes (e.g., heart failure, hypokalemia).
9. Subject had a family history of sudden cardiac death not clearly due to acute myocardial infarction.
10. Subject had a seizure disorder or history of seizures (not including childhood febrile seizures) or a past history that increased seizure risks such as significant head injury that caused loss of consciousness or other changes in the subject's daily function, concussion, stroke, central nervous system infection or disease, or alcohol or drug abuse, or family history or idiopathic seizures.
11. Subject had a history of a peptic ulcer or significant gastrointestinal bleed.
12. Subject had a bleeding disorder diagnosed by a doctor (e.g., factor deficiency, coagulopathy, or platelet disorder requiring special precautions) or significant bruising or bleeding difficulties with blood draws.
13. Subject had a malignancy that was active, or treated malignancy for which there was not a reasonable assurance of sustained cure, or malignancy that was likely to recur during the period of the study (subject should have been in complete remission for at least 5 years).
14. Subject had neutropenia or other blood dyscrasia determined to be clinically significant by the investigator.
15. Subject had used any of the following prohibited medications from within 7 days (or 5 half-lives; whichever was longer) before the first dose of study drug: antidiabetic medication; anticoagulants; anticonvulsants; substrates of the breast cancer resistance protein (BCRP) transporter including methotrexate, mitoxantrone, imatinib, irinotecan, lapatinib, rosuvastatin, sulfasalazine, and topotecan; substrates of cytochrome P450

(CYP) 2C8 including repaglinide, paclitaxel, Montelukast, pioglitazone, rosiglitazone; and substrates of CYP2C19 including S-mephenytoin, clobazam, diazepam, rabeprazole, voriconazole, lansoprazole, and omeprazole. Medications not listed here that were known (or thought) to be CYP3A4 substrates may have been allowed at the investigator's discretion, after consultation with the medical monitor, if administration posed little to no risk to the subject.

16. Subject had a history of drug or alcohol abuse or dependency within the last year before screening.
17. Subject had a history of an eating disorder.
18. Subject had a current or recent (<30 days before screening) history of clinically significant bacterial, fungal, or mycobacterial infection.
19. Subject had a current clinically significant viral infection.
20. Subject had a known clinically significant chronic viral infection (e.g., human T cell lymphotropic virus I or II).
21. Subject had consumed grapefruit or grapefruit juice, Seville orange or Seville orange-containing products (e.g., marmalade), or caffeine- or xanthine-containing products within 48 hours before the first dose of study drug or throughout the study.
22. Subject had used any prescription (excluding hormonal birth control) or over-the-counter medication (including herbal or nutritional supplements) within 14 days before the first dose of study drug.
23. Subject demonstrated long-term use (≥14 consecutive days) of glucocorticoids including oral or parenteral prednisone or equivalent (>20 mg total dose per day) or high-dose inhaled steroids (>800 mcg/day or beclomethasone dipropionate or equivalent) within the preceding 1 month (low dose [≤800 mcg/day of beclomethasone dipropionate or equivalent] inhaled and topical steroids were allowed).
24. Subject had donated >450 mL blood or blood components within 30 days before the first dose of study drug. The investigator instructed subjects who participated in this study not to donate blood or blood components for 4 weeks after the completion of the study.
25. Subject was a smoker or had used nicotine or nicotine-containing products (e.g., cigarettes, electronic vapor cigarettes, cigars, chewing tobacco, snuff, nicotine patches, or nicotine gum) within 6 months before the first dose of study drug.
26. Subject had consumed pomegranate or pomegranate juice, pomelo fruits or pomelo juice, or alcohol within 72 hours before the first dose of study drug.

27. Subject reported participation in strenuous activity or contact sports within 24 hours before the first dose of study drug.
28. Subject had known hepatitis B or C infection or positive test for hepatitis B surface antigen (HBsAg), hepatitis C virus (HCV) antibody, or human immunodeficiency virus (HIV) type 1 or 2 antibodies at screening.
29. Subject had a positive test result for amphetamines (including methamphetamines and ecstasy/methylenedioxymethamphetamine), barbiturates, benzodiazepines, cannabinoids (including tetrahydrocannabinol), cocaine metabolites, opiates (including heroin, codeine, and oxycodone), or alcohol at screening or check-in.
30. Subject had any of the following laboratory test results within 28 days before the first dose of study drug:
    - Estimated serum creatinine clearance (Cockcroft-Gault) <90 mL/min.
    - Creatinine in males >1.7 mg/dL and in females >1.4 mg/dL (1.3 times the upper central laboratory reference range).
    - Hemoglobin ≤10% of the lower central laboratory reference range.
    - White blood cell count not within the central laboratory reference range.
    - Absolute neutrophil count <1000 cells/mm^3.
    - Platelets not within ±10% of central laboratory reference range.
    - Alanine aminotransferase >1.5 times above the upper central laboratory reference range.
    - Aspartate aminotransferase >1.5 times above the upper central laboratory reference range.
    - Alkaline phosphatase >20% above the upper central laboratory reference range.
    - Hemoglobin A1c ≥7.0%.
    - Cholesterol ≥300 mg/dL and low-density lipoprotein ≥190 mg/dL.
31. Subject had a blood pressure considered to be clinically significant by the investigator. Blood pressure could have been retested twice in the sitting position at 5-minute intervals.
32. Subject had a resting heart rate of <40 beats per minute or >100 beats per minute at screening.
33. Subject had an abnormal ECG at screening that was determined by the investigator to be clinically significant.

34. Male subject had a QT interval corrected using Fridericia's formula (QTcF) >450 ms or female subject had a QTcF >470 ms at screening or Day –1.

35. In the opinion of the investigator, the subject was not suitable for entry into the study.

9.3.3 Subject Restrictions During the Study

Subject must have been willing to remain confined at the study site from check-in (Day –1) until safety assessments were completed on Day 9. Subjects who had abnormal physical examination findings or an ongoing AE/SAE on Day 9 that was deemed related to study drug or per investigator or SIGA discretion, returned to the study site on Day 14 (+2 days) for a follow-up visit.

9.3.4 Removal of Subjects From the Study

Reasons for Withdrawal

Subject could withdraw consent and discontinue from the study at any time, for any reason, without prejudice to further treatment.

The investigator may have withdrawn a subject from the study for any of the following:

- The subject was in violation of the protocol.
- The subject experienced a serious or intolerable AE.
- The subject became pregnant.
- The subject was noncompliant.
- The subject had laboratory abnormalities for assessments listed in Sections 9.3.1 or 9.3.2 that met Grade 3 or 4 on the Division of Acquired Immune Deficiency Syndrome (DAIDS) AE Grading Table, version 2.1 July 2017; or any other Grade 3 or 4 AE; or a Grade 2 or higher rash considered by the investigator to be possibly, probably, or definitely related to study drug.
- The subject developed, during the course of the study, symptoms or conditions listed in the exclusion criteria (Section 9.3.2).
- The subject required a medication prohibited by the protocol.
- The subject requested an early discontinuation for any reason.
- The subject's primary care provider requested that the subject be withdrawn.

- The independent safety monitor (ISM), SIGA, or the FDA requested subject withdrawal based on study safety findings.

Handling of Withdrawals

Subjects were free to withdraw from the study at any time upon request. Subject participation in the study may have been stopped at any time at the discretion of the investigator or at the request of SIGA.

In the event that a subject withdrew from the study, the reason(s) for withdrawal were to be recorded by the investigator in the eCRF. Wherever possible, any subject who withdrew from the study were to prematurely undergo all Day 9/early discontinuation assessments (Table 9-3). Any subject who failed to return for final assessments was to be contacted by the study site personnel in an attempt to have them comply with the protocol. The status of subject who failed to complete final assessments was to be documented in the eCRF.

Halting Rules

The medical monitor, investigator, SIGA, and ISM reviewed all AEs. All AEs determined by the investigator to be severe and possibly, probably, or definitely related to study drug, as well as all clinical assessments, laboratory test results, ECG results, or vital sign measurements that met Grade 3 criteria based on the DAIDS AE Grading Table were assessed by the medical monitor, who made a recommendation as to whether or not halting of the study should have occurred. At the discretion of the medical monitor, depending on the assessment of the severity of the event, the recommendation to halt the study may have been made after consultation with the investigator, SIGA, and the ISM.

The study was to be temporarily halted (no new enrollments and no further study drug administration) by the investigator and the medical monitor, SIGA, and the ISM were promptly notified according to the following criteria:

- One subject experienced a Grade 4 AE assessed as possibly, probably, or definitely related to study drug.
- There was a subject death assessed as possibly, probably, or definitely related to study drug.
- One subject experienced a seizure assessed as possibly, probably, or definitely related to study drug.
- Two or more subjects experienced the same or similar SAEs that were assessed as possibly, probably, or definitely related to study drug.

- Three or more subjects experienced the same or similar AEs that were Grade 3 or above and were assessed as possibly, probably, or definitely related to study drug.

Study enrollment and study drug administration were only to resume if the review of the AEs that caused the halt, resulted in the recommendation to permit further continuation. In such an instance, SIGA, with participation by the investigator and the medical monitor, were to consult with the ISM to conduct the review of all AEs that met the criteria for halting the study. The study was to remain suspended until the events were reviewed by the ISM and a recommendation was made as to whether the study should have been continued or stopped. This constituted a minimum criterion, and the decision to halt the study may have been made based on any other criteria that, in the judgment of the investigator with agreement of the medical monitor and ISM, indicated a potentially serious safety concern. The investigator advised SIGA immediately if any of the halting rules had been met.

This study was not halted.

Replacements

At the discretion of the investigator, and after consultation with the medical monitor, any subject who withdrew before completing the study may have been replaced to retain the target of 32 evaluable enrolled subjects.

9.4 TREATMENT

9.4.1 Treatment Administered

On Days 1 to 7, all subjects received an oral dose of TPOXX 600 mg (3 × 200-mg capsules) BID, approximately 12 hours (±30 minutes) apart, for 7 days within 30 minutes of completing a meal consisting of approximately 600 calories and 25 g of fat.

9.4.2 Identity of Investigational Product

The investigational product used in the study is presented in Table 9-1.

Table 9-1 Investigational Products Used in the Study

Product	Formulation	Lot Number
TPOXX®	200-mg capsule	[redacted]

TPOXX was supplied as 200-mg capsules containing tecovirimat monohydrate as the active pharmaceutical ingredient. The TPOXX capsules were immediate release, size 0, orange and black, hard gelatin capsules containing white to off white powder. All inactive

ingredients/excipients are generally recognized as safe and were US Pharmacopeia/National Formulary grade. The TPOXX excipients are presented in Table 9-2.

Table 9-2 Excipients of TPOXX® Capsule

Component	Quality Designation
[redacted]	[redacted]

[redacted].

(a) Microcrystalline cellulose and croscarmellose sodium were added as intragranular and extragranular excipients.

(b) Removed during processing.

Compendial components were tested and released in accordance with full compendial methods and specifications before their use in clinical formulations. TPOXX 200-mg capsules were manufactured and analyzed for clinical use in accordance with Current Good Manufacturing Practices by Catalent Pharma Solutions (Winchester, KY). Further information on TPOXX can be found in the TPOXX full prescribing information.[2]

9.4.3 Method of Assigning Subjects to Treatment Group

This was an open-label, nonrandomized study. All subjects who fulfilled the eligibility criteria and provided written informed consent were enrolled in the study and received an oral dose of TPOXX 600 mg (3 × 200-mg capsules) BID for 7 days.

9.4.4 Selection of Doses in the Study

The rationale for selection of the TPOXX dose used in this study was based on a strong safety profile observed with 600 mg tecovirimat BID oral dosing. This dose was considered appropriate for evaluation of tecovirimat PK profiles in subjects weighing at least 120 kg.

9.4.5 Selection and Timing of Dose for Each Subject

All subjects were provided meals consisting of approximately 600 calories and 25 g fat, 30 minutes before oral TPOXX administration. Subjects were to eat this meal within 30 minutes or less of taking TPOXX. TPOXX was administered approximately 30 minutes after the start of the meal. All doses were administered to subjects by study site personnel with approximately 240 mL of water. Subjects fasted for 2 hours after taking TPOXX.

TPOXX and meals were taken with water only, and no other beverage except water was ingested within 3 hours before or 3 hours after TPOXX administration.

9.4.6 Blinding

This was an open-label study.

9.4.7 Prior and Concomitant Therapy

Restrictions for prior and concomitant medications are provided in Sections 9.3.1 and 9.3.2.

Information regarding prior medications taken by the subjects within the 30 days before signing the ICF were recorded in the subject's eCRF.

Any concomitant medication deemed necessary for the welfare of the subject during the study was given at the discretion of the investigator. If a concomitant medication listed in Section 9.3.2 was taken, it was documented as a protocol deviation and a joint decision was made by the investigator and SIGA to continue or discontinue the subject based on the time the medication was administered, its pharmacology and PK, and whether the use of the medication compromised the safety of the subject or the interpretation of the data. The investigator was responsible for ensuring that details regarding the medication were adequately recorded in both the subject's source document and the eCRF.

Prior and concomitant medications and therapies were coded using the World Health Organization Drug Dictionary (WHODrug, version March 2019 Global B3).

9.4.8 Treatment Compliance

All doses of study drug were administered at the study site under direct observation of study site personnel and recorded in the eCRF. Per standard clinic procedure, study site personnel performed a mouth check and inspected all dose containers to ensure that the entire dose was administered. Following completion of dosing procedures and return of dosing containers to the pharmacy by team members, pharmacy staff followed standard clinic procedures for study drug reconciliation. SIGA provided information to PPD for destruction of returned used and unused study drug and study drug bottles.

The date and time of study drug dosing was captured and recorded on the appropriate page of the eCRF. If a subject was not administered study drug, the reason for the missed dose was recorded.

9.5 PHARMACOKINETIC AND SAFETY VARIABLES

9.5.1 Pharmacokinetic and Safety Measurements Assessed and Schedule of Events

9.5.1.1 Pharmacokinetic Assessments

Blood samples for the PK analysis of TPOXX were collected from all subjects on Day 1 before study drug administration (0 hour), at 0.5, 1, 2, 4, 6, 8, 12 (before the PM dose), 14, 16, 18, 20, and 24 hours (before the AM dose on Day 2), on Day 6 (before the AM dose and 4 hours after the AM dose), on Day 7 before the AM dose (0 hour), at 0.5, 1, 2, 4, 6, 8, 12 (before the PM dose), 14, 16, 18, 20, and 24 hours (Day 8, 24 hours after the AM dose on Day 7), and on Day 9 (48 hours after the AM dose on Day 7).

For PK samples, the acceptable window for collection from the scheduled collection time point was as follows: ±5 minutes for the time points from 1 to 8 hours, and ±15 minutes for the 12- to 48-hour time points.

9.5.1.2 Safety Assessments

Safety and tolerability were assessed by monitoring and recording of AEs, clinical laboratory test results (hematology, serum chemistry, pregnancy, and urinalysis), vital sign measurements (systolic and diastolic blood pressures, heart rate, respiratory rate, and body temperature), 12-lead ECG results, and physical examination findings.

9.5.1.2.1 Adverse Events

The investigator was responsible for reporting all AEs observed or reported during the study from the first dose of study drug through the follow-up telephone call on Day 37 (+2 days), regardless of the relationship to study drug or clinical significance. If there was any doubt as to whether a clinical observation was an AE, the event was to be reported. All AEs were recorded on the AE page of the eCRF.

The AE definitions, assignment of severity and causality, procedures for reporting SAEs, and follow-up of AEs are provided in the protocol (Appendix 16.1.1).

9.5.1.2.2 Clinical Laboratory Tests

The PPD Central Laboratory performed clinical laboratory tests. Blood and urine samples for hematology, serum chemistry, pregnancy, urinalysis, and drug screen tests were collected at the time points indicated in the schedule of events (Table 9-3) and were prepared using standard procedures. Repeat clinical laboratory tests may have been performed at the

discretion of the investigator, if necessary, to evaluate inclusion and exclusion criteria or clinical laboratory abnormalities. The clinical laboratory that performed the tests provided the reference ranges for all clinical laboratory parameters.

The following clinical laboratory tests were performed:

Hematology	Hematocrit, hemoglobin, mean corpuscular hemoglobin, mean corpuscular hemoglobin concentration, total and differential leukocyte count (basophils, eosinophils, lymphocytes, monocytes, neutrophils), mean corpuscular volume, platelet count, red blood cell count, and red blood cell distribution width
Serum chemistry	Alanine aminotransferase, albumin, alkaline phosphatase, anion gap, aspartate aminotransferase, bilirubin (total), blood urea nitrogen, calcium, carbon dioxide, chloride, creatinine clearance (calculated[(a)]), gamma-glutamyltransferase, globulin, glucose, lactate dehydrogenase, phosphorus, potassium, sodium, total protein, and uric acid
Urinalysis	Appearance, bilirubin, blood, color, glucose, ketones, leukocytes microscopy (performed if dipstick was ≥1+ and included bacteria, casts, crystals, epithelial cells, red blood cells, and white blood cells), nitrites, pH, protein, specific gravity, turbidity, and urobilinogen
Serology	HBsAg, HCV antibody, and HIV types 1 and 2 (screening only)
Other analyses	Urine drug screen (alcohol, amphetamines [including methamphetamines and ecstasy/methylenedioxymethamphetamine], barbiturates, benzodiazepines, cannabinoids [including tetrahydrocannabinol], cocaine metabolites, and opiates [including heroin, codeine, and oxycodone])

[(a)] Creatinine clearance (CLcr) was calculated using the Cockcroft-Gault formula:

$$CLcr\ (mL/min) = \frac{[140 - age(years)] \times weight\ (kg)}{72\ \times serum\ creatinine\ (mg/dL)} \{\times 0.85\ if\ female\}$$

Glycosylated hemoglobin A1c and a fasting lipid panel including cholesterol (total, high-density lipoprotein, calculated low-density lipoprotein, and triglycerides) were performed at screening.

A serum pregnancy test (β human chorionic gonadotropin) for women of childbearing potential was performed at screening and on Day –1.

A serum FSH test for postmenopausal women was to be performed at screening.

Human immunodeficiency virus (types 1 and 2) antibodies, HBsAg, and HCV antibody were assessed at screening only.

Abnormal clinical laboratory values were flagged as either high or low (or normal or abnormal) based on the reference ranges for each laboratory parameter. The investigator determined whether any of the abnormally high or low results were clinically significant or not clinically significant. Clinical significance was defined as any variation in results that had medical relevance and may have resulted in an alteration in medical care (e.g., active observation, diagnostic measures, or therapeutic measures). If a clinically significant change from screening was noted, the clinically significant value and the reason for clinical significance was documented on the AE page of the eCRF. The investigator continued to monitor the subject with additional assessments until the values had reached the reference range or the values at screening or until the investigator determined that follow-up was no longer medically necessary.

9.5.1.2.3 Vital Sign Measurements

Vital sign measurements included systolic and diastolic blood pressures, heart rate, respiratory rate, and body temperature. The subject was seated for at least 5 minutes before all measurements were taken. Vital sign measurements were measured at the time points indicated in the schedule of events (Table 9-3).

When procedures overlapped and occurred at the same time point, the order of the procedures was ECG, vital sign measurements, then blood collection, with the blood collection scheduled to occur at the nominal time point, unless dictated by other study events happening at the same time, such as dosing requirements.

The investigator determined whether any of the vital sign measurements were clinically significant or not clinically significant. Clinical significance was defined as any variation in results that had medical relevance and may have resulted in an alteration in medical care (e.g., active observation, diagnostic measures, or therapeutic measures). If a clinically significant change from screening was noted, the clinically significant value and the reason for clinical significance was documented on the AE page of the eCRF. The investigator continued to monitor the subject with additional assessments until the values had reached the reference range or the values at screening or until the investigator determined that follow-up was no longer medically necessary.

9.5.1.2.4 Twelve-Lead Electrocardiogram

Single 12-lead ECGs were obtained after the subject had been in the supine position for at least 10 minutes at the time points indicated in the schedule of events (Table 9-3). On Days 1,

4, and 7, an ECG was recorded 4 hours after the AM study drug administration. The acceptable window for collection from the scheduled collection time point was ±15 minutes.

Electrocardiogram assessments included comments on whether the tracings were normal or abnormal, rhythm, presence of arrhythmia or conduction defects, morphology, any evidence of myocardial infarction, or ST-segment, T-wave, and U-wave abnormalities. In addition, the following parameters were measured and reported: heart rate, PR, RR, and QT intervals; QTcF; QT interval corrected using Bazett's formula (QTcB); and QRS durations. All ECGs were performed by an experienced ECG technician.

The investigator determined whether any of the 12-lead ECG results were clinically significant or not clinically significant. Clinical significance was defined as any variation in results that had medical relevance and may have resulted in an alteration in medical care (e.g., active observation, diagnostic measures, or therapeutic measures). If a clinically significant change from screening was noted, the clinically significant value and the reason for clinical significance was documented on the AE page of the eCRF. The investigator continued to monitor the subject with additional assessments until the values had reached the reference range or the values at screening or until the investigator determined that follow-up was no longer medically necessary.

9.5.1.2.5 Physical Examination

A full physical examination was performed at the time points indicated in the schedule of events (Table 9-3). The examination included assessment of the following body systems: head, ears, eyes, nose, throat; cardiac (including auscultation of heart); pulmonary (chest) auscultation of lungs; abdomen; skin; musculoskeletal system; lymphatic system; and neurologic system (cranial nerves, sensation, motor function, coordination, reflexes, and mental status).

A symptom-directed physical examination was performed at the time points indicated in the schedule of events (Table 9-3) for those subjects who required it, and at unscheduled visits, as necessary. This examination included an assessment of the heart, lungs, abdomen, a neurologic review, and a review of symptoms for assessments and/or follow-up of reported or potential AEs.

Weight was measured without shoes and in light clothing at screening and without shoes and in hospital gowns at all other time points indicated in the schedule of events (Table 9-3). The scale was calibrated prior to the start of the study and did not require recalibration during use in the study (per the manufacturer, the scale was recommended for recalibration twice

yearly). The same weight scale was used throughout the study starting with screening and through Day 9. Weight measurements were rounded to 1 decimal place. Height was measured at check-in on Day –1.

9.5.1.2.6 Other Safety Measures

At this time, there is no definitive information on allergic activity of TPOXX. Reactogenicity was monitored in subjects during the study treatment and confinement period.

Pregnant women were not eligible to participate in the study. Pregnancy reporting procedures, follow-up of pregnancy in female subjects, and procedures for events wherein the partner of male subjects become pregnant are provided in the protocol (Appendix 16.1.1). There were no pregnancies reported during the study.

A complete medical history was obtained, including a review of systems, recreational drug use, prescription drug use, over-the-counter drug use, nicotine and alcohol use, and past hospitalizations.

9.5.1.3 Schedule of Events

The schedule of events is presented in Table 9-3.

Table 9-3 Schedule of Events

	Screening	Check-in	Treatment and Confinement Period									Telephone Call or Follow-up Visit[a]	Follow-up Telephone Call[b]
Procedure[c] Day	**–28 to –2**	**–1**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9 or Early Discontinuation**	**14 (+2)**	**37 (+2)**
Admission to the clinic		X											
Discharge from the clinic[d]											X		
Informed consent	X												
Inclusion/exclusion criteria	X	X											
Medical history[e]	X	X											
Complete physical examination[f]	X	X							X		X		
Weight[g]	X	X	X[h]								X		
Height		X											
Vital sign measurements[i]	X	X	X[j]			X[j]			X[j]	X	X	X[k]	
Glycosylated hemoglobin (HbA1c)	X												
Fasting lipid panel[l]	X												
Clinical laboratory testing[m]	X[n]	X				X				X[o]	X[n]		
Serum FSH test[p]	X												
Serum pregnancy test[q]	X	X											
Urine drug/alcohol screen[r]	X	X											
Serology (HBsAg, HCV, and HIV)	X												
12-lead ECG[s]	X	X	X			X			X		X		
TPOXX administration[t]			X	X	X	X	X	X	X				
Pharmacokinetic sampling[u]			X	X				X	X	X	X		
Symptom-directed physical examination[v]				X	X	X	X	X				X[k]	
Adverse events			◄	─	─	─	─	─	─	─	X ►	◄	─ ►
Prior/concomitant medications	◄	─	─	─	─	─	─	─	─	X ►	◄	─	─ ►

Abbreviations: AE, adverse event; BID, twice daily; ECG, electrocardiogram; FSH, follicle-stimulating hormone; HbA1c, glycosylated hemoglobin; HBsAg, hepatitis B surface antigen; HCV, hepatitis C virus; HIV, human immunodeficiency virus; PK, pharmacokinetic; SAE, serious adverse event.

[a] The follow-up visit or telephone call occurred on Day 14 (+2 days), 7 days after the last dose of study drug. Subjects who had abnormal physical examination findings or an ongoing AE/SAE at Day 9 that was deemed related to study drug or per the investigator or SIGA discretion, returned to the study site on Day 14 (+2 days) for a follow-up visit. All other subjects had the Day 14 (+2 days) follow-up via a telephone call.

[b] The follow-up telephone call was made 30 days after the last dose of study drug (Day 37 [+2 days]).

[c] When procedures overlapped and occurred at the same time point, the order of procedures was ECG, vital sign measurements, and then blood collection, with the blood collection scheduled to occur at the nominal time point, unless dictated by other study events happening at that time, such as dosing requirements.
[d] Discharge occurred following collection of all safety assessments.
[e] Included a review of systems; recreational drug use, prescription drug use, and over-the-counter drug use; nicotine and alcohol use; and past hospitalizations.
[f] Included an assessment of the following body systems: head, ears, eyes, nose, and throat; cardiac (including auscultation of heart); pulmonary (chest) auscultation of the lungs; abdomen; skin; musculoskeletal system; lymphatic system; and neurologic system (cranial nerves, sensation, motor function, coordination, reflexes, and mental status).
[g] Weight was measured without shoes and in light clothing at screening and without shoes and in hospital gowns at all other time points. The scale was calibrated prior to the start of the study and did not require recalibration during use in the study (per the manufacturer, the scale was recommended for recalibration twice yearly). The same weight scale was used throughout the study starting with screening and through Day 9. Weight measurements were rounded to 1 decimal place.
[h] Weight was collected prior to dosing.
[i] Vital sign measurements included systolic and diastolic blood pressures, heart rate, respiratory rates, and body temperature. Vital signs were measured after the subject had been seated for at least 5 minutes.
[j] Vital sign measurements were performed before dosing and 4 hours after the AM study drug administration on Days 1 and 7, and 4 hours after the AM study drug administration on Day 4. The acceptable window for collection from the scheduled collection time point was ±15 minutes.
[k] Collected only if subjects were required to return to the study site on Day 14 (+2 days) for a follow-up visit.
[l] Included cholesterol (total, high-density lipoprotein, calculated low-density lipoprotein, and triglycerides).
[m] Clinical laboratory testing included hematology and serum chemistry.
[n] Clinical laboratory testing at screening and at Day 9 or early discontinuation included hematology, serum chemistry, and urinalysis.
[o] Collected 12 hours after the PM study drug administration on Day 7.
[p] For postmenopausal women, a serum FSH test was performed at screening.
[q] Women of childbearing potential only.
[r] Included alcohol, amphetamines (including methamphetamines and ecstasy/methylenedioxymethamphetamine), barbiturates, benzodiazepines, cannabinoids (including tetrahydrocannabinol), cocaine metabolites, and opiates (including heroin, codeine, and oxycodone).
[s] A 12-lead ECG was collected after the subject had been in the supine position for at least 10 minutes. On Days 1, 4, and 7, an ECG was recorded 4 hours after the AM study drug administration. The acceptable window for collection from the scheduled collection time point was ±15 minutes.
[t] TPOXX, 600 mg (3 × 200-mg capsules) was administered orally BID, approximately 12 hours (±30 minutes) apart on Days 1 through 7. All subjects were provided meals consisting of approximately 600 calories and 25 g fat, which started 30 minutes before study drug administration. Subjects ate this meal within 30 minutes or less of taking study drug. Study drug was administered approximately 30 minutes after the start of the meal. All doses of study drug were administered to subjects by study site personnel with approximately 240 mL of water. Subjects fasted 2 hours after taking study drug. Study drug and meals were taken with water only, and no other beverage except water was ingested within 3 hours before or 3 hours after study drug administration.
[u] Blood samples for the PK analysis of TPOXX were collected from all subjects at the following time points: on Day 1 before study drug administration (0 hour), at 0.5, 1, 2, 4, 6, 8, 12 (before the PM dose), 14, 16, 18, 20, and 24 hours (before the AM dose on Day 2), on Day 6 (before the AM dose and 4 hours after the AM dose), on Day 7 before the AM dose (0 hour), at 0.5, 1, 2, 4, 6, 8, 12 (before the PM dose), 14, 16, 18, 20, and 24 hours (Day 8, 24 hours after the AM dose on Day 7), and on Day 9 (48 hours after the AM dose on Day 7). For PK blood samples, the acceptable window for collection from the scheduled collection time point was as follows: ±5 minutes for the time points from 1 to 8 hours and ±15 minutes for the 12- to 48-hour time points.
[v] Included an assessment of heart, lungs, abdomen, a neurologic review, and a review of symptoms for assessment and/or follow-up of reported or potential AEs.

9.5.2 Appropriateness of Measurements

The PK evaluation in this study used the standard accepted methods to describe the PK profile of a drug in plasma in accordance with US FDA Guidance for Industry on Bioanalytical Method Validation.[3] The safety assessments performed were standard and are recognized as reliable, accurate, and relevant.

9.5.3 Pharmacokinetic Variables

9.5.3.1 Pharmacokinetic Variables

The individual plasma concentration versus actual time data for TPOXX were used to derive the PK parameters, by noncompartmental methods using Phoenix® WinNonlin® Version 8.0 (Certara USA, Inc., Princeton, NJ):

Parameter	Day(s)	Definition
$AUC_{0\text{-}t}$	1, 7	Area under the plasma concentration versus time curve (AUC) from time 0 to the last quantifiable measurement, calculated using the linear trapezoidal rule. $AUC_{0\text{-}t} = \sum_{i=1}^{n} \frac{(C_i + C_{i-1})}{2}(t_i - t_{i-1})$, where C_i and C_{i-1} was the plasma concentration at t_i and t_{i-1}, respectively, and t_i-t_{i-1} was the time interval.
$AUC_{0\text{-}24}$	1, 7	AUC from time 0 to 24 hours postdose, calculated using the linear trapezoidal rule.
$AUC_{0\text{-}tau}$	1, 7	AUC during the first dosing interval (tau = 12 hours).
$AUC_{0\text{-}inf}$	7	AUC from time 0 extrapolated to infinity, calculated using the linear trapezoidal rule, $AUC_{0\text{-}inf} = AUC_{0\text{-}t} + C_{last}/\lambda_z$, where C_{last} was the last quantifiable plasma drug concentration and λ_z was the terminal elimination rate constant.
$\%AUC_{extrap}$	7	Percentage of $AUC_{0\text{-}inf}$ extrapolated from the last quantifiable measurement to infinity.
C_{max}	1, 7	Maximum observed plasma drug concentration.
T_{max}	1, 7	Time to reach C_{max}.
λ_z	1, 7	Terminal elimination rate constant.
$t_{1/2}$	1, 7	Terminal elimination half-life, calculated as $t_{1/2} = \ln 2/\lambda_z$.
CL/F	7	Apparent total body clearance, calculated as: $Dose/AUC_{0\text{-}tau}$.
V_d/F	7	Apparent volume of distribution, calculated as: $CL/F/\lambda_z$.
C_{trough}	1, 2, 6, 7	Concentration observed prior to the next dose administration

9.5.4 Drug Concentration Measurements

Blood samples (approximately 5 mL) for the determination of plasma concentrations of TPOXX were collected in 5-mL lavender-topped K_3EDTA Vacutainer® tubes using a 21 gauge or larger needle, or from an indwelling intravenous catheter using a vacutainer tube. Blood samples were placed on wet ice or equivalent (approximately 4ºC to 8ºC) and kept at this temperature until processed to separate plasma.

The exact time and date of sample collection was recorded for each sample by the investigator or designee in the subject's eCRF, the vacutainer and cryovial labels, and the specimen shipping log. In addition, the time of study drug administration before PK sampling was recorded in the subject's eCRF. Labels were created by the site which contained the protocol number, matrix (plasma), subject number, date, and time drawn. For information that was not preprinted on the label, a fine tipped indelible marking pen was used to complete the entry.

The 5-mL blood sample was centrifuged in a refrigerated centrifuge immediately, if possible, or within 60 minutes of collection at 1000 to 1200 × *g* (2000 to 3000 rpm) for 10 minutes to separate plasma. Each plasma sample was transferred via pipette into 2 cryovials labeled as previously described and were capped tightly. The second tube was a duplicate and was retained at the study site as a backup sample. If red blood cells were inadvertently drawn into the plasma, the sample was recentrifuged as soon as possible. Adequate space between the solution and the tube cap was allowed for expansion during freezing.

Cryovial tubes containing plasma samples were stored frozen in a freezer equipped with a temperature monitor and temperature alarm at –70ºC or below until shipment. Uncentrifuged specimens were not frozen. All plasma samples were shipped frozen to the bioanalytical laboratory (Alturas Analytics, Inc.) using dry ice.

9.6 DATA QUALITY ASSURANCE

This study was conducted using quality processes described in applicable procedural documents. The quality management approach implemented was documented and complied with the current ICH guidance on quality and risk management. All aspects of the study were monitored for compliance with applicable government regulatory requirements, current Good Clinical Practice, the protocol, and standard operating procedures. The monitor maintained current personal knowledge of the study through observation, review of study records and source documentation, and discussion of the conduct of the study with the investigator and staff. Electronic CRFs and electronic data capture were utilized. The electronic data capture

system is validated and compliant with US Title 21 CFR Part 11. Each person involved with the study had an individual identification code and password that allowed for record traceability. Data were continuously monitored for quality and compliance at every monitoring visit throughout the study. Additional reviews performed by the clinical monitor included query review and resolution, and protocol deviation review. Protocol deviations are presented in Section 10.2.

9.7 STATISTICAL METHODS PLANNED IN THE PROTOCOL AND DETERMINATION OF SAMPLE SIZE

9.7.1 Statistical and Analytical Plans

All analyses were performed using SAS® Version 9.4 (SAS Institute, Cary, NC).

All data collected are presented in data listings. Data from subjects excluded from an analysis population are presented in the data listings but not included in the calculation of summary statistics.

For categorical variables, frequencies and percentages are presented. Continuous variables are summarized using descriptive statistics (number of subjects, mean, median, SD, minimum, and maximum).

Unless specified otherwise, baseline is defined as the last nonmissing assessment prior to dosing. Unscheduled visits were used in determining baseline.

The statistical analysis plan for this study is provided in Appendix 16.1.9.

9.7.1.1 Analysis Populations

The safety population included all subjects who received at least 1 dose of study drug.

The PK population included subjects who received study drug and had sufficient concentration data to facilitate the calculation of PK variables.

9.7.1.2 Analysis of Subject Disposition and Demographics

Subject disposition is summarized overall for all subjects.

The number of subjects who enrolled in the study and the number and percentage of subjects who completed the study are presented. The frequency and percentage of subjects who withdrew or discontinued from the study and the reason for withdrawal or discontinuation are also summarized.

Subject disposition data and analysis populations are presented in data listings.

Baseline demographic and background variables are summarized overall for all subjects and presented in a data listing.

The demographic characteristics consist of age (years), sex, race, and ethnicity. The baseline characteristics consist of baseline weight (kg) and height (cm). A subject's age in years was calculated using the date of informed consent and date of birth. Age (years) and baseline weight (kg) are summarized using descriptive statistics. The number and percentage of subjects by race (American Indian or Alaska Native, Asian, black or African American, Native Hawaiian or Other Pacific Islander, and white), ethnicity (Hispanic or Latino, Not Hispanic or Latino), and reproductive status (for females only; Sterile, Post-Menopausal, Potentially Able to Bear Children) are also reported. Percentages are based on the total number of subjects in the safety population.

Subject demographic and baseline characteristics are presented in a data listing.

9.7.1.3 Analysis of Pharmacokinetic Data

9.7.1.3.1 Plasma Drug Concentrations

Individual plasma concentrations, actual time, and deviation from the scheduled time are presented in a data listing by subject, study day, and nominal time point. Plasma concentration data are summarized by day and time point using the following descriptive statistics: sample size (n), arithmetic mean, geometric mean, SD, geometric SD, coefficient of variation (CV), geometric CV (calculated as sqrt [exp [variance for log transformed data] – 1] × 100), median, minimum, and maximum.

If the minimum value was zero, the geometric mean was not calculated and displayed. If the mean concentration values were below the limit of quantification (BLQ), they are displayed as BLQ; in this case the SD and CV are reported as not applicable.

Plasma concentrations that were BLQ are treated as zero for descriptive statistics. Missing concentrations were excluded from the calculations.

Individual, mean (±SD), and trough (±SD) plasma TPOXX concentration versus time profiles are presented in figures on both linear and semilogarithmic scales. Mean plasma concentration versus time profiles are presented using nominal time and individual plasma concentration versus time profiles are presented using actual time.

9.7.1.3.2 Plasma Pharmacokinetic Parameters

Actual sampling times, rather than scheduled sampling times, are used in the computation of PK parameters. However, for ease of presentation, scheduled sampling time are used to present results in summary tables. The individual PK parameters of TPOXX are presented in a data listing. The PK parameters are summarized by day using the following descriptive statistics: n, arithmetic mean, geometric mean, SD, CV, geometric SD, geometric CV, median, minimum, and maximum. For T_{max}, only n, median, minimum, and maximum are included in descriptive statistics. Geometric mean, geometric SD, and geometric CV are included for the AUCs and C_{max}.

9.7.1.3.3 Statistical Analysis of Pharmacokinetic Data

No formal statistical analysis of PK data was performed for this study. Key PK parameters are summarized with descriptive statistics.

9.7.1.4 Analysis of Safety Data

All safety summaries and analyses were conducted for the safety population. Safety data are presented in data listings.

9.7.1.4.1 Adverse Events

Adverse events were coded by preferred term (PT) and system organ class (SOC) using the Medical Dictionary for Regulatory Activities (MedDRA, Version 22.0).

An overall summary of all AEs is presented. The number and percentage of subjects, as well as the number of AEs are presented for each of the following categories: any AE; any Grade 2, Grade 3, Grade 4, and Grade 5 AE; any treatment-related AE (TRAE); any Grade 2, Grade 3, Grade 4, and Grade 5 TRAE; any SAE; any serious TRAE, and any AE leading to discontinuation of study drug. In addition, the table includes a summary of the time to first AE and the time to first AE of Grade 3 or higher. Time to first AE was calculated for each period of the study in days as the date of the first AE in the period – the date of first dose of study drug in the period + 1. Time to first AE of Grade 3 or higher was computed similarly. These times were summarized overall.

Adverse events were summarized by SOC and PT and by PT alone, including the total number of AEs and the number and percentage of subjects with at least one AE. At each level of subject summarization, a subject was counted once if the subject reported one or more events. Percentages were calculated out of the number of subjects in the safety population.

A summary of AEs by relationship to study drug is presented in a table by incidence of occurrence. The investigator provided an assessment of the relationship of the event to the study drug. The possible relationships were: not related, unlikely related, possibly related, probably related, and definitely related. In the summary of AEs by relationship, if a subject reported multiple occurrence of the same AE, only the most closely related occurrence is presented. Adverse events that were missing a relationship are presented in the summary table as definitely related but are presented in the data listing with a missing relationship. Percentages were calculated based on the number of subjects in the safety population.

An AE was considered treatment-related if it was assessed as probably, possibly, or definitely related by the investigator. Treatment-related AEs are presented in a data listing.

A summary of AEs by severity is presented in a table. The severity that is presented represents the most extreme severity captured on the eCRF page. In this summary, if a subject reported multiple occurrences of the same AE, only the most severe is presented. Adverse events that were missing severity are presented in tables as Grade 3 but are presented in the data listing with a missing severity. Percentages were calculated out of the number of subjects in the safety population.

All AEs and SAEs are presented in a data listing. All AEs leading to study drug discontinuation are presented in a data listing.

9.7.1.4.2 Clinical Laboratory Tests

Observed values and changes from baseline are summarized for hematology, serum chemistry, and urinalysis laboratory tests with numeric values for subjects in the safety population. Changes from baseline to each scheduled postbaseline visit are presented.

Changes in low, normal, high, and abnormal classifications are summarized in shift tables comparing the results at each scheduled postbaseline visit with those at the baseline visit. Shift tables are presented for subjects in the safety population.

Where possible, abnormal clinical laboratory values were graded for severity according to the DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events. The maximum increase in DAIDS grade postbaseline (including both scheduled and unscheduled visits) is summarized and presented.

Microscopy data are not included in the summaries.

All hematology, serum chemistry, and urinalysis laboratory data are presented in data listings. The results of glycosylated hemoglobin A1c, serum pregnancy test, serum FSH (for postmenopausal women only), HIV, HBsAg, HCV, and urine drug and alcohol screen assessments are presented in a data listing.

9.7.1.4.3 Vital Sign Measurements

Observed values and changes from baseline are summarized for vital sign data for subjects in the safety population. Changes from baseline to each scheduled postbaseline visit are presented. All vital sign data are presented in a data listing.

9.7.1.4.4 Twelve-Lead Electrocardiogram

Observed values and changes from baseline are summarized for ECG numeric results for subjects in the safety population. Changes from baseline to each scheduled postbaseline visit are presented. All ECG data are presented in a data listing.

9.7.1.4.5 Physical Examination

Physical examination results are presented in a data listing.

9.7.1.4.6 Physical Measurements

Physical measurements are presented in a data listing.

9.7.1.4.7 Ancillary Data

A protocol deviation was any change, divergence, or departure from the study design or procedures defined in the protocol. An important protocol deviation (sometimes referred to as a protocol violation or a major protocol deviation) was a subset of protocol deviations that might have significantly affected the reliability of the study data or that might have significantly affected a subject's safety. An important deviation could have included nonadherence to inclusion or exclusion criteria or nonadherence to FDA regulations or ICH E6(R2) guidelines.

Protocol deviations were documented by the clinical monitor throughout the course of monitoring visits. The investigator was notified in writing by the monitor of deviations. The IRB was notified of all protocol deviations, if appropriate, in a timely manner.

Major protocol deviations are summarized overall. All protocol deviations are presented in a data listing, including the categorization of the deviation as major or minor.

A complete medical history was obtained from subjects, including recreational drug use, prescription drug use, over-the-counter drug use, nicotine and alcohol use, and past hospitalizations. Medical history was coded using MedDRA (Version 22.0) and is presented in a data listing.

All inclusion/exclusion criteria deviations recorded in the eCRF are presented in a data listing.

A prior medication was defined as any medication that was taken within 30 days before signing the ICF. A concomitant medication was defined as any medication that had a start date on or after date of the first dose of study drug. Prior and concomitant medications and therapies were coded using WHODrug (Version March 21019 Global B3) and are presented in a data listing.

All medical and surgical treatment procedures were coded using MedDRA (Version 22.0) and are presented in a data listing.

A summary of study drug administration data is presented. The summary includes the number and percentage of subjects dosed, as well as summary statistics of the number of complete doses received and the number and percentage of subjects who received all 14 planned doses. All study drug administration data are presented in a data listing.

Meal data, height and weight data and follow-up visit/call data are presented in data listings.

9.7.2 Determination of Sample Size

The sample size (N = 36 [to allow at least 32 enrolled subjects to complete]) for this study is based on clinical and practical considerations and not on a formal statistical power calculation. The sample size was considered sufficient to effectively assess the PK and safety profiles of TPOXX.

9.8 CHANGES IN THE CONDUCT OF THE STUDY OR PLANNED ANALYSES

There were 2 amendments to the original study protocol dated 19 February 2019 (Appendix 16.1.1).

Amendment 1, dated 27 June 2019, was issued to:

- Clarify the weight requirements for qualified subjects on Days –1 and 1.

- Clarify that the same scale would be used in screening and how rounding procedures would be applied.
- Update Reference 3 to cite the current FDA Guidance.
- Remove the ±2-day window for the Day 9/Early Discontinuation visit.
- Remove the symptom-directed physical examination from Day 7.

Amendment 2, dated 02 August 2019, was issued to:

- Revise exclusion criterion 31.
- Remove redundant exclusion criteria.
- Add the measurement of height to the Day –1 check-in procedures.
- Remove the 1-hour observation period for allergic reaction following dosing.

10. STUDY SUBJECTS

10.1 DISPOSITION OF SUBJECTS

Subject disposition is summarized in Table 10-1.

Table 10-1 Summary of Subject Disposition (Enrolled Population)

	Total (N=34) n (%)
Total number of subjects	
Completed	34 (100.0)
Discontinued	0
Analysis populations	
Safety population	34 (100.0)
PK population	34 (100.0)

Abbreviation: PK, pharmacokinetic.

Notes: The safety population included all subjects who received at least 1 dose of study drug.

The PK population included all subjects who received study drug and had sufficient concentration data to facilitate the calculation of PK variables.

All percentages were based on the enrolled subjects.

TPOXX 600 mg (3 × 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.

Source: End-of-Text Table 14.1.1.1.

A total of 34 subjects were enrolled, and all 34 subjects (100.0%) completed the study. All 34 subjects (100.0%) were included in the safety and PK populations.

Subject disposition and reasons for discontinuation are summarized in End-of-Text Table 14.1.1.1 and presented by subject in Data Listing 16.2.1.1. Analysis sets are presented by subject in Data Listing 16.2.1.2.

10.2 PROTOCOL DEVIATIONS

Information on the monitoring and documenting of protocol deviations is presented in Section 9.6.

There were no inclusion/exclusion criteria deviations. Overall, 6 subjects (17.6%) experienced major protocol deviations in the category of missing endpoint assessments, and 1 subject (2.9%) experienced a major protocol deviation in the category of study procedures and/or assessments. The majority of protocol deviations were assessed as minor, and none of the protocol deviations were deemed likely to affect the results of the study or the integrity of the data.

Major protocol deviations are summarized in End-of-Text Table 14.1.1.2. All protocol deviations are presented by subject in Data Listing 16.2.2.1. Inclusion/exclusion criteria deviations are presented in Data Listing 16.2.2.2.

10.3 DATASETS ANALYZED

The safety population included 34 subjects who received at least 1 dose of study drug

The PK population included 34 subjects who received study drug and had sufficient concentration data to facilitate the calculation of PK variables.

10.4 DEMOGRAPHIC AND OTHER BASELINE CHARACTERISTICS

10.4.1 Demographics and Baseline Characteristics

Subject demographic and baseline characteristics are summarized in Table 10-2.

Table 10-2 Summary of Subject Demographics and Baseline Characteristics (Safety Population)

	Total (N=34)
Age (years)	
Mean (SD)	35.5 (8.31)
Median	34.5
Minimum, maximum	20, 50
Sex, n (%)	
Male	23 (67.6)
Female	11 (32.4)
Reproductive Status, n (%)[a]	
Potentially able to bear children	8 (72.7)
Sterile	3 (27.3)
Race, n (%)	
White	12 (35.3)
Black or African American	22 (64.7)
Ethnicity, n (%)	
Hispanic or Latino	5 (14.7)
Not Hispanic or Latino	29 (85.3)
Weight (kg)	
Mean (SD)	138.13 (20.881)
Median	131.15
Minimum, maximum	120.3, 220.4
Height (cm)	
Mean (SD)	176.40 (9.649)
Median	176.55
Minimum, maximum	151.2, 195.3

Note: TPOXX 600 mg (3 × 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.

[a] Reproductive status is presented for female subjects only, and percentages were computed based on the total number of females.

Source: End-of-Text Table 14.1.2.

The majority of subjects were black or African American (22 subjects, 64.7%). There were more male (23 subjects, 67.6%) than female subjects (11 subjects, 32.4%). More female subjects were of childbearing potential (8 subjects, 72.7%) than sterile (3 subjects, 27.3%). The mean age was 35.5 years (range: 20 to 50 years), and all subjects weighed more than 120 kg with a mean weight of 138.13 kg (range: 120.3 to 220.4 kg).

Demographics characteristics are summarized for the safety population in End-of-Text Table 14.1.2. Demographics are presented by subject in Data Listing 16.2.4.1.

10.4.2 Other Baseline Characteristics

None of the medical history findings precluded any subject from participating in the study. All HIV, HBsAg, and HCV test results were negative or nonreactive at screening. Serum FSH testing was not performed because none of the female subjects were postmenopausal. At

screening and on Day –1, all subjects tested negative for drugs and alcohol, and all female subjects tested negative for pregnancy (β human chorionic gonadotropin less than 5.0 IU/L). Two subjects had a high hemoglobin A1c value at screening, which were assessed as abnormal but not clinically significant in both cases.

Medical history is presented by subject in Data Listing 16.2.4.2. Laboratory test results for HIV, HBsAg, HCV, hemoglobin A1c, drugs and alcohol, and serum pregnancy tests are presented by subject in Data Listing 16.2.8.4.

10.5 PRIOR AND CONCOMITANT MEDICATIONS

Several subjects reported prior medications, including biotin, cholecalciferol, ibuprofen, lysine, chlorphenamine maleate, finasteride, paracetamol, tramadol, and vitamins and minerals not otherwise specified that were not ongoing during the study. Concomitant medications were received by the following subjects:

- Subject 9021 received prune juice to treat the AE of infrequent bowel movements.
- Subject 9025 received chlorphenamine maleate to manage the medical history of seasonal allergies.
- Subject 9061 received nitrofurantoin to treat the AE of urinary tract infection.
- Subject 9095 received loratadine to manage the medical history of seasonal allergies.

The only medical or surgical treatment procedures included ad hoc safety observations (18 September 2019 to 19 September 2019) and rhythm strips (18 September 2019) for Subject 9025 to assess frequent premature ventricular contractions, which were not assessed as an AE by the investigator and were not ongoing at the end of the study. No other subjects reported medical or surgical treatment procedures.

Prior and concomitant medications are presented by subject in Data Listing 16.2.4.3. Medical and surgical treatment procedures are presented by subject in Data Listing 16.2.4.4.

10.6 EXPOSURE AND COMPLIANCE

10.6.1 Extent of Exposure

Study drug administration is presented in Table 10-3.

Table 10-3 Study Drug Administration (Enrolled Population)

	Total (N=34)
Subjects enrolled	
Dosed, n (%)	34 (100.0)
Number of complete doses received (maximum of 14)	
Mean (SD)	14.0 (0.00)
Median	14.0
Minimum, maximum	14, 14
Number of subjects completing all 14 doses of study drug, n (%)	34 (100.0)

Notes: Percentages were based on the number of subjects in the safety population.
TPOXX 600 mg (3 × 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source: End-of-Text Table 14.1.3.

All 34 subjects received all 14 planned doses (100.0%) of oral TPOXX in this study.

Study drug administration data are summarized for the safety population in End-of-Text Table 14.1.3 and presented by subject in Data Listing 16.2.5.1.

Meal data are presented by subject in Data Listing 16.2.5.2.

10.6.2 Measures of Treatment Compliance

All doses of study drug were administered at the study site under direct observation of study site personnel and recorded in the eCRF. Per standard clinic procedure, study site personnel performed a mouth check and inspected all dose containers to ensure that the entire dose was administered. The date and time of study drug dosing were captured and recorded on the appropriate page of the eCRF. If a subject was not administered study drug, the reason for the missed dose was recorded.

Study drug administration data are presented by subject in Data Listing 16.2.5.1.

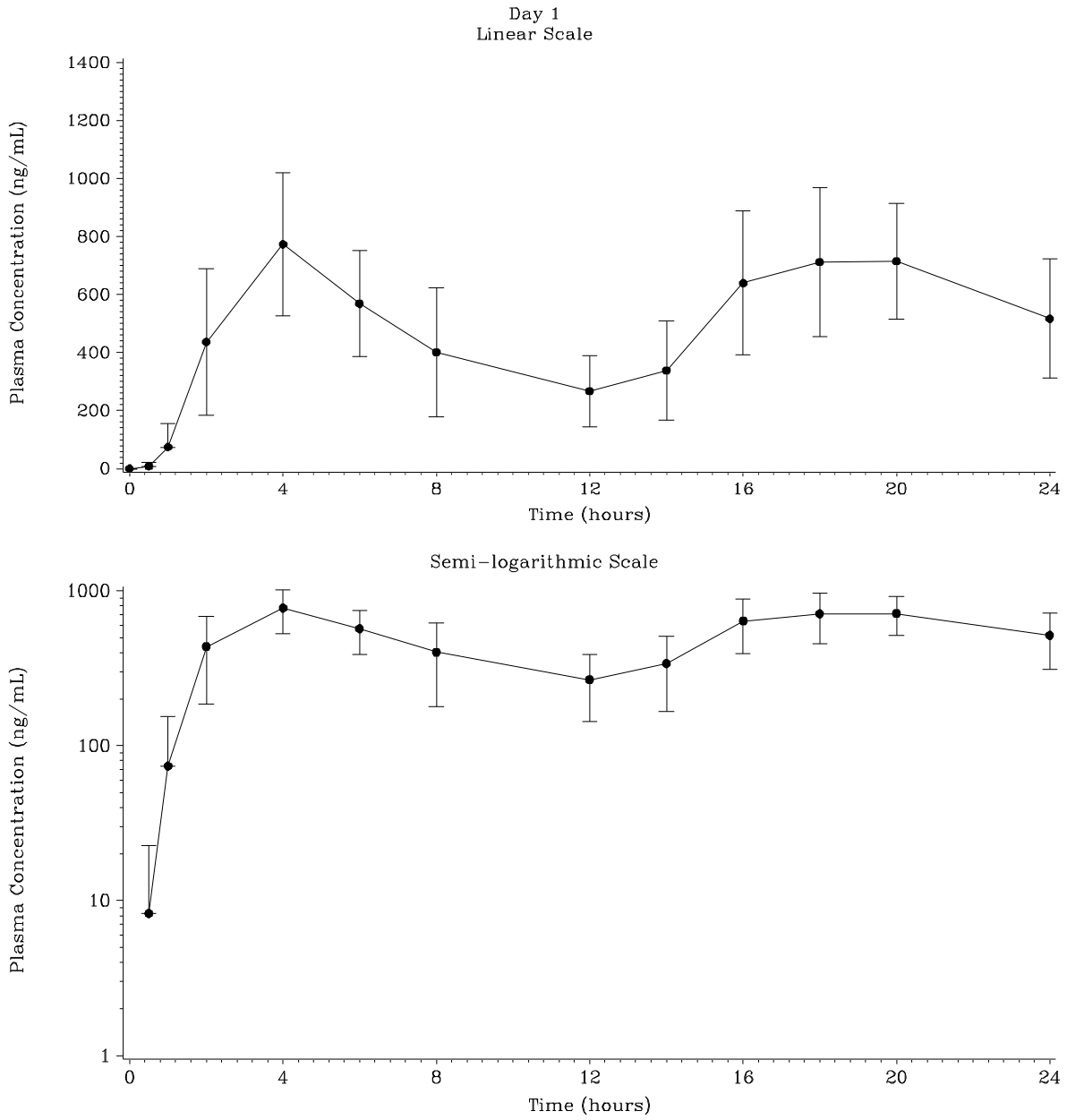
11. PHARMACOKINETIC EVALUATION

11.1 ANALYSIS OF PHARMACOKINETICS

11.1.1 Plasma Concentrations of TPOXX

Mean plasma concentrations of TPOXX are presented in Figure 11-1 (Day 1) and Figure 11-2 (Day 7). Mean plasma trough concentrations of TPOXX are presented in Figure 11-3.

Figure 11-1 **Mean Plasma Concentrations of TPOXX Versus Time: Day 1 (Linear and Semilogarithmic Scales) (Pharmacokinetic Population)**

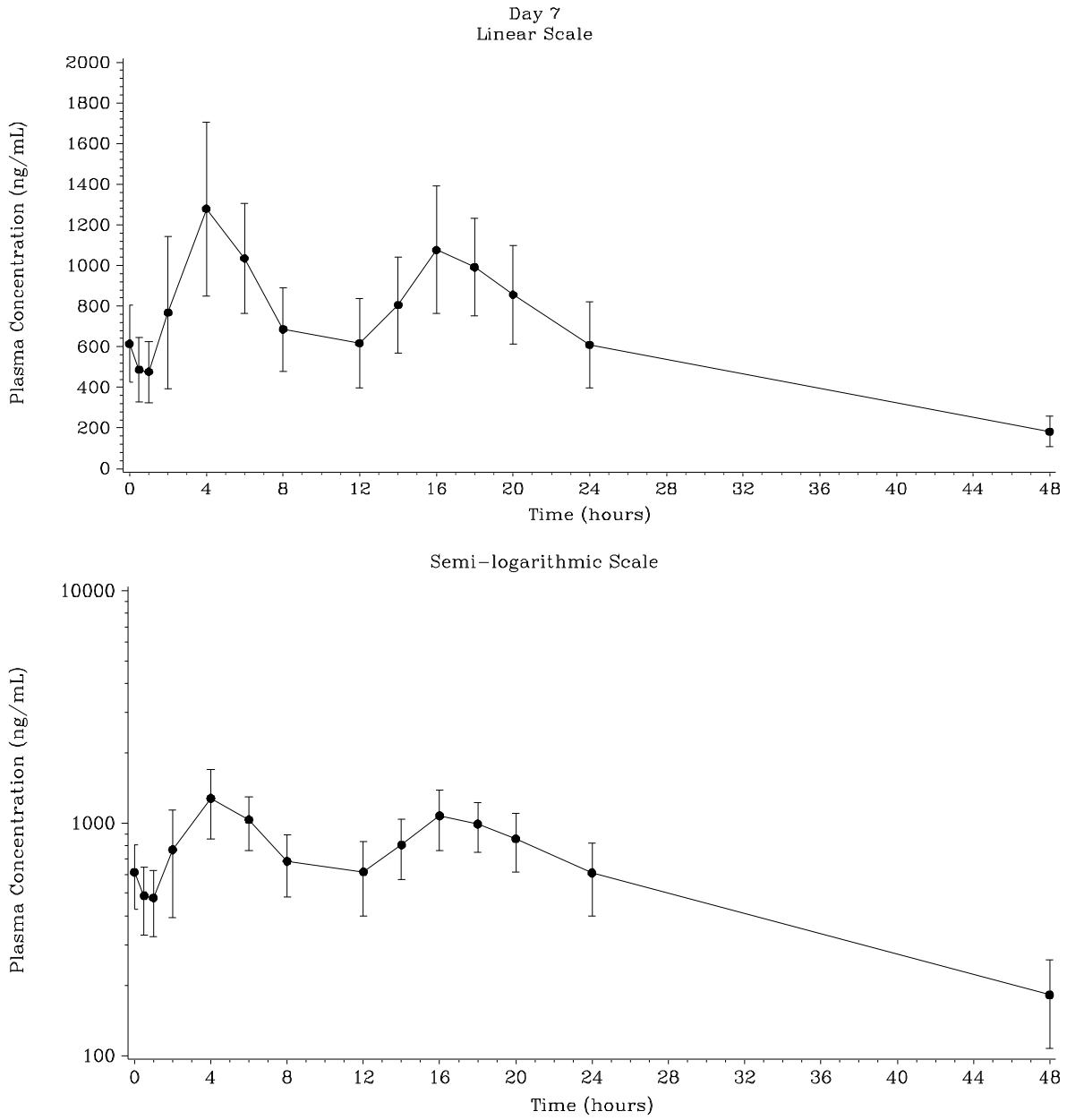


Abbreviation: BID, twice daily.

Treatment: TPOXX 600 mg (3 × 200-mg capsules) was administered orally BID on Days 1 to 7, approximately 12 hours (±30 minutes) apart.

Source: End-of-Text Figure 14.2.1.

Figure 11-2 **Mean Plasma Concentrations of TPOXX Versus Time: Day 7 (Linear and Semilogarithmic Scales) (Pharmacokinetic Population)**

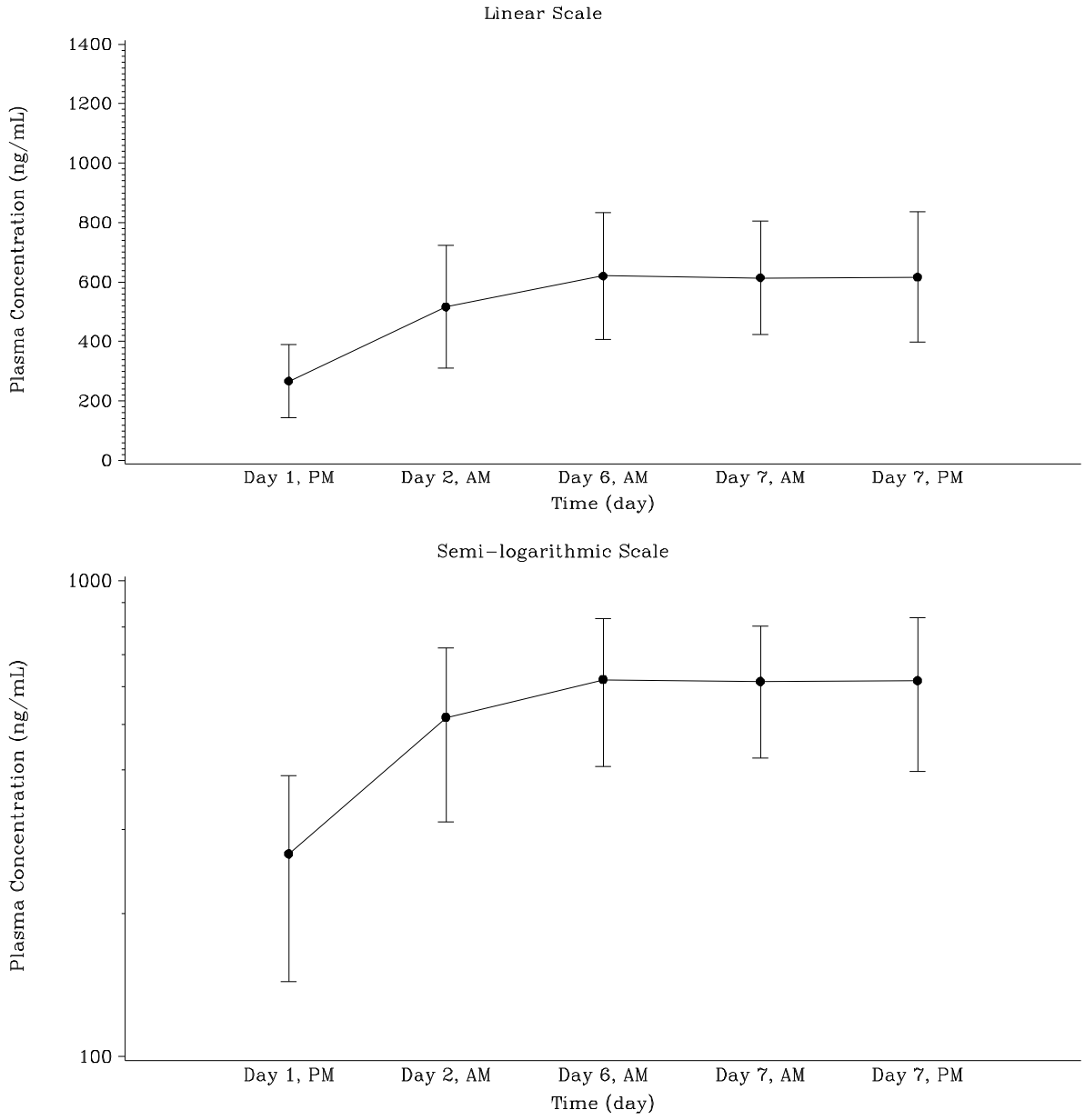


Abbreviation: BID, twice daily.

Treatment: TPOXX 600 mg (3 × 200-mg capsules) was administered orally BID on Days 1 to 7, approximately 12 hours (±30 minutes) apart.

Source: End-of-Text Figure 14.2.1.

Figure 11-3 **Mean (±SD) Plasma Trough Concentrations of TPOXX Versus Time (Linear and Semilogarithmic Scales) (Pharmacokinetic Population)**



Abbreviation: BID, twice daily.

Treatment: TPOXX 600 mg (3 × 200-mg capsules) was administered orally BID on Days 1 to 7, approximately 12 hours (±30 minutes) apart.

Source: End-of-Text Figure 14.2.2.

Following BID oral administration of TPOXX 600 mg, plasma concentrations of TPOXX were detected immediately after dosing and reached peak levels around 4 hours after dosing.

Mean plasma concentrations of TPOXX achieved steady state by Day 6 after administration of TPOXX for 7 days.

Mean plasma concentrations of TPOXX are presented in End-of-Text Figure 14.2.1. Mean plasma trough concentrations of TPOXX are presented in End-of-Text Figure 14.2.2. Individual plasma concentrations (as an overlay plot) of TPOXX are presented in End-of-Text Figure 14.2.3. Individual plasma collection times and concentrations of TPOXX are presented in Data Listing 16.2.6.1. A summary of plasma concentrations of TPOXX is presented in End-of-Text Table 14.2.1.

11.1.2 Plasma Pharmacokinetic Parameters of TPOXX

Plasma PK parameters of TPOXX for Day 1 and Day 7 are summarized in Table 11-1.

Table 11-1 Mean (CV) Plasma Pharmacokinetic Parameters of TPOXX (Pharmacokinetic Population)

Parameter (unit)	Day 1 N=34	Day 7 N=34
C_{max} (ng/mL)	847 (24.9)	1350 (29.0)
AUC_{0-24} (ng•h/mL)	11900 (23.8)	20000 (23.0)
AUC_{0-t} (ng•h/mL)	11900 (23.8)	29500 (26.0)
AUC_{0-tau} (ng•h/mL)	5130 (22.6)	9830 (23.9)
AUC_{0-inf} (ng•h/mL)	–	33200 (27.8)[b]
T_{max} (h)[a]	4.00 (2.00, 8.02)	4.00 (2.00, 11.95)
$t_{1/2}$ (h)	8.46 (45.5)[c]	12.9 (19.3)[b]
CL/F (L/h)	–	64.8 (26.0)
V_d/F (L)	–	1180 (29.9)[b]
C_{trough} (ng/mL)	517 (39.8)[d]	617 (35.6)[e]

Abbreviations: AUC_{0-24}, area under the plasma concentration versus time curve from time 0 to 24 hours postdose; AUC_{0-inf}, area under the plasma concentration versus time curve from time 0 extrapolated to infinity; AUC_{0-t}, area under the plasma concentration versus time curve from time 0 to the last quantifiable measurement; AUC_{0-tau}, area under the plasma concentration versus time curve during the first dosing interval; CL/F, apparent total body clearance; C_{max}, maximum observed plasma drug concentration; C_{trough}, concentration observed prior to the next dose administration; CV, coefficient of variation; $t_{1/2}$, terminal elimination half-life; T_{max}, time to reach C_{max}; V_d/F, apparent volume of distribution.

[a] For T_{max}, the median (minimum, maximum) values are presented.

[b] n = 33.

[c] n = 11.

[d] Prior to the third dose.

[e] Prior to the second dose on Day 7.

Source: End-of-Text Tables 14.2.2, 14.2.3, and 14.2.4.

Pharmacokinetic parameters were calculated using the 24-hour concentration profile for Days 1 and 7.

Following BID oral administration of TPOXX 600 mg, mean plasma exposure values for C_{max}, AUC_{0-24}, and AUC_{0-tau} were 847 ng/mL, 11900 ng*h/mL, and 5130 ng*h/mL, respectively, on Day 1. Mean $t_{1/2}$ was 8.46 hours on Day 1, although half-life for most of the Day 1 concentration profiles could not be calculated due to not having at least 3 time points excluding C_{max} in the elimination phase. Mean plasma trough concentration, calculated prior to the third dose, was 517 ng/mL. Median T_{max} was 4 hours after dosing on Day 1.

The steady-state mean plasma exposure values for C_{max}, AUC_{0-24}, and AUC from time 0 to 12 hours postdose (AUC_{0-12}) were 1350 ng/mL, 20000 ng*h/mL, and 9830 ng*h/mL, respectively, on Day 7. The mean steady-state $t_{1/2}$ and CL/F values were 12.9 h and 64.8 L/h, respectively. Mean plasma steady-state trough concentration, calculated prior to the second dose on Day 7, was 617 ng/mL. Median T_{max} was 4 hours after dosing at steady state.

The ratio (Day 7/Day 1) of mean plasma exposure C_{max}, AUC_{0-24}, and AUC_{0-tau} were 1.6, 1.7, and 1.9, respectively, suggesting plasma accumulation of TPOXX at a steady-state.

A summary of plasma PK parameters of TPOXX is presented in End-of-Text Table 14.2.2 (Day 1) and End-of-Text Table 14.2.3 (Day 7). A summary of plasma trough concentrations of TPOXX is presented in End-of-Text Table 14.2.4. Individual plasma PK parameters of TPOXX are presented in Data Listing 16.2.6.2 (Day 1) and Data Listing 16.2.6.3 (Day 7).

11.2 STATISTICAL/ANALYTICAL ISSUES

11.2.1 Adjustments for Covariates

Not applicable.

11.2.2 Handling of Dropouts or Missing Data

For the calculation of PK parameters, all plasma concentrations that were BLQ prior to the first measurable concentration were set to zero and treated as missing thereafter. No concentration estimates were imputed for missing sample values. Any sample with a missing value was treated as if the sample had not been scheduled for collection and was ignored when calculating mean concentrations or PK parameters.

11.2.3 Interim Analyses and Data Monitoring

No interim analysis was performed.

11.2.4 Multicenter Studies

This was a single-center study.

11.2.5 Multiple Comparison/Multiplicity

Not applicable.

11.2.6 Use of an "Efficacy Subset" of Subjects

Not applicable.

11.2.7 Active-Control Studies Intended to Show Equivalence

Not applicable.

11.2.8 Examination of Subgroups

Not applicable.

11.3 TABULATION OF INDIVIDUAL RESPONSE DATA

Individual plasma concentrations of TPOXX are presented in Data Listing 16.2.6.1. Individual plasma PK parameters of TPOXX on Days 1 and 7 are presented in Data Listings 16.2.6.2 and 16.2.6.3, respectively.

11.4 DRUG DOSE, DRUG CONCENTRATION, AND RELATIONSHIPS TO RESPONSE

Not applicable.

11.5 DRUG-DRUG AND DRUG-DISEASE INTERACTIONS

Not applicable.

11.6 BY-SUBJECT DISPLAYS

Individual plasma concentrations of TPOXX are presented in End-of-Text Figure 14.2.3.

11.7 PHARMACOKINETIC CONCLUSIONS

- Following BID oral administration of TPOXX 600 mg, plasma concentrations of TPOXX were detected immediately after dosing and reached peak levels around 4 hours after dosing.
- Steady state was achieved by Day 6 following administration of TPOXX for 7 days.
- On Day 1, mean plasma exposure values for C_{max}, AUC_{0-24}, and AUC_{0-tau} were 847 ng/mL, 11900 ng*h/mL, and 5130 ng*h/mL, respectively. Mean plasma trough

concentration, calculated prior to the third dose, was 517 ng/mL and median T_{max} was 4 hours after dosing. The mean $t_{1/2}$ was 8.46 hours (note that this could only be calculated in 32% of the total subjects due to having insufficient data in the terminal phase).

- On Day 7, steady-state mean plasma exposure values for C_{max}, AUC_{0-24}, and AUC_{0-12} were 1350 ng/mL, 20000 ng*h/mL, and 9830 ng*h/mL, respectively. The mean steady-state $t_{1/2}$ and CL/F values were 12.9 hours and 64.8 L/h, respectively. Mean plasma steady-state trough concentration, calculated prior to the second dose on Day 7, was 617 ng/mL. Median T_{max} was 4 hours after dosing at steady state.
- The ratio (Day 7/Day 1) of mean plasma exposure C_{max}, AUC_{0-24}, and AUC_{0-tau} ranged from 1.6 to 1.9, suggesting plasma accumulation of TPOXX at steady-state.

12. SAFETY EVALUATION

12.1 ADVERSE EVENTS

12.1.1 Brief Summary of Adverse Events

A total of 9 of 34 subjects (26.5%) reported 12 AEs during the study. A total of 2 of 34 subjects (5.9%) reported 2 TRAEs. The most commonly reported AEs were in the SOCs of gastrointestinal disorders (3 subjects, 8.8%) and nervous system disorders (2 subjects, 5.9%). The most commonly reported AEs were nausea and headache (2 subjects, 5.9% each). All other AEs were reported by 1 subject (2.9%) each. No AEs above Grade 1 (mild; 9 subjects) were reported in this study. All AEs were reported as recovered/resolved by the end of the study. There were no SAEs, serious TRAEs, or AEs leading to study drug or study discontinuation during the study.

12.1.2 Display of Adverse Events

An overall summary of AEs is presented in Table 12-1. A summary of AEs by SOC and PT is presented in Table 12-2.

Table 12-1 Overall Summary of Adverse Events (Safety Population)

Category	Total (N=34) n (%) [E]
Any AE	9 (26.5) [12]
Time to first AE (days)	
n	9
Mean (SD)	5.0 (5.45)
Median	3.0
Minimum, maximum	2, 19
Any Grade 2 (moderate) AE	0
Any Grade 3 (severe) AE	0
Any Grade 4 (life-threatening) AE	0
Any Grade 5 (death) AE	0
Any TRAE	2 (5.9) [2]
Any Grade 2 (moderate) TRAE	0
Any Grade 3 (severe) TRAE	0
Any Grade 4 (life-threatening) TRAE	0
Any Grade 5 (death) TRAE	0
Any serious AE	0
Any serious TRAE	0
Any AE leading to study drug discontinuation	0
Any AE leading to study discontinuation	0

Abbreviations: AE, adverse event; BID, twice daily; [E], the number of events at each level of summarization; n, the number of subjects at each level of summarization; TRAE, treatment-related adverse event.

Notes: An AE was considered a TRAE if it was assessed as probably, possibly, or definitely related.

At each level of subject summarization, a subject was counted once if the subject reported one or more events.

If the relationship of an AE was missing, the AE was considered related; if the severity of an AE was missing, the AE was considered Grade 3 (severe) in severity.

Time to first AE was calculated in days as the date of the first AE — the date of first dose of study drug + 1. Only treatment-emergent AEs were considered.

TPOXX 600 mg (3 × 200-mg capsules) was administered orally BID on Days 1 to 7, approximately 12 hours (±30 minutes) apart.

Percentages were based on the number of subjects in the safety population.

Source: End-of-Text Table 14.3.1.1.

Table 12-2 Adverse Events by System Organ Class and Preferred Term (Safety Population)

System Organ Class Preferred Term	Total (N=34) n (%)
Total number of AEs	12
Number of subjects with at least 1 AE	9 (26.5)
Gastrointestinal disorders	3 (8.8)
Nausea	2 (5.9)
Infrequent bowel movements	1 (2.9)
Lip dry	1 (2.9)
Nervous system disorders	2 (5.9)
Headache	2 (5.9)
Eye disorders	1 (2.9)
Scleral hyperaemia	1 (2.9)
Infections and infestations	1 (2.9)
Urinary tract infection	1 (2.9)
Injury, poisoning and procedural complications	1 (2.9)
Palate injury	1 (2.9)
Musculoskeletal and connective tissue disorders	1 (2.9)
Back pain	1 (2.9)
Renal and urinary disorders	1 (2.9)
Dysuria	1 (2.9)
Skin and subcutaneous tissue disorders	1 (2.9)
Dermatitis contact	1 (2.9)

Abbreviations: AE, adverse event; n, the number of subjects at each level of summarization.

Notes: The total number of AEs counts all AEs for subjects.
At each level of summarization, a subject was counted once if the subject counted 1 or more events.
Adverse events were coded using the Medical Dictionary for Regulatory Activities, Version 22.0.
TPOXX 600 mg (3 × 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.

Source: End-of-Text Table 14.3.1.2.

12.1.3 Analysis of Adverse Events

A total of 9 of 34 subjects (26.5%) reported 12 AEs during the study. A total of 2 of 34 subjects (5.9%) reported 2 TRAEs (nausea and headache, reported by 1 subject [2.9%] each). The most commonly reported AEs were in the SOCs of gastrointestinal disorders (3 subjects, 8.8%) and nervous system disorders (2 subjects, 5.9%). The most commonly reported AEs were nausea and headache (2 subjects, 5.9% each). All other AEs were reported by 1 subject (2.9%) each. No AEs above Grade 1 (mild; 9 subjects) were reported in this study. All AEs were reported as recovered/resolved by the end of the study. There were no SAEs, serious TRAEs, or AEs leading to study drug or study discontinuation during the study.

An overall summary of AEs is presented in End-of-Text Table 14.3.1.1. Adverse events are summarized by SOC and PT in End-of-Text Table 14.3.1.2, by PT in End-of-Text

Table 14.3.1.3, by relationship to study drug in End-of-Text Table 14.3.1.4, and by severity in End-of Text Table 14.3.1.5.

12.1.4 Listing of Adverse Events by Subject

Details of all AEs and TRAEs are presented by subject in Data Listings 16.2.7.1 and 16.2.7.2, respectively.

12.2 DEATHS, OTHER SERIOUS ADVERSE EVENTS, AND OTHER SIGNIFICANT ADVERSE EVENTS

12.2.1 Listing of Deaths, Other Serious Adverse Events and Other Significant Adverse Events

12.2.1.1 Deaths

There were no deaths in this study (Data Listing 16.2.7.3).

12.2.1.2 Other Serious Adverse Events

There were no SAEs in this study (Data Listing 16.2.7.3).

12.2.1.3 Other Significant Adverse Events

No subject discontinued study drug because of an AE (Data Listing 16.2.7.4).

12.2.2 Narratives of Deaths, Other Serious Adverse Events, and Certain Other Significant Adverse Events

Not applicable.

12.2.3 Analysis and Discussion of Deaths, Serious Adverse Events, and Other Significant Adverse Events

Not applicable.

12.3 CLINICAL LABORATORY EVALUATION

12.3.1 Listing of Individual Laboratory Measurements by Subject and Each Abnormal Laboratory Value

Individual hematology, serum chemistry, and urinalysis results are presented by subject in Data Listings 16.2.8.1, 16.2.8.2, and 16.2.8.3, respectively.

12.3.2 Evaluation of Each Laboratory Parameter

12.3.2.1 Laboratory Values Over Time

Hematology

Mean hematology results were within the reference ranges at the time points assessed and the mean values observed after dosing were generally similar to those observed at baseline. None of the postbaseline hematology results increased in DAIDS grade.

Serum Chemistry

Mean serum chemistry results were within the reference ranges at the time points assessed and the mean values observed after dosing were generally similar to those observed at baseline.

Several subjects had postbaseline serum chemistry results that increased in DAIDS grade. None of the postbaseline increases in DAIDS grade were higher than a maximum of Grade 1. Overall, 2 subjects (5.9%) each had low albumin and high glucose values assessed as DAIDS Grade 1 postbaseline and 3 subjects (8.8%) each had low sodium and high urate values assessed as DAIDS Grade 1 postbaseline.

Urinalysis

Mean urinalysis results were within the reference ranges at the time points assessed, and the mean values observed after dosing were generally similar to those observed at baseline. None of the postbaseline urinalysis results increased in DAIDS grade.

Summary statistics and change from baseline in mean hematology, serum chemistry, and urinalysis values are provided in End-of-Text Tables 14.3.2.1.1, 14.3.2.2.1, and 14.3.2.3.1, respectively. Summary statistics of hematology, serum chemistry, and urinalysis results by maximum grade increase postbaseline relative to baseline are provided in End-of-Text Tables 14.3.2.1.3, 14.3.2.2.3, and 14.3.2.3.3, respectively.

12.3.2.2 Individual Subject Changes

Shifts in hematology values from normal at baseline to low or high after dosing were only observed in more than 1 subject for basophils. Overall, 2 subjects (5.9%) shifted to high on Days 8 and 9/early discontinuation (ED).

Shifts in serum chemistry values from normal at baseline to low or high after dosing in more than 1 subject were as follows:

- Lactate dehydrogenase: 2 subjects (5.9%) shifted to high on Days 8 and 9/ED.
- Urate: 3 subjects (8.8%) shifted to high on Day 4, and 6 subjects (17.6%) shifted to high on Days 8 and 9/ED.

Shifts in urinalysis values from normal at baseline to low, high, or abnormal after dosing in more than 1 subject were as follows:

- Clarity: 3 subjects (8.8%) shifted to abnormal on Day 9/ED.
- Leukocyte esterase: 2 subjects (5.9%) shifted to abnormal on Day 9/ED.
- Occult blood: 3 subjects (8.8%) shifted to abnormal on Day 9/ED.
- Urine protein: 2 subjects (5.9%) shifted to abnormal on Day 9/ED.

Shifts from baseline in hematology, serum chemistry, and urinalysis values are presented in End-of-Text Tables 14.3.2.1.2, 14.3.2.2.2, and 14.3.2.3.2, respectively.

12.3.2.3 Individual Clinically Significant Abnormalities

No individual hematology, serum chemistry, or urinalysis abnormality was considered clinically significant or reported as an AE by the investigator.

Laboratory results meeting DAIDS toxicity Grade 1 or higher are presented by subject in Data Listing 16.2.8.5. All clinical laboratory test results with toxicity grades were no higher than DAIDS Grade 1 or 2.

Of note, 3 subjects had negative urine protein and urine glucose test results for the Day 9 urinalysis sample, which were within the normal range for this study; however, a limitation within the Lab Trend View system used in this study forced an assessment code to be assigned to these laboratory values by the investigator in order for the laboratory results to be signed. The investigator assessed these values as not clinically significant. The Lab Trend View system will soon be decommissioned, and no fix has been planned for the system. This limitation was identified and is characterized in a note to file dated 30 January 2020.

12.4 VITAL SIGNS, PHYSICAL FINDINGS, AND OTHER OBSERVATIONS RELATED TO SAFETY

12.4.1 Vital Sign Measurements

Mean vital sign measurements were generally similar at the time points assessed. No individual vital sign measurement was reported as an AE by the investigator.

Summary statistics and change from baseline in vital sign measurements are presented in End-of-Text Table 14.3.3.1.1. Individual vital sign measurements are presented by subject in Data Listing 16.2.8.6.

12.4.2 Twelve-Lead Electrocardiograms

Mean 12-lead ECG values were generally similar at the time points assessed. No individual 12-lead ECG value was reported as an AE, and none of the abnormal 12-lead ECG values were assessed as clinically significant by the investigator.

Summary statistics and change from baseline in 12-lead ECG parameters are presented in End-of-Text Table 14.3.4.1.1. Individual 12-lead ECG parameters are presented by subject in Data Listing 16.2.8.7.

12.4.3 Physical Measurements

Individual physical measurements are presented by subject in Data Listing 16.2.8.9.

12.4.4 Physical Examinations

None of the subjects had abnormal postbaseline physical examination findings that had not been previously observed at screening and none of the physical examination findings were associated with AEs or reported as clinically significant by the investigator.

Individual physical examination findings are presented by subject in Data Listing 16.2.8.8.

12.4.5 Follow-up Visit or Telephone Call

Individual follow-up visit/telephone call information is presented by subject in Data Listing 16.2.8.10.

12.4.6 Pregnancies

There were no pregnancies reported during this study.

12.5 SAFETY CONCLUSIONS

- TPOXX was considered safe and generally well tolerated when administered orally at a dose of 600 mg BID for 7 days in adult subjects weighing more than 120 kg.
- A total of 9 subjects (26.5%) reported 12 AEs during the study. A total of 2 of 34 subjects (5.9%) reported 2 TRAEs.
- The most commonly reported AEs were in the SOCs of gastrointestinal disorders (3 subjects, 8.8%) and nervous system disorders (2 subjects, 5.9%). The most commonly reported AEs were nausea and headache (2 subjects, 5.9% each).
- No AEs above Grade 1 (mild; 9 subjects) were reported in this study.
- There were no SAEs, serious TRAEs, or AEs leading to study drug or study discontinuation during the study.
- Mean clinical laboratory test results (hematology, serum chemistry, and urinalysis), vital sign measurements, physical examination findings, and 12-lead ECG values after dosing were generally similar to baseline values.
- No individual clinical laboratory test result, vital sign measurement, physical examination finding, or 12-lead ECG value was associated with an AE or considered clinically significant by the investigator. All clinical laboratory test results with toxicity grades were no higher than DAIDS Grade 1 or 2.

13. DISCUSSION AND OVERALL CONCLUSIONS

13.1 DISCUSSION

This was an open-label, multiple-dose study to assess the safety, tolerability, and PK of TPOXX 600 mg BID when administered orally for 7 days to adult subjects weighing more than 120 kg. A total of 34 subjects, aged 20 to 50 years, inclusive, were enrolled. The study consisted of a screening period (Day –28 to –2), a treatment and confinement period (Days –1 to 9), a follow-up telephone call or visit (Day 14 [+2 days]), and a follow-up telephone call (Day 37 [+2 days]).

The primary objective of this study was to determine the PK profile of 600 mg oral TPOXX (3 × 200-mg capsules) administered BID for 7 days in adult subjects weighing more than 120 kg to determine if a change in TPOXX dosing regimen would be needed in these patients.

Following BID oral administration of TPOXX 600 mg, plasma concentrations of TPOXX were detected immediately after dosing and reached peak levels around 4 hours after dosing. Steady state was achieved by Day 6 following administration of TPOXX for 7 days. The ratios of mean plasma exposure C_{max}, AUC_{0-24}, and AUC_{0-tau} on Day 7/Day 1 ranged from 1.6 to 1.9, suggesting plasma accumulation of TPOXX at steady-state.

The secondary objective of this study was to evaluate the safety and tolerability of 600 mg oral TPOXX administered BID for 7 days in adult subjects weighing more than 120 kg.

A total of 9 subjects (26.5%) reported 12 AEs during the study. A total of 2 of 34 subjects (5.9%) reported 2 TRAEs. The most commonly reported AEs were in the SOCs of gastrointestinal disorders (3 subjects, 8.8%) and nervous system disorders (2 subjects, 5.9%). The most commonly reported AEs were nausea and headache (2 subjects, 5.9% each). All other AEs were reported by 1 subject (2.9%) each. No AEs above Grade 1 (mild; 9 subjects) were reported in this study. There were no SAEs, serious TRAEs, or AEs leading to study drug or study discontinuation during the study. There were no notable safety signals in results from safety assessments.

Mean clinical laboratory test results (hematology, serum chemistry, and urinalysis), vital sign measurements, physical examination findings, and 12-lead ECG values after dosing were generally similar to baseline values. No individual clinical laboratory test result, vital sign measurement, physical examination finding, or 12-lead ECG value was associated with an AE or considered clinically significant by the investigator. All clinical laboratory test results with toxicity grades were no higher than DAIDS Grade 1 or 2.

13.2 OVERALL CONCLUSIONS

Pharmacokinetics:

SIGA will incorporate the PK data for the 34 subjects enrolled in this study into a population PK model which is being developed outside of this clinical study to inform if a change in dosing regimen would be needed in these patients.

Safety:

TPOXX was considered safe and generally well tolerated when administered orally at a dose of 600 mg BID for 7 days in adult subjects weighing more than 120 kg.

14. TABLES AND FIGURES REFERRED TO BUT NOT INCLUDED IN THE TEXT

14.1 DEMOGRAPHIC DATA

14.2 PHARMACOKINETIC DATA

14.3 SAFETY DATA

14.3.1 Displays of Adverse Events

14.3.2 Listings of Deaths, Other Serious and Significant Adverse Events

Not applicable.

14.3.3 Narratives of Deaths, Other Serious and Certain Other Significant Adverse Events

There were no deaths, SAEs, or other significant AEs during the study (Section 12.2).

14.3.4 Laboratory and Other Safety Data

Table 14.1.1.1
Subject Disposition
Enrolled Population

	Total (N=34) n (%)
Total Number of Subjects	
Completed	34 (100.0)
Discontinued	0
Analysis Populations	
Safety Population	34 (100.0)
PK Population	34 (100.0)
Primary Reason for Discontinuation	
Adverse Event	0
Death	0
Lost to Follow-up	0
Physician Decision	0
Protocol Deviation	0
Screen Failure	0
Withdrawal by Subject	0
Other	0

Note: The Safety population includes all subjects who receive at least 1 dose of study drug.
The PK population includes all subjects who receive study drug and have sufficient concentration data to facilitate the calculation of PK variables.
All percentages are based on the Enrolled population.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Listing 16.2.1.1
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Table 14.1.1.2
Major Protocol Deviations
Safety Population

Category	Total (N=34) n (%)
Missing Endpoint Assessments	6 (17.6)
Study Procedures/Assessments	1 (2.9)

Note: Subjects could have more than one major protocol deviation, but are counted once for each level of summarization.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Listing 16.2.2.1
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Table 14.1.2
Demographics
Safety Population

	Total (N=34)
Age (Years)	
n	34
Mean (SD)	35.5 (8.31)
Median	34.5
Min, Max	20, 50
Sex, n (%)	
MALE	23 (67.6)
FEMALE	11 (32.4)
Reproductive Status, n (%) [1]	
POTENTIALLY ABLE TO BEAR CHILDREN	8 (72.7)
STERILE	3 (27.3)
Race, n (%)	
WHITE	12 (35.3)
BLACK OR AFRICAN AMERICAN	22 (64.7)
ASIAN	0
AMERICAN INDIAN OR ALASKA NATIVE	0
NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	0
Ethnicity, n (%)	
HISPANIC OR LATINO	5 (14.7)
NOT HISPANIC OR LATINO	29 (85.3)

Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] Reproductive status is presented for female subjects only and percentages are computed based on the total number of females.
Source Data: Listing 16.2.4.1
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Table 14.1.2
Demographics
Safety Population

	Total (N=34)
Weight (kg)	
n	34
Mean (SD)	138.13 (20.881)
Median	131.15
Min, Max	120.3, 220.4
Height (cm)	
n	34
Mean (SD)	176.40 (9.649)
Median	176.55
Min, Max	151.2, 195.3

Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] Reproductive status is presented for female subjects only and percentages are computed based on the total number of females.
Source Data: Listing 16.2.4.1
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Table 14.1.3
Study Drug Administration
Enrolled Population

	Total (N=34)
Subjects Enrolled	34
Dosed n (%)	34 (100.0)
Number of complete doses received (maximum of 14)	
Mean (SD)	14.0 (0.00)
Median	14.0
Min, Max	14, 14
Number of subjects completing all 14 doses of study drug	34 (100.0)

Note: Percentages are based on the number of subjects in the safety population.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Listing 16.2.5.1
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Table 14.2.1
Summary of Plasma Concentrations (ng/mL) of TPOXX
Pharmacokinetic Population

Day = Day 1

	Scheduled Time (hours)												
Statistics	PREDOSE	0.5	1	2	4	6	8	12	14	16	18	20	24
n	34	34	34	34	34	34	33	33	34	34	33	33	34
Mean	BLQ	8.26	74.0	436	773	568	401	267	339	640	711	714	517
Geometric Mean	.	.	.	342	728	538	360	246	304	597	673	687	484
SD	NA	14.3	80.4	251	246	182	223	123	172	248	257	200	206
CV%	NA	172.9	108.7	57.6	31.9	32.0	55.6	46.2	50.8	38.8	36.1	28.0	39.8
Geometric SD	.	.	.	2.30	1.46	1.42	1.58	1.48	1.59	1.45	1.39	1.34	1.43
Geometric CV%	.	.	.	99.8	39.5	36.1	48.2	41.0	48.7	38.8	33.9	29.6	37.0
Median	0	0	43.5	454	760	564	361	241	269	541	642	704	471
Min	0	0	0	25.6	192	232	136	121	148	240	382	395	215
Max	0	73.2	355	940	1310	941	1330	758	745	1220	1520	1100	1170

NA = Not applicable.
Note: Concentrations below the limit of quantification (BLQ) were treated as zero for descriptive statistics.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Listing 16.2.6.1
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Table 14.2.1
Summary of Plasma Concentrations (ng/mL) of TPOXX
Pharmacokinetic Population

Day = Day 6

	Scheduled Time (hours)	
Statistics	PREDOSE	4
n	34	34
Mean	620	1280
Geometric Mean	584	1230
SD	213	337
CV%	34.3	26.4
Geometric SD	1.44	1.31
Geometric CV%	37.6	27.6
Median	586	1220
Min	227	633
Max	1200	2000

NA = Not applicable.
Note: Concentrations below the limit of quantification (BLQ) were treated as zero for descriptive statistics.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Listing 16.2.6.1
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\t140201.SAS Executed: 24JAN2020 08:06

Table 14.2.1
Summary of Plasma Concentrations (ng/mL) of TPOXX
Pharmacokinetic Population

Day = Day 7

	Scheduled Time (hours)													
Statistics	PREDOSE	0.5	1	2	4	6	8	12	14	16	18	20	24	48
n	34	34	34	34	34	34	34	34	34	34	33	34	34	34
Mean	615	487	476	768	1280	1030	686	617	806	1080	991	856	610	182
Geometric Mean	585	462	453	694	1210	996	652	584	772	1030	963	819	573	165
SD	190	158	151	376	427	270	206	219	236	314	239	243	212	75.0
CV%	30.9	32.4	31.8	48.9	33.4	26.1	30.0	35.6	29.3	29.1	24.2	28.4	34.8	41.2
Geometric SD	1.39	1.40	1.38	1.57	1.39	1.34	1.41	1.39	1.35	1.34	1.28	1.37	1.45	1.65
Geometric CV%	34.0	34.8	33.4	47.3	34.2	29.6	35.1	34.2	30.9	29.5	25.4	32.6	38.2	53.1
Median	605	455	446	697	1200	1030	685	562	841	1000	979	874	592	171
Min	247	192	157	291	516	459	285	265	439	641	539	322	263	27.9
Max	1090	978	897	1860	2270	1480	1210	1280	1330	1850	1490	1300	1090	381

NA = Not applicable.
Note: Concentrations below the limit of quantification (BLQ) were treated as zero for descriptive statistics.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Listing 16.2.6.1
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\t140201.SAS Executed: 24JAN2020 08:06

Table 14.2.2
Summary of Plasma Pharmacokinetic Parameters of TPOXX — Day 1
Pharmacokinetic Population

	Scheduled Time (hours)						
Statistics	Cmax (ng/mL)	AUC0-24 (h*ng/mL)	AUC0-t (h*ng/mL)	AUC0-tau (h*ng/mL)	Tmax (h)	t1/2 (h)	Lambda_z (1/h)
n	34	34	34	34	34	11	11
Mean	847	11900	11900	5130	.	8.46	0.0938
Geometric Mean	823	11600	11600	5000	.	.	.
SD	211	2820	2820	1160	.	3.85	0.0309
CV%	24.9	23.8	23.8	22.6	.	45.5	32.9
Geometric SD	1.28	1.28	1.28	1.26	.	.	.
Geometric CV%	25.0	24.7	24.7	23.6	.	.	.
Median	848	11800	11800	5070	4.00	6.49	0.1069
Min	523	6210	6210	2960	2.00	5.09	0.0380
Max	1330	19000	19000	7270	8.02	18.2	0.1362

Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Listing 16.2.6.2
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\t140202.SAS Executed: 24JAN2020 08:07

Table 14.2.3
Summary of Plasma Pharmacokinetic Parameters of TPOXX — Day 7
Pharmacokinetic Population

	Scheduled Time (hours)										
Statistics	Cmax (ng/mL)	AUC0-24 (h*ng/mL)	AUC0-t (h*ng/mL)	AUC0-tau (h*ng/mL)	AUC0-inf (h*ng/mL)	Tmax (h)	t1/2 (h)	Lambda_z (1/h)	CL/F (L/h)	Vz/F (L)	%AUCextrap (%)
n	34	34	34	34	33	34	33	33	34	33	33
Mean	1350	20000	29500	9830	33200	.	12.9	0.0559	64.8	1180	10.4
Geometric Mean	1300	19500	28500	9550	31900	.	.	.	.	.	.
SD	393	4590	7670	2350	9240	.	2.48	0.0113	16.8	355	4.06
CV%	29.0	23.0	26.0	23.9	27.8	.	19.3	20.3	26.0	29.9	39.2
Geometric SD	1.33	1.27	1.31	1.28	1.34	.	.	.	.	.	.
Geometric CV%	29.1	24.3	27.8	25.1	30.2	.	.	.	.	.	.
Median	1280	19200	29000	9510	33000	4.00	12.5	0.0552	63.1	1170	9.78
Min	690	10900	15500	5280	15900	2.00	7.65	0.0379	40.6	698	1.94
Max	2270	27600	45300	14800	54500	11.95	18.3	0.0906	114	2430	19.1

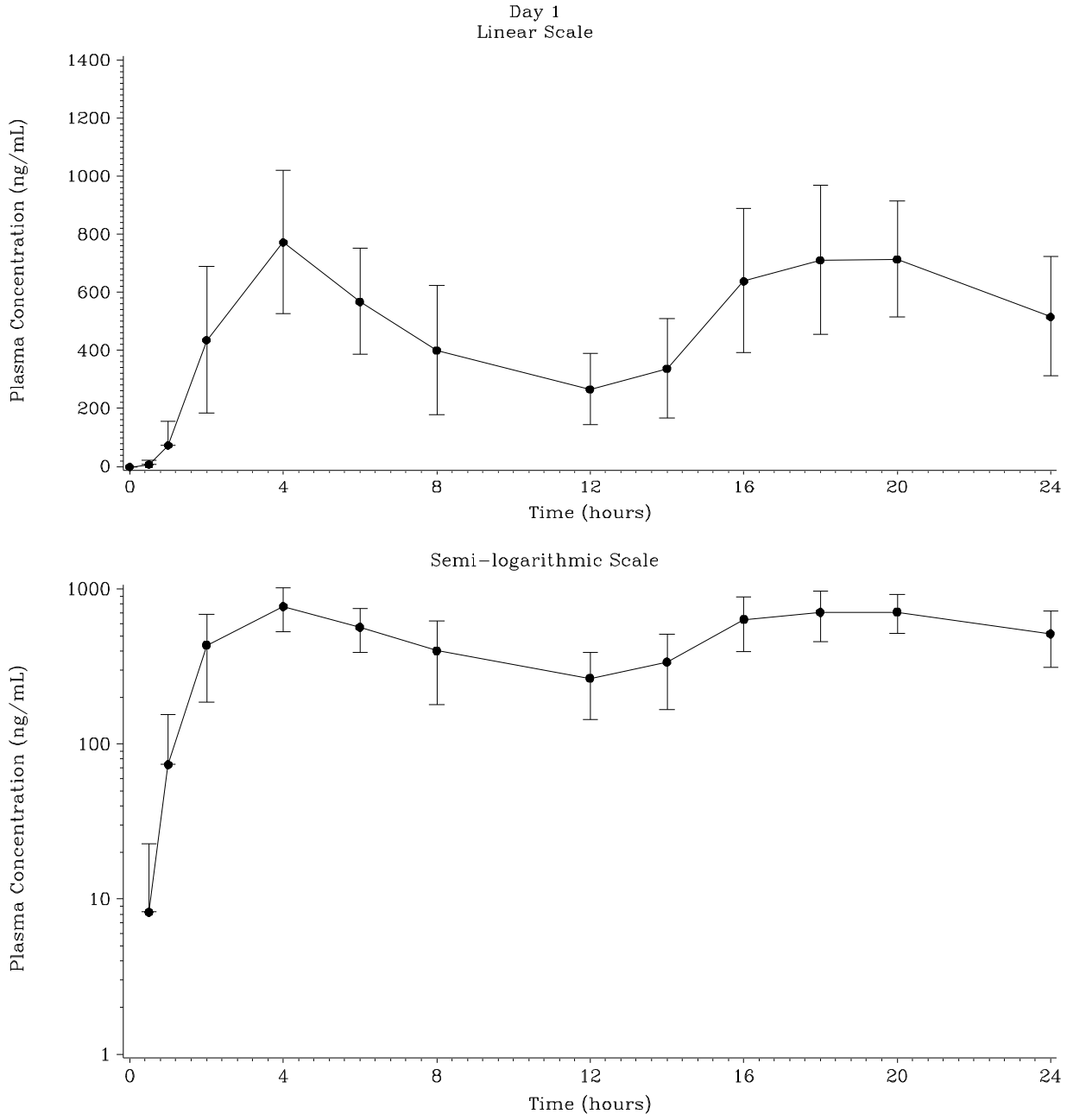
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Note: CL/F is calculated as Dose/AUC0-12. Vz/F is calculated as Dose/(AUC0-12*Lambda_z).
Source Data: Listing 16.2.6.3
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\t140203.SAS Executed: 24JAN2020 08:07

Table 14.2.4
Summary of Trough Concentration (ng/mL) of TPOXX
Pharmacokinetic Population

	Scheduled Time (hours)				
Statistics	Day 1 Before PM Dose	Day 2 Before AM Dose	Day 6 Before AM Dose	Day 7 Before AM Dose	Day 7 Before PM Dose
n	33	34	34	34	34
Mean	267	517	620	615	617
Geometric Mean	246	484	584	585	584
SD	123	206	213	190	219
CV%	46.2	39.8	34.3	30.9	35.6
Geometric SD	1.48	1.43	1.44	1.39	1.39
Geometric CV%	41.0	37.0	37.6	34.0	34.2
Median	241	471	586	605	562
Min	121	215	227	247	265
Max	758	1170	1200	1090	1280

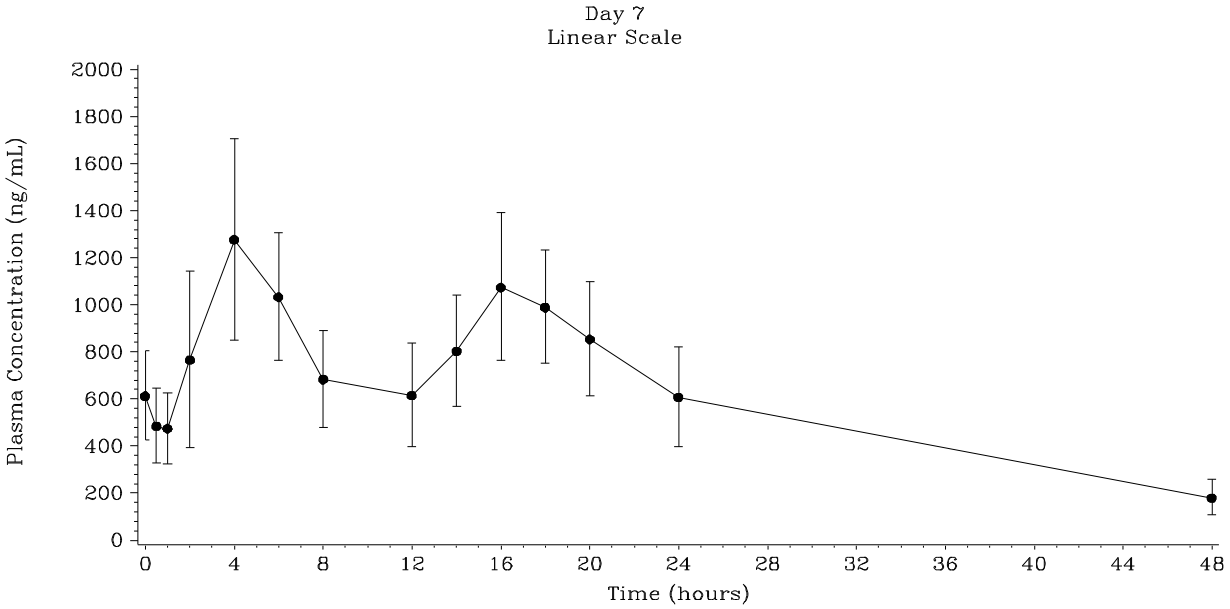
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Listing 16.2.6.1
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\t140204.SAS Executed: 24JAN2020 08:07

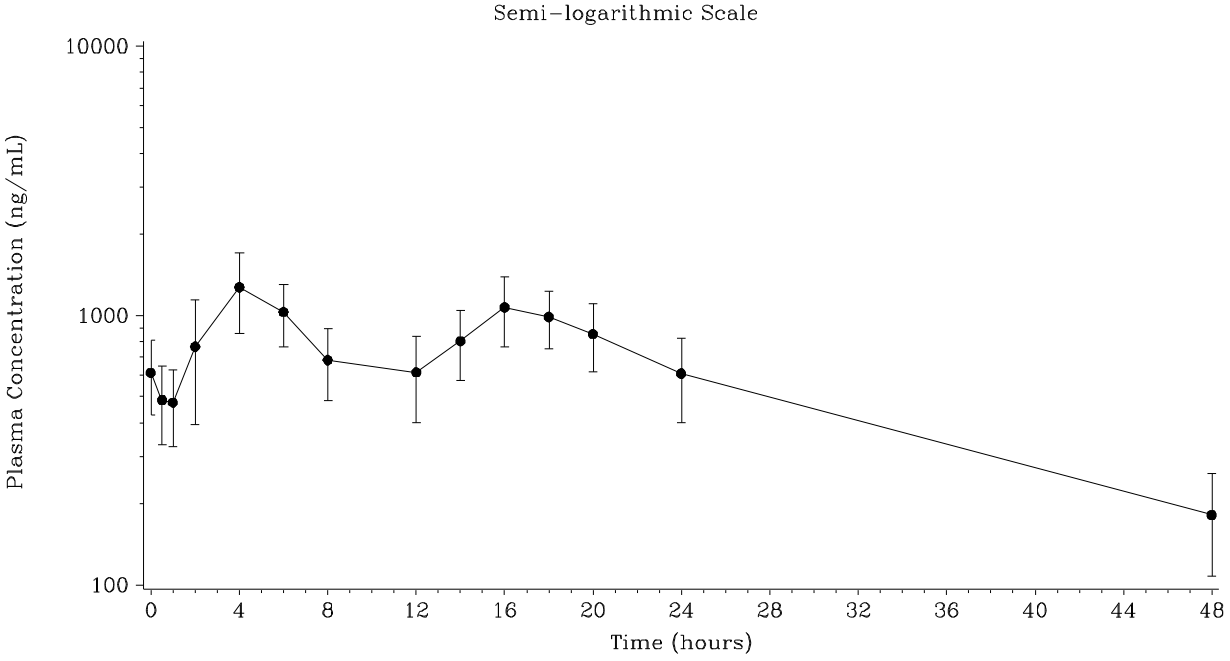
Figure 14.2.1
Mean (±SD) Plasma Concentrations of TPOXX versus Time
Pharmacokinetic Population



Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Table 14.2.1
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\f140201.SAS
Executed: 24JAN2020 08:03

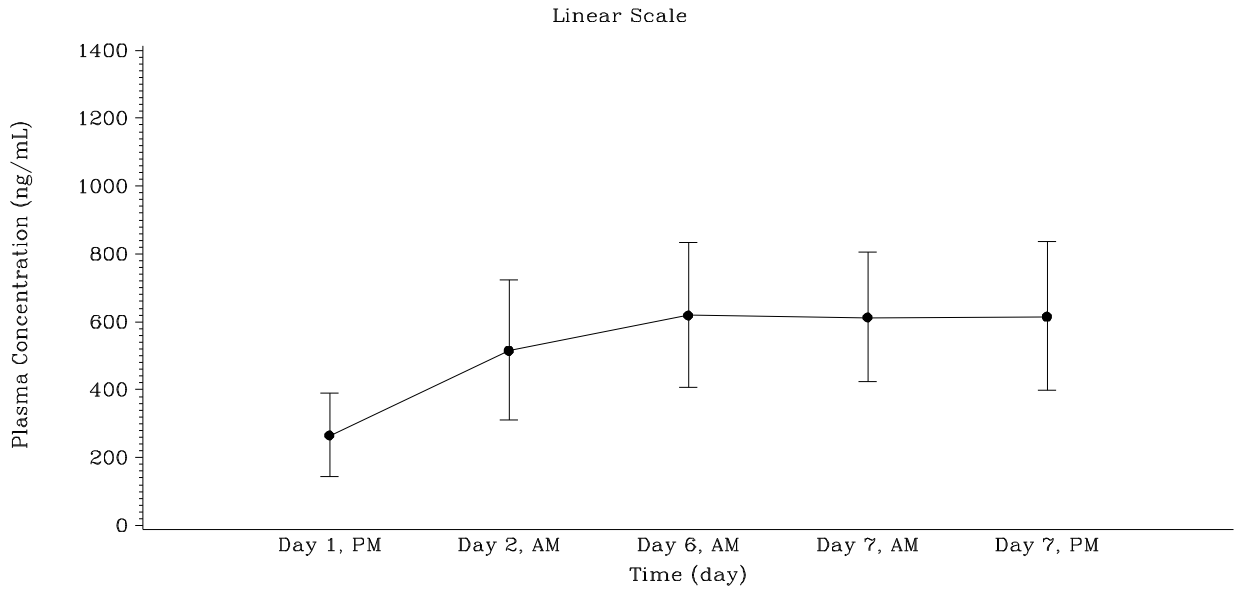
Figure 14.2.1
Mean (±SD) Plasma Concentrations of TPOXX versus Time
Pharmacokinetic Population

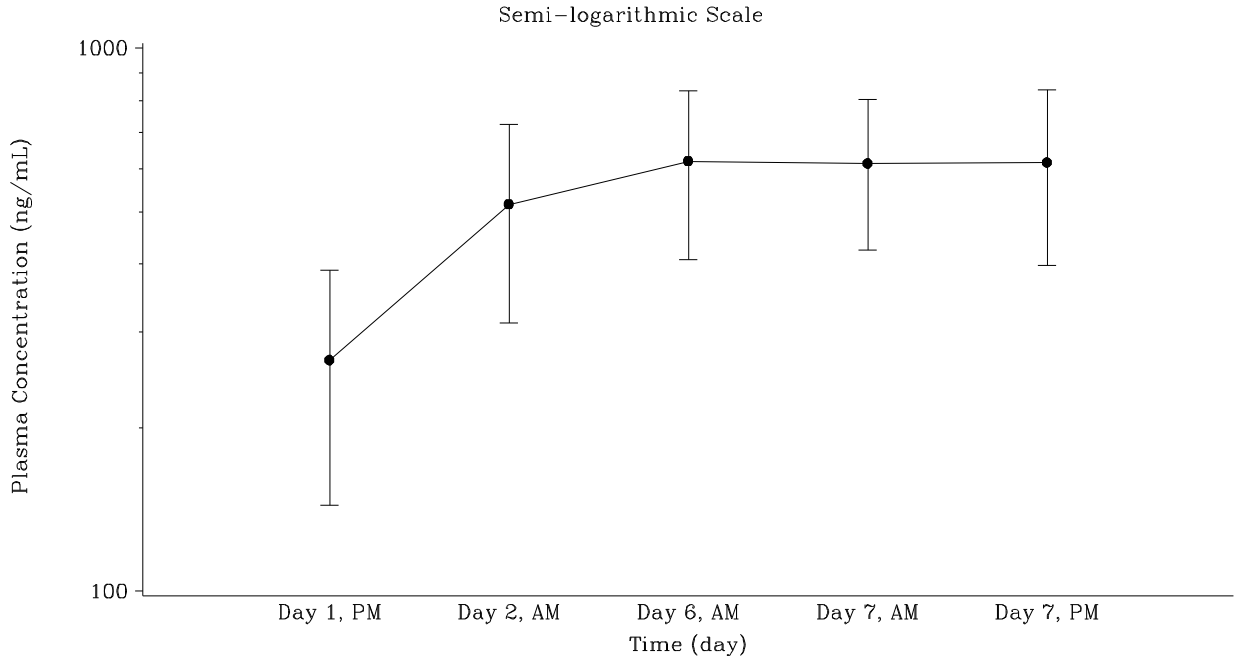




Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Table 14.2.1
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\f140201.SAS
Executed: 24JAN2020 08:03

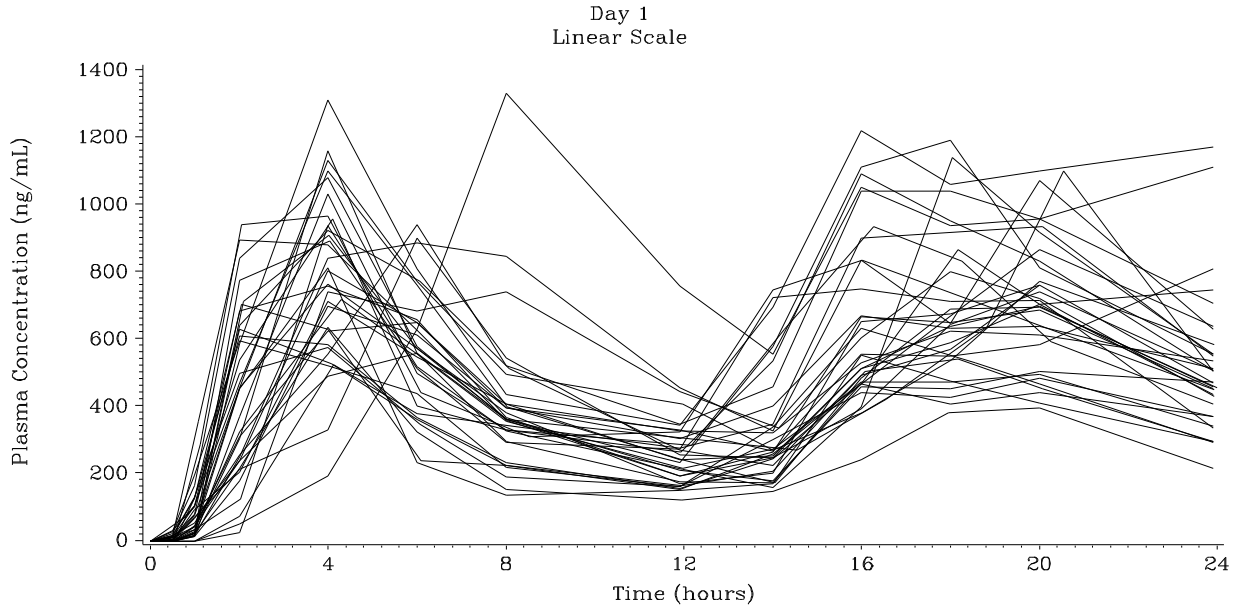
Figure 14.2.2
Mean (±SD) Plasma Trough Concentrations of TPOXX versus Time
Pharmacokinetic Population

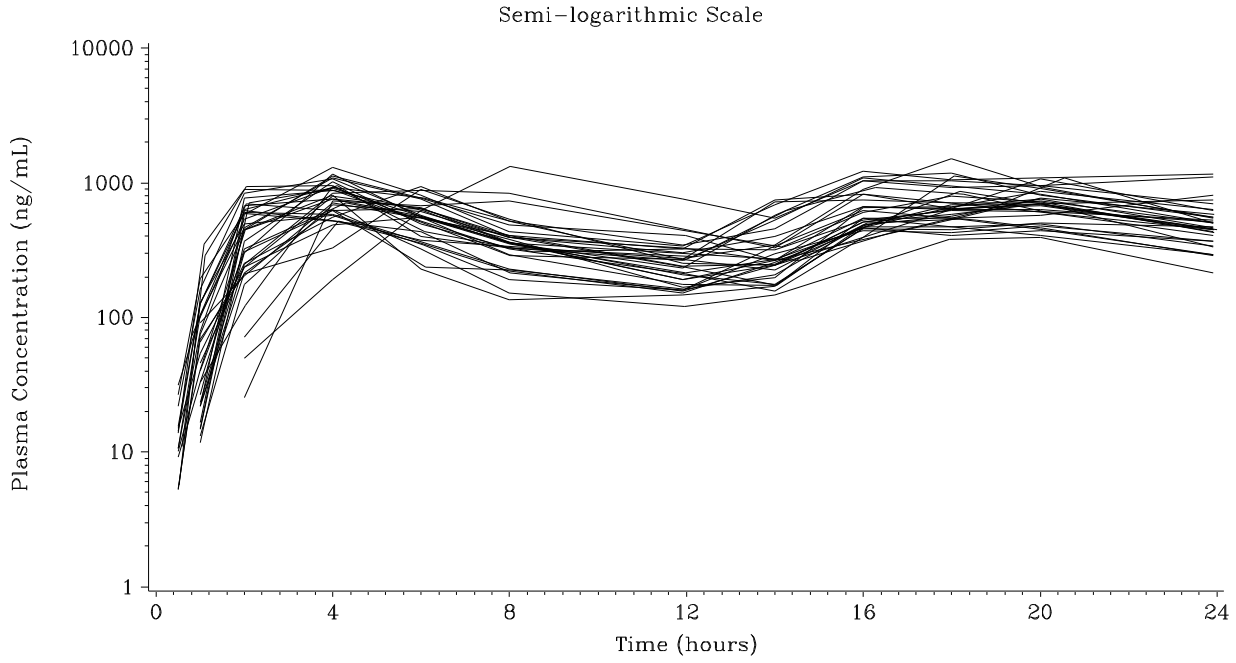




Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Table 14.2.1
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\f140202.SAS
Executed: 24JAN2020 08:04

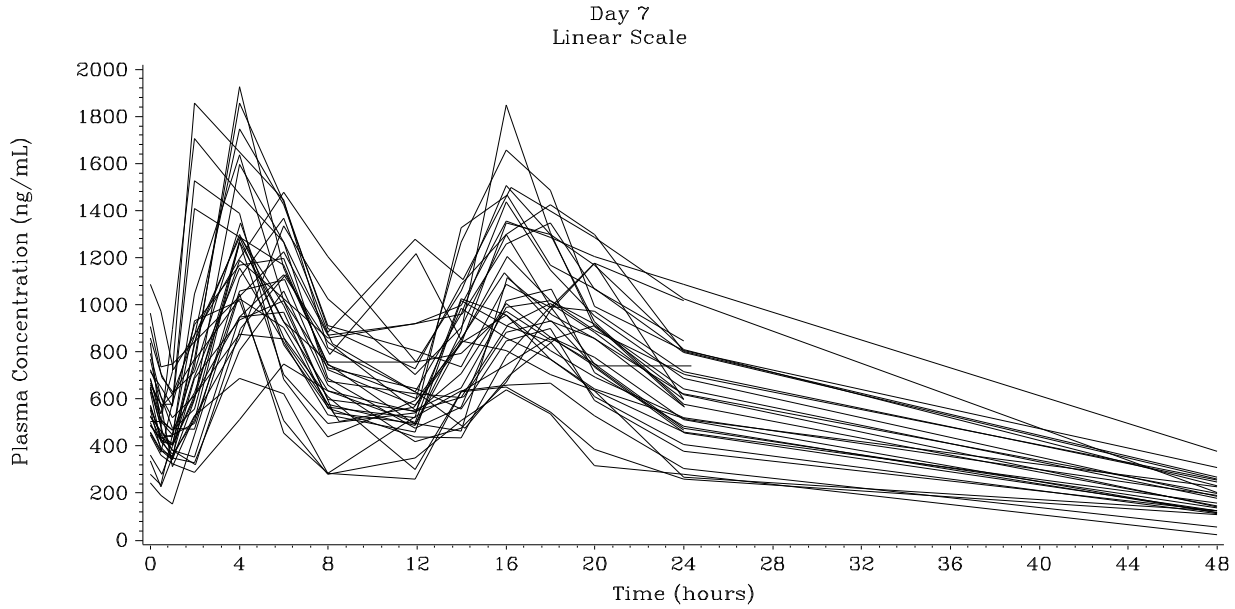
Figure 14.2.3
Individual Plasma Concentrations of TPOXX versus Time
Safety Population

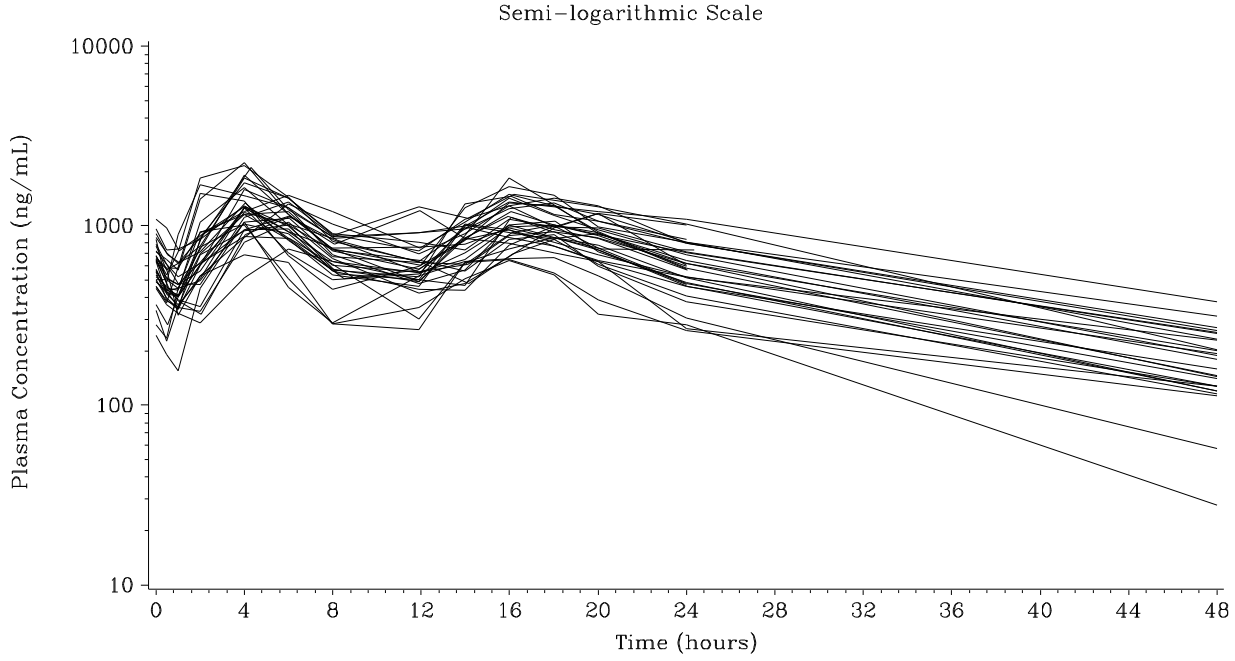




Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Listing 16.2.6.1
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\f140203.SAS
Executed: 24JAN2020 08:04

Figure 14.2.3
Individual Plasma Concentrations of TPOXX versus Time
Safety Population





Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Listing 16.2.6.1
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\f140203.SAS
Executed: 24JAN2020 08:04

Table 14.3.1.1
Overall Summary of Adverse Events
Safety Population

	Total (N=34) n (%) [E]
Any AE	9 (26.5) [12]
Time to first TEAE (days)	
n	9
Mean (SD)	5.0 (5.45)
Median	3.0
Min, Max	2, 19
Any Grade 2 (Moderate) AE	0
Any Grade 3 (Severe) AE	0
Any Grade 4 (Life-Threatening) AE	0
Any Grade 5 (Death) AE	0
Time to first TEAE of Grade 3 or higher (days)	
n	0
Mean (SD)	
Median	
Min, Max	

Note: An AE is considered a treatment-related AE (TRAE) if it is assessed as probably, possibly, or definitely related.
At each level of subject summarization, a subject is counted once if the subject reported one or more events. n represents the number of subjects at each level of summarization. Percentages are based on the number of subjects in the safety population. [E] represents the number of events at each level of summarization.
If the relationship of an AE is missing, the AE will be considered 'Related'; if the severity of an AE is missing, the AE will be considerd 'Grade 3 (Severe)'.
Time to first AE is calculated in days as the date of the first AE – the date of first dose of study drug + 1. Time to first AE of grade 3 or higher is calculated similarly. Only treatment-emergent AEs are considered.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Listing 16.2.7.1
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Table 14.3.1.1
Overall Summary of Adverse Events
Safety Population

	Total (N=34) n (%) [E]
Any Treatment-Related AE (TRAE)	2 (5.9) [2]
Any Grade 2 (Moderate) TRAE	0
Any Grade 3 (Severe) TRAE	0
Any Grade 4 (Life-Threatening) TRAE	0
Any Grade 5 (Death) TRAE	0
Any Serious AE	0
Any Serious TRAE	0
Any AE leading to study drug discontinuation	0
Any AE leading to study discontinuation	0

Note: An AE is considered a treatment-related AE (TRAE) if it is assessed as probably, possibly, or definitely related.
At each level of subject summarization, a subject is counted once if the subject reported one or more events. n represents the number of subjects at each level of summarization. Percentages are based on the number of subjects in the safety population. [E] represents the number of events at each level of summarization.
If the relationship of an AE is missing, the AE will be considered 'Related'; if the severity of an AE is missing, the AE will be considerd 'Grade 3 (Severe)'.
Time to first AE is calculated in days as the date of the first AE – the date of first dose of study drug + 1. Time to first AE of grade 3 or higher is calculated similarly. Only treatment-emergent AEs are considered.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Listing 16.2.7.1
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Table 14.3.1.2
Adverse Events by System Organ Class and Preferred Term
Safety Population

System Organ Class Preferred Term	Total (N=34) n (%)
Total number of adverse events	12
Number of subjects with at least one adverse event	9 (26.5)
Gastrointestinal disorders	3 (8.8)
Nausea	2 (5.9)
Infrequent bowel movements	1 (2.9)
Lip dry	1 (2.9)
Nervous system disorders	2 (5.9)
Headache	2 (5.9)
Eye disorders	1 (2.9)
Scleral hyperaemia	1 (2.9)
Infections and infestations	1 (2.9)
Urinary tract infection	1 (2.9)
Injury, poisoning and procedural complications	1 (2.9)
Palate injury	1 (2.9)
Musculoskeletal and connective tissue disorders	1 (2.9)
Back pain	1 (2.9)
Renal and urinary disorders	1 (2.9)
Dysuria	1 (2.9)

Note: The total number of AEs counts all AEs for subjects. At each level of subject summarization, a subject is counted once if the subject reported one or more events.
Adverse Events were coded using MedDRA, Version 22.0.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Listing 16.2.7.1
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Table 14.3.1.2
Adverse Events by System Organ Class and Preferred Term
Safety Population

System Organ Class Preferred Term	Total (N=34) n (%)
Skin and subcutaneous tissue disorders	1 (2.9)
Dermatitis contact	1 (2.9)

Note: The total number of AEs counts all AEs for subjects. At each level of subject summarization, a subject is counted once if the subject reported one or more events.
Adverse Events were coded using MedDRA, Version 22.0.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Listing 16.2.7.1
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Table 14.3.1.3
Adverse Events by Preferred Term
Safety Population

Preferred Term	Total (N=34) n (%)
Total number of adverse events	12
Number of subjects with at least one adverse event	9 (26.5)
Headache	2 (5.9)
Nausea	2 (5.9)
Back pain	1 (2.9)
Dermatitis contact	1 (2.9)
Dysuria	1 (2.9)
Infrequent bowel movements	1 (2.9)
Lip dry	1 (2.9)
Palate injury	1 (2.9)
Scleral hyperaemia	1 (2.9)
Urinary tract infection	1 (2.9)

Note: The total number of AEs counts all AEs for subjects. At each level of subject summarization, a subject is counted once if the subject reported one or more events.
Adverse Events were coded using MedDRA, Version 22.0.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data : Listing 16.2.7.1
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Table 14.3.1.4
Adverse Events by Relationship to Study Drug
Safety Population

System Organ Class Preferred Term Relationship	Total (N=34) n (%)
Total number of adverse events	12
NOT RELATED	4
UNLIKELY RELATED	6
POSSIBLY RELATED	2
PROBABLY RELATED	0
DEFINITELY RELATED	0
Number of subjects with at least one adverse event	9 (26.5)
NOT RELATED	3 (8.8)
UNLIKELY RELATED	4 (11.8)
POSSIBLY RELATED	2 (5.9)
PROBABLY RELATED	0
DEFINITELY RELATED	0
Gastrointestinal disorders	3 (8.8)
NOT RELATED	1 (2.9)
UNLIKELY RELATED	1 (2.9)
POSSIBLY RELATED	1 (2.9)
PROBABLY RELATED	0
DEFINITELY RELATED	0

Note: The total number of AEs counts all AEs for subjects. At each level of subject summarization, a subject is counted once for the most related event if the subject reported one or more events.
If the relationship of an AE is missing, the AE is reported as 'DEFINITELY RELATED'.
Adverse Events were coded using MedDRA, Version 22.0.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Listing 16.2.7.1
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Table 14.3.1.4
Adverse Events by Relationship to Study Drug
Safety Population

System Organ Class Preferred Term Relationship	Total (N=34) n (%)
Gastrointestinal disorders (cont.)	
Nausea	2 (5.9)
NOT RELATED	0
UNLIKELY RELATED	1 (2.9)
POSSIBLY RELATED	1 (2.9)
PROBABLY RELATED	0
DEFINITELY RELATED	0
Infrequent bowel movements	1 (2.9)
NOT RELATED	0
UNLIKELY RELATED	1 (2.9)
POSSIBLY RELATED	0
PROBABLY RELATED	0
DEFINITELY RELATED	0
Lip dry	1 (2.9)
NOT RELATED	1 (2.9)
UNLIKELY RELATED	0
POSSIBLY RELATED	0
PROBABLY RELATED	0
DEFINITELY RELATED	0

Note: The total number of AEs counts all AEs for subjects. At each level of subject summarization, a subject is counted once for the most related event if the subject reported one or more events.
If the relationship of an AE is missing, the AE is reported as 'DEFINITELY RELATED'.
Adverse Events were coded using MedDRA, Version 22.0.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Listing 16.2.7.1
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Table 14.3.1.4
Adverse Events by Relationship to Study Drug
Safety Population

System Organ Class Preferred Term Relationship	Total (N=34) n (%)
Nervous system disorders	2 (5.9)
NOT RELATED	0
UNLIKELY RELATED	1 (2.9)
POSSIBLY RELATED	1 (2.9)
PROBABLY RELATED	0
DEFINITELY RELATED	0
Headache	2 (5.9)
NOT RELATED	0
UNLIKELY RELATED	1 (2.9)
POSSIBLY RELATED	1 (2.9)
PROBABLY RELATED	0
DEFINITELY RELATED	0
Eye disorders	1 (2.9)
NOT RELATED	0
UNLIKELY RELATED	1 (2.9)
POSSIBLY RELATED	0
PROBABLY RELATED	0
DEFINITELY RELATED	0

Note: The total number of AEs counts all AEs for subjects. At each level of subject summarization, a subject is counted once for the most related event if the subject reported one or more events.
If the relationship of an AE is missing, the AE is reported as 'DEFINITELY RELATED'.
Adverse Events were coded using MedDRA, Version 22.0.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Listing 16.2.7.1
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Table 14.3.1.4
Adverse Events by Relationship to Study Drug
Safety Population

System Organ Class Preferred Term Relationship	Total (N=34) n (%)
Eye disorders (cont.)	
Scleral hyperaemia	1 (2.9)
NOT RELATED	0
UNLIKELY RELATED	1 (2.9)
POSSIBLY RELATED	0
PROBABLY RELATED	0
DEFINITELY RELATED	0
Infections and infestations	1 (2.9)
NOT RELATED	1 (2.9)
UNLIKELY RELATED	0
POSSIBLY RELATED	0
PROBABLY RELATED	0
DEFINITELY RELATED	0
Urinary tract infection	1 (2.9)
NOT RELATED	1 (2.9)
UNLIKELY RELATED	0
POSSIBLY RELATED	0
PROBABLY RELATED	0
DEFINITELY RELATED	0

Note: The total number of AEs counts all AEs for subjects. At each level of subject summarization, a subject is counted once for the most related event if the subject reported one or more events.
If the relationship of an AE is missing, the AE is reported as 'DEFINITELY RELATED'.
Adverse Events were coded using MedDRA, Version 22.0.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Listing 16.2.7.1
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Table 14.3.1.4
Adverse Events by Relationship to Study Drug
Safety Population

System Organ Class Preferred Term Relationship	Total (N=34) n (%)
Injury, poisoning and procedural complications	1 (2.9)
NOT RELATED	1 (2.9)
UNLIKELY RELATED	0
POSSIBLY RELATED	0
PROBABLY RELATED	0
DEFINITELY RELATED	0
Palate injury	1 (2.9)
NOT RELATED	1 (2.9)
UNLIKELY RELATED	0
POSSIBLY RELATED	0
PROBABLY RELATED	0
DEFINITELY RELATED	0
Musculoskeletal and connective tissue disorders	1 (2.9)
NOT RELATED	1 (2.9)
UNLIKELY RELATED	0
POSSIBLY RELATED	0
PROBABLY RELATED	0
DEFINITELY RELATED	0

Note: The total number of AEs counts all AEs for subjects. At each level of subject summarization, a subject is counted once for the most related event if the subject reported one or more events.
If the relationship of an AE is missing, the AE is reported as 'DEFINITELY RELATED'.
Adverse Events were coded using MedDRA, Version 22.0.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Listing 16.2.7.1
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Table 14.3.1.4
Adverse Events by Relationship to Study Drug
Safety Population

System Organ Class Preferred Term Relationship	Total (N=34) n (%)
Musculoskeletal and connective tissue disorders (cont.)	
Back pain	1 (2.9)
NOT RELATED	1 (2.9)
UNLIKELY RELATED	0
POSSIBLY RELATED	0
PROBABLY RELATED	0
DEFINITELY RELATED	0
Renal and urinary disorders	1 (2.9)
NOT RELATED	0
UNLIKELY RELATED	1 (2.9)
POSSIBLY RELATED	0
PROBABLY RELATED	0
DEFINITELY RELATED	0
Dysuria	1 (2.9)
NOT RELATED	0
UNLIKELY RELATED	1 (2.9)
POSSIBLY RELATED	0
PROBABLY RELATED	0
DEFINITELY RELATED	0

Note: The total number of AEs counts all AEs for subjects. At each level of subject summarization, a subject is counted once for the most related event if the subject reported one or more events.
If the relationship of an AE is missing, the AE is reported as 'DEFINITELY RELATED'.
Adverse Events were coded using MedDRA, Version 22.0.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Listing 16.2.7.1
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Table 14.3.1.4
Adverse Events by Relationship to Study Drug
Safety Population

System Organ Class Preferred Term Relationship	Total (N=34) n (%)
Skin and subcutaneous tissue disorders	1 (2.9)
NOT RELATED	0
UNLIKELY RELATED	1 (2.9)
POSSIBLY RELATED	0
PROBABLY RELATED	0
DEFINITELY RELATED	0
Dermatitis contact	1 (2.9)
NOT RELATED	0
UNLIKELY RELATED	1 (2.9)
POSSIBLY RELATED	0
PROBABLY RELATED	0
DEFINITELY RELATED	0

Note: The total number of AEs counts all AEs for subjects. At each level of subject summarization, a subject is counted once for the most related event if the subject reported one or more events.
If the relationship of an AE is missing, the AE is reported as 'DEFINITELY RELATED'.
Adverse Events were coded using MedDRA, Version 22.0.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Listing 16.2.7.1
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Table 14.3.1.5
Adverse Events by Severity
Safety Population

System Organ Class Preferred Term Severity	Total (N=34) n (%)
Total number of adverse events	12
Grade 1 (MILD)	12
Grade 2 (MODERATE)	0
Grade 3 (SEVERE)	0
Grade 4 (LIFE-THREATENING)	0
Grade 5 (DEATH)	0
Number of subjects with at least one adverse event	9 (26.5)
Grade 1 (MILD)	9 (26.5)
Grade 2 (MODERATE)	0
Grade 3 (SEVERE)	0
Grade 4 (LIFE-THREATENING)	0
Grade 5 (DEATH)	0
Gastrointestinal disorders	3 (8.8)
Grade 1 (MILD)	3 (8.8)
Grade 2 (MODERATE)	0
Grade 3 (SEVERE)	0
Grade 4 (LIFE-THREATENING)	0
Grade 5 (DEATH)	0

Note: The total number of AEs counts all AEs for subjects. At each level of subject summarization, a subject is counted once for the most severe event if the subject reported one or more events.
If the severity of an AE is missing, the AE is reported as 'Grade 3 (SEVERE)'.
Adverse Events were coded using MedDRA, Version 22.0.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Listing 16.2.7.1
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Table 14.3.1.5
Adverse Events by Severity
Safety Population

System Organ Class Preferred Term Severity	Total (N=34) n (%)
Gastrointestinal disorders (cont.)	
Nausea	2 (5.9)
Grade 1 (MILD)	2 (5.9)
Grade 2 (MODERATE)	0
Grade 3 (SEVERE)	0
Grade 4 (LIFE-THREATENING)	0
Grade 5 (DEATH)	0
Infrequent bowel movements	1 (2.9)
Grade 1 (MILD)	1 (2.9)
Grade 2 (MODERATE)	0
Grade 3 (SEVERE)	0
Grade 4 (LIFE-THREATENING)	0
Grade 5 (DEATH)	0
Lip dry	1 (2.9)
Grade 1 (MILD)	1 (2.9)
Grade 2 (MODERATE)	0
Grade 3 (SEVERE)	0
Grade 4 (LIFE-THREATENING)	0
Grade 5 (DEATH)	0

Note: The total number of AEs counts all AEs for subjects. At each level of subject summarization, a subject is counted once for the most severe event if the subject reported one or more events.
If the severity of an AE is missing, the AE is reported as 'Grade 3 (SEVERE)'.
Adverse Events were coded using MedDRA, Version 22.0.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Listing 16.2.7.1
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Table 14.3.1.5
Adverse Events by Severity
Safety Population

System Organ Class Preferred Term Severity	Total (N=34) n (%)
Nervous system disorders	2 (5.9)
Grade 1 (MILD)	2 (5.9)
Grade 2 (MODERATE)	0
Grade 3 (SEVERE)	0
Grade 4 (LIFE-THREATENING)	0
Grade 5 (DEATH)	0
Headache	2 (5.9)
Grade 1 (MILD)	2 (5.9)
Grade 2 (MODERATE)	0
Grade 3 (SEVERE)	0
Grade 4 (LIFE-THREATENING)	0
Grade 5 (DEATH)	0
Eye disorders	1 (2.9)
Grade 1 (MILD)	1 (2.9)
Grade 2 (MODERATE)	0
Grade 3 (SEVERE)	0
Grade 4 (LIFE-THREATENING)	0
Grade 5 (DEATH)	0

Note: The total number of AEs counts all AEs for subjects. At each level of subject summarization, a subject is counted once for the most severe event if the subject reported one or more events.
If the severity of an AE is missing, the AE is reported as 'Grade 3 (SEVERE)'.
Adverse Events were coded using MedDRA, Version 22.0.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Listing 16.2.7.1
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Table 14.3.1.5
Adverse Events by Severity
Safety Population

System Organ Class Preferred Term Severity	Total (N=34) n (%)
Eye disorders (cont.)	
Scleral hyperaemia	1 (2.9)
Grade 1 (MILD)	1 (2.9)
Grade 2 (MODERATE)	0
Grade 3 (SEVERE)	0
Grade 4 (LIFE-THREATENING)	0
Grade 5 (DEATH)	0
Infections and infestations	1 (2.9)
Grade 1 (MILD)	1 (2.9)
Grade 2 (MODERATE)	0
Grade 3 (SEVERE)	0
Grade 4 (LIFE-THREATENING)	0
Grade 5 (DEATH)	0
Urinary tract infection	1 (2.9)
Grade 1 (MILD)	1 (2.9)
Grade 2 (MODERATE)	0
Grade 3 (SEVERE)	0
Grade 4 (LIFE-THREATENING)	0
Grade 5 (DEATH)	0

Note: The total number of AEs counts all AEs for subjects. At each level of subject summarization, a subject is counted once for the most severe event if the subject reported one or more events.
If the severity of an AE is missing, the AE is reported as 'Grade 3 (SEVERE)'.
Adverse Events were coded using MedDRA, Version 22.0.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Listing 16.2.7.1
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Table 14.3.1.5
Adverse Events by Severity
Safety Population

System Organ Class Preferred Term Severity	Total (N=34) n (%)
Injury, poisoning and procedural complications	1 (2.9)
Grade 1 (MILD)	1 (2.9)
Grade 2 (MODERATE)	0
Grade 3 (SEVERE)	0
Grade 4 (LIFE-THREATENING)	0
Grade 5 (DEATH)	0
Palate injury	1 (2.9)
Grade 1 (MILD)	1 (2.9)
Grade 2 (MODERATE)	0
Grade 3 (SEVERE)	0
Grade 4 (LIFE-THREATENING)	0
Grade 5 (DEATH)	0
Musculoskeletal and connective tissue disorders	1 (2.9)
Grade 1 (MILD)	1 (2.9)
Grade 2 (MODERATE)	0
Grade 3 (SEVERE)	0
Grade 4 (LIFE-THREATENING)	0
Grade 5 (DEATH)	0

Note: The total number of AEs counts all AEs for subjects. At each level of subject summarization, a subject is counted once for the most severe event if the subject reported one or more events.
If the severity of an AE is missing, the AE is reported as 'Grade 3 (SEVERE)'.
Adverse Events were coded using MedDRA, Version 22.0.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Listing 16.2.7.1
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Table 14.3.1.5
Adverse Events by Severity
Safety Population

System Organ Class Preferred Term Severity	Total (N=34) n (%)
Musculoskeletal and connective tissue disorders (cont.)	
Back pain	1 (2.9)
Grade 1 (MILD)	1 (2.9)
Grade 2 (MODERATE)	0
Grade 3 (SEVERE)	0
Grade 4 (LIFE-THREATENING)	0
Grade 5 (DEATH)	0
Renal and urinary disorders	1 (2.9)
Grade 1 (MILD)	1 (2.9)
Grade 2 (MODERATE)	0
Grade 3 (SEVERE)	0
Grade 4 (LIFE-THREATENING)	0
Grade 5 (DEATH)	0
Dysuria	1 (2.9)
Grade 1 (MILD)	1 (2.9)
Grade 2 (MODERATE)	0
Grade 3 (SEVERE)	0
Grade 4 (LIFE-THREATENING)	0
Grade 5 (DEATH)	0

Note: The total number of AEs counts all AEs for subjects. At each level of subject summarization, a subject is counted once for the most severe event if the subject reported one or more events.
If the severity of an AE is missing, the AE is reported as 'Grade 3 (SEVERE)'.
Adverse Events were coded using MedDRA, Version 22.0.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Listing 16.2.7.1
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Table 14.3.1.5
Adverse Events by Severity
Safety Population

System Organ Class Preferred Term Severity	Total (N=34) n (%)
Skin and subcutaneous tissue disorders	1 (2.9)
Grade 1 (MILD)	1 (2.9)
Grade 2 (MODERATE)	0
Grade 3 (SEVERE)	0
Grade 4 (LIFE-THREATENING)	0
Grade 5 (DEATH)	0
Dermatitis contact	1 (2.9)
Grade 1 (MILD)	1 (2.9)
Grade 2 (MODERATE)	0
Grade 3 (SEVERE)	0
Grade 4 (LIFE-THREATENING)	0
Grade 5 (DEATH)	0

Note: The total number of AEs counts all AEs for subjects. At each level of subject summarization, a subject is counted once for the most severe event if the subject reported one or more events.
If the severity of an AE is missing, the AE is reported as 'Grade 3 (SEVERE)'.
Adverse Events were coded using MedDRA, Version 22.0.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Listing 16.2.7.1
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Table 14.3.2.1.1
Summary of Actual Value and Change from Baseline in Hematology
Safety Population

Lab Parameter / Visit	Actual Value n	Mean	SD	Median	Min	Max	Change From Baseline [1] n	Mean	SD	Median	Min	Max
Basophils (10^9/L)												
Baseline	34	0.044	0.0197	0.040	0.01	0.09						
Day 4	34	0.046	0.0187	0.040	0.02	0.09	34	0.003	0.0124	0.000	-0.03	0.03
Day 8	34	0.045	0.0160	0.040	0.02	0.08	34	0.001	0.0113	0.000	-0.02	0.03
Day 9/ED	34	0.043	0.0193	0.040	0.01	0.09	34	-0.001	0.0098	0.000	-0.02	0.02
Basophils/Leukocytes (%)												
Baseline	34	0.68	0.424	0.60	0.2	2.8						
Day 4	34	0.70	0.405	0.60	0.3	2.6	34	0.02	0.180	0.00	-0.3	0.4
Day 8	34	0.74	0.366	0.60	0.3	2.4	34	0.06	0.196	0.00	-0.4	0.6
Day 9/ED	34	0.71	0.365	0.60	0.3	2.2	34	0.02	0.219	0.00	-0.6	0.5
Eosinophils (10^9/L)												
Baseline	34	0.159	0.0907	0.135	0.03	0.44						
Day 4	34	0.156	0.0687	0.160	0.03	0.34	34	-0.003	0.0606	0.010	-0.19	0.14
Day 8	34	0.147	0.0532	0.140	0.04	0.26	34	-0.011	0.0673	0.000	-0.23	0.12
Day 9/ED	34	0.131	0.0501	0.125	0.04	0.27	34	-0.028	0.0711	-0.005	-0.26	0.08
Eosinophils/Leukocytes (%)												
Baseline	34	2.36	1.235	2.30	0.6	6.7						
Day 4	34	2.32	0.948	2.20	0.7	4.2	34	-0.03	0.841	0.10	-2.8	1.6
Day 8	34	2.31	0.872	2.20	0.8	4.0	34	-0.05	1.008	0.10	-3.5	2.1
Day 9/ED	34	2.21	0.870	2.10	1.0	4.3	34	-0.15	1.086	0.10	-3.7	1.9

Note: Baseline is defined as the last non-missing measurement prior to first dosing.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
ED = Early Discontinuation.
[1] Change from baseline: post-baseline value – baseline value.
Source Data: Listing 16.2.8.1
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Table 14.3.2.1.1
Summary of Actual Value and Change from Baseline in Hematology
Safety Population

Lab Parameter / Visit	Actual Value n	Mean	SD	Median	Min	Max	Change From Baseline [1] n	Mean	SD	Median	Min	Max
Ery. Mean Corpuscular HGB Concentration (g/L)												
Baseline	34	334.3	9.82	336.0	309	351						
Day 4	34	334.8	9.26	335.0	307	351	34	0.5	3.31	0.0	-5	9
Day 8	34	335.1	9.54	336.0	311	352	34	0.9	4.02	0.5	-7	8
Day 9/ED	34	334.8	10.10	337.5	308	349	34	0.5	3.98	1.0	-8	8
Ery. Mean Corpuscular Hemoglobin (pg)												
Baseline	34	28.54	2.854	29.05	19.0	32.8						
Day 4	34	28.57	2.776	29.00	19.4	32.6	34	0.03	0.296	0.00	-0.4	0.7
Day 8	34	28.64	2.771	29.35	19.2	32.3	34	0.11	0.356	0.15	-0.6	0.9
Day 9/ED	34	28.60	2.817	29.10	18.9	32.3	34	0.06	0.374	0.05	-0.5	0.8
Ery. Mean Corpuscular Volume (fL)												
Baseline	34	85.28	7.025	86.85	60.9	97.4						
Day 4	34	85.24	6.908	86.30	61.5	97.7	34	-0.04	0.576	-0.10	-1.2	1.0
Day 8	34	85.34	6.865	86.50	60.8	97.7	34	0.06	0.757	-0.05	-1.1	1.7
Day 9/ED	34	85.27	6.804	86.30	61.4	97.5	34	0.00	0.728	0.00	-1.7	1.7
Erythrocytes (10^12/L)												
Baseline	34	4.857	0.4635	4.830	3.76	6.66						
Day 4	34	5.014	0.4500	4.985	3.79	6.60	34	0.156	0.2066	0.120	-0.15	0.62
Day 8	34	4.981	0.4635	4.985	3.80	6.59	34	0.124	0.1743	0.080	-0.24	0.47
Day 9/ED	34	4.942	0.4907	4.880	3.78	6.82	34	0.085	0.1558	0.100	-0.21	0.38

Note: Baseline is defined as the last non-missing measurement prior to first dosing.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
ED = Early Discontinuation.
[1] Change from baseline: post-baseline value – baseline value.
Source Data: Listing 16.2.8.1
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Table 14.3.2.1.1
Summary of Actual Value and Change from Baseline in Hematology
Safety Population

Lab Parameter / Visit	Actual Value n	Actual Value Mean	Actual Value SD	Actual Value Median	Actual Value Min	Actual Value Max	Change From Baseline [1] n	Change From Baseline [1] Mean	Change From Baseline [1] SD	Change From Baseline [1] Median	Change From Baseline [1] Min	Change From Baseline [1] Max
Erythrocytes Distribution Width (%)												
Baseline	34	14.36	1.697	14.00	12.4	20.4						
Day 4	34	14.37	1.778	13.90	12.3	20.9	34	0.01	0.299	0.00	-0.6	0.6
Day 8	34	14.26	1.728	13.85	12.1	21.1	34	-0.11	0.311	-0.10	-1.0	0.7
Day 9/ED	34	14.24	1.736	13.90	12.4	21.2	34	-0.12	0.358	-0.10	-1.2	0.8
Hematocrit (fraction of 1)												
Baseline	34	0.4121	0.03127	0.4140	0.336	0.460						
Day 4	34	0.4256	0.03540	0.4340	0.334	0.483	34	0.0135	0.01866	0.0110	-0.014	0.058
Day 8	34	0.4234	0.03446	0.4350	0.342	0.476	34	0.0112	0.01517	0.0095	-0.025	0.037
Day 9/ED	34	0.4193	0.03250	0.4280	0.334	0.467	34	0.0072	0.01419	0.0110	-0.022	0.035
Hemoglobin (g/L)												
Baseline	34	138.0	12.45	138.0	104	160						
Day 4	34	142.6	14.43	145.0	102	164	34	4.6	5.95	4.0	-4	17
Day 8	34	142.0	13.40	144.5	107	162	34	4.0	5.39	3.5	-7	15
Day 9/ED	34	140.6	13.35	144.0	104	161	34	2.6	5.06	4.0	-9	12
Leukocytes (10^9/L)												
Baseline	34	6.72	1.653	6.70	3.2	9.7						
Day 4	34	6.84	1.620	6.85	3.3	10.4	34	0.12	0.845	0.10	-1.7	1.6
Day 8	34	6.54	1.389	6.70	3.2	9.3	34	-0.18	0.911	-0.20	-2.4	1.9
Day 9/ED	34	6.18	1.379	6.35	3.1	9.0	34	-0.54	0.807	-0.45	-2.3	1.0

Note: Baseline is defined as the last non-missing measurement prior to first dosing.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
ED = Early Discontinuation.
[1] Change from baseline: post-baseline value – baseline value.
Source Data: Listing 16.2.8.1
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Table 14.3.2.1.1
Summary of Actual Value and Change from Baseline in Hematology
Safety Population

Lab Parameter / Visit	Actual Value n	Mean	SD	Median	Min	Max	Change From Baseline [1] n	Mean	SD	Median	Min	Max
Lymphocytes (10^9/L)												
Baseline	34	2.075	0.6190	1.970	1.09	3.83						
Day 4	34	2.280	0.5440	2.330	1.32	3.68	34	0.205	0.3087	0.205	-0.58	0.79
Day 8	34	2.134	0.5743	2.110	1.12	4.05	34	0.059	0.4129	0.055	-1.35	0.85
Day 9/ED	34	1.945	0.4578	1.885	0.84	3.01	34	-0.129	0.3883	-0.110	-1.63	0.44
Lymphocytes/Leukocytes (%)												
Baseline	34	31.32	6.777	30.85	18.8	47.0						
Day 4	34	34.14	7.154	33.55	20.2	46.2	34	2.82	3.361	3.15	-4.8	10.6
Day 8	34	33.11	7.374	32.50	20.3	48.2	34	1.79	4.492	2.25	-12.2	9.7
Day 9/ED	34	32.03	6.485	31.10	19.9	47.4	34	0.71	3.898	1.40	-9.7	8.9
Monocytes (10^9/L)												
Baseline	34	0.527	0.1372	0.515	0.30	0.82						
Day 4	34	0.535	0.1273	0.510	0.27	0.91	34	0.008	0.1064	0.000	-0.24	0.20
Day 8	34	0.520	0.1081	0.510	0.37	0.81	34	-0.007	0.1031	-0.005	-0.23	0.20
Day 9/ED	34	0.497	0.1128	0.475	0.30	0.84	34	-0.030	0.1029	-0.015	-0.30	0.16
Monocytes/Leukocytes (%)												
Baseline	34	8.03	1.908	8.05	5.0	13.9						
Day 4	34	8.05	1.891	8.10	5.2	13.9	34	0.02	1.255	0.05	-2.2	3.1
Day 8	34	8.19	1.995	7.85	5.0	14.3	34	0.16	1.179	0.20	-1.8	2.5
Day 9/ED	34	8.33	2.433	8.25	5.3	17.1	34	0.30	1.542	0.40	-3.2	5.7

Note: Baseline is defined as the last non-missing measurement prior to first dosing.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
ED = Early Discontinuation.
[1] Change from baseline: post-baseline value – baseline value.
Source Data: Listing 16.2.8.1
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Table 14.3.2.1.1
Summary of Actual Value and Change from Baseline in Hematology
Safety Population

Lab Parameter / Visit	Actual Value n	Mean	SD	Median	Min	Max	Change From Baseline [1] n	Mean	SD	Median	Min	Max
Neutrophils (10^9/L)												
Baseline	34	3.925	1.2035	4.065	1.54	5.97						
Day 4	34	3.827	1.2783	3.750	1.35	6.91	34	-0.098	0.6657	-0.120	-1.43	1.35
Day 8	34	3.697	1.1210	3.645	1.48	6.30	34	-0.227	0.6436	-0.260	-2.03	1.32
Day 9/ED	34	3.561	1.0839	3.500	1.50	5.70	34	-0.363	0.6039	-0.280	-1.97	0.67
Neutrophils/Leukocytes (%)												
Baseline	34	57.64	7.321	58.30	43.6	73.4						
Day 4	34	54.82	7.979	55.00	40.8	71.6	34	-2.82	4.369	-2.95	-12.2	6.8
Day 8	34	55.73	8.191	55.75	40.3	72.1	34	-1.91	4.971	-2.45	-12.9	7.7
Day 9/ED	34	56.76	7.259	56.60	41.6	71.3	34	-0.88	4.346	-0.65	-10.9	10.0
Platelets (10^9/L)												
Baseline	34	267.1	58.58	253.0	184	403						
Day 4	34	281.6	62.14	268.5	197	432	34	14.6	14.68	15.0	-14	42
Day 8	34	280.5	60.67	269.0	195	437	34	13.5	18.11	11.5	-24	50
Day 9/ED	34	279.9	59.59	274.0	196	420	34	12.9	13.90	13.5	-21	40

Note: Baseline is defined as the last non-missing measurement prior to first dosing.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
ED = Early Discontinuation.
[1] Change from baseline: post-baseline value – baseline value.
Source Data: Listing 16.2.8.1
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Table 14.3.2.1.2
Shift from Baseline in Hematology
Safety Population

Parameter: Basophils (10^9/L)

	Baseline		
Post-Baseline Visit	Low	Normal	High
Day 4			
Low	0	0	0
Normal	0	31 (91.2)	1 (2.9)
High	0	1 (2.9)	1 (2.9)
Day 8			
Low	0	0	0
Normal	0	32 (94.1)	0
High	0	2 (5.9)	0
Day 9/ED			
Low	0	0	0
Normal	0	31 (91.2)	1 (2.9)
High	0	2 (5.9)	0

Note: Counts represent subjects with a baseline value in addition to having a value at each post-baseline visit summarized. 'Low' denotes a value below the reference range. 'High' denotes a value above the reference range. Baseline is defined as the last non-missing measurement prior to first dosing.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
ED = Early Discontinuation.
Source Data: Listing 16.2.8.1
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Table 14.3.2.1.2
Shift from Baseline in Hematology
Safety Population

Parameter: Basophils/Leukocytes (%)

	Baseline		
Post-Baseline Visit	Low	Normal	High
Day 4			
Low	0	0	0
Normal	0	33 (97.1)	0
High	0	0	1 (2.9)
Day 8			
Low	0	0	0
Normal	0	33 (97.1)	0
High	0	0	1 (2.9)
Day 9/ED			
Low	0	0	0
Normal	0	33 (97.1)	0
High	0	0	1 (2.9)

Note: Counts represent subjects with a baseline value in addition to having a value at each post-baseline visit summarized. 'Low' denotes a value below the reference range. 'High' denotes a value above the reference range. Baseline is defined as the last non-missing measurement prior to first dosing.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
ED = Early Discontinuation.
Source Data: Listing 16.2.8.1
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Table 14.3.2.1.2
Shift from Baseline in Hematology
Safety Population

Parameter: Eosinophils (10^9/L)

	Baseline		
Post-Baseline Visit	Low	Normal	High
Day 4			
Low	0	0	0
Normal	0	33 (97.1)	0
High	0	1 (2.9)	0
Day 8			
Low	0	0	0
Normal	0	33 (97.1)	0
High	0	1 (2.9)	0
Day 9/ED			
Low	0	0	0
Normal	0	33 (97.1)	0
High	0	1 (2.9)	0

Note: Counts represent subjects with a baseline value in addition to having a value at each post-baseline visit summarized. 'Low' denotes a value below the reference range. 'High' denotes a value above the reference range. Baseline is defined as the last non-missing measurement prior to first dosing.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
ED = Early Discontinuation.
Source Data: Listing 16.2.8.1
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Table 14.3.2.1.2
Shift from Baseline in Hematology
Safety Population

Parameter: Eosinophils/Leukocytes (%)

	Baseline		
Post-Baseline Visit	Low	Normal	High
Day 4			
Low	0	0	0
Normal	0	33 (97.1)	0
High	0	1 (2.9)	0
Day 8			
Low	0	0	0
Normal	0	33 (97.1)	0
High	0	1 (2.9)	0
Day 9/ED			
Low	0	0	0
Normal	0	33 (97.1)	0
High	0	1 (2.9)	0

Note: Counts represent subjects with a baseline value in addition to having a value at each post-baseline visit summarized. 'Low' denotes a value below the reference range. 'High' denotes a value above the reference range. Baseline is defined as the last non-missing measurement prior to first dosing.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
ED = Early Discontinuation.
Source Data: Listing 16.2.8.1
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Table 14.3.2.1.2
Shift from Baseline in Hematology
Safety Population

Parameter: Ery. Mean Corpuscular HGB Concentration (g/L)

	Baseline		
Post-Baseline Visit	Low	Normal	High
Day 4			
Low	2 (5.9)	0	0
Normal	0	31 (91.2)	0
High	0	1 (2.9)	0
Day 8			
Low	2 (5.9)	0	0
Normal	0	31 (91.2)	0
High	0	0	1 (2.9)
Day 9/ED			
Low	2 (5.9)	0	0
Normal	0	31 (91.2)	0
High	0	1 (2.9)	0

Note: Counts represent subjects with a baseline value in addition to having a value at each post-baseline visit summarized. 'Low' denotes a value below the reference range. 'High' denotes a value above the reference range. Baseline is defined as the last non-missing measurement prior to first dosing.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
ED = Early Discontinuation.
Source Data: Listing 16.2.8.1
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Table 14.3.2.1.2
Shift from Baseline in Hematology
Safety Population

Parameter: Ery. Mean Corpuscular Hemoglobin (pg)

	Baseline		
Post-Baseline Visit	Low	Normal	High
Day 4			
Low	2 (5.9)	0	0
Normal	0	32 (94.1)	0
High	0	0	0
Day 8			
Low	2 (5.9)	0	0
Normal	0	32 (94.1)	0
High	0	0	0
Day 9/ED			
Low	2 (5.9)	0	0
Normal	0	32 (94.1)	0
High	0	0	0

Note: Counts represent subjects with a baseline value in addition to having a value at each post-baseline visit summarized. 'Low' denotes a value below the reference range. 'High' denotes a value above the reference range. Baseline is defined as the last non-missing measurement prior to first dosing.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
ED = Early Discontinuation.
Source Data: Listing 16.2.8.1
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Table 14.3.2.1.2
Shift from Baseline in Hematology
Safety Population

Parameter: Ery. Mean Corpuscular Volume (fL)

	Baseline		
Post-Baseline Visit	Low	Normal	High
Day 4			
Low	2 (5.9)	0	0
Normal	0	32 (94.1)	0
High	0	0	0
Day 8			
Low	2 (5.9)	0	0
Normal	0	32 (94.1)	0
High	0	0	0
Day 9/ED			
Low	2 (5.9)	0	0
Normal	0	32 (94.1)	0
High	0	0	0

Note: Counts represent subjects with a baseline value in addition to having a value at each post-baseline visit summarized. 'Low' denotes a value below the reference range. 'High' denotes a value above the reference range. Baseline is defined as the last non-missing measurement prior to first dosing.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
ED = Early Discontinuation.
Source Data: Listing 16.2.8.1
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Table 14.3.2.1.2
Shift from Baseline in Hematology
Safety Population

Parameter: Erythrocytes (10^12/L)

	Baseline					
Post-Baseline Visit	Low		Normal		High	
Day 4						
Low	1	(2.9)	0		0	
Normal	0		32	(94.1)	0	
High	0		0		1	(2.9)
Day 8						
Low	1	(2.9)	0		0	
Normal	0		32	(94.1)	0	
High	0		0		1	(2.9)
Day 9/ED						
Low	1	(2.9)	0		0	
Normal	0		32	(94.1)	0	
High	0		0		1	(2.9)

Note: Counts represent subjects with a baseline value in addition to having a value at each post-baseline visit summarized. 'Low' denotes a value below the reference range. 'High' denotes a value above the reference range. Baseline is defined as the last non-missing measurement prior to first dosing.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
ED = Early Discontinuation.
Source Data: Listing 16.2.8.1
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Table 14.3.2.1.2
Shift from Baseline in Hematology
Safety Population

Parameter: Erythrocytes Distribution Width (%)

	Baseline		
Post-Baseline Visit	Low	Normal	High
Day 4			
Low	0	0	0
Normal	0	28 (82.4)	1 (2.9)
High	0	1 (2.9)	4 (11.8)
Day 8			
Low	0	0	0
Normal	0	28 (82.4)	1 (2.9)
High	0	1 (2.9)	4 (11.8)
Day 9/ED			
Low	0	0	0
Normal	0	28 (82.4)	1 (2.9)
High	0	1 (2.9)	4 (11.8)

Note: Counts represent subjects with a baseline value in addition to having a value at each post-baseline visit summarized. 'Low' denotes a value below the reference range. 'High' denotes a value above the reference range. Baseline is defined as the last non-missing measurement prior to first dosing.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
ED = Early Discontinuation.
Source Data: Listing 16.2.8.1
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Table 14.3.2.1.2
Shift from Baseline in Hematology
Safety Population

Parameter: Hematocrit (fraction of 1)

	Baseline					
Post-Baseline Visit	Low		Normal		High	
Day 4						
Low	0		1	(2.9)	0	
Normal	1	(2.9)	31	(91.2)	1	(2.9)
High	0		0		0	
Day 8						
Low	0		1	(2.9)	0	
Normal	0		33	(97.1)	0	
High	0		0		0	
Day 9/ED						
Low	0		1	(2.9)	0	
Normal	1	(2.9)	32	(94.1)	0	
High	0		0		0	

Note: Counts represent subjects with a baseline value in addition to having a value at each post-baseline visit summarized. 'Low' denotes a value below the reference range. 'High' denotes a value above the reference range. Baseline is defined as the last non-missing measurement prior to first dosing.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
ED = Early Discontinuation.
Source Data: Listing 16.2.8.1
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Table 14.3.2.1.2
Shift from Baseline in Hematology
Safety Population

Parameter: Hemoglobin (g/L)

	Baseline		
Post-Baseline Visit	Low	Normal	High
Day 4			
Low	1 (2.9)	1 (2.9)	0
Normal	0	32 (94.1)	0
High	0	0	0
Day 8			
Low	2 (5.9)	0	0
Normal	0	32 (94.1)	0
High	0	0	0
Day 9/ED			
Low	1 (2.9)	1 (2.9)	0
Normal	0	32 (94.1)	0
High	0	0	0

Note: Counts represent subjects with a baseline value in addition to having a value at each post-baseline visit summarized. 'Low' denotes a value below the reference range. 'High' denotes a value above the reference range. Baseline is defined as the last non-missing measurement prior to first dosing.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
ED = Early Discontinuation.
Source Data: Listing 16.2.8.1
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Table 14.3.2.1.2
Shift from Baseline in Hematology
Safety Population

Parameter: Leukocytes (10^9/L)

	Baseline		
Post-Baseline Visit	Low	Normal	High
Day 4			
Low	0	0	0
Normal	0	32 (94.1)	2 (5.9)
High	0	0	0
Day 8			
Low	0	0	0
Normal	0	34 (100.0)	0
High	0	0	0
Day 9/ED			
Low	0	0	0
Normal	0	34 (100.0)	0
High	0	0	0

Note: Counts represent subjects with a baseline value in addition to having a value at each post-baseline visit summarized. 'Low' denotes a value below the reference range. 'High' denotes a value above the reference range. Baseline is defined as the last non-missing measurement prior to first dosing.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
ED = Early Discontinuation.
Source Data: Listing 16.2.8.1
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Table 14.3.2.1.2
Shift from Baseline in Hematology
Safety Population

Parameter: Lymphocytes (10^9/L)

	Baseline		
Post-Baseline Visit	Low	Normal	High
Day 4			
Low	0	0	0
Normal	0	30 (88.2)	2 (5.9)
High	0	0	2 (5.9)
Day 8			
Low	0	0	0
Normal	0	32 (94.1)	0
High	0	1 (2.9)	1 (2.9)
Day 9/ED			
Low	0	0	0
Normal	0	32 (94.1)	0
High	0	1 (2.9)	1 (2.9)

Note: Counts represent subjects with a baseline value in addition to having a value at each post-baseline visit summarized. 'Low' denotes a value below the reference range. 'High' denotes a value above the reference range. Baseline is defined as the last non-missing measurement prior to first dosing.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
ED = Early Discontinuation.
Source Data: Listing 16.2.8.1
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Table 14.3.2.1.2
Shift from Baseline in Hematology
Safety Population

Parameter: Lymphocytes/Leukocytes (%)

	Baseline		
Post-Baseline Visit	Low	Normal	High
Day 4			
Low	0	0	0
Normal	0	34 (100.0)	0
High	0	0	0
Day 8			
Low	0	0	0
Normal	0	34 (100.0)	0
High	0	0	0
Day 9/ED			
Low	0	0	0
Normal	0	34 (100.0)	0
High	0	0	0

Note: Counts represent subjects with a baseline value in addition to having a value at each post-baseline visit summarized. 'Low' denotes a value below the reference range. 'High' denotes a value above the reference range. Baseline is defined as the last non-missing measurement prior to first dosing.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
ED = Early Discontinuation.
Source Data: Listing 16.2.8.1
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Table 14.3.2.1.2
Shift from Baseline in Hematology
Safety Population

Parameter: Monocytes (10^9/L)

	Baseline		
Post-Baseline Visit	Low	Normal	High
Day 4			
Low	0	0	0
Normal	0	32 (94.1)	0
High	0	0	2 (5.9)
Day 8			
Low	0	0	0
Normal	0	32 (94.1)	0
High	0	1 (2.9)	1 (2.9)
Day 9/ED			
Low	0	0	0
Normal	0	32 (94.1)	0
High	0	1 (2.9)	1 (2.9)

Note: Counts represent subjects with a baseline value in addition to having a value at each post-baseline visit summarized. 'Low' denotes a value below the reference range. 'High' denotes a value above the reference range. Baseline is defined as the last non-missing measurement prior to first dosing.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
ED = Early Discontinuation.
Source Data: Listing 16.2.8.1
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Table 14.3.2.1.2
Shift from Baseline in Hematology
Safety Population

Parameter: Monocytes/Leukocytes (%)

	Baseline		
Post-Baseline Visit	Low	Normal	High
Day 4			
Low	0	0	0
Normal	0	32 (94.1)	1 (2.9)
High	0	0	1 (2.9)
Day 8			
Low	0	0	0
Normal	0	32 (94.1)	1 (2.9)
High	0	0	1 (2.9)
Day 9/ED			
Low	0	0	0
Normal	0	32 (94.1)	1 (2.9)
High	0	0	1 (2.9)

Note: Counts represent subjects with a baseline value in addition to having a value at each post-baseline visit summarized. 'Low' denotes a value below the reference range. 'High' denotes a value above the reference range. Baseline is defined as the last non-missing measurement prior to first dosing.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
ED = Early Discontinuation.
Source Data: Listing 16.2.8.1
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Table 14.3.2.1.2
Shift from Baseline in Hematology
Safety Population

Parameter: Neutrophils (10^9/L)

	Baseline		
Post-Baseline Visit	Low	Normal	High
Day 4			
Low	0	0	0
Normal	1 (2.9)	32 (94.1)	1 (2.9)
High	0	0	0
Day 8			
Low	0	0	0
Normal	1 (2.9)	33 (97.1)	0
High	0	0	0
Day 9/ED			
Low	0	0	0
Normal	0	34 (100.0)	0
High	0	0	0

Note: Counts represent subjects with a baseline value in addition to having a value at each post-baseline visit summarized. 'Low' denotes a value below the reference range. 'High' denotes a value above the reference range. Baseline is defined as the last non-missing measurement prior to first dosing.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
ED = Early Discontinuation.
Source Data: Listing 16.2.8.1
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Table 14.3.2.1.2
Shift from Baseline in Hematology
Safety Population

Parameter: Neutrophils/Leukocytes (%)

	Baseline		
Post-Baseline Visit	Low	Normal	High
Day 4			
Low	0	0	0
Normal	0	34 (100.0)	0
High	0	0	0
Day 8			
Low	0	0	0
Normal	0	34 (100.0)	0
High	0	0	0
Day 9/ED			
Low	0	0	0
Normal	0	34 (100.0)	0
High	0	0	0

Note: Counts represent subjects with a baseline value in addition to having a value at each post-baseline visit summarized. 'Low' denotes a value below the reference range. 'High' denotes a value above the reference range. Baseline is defined as the last non-missing measurement prior to first dosing.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
ED = Early Discontinuation.
Source Data: Listing 16.2.8.1
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Table 14.3.2.1.2
Shift from Baseline in Hematology
Safety Population

Parameter: Platelets (10^9/L)

	Baseline		
Post-Baseline Visit	Low	Normal	High
Day 4			
Low	0	0	0
Normal	0	32 (94.1)	1 (2.9)
High	0	0	1 (2.9)
Day 8			
Low	0	0	0
Normal	0	32 (94.1)	1 (2.9)
High	0	1 (2.9)	0
Day 9/ED			
Low	0	0	0
Normal	0	32 (94.1)	1 (2.9)
High	0	1 (2.9)	0

Note: Counts represent subjects with a baseline value in addition to having a value at each post-baseline visit summarized. 'Low' denotes a value below the reference range. 'High' denotes a value above the reference range. Baseline is defined as the last non-missing measurement prior to first dosing.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
ED = Early Discontinuation.
Source Data: Listing 16.2.8.1
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Table 14.3.2.1.3
Summary of Hematology Results by Maximum Grade Increase Post-Baseline Relative to Baseline
Safety Population

Test (units)/ Term		Total (N=34) n (%)
Hemoglobin (g/L)/	n	34
Low	Increase to Grade 1	0
	Increase to Grade 2	0
	Increase to Grade 3	0
	Increase to Grade 4	0
	Increase to Grades 1 to 4	0
	Increase to Grades 2 to 4	0
	Increase to Grades 3 to 4	0
Leukocytes (10^9/L)/	n	34
Low	Increase to Grade 1	0
	Increase to Grade 2	0
	Increase to Grade 3	0
	Increase to Grade 4	0
	Increase to Grades 1 to 4	0
	Increase to Grades 2 to 4	0
	Increase to Grades 3 to 4	0

Note: Counts represent subjects with a baseline value in addition to having at least one post-baseline value, including unscheduled visits. Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Listing 16.2.8.1
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Table 14.3.2.1.3
Summary of Hematology Results by Maximum Grade Increase Post-Baseline Relative to Baseline
Safety Population

Test (units)/ Term		Total (N=34) n (%)
Lymphocytes (10^9/L)/	n	34
Low	Increase to Grade 1	0
	Increase to Grade 2	0
	Increase to Grade 3	0
	Increase to Grade 4	0
	Increase to Grades 1 to 4	0
	Increase to Grades 2 to 4	0
	Increase to Grades 3 to 4	0
Neutrophils (10^9/L)/	n	34
Low	Increase to Grade 1	0
	Increase to Grade 2	0
	Increase to Grade 3	0
	Increase to Grade 4	0
	Increase to Grades 1 to 4	0
	Increase to Grades 2 to 4	0
	Increase to Grades 3 to 4	0

Note: Counts represent subjects with a baseline value in addition to having at least one post-baseline value, including unscheduled visits. Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Listing 16.2.8.1
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Table 14.3.2.1.3
Summary of Hematology Results by Maximum Grade Increase Post-Baseline Relative to Baseline
Safety Population

Test (units)/ Term		Total (N=34) n (%)
Platelets (10^9/L)/	n	34
Low	Increase to Grade 1	0
	Increase to Grade 2	0
	Increase to Grade 3	0
	Increase to Grade 4	0
	Increase to Grades 1 to 4	0
	Increase to Grades 2 to 4	0
	Increase to Grades 3 to 4	0

Note: Counts represent subjects with a baseline value in addition to having at least one post-baseline value, including unscheduled visits. Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Listing 16.2.8.1
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Table 14.3.2.2.1
Summary of Actual Value and Change from Baseline in Serum Chemistry
Safety Population

Lab Parameter / Visit	Actual Value n	Actual Value Mean	Actual Value SD	Actual Value Median	Actual Value Min	Actual Value Max	Change From Baseline [1] n	Change From Baseline [1] Mean	Change From Baseline [1] SD	Change From Baseline [1] Median	Change From Baseline [1] Min	Change From Baseline [1] Max
Alanine Aminotransferase (IU/L)												
Baseline	34	21.8	8.87	20.0	11	45						
Day 4	34	23.5	11.84	20.5	10	61	34	1.7	6.11	1.0	-7	22
Day 8	34	25.0	11.70	22.5	10	56	34	3.2	7.66	2.0	-9	36
Day 9/ED	34	25.6	12.21	23.0	11	56	34	3.9	7.77	2.5	-10	34
Albumin (g/L)												
Baseline	34	42.4	2.78	43.0	37	47						
Day 4	34	43.4	3.35	44.0	37	49	34	0.9	2.26	1.0	-4	7
Day 8	34	43.5	2.61	44.0	37	48	34	1.1	1.95	1.0	-3	5
Day 9/ED	34	44.2	2.73	44.0	38	50	34	1.8	2.29	2.0	-2	7
Alkaline Phosphatase (IU/L)												
Baseline	34	64.9	20.51	63.5	30	108						
Day 4	34	61.0	19.42	58.5	29	121	34	-3.9	6.77	-3.0	-20	15
Day 8	34	66.9	20.90	66.0	33	124	34	2.0	6.31	3.0	-14	18
Day 9/ED	34	67.4	20.56	64.0	30	127	34	2.5	6.33	3.0	-16	21
Anion Gap (mmol/L)												
Baseline	34	10.6	1.50	10.5	8	15						
Day 4	34	10.4	2.15	11.0	6	15	34	-0.2	2.47	0.0	-6	4
Day 8	34	10.6	1.65	11.0	6	13	34	0.0	2.04	0.0	-5	5
Day 9/ED	34	10.3	1.38	10.0	8	14	34	-0.3	1.96	0.0	-5	4

Note: Baseline is defined as the last non-missing measurement prior to first dosing.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
ED = Early Discontinuation.
[1] Change from baseline: post-baseline value – baseline value.
Source Data: Listing 16.2.8.2
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Table 14.3.2.2.1
Summary of Actual Value and Change from Baseline in Serum Chemistry
Safety Population

Lab Parameter / Visit	Actual Value n	Mean	SD	Median	Min	Max	Change From Baseline [1] n	Mean	SD	Median	Min	Max
Aspartate Aminotransferase (IU/L)												
Baseline	34	17.6	4.63	18.0	11	33						
Day 4	34	18.2	5.69	17.0	11	37	34	0.6	3.62	0.5	-8	13
Day 8	34	17.9	4.49	17.5	11	29	34	0.3	3.37	1.0	-7	13
Day 9/ED	34	18.3	4.46	18.0	11	28	34	0.7	2.94	0.0	-6	9
Bilirubin (umol/L)												
Baseline	34	7.96	3.339	7.20	3.2	21.2						
Day 4	34	10.24	3.760	10.00	5.5	23.6	34	2.28	1.833	2.15	-1.1	6.4
Day 8	34	10.25	3.393	10.10	6.0	20.5	34	2.29	2.057	2.10	-0.7	7.7
Day 9/ED	34	9.04	2.881	9.00	5.1	17.1	34	1.08	2.236	0.50	-5.1	6.7
Blood Urea Nitrogen (mmol/L)												
Baseline	34	4.415	1.0537	4.445	2.25	6.46						
Day 4	34	4.231	0.7147	4.180	2.82	6.18	34	-0.184	0.9306	-0.145	-2.18	1.40
Day 8	34	4.091	0.6397	4.230	3.00	5.39	34	-0.325	0.9451	-0.195	-2.29	2.07
Day 9/ED	34	4.346	0.6745	4.285	3.11	6.46	34	-0.069	0.9951	-0.035	-1.82	2.18
Calcium (mmol/L)												
Baseline	34	2.304	0.0980	2.315	2.10	2.53						
Day 4	34	2.360	0.0921	2.350	2.15	2.58	34	0.056	0.0750	0.060	-0.10	0.20
Day 8	34	2.397	0.0755	2.400	2.23	2.58	34	0.092	0.0752	0.100	-0.08	0.20
Day 9/ED	34	2.348	0.0852	2.350	2.18	2.50	34	0.043	0.0887	0.050	-0.13	0.18

Note: Baseline is defined as the last non-missing measurement prior to first dosing.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
ED = Early Discontinuation.
[1] Change from baseline: post-baseline value – baseline value.
Source Data: Listing 16.2.8.2
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Table 14.3.2.2.1
Summary of Actual Value and Change from Baseline in Serum Chemistry
Safety Population

Lab Parameter / Visit	Actual Value n	Mean	SD	Median	Min	Max	Change From Baseline [1] n	Mean	SD	Median	Min	Max
Carbon Dioxide (mmol/L)												
Baseline	34	29.2	1.47	29.0	26	31						
Day 4	34	29.5	2.02	29.5	24	33	34	0.3	1.89	0.0	-4	4
Day 8	34	29.8	1.55	30.0	27	33	34	0.6	1.46	1.0	-3	3
Day 9/ED	34	29.4	1.78	30.0	26	33	34	0.2	1.67	0.0	-4	3
Chloride (mmol/L)												
Baseline	34	102.6	1.48	102.5	100	105						
Day 4	34	103.0	1.55	103.0	100	106	34	0.4	1.99	0.5	-3	6
Day 8	34	102.2	1.68	102.0	99	107	34	-0.4	1.87	0.0	-3	5
Day 9/ED	34	101.9	1.56	102.0	98	105	34	-0.7	1.99	-1.0	-5	5
Cholesterol (mmol/L)												
Baseline	34	4.815	0.9557	4.660	3.24	6.84						
Creatinine (umol/L)												
Baseline	34	80.26	16.181	80.00	46.0	109.6						
Day 4	34	80.60	15.558	77.80	47.7	108.7	34	0.34	5.090	0.85	-12.3	10.6
Day 8	34	82.52	16.787	81.30	49.5	118.5	34	2.27	6.553	0.85	-12.4	21.2
Day 9/ED	34	83.07	15.678	83.10	52.2	114.9	34	2.82	6.208	3.10	-12.4	13.3
Creatinine Clearance (mL/min)												
Baseline	34	224.69	50.724	223.30	131.8	338.3						

Note: Baseline is defined as the last non-missing measurement prior to first dosing.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
ED = Early Discontinuation.
[1] Change from baseline: post-baseline value – baseline value.
Source Data: Listing 16.2.8.2
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Table 14.3.2.2.1
Summary of Actual Value and Change from Baseline in Serum Chemistry
Safety Population

Lab Parameter / Visit	Actual Value n	Mean	SD	Median	Min	Max	Change From Baseline [1] n	Mean	SD	Median	Min	Max
Gamma Glutamyl Transferase (IU/L)												
Baseline	34	27.4	12.89	25.5	13	64						
Day 4	34	27.6	12.81	26.0	12	69	34	0.2	3.44	0.0	-9	13
Day 8	34	28.6	12.91	26.0	13	65	34	1.2	5.68	1.0	-14	21
Day 9/ED	34	28.6	13.01	25.5	12	66	34	1.2	6.07	1.0	-13	23
Globulin (g/L)												
Baseline	34	27.3	3.87	27.5	19	35						
Day 4	34	29.1	3.53	29.0	21	36	34	1.7	1.56	2.0	-2	5
Day 8	34	28.6	3.78	29.0	18	35	34	1.3	2.26	2.0	-5	6
Day 9/ED	34	28.9	3.81	29.0	19	36	34	1.6	1.84	1.0	-2	5
Glucose (mmol/L)												
Baseline	34	5.401	0.4533	5.465	4.38	6.33						
Day 4	34	5.276	0.4118	5.245	4.61	6.11	34	-0.125	0.4346	-0.135	-1.06	1.06
Day 8	34	5.088	0.4252	5.025	4.44	6.33	34	-0.314	0.4706	-0.300	-1.39	0.61
Day 9/ED	34	5.169	0.3683	5.160	4.61	6.11	34	-0.232	0.4249	-0.135	-1.27	0.45
HDL Cholesterol (mmol/L)												
Baseline	34	1.130	0.2600	1.110	0.73	1.81						
LDL Cholesterol (mmol/L)												
Baseline	34	2.982	0.8138	2.695	1.79	4.77						

Note: Baseline is defined as the last non-missing measurement prior to first dosing.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
ED = Early Discontinuation.
[1] Change from baseline: post-baseline value – baseline value.
Source Data: Listing 16.2.8.2
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Table 14.3.2.2.1
Summary of Actual Value and Change from Baseline in Serum Chemistry
Safety Population

Lab Parameter / Visit	Actual Value n	Mean	SD	Median	Min	Max	Change From Baseline [1] n	Mean	SD	Median	Min	Max
Lactate Dehydrogenase (IU/L)												
Baseline	34	159.2	33.00	159.5	82	233						
Day 4	34	147.8	34.86	146.5	82	226	34	-11.4	12.16	-11.0	-40	14
Day 8	34	142.9	33.20	136.5	75	222	34	-16.3	12.78	-17.5	-40	20
Day 9/ED	34	148.1	31.10	144.0	85	223	34	-11.1	13.93	-12.0	-33	22
Phosphate (mmol/L)												
Baseline	34	1.115	0.1642	1.100	0.78	1.71						
Day 4	34	1.246	0.1668	1.230	0.94	1.65	34	0.130	0.1376	0.115	-0.10	0.42
Day 8	34	1.282	0.1600	1.260	1.03	1.81	34	0.167	0.1115	0.160	0.00	0.52
Day 9/ED	34	1.104	0.1363	1.100	0.84	1.42	34	-0.011	0.1259	-0.030	-0.29	0.32
Potassium (mmol/L)												
Baseline	34	4.12	0.263	4.10	3.7	4.6						
Day 4	34	4.15	0.230	4.15	3.6	4.8	34	0.03	0.275	0.00	-0.6	0.5
Day 8	34	4.17	0.244	4.20	3.7	4.7	34	0.05	0.256	0.10	-0.6	0.5
Day 9/ED	34	4.13	0.303	4.10	3.5	5.1	34	0.01	0.282	0.00	-0.8	0.8
Protein (g/L)												
Baseline	34	69.7	5.13	70.0	58	79						
Day 4	34	72.4	5.16	73.5	60	83	34	2.7	3.52	2.0	-5	12
Day 8	34	72.1	4.46	72.5	59	79	34	2.4	3.69	2.5	-8	11
Day 9/ED	34	73.1	4.90	72.5	60	83	34	3.4	3.53	3.0	-4	11

Note: Baseline is defined as the last non-missing measurement prior to first dosing.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
ED = Early Discontinuation.
[1] Change from baseline: post-baseline value – baseline value.
Source Data: Listing 16.2.8.2
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Table 14.3.2.2.1
Summary of Actual Value and Change from Baseline in Serum Chemistry
Safety Population

Lab Parameter / Visit	Actual Value n	Actual Value Mean	Actual Value SD	Actual Value Median	Actual Value Min	Actual Value Max	Change From Baseline [1] n	Change From Baseline [1] Mean	Change From Baseline [1] SD	Change From Baseline [1] Median	Change From Baseline [1] Min	Change From Baseline [1] Max
Sodium (mmol/L)												
Baseline	34	138.2	1.57	138.5	135	142						
Day 4	34	138.9	1.62	139.0	136	144	34	0.6	1.57	1.0	-2	5
Day 8	34	138.5	1.69	138.0	135	142	34	0.3	1.78	0.0	-4	4
Day 9/ED	34	137.4	1.88	138.0	133	140	34	-0.8	2.04	-0.5	-6	3
Triglycerides (mmol/L)												
Baseline	34	1.537	0.9103	1.265	0.41	4.19						
Urate (umol/L)												
Baseline	34	386.6	68.53	384.0	274	535						
Day 4	34	406.0	66.99	404.0	309	589	34	19.4	42.17	18.0	-71	125
Day 8	34	391.2	65.17	393.0	280	571	34	4.6	44.21	6.0	-107	107
Day 9/ED	34	391.5	62.74	390.0	286	577	34	4.9	43.70	6.0	-101	113

Note: Baseline is defined as the last non-missing measurement prior to first dosing.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
ED = Early Discontinuation.
[1] Change from baseline: post-baseline value – baseline value.
Source Data: Listing 16.2.8.2
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Table 14.3.2.2.2
Shift from Baseline in Serum Chemistry
Safety Population

Parameter: Alanine Aminotransferase (IU/L)

	Baseline		
Post-Baseline Visit	Low	Normal	High
Day 4			
Low	0	0	0
Normal	0	33 (97.1)	1 (2.9)
High	0	0	0
Day 8			
Low	0	0	0
Normal	0	34 (100.0)	0
High	0	0	0
Day 9/ED			
Low	0	0	0
Normal	0	34 (100.0)	0
High	0	0	0

Note: Counts represent subjects with a baseline value in addition to having a value at each post-baseline visit summarized. 'Low' denotes a value below the reference range. 'High' denotes a value above the reference range. Baseline is defined as the last non-missing measurement prior to first dosing.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
ED = Early Discontinuation.
[1] Change from baseline: post-baseline value – baseline value.
Source Data: Listing 16.2.8.2
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Table 14.3.2.2.2
Shift from Baseline in Serum Chemistry
Safety Population

Parameter: Albumin (g/L)

	Baseline		
Post-Baseline Visit	Low	Normal	High
Day 4			
Low	0	0	0
Normal	2 (5.9)	32 (94.1)	0
High	0	0	0
Day 8			
Low	0	0	0
Normal	1 (2.9)	33 (97.1)	0
High	0	0	0
Day 9/ED			
Low	0	0	0
Normal	0	34 (100.0)	0
High	0	0	0

Note: Counts represent subjects with a baseline value in addition to having a value at each post-baseline visit summarized. 'Low' denotes a value below the reference range. 'High' denotes a value above the reference range. Baseline is defined as the last non-missing measurement prior to first dosing.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
ED = Early Discontinuation.
[1] Change from baseline: post-baseline value – baseline value.
Source Data: Listing 16.2.8.2
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Table 14.3.2.2.2
Shift from Baseline in Serum Chemistry
Safety Population

Parameter: Alkaline Phosphatase (IU/L)

	Baseline		
Post-Baseline Visit	Low	Normal	High
Day 4			
Low	0	0	0
Normal	0	33 (97.1)	1 (2.9)
High	0	0	0
Day 8			
Low	0	0	0
Normal	0	33 (97.1)	1 (2.9)
High	0	0	0
Day 9/ED			
Low	0	0	0
Normal	0	33 (97.1)	1 (2.9)
High	0	0	0

Note: Counts represent subjects with a baseline value in addition to having a value at each post-baseline visit summarized. 'Low' denotes a value below the reference range. 'High' denotes a value above the reference range. Baseline is defined as the last non-missing measurement prior to first dosing.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
ED = Early Discontinuation.
[1] Change from baseline: post-baseline value – baseline value.
Source Data: Listing 16.2.8.2
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Table 14.3.2.2.2
Shift from Baseline in Serum Chemistry
Safety Population

Parameter: Anion Gap (mmol/L)

	Baseline		
Post-Baseline Visit	Low	Normal	High
Day 4			
Low	0	0	0
Normal	0	34 (100.0)	0
High	0	0	0
Day 8			
Low	0	0	0
Normal	0	34 (100.0)	0
High	0	0	0
Day 9/ED			
Low	0	0	0
Normal	0	34 (100.0)	0
High	0	0	0

Note: Counts represent subjects with a baseline value in addition to having a value at each post-baseline visit summarized. 'Low' denotes a value below the reference range. 'High' denotes a value above the reference range. Baseline is defined as the last non-missing measurement prior to first dosing.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
ED = Early Discontinuation.
[1] Change from baseline: post-baseline value – baseline value.
Source Data: Listing 16.2.8.2
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Table 14.3.2.2.2
Shift from Baseline in Serum Chemistry
Safety Population

Parameter: Aspartate Aminotransferase (IU/L)

	Baseline		
Post-Baseline Visit	Low	Normal	High
Day 4			
Low	0	0	0
Normal	0	34 (100.0)	0
High	0	0	0
Day 8			
Low	0	0	0
Normal	0	34 (100.0)	0
High	0	0	0
Day 9/ED			
Low	0	0	0
Normal	0	34 (100.0)	0
High	0	0	0

Note: Counts represent subjects with a baseline value in addition to having a value at each post-baseline visit summarized. 'Low' denotes a value below the reference range. 'High' denotes a value above the reference range. Baseline is defined as the last non-missing measurement prior to first dosing.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
ED = Early Discontinuation.
[1] Change from baseline: post-baseline value – baseline value.
Source Data: Listing 16.2.8.2
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Table 14.3.2.2.2
Shift from Baseline in Serum Chemistry
Safety Population

Parameter: Bilirubin (umol/L)

	Baseline		
Post-Baseline Visit	Low	Normal	High
Day 4			
Low	0	0	0
Normal	0	34 (100.0)	0
High	0	0	0
Day 8			
Low	0	0	0
Normal	0	34 (100.0)	0
High	0	0	0
Day 9/ED			
Low	0	0	0
Normal	0	34 (100.0)	0
High	0	0	0

Note: Counts represent subjects with a baseline value in addition to having a value at each post-baseline visit summarized. 'Low' denotes a value below the reference range. 'High' denotes a value above the reference range. Baseline is defined as the last non-missing measurement prior to first dosing.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
ED = Early Discontinuation.
[1] Change from baseline: post-baseline value – baseline value.
Source Data: Listing 16.2.8.2
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Table 14.3.2.2.2
Shift from Baseline in Serum Chemistry
Safety Population

Parameter: Blood Urea Nitrogen (mmol/L)

	Baseline		
Post-Baseline Visit	Low	Normal	High
Day 4			
Low	0	0	0
Normal	0	34 (100.0)	0
High	0	0	0
Day 8			
Low	0	0	0
Normal	0	34 (100.0)	0
High	0	0	0
Day 9/ED			
Low	0	0	0
Normal	0	34 (100.0)	0
High	0	0	0

Note: Counts represent subjects with a baseline value in addition to having a value at each post-baseline visit summarized. 'Low' denotes a value below the reference range. 'High' denotes a value above the reference range. Baseline is defined as the last non-missing measurement prior to first dosing.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
ED = Early Discontinuation.
[1] Change from baseline: post-baseline value – baseline value.
Source Data: Listing 16.2.8.2
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Table 14.3.2.2.2
Shift from Baseline in Serum Chemistry
Safety Population

Parameter: Calcium (mmol/L)

	Baseline		
Post-Baseline Visit	Low	Normal	High
Day 4			
Low	0	1 (2.9)	0
Normal	0	33 (97.1)	0
High	0	0	0
Day 8			
Low	0	1 (2.9)	0
Normal	0	33 (97.1)	0
High	0	0	0
Day 9/ED			
Low	0	1 (2.9)	0
Normal	0	33 (97.1)	0
High	0	0	0

Note: Counts represent subjects with a baseline value in addition to having a value at each post-baseline visit summarized. 'Low' denotes a value below the reference range. 'High' denotes a value above the reference range. Baseline is defined as the last non-missing measurement prior to first dosing.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
ED = Early Discontinuation.
[1] Change from baseline: post-baseline value – baseline value.
Source Data: Listing 16.2.8.2
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Table 14.3.2.2.2
Shift from Baseline in Serum Chemistry
Safety Population

Parameter: Carbon Dioxide (mmol/L)

	Baseline		
Post-Baseline Visit	Low	Normal	High
Day 4			
Low	0	0	0
Normal	0	34 (100.0)	0
High	0	0	0
Day 8			
Low	0	0	0
Normal	0	34 (100.0)	0
High	0	0	0
Day 9/ED			
Low	0	0	0
Normal	0	34 (100.0)	0
High	0	0	0

Note: Counts represent subjects with a baseline value in addition to having a value at each post-baseline visit summarized. 'Low' denotes a value below the reference range. 'High' denotes a value above the reference range. Baseline is defined as the last non-missing measurement prior to first dosing.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
ED = Early Discontinuation.
[1] Change from baseline: post-baseline value – baseline value.
Source Data: Listing 16.2.8.2
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Table 14.3.2.2.2
Shift from Baseline in Serum Chemistry
Safety Population

Parameter: Chloride (mmol/L)

	Baseline		
Post-Baseline Visit	Low	Normal	High
Day 4			
Low	0	0	0
Normal	0	34 (100.0)	0
High	0	0	0
Day 8			
Low	0	0	0
Normal	0	34 (100.0)	0
High	0	0	0
Day 9/ED			
Low	0	0	0
Normal	0	34 (100.0)	0
High	0	0	0

Note: Counts represent subjects with a baseline value in addition to having a value at each post-baseline visit summarized. 'Low' denotes a value below the reference range. 'High' denotes a value above the reference range. Baseline is defined as the last non-missing measurement prior to first dosing.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
ED = Early Discontinuation.
[1] Change from baseline: post-baseline value – baseline value.
Source Data: Listing 16.2.8.2
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Table 14.3.2.2.2
Shift from Baseline in Serum Chemistry
Safety Population

Parameter: Creatinine (umol/L)

	Baseline		
Post-Baseline Visit	Low	Normal	High
Day 4			
Low	0	0	0
Normal	0	34 (100.0)	0
High	0	0	0
Day 8			
Low	0	0	0
Normal	0	33 (97.1)	1 (2.9)
High	0	0	0
Day 9/ED			
Low	0	0	0
Normal	0	34 (100.0)	0
High	0	0	0

Note: Counts represent subjects with a baseline value in addition to having a value at each post-baseline visit summarized. 'Low' denotes a value below the reference range. 'High' denotes a value above the reference range. Baseline is defined as the last non-missing measurement prior to first dosing.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
ED = Early Discontinuation.
[1] Change from baseline: post-baseline value – baseline value.
Source Data: Listing 16.2.8.2
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Table 14.3.2.2.2
Shift from Baseline in Serum Chemistry
Safety Population

Parameter: Gamma Glutamyl Transferase (IU/L)

	Baseline		
Post-Baseline Visit	Low	Normal	High
Day 4			
Low	0	0	0
Normal	0	34 (100.0)	0
High	0	0	0
Day 8			
Low	0	0	0
Normal	0	34 (100.0)	0
High	0	0	0
Day 9/ED			
Low	0	0	0
Normal	0	34 (100.0)	0
High	0	0	0

Note: Counts represent subjects with a baseline value in addition to having a value at each post-baseline visit summarized. 'Low' denotes a value below the reference range. 'High' denotes a value above the reference range. Baseline is defined as the last non-missing measurement prior to first dosing.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
ED = Early Discontinuation.
[1] Change from baseline: post-baseline value – baseline value.
Source Data: Listing 16.2.8.2
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Table 14.3.2.2.2
Shift from Baseline in Serum Chemistry
Safety Population

Parameter: Globulin (g/L)

	Baseline		
Post-Baseline Visit	Low	Normal	High
Day 4			
Low	0	0	0
Normal	0	34 (100.0)	0
High	0	0	0
Day 8			
Low	0	0	0
Normal	1 (2.9)	33 (97.1)	0
High	0	0	0
Day 9/ED			
Low	0	0	0
Normal	0	34 (100.0)	0
High	0	0	0

Note: Counts represent subjects with a baseline value in addition to having a value at each post-baseline visit summarized. 'Low' denotes a value below the reference range. 'High' denotes a value above the reference range. Baseline is defined as the last non-missing measurement prior to first dosing.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
ED = Early Discontinuation.
[1] Change from baseline: post-baseline value – baseline value.
Source Data: Listing 16.2.8.2
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Table 14.3.2.2.2
Shift from Baseline in Serum Chemistry
Safety Population

Parameter: Glucose (mmol/L)

	Baseline		
Post-Baseline Visit	Low	Normal	High
Day 4			
Low	0	0	0
Normal	0	34 (100.0)	0
High	0	0	0
Day 8			
Low	0	0	0
Normal	0	34 (100.0)	0
High	0	0	0
Day 9/ED			
Low	0	0	0
Normal	0	34 (100.0)	0
High	0	0	0

Note: Counts represent subjects with a baseline value in addition to having a value at each post-baseline visit summarized. 'Low' denotes a value below the reference range. 'High' denotes a value above the reference range. Baseline is defined as the last non-missing measurement prior to first dosing.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
ED = Early Discontinuation.
[1] Change from baseline: post-baseline value – baseline value.
Source Data: Listing 16.2.8.2
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Table 14.3.2.2.2
Shift from Baseline in Serum Chemistry
Safety Population

Parameter: Lactate Dehydrogenase (IU/L)

Post-Baseline Visit	Baseline: Low	Baseline: Normal	Baseline: High
Day 4			
Low	0	0	0
Normal	0	32 (94.1)	0
High	0	0	2 (5.9)
Day 8			
Low	0	0	0
Normal	1 (2.9)	30 (88.2)	1 (2.9)
High	0	2 (5.9)	0
Day 9/ED			
Low	0	0	0
Normal	0	31 (91.2)	1 (2.9)
High	0	2 (5.9)	0

Note: Counts represent subjects with a baseline value in addition to having a value at each post-baseline visit summarized. 'Low' denotes a value below the reference range. 'High' denotes a value above the reference range. Baseline is defined as the last non-missing measurement prior to first dosing.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
ED = Early Discontinuation.
[1] Change from baseline: post-baseline value – baseline value.
Source Data: Listing 16.2.8.2
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Table 14.3.2.2.2
Shift from Baseline in Serum Chemistry
Safety Population

Parameter: Phosphate (mmol/L)

	Baseline		
Post-Baseline Visit	Low	Normal	High
Day 4			
Low	0	0	0
Normal	0	33 (97.1)	0
High	0	0	1 (2.9)
Day 8			
Low	0	0	0
Normal	0	33 (97.1)	0
High	0	0	1 (2.9)
Day 9/ED			
Low	0	0	0
Normal	0	33 (97.1)	0
High	0	1 (2.9)	0

Note: Counts represent subjects with a baseline value in addition to having a value at each post-baseline visit summarized. 'Low' denotes a value below the reference range. 'High' denotes a value above the reference range. Baseline is defined as the last non-missing measurement prior to first dosing.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
ED = Early Discontinuation.
[1] Change from baseline: post-baseline value – baseline value.
Source Data: Listing 16.2.8.2
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Table 14.3.2.2.2
Shift from Baseline in Serum Chemistry
Safety Population

Parameter: Potassium (mmol/L)

Post-Baseline Visit	Baseline		
	Low	Normal	High
Day 4			
Low	0	0	0
Normal	0	34 (100.0)	0
High	0	0	0
Day 8			
Low	0	0	0
Normal	0	34 (100.0)	0
High	0	0	0
Day 9/ED			
Low	0	0	0
Normal	0	33 (97.1)	1 (2.9)
High	0	0	0

Note: Counts represent subjects with a baseline value in addition to having a value at each post-baseline visit summarized. 'Low' denotes a value below the reference range. 'High' denotes a value above the reference range. Baseline is defined as the last non-missing measurement prior to first dosing.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
ED = Early Discontinuation.
[1] Change from baseline: post-baseline value – baseline value.
Source Data: Listing 16.2.8.2
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Table 14.3.2.2.2
Shift from Baseline in Serum Chemistry
Safety Population

Parameter: Protein (g/L)

	Baseline		
Post-Baseline Visit	Low	Normal	High
Day 4			
Low	0	0	0
Normal	0	34 (100.0)	0
High	0	0	0
Day 8			
Low	0	0	0
Normal	0	34 (100.0)	0
High	0	0	0
Day 9/ED			
Low	0	0	0
Normal	0	34 (100.0)	0
High	0	0	0

Note: Counts represent subjects with a baseline value in addition to having a value at each post-baseline visit summarized. 'Low' denotes a value below the reference range. 'High' denotes a value above the reference range. Baseline is defined as the last non-missing measurement prior to first dosing.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
ED = Early Discontinuation.
[1] Change from baseline: post-baseline value – baseline value.
Source Data: Listing 16.2.8.2
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Table 14.3.2.2.2
Shift from Baseline in Serum Chemistry
Safety Population

Parameter: Sodium (mmol/L)

	Baseline		
Post-Baseline Visit	Low	Normal	High
Day 4			
Low	0	0	0
Normal	0	34 (100.0)	0
High	0	0	0
Day 8			
Low	0	0	0
Normal	0	34 (100.0)	0
High	0	0	0
Day 9/ED			
Low	0	0	0
Normal	0	34 (100.0)	0
High	0	0	0

Note: Counts represent subjects with a baseline value in addition to having a value at each post-baseline visit summarized. 'Low' denotes a value below the reference range. 'High' denotes a value above the reference range. Baseline is defined as the last non-missing measurement prior to first dosing.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
ED = Early Discontinuation.
[1] Change from baseline: post-baseline value – baseline value.
Source Data: Listing 16.2.8.2
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Table 14.3.2.2.2
Shift from Baseline in Serum Chemistry
Safety Population

Parameter: Urate (umol/L)

Post-Baseline Visit	Baseline: Low	Baseline: Normal	Baseline: High
Day 4			
Low	0	0	0
Normal	0	21 (61.8)	4 (11.8)
High	0	3 (8.8)	6 (17.6)
Day 8			
Low	0	0	0
Normal	0	23 (67.6)	2 (5.9)
High	0	6 (17.6)	3 (8.8)
Day 9/ED			
Low	0	0	0
Normal	0	22 (64.7)	3 (8.8)
High	0	6 (17.6)	3 (8.8)

Note: Counts represent subjects with a baseline value in addition to having a value at each post-baseline visit summarized. 'Low' denotes a value below the reference range. 'High' denotes a value above the reference range. Baseline is defined as the last non-missing measurement prior to first dosing.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
ED = Early Discontinuation.
[1] Change from baseline: post-baseline value – baseline value.
Source Data: Listing 16.2.8.2
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Table 14.3.2.2.3
Summary of Serum Chemistry Results by Maximum Grade Increase Post-Baseline Relative to Baseline
Safety Population

Test (units)/ Term		Total (N=34) n (%)
Alanine Aminotransferase (IU/L)/	n	34
High	Increase to Grade 1	0
	Increase to Grade 2	0
	Increase to Grade 3	0
	Increase to Grade 4	0
	Increase to Grades 1 to 4	0
	Increase to Grades 2 to 4	0
	Increase to Grades 3 to 4	0
Albumin (g/L)/	n	34
Low	Increase to Grade 1	2 (5.9)
	Increase to Grade 2	0
	Increase to Grade 3	0
	Increase to Grade 4	0
	Increase to Grades 1 to 4	2 (5.9)
	Increase to Grades 2 to 4	0
	Increase to Grades 3 to 4	0

Note: Counts represent subjects with a baseline value in addition to having at least one post-baseline value, including unscheduled visits. Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Listing 16.2.8.2
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Table 14.3.2.2.3
Summary of Serum Chemistry Results by Maximum Grade Increase Post-Baseline Relative to Baseline
Safety Population

Test (units)/ Term		Total (N=34) n (%)
Alkaline Phosphatase (IU/L)/	n	34
High	Increase to Grade 1	0
	Increase to Grade 2	0
	Increase to Grade 3	0
	Increase to Grade 4	0
	Increase to Grades 1 to 4	0
	Increase to Grades 2 to 4	0
	Increase to Grades 3 to 4	0
Aspartate Aminotransferase (IU/L)/	n	34
High	Increase to Grade 1	0
	Increase to Grade 2	0
	Increase to Grade 3	0
	Increase to Grade 4	0
	Increase to Grades 1 to 4	0
	Increase to Grades 2 to 4	0
	Increase to Grades 3 to 4	0

Note: Counts represent subjects with a baseline value in addition to having at least one post-baseline value, including unscheduled visits. Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Listing 16.2.8.2
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Table 14.3.2.2.3
Summary of Serum Chemistry Results by Maximum Grade Increase Post-Baseline Relative to Baseline
Safety Population

Test (units)/ Term		Total (N=34) n (%)
Bilirubin (umol/L)/	n	34
High	Increase to Grade 1	0
	Increase to Grade 2	0
	Increase to Grade 3	0
	Increase to Grade 4	0
	Increase to Grades 1 to 4	0
	Increase to Grades 2 to 4	0
	Increase to Grades 3 to 4	0
Calcium (mmol/L)/	n	34
Low	Increase to Grade 1	0
	Increase to Grade 2	0
	Increase to Grade 3	0
	Increase to Grade 4	0
	Increase to Grades 1 to 4	0
	Increase to Grades 2 to 4	0
	Increase to Grades 3 to 4	0

Note: Counts represent subjects with a baseline value in addition to having at least one post-baseline value, including unscheduled visits. Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Listing 16.2.8.2
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Table 14.3.2.2.3
Summary of Serum Chemistry Results by Maximum Grade Increase Post-Baseline Relative to Baseline
Safety Population

Test (units)/ Term		Total (N=34) n (%)
Calcium (mmol/L)/	n	34
High	Increase to Grade 1	0
	Increase to Grade 2	0
	Increase to Grade 3	0
	Increase to Grade 4	0
	Increase to Grades 1 to 4	0
	Increase to Grades 2 to 4	0
	Increase to Grades 3 to 4	0
Carbon Dioxide (mmol/L)/	n	34
Low	Increase to Grade 1	0
	Increase to Grade 2	0
	Increase to Grade 3	0
	Increase to Grade 4	0
	Increase to Grades 1 to 4	0
	Increase to Grades 2 to 4	0
	Increase to Grades 3 to 4	0

Note: Counts represent subjects with a baseline value in addition to having at least one post-baseline value, including unscheduled visits. Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Listing 16.2.8.2
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Table 14.3.2.2.3
Summary of Serum Chemistry Results by Maximum Grade Increase Post-Baseline Relative to Baseline
Safety Population

Test (units)/ Term		Total (N=34) n (%)
Creatinine (umol/L)/	n	34
High	Increase to Grade 1	0
	Increase to Grade 2	0
	Increase to Grade 3	0
	Increase to Grade 4	0
	Increase to Grades 1 to 4	0
	Increase to Grades 2 to 4	0
	Increase to Grades 3 to 4	0
Glucose (mmol/L)/	n	34
Low	Increase to Grade 1	0
	Increase to Grade 2	0
	Increase to Grade 3	0
	Increase to Grade 4	0
	Increase to Grades 1 to 4	0
	Increase to Grades 2 to 4	0
	Increase to Grades 3 to 4	0

Note: Counts represent subjects with a baseline value in addition to having at least one post-baseline value, including unscheduled visits. Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Listing 16.2.8.2
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Table 14.3.2.2.3
Summary of Serum Chemistry Results by Maximum Grade Increase Post-Baseline Relative to Baseline
Safety Population

Test (units)/ Term		Total (N=34) n (%)
Glucose (mmol/L)/	n	34
High	Increase to Grade 1	2 (5.9)
	Increase to Grade 2	0
	Increase to Grade 3	0
	Increase to Grade 4	0
	Increase to Grades 1 to 4	2 (5.9)
	Increase to Grades 2 to 4	0
	Increase to Grades 3 to 4	0
Phosphate (mmol/L)/	n	34
Low	Increase to Grade 1	0
	Increase to Grade 2	0
	Increase to Grade 3	0
	Increase to Grade 4	0
	Increase to Grades 1 to 4	0
	Increase to Grades 2 to 4	0
	Increase to Grades 3 to 4	0

Note: Counts represent subjects with a baseline value in addition to having at least one post-baseline value, including unscheduled visits. Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Listing 16.2.8.2
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Table 14.3.2.2.3
Summary of Serum Chemistry Results by Maximum Grade Increase Post-Baseline Relative to Baseline
Safety Population

Test (units)/ Term		Total (N=34) n (%)
Potassium (mmol/L)/ Low	n	34
	Increase to Grade 1	0
	Increase to Grade 2	0
	Increase to Grade 3	0
	Increase to Grade 4	0
	Increase to Grades 1 to 4	0
	Increase to Grades 2 to 4	0
	Increase to Grades 3 to 4	0
Potassium (mmol/L)/ High	n	34
	Increase to Grade 1	0
	Increase to Grade 2	0
	Increase to Grade 3	0
	Increase to Grade 4	0
	Increase to Grades 1 to 4	0
	Increase to Grades 2 to 4	0
	Increase to Grades 3 to 4	0

Note: Counts represent subjects with a baseline value in addition to having at least one post-baseline value, including unscheduled visits. Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Listing 16.2.8.2
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Table 14.3.2.2.3
Summary of Serum Chemistry Results by Maximum Grade Increase Post-Baseline Relative to Baseline
Safety Population

Test (units)/ Term		Total (N=34) n (%)
Sodium (mmol/L)/ Low	n	34
	Increase to Grade 1	3 (8.8)
	Increase to Grade 2	0
	Increase to Grade 3	0
	Increase to Grade 4	0
	Increase to Grades 1 to 4	3 (8.8)
	Increase to Grades 2 to 4	0
	Increase to Grades 3 to 4	0
Sodium (mmol/L)/ High	n	34
	Increase to Grade 1	0
	Increase to Grade 2	0
	Increase to Grade 3	0
	Increase to Grade 4	0
	Increase to Grades 1 to 4	0
	Increase to Grades 2 to 4	0
	Increase to Grades 3 to 4	0

Note: Counts represent subjects with a baseline value in addition to having at least one post-baseline value, including unscheduled visits. Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Listing 16.2.8.2
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Table 14.3.2.2.3
Summary of Serum Chemistry Results by Maximum Grade Increase Post-Baseline Relative to Baseline
Safety Population

Test (units)/ Term		Total (N=34) n (%)
Urate (umol/L)/	n	34
High	Increase to Grade 1	3 (8.8)
	Increase to Grade 2	0
	Increase to Grade 3	0
	Increase to Grade 4	0
	Increase to Grades 1 to 4	3 (8.8)
	Increase to Grades 2 to 4	0
	Increase to Grades 3 to 4	0

Note: Counts represent subjects with a baseline value in addition to having at least one post-baseline value, including unscheduled visits. Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Listing 16.2.8.2
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Table 14.3.2.3.1
Summary of Actual Value and Change from Baseline in Urinalysis
Safety Population

Lab Parameter / Visit	Actual Value n	Mean	SD	Median	Min	Max	Change From Baseline [1] n	Mean	SD	Median	Min	Max
Specific Gravity												
Baseline	34	1.0168	0.00807	1.0185	1.003	1.029						
Day 9/ED	34	1.0196	0.00640	1.0205	1.006	1.034	34	0.0028	0.00903	0.0010	-0.016	0.022
Urobilinogen (umol/dL)												
Baseline	34	0.697	0.6045	0.340	0.34	1.69						
Day 9/ED	34	0.499	0.4415	0.340	0.34	1.69	34	-0.199	0.6756	0.000	-1.35	1.35
pH												
Baseline	34	5.97	0.550	6.00	5.0	7.0						
Day 9/ED	34	5.93	0.566	6.00	5.0	7.0	34	-0.04	0.711	0.00	-2.0	1.5

Note: Baseline is defined as the last non-missing measurement prior to first dosing.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
ED = Early Discontinuation.
[1] Change from baseline: post-baseline value – baseline value.
Source Data: Listing 16.2.8.3

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Table 14.3.2.3.2
Shift from Baseline in Urinalysis
Safety Population

Parameter (Unit): Specific Gravity

	Baseline		
Post-Baseline Visit	Low	Normal	High
Screening			
Low	0	0	0
Normal	0	34 (100.0)	0
High	0	0	0
Day 9/ED			
Low	0	0	0
Normal	0	33 (97.1)	0
High	0	1 (2.9)	0

Note: Counts represent subjects with a baseline value in addition to having a value at each post-baseline visit summarized. 'Low' denotes a value below the reference range. 'High' denotes a value above the reference range. 'Abnormal' denotes a value outside the reference range. Baseline is defined as the last non-missing measurement prior to first dosing.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
ED = Early Discontinuation.
[1] Change from baseline: post-baseline value – baseline value.
Source Data: Listing 16.2.8.3
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Table 14.3.2.3.2
Shift from Baseline in Urinalysis
Safety Population

Parameter (Unit): Urobilinogen (umol/dL)

	Baseline		
Post-Baseline Visit	Low	Normal	High
Screening			
Low	0	0	0
Normal	0	34 (100.0)	0
High	0	0	0
Day 9/ED			
Low	0	0	0
Normal	0	34 (100.0)	0
High	0	0	0

Note: Counts represent subjects with a baseline value in addition to having a value at each post-baseline visit summarized. 'Low' denotes a value below the reference range. 'High' denotes a value above the reference range. 'Abnormal' denotes a value outside the reference range. Baseline is defined as the last non-missing measurement prior to first dosing.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
ED = Early Discontinuation.
[1] Change from baseline: post-baseline value – baseline value.
Source Data: Listing 16.2.8.3
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Table 14.3.2.3.2
Shift from Baseline in Urinalysis
Safety Population

Parameter (Unit): pH

	Baseline		
Post-Baseline Visit	Low	Normal	High
Screening			
Low	0	0	0
Normal	0	34 (100.0)	0
High	0	0	0
Day 9/ED			
Low	0	0	0
Normal	0	34 (100.0)	0
High	0	0	0

Note: Counts represent subjects with a baseline value in addition to having a value at each post-baseline visit summarized. 'Low' denotes a value below the reference range. 'High' denotes a value above the reference range. 'Abnormal' denotes a value outside the reference range. Baseline is defined as the last non-missing measurement prior to first dosing.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
ED = Early Discontinuation.
[1] Change from baseline: post-baseline value – baseline value.
Source Data: Listing 16.2.8.3
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Table 14.3.2.3.2
Shift from Baseline in Urinalysis
Safety Population

Parameter (Unit): Clarity

	Baseline	
Post-Baseline Visit	Normal	Abnormal
Screening		
Normal	34 (100.0)	0
Abnormal	0	0
Day 9/ED		
Normal	31 (91.2)	0
Abnormal	3 (8.8)	0

Note: Counts represent subjects with a baseline value in addition to having a value at each post-baseline visit summarized. 'Low' denotes a value below the reference range. 'High' denotes a value above the reference range. 'Abnormal' denotes a value outside the reference range. Baseline is defined as the last non-missing measurement prior to first dosing.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
ED = Early Discontinuation.
[1] Change from baseline: post-baseline value – baseline value.
Source Data: Listing 16.2.8.3
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Table 14.3.2.3.2
Shift from Baseline in Urinalysis
Safety Population

Parameter (Unit): Color

	Baseline	
Post-Baseline Visit	Normal	Abnormal
Screening		
Normal	34 (100.0)	0
Abnormal	0	0
Day 9/ED		
Normal	34 (100.0)	0
Abnormal	0	0

Note: Counts represent subjects with a baseline value in addition to having a value at each post-baseline visit summarized. 'Low' denotes a value below the reference range. 'High' denotes a value above the reference range. 'Abnormal' denotes a value outside the reference range. Baseline is defined as the last non-missing measurement prior to first dosing.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
ED = Early Discontinuation.
[1] Change from baseline: post-baseline value – baseline value.
Source Data: Listing 16.2.8.3
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Table 14.3.2.3.2
Shift from Baseline in Urinalysis
Safety Population

Parameter (Unit): Ketones

	Baseline	
Post-Baseline Visit	Normal	Abnormal
Screening		
Normal	34 (100.0)	0
Abnormal	0	0
Day 9/ED		
Normal	34 (100.0)	0
Abnormal	0	0

Note: Counts represent subjects with a baseline value in addition to having a value at each post-baseline visit summarized. 'Low' denotes a value below the reference range. 'High' denotes a value above the reference range. 'Abnormal' denotes a value outside the reference range. Baseline is defined as the last non-missing measurement prior to first dosing.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
ED = Early Discontinuation.
[1] Change from baseline: post-baseline value – baseline value.
Source Data: Listing 16.2.8.3
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Table 14.3.2.3.2
Shift from Baseline in Urinalysis
Safety Population

Parameter (Unit): Leukocyte Esterase

	Baseline	
Post-Baseline Visit	Normal	Abnormal
Screening		
Normal	32 (94.1)	0
Abnormal	0	2 (5.9)
Day 9/ED		
Normal	30 (88.2)	0
Abnormal	2 (5.9)	2 (5.9)

Note: Counts represent subjects with a baseline value in addition to having a value at each post-baseline visit summarized. 'Low' denotes a value below the reference range. 'High' denotes a value above the reference range. 'Abnormal' denotes a value outside the reference range. Baseline is defined as the last non-missing measurement prior to first dosing.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
ED = Early Discontinuation.
[1] Change from baseline: post-baseline value – baseline value.
Source Data: Listing 16.2.8.3
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Table 14.3.2.3.2
Shift from Baseline in Urinalysis
Safety Population

Parameter (Unit): Nitrite

	Baseline	
Post-Baseline Visit	Normal	Abnormal
Screening		
Normal	33 (97.1)	0
Abnormal	0	1 (2.9)
Day 9/ED		
Normal	32 (94.1)	1 (2.9)
Abnormal	1 (2.9)	0

Note: Counts represent subjects with a baseline value in addition to having a value at each post-baseline visit summarized. 'Low' denotes a value below the reference range. 'High' denotes a value above the reference range. 'Abnormal' denotes a value outside the reference range. Baseline is defined as the last non-missing measurement prior to first dosing.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
ED = Early Discontinuation.
[1] Change from baseline: post-baseline value – baseline value.
Source Data: Listing 16.2.8.3
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Table 14.3.2.3.2
Shift from Baseline in Urinalysis
Safety Population

Parameter (Unit): Occult Blood

	Baseline	
Post-Baseline Visit	Normal	Abnormal
Screening		
Normal	32 (94.1)	0
Abnormal	0	2 (5.9)
Day 9/ED		
Normal	29 (85.3)	1 (2.9)
Abnormal	3 (8.8)	1 (2.9)

Note: Counts represent subjects with a baseline value in addition to having a value at each post-baseline visit summarized. 'Low' denotes a value below the reference range. 'High' denotes a value above the reference range. 'Abnormal' denotes a value outside the reference range. Baseline is defined as the last non-missing measurement prior to first dosing.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
ED = Early Discontinuation.
[1] Change from baseline: post-baseline value – baseline value.
Source Data: Listing 16.2.8.3
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Table 14.3.2.3.2
Shift from Baseline in Urinalysis
Safety Population

Parameter (Unit): Urine Bilirubin

	Baseline	
Post-Baseline Visit	Normal	Abnormal
Screening		
Normal	34 (100.0)	0
Abnormal	0	0
Day 9/ED		
Normal	34 (100.0)	0
Abnormal	0	0

Note: Counts represent subjects with a baseline value in addition to having a value at each post-baseline visit summarized. 'Low' denotes a value below the reference range. 'High' denotes a value above the reference range. 'Abnormal' denotes a value outside the reference range. Baseline is defined as the last non-missing measurement prior to first dosing.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
ED = Early Discontinuation.
[1] Change from baseline: post-baseline value – baseline value.
Source Data: Listing 16.2.8.3
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Table 14.3.2.3.2
Shift from Baseline in Urinalysis
Safety Population

Parameter (Unit): Urine Glucose

	Baseline	
Post-Baseline Visit	Normal	Abnormal
Screening		
Normal	34 (100.0)	0
Abnormal	0	0
Day 9/ED		
Normal	34 (100.0)	0
Abnormal	0	0

Note: Counts represent subjects with a baseline value in addition to having a value at each post-baseline visit summarized. 'Low' denotes a value below the reference range. 'High' denotes a value above the reference range. 'Abnormal' denotes a value outside the reference range. Baseline is defined as the last non-missing measurement prior to first dosing.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
ED = Early Discontinuation.
[1] Change from baseline: post-baseline value – baseline value.
Source Data: Listing 16.2.8.3
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Table 14.3.2.3.2
Shift from Baseline in Urinalysis
Safety Population

Parameter (Unit): Urine Protein

	Baseline	
Post-Baseline Visit	Normal	Abnormal
Screening		
Normal	34 (100.0)	0
Abnormal	0	0
Day 9/ED		
Normal	32 (94.1)	0
Abnormal	2 (5.9)	0

Note: Counts represent subjects with a baseline value in addition to having a value at each post-baseline visit summarized. 'Low' denotes a value below the reference range. 'High' denotes a value above the reference range. 'Abnormal' denotes a value outside the reference range. Baseline is defined as the last non-missing measurement prior to first dosing.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
ED = Early Discontinuation.
[1] Change from baseline: post-baseline value – baseline value.
Source Data: Listing 16.2.8.3
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Table 14.3.2.3.3
Summary of Urinalysis Results by Maximum Grade Increase Post -Baseline Relative to Baseline
Safety Population

Test (units)/ Term		Total (N=34) n (%)
Urine Erythrocytes (/HPF)/	n	10
High	Increase to Grade 1	0
	Increase to Grade 2	0
	Increase to Grade 3	0
	Increase to Grade 4	0
	Increase to Grades 1 to 4	0
	Increase to Grades 2 to 4	0
	Increase to Grades 3 to 4	0
Urine Glucose/	n	34
High	Increase to Grade 1	0
	Increase to Grade 2	0
	Increase to Grade 3	0
	Increase to Grade 4	0
	Increase to Grades 1 to 4	0
	Increase to Grades 2 to 4	0
	Increase to Grades 3 to 4	0

Note: Counts represent subjects with a baseline value in addition to having at least one post-baseline value, including unscheduled visits. Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Listing 16.2.8.3
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Table 14.3.2.3.3
Summary of Urinalysis Results by Maximum Grade Increase Post -Baseline Relative to Baseline
Safety Population

Test (units)/ Term		Total (N=34) n (%)
Urine Protein/	n	34
High	Increase to Grade 1	0
	Increase to Grade 2	0
	Increase to Grade 3	0
	Increase to Grade 4	0
	Increase to Grades 1 to 4	0
	Increase to Grades 2 to 4	0
	Increase to Grades 3 to 4	0

Note: Counts represent subjects with a baseline value in addition to having at least one post-baseline value, including unscheduled visits. Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Listing 16.2.8.3
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Table 14.3.3.1.1
Summary of Actual Value and Change from Baseline in Vital Signs
Safety Population

Parameter Visit – Time Point	Actual Value n	Mean	SD	Median	Min	Max	Change From Baseline [1] n	Mean	SD	Median	Min	Max
Systolic Blood Pressure (mmHg)												
Baseline	34	124.9	11.55	123.0	100	150						
Day 1 – 4 hr after AM dose	34	126.5	15.84	124.0	98	182	34	1.6	13.49	-3.0	-23	44
Day 4 – 4 hr after AM dose	34	125.8	14.03	125.5	84	166	34	0.9	12.06	1.5	-32	28
Day 7 – before dosing	34	122.6	13.17	122.0	100	162	34	-2.3	10.72	-3.0	-23	28
Day 7 – 4 hr after AM dose	34	126.9	13.18	122.5	106	154	34	2.0	9.84	2.0	-19	21
Day 8	34	123.0	13.52	123.0	102	172	34	-1.9	12.12	-2.5	-20	34
Day 9/ED	34	122.9	11.41	121.0	101	149	34	-2.1	11.52	-1.0	-22	31
Diastolic Blood Pressure (mmHg)												
Baseline	34	71.8	10.03	70.0	57	100						
Day 1 – 4 hr after AM dose	34	71.0	8.84	71.0	56	87	34	-0.7	9.21	-0.5	-18	19
Day 4 – 4 hr after AM dose	34	69.5	9.91	68.5	47	100	34	-2.3	7.44	-0.5	-20	9
Day 7 – before dosing	34	67.6	10.60	68.0	50	95	34	-4.2	10.41	-2.5	-32	20
Day 7 – 4 hr after AM dose	34	69.2	9.51	69.0	50	90	34	-2.6	8.14	-2.5	-23	10
Day 8	34	70.2	7.65	70.0	56	91	34	-1.5	8.27	-0.5	-16	19
Day 9/ED	34	67.1	8.91	66.5	54	88	34	-4.6	6.76	-5.0	-18	9

Note: Baseline is defined as the last non-missing measurement prior to first dosing.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
ED = Early Discontinuation.
[1] Change from baseline: post-baseline value – baseline value.
Source Data: Listing 16.2.8.5
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Table 14.3.3.1.1
Summary of Actual Value and Change from Baseline in Vital Signs
Safety Population

Parameter Visit – Time Point	Actual Value						Change From Baseline [1]					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Heart Rate (beats/min)												
Baseline	34	73.1	10.90	72.5	44	93						
Day 1 – 4 hr after AM dose	34	70.4	9.60	73.5	46	83	34	-2.7	6.24	-3.5	-15	10
Day 4 – 4 hr after AM dose	34	70.5	9.03	71.0	50	84	34	-2.6	7.82	-2.5	-20	14
Day 7 – before dosing	34	75.1	11.19	75.0	44	107	34	2.0	7.53	1.0	-11	22
Day 7 – 4 hr after AM dose	34	69.6	8.95	70.0	47	91	34	-3.6	7.48	-4.0	-22	11
Day 8	34	76.0	10.46	77.5	57	101	34	2.9	8.21	3.0	-16	20
Day 9/ED	34	77.0	9.96	79.0	49	92	34	3.9	9.23	3.0	-12	25
Respiratory Rate (breaths/min)												
Baseline	34	14.4	2.23	14.0	10	20						
Day 1 – 4 hr after AM dose	34	14.4	2.13	14.0	12	18	34	0.1	2.67	0.0	-6	6
Day 4 – 4 hr after AM dose	34	14.9	2.57	16.0	8	18	34	0.5	3.16	2.0	-6	6
Day 7 – before dosing	34	15.5	1.97	16.0	10	20	34	1.2	2.61	2.0	-4	6
Day 7 – 4 hr after AM dose	34	14.7	2.20	15.0	10	18	34	0.4	2.53	0.0	-6	4
Day 8	34	13.6	1.87	14.0	10	18	34	-0.7	3.19	0.0	-10	4
Day 9/ED	34	14.8	2.15	14.0	12	18	34	0.4	2.73	0.0	-6	4

Note: Baseline is defined as the last non-missing measurement prior to first dosing.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
ED = Early Discontinuation.
[1] Change from baseline: post-baseline value – baseline value.
Source Data: Listing 16.2.8.5
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Table 14.3.3.1.1
Summary of Actual Value and Change from Baseline in Vital Signs
Safety Population

Parameter Visit – Time Point	Actual Value						Change From Baseline [1]					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Temperature (C)												
Baseline	34	36.37	0.319	36.40	35.7	36.9						
Day 1 – 4 hr after AM dose	34	36.18	0.303	36.20	35.2	36.7	34	-0.19	0.404	-0.20	-1.3	0.7
Day 4 – 4 hr after AM dose	34	36.40	0.330	36.40	35.7	37.2	34	0.03	0.427	0.00	-1.0	1.0
Day 7 – before dosing	34	36.35	0.345	36.35	35.7	37.1	34	-0.02	0.288	0.00	-0.6	0.7
Day 7 – 4 hr after AM dose	34	36.41	0.378	36.40	35.7	37.2	34	0.04	0.427	0.00	-1.0	1.0
Day 8	34	36.30	0.416	36.40	35.1	37.2	34	-0.07	0.384	-0.10	-1.4	0.7
Day 9/ED	34	36.50	0.281	36.45	35.9	37.2	34	0.13	0.324	0.10	-0.6	0.8

Note: Baseline is defined as the last non-missing measurement prior to first dosing.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
ED = Early Discontinuation.
[1] Change from baseline: post-baseline value – baseline value.
Source Data: Listing 16.2.8.5
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Table 14.3.4.1.1
Summary of Actual Value and Change from Baseline in Electrocardiogram Results
Safety Population

Parameter Visit – Time Point	Actual Value						Change From Baseline [1]					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
ECG Mean Heart Rate (beats/min)												
Baseline	34	71.9	11.13	74.0	47	93						
Day 1 – 4 hr after AM dose	34	64.6	8.77	66.0	48	78	34	-7.3	7.16	-4.5	-27	2
Day 4 – 4 hr after AM dose	34	67.0	8.33	67.5	50	84	34	-4.9	7.39	-4.0	-23	14
Day 7 – 4 hr after AM dose	34	66.2	8.92	66.0	50	86	34	-5.7	7.91	-6.0	-21	9
Day 9/ED	34	71.0	9.66	71.0	48	92	34	-0.9	7.64	0.0	-21	14
PR Interval, Aggregate (msec)												
Baseline	34	168.1	22.50	162.0	130	219						
Day 1 – 4 hr after AM dose	34	169.1	21.34	168.0	134	217	34	0.9	9.25	1.0	-20	26
Day 4 – 4 hr after AM dose	34	170.0	21.53	166.0	136	220	34	1.9	8.96	0.5	-14	26
Day 7 – 4 hr after AM dose	34	170.1	22.29	168.0	126	217	34	1.9	9.27	1.0	-18	26
Day 9/ED	34	171.1	20.43	167.0	128	221	34	2.9	16.19	5.0	-56	34
QRS Duration, Aggregate (msec)												
Baseline	34	96.1	10.10	93.5	75	124						
Day 1 – 4 hr after AM dose	34	95.8	9.63	93.0	74	114	34	-0.3	6.11	-0.5	-15	13
Day 4 – 4 hr after AM dose	34	94.4	9.43	92.5	79	113	34	-1.7	5.60	-1.0	-19	11
Day 7 – 4 hr after AM dose	34	95.6	10.37	93.5	77	121	34	-0.5	5.94	0.0	-20	10
Day 9/ED	34	95.9	10.38	97.0	73	116	34	-0.2	5.92	-1.0	-16	13

Note: Baseline is defined as the last non-missing measurement prior to first dosing.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
ED = Early Discontinuation.
[1] Change from baseline: post-baseline value – baseline value.
Source Data: Listing 16.2.8.7
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Table 14.3.4.1.1
Summary of Actual Value and Change from Baseline in Electrocardiogram Results
Safety Population

Parameter Visit – Time Point	Actual Value						Change From Baseline [1]					
	n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
QTcB Interval, Aggregate (msec)												
Baseline	34	420.1	22.21	418.5	367	464						
Day 1 – 4 hr after AM dose	34	417.4	23.81	420.0	364	463	34	-2.7	11.79	-1.0	-31	16
Day 4 – 4 hr after AM dose	34	411.9	21.68	411.5	363	454	34	-8.3	13.53	-4.0	-37	17
Day 7 – 4 hr after AM dose	34	411.9	21.32	419.5	365	444	34	-8.2	14.60	-9.0	-36	21
Day 9/ED	34	412.1	20.31	411.5	366	454	34	-8.0	9.68	-8.0	-28	12
QTcF Interval, Aggregate (msec)												
Baseline	34	407.8	17.17	408.5	372	446						
Day 1 – 4 hr after AM dose	34	412.2	19.03	414.5	378	462	34	4.4	9.68	4.0	-16	23
Day 4 – 4 hr after AM dose	34	405.3	19.11	402.5	371	445	34	-2.6	12.34	-2.0	-27	19
Day 7 – 4 hr after AM dose	34	405.3	18.82	411.0	372	438	34	-2.5	11.70	-1.5	-24	18
Day 9/ED	34	400.9	16.49	399.0	373	429	34	-6.9	9.53	-7.0	-29	13
RR Interval, Aggregate (msec)												
Baseline	34	846.7	143.52	809.0	645	1272						
Day 1 – 4 hr after AM dose	34	939.5	138.35	902.0	764	1239	34	92.7	84.53	80.5	-35	287
Day 4 – 4 hr after AM dose	34	901.8	114.18	885.0	708	1185	34	55.1	90.43	52.0	-159	244
Day 7 – 4 hr after AM dose	34	916.1	125.13	900.5	697	1198	34	69.4	95.47	82.0	-117	263
Day 9/ED	34	855.9	122.72	840.0	647	1230	34	9.2	85.47	7.0	-179	208

Note: Baseline is defined as the last non-missing measurement prior to first dosing.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
ED = Early Discontinuation.
[1] Change from baseline: post-baseline value – baseline value.
Source Data: Listing 16.2.8.7
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15. REFERENCE LIST

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3. Department of Health and Human Services, Food and Drug Administration (US). Guidance for Industry. Bioanalytical Method Validation. May 2018. Available from: https://www.fda.gov/files/drugs/published/Bioanalytical-Method-Validation-Guidance-for-Industry.pdf.

16. APPENDICES

16.1 STUDY INFORMATION

16.1.1 Protocol and Protocol Amendments

This section contains the following documents:

Protocol Original dated 19 February 2019

Protocol Amendment 1.0 dated 27 June 2019

Protocol Administrative Letter dated 19 July 2019

Protocol Amendment 2.0 dated 02 August 2019

CLINICAL STUDY PROTOCOL
IND 69,019

A POST MARKETING STUDY OF THE SAFETY, TOLERABILITY, AND PHARMACOKINETICS OF TPOXX® IN ADULT SUBJECTS WEIGHING MORE THAN 120 KG

Post Marketing Commitment: 3417-4

SIGA-246-022

Sponsor:	SIGA Technologies, Inc. 4575 SW Research Way, Suite 110 Corvallis, OR 97333
Sponsor Contact:	Candace Lovejoy, CPCM, PMP SIGA Technologies, Inc. 4575 SW Research Way, Suite 110 Corvallis, OR 97333
Medical Monitor:	Rahul Bhatnagar, MD PPD Phase I Clinic 7551 Metro Center Drive, Suite 300 Austin, TX 78744
Version of Protocol:	Final 1.0
Date of Protocol:	19 February 2019

CONFIDENTIAL

The study will be conducted according to the International Council for Harmonisation Guideline E6(R2): Good Clinical Practice.

SIGNATURE PAGE

PROTOCOL TITLE: A Post Marketing Study of the Safety, Tolerability, and Pharmacokinetics of TPOXX® in Adult Subjects Weighing More Than 120 kg

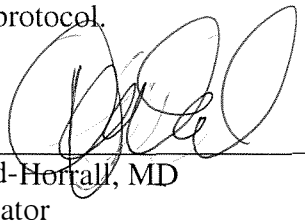
PROTOCOL NUMBER: SIGA-246-022

Dennis E. Hruby, PhD
Chief Scientific Officer
SIGA Technologies, Inc.

21 Feb 2019
Date

INVESTIGATOR PROTOCOL AGREEMENT PAGE

I agree to conduct the study as outlined in the protocol titled "A Post Marketing Study of the Safety, Tolerability, and Pharmacokinetics of TPOXX® in Adult Subjects Weighing More Than 120 kg" in accordance with the guidelines and all applicable government regulations, including US Title 21 of the Code of Federal Regulations Part 54. I have read and understand all sections of the protocol.



28 MAR 2019

Rebecca N. Wood-Horrall, MD
Principal Investigator
PPD

Date

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PROTOCOL SYNOPSIS

PROTOCOL NO.: SIGA-246-022

TITLE: A Post Marketing Study of the Safety, Tolerability, and Pharmacokinetics of TPOXX® in Adult Subjects Weighing More Than 120 kg

STUDY PHASE: 4 Post Marketing Study

STUDY SITE: PPD Phase I Clinic, 7551 Metro Center Drive, Suite 200, Austin, TX 78744, USA.

OBJECTIVES:

Primary:

The primary objective of this study is to determine the pharmacokinetic (PK) profile of 600 mg oral TPOXX (3 × 200-mg capsules) administered twice daily (BID) for 7 days in adult subjects weighing more than 120 kg to determine if a change in dosing regimen would be needed in these patients.

Secondary:

The secondary objective of this study is to evaluate the safety and tolerability of 600 mg oral TPOXX administered BID for 7 days in healthy adult subjects weighing more than 120 kg.

STUDY DESIGN AND METHODOLOGY:

This is an open-label, multiple-dose study to assess the safety, tolerability, and PK of TPOXX 600 mg BID when administered orally for 7 days to adult subjects weighing more than 120 kg. A total of 36 subjects, ages 18 to 50, inclusive, will be enrolled. The study will consist of a screening period (Day –28 to Day –2), a treatment and confinement period (Days –1 to 9), a follow-up telephone call or visit (Day 14 [+2 days]), and a follow-up telephone call (Day 37 [+2 days]).

Subjects will undergo screening evaluations to determine eligibility within 28 days before study drug administration. Subjects will be admitted to the study site on Day –1 to complete baseline assessments; results of these assessments must be reviewed by the investigator before dosing. Starting in the morning of Day 1, subjects will receive 600 mg oral TPOXX BID for 7 days (Days 1 through 7).

All subjects will be provided meals (consisting of approximately 600 calories and 25 g fat) 30 minutes prior to study drug administration and subjects must fast for 2 hours after taking study drug. Subjects should eat this meal within 30 minutes or less of taking study drug. Study drug and meals must be taken with water only, and no other beverage except water should be ingested within 3 hours before or 3 hours after study drug administration.

Subjects will remain confined to the study site for collection of PK samples and will be carefully monitored for safety and tolerability until discharge on Day 9. Subjects who have abnormal physical examination findings or an ongoing adverse event (AE)/serious adverse event (SAE) on Day 9 that is deemed related to study drug or per investigator or SIGA discretion will return to the study site on Day 14 (+2 days) for a follow-up visit. All other subjects will have the Day 14 (+2 days) follow-up via telephone. All subjects will have a

follow-up telephone call 30 days after administration of the last dose of study drug (Day 37 [+2 days]) to report any SAEs. At the time of discharge from the clinical research unit, subjects will be instructed to notify the investigator of any SAEs that occur within 30 days after administration of the last dose of study drug. Serious AEs will be followed until the SAE is stable or until resolution as determined by the investigator and/or medical monitor.

The total duration of the study for each subject, including the screening period, treatment period, and the Day 37 (+2 days) follow-up telephone call, will be approximately 65 days.

STUDY POPULATION:

Inclusion Criteria:

Each subject must meet all the following criteria to be enrolled in this study:

1. Subject is male or female between 18 and 50 years of age, inclusive.
2. Subject has a body weight >120 kg at screening.
3. Women of childbearing potential, have a negative β human chorionic gonadotropin pregnancy test (serum) at the screening visit and a confirmatory negative serum pregnancy test on Day –1 before receipt of study drug, and meet 1 of the following criteria:
   a. The subject or their partner has undergone surgical sterilization
   b. The subject is postmenopausal, defined as 12 consecutive months with no menses without an alternative medical cause and has a documented plasma follicle-stimulating hormone level >40 IU/mL
   c. The subject agrees to be abstinent (ie, heterosexually inactive or women in a religious order)
   d. The subject agrees to consistently use 1 of the following methods of contraception from the beginning of screening (which they had been consistently using for at least 30 days before the first dose of study drug) through 30 days after the last dose of study drug:
      i. Condoms, male or female, with a spermicide

         NOTE: For male subjects, condoms must be used for 90 days after the last dose of study drug.
      ii. Diaphragm or cervical cap with spermicide
      iii. Intrauterine device with spermicide
      iv. Oral contraceptives or other hormonal methods

         NOTE: Subject must agree to use an additional nonhormonal method of contraception in conjunction with oral contraceptives.
      v. Male sexual partner who had undergone a vasectomy at least 3 months before screening
4. Male subjects must agree to not donate sperm from the first dose of study drug through 90 days after the last dose of study drug.

5. Subject is considered by the investigator to be in good general health as determined by medical history (no hospitalizations for chronic medical conditions in the previous 2 years), clinical laboratory results, vital sign measurements, 12-lead electrocardiogram (ECG) results, and physical examination findings at screening.
6. Subject agrees to comply with all protocol requirements.
7. Subject is able to provide written informed consent.
8. Subject agrees to comply with the dietary requirements.
9. Subject does not intend to lose weight (diet or weight loss) from the screening visit and throughout the study.

EXCLUSION CRITERIA:
Subjects meeting any of the following criteria will be excluded from the study:

1. Subject is a female who is pregnant or breastfeeding or planning to become pregnant within 3 months after the last dose of study drug.
2. Subject has a history of any clinically significant conditions including:
   - Asthma treated with oral systemic steroids within the past 6 months
   - Diabetes mellitus (type 1 or 2), with the exception of gestational diabetes
   - Hypertension that is poorly controlled (repeat readings >140 mm Hg systolic and/or >90 mm Hg diastolic)
   - Thyroidectomy or thyroid disease that required medication within the past 12 months
   - Serious angioedema episodes within the previous 3 years or requiring medication in the previous 2 years
   - Head trauma resulting in a diagnosis of traumatic brain injury other than concussion
   - Frequent episodes of headache.
3. Subject has received treatment in another clinical study of an investigational drug (or medical device) within 30 days or 5 half-lives (whichever is longer) before the first dose of study drug.
4. Subject has been previously enrolled in any clinical study involving TPOXX (tecovirimat).
5. Subject has a history of relevant drug and/or food allergies (ie, allergy to tecovirimat or excipients, or any significant food allergy that could preclude a standard diet in the study site).
6. Subject has any condition possibly affecting drug absorption (eg, previous surgery on the gastrointestinal tract, including removal of parts of the stomach, bowel, liver, gallbladder, or pancreas, with the exception of appendectomy).
7. Subject has evidence or history of clinically significant allergic (except for untreated, asymptomatic, seasonal allergies at time of the first dose of study drug), hematological, endocrine, pulmonary, gastrointestinal, cardiovascular, hepatic, psychiatric, or neurological disease. Exceptions to these criteria (eg, stable, mild joint disease

unassociated with collagen vascular disease) may be made following discussions with the medical monitor.

8. Subject has a history of cardiac disease, symptomatic or asymptomatic arrhythmias, syncopal episodes, or risk factors for torsades de pointes (eg, heart failure, hypokalemia).
9. Subject has a family history of sudden cardiac death, not clearly due to acute myocardial infarction.
10. Subject has a seizure disorder or history of seizures (does not include childhood febrile seizures) or a past history that increases seizure risks such as significant head injury that caused loss of consciousness or other changes in the subject's daily function, concussion, stroke, central nervous system infection or disease, or alcohol or drug abuse or family history of idiopathic seizures.
11. Subject has a history of a peptic ulcer or significant gastrointestinal bleed.
12. Subject has a bleeding disorder diagnosed by a doctor (eg, factor deficiency, coagulopathy, or platelet disorder requiring special precautions) or significant bruising or bleeding difficulties with blood draws.
13. Subject has a malignancy that is active, or treated malignancy for which there is not reasonable assurance of sustained cure, or malignancy that is likely to recur during the period of the study (subject should be in complete remission for at least 5 years).
14. Subject has neutropenia or other blood dyscrasia determined to be clinically significant by the investigator.
15. Subject has used any of the following prohibited medications from within 7 days (or 5 half-lives, whichever is longer) before the first dose of study drug: antidiabetic medication; anticoagulants; anticonvulsants; substrates of the breast cancer resistance protein transporter including methotrexate, mitoxantrone, imatinib, irinotecan, lapatinib, rosuvastatin, sulfasalazine, and topotecan; substrates of CYP2C8 including repaglinide, paclitaxel, Montelukast, pioglitazone, rosiglitazone; and substrates of CYP2C19 including S-mephenytoin, clobazam, diazepam, rabeprazole, voriconazole, lansoprazole, and omeprazole. Medications not listed here that are known (or thought) to be CYP3A4 substrates may be allowed at the investigator's discretion, after consultation with the medical monitor, if administration poses little to no risk to the subject.
16. Subject has a history of drug or alcohol abuse or dependency within the last year before screening.
17. Subject has a history of an eating disorder.
18. Subject has a current or recent (<30 days before screening) history of clinically significant bacterial, fungal, or mycobacterial infection.
19. Subject has a current clinically significant viral infection.
20. Subject has a known clinically significant chronic viral infection (eg, human T cell lymphotropic virus I or II).
21. Subject has consumed grapefruit or grapefruit juice, Seville orange or Seville orange-containing products (eg, marmalade), or caffeine- or xanthine-containing products within 48 hours before the first dose of study drug or throughout the study.

22. Subject has used any prescription (excluding hormonal birth control) or over-the-counter medication (including herbal or nutritional supplements) within 14 days before the first dose of study drug.
23. Subject demonstrates long-term use (≥14 consecutive days) of glucocorticoids including oral or parenteral prednisone or equivalent (>20 mg total dose per day) or high-dose inhaled steroids (>800 mcg/day of beclomethasone dipropionate or equivalent) within the preceding 1 month (low-dose [≤800 mcg/day of beclomethasone dipropionate or equivalent] inhaled and topical steroids are allowed).
24. Subject has donated >450 mL blood or blood components within 30 days before the first dose of study drug. The investigator should instruct subjects who participate in this study to not donate blood or blood components for 4 weeks after the completion of the study.
25. Subject is a smoker or has used nicotine or nicotine-containing products (eg, cigarettes, electronic vapor cigarettes, cigars, chewing tobacco, snuff, nicotine patches, or nicotine gum) within 6 months before the first dose of study drug.
26. Subject has consumed pomegranate or pomegranate juice, pomelo fruits or pomelo juice, or alcohol within 72 hours before the first dose of study drug.
27. Subject reports participation in strenuous activity or contact sports within 24 hours before the first dose of study drug.
28. Subject has known hepatitis B or C infection or positive test for hepatitis B surface antigen, hepatitis C virus antibody, or human immunodeficiency virus type 1 or 2 antibodies at screening.
29. Subject has a positive test result for amphetamines (including methamphetamines and ecstasy/methylenedioxymethamphetamine), barbiturates, benzodiazepines, cannabinoids (including tetrahydrocannabinol), cocaine metabolites, opiates (including heroin, codeine, and oxycodone), or alcohol at screening or check-in.
30. Subject has any of the following laboratory test results within 28 days before the first dose of study drug:
    - Estimated serum creatinine clearance (Cockcroft-Gault) <90 mL/min
    - Creatinine in males >1.7 mg/dL and in females >1.4 mg/dL (1.3 times the upper central laboratory reference range)
    - Hemoglobin ≤10% of the lower central laboratory reference range
    - White blood cell count not within the central laboratory reference range
    - Absolute neutrophil count <1000 cells/mm^3
    - Platelets not within ±10% of central laboratory reference range
    - Alanine aminotransferase >1.5 times above the upper central laboratory reference range
    - Aspartate aminotransferase >1.5 times above the upper central laboratory reference range
    - Alkaline phosphatase >20% above the upper central laboratory reference range
    - Hemoglobin A1c ≥7.0%

- Cholesterol ≥300 mg/dL and low-density lipoprotein ≥190 mg/dL.

31. Subject has a sustained sitting systolic blood pressure >140 mm Hg or <100 mm Hg or a diastolic blood pressure >90 mm Hg at screening. Blood pressure may be retested twice in the sitting position at 5-minute intervals. The pressure elevation is considered sustained if either the systolic or the diastolic pressure exceeds the stated limits on all 3 assessments.
32. Subject has a resting heart rate of <40 beats per minute or >100 beats per minute at screening.
33. Subject has an abnormal ECG at screening that is determined by the investigator to be clinically significant.
34. Male subject has a QTcF >450 ms or female subject has a QTcF >470 ms at screening or Day –1.
35. In the opinion of the investigator, the subject is not suitable for entry into the study.

EVALUATION PROCEDURES:

Pharmacokinetic Assessments:

Blood samples for PK analysis of TPOXX will be collected from all subjects on Day 1 before study drug administration (0 hour), at 0.5, 1, 2, 4, 6, 8, 12 (before the PM dose), 14, 16, 18, 20, and 24 hours (before the AM dose on Day 2), on Day 6 (before the AM dose and 4 hours after the AM dose), on Day 7 before the AM dose (0 hour), at 0.5, 1, 2, 4, 6, 8, 12 (before the PM dose), 14, 16, 18, 20, and 24 hours (Day 8, 24 hours after the AM dose on Day 7), and on Day 9 (48 hours after the AM dose on Day 7).

For PK samples, the acceptable window for collection from the scheduled collection time point will be as follows: ±5 minutes for the time points from 1 to 8 hours and ±15 minutes for the 12- to 48-hour time points.

The following plasma PK parameters will be calculated for TPOXX using actual sampling times rather than scheduled sampling times and will include but are not limited to:

- Area under the plasma concentration-time curve (AUC) from time 0 to the last quantifiable measurement (AUC_{0-t})
- AUC from time 0 extrapolated to infinity ($AUC_{0-\infty}$)
- AUC from time 0 to 24 hours (AUC_{0-24})
- AUC during the first dosing interval (tau = 12 hours) (AUC_{0-tau})
- Maximum drug concentration in plasma (C_{max})
- Time to C_{max} (T_{max})
- Apparent volume of distribution (V_d/F)
- Apparent total body clearance (CL/F)
- Concentration observed prior to the next dose administration (C_{trough})
- Terminal elimination half-life ($t_{1/2}$)
- Terminal elimination rate constant (λ_z)

- Percentage of $AUC_{0-\infty}$ extrapolated from the last quantifiable measurement to infinity ($\%AUC_{extrap}$).

Safety Assessments:
Safety and tolerability will be assessed by monitoring and recording of AEs, clinical laboratory test results (hematology, serum chemistry, pregnancy, and urinalysis), vital sign measurements (systolic and diastolic blood pressures, heart rate, respiratory rate, and body temperature), 12-lead ECG results, and physical examination findings.

STUDY DRUG, DOSAGE, AND ROUTE OF ADMINISTRATION:
TPOXX, 600 mg (3 × 200-mg capsules), will be administered orally twice daily, approximately 12 hours (±30 minutes) apart, on Days 1 through 7.

STATISTICAL METHODS:
Complete, detailed statistical methods will be described in the statistical analysis plan.

Sample Size:
The sample size (N = 36 [to allow at least 32 enrolled subjects to complete]) for this study is based on clinical and practical considerations and not on a formal statistical power calculation. The sample size is considered sufficient to effectively assess the PK and safety profiles of TPOXX.

Analysis Populations:

- The Safety Population will include all subjects who receive at least 1 dose of study drug.
- The PK Population will include subjects who receive study drug and have sufficient concentration data to facilitate the calculation of PK variables.

Pharmacokinetic Analyses:
Individual plasma concentration and time deviation data will be presented in a data listing. Plasma concentration data will be listed and summarized using the following descriptive statistics: number of subjects, arithmetic mean, standard deviation (SD), coefficient of variation (CV), geometric mean, geometric CV, median, minimum, and maximum. Individual and mean plasma concentration versus time profiles will be presented in figures on both linear and semilogarithmic scales.

The PK parameters of TPOXX will be analyzed based on the actual sampling times. All parameters will be determined using noncompartmental methods using Phoenix® WinNonlin® Version 6.4 or higher (Certara, L.P., Princeton, New Jersey) or SAS® Version 9.4 or higher (SAS Institute Inc., Cary, North Carolina).

The individual PK parameters and weight-normalized PK parameters will be presented in data listings and summarized using the following descriptive statistics: number of subjects, arithmetic mean, SD, CV, median, minimum, maximum, geometric mean, geometric SD, and geometric CV.

Safety Analyses:
Adverse events will be coded by preferred term and system organ class using the latest version of the Medical Dictionary for Regulatory Activities and summarized overall. All AE data will be presented in a data listing. Treatment-emergent AEs will be summarized overall,

as well as by severity and relationship to study drug. Serious AEs and AEs leading to discontinuation of study drug will also be presented in the data listings and summarized overall.

Actual values and changes from baseline for clinical laboratory test results, vital sign measurements, and 12-lead ECG results will be summarized at each time point using descriptive statistics (number of subjects, mean, SD, median, minimum, and maximum). Shift tables will be generated for clinical laboratory test results. Clinical laboratory data, vital sign measurements, 12-lead ECG results, and physical examination findings will be presented in data listings.

DATE OF PROTOCOL: 19 February 2019

1. INTRODUCTION

1.1 BACKGROUND

Historically, variola virus (VARV), the etiologic agent of smallpox, has been one of the more important human pathogens. Smallpox is highly communicable and carries exceptionally high morbidity. Secondary attack rates from 30% to 80% have been reported among unvaccinated members of households.[1] Mortality rates range from 1% for variola minor to 30% for variola major.[1] With the advent of biowarfare as an instrument of terrorism, smallpox can no longer be thought of as a disease only of historic impact.

In July 2018, the FDA approved the oral formulation of TPOXX for the treatment of patients with human smallpox disease caused by VARV.

1.2 RATIONALE FOR STUDY

This study is being conducted as an FDA post marketing commitment to the approved New Drug Application for TPOXX. SIGA is required to conduct a study to determine the pharmacokinetic (PK) profile of TPOXX in subjects with a body weight greater than 120 kilograms (>120 kg) to determine if a change in dosing regimen would be needed in these patients.

1.3 POTENTIAL RISKS AND BENEFITS

1.3.1 Potential Risks

The effect of TPOXX on a fetus or nursing baby is not yet known; therefore, women of childbearing potential participating in this study will be required to agree to use an acceptable means of birth control from 30 days before the first dose of study drug and continuing through 30 days after the last dose of study drug. Pregnancy testing will be performed at the screening visit and checked by the investigator for negative pregnancy before administration of study drug on Day –1. Women who are pregnant or lactating or plan to become pregnant within 3 months after study drug administration will be excluded from the study; if a female subject becomes pregnant during study participation, study drug dosing will be discontinued, and the subject will be withdrawn from the study (Section 6.2.1.9).

As with all drugs, there is potential risk of an allergic reaction. At this time, there is no definitive information on the allergic activity of TPOXX. Headache and nausea have been the most common AEs in clinical studies completed to date. There may be other side effects

of TPOXX that are not yet known. Full details can be found in the TPOXX full prescribing information.[2]

1.3.2 Known Potential Benefits

As this study will be conducted in subjects free from smallpox, no direct health benefits from taking the study drug are expected. Study subjects may benefit from receiving the laboratory testing, ECGs, and physical examinations. Others may benefit from knowledge gained in this study that may aid in the development of a drug for the treatment of smallpox.

2. STUDY OBJECTIVES

2.1 PRIMARY OBJECTIVE

The primary objective of this study is to determine the PK profile of 600 mg oral TPOXX (3 × 200-mg capsules) administered twice daily (BID) for 7 days in adult subjects weighing more than 120 kg to determine if a change in dosing regimen would be needed in these patients.

2.2 SECONDARY OBJECTIVE

The secondary objective of this study is to evaluate the safety and tolerability of 600 mg oral TPOXX administered BID for 7 days in adult subjects weighing more than 120 kg.

3. STUDY DESIGN

This is an open-label, multiple-dose study to assess the safety, tolerability, and PK of TPOXX 600 mg BID when administered orally for 7 days to adult subjects weighing more than 120 kg. A total of 36 subjects, ages 18 to 50, inclusive, will be enrolled. The study will consist of a screening period (Day –28 to Day –2), a treatment and confinement period (Days –1 to 9), a follow-up telephone call or visit (Day 14 [+2 days]), and a follow-up telephone call (Day 37 [+2 days]).

Subjects will undergo screening evaluations to determine eligibility within 28 days before study drug administration. Subjects will be admitted to the study site on Day –1 to complete baseline assessments; results of these assessments must be reviewed by the investigator before dosing. Starting in the morning of Day 1, subjects will receive 600 mg oral TPOXX BID for 7 days (Days 1 through 7).

All subjects will be provided meals (consisting of approximately 600 calories and 25 g fat) 30 minutes prior to study drug administration and subjects must fast for 2 hours after taking study drug. Subjects should eat this meal within 30 minutes or less of taking study drug. Study drug and meals must be taken with water only, and no other beverage except water should be ingested within 3 hours before or 3 hours after study drug administration.

Subjects will remain confined to the study site for collection of PK samples and will be carefully monitored for safety and tolerability until discharge on Day 9. Subjects who have abnormal physical examination findings or an ongoing adverse event (AE)/serious adverse event (SAE) on Day 9 that is deemed related to study drug or per investigator or SIGA discretion will return to the study site on Day 14 (+2 days) for a follow-up visit. All other subjects will have the Day 14 (+2 days) follow-up via telephone. All subjects will have a follow-up telephone call 30 days after administration of the last dose of study drug (Day 37 [+2 days]) to report any SAEs. At the time of discharge from the clinical research unit, subjects will be instructed to notify the investigator of any SAEs that occur within 30 days after administration of the last dose of study drug. Serious AEs will be followed until the SAE is stable or until resolution as determined by the investigator and/or medical monitor.

The total duration of the study for each subject, including the screening period, treatment period, and the Day 37 (+2 days) follow-up telephone call, will be approximately 65 days.

4. STUDY POPULATION

Approximately 36 male and female subjects will be enrolled at a single center in the United States to achieve at least 32 evaluable enrolled subjects.

4.1 INCLUSION CRITERIA

Each subject must meet all the following criteria to be enrolled in this study:

1. Subject is male or female between 18 and 50 years of age, inclusive.
2. Subject has a body weight >120 kg at screening.
3. Women of childbearing potential, have a negative β human chorionic gonadotropin pregnancy test (serum) at the screening visit and a confirmatory negative serum pregnancy test on Day –1 before receipt of study drug, and meet 1 of the following criteria:
    a. The subject or their partner has undergone surgical sterilization

b. The subject is postmenopausal, defined as 12 consecutive months with no menses without an alternative medical cause and has a documented plasma follicle-stimulating hormone level >40 IU/mL

c. The subject agrees to be abstinent (ie, heterosexually inactive or women in a religious order)

d. The subject agrees to consistently use 1 of the following methods of contraception from the beginning of screening (which they had been consistently using for at least 30 days before the first dose of study drug) through 30 days after the last dose of study drug:

   i. Condoms, male or female, with a spermicide

      NOTE: For male subjects, condoms must be used for 90 days after the last dose of study drug.

   ii. Diaphragm or cervical cap with spermicide

   iii. Intrauterine device with spermicide

   iv. Oral contraceptives or other hormonal methods

      NOTE: Subject must agree to use an additional nonhormonal method of contraception in conjunction with oral contraceptives.

   v. Male sexual partner who had undergone a vasectomy at least 3 months before screening.

4. Male subjects must agree to not donate sperm from the first dose of study drug through 90 days after the last dose of study drug.
5. Subject is considered by the investigator to be in good general health as determined by medical history (no hospitalizations for chronic medical conditions in the previous 2 years), clinical laboratory results, vital sign measurements, 12-lead ECG results, and physical examination findings at screening.
6. Subject agrees to comply with all protocol requirements.
7. Subject is able to provide written informed consent.
8. Subject agrees to comply with the dietary requirements.
9. Subject does not intend to lose weight (diet or weight loss) from the screening visit and throughout the study.

4.2 EXCLUSION CRITERIA

Subjects meeting any of the following criteria will be excluded from the study:

1. Subject is a female who is pregnant or breastfeeding or planning to become pregnant within 3 months after the last dose of study drug.
2. Subject has a history of any clinically significant conditions including:
   - Asthma treated with oral systemic steroids within the past 6 months
   - Diabetes mellitus (type 1 or 2), with the exception of gestational diabetes
   - Hypertension that is poorly controlled (repeat readings >140 mm Hg systolic and/or >90 mm Hg diastolic)
   - Thyroidectomy or thyroid disease that required medication within the past 12 months
   - Serious angioedema episodes within the previous 3 years or requiring medication in the previous 2 years
   - Head trauma resulting in a diagnosis of traumatic brain injury other than concussion
   - Frequent episodes of headache.
3. Subject has received treatment in another clinical study of an investigational drug (or medical device) within 30 days or 5 half-lives (whichever is longer) before the first dose of study drug.
4. Subject has been previously enrolled in any clinical study involving TPOXX (tecovirimat).
5. Subject has a history of relevant drug and/or food allergies (ie, allergy to tecovirimat or excipients, or any significant food allergy that could preclude a standard diet in the study site).
6. Subject has any condition possibly affecting drug absorption (eg, previous surgery on the gastrointestinal tract, including removal of parts of the stomach, bowel, liver, gallbladder, or pancreas, with the exception of appendectomy).
7. Subject has evidence or history of clinically significant allergic (except for untreated, asymptomatic, seasonal allergies at time of the first dose of study drug), hematological, endocrine, pulmonary, gastrointestinal, cardiovascular, hepatic, psychiatric, or neurological disease. Exceptions to these criteria (eg, stable, mild joint disease unassociated with collagen vascular disease) may be made following discussions with the medical monitor.

8. Subject has a history of cardiac disease, symptomatic or asymptomatic arrhythmias, syncopal episodes, or risk factors for torsades de pointes (eg, heart failure, hypokalemia).
9. Subject has a family history of sudden cardiac death not clearly due to acute myocardial infarction.
10. Subject has a seizure disorder or history of seizures (does not include childhood febrile seizures) or a past history that increases seizure risks such as significant head injury that caused loss of consciousness or other changes in the subject's daily function, concussion, stroke, central nervous system infection or disease, or alcohol or drug abuse or family history of idiopathic seizures.
11. Subject has a history of a peptic ulcer or significant gastrointestinal bleed.
12. Subject has a bleeding disorder diagnosed by a doctor (eg, factor deficiency, coagulopathy, or platelet disorder requiring special precautions) or significant bruising or bleeding difficulties with blood draws.
13. Subject has a malignancy that is active, or treated malignancy for which there is not reasonable assurance of sustained cure, or malignancy that is likely to recur during the period of the study (subject should be in complete remission for at least 5 years).
14. Subject has neutropenia or other blood dyscrasia determined to be clinically significant by the investigator.
15. Subject has used any of the following prohibited medications from within 7 days (or 5 half-lives, whichever is longer) before the first dose of study drug: antidiabetic medication; anticoagulants; anticonvulsants; substrates of the BCRP transporter including methotrexate, mitoxantrone, imatinib, irinotecan, lapatinib, rosuvastatin, sulfasalazine, and topotecan; substrates of CYP2C8 including repaglinide, paclitaxel, Montelukast, pioglitazone, rosiglitazone; and substrates of CYP2C19 including S-mephenytoin, clobazam, diazepam, rabeprazole, voriconazole, lansoprazole, and omeprazole. Medications not listed here that are known (or thought) to be CYP3A4 substrates may be allowed at the investigator's discretion, after consultation with the medical monitor, if administration poses little to no risk to the subject.
16. Subject has a history of drug or alcohol abuse or dependency within the last year before screening.
17. Subject has a history of an eating disorder.

18. Subject has a current or recent (<30 days before screening) history of clinically significant bacterial, fungal, or mycobacterial infection.
19. Subject has a current clinically significant viral infection.
20. Subject has a known clinically significant chronic viral infection (eg, human T cell lymphotropic virus I or II).
21. Subject has consumed grapefruit or grapefruit juice, Seville orange or Seville orange-containing products (eg, marmalade), or caffeine- or xanthine-containing products within 48 hours before the first dose of study drug or throughout the study.
22. Subject has used any prescription (excluding hormonal birth control) or over-the-counter medication (including herbal or nutritional supplements) within 14 days before the first dose of study drug.
23. Subject demonstrates long-term use (≥14 consecutive days) of glucocorticoids including oral or parenteral prednisone or equivalent (>20 mg total dose per day) or high-dose inhaled steroids (>800 mcg/day of beclomethasone dipropionate or equivalent) within the preceding 1 month (low-dose [≤800 mcg/day of beclomethasone dipropionate or equivalent] inhaled and topical steroids are allowed).
24. Subject has donated >450 mL blood or blood components within 30 days before the first dose of study drug. The investigator should instruct subjects who participate in this study to not donate blood or blood components for 4 weeks after the completion of the study.
25. Subject is a smoker or has used nicotine or nicotine-containing products (eg, cigarettes, electronic vapor cigarettes, cigars, chewing tobacco, snuff, nicotine patches, or nicotine gum) within 6 months before the first dose of study drug.
26. Subject has consumed pomegranate or pomegranate juice, pomelo fruits or pomelo juice, or alcohol within 72 hours before the first dose of study drug.
27. Subject reports participation in strenuous activity or contact sports within 24 hours before the first dose of study drug.
28. Subject has known hepatitis B or C infection or positive test for hepatitis B surface antigen, hepatitis C virus antibody, or human immunodeficiency virus type 1 or 2 antibodies at screening.
29. Subject has a positive test result for amphetamines (including methamphetamines and ecstasy/methylenedioxymethamphetamine), barbiturates, benzodiazepines,

cannabinoids (including tetrahydrocannabinol), cocaine metabolites, opiates (including heroin, codeine, and oxycodone), or alcohol at screening or check-in.

30. Subject has any of the following laboratory test results within 28 days before the first dose of study drug:
    - Estimated serum creatinine clearance (Cockcroft-Gault) <90 mL/min
    - Creatinine in males >1.7 mg/dL and in females >1.4 mg/dL (1.3 times the upper central laboratory reference range)
    - Hemoglobin ≤10% of the lower central laboratory reference range
    - White blood cell count not within the central laboratory reference range
    - Absolute neutrophil count <1000 cells/mm^3
    - Platelets not within ±10% of central laboratory reference range
    - Alanine aminotransferase >1.5 times above the upper central laboratory reference range
    - Aspartate aminotransferase >1.5 times above the upper central laboratory reference range
    - Alkaline phosphatase >20% above the upper central laboratory reference range
    - Hemoglobin A1c ≥7.0%
    - Cholesterol ≥300 mg/dL and low-density lipoprotein ≥190 mg/dL.
31. Subject has a sustained sitting systolic blood pressure >140 mm Hg or <100 mm Hg or a diastolic blood pressure >90 mm Hg at screening. Blood pressure may be retested twice in the sitting position at 5-minute intervals. The pressure elevation is considered sustained if either the systolic or the diastolic pressure exceeds the stated limits on all 3 assessments.
32. Subject has a resting heart rate of <40 beats per minute or >100 beats per minute at screening.
33. Subject has an abnormal ECG at screening that is determined by the investigator to be clinically significant.
34. Male subject has a QTcF >450 ms or female subject has a QTcF >470 ms at screening or Day –1.
35. In the opinion of the investigator, the subject is not suitable for entry into the study.

4.3 OTHER SCREENING CONSIDERATIONS

4.3.1 Subject Restrictions During the Study

- Subjects must be willing to remain confined at the study site from Check-in (Day –1) until safety assessments are completed on Day 9.
- Subjects who have abnormal physical examination findings or an ongoing AE/SAE on Day 9 that is deemed related to study drug or per investigator or SIGA discretion will return to the study site on Day 14 (+2 days) for a follow-up visit.

4.4 WITHDRAWAL OF SUBJECTS FROM THE STUDY

4.4.1 Reasons for Withdrawal

Subjects can withdraw consent and discontinue from the study at any time, for any reason, without prejudice to further treatment.

The investigator may withdraw a subject from the study for any of the following:

- The subject is in violation of the protocol.
- The subject experiences a serious or intolerable AE.
- The subject becomes pregnant.
- The subject is noncompliant.
- The subject has laboratory abnormalities for assessments listed in Sections 4.1 or 4.2 that meet Grade 3 or Grade 4 on the Division of Acquired Immune Deficiency Syndrome (DAIDS) AE Grading Table (https://rsc.tech-res.com/docs/default-source/safety/division-of-aids-(daids)-table-for-grading-the-severity-of-adult-and-pediatric-adverse-events-corrected-v-2-1.pdf?sfvrsn=2), any other Grade 3 or Grade 4 AE; or a Grade 2 or higher rash considered by the investigator to be possibly, probably, or definitely related to study drug.
- The subject develops, during the course of the study, symptoms or conditions listed in the exclusion criteria.
- The subject requires a medication prohibited by the protocol.
- The subject requests an early discontinuation for any reason.
- The subject's primary care provider requests that the subject be withdrawn.

- The independent safety monitor (ISM), SIGA, or the FDA requests subject withdrawal based on study safety findings.

The investigator can also withdraw a subject upon the request of SIGA or if SIGA terminates the study. Upon occurrence of a SAE or intolerable AE, the investigator will confer with SIGA. If a subject is discontinued because of an AE, the event will be followed until it is resolved or stabilized as determined by the investigator and/or the medical monitor.

4.4.2 Handling of Withdrawals

Subjects are free to withdraw from the study at any time upon request. Subject participation in the study may be stopped at any time at the discretion of the investigator or at the request of SIGA.

When a subject withdraws from the study, the reason(s) for withdrawal will be recorded by the investigator in the electronic case report form (eCRF). Whenever possible, any subject who withdraws from the study prematurely will undergo all Day 9/early discontinuation assessments (±2 days) (Table 9-1). Any subject who fails to return for final assessments will be contacted by the study site personnel in an attempt to have them comply with the protocol. The status of subjects who fail to complete final assessments will be documented in the eCRF.

4.4.3 Halting Rules

The medical monitor, investigator, SIGA, and ISM will review all AEs. All AEs determined by the investigator to be severe and possibly, probably, or definitely related to study drug, as well as all clinical assessments, laboratory test results, ECG results, or vital sign measurements that meet Grade 3 criteria on the DAIDS AE Grading Table will be assessed by the medical monitor, who will make a recommendation as to whether or not halting of the study should occur. At the discretion of the medical monitor, depending on the assessment of the severity of the event, the recommendation to halt the study may be made after consultation with the investigator, SIGA, and the ISM.

The study will be temporarily halted (no new enrollments and no further study drug administration) by the investigator and the medical monitor, SIGA, and the ISM will be promptly notified according to the following criteria:

- One subject experiences a Grade 4 AE assessed as possibly, probably, or definitely related to study drug.

- There is a subject death assessed as possibly, probably, or definitely related to study drug.
- One subject experiences a seizure assessed as possibly, probably, or definitely related to study drug.
- Two or more subjects experience the same or similar SAEs that are possibly, probably, or definitely related to the study drug.
- Three or more subjects experience the same or similar AEs that are Grade 3 or above and are possibly, probably, or definitely related to the study drug.

Study enrollment and study drug administration would resume if review of the AEs that caused the halt resulted in a recommendation to permit further continuation. In such an instance, SIGA, with participation by the investigator and the medical monitor, would consult with the ISM to conduct the review of all AEs that meet the criteria for halting the study. The study would remain suspended until the events were reviewed by the ISM and a recommendation was made as to whether the study should be continued or stopped. This constitutes a minimum criterion, and the decision to halt the study may be made based on any other criteria that, in the judgment of the investigator, with agreement of the medical monitor and ISM, indicate a potentially serious safety concern. The investigator will advise SIGA immediately if any of the halting rules are met.

4.4.4 Replacements

At the discretion of the investigator, and after consultation with the medical monitor, any subject who withdraws before completing the study may be replaced to retain the target of 32 evaluable enrolled subjects.

5. STUDY TREATMENT

5.1 TREATMENT ADMINISTERED

On Days 1 to 7, all subjects will receive an oral dose of TPOXX 600 mg (3 × 200-mg capsules) BID, approximately 12 hours (±30 minutes) apart, for 7 days.

All subjects will be provided meals consisting of approximately 600 calories and 25 g fat, 30 minutes before study drug administration. Subjects should eat this meal within 30 minutes or less of taking study drug. Study drug will be administered approximately 30 minutes after the start of the meal. All doses of study drug will be administered to subjects by study site personnel with approximately 240 mL of water. Subjects must fast 2 hours after taking study

drug. Study drug and meals must be taken with water only, and no other beverage except water should be ingested within 3 hours before or 3 hours after study drug administration.

5.2 STUDY DRUG

TPOXX will be supplied as 200-mg capsules containing tecovirimat monohydrate as the active pharmaceutical ingredient. The TPOXX capsules are immediate release, size 0, orange and black, hard gelatin capsules containing white to off white powder. All inactive ingredients/excipients are generally recognized as safe and are United States Pharmacopeia/National Formulary grade. The TPOXX excipients are shown in Table 5-1.

Table 5-1 Excipients of TPOXX Capsules

Component	Quality Designation
Microcrystalline cellulose	NF[a]
Lactose monohydrate	NF
Croscarmellose sodium	NF[a]
Colloidal silicon dioxide	NF
Hydroxypropyl methylcellulose	USP
Sodium lauryl sulfate	NF
Purified water[b]	USP
Magnesium stearate	NF

Abbreviations: NF, National Formulary; USP, United States Pharmacopeia.

[a] Microcrystalline cellulose and croscarmellose sodium are added as intragranular and extragranular excipients.

[b] Removed during processing.

Compendial components are tested and released in accordance with full compendial methods and specifications before their use in clinical formulations. TPOXX 200-mg capsules are manufactured and analyzed for clinical use in accordance with Current Good Manufacturing Practices.

TPOXX capsules are manufactured by:
Catalent Pharma Solutions
1100 Enterprise Drive
Winchester, KY 40391.

Further information on TPOXX can be found in the TPOXX full prescribing information.[2]

5.2.1 Study Drug Packaging and Storage

TPOXX capsules are packaged, labeled, distributed, and placed on stability testing in accordance with Current Good Manufacturing Practice and International Council for Harmonisation (ICH) guidelines.

The 200-mg TPOXX capsules are supplied in 75-mL high density polyethylene bottles fitted with a heat induction seal and child-resistant screw cap closure system. Each bottle of study drug will contain 42 capsules and will be labeled with the drug name, SIGA's name, a space to fill in the protocol number, and a space to fill in the bottle number.

SIGA (or designee) will provide the investigator and study site with adequate quantities of TPOXX.

All study drug must be stored in a secure area (eg, a locked cabinet), protected from moisture and light, and stored at 15°C to 30°C (59°F to 86°F). Study drug should not be refrigerated or used beyond the expiration dates provided by the manufacturer. The study site will be required to keep a temperature log to establish a record of compliance with these study drug storage conditions. All study drug will be kept in a secure cabinet or room with access restricted to necessary study site personnel.

5.2.2 Study Drug Accountability

The investigator will maintain accurate records of receipt of all study drug, including dates of receipt. Accurate records will be kept regarding when and how much study drug is dispensed and used by each subject in the study. Reasons for departure from the expected dispensing regimen must also be recorded. Study drug accountability will be recorded in the subject source documentation, entered into the eCRF, and should be reviewed by the monitor during each monitoring visit. On a regular basis and at the completion of the study, to satisfy regulatory requirements regarding drug accountability, all study drug will be reconciled and retained or destroyed according to applicable regulations.

5.3 TREATMENT COMPLIANCE

All doses of the study drug will be administered in the study site under direct observation of study site personnel and recorded in the eCRF. Per standard clinic procedure, study site personnel will perform a mouth check and inspect all dose containers to ensure that the entire dose was administered. Following completion of dosing procedures and return of dosing containers to the pharmacy by team members, pharmacy staff will follow standard clinic

procedures for study drug reconciliation. SIGA will provide information to PPD for destruction of returned used and unused study drug and study drug bottles.

The date and time of study drug dosing will be captured and recorded on the appropriate page of the eCRF. If a subject is not administered study drug, the reason for the missed dose will be recorded.

5.3.1 Prior and Concomitant Medications

Restrictions for prior and concomitant medications and therapies are provided in Sections 4.1 and 4.2. Prior and concomitant medications and therapies will be coded using the latest version of the World Health Organization Drug Dictionary.

5.3.1.1 Prior Medications

Information regarding prior medications taken by the subject within the 30 days before signing the informed consent form (ICF) will be recorded in the subject's eCRF.

5.3.1.2 Concomitant Medications

Any concomitant medication deemed necessary for the welfare of the subject during the study may be given at the discretion of the investigator. If a concomitant medication listed in Section 4.2 is taken it will be documented as a protocol deviation and a joint decision will be made by the investigator and SIGA to continue or discontinue the subject based on the time the medication was administered, its pharmacology and PK, and whether the use of the medication will compromise the safety of the subject or the interpretation of the data. The investigator is responsible for ensuring that details regarding the medication are adequately recorded in both the subject's source document and the eCRF.

6. STUDY PROCEDURES

Before performing any study procedures, all potential subjects will sign an ICF as outlined in Section 9.3.2.3. Subjects will undergo study procedures at the time points specified in the schedule of events (Table 9-1).

The total amount of blood collected from each subject over the duration of the study, including any extra assessments that may be required, will not exceed 500 mL.

6.1 PHARMACOKINETIC ASSESSMENTS AND ENDPOINTS

Blood samples for PK analysis of TPOXX will be collected from all subjects Day 1 before study drug administration (0 hour), at 0.5, 1, 2, 4, 6, 8, 12 (before the PM dose), 14, 16, 18, 20, and 24 hours (before the AM dose on Day 2), on Day 6 (before the AM dose and 4 hours after the AM dose), on Day 7 before the AM dose (0 hour), at 0.5, 1, 2, 4, 6, 8, 12 (before the PM dose), 14, 16, 18, 20, and 24 hours (Day 8, 24 hours after the AM dose on Day 7), and on Day 9 (48 hours after the AM dose on Day 7).

For PK samples, the acceptable window for collection from the scheduled collection time point will be as follows: ±5 minutes for the time points from 1 to 8 hours and ±15 minutes for the 12- to 48-hour time points.

The following plasma PK parameters will be calculated for TPOXX using actual sampling times rather than scheduled sampling times and will include but are not limited to:

- Area under the plasma concentration-time curve (AUC) from time 0 to the last quantifiable measurement (AUC_{0-t})
- AUC from time 0 extrapolated to infinity ($AUC_{0-\infty}$)
- AUC from time 0 to 24 hour (AUC_{0-24})
- AUC during the first dosing interval (tau = 12 hours) (AUC_{0-tau})
- Maximum drug concentration in plasma (C_{max})
- Time to C_{max} (T_{max})
- Apparent volume of distribution (V_d/F)
- Apparent total body clearance (CL/F)
- Concentration observed prior to the next dose administration (C_{trough})
- Terminal elimination half-life ($t_{1/2}$)
- Terminal elimination rate constant (λ_z)
- Percentage of $AUC_{0-\infty}$ extrapolated from the last quantifiable measurement to infinity ($\%AUC_{extrap}$).

6.1.1 Pharmacokinetic Sample Collection, Shipping, and Storage

Blood samples (approximately 5 mL) for the determination of plasma concentrations of TPOXX will be collected in 5-mL lavender-topped K_3EDTA Vacutainer® tubes using a 21 gauge or larger needle, or from an indwelling intravenous catheter using a vacutainer tube. Blood samples should be placed on wet ice or equivalent (approximately 4°C to 8°C) and kept at this temperature until processed to separate plasma.

The exact time and date of sample collection will be recorded for each sample by the investigator or designee on the subject's eCRF, the vacutainer and cryovial labels, and the specimen shipping log. In addition, the time of study drug administration before PK sampling will be recorded on the subject's eCRF. Labels will be created by the site and should contain the protocol number, matrix (plasma), subject number, date, and time drawn. For information that is not preprinted on the label, a fine tipped indelible marking pen is to be used to complete the entry.

The 5-mL blood sample will be centrifuged in a refrigerated centrifuge immediately, if possible, or within 60 minutes of collection at 1000 to 1200 × *g* (2000 to 3000 rpm) for 10 minutes to separate plasma. Each plasma sample should be transferred via pipette into 2 cryovials labeled as described previously and should be capped tightly. The second tube will be a duplicate and retained at the site as a backup sample. If red blood cells are inadvertently drawn into the plasma, the sample should be re-centrifuged as soon as possible. Adequate space between the solution and the tube cap should be allowed for expansion during freezing.

Cryovial tubes containing plasma samples must be frozen at –70°C or below until shipment in a freezer equipped with a temperature monitor and temperature-activated alarm. Uncentrifuged specimens should not be frozen.

The study site will batch ship sets of frozen plasma samples. A log sheet listing the samples being shipped will be included in each shipment. The samples will be sent on dry ice via courier to Alturas Analytics (Moscow, ID). The back-up sets will remain at the site until confirmation that the first sets have been received. After receipt confirmation is received from Alturas Analytics, the back-up sets should be shipped. The site will contact Alturas Analytics and coordinate the shipment prior to sending the samples. Shipments before weekends or holidays must be avoided.

The samples will be shipped for analysis to:

Alturas Analytics
1324 Alturas Drive
Moscow, ID 83843

The bioanalytical laboratory will store all plasma samples at –70°C until analysis for tecovirimat is complete. SIGA will advise Alturas to destroy any remaining plasma samples after regulatory review is complete or the samples have met their applicable length of stability, whichever comes sooner.

6.1.2 Pharmacokinetic Sample Analysis

Pharmacokinetic samples will be analyzed by Alturas Analytics using a validated liquid chromatography coupled with tandem mass spectrometry assay for tecovirimat in human plasma method in accordance with the US FDA Guidance for Industry on Bioanalytical Method Validation.[3]

6.2 SAFETY ASSESSMENTS AND ENDPOINTS

Safety and tolerability will be assessed by monitoring and recording of AEs, clinical laboratory test results (hematology, serum chemistry, pregnancy, and urinalysis), vital sign measurements (systolic and diastolic blood pressures, heart rate, respiratory rate, and body temperature), 12-lead ECG results, and physical examination findings. Adverse events will be assessed from the time of the first dose of study drug until the follow-up telephone call on Day 37 (+2 days).

6.2.1 Adverse Events

6.2.1.1 Adverse Event Definitions

The investigator is responsible for reporting all AEs that are observed or reported during the study, regardless of their relationship to study drug or clinical significance. If there is any doubt as to whether a clinical observation is an AE, the event should be reported.

An AE is any event or other untoward medical occurrence, including those AEs that result from dosing errors, which may present during administration of a study drug or during a reasonable follow-up period and which does not necessarily have a causal relationship with this treatment. An AE is any unfavorable and unintended sign (eg, a clinically significant

abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal product, whether or not considered to be related to the medicinal product. All AEs will be followed until the AE is resolved or stabilized as determined by the investigator and/or the medical monitor.

A treatment-emergent AE (TEAE) is defined as any event not present before exposure to study drug or any event already present that worsens in intensity or frequency after exposure to study drug.

An adverse reaction is any AE caused by a drug. Adverse reactions are a subset of all suspected adverse reactions for which there are reasons to conclude that the drug caused the event.

A suspected adverse reaction is any AE for which there is a reasonable possibility that the study drug caused the AE. For the purposes of IND safety reporting, "reasonable possibility" means that there is evidence to suggest a causal relationship between the drug and the AE. A suspected adverse reaction implies a lesser degree of certainty about causality than adverse reaction, which means any AE caused by a study drug.

An AE or suspected adverse reaction is considered "unexpected" if it is not listed in the TPOXX full prescribing information or at the specificity or severity that has been observed with the study drug being tested. For example, under this definition, hepatic necrosis would be unexpected (by virtue of greater severity) if the TPOXX full prescribing information referred only to elevated hepatic enzymes or hepatitis. Similarly, cerebral thromboembolism and cerebral vasculitis would be unexpected (by virtue of greater specificity) if the TPOXX full prescribing information listed only cerebral vascular accidents. "Unexpected," as used in this definition, also refers to AEs or suspected adverse reactions that are mentioned in the TPOXX full prescribing information as occurring with a class of drugs or as anticipated from the pharmacological properties of the drug, but are not specifically mentioned as occurring with the particular drug under investigation.

An AE or suspected adverse reaction is considered an SAE if, in the view of either the investigator or SIGA, it results in any of the following outcomes:

- Results in death.
- Is life threatening (subject is at immediate risk of death at the time of the event).
- Requires inpatient hospitalization or prolongation of existing hospitalization, other than elective hospitalization, during the period of protocol defined surveillance.

- Results in congenital anomaly or birth defect.
- Results in a persistent or significant disability/incapacity.
- Any other important medical event that may not result in death, be life threatening, or requires hospitalization may be considered an SAE when, based on appropriate medical judgment, the event may jeopardize the subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition or is otherwise considered to be medically significant.

Important medical events that may not result in death, be life threatening, or require hospitalization may be considered serious when, based upon appropriate medical judgement, they may jeopardize the subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. Examples of such medical events include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse.

An AE or suspected adverse reaction is considered "life-threatening" if, in the view of either the investigator or SIGA, its occurrence places the subject at immediate risk of death. It does not include an AE or suspected adverse reaction that, had it occurred in a more severe form, might have caused death.

Serious AEs will be followed until the SAE is stable or until resolution as determined by the investigator and/or the medical monitor.

6.2.1.2 Eliciting and Documenting Adverse Events

The investigator is responsible for ensuring that all AEs and SAEs are recorded in the eCRF and reported to SIGA by PPD. Adverse events and SAEs will be assessed from the first dose of study drug through the telephone call on Day 37 (+2 days).

At every study visit or assessment, subjects will be asked a standard question to elicit any medically related changes in their well-being. They will also be asked if they have been hospitalized, had any accidents, used any new medications, or changed concomitant medication regimens (both prescription and over-the-counter medications).

In addition to subject observations, AEs will be documented from any data collected on the AE page of the eCRF (eg, laboratory values, physical examination findings, and ECG changes) or other documents that are relevant to subject safety.

6.2.1.3 Reporting Adverse Events

All AEs reported or observed from the first dose of study drug through the follow-up telephone call on Day 37 (+2 days) will be recorded on the AE page of the eCRF. Information to be collected includes drug treatment, type of event, date and time of onset, investigator-specified assessment of severity and relationship to study drug, date and time of resolution of the event, seriousness, as well as any required treatment or evaluations, and outcome. Adverse events resulting from concurrent illnesses, reactions to concurrent illnesses, reactions to concurrent medications, or progression of disease states must also be reported.

All AEs will be followed until they are resolved or stabilized as determined by the investigator and/or medical monitor. These data will be reviewed on an ongoing basis by the study coordinator, the investigator, the medical monitor, and the ISM. This requirement indicates that for some events, follow-up may be required after the subject has completed study participation. These events will be reported by SIGA, as required, to the FDA.

Any medical condition that is present at the time that the subject is screened but does not deteriorate should not be reported as an AE. However, if it deteriorates at any time during the study, it should be recorded as an AE. Prior to this, medical conditions reported by subjects are considered medical history.

6.2.1.4 Reporting of Serious Adverse Events

Any AE considered serious by the investigator or which meets SAE criteria (Section 6.2.1.1), or any other event or condition regardless of grade, which in their judgment represents a reportable event, must be reported to the medical monitor and SIGA as soon as the investigator becomes aware of the event. In addition, the event must be reported to PPD via the SAE hotline. The PPD SAE Report Form must be submitted within 24 hours of knowledge of the event. SIGA (or designee) will be responsible for notifying the relevant regulatory authorities of any SAE as outlined in US Title 21 Code of Federal Regulations (CFR) Parts 312 and 320. The investigator is responsible for notifying the institutional review board (IRB) directly.

In addition, the investigator (or designee) must report any Grade 3 (severe) AE that they deem possibly, probably, or definitely related to study drug to the medical monitor and SIGA within 24 hours after becoming aware of the event.

After notification from the investigator, SIGA will report all study drug-related and unexpected SAEs (those not listed in the TPOXX full prescribing information) to the FDA within 15 calendar days of first knowledge. Fatalities or life-threatening events assessed as related and unexpected will be reported to the FDA within 7 calendar days of first knowledge. The ISM will also receive these reports.

The following contact information is to be used for SAE reporting:

PPD Medical Monitor: Rahul Bhatnagar, MD
PPD Phase I Clinic
7551 Metro Center Drive, Suite 300
Austin, TX 78744
Telephone: 888-483-7729

PPD SAE Hotline: 888-483-7729
PPD SAE Fax line: 888-529-3580

The collection and monitoring period for SAEs is 30 days after administration of the last dose of study drug. At the time of discharge or early termination from the study site, the subject will be instructed to notify the investigator of any SAEs that occur within 30 days after the last dose of study drug.

All subjects will have a follow-up telephone call 30 days after administration of the last dose of study drug (Day 37 [+2 days]) to report any SAEs.

6.2.1.5 Assessment of Severity

All AEs will be graded for intensity according to the current DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events. The table may be accessed at the following link: https://rsc.tech-res.com/docs/default-source/safety/division-of-aids-(daids)-table-for-grading-the-severity-of-adult-and-pediatric-adverse-events-corrected-v-2-1.pdf?sfvrsn=2.

Any laboratory or clinical AE that is not listed on the DAIDS Table will be assessed for severity and classified into 1 of 5 clearly defined categories as follows:

- Grade 1 (Mild): Events require minimal or no treatment and do not interfere with the subject's daily activities.
- Grade 2 (Moderate): Events result in a low level of inconvenience or concern with the therapeutic measures and may cause some interference with normal functioning.

- Grade 3 (Severe): Events interrupt a subject's usual daily activity, may require systemic drug therapy or other treatment, and are usually incapacitating.

- Grade 4 (Life-threatening): Event that, in the opinion of the investigator, places the subject at immediate risk of death from the reaction as it occurred (ie, it does not include a reaction that, had it occurred in a more severe form, might have caused death).

- Grade 5 (Death).

Changes in the severity of an AE should be documented to allow an assessment of the duration of the event at each level of intensity to be performed. An AE characterized as intermittent requires documentation of onset and duration of each episode.

6.2.1.6 Assessment of Causality

Any occurrence of an AE will be assessed for relationship to the study drug. A causal relationship means that the study drug caused (or is reasonably likely to have caused) the AE. This usually implies a relationship in time between the drug and the AE; for example, the AE occurred shortly after the subject received the study drug.

The investigator who examines and evaluates the subject will determine AE causality based on the temporal relationship to administration of the study drug, the pharmacology of the study drug, and their clinical judgment. Terms used to describe the degree of causality between a study drug and an AE are definitely related, probably related, possibly related, unlikely related, or not related.

The best estimate at the time of reporting of an event and the degree of certainty about the causal relationship between the study drug administration and the AE will be graded as follows:

<u>Associated</u>

- Definitely Related: The AE and administration of study drug are related in time, and a direct association can be demonstrated (eg, the event disappears or decreases with reduction in dose or cessation of study drug and recurs with re-exposure).

- Probably Related: The AE and administration of study drug are reasonably related in time and/or follow a known pattern of response, and the AE is more likely explained by study drug than other causes.

- Possibly Related: The AE and administration of study drug are reasonably related in time and/or follow a known pattern of response, but the AE can be explained equally well by causes other than study drug (eg, could readily have been produced by the subject's clinical state or could have been due to environmental or other interventions).

Not Associated

- Unlikely Related: A potential relationship between study drug and the AE could exist (ie, the possibility cannot be excluded), but the AE is most likely explained by causes other than the study drug (eg, could readily have been produced by the subject's clinical state or could have been due to environmental or other interventions).

- Not Related: The AE is clearly due to extraneous causes (eg, underlying disease, environment) or exposure to the study drug has not occurred. Such events MUST have an alternative, definitive etiology documented in the subject's medical record.

6.2.1.7 Follow-up of Adverse Events

All AEs must be reported in detail on the appropriate page of the eCRF and followed until they are resolved or stabilized as determined by the investigator and/or medical monitor.

6.2.1.8 Reactogenicity

At this time, there is no definitive information on allergic activity of TPOXX. Reactogenicity will be monitored in subjects during the study treatment period. The study site personnel will observe the subjects for signs of allergic reaction for at least 1 hour after the study drug is ingested.

6.2.1.9 Reporting of Pregnancy

Pregnant women are not eligible to participate in the study. Subjects must be counseled regarding prevention of pregnancy and encouraged to make every effort to avoid pregnancy during study participation. If a female subject becomes pregnant during study participation, study drug dosing will be discontinued, and the subject will be withdrawn from the study. The pregnancy itself is not considered an SAE. However, the investigator must complete the pregnancy report form and fax it to PPD Pharmacovigilance within 24 hours of knowledge of the pregnancy. After delivery or termination of pregnancy, the follow-up pregnancy report form should be completed and submitted via fax to PPD Pharmacovigilance. Spontaneous abortions should always be reported as SAEs. Pregnancy data will be captured and followed

by PPD. All pregnancies and outcomes will be tracked. The case will not be closed until after the child is followed for 3 months.

If there are complications during the pregnancy, the complications will be recorded as AEs in the usual manner. The subject will be asked to report the outcome of the pregnancy. If there is a congenital anomaly in the infant, this will be recorded as an SAE in the data forms for the mother (ie, the study subject).

If a subject becomes pregnant during the study after receiving the study drug, all safety evaluations will be collected as per protocol. In addition, at the time that the pregnancy is reported, consent will be requested to contact the subject and her physician in the postpartum period to assess delivery and health status of the neonate.

If the partner of a male subject becomes pregnant, the partner will be asked for consent to allow her treating physician to provide SIGA or its designee with follow-up information regarding the pregnancy and its outcome.

6.2.2 Clinical Laboratory Testing

Clinical laboratory tests will be performed by the PPD Central Laboratory. Blood samples will be collected at the time points indicated in the schedule of events (Table 9-1) and will be prepared using standard procedures.

Repeat clinical laboratory tests may be performed at the discretion of the investigator, if necessary, to evaluate inclusion and exclusion criteria or clinical laboratory abnormalities. PPD central laboratory will provide the reference ranges for all clinical laboratory safety parameters.

The following clinical laboratory assessments will be performed:

Hematology	Hematocrit, hemoglobin, mean corpuscular hemoglobin, mean corpuscular hemoglobin concentration, total and differential leukocyte count (basophils, eosinophils, lymphocytes, monocytes, neutrophils), mean corpuscular volume, platelet count, red blood cell count, and red cell distribution width
Serum Chemistry	Alanine aminotransferase, albumin, alkaline phosphatase, anion gap, aspartate aminotransferase, bilirubin (total), blood urea nitrogen, calcium, carbon dioxide, chloride, creatinine clearance (calculated[a]), gamma-glutamyltransferase, globulin, glucose, lactate dehydrogenase, phosphorus, potassium, sodium, total protein, and uric acid

Urinalysis	Appearance, bilirubin, blood, color, glucose, ketones, leukocytes, microscopy (performed if dipstick is ≥1+; includes bacteria, cast, crystals, epithelial cells, red blood cells, and white blood cells), nitrates, pH, protein, specific gravity, turbidity, and urobilinogen

[a] Creatinine clearance (CLcr) will be calculated using the Cockcroft-Gault formula:

$$CLcr\ (mL/min) = \frac{[140 - age(years)] \times weight\ (kg)}{72\ \times serum\ creatinine\ (mg/dL)}\{\times 0.85\ if\ female\}$$

Glycosylated hemoglobin A1c and a fasting lipid panel including cholesterol (total, high-density lipoprotein, calculated low-density lipoprotein, and triglycerides) will be performed at screening.

Serum pregnancy test (β human chorionic gonadotropin) for women of childbearing potential will be performed at screening and on Day –1.

A serum follicle-stimulating hormone test for postmenopausal women will be performed at screening.

Human immunodeficiency virus (type 1 and 2) antibodies, hepatitis B surface antigen, and hepatitis C virus antibody will be assessed at screening only.

A urine drug screen for alcohol, amphetamines (including methamphetamines and ecstasy/methylenedioxymethamphetamine), barbiturates, benzodiazepines, cannabinoids (including tetrahydrocannabinol), cocaine metabolites, and opiates (including heroin, codeine, and oxycodone) will be performed at screening and on Day –1.

Abnormal clinical laboratory values will be flagged as either high or low (or normal or abnormal) based on the reference ranges for each laboratory parameter. The investigator will determine whether any of the abnormally high or low results are clinically significant or not clinically significant. Clinical significance is defined as any variation in results that has medical relevance and may result in an alteration in medical care (eg, active observation, diagnostic measures, or therapeutic measures). If a clinically significant change from the screening value is noted, the clinically significant value and reason for clinical significance will be documented on the AE page of the eCRF. The investigator will continue to monitor the subject with additional assessments until the values have reached the reference range or the values at screening or until the investigator determines that follow-up is no longer medically necessary.

6.2.3 Medical History

A complete medical history will be obtained, including a review of systems, recreational and prescription drug use, over-the-counter drug use, nicotine and alcohol use, and past hospitalizations.

6.2.4 Vital Sign Measurements

Vital signs will be measured after the subject has been seated for at least 5 minutes at the time points indicated in the schedule of events (Table 9-1).

Vital sign measurements will include systolic and diastolic blood pressures, heart rate, respiratory rate, and body temperature.

When procedures are overlapping and occurring at the same time point, the order of procedures should be ECG, vital sign measurements, and then blood collection, with the blood collection scheduled to occur at the nominal time point, unless dictated by other study events happening at that time, such as dosing requirements.

The investigator will determine whether any of the vital sign measurements are clinically significant or not clinically significant. Clinical significance is defined as any variation in results that has medical relevance and may result in an alteration in medical care (eg, active observation, diagnostic measures, or therapeutic measures). If a clinically significant change from the screening values is noted, the clinically significant value and reason for clinical significance will be documented on the AE page of the subject's eCRF. The investigator will continue to monitor the subject with additional assessments until the value has reached the reference range or the value at screening or until the investigator determines that follow up is no longer medically necessary.

6.2.5 Electrocardiograms

A 12-lead ECG will be obtained after the subject has been in the supine position for at least 10 minutes at the time points indicated in the schedule of events (Table 9-1). On Days 1, 4, and 7, an ECG will be recorded 4 hours after the AM study drug administration. The acceptable window for collection from the scheduled collection time point will ±15 minutes.

Electrocardiogram assessments will include comments on whether the tracings are normal or abnormal, rhythm, presence of arrhythmia or conduction defects, morphology, any evidence of myocardial infarction, or ST segment, T wave, and U wave abnormalities. In addition, the

following parameters will be measured and reported: heart rate; PR, RR, and QT intervals; QTcF; QT interval corrected using Bazett's formula; and QRS duration. All ECGs must be performed by an experienced ECG technician.

The investigator will determine whether any of the 12-lead ECG results are clinically significant or not clinically significant. Clinical significance is defined as any variation in results that has medical relevance and may result in an alteration in medical care (eg, active observation, diagnostic measures, or therapeutic measures). If a clinically significant change from screening is noted, the clinically significant value and reason for clinical significance will be documented on the AE page of the subject's eCRF. The investigator will continue to monitor the subject with additional assessments until either the values have reached reference range or the values at screening or until the investigator determines that follow-up is no longer medically necessary.

6.2.6 Physical Examinations

A full physical examination will be performed at the time points indicated in the schedule of events (Table 9-1) and will include assessment of the following body systems: head, ears, eyes, nose, and throat; cardiac (including auscultation of heart); pulmonary (chest) auscultation of lungs; abdomen; skin; musculoskeletal system; lymphatic system; and neurologic system (cranial nerves, sensation, motor function, coordination, reflexes, and mental status).

A symptom-directed physical examination will be performed at the time points indicated in the schedule of events (Table 9-1) (for those subjects who require it), and at unscheduled visits as necessary. This examination will include an assessment of the heart, lungs, abdomen, a neurologic review, and a review of symptoms for assessments and/or follow-up of reported or potential AEs.

Weight will be measured without shoes and in light clothing at screening and without shoes and in hospital gowns at all other time points indicated in the schedule of events (Table 9-1). The scales should be calibrated, and the same weight scale should be used throughout the study starting on Day –1.

6.2.7 Unscheduled Visits

Subjects will be provided with the contact information for the study site personnel. Subjects are free to contact study site personnel at any time, and the site may require an unscheduled visit for the purpose of physical examinations, laboratory tests, etc. Unscheduled visits will

be documented by the site personnel in the source documents. Unscheduled procedures and laboratory tests and results will also be recorded in the eCRF.

7. STATISTICAL ANALYSIS PLANS

7.1 SAMPLE SIZE CALCULATIONS

The sample size (N = 36 [to allow at least 32 enrolled subjects to complete]) for this study is based on clinical and practical considerations and not on a formal statistical power calculation. The sample size is considered sufficient to effectively assess the PK and safety profiles of TPOXX.

7.2 ANALYSIS POPULATIONS

The Safety Population will include all subjects who receive at least 1 dose of study drug.

The PK Population will include subjects who receive study drug and have sufficient concentration data to facilitate the calculation of PK variables.

7.3 STATISTICAL ANALYSIS

Details of all statistical analyses will be described in a statistical analysis plan. All data collected will be presented in data listings. Data from subjects excluded from an analysis population will be presented in the data listings, but not included in the calculation of summary statistics.

For categorical variables, frequencies and percentages will be presented. Continuous variables will be summarized using descriptive statistics (number of subjects, mean, median, standard deviation [SD], minimum, and maximum).

Baseline demographic and background variables will be summarized overall for all subjects. The number of subjects who enroll in the study and the number and percentage of subjects who complete the study will be presented. Frequency and percentage of subjects who withdraw or discontinue from the study, and the reason for withdrawal or discontinuation, will also be summarized.

7.3.1 Pharmacokinetic Analyses

Individual plasma concentration and time deviation data will be presented in a data listing. Plasma concentration data will be listed and summarized using the following descriptive

statistics: number of subjects, arithmetic mean, SD, coefficient of variation (CV), geometric mean, geometric CV, median, minimum, and maximum. Individual and mean plasma concentration versus time profiles will be presented in figures on both linear and semilogarithmic scales.

The PK parameters of TPOXX will be analyzed based on the actual sampling times. All parameters will be determined using noncompartmental methods using Phoenix® WinNonlin® Version 6.4 or higher (Certara, L.P., Princeton, New Jersey) or SAS® Version 9.4 or higher (SAS Institute Inc., Cary, North Carolina).

The individual PK parameters and body weight-normalized PK parameters will be presented in data listings and summarized using the following descriptive statistics: number of subjects, arithmetic mean, SD, CV, median, minimum, maximum, geometric mean, geometric SD, and geometric CV.

7.3.2 Safety Analyses

Adverse events will be coded by preferred term and system organ class using the latest version of the Medical Dictionary for Regulatory Activities and summarized overall. All AE data will be presented in a data listing. Treatment-emergent AEs will be summarized overall, as well as by severity and relationship to study drug. Serious AEs and AEs leading to discontinuation of study drug will also be presented in the data listings and summarized overall.

Actual values and changes from baseline for clinical laboratory test results, vital sign measurements, and 12-lead ECG results will be summarized at each time point using descriptive statistics (number of subjects, mean, SD, median, minimum, and maximum). Shift tables will be generated for clinical laboratory test results. Clinical laboratory data, vital sign measurements, 12-lead ECG results, and physical examination findings will be presented in data listings.

7.4 HANDLING OF BELOW THE LIMIT OF QUANTIFICATION AND MISSING DATA

Plasma concentrations that are below the limit of quantification (BLQ) will be treated as zero for descriptive statistics. Geometric mean values will not be calculated or displayed when zero is the minimal value. Mean BLQ concentrations will be presented as BLQ, and the SD

and CV will be reported as not applicable. Missing concentrations will be excluded from the calculations.

7.5 INTERIM ANALYSES

No formal interim safety analyses will be performed in this study.

8. REFERENCE LIST

1. Breman JG, Henderson DA. Diagnosis and management of smallpox. N Engl J Med. 2002;346(17):1300-8.

2. TPOXX (tecovirimat) [full prescribing information]. SIGA Technologies, Inc. Corvallis (OR); 2018. 18 p.

3. Department of Health and Human Services, Food and Drug Administration (US). Guidance for Industry. Bioanalytical Method Validation. May 2001. Available from: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm070107.pdf.

9. APPENDICES

9.1 APPENDIX 1: LIST OF ABBREVIATIONS

Abbreviation	Term
$\%AUC_{extrap}$	percentage of $AUC_{0-\infty}$ extrapolated from the last quantifiable measurement to infinity
λ_z	terminal elimination rate constant
AE	adverse event
AUC	area under the plasma concentration-time curve
AUC_{0-24}	area under the plasma concentration-time curve from time 0 to 24 hours
$AUC_{0-\infty}$	area under the plasma concentration-time curve from time 0 extrapolated to infinity
AUC_{0-t}	area under the plasma concentration-time curve from time 0 to the last quantifiable measurement
AUC_{0-tau}	area under the plasma concentration-time curve during the first dosing interval
BCRP	breast cancer resistance protein
BID	twice daily
BLQ	below the limit of quantification
CFR	Code of Federal Regulations
CL/F	apparent total body clearance
C_{max}	maximum drug concentration in plasma
C_{trough}	concentration observed prior to the next dose administration
CRA	clinical research associate
CV	coefficient of variation
CYP	cytochrome P450
DAIDS	Division of Acquired Immune Deficiency Syndrome
ECG	electrocardiogram
eCRF	electronic case report form
FDA	Food and Drug Administration
ICF	informed consent form
ICH	International Council for Harmonisation
IRB	institutional review board
ISM	independent safety monitor
MedDRA	Medical Dictionary for Regulatory Activities
PK	pharmacokinetic(s)
QTcF	QT interval corrected using Fridericia's formula
SAE	serious adverse event
SD	standard deviation
SOP	standard operating procedures
$t_{1/2}$	terminal elimination half-life
TEAE	treatment-emergent adverse event

Abbreviation	Term
T_{max}	time to maximum drug concentration in plasma
UGT	uridine diphosphate-glucuronosyltransferase
VARV	variola virus
V_d/F	apparent volume of distribution

9.2 APPENDIX 2: SCHEDULE OF EVENTS

Table 9-1 Schedule of Events

Procedure[c] / Day	Screening	Check-in	Treatment Period									Telephone Call or Follow-up Visit[a]	Follow-up Telephone Call[b]
	–28 to –2	–1	1	2	3	4	5	6	7	8	9 or Early Discontinuation (±2)	14 (+2)	37 (+2)
Admission to clinic		X											
Discharge from clinic[d]											X		
Informed consent	X												
Inclusion/exclusion criteria	X	X											
Medical history[e]	X	X											
Complete physical examination[f]	X	X							X		X		
Weight[g]	X	X	X[h]								X		
Vital sign measurements[i]	X	X	X[j]			X[j]			X[j]	X	X	X[k]	
Glycosylated hemoglobin (HbA1c)	X												
Fasting lipid panel[l]	X												
Clinical laboratory testing[m]	X[n]	X				X				X[o]	X[n]		
Serum follicle-stimulating hormone[p]	X												
Serum pregnancy test[q]	X	X											
Urine drug/alcohol screen[r]	X	X											
Serology (HBsAg, HCV, and HIV)	X												
12-Lead ECG[s]	X	X	X			X			X		X		
TPOXX administration[t]			X	X	X	X	X	X	X				
Pharmacokinetic sampling[u]			X	X				X	X	X	X		
Symptom-directed physical examination[v]				X	X	X	X	X	X			X[k]	
Reactogenicity[w]			X	X	X	X	X	X	X				
Adverse events			←	←	←	←	←	←	←	←	X →		
Prior/concomitant medications	←	←	←	←	←	←	←	←	←	←	X →	→	→

Abbreviations: AE, adverse event; ECG, electrocardiogram; HBsAg, hepatitis B surface antigen; HCV, hepatitis C virus; HIV, human immunodeficiency virus; PK, pharmacokinetic; SAE, serious adverse event.

Notes:

[a] The follow-up visit or telephone call will occur on Day 14 (+2 days), 7 days after the last dose of study drug. Subjects who have abnormal physical examination findings or an ongoing AE/SAE on Day 9 that is deemed related to study drug or per investigator or SIGA discretion will return to the study site on Day 14 (+2 days) for a follow-up visit. All other subjects will have the Day 14 (+2 days) follow-up via telephone.

[b] The follow-up telephone call will be made 30 days after the last dose of study drug (Day 37 [+2 days]).

[c] When procedures are overlapping and occurring at the same time point, the order of procedures should be ECG, vital sign measurements, and then blood collection, with the blood collection scheduled to occur at the nominal time point, unless dictated by other study events happening at that time, such as dosing requirements.

[d] Discharge following collection of all safety assessments.

[e] Including a review of systems; recreational, prescription, and over-the-counter drug use; nicotine and alcohol use; and past hospitalizations.

[f] Including assessment of the following body systems: head, ears, eyes, nose, and throat; cardiac (including auscultation of heart); pulmonary (chest) auscultation of lungs; abdomen; skin; musculoskeletal system; lymphatic system; and neurologic system (cranial nerves, sensation, motor function, coordination, reflexes, and mental status).

[g] Weight will be measured without shoes and in light clothing at screening and without shoes and in hospital gowns at all other time points. The scales should be calibrated and the same weight scale should be used throughout the study starting on Day –1.

[h] Weight will be collected prior to dosing.

[i] Vital sign measurements will include systolic and diastolic blood pressures, heart rate, respiratory rate, and body temperature. Vital signs will be measured after the subject has been seated for at least 5 minutes.

[j] Vital sign measurements will be performed before dosing and 4 hours after the AM study drug administration on Days 1 and 7 and 4 hours after the AM study drug administration on Day 4. The acceptable window for collection from the scheduled collection time point is ±15 minutes.

[k] Collected only if subjects are required to return to the study site on Day 14 (+2 days) for a follow-up visit.

[l] Including cholesterol (total, high-density lipoprotein, calculated low-density lipoprotein, and triglycerides).

[m] Clinical laboratory testing will include hematology and serum chemistry.

[n] Clinical laboratory testing at screening and at Day 9 or early discontinuation will include hematology, serum chemistry, and urinalysis.

[o] Collect 12 hours after the PM study drug administration on Day 7.

[p] For postmenopausal women, a serum follicle-stimulating hormone test will be performed at screening.

[q] Women of childbearing potential only.

[r] Includes alcohol, amphetamines (including methamphetamines and ecstasy/methylenedioxymethamphetamine), barbiturates, benzodiazepines, cannabinoids (including tetrahydrocannabinol), cocaine metabolites, and opiates (including heroin, codeine, and oxycodone).

[s] A 12-lead ECG will be collected after the subject has been in the supine position for at least 10 minutes. On Days 1, 4, and 7, an ECG will be recorded 4 hours after the AM study drug administration. The acceptable window for collection from the scheduled collection time point is ±15 minutes.

[t] TPOXX, 600 mg (3 × 200-mg capsules) will be administered orally twice daily, approximately 12 hours (± 30 minutes) apart on Days 1 through 7. All subjects will be provided meals consisting of approximately 600 calories and 25 g fat, which will start 30 minutes before study drug administration. Subjects should eat this meal within 30 minutes or less of taking study drug. Study drug will be administered approximately 30 minutes after the start of the meal. All doses of study drug will be administered to subjects by study site personnel with approximately 240 mL of water. Subjects must fast 2 hours after taking study drug. Study drug and meals must be taken with water only, and no other beverage except water should be ingested within 3 hours before or 3 hours after study drug administration.

[u] Blood samples for PK analysis of TPOXX will be collected from all subjects at the following tome points: on Day 1 before study drug administration (0 hour), at 0.5, 1, 2, 4, 6, 8, 12 (before the PM dose), 14, 16, 18, 20, and 24 hours (before the AM dose on Day 2), on Day 6 (before the AM dose and 4 hours after the AM dose), on Day 7 before the AM dose (0 hour), at 0.5, 1, 2, 4, 6, 8, 12 (before the PM dose), 14, 16, 18, 20, and 24 hours (Day 8, 24 hours after the AM dose on Day 7), and on Day 9 (48 hours after the AM dose on Day 7). For PK blood samples, the acceptable window for collection from the scheduled collection time point will be as follows: ±5 minutes for the time points from 1 to 8 hours and ±15 minutes for the 12- to 48-hour time points.

[v] Including assessment of heart, lungs, abdomen, a neurologic review, and a review of symptoms for assessment and/or follow-up of reported or potential adverse events.

[w] The study site personnel will observe the subjects for signs of allergic reaction for at least 1 hour after the study drug is ingested.

9.3 APPENDIX 3: STUDY GOVERNANCE

9.3.1 Data Quality Assurance

This study will be conducted using the quality processes described in applicable procedural documents. The quality management approach to be implemented will be documented and will comply with current ICH guidance on quality and risk management. All aspects of the study will be monitored for compliance with applicable government regulatory requirements, current Good Clinical Practice, the protocol, and standard operating procedures (SOPs). The monitor will maintain current personal knowledge of the study through observation, review of study records and source documentation, and discussion of the conduct of the study with the investigator and staff. Electronic CRFs and electronic data capture will be utilized. The electronic data capture system is validated and compliant with US Title 21 CFR Part 11. Each person involved with the study will have an individual identification code and password that allows for record traceability. There may be an internal quality review audit of the data and additional reviews by the clinical monitor.

Steps to be taken to ensure the accuracy and reliability of data include, but are not limited to: selection of qualified investigator and appropriate study center, protocol training and review of protocol procedures with the investigator and study site personnel before the start of the study, site initiation and periodic interim monitoring visits by SIGA or PPD, and direct transmission of safety laboratory data into the PPD study database for all clinical safety laboratory tests performed. The eCRF will be reviewed for accuracy and completeness by PPD Clinical research associate (CRA) remotely and during on-site monitoring visits. Discrepancies will be resolved with the investigator or designees, as appropriate. The data will be entered into the clinical study database and validated for accuracy. During on-site monitoring visits, 100% of the data will be verified using source documentation. SIGA or Biomedical Advanced Research and Development Authority representatives may accompany the PPD CRA on any scheduled site visit. The investigator will be informed in advance of any visitors to the study site in addition to the PPD CRA.

Representatives of SIGA's Quality Assurance department (or designee) may visit the site to carry out an audit of the study in compliance with regulatory guidelines and PPD policy. Such audits will require access to all study records, including source documents, for inspection and source document verification with the eCRF. Subject privacy must, however, be respected. Sufficient prior notice will be provided to allow the investigator to prepare properly for the audit. Similar auditing procedures may also be conducted by any regulatory body reviewing the results of this study in support of a Licensing Application. The

investigator will immediately notify SIGA if they are contacted by a regulatory agency requesting a site inspection.

9.3.2 Investigator Obligations

The following administrative items are meant to guide the investigator in the conduct of the study and may be subject to change based on industry and government SOPs, working practice documents, or guidelines. Changes will be reported to the IRB but will not result in protocol amendments.

9.3.2.1 Confidentiality

All laboratory specimens, evaluation forms, reports, and other records will be identified in a manner designed to maintain subject confidentiality. All records will be kept in a secure storage area with limited access. Subjects will not be identified by name in any reports in this study. All records will be kept confidential to the extent provided by federal, state, and local law. Medical records are made available for review when required by the FDA or other authorized users only under the guidelines set by the Federal Privacy Act. Direct access, as defined in the Federal Privacy Act, includes examining, analyzing, verifying, and reproducing any records and reports that are important to the evaluation of the study. The investigator is obligated to inform the subjects that these representatives may review their study-related records without violating the confidentiality of the subjects. The requirement to maintain subject confidentiality is included in the study informed consent document.

The investigator and all employees and coworkers involved with this study may not disclose or use for any purpose other than performance of the study, any data, record, or other unpublished, confidential information disclosed to those individuals for the purpose of the study. Prior written agreement from SIGA or its designee must be obtained for the disclosure of any said confidential information to other parties.

9.3.2.2 Institutional Review

Federal regulations and ICH guidelines require that approval be obtained from an IRB before participation of human subjects in research studies. Before study onset, the protocol, ICF, advertisements to be used for the recruitment of study subjects, and any other written information regarding this study to be provided to the subject or the subject's legal guardian must be approved by the IRB. Documentation of all IRB approvals and of the IRB

compliance with the ICH harmonised tripartite guideline E6(R2): Good Clinical Practice will be maintained by the site and will be available for review by SIGA or its designee.

All IRB approvals should be signed by the IRB chairman or designee and must identify the IRB name and address, the clinical protocol by title or protocol number or both, and the date approval or a favorable opinion was granted.

9.3.2.3 Subject Consent

Written documentation of informed consent in compliance with US Title 21 CFR Part 50 shall be obtained from each subject before any study-related procedures are performed and study drug is administered. If any institution-specific modifications to study-related procedures are proposed or made by the site, the consent should be reviewed by SIGA or its designee or both before IRB submission. Once reviewed, the investigator will submit the ICF to the IRB for review and approval before the start of the study. If the ICF is revised during the course of the study, all active participating subjects must sign the revised ICF.

Before recruitment and enrollment, each prospective subject or his/her legal guardian will be given a full explanation of the study and will be asked to read and review the approved ICF. Once the investigator is assured that the subject/legal guardian understands the implications of participating in the study, the subject/legal guardian will be asked to give his or her consent to participate in the study by signing the ICF. A copy of the ICF will be provided to the subject/legal guardian.

9.3.2.4 Exclusion of Children

Effort will be made to include women and minorities in proportions similar to that of the community from which they are recruited. Because this study is designed to establish safety of the study drug in adults, enrollment will be limited to persons at least 18 years of age, and no older than 50 years. Children are excluded from participation in this clinical study because it does not meet the Department of Health and Human Services' guidelines (45 CFR 46, Subpart D, 401-409) for inclusion of children in research. These guidelines provide guidance for the protection of children in research. Generally, healthy children can be studied when the research is considered as "not greater than minimal risk." Children can be involved in research with greater than minimal risk only when it presents the prospect of direct benefit to the individual child or is likely to yield generalizable knowledge about the child's disorder or condition.

9.3.2.5 Study Reporting Requirements

By participating in this study, the investigator agrees to submit reports of SAEs according to the time line and method outlined in this protocol. In addition, the investigator agrees to submit annual reports to his or her IRB as appropriate.

9.3.2.6 Financial Disclosure and Obligations

The investigator is required to provide financial disclosure information to allow SIGA to submit the complete and accurate certification or disclosure statements required under US Title 21 CFR Part 54. In addition, the investigator must provide to SIGA a commitment to promptly update this information if any relevant changes occur during the course of the investigation and for 1 year following the completion of the study.

Neither SIGA nor PPD is financially responsible for further testing or treatment of any medical condition that may be detected during the screening process. In addition, in the absence of specific arrangements, neither SIGA nor PPD is financially responsible for further treatment of the disease under study.

9.3.2.7 Investigator Documentation

Prior to beginning the study, the investigator will be asked to comply with ICH E6(R2) Section 8.2 and US Title 21 of the CFR by providing essential documents, including but not limited to, the following:

- IRB approval.
- An original investigator-signed investigator agreement page of the protocol.
- Form FDA 1572, fully executed, and all updates on a new fully executed Form FDA 1572.
- Curriculum vitae for the principal investigator and each subinvestigator listed on Form FDA 1572. Current licensure must be noted on the curriculum vitae. Curriculum vitae will be signed and dated by the principal investigators and subinvestigators at study start-up, indicating that they are accurate and current.
- Financial disclosure information to allow SIGA to submit complete and accurate certification or disclosure statements required under US Title 21 CFR Part 54. In addition, the investigators must provide to SIGA a commitment to promptly update this

information if any relevant changes occur during the course of the investigation and for 1 year after the completion of the study.

- An IRB-approved ICF, samples of site advertisements for recruitment for this study, and any other written information about this study that is to be provided to the subject or legal guardians.
- Laboratory certifications and reference ranges for any local laboratories used by the site, in accordance with US Title 42 CFR Part 493.

9.3.2.8 Study Conduct

The investigator agrees to perform all aspects of this study in accordance with the ethical principles that have their origin in the Declaration of Helsinki, ICH E6(R2): Good Clinical Practice; the protocol; and all national, state, and local laws or regulations.

9.3.2.9 Case Report Forms and Source Documents

Site personnel will maintain source documentation, enter subject data into the eCRF as accurately as possible, and will rapidly respond to any reported discrepancies.

Electronic CRFs and electronic data capture will be utilized. The electronic data capture system is validated and compliant with US Title 21 CFR Part 11. Each person involved with the study will have an individual identification code and password that allows for record traceability. Thus, the system, and any subsequent investigative reviews, can identify coordinators, investigators, and individuals who have entered or modified records, as well as the time and date of any modifications. There may be an internal quality review audit of the data and additional reviews by PPD's CRA.

Each eCRF is presented as an electronic copy, allowing data entry by site personnel, who can add and edit data, add new subjects, identify and resolve discrepancies, and view records. This system provides immediate direct data transfer to the database, as well as immediate detection of discrepancies, enabling site coordinators to resolve and manage discrepancies in a timely manner.

Paper copies of the eCRFs and other database reports may be printed and signed by the investigator. This system provides site personnel, PPD CRAs, and reviewers with access to hardcopy audits, discrepancy reviews, and investigator comment information.

9.3.2.10 Adherence to Protocol

The investigator agrees to conduct the study as outlined in this protocol, in accordance with ICH E6(R2) and all applicable guidelines and regulations.

9.3.2.11 Reporting Adverse Events

By participating in this study, the investigator agrees to submit reports of SAEs according to the timeline and method outlined in this protocol. In addition, the investigator agrees to submit annual reports to his or her IRB as appropriate. The investigator also agrees to provide SIGA with an adequate report, if applicable, shortly after completion of the investigator's participation in the study.

9.3.2.12 Investigator's Final Report

Upon completion of the study, the investigator, where applicable, should inform the institution; the investigator/institution should provide the IRB with a summary of the study's outcome and SIGA and regulatory authorities with any reports required.

9.3.2.13 Records Retention

Essential documents should be retained until at least 2 years after the last approval of a marketing application in an ICH region and until there are no pending or contemplated marketing applications in an ICH region or until at least 2 years have elapsed since the formal discontinuation of clinical development of the study drug. These documents should be retained for a longer period, however, if required by applicable regulatory requirements or by an agreement with SIGA. SIGA is responsible for informing the investigator/institution when these documents no longer need to be retained.

9.3.2.14 Publications

All information concerning TPOXX, SIGA operations, patent application, formulas, manufacturing processes, basic scientific data, and formula information, supplied by SIGA to the investigator and not previously published, is considered confidential and remains the sole property of SIGA. The investigator agrees to use this information only to accomplish this study and will not use it for other purposes without SIGA's written consent. The investigator understands that the information developed in the clinical study will be used by SIGA, in connection with the continued development of TPOXX, and thus may be disclosed as required to other clinical investigators or government regulatory agencies. To permit the

information derived from the clinical studies to be used, the investigator is obligated to provide SIGA with all data obtained in the study. Any publication or other public presentation of results from this study, including manuscripts and materials for presentation at scientific meetings, should be provided to SIGA at least 30 working days before abstract or other relevant submission deadlines. Authorship of publications resulting from this study will be determined at the discretion of SIGA.

9.3.3 Study Management

9.3.3.1 Monitoring

9.3.3.1.1 Monitoring of the Study

Site monitoring for safety is conducted to ensure that human subject protection, study procedures, and laboratory, study drug dosing, and data collection processes are of high quality and meet SIGA, GCP/ICH, and regulatory guidelines. PPD CRA(s) will conduct site monitoring visits as detailed in the monitoring plan.

Site investigators will allow the CRA(s), the designated IRB, SIGA or its designee and the FDA to review, audit, and inspect study documents (eg, ICFs, drug accountability and distribution forms, eCRF), pertinent hospital and site records, and source documentation for verification of the study data.

Clinical research associates will conduct site visits in accordance with PPD SOPs to monitor the following: study operations, the quality of data collected in the research records, the accuracy and timeliness of data entered in the database, and to determine that all process and regulatory requirements are met. Study monitoring visits will occur at initiation of the study site, at intervals determined by SIGA during conduct of the study, and at completion of the study.

The CRA will maintain current personal knowledge of the study through observation, review of study records and source documentation, and discussion of the conduct of the study with the investigator and staff. During the routine monitoring visits, the CRA will perform a 100% source document verification of all subject data entered into the eCRF. Discrepancies, if any, will be clarified with the study site coordinator and investigator, and corrected at the site by the study coordinator. Any questions or required data clarifications will be sent to the study site electronically.

9.3.4 Safety Monitoring Plan

Close cooperation between the designated members of the study team will occur to evaluate and respond to individual AEs in a timely manner. Designated team members (investigator, subinvestigators, study coordinator, and other designated study clinicians) will review the subject safety information and data (laboratory test results, ECGs, AEs, and concomitant medications) and update the PPD project team and the ISM on the status of all enrolled subjects at their site on a weekly basis (or more frequently if required because of an unexpected safety issue) through completion of each subject's final study visit.

9.3.5 Medical Monitor

The medical monitor, or their qualified designee, will receive reports within 24 hours of study site awareness of all SAEs and within 7 days of study site awareness of all other AEs. The safety monitors will review all safety data and alert the medical monitor of SAEs and AEs of interest. The medical monitor may make a request for data to the investigator as necessary for safety evaluations.

The medical monitor will review each significant AE in a timely fashion and ensure that appropriate management is initiated and completed. Drug safety representatives and the medical monitor will have direct contact with the investigators and follow all significant events as needed.

9.3.6 Safety Oversite (Independent Safety Monitor)

In addition to the investigator's ongoing review of the safety data, the ISM will review the protocol for any major concerns and will be involved in data review in coordination with the investigator. The primary role of the ISM will be to evaluate the study safety and tolerability data. The ISM will provide independent safety monitoring in a timely fashion, which will include reviewing individual SAE reports and a review of periodic cumulative AE reports. Clinical safety and laboratory data, clinical records, and other safety study-related records will be made available for the ISM to review. Based on review of this data, the ISM may make recommendations regarding the safe continuation of the study. Specific details will be outlined in the Safety and Medical Management Plan.

9.3.6.1 Inspection of Records

The investigator and study site involved in the study will permit study-related monitoring, audits, IRB review, and regulatory inspections by providing direct access to all study records.

In the event of an audit, the investigator agrees to allow SIGA, their representatives, the FDA, or other regulatory agencies access to all study records.

The investigator should promptly notify SIGA and study site of any audits scheduled by any regulatory authorities and promptly forward copies of any audit reports received to SIGA.

9.3.6.2 Management of Protocol Amendments and Deviations

9.3.6.2.1 Modification of the Protocol

Any changes in this research activity, except those necessary to remove an apparent immediate hazard to the subject, must be reviewed and approved by SIGA or designee. Amendments to the protocol must be submitted in writing to the IRB for approval before subjects are enrolled into an amended protocol.

9.3.6.2.2 Protocol Deviations

The investigator or designee must document and explain in the subject's source documentation any deviation from the approved protocol. The investigator may implement a deviation from, or a change to, the protocol to eliminate an immediate hazard to study subjects without prior IRB approval. As soon as possible after such an occurrence, the implemented deviation or change, the reasons for it, and any proposed protocol amendments should be submitted to the IRB for review and approval, to SIGA for agreement, and to the regulatory authorities, if required.

A *protocol deviation* is any change, divergence, or departure from the study design or procedures defined in the protocol. An *important protocol deviation* (sometimes referred to as a protocol violation or a major protocol deviation) is a subset of protocol deviations that might significantly affect the reliability of the study data or that might significantly affect a subject's safety. An important deviation can include nonadherence to inclusion or exclusion criteria or nonadherence to FDA regulations or ICH E6(R2) guidelines.

Protocol deviations will be documented by the clinical monitor throughout the course of monitoring visits. The investigator will be notified in writing by the monitor of deviations. The IRB should be notified of all protocol deviations, if appropriate, in a timely manner.

9.3.6.3 Study Termination

Although SIGA has every intention of completing the study, they reserve the right to discontinue it at any time for clinical or administrative reasons.

An initiative for closure of the clinical investigative site or termination of the study can be taken at any time either by SIGA, PPD, or the investigator provided there is reasonable cause and sufficient notice is given in advance of the intended termination. Reasons for such action include, but are not limited to:

- Study site closure
    - Inadequate site recruitment/enrollment of subjects
    - Failure of an investigator to comply with the protocol, PPD SOPs, GCP guidelines, or applicable federal regulations
- Termination of enrollment
    - Enrollment of the required estimated number of subjects for the study
- Study termination
    - Completion of the study
    - Safety concerns

In addition, the ISM and FDA have the prerogative to delay or terminate the study.

The end of the study is defined as the date on which the last subject completes the last visit (includes the follow-up visit and the follow-up telephone call). Any additional long-term follow-up that is required for monitoring of the resolution of an AE or finding may be reported through an amendment to the clinical study report.

9.3.6.4 Final Report

Whether the study is completed or prematurely terminated, SIGA will ensure that clinical study reports are prepared and provided to regulatory agency(ies) as required by the applicable regulatory requirement(s). SIGA will also ensure that clinical study reports in marketing applications meet the standards of the ICH harmonised tripartite guideline E3: Structure and content of clinical study reports.

Upon completion of the clinical study report, the investigator will be provided with the final approved clinical study report, as appropriate.

CLINICAL STUDY PROTOCOL AMENDMENT 1
IND 69,019

A POST MARKETING STUDY OF THE SAFETY, TOLERABILITY, AND PHARMACOKINETICS OF TPOXX® IN ADULT SUBJECTS WEIGHING MORE THAN 120 KG

Post Marketing Commitment: 3417-4

SIGA-246-022

Sponsor:	SIGA Technologies, Inc. 4575 SW Research Way, Suite 110 Corvallis, OR 97333
Sponsor Contact:	Kady Honeychurch, PhD, PMP SIGA Technologies, Inc. 4575 SW Research Way, Suite 110 Corvallis, OR 97333
Medical Monitor:	Rahul Bhatnagar, MD PPD Phase I Clinic 7551 Metro Center Drive, Suite 300 Austin, TX 78744
Version of Protocol:	Final 2.0
Date of Protocol:	27 June 2019

CONFIDENTIAL

The study will be conducted according to the International Council for Harmonisation Guideline E6(R2): Good Clinical Practice.

SIGNATURE PAGE

PROTOCOL TITLE: A Post Marketing Study of the Safety, Tolerability, and Pharmacokinetics of TPOXX® in Adult Subjects Weighing More Than 120 kg

PROTOCOL NUMBER: SIGA-246-022

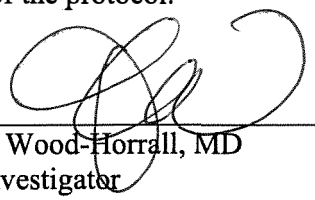
Dennis E Hruby

Dennis E. Hruby, PhD
Chief Scientific Officer
SIGA Technologies, Inc.

01 Jul 2019
Date

INVESTIGATOR PROTOCOL AGREEMENT PAGE

I agree to conduct the study as outlined in the protocol titled "A Post Marketing Study of the Safety, Tolerability, and Pharmacokinetics of TPOXX® in Adult Subjects Weighing More Than 120 kg" in accordance with the guidelines and all applicable government regulations, including US Title 21 of the Code of Federal Regulations Part 54. I have read and understand all sections of the protocol.



28 JUN 2019

Rebecca N. Wood-Horrall, MD
Principal Investigator
PPD

Date

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PROTOCOL SYNOPSIS

PROTOCOL NO.: SIGA-246-022

TITLE: A Post Marketing Study of the Safety, Tolerability, and Pharmacokinetics of TPOXX® in Adult Subjects Weighing More Than 120 kg

STUDY PHASE: 4 Post Marketing Study

STUDY SITE: PPD Phase I Clinic, 7551 Metro Center Drive, Suite 200, Austin, TX 78744, USA.

OBJECTIVES:

Primary:

The primary objective of this study is to determine the pharmacokinetic (PK) profile of 600 mg oral TPOXX (3 × 200-mg capsules) administered twice daily (BID) for 7 days in adult subjects weighing more than 120 kg to determine if a change in dosing regimen would be needed in these patients.

Secondary:

The secondary objective of this study is to evaluate the safety and tolerability of 600 mg oral TPOXX administered BID for 7 days in healthy adult subjects weighing more than 120 kg.

STUDY DESIGN AND METHODOLOGY:

This is an open-label, multiple-dose study to assess the safety, tolerability, and PK of TPOXX 600 mg BID when administered orally for 7 days to adult subjects weighing more than 120 kg. A total of 36 subjects, ages 18 to 50, inclusive, will be enrolled. The study will consist of a screening period (Day –28 to Day –2), a treatment and confinement period (Days –1 to 9), a follow-up telephone call or visit (Day 14 [+2 days]), and a follow-up telephone call (Day 37 [+2 days]).

Subjects will undergo screening evaluations to determine eligibility within 28 days before study drug administration. Subjects will be admitted to the study site on Day –1 to complete baseline assessments; results of these assessments must be reviewed by the investigator before dosing. Starting in the morning of Day 1, subjects will receive 600 mg oral TPOXX BID for 7 days (Days 1 through 7).

All subjects will be provided meals (consisting of approximately 600 calories and 25 g fat) 30 minutes prior to study drug administration and subjects must fast for 2 hours after taking study drug. Subjects should eat this meal within 30 minutes or less of taking study drug. Study drug and meals must be taken with water only, and no other beverage except water should be ingested within 3 hours before or 3 hours after study drug administration.

Subjects will remain confined to the study site for collection of PK samples and will be carefully monitored for safety and tolerability until discharge on Day 9. Subjects who have abnormal physical examination findings or an ongoing adverse event (AE)/serious adverse event (SAE) on Day 9 that is deemed related to study drug or per investigator or SIGA discretion will return to the study site on Day 14 (+2 days) for a follow-up visit. All other subjects will have the Day 14 (+2 days) follow-up via telephone. All subjects will have a

follow-up telephone call 30 days after administration of the last dose of study drug (Day 37 [+2 days]) to report any SAEs. At the time of discharge from the clinical research unit, subjects will be instructed to notify the investigator of any SAEs that occur within 30 days after administration of the last dose of study drug. Serious AEs will be followed until the SAE is stable or until resolution as determined by the investigator and/or medical monitor.

The total duration of the study for each subject, including the screening period, treatment period, and the Day 37 (+2 days) follow-up telephone call, will be approximately 65 days.

STUDY POPULATION:

Inclusion Criteria:

Each subject must meet all the following criteria to be enrolled in this study:

1. Subject is male or female between 18 and 50 years of age, inclusive.
2. Subject has a body weight >120 kg at screening, at check-in on Day -1, and prior to dosing on Day 1.
3. Women of childbearing potential, have a negative β human chorionic gonadotropin pregnancy test (serum) at the screening visit and a confirmatory negative serum pregnancy test on Day –1 before receipt of study drug, and meet 1 of the following criteria:
   a. The subject or their partner has undergone surgical sterilization
   b. The subject is postmenopausal, defined as 12 consecutive months with no menses without an alternative medical cause and has a documented plasma follicle-stimulating hormone level >40 IU/mL
   c. The subject agrees to be abstinent (ie, heterosexually inactive or women in a religious order)
   d. The subject agrees to consistently use 1 of the following methods of contraception from the beginning of screening (which they had been consistently using for at least 30 days before the first dose of study drug) through 30 days after the last dose of study drug:
      i. Condoms, male or female, with a spermicide

         NOTE: For male subjects, condoms must be used for 90 days after the last dose of study drug.
      ii. Diaphragm or cervical cap with spermicide
      iii. Intrauterine device with spermicide
      iv. Oral contraceptives or other hormonal methods

         NOTE: Subject must agree to use an additional nonhormonal method of contraception in conjunction with oral contraceptives.
      v. Male sexual partner who had undergone a vasectomy at least 3 months before screening
4. Male subjects must agree to not donate sperm from the first dose of study drug through 90 days after the last dose of study drug.

5. Subject is considered by the investigator to be in good general health as determined by medical history (no hospitalizations for chronic medical conditions in the previous 2 years), clinical laboratory results, vital sign measurements, 12-lead electrocardiogram (ECG) results, and physical examination findings at screening.
6. Subject agrees to comply with all protocol requirements.
7. Subject is able to provide written informed consent.
8. Subject agrees to comply with the dietary requirements.
9. Subject does not intend to lose weight (diet or weight loss) from the screening visit and throughout the study.

EXCLUSION CRITERIA:
Subjects meeting any of the following criteria will be excluded from the study:

1. Subject is a female who is pregnant or breastfeeding or planning to become pregnant within 3 months after the last dose of study drug.
2. Subject has a history of any clinically significant conditions including:
   - Asthma treated with oral systemic steroids within the past 6 months
   - Diabetes mellitus (type 1 or 2), with the exception of gestational diabetes
   - Hypertension that is poorly controlled (repeat readings >140 mm Hg systolic and/or >90 mm Hg diastolic)
   - Thyroidectomy or thyroid disease that required medication within the past 12 months
   - Serious angioedema episodes within the previous 3 years or requiring medication in the previous 2 years
   - Head trauma resulting in a diagnosis of traumatic brain injury other than concussion
   - Frequent episodes of headache.
3. Subject has received treatment in another clinical study of an investigational drug (or medical device) within 30 days or 5 half-lives (whichever is longer) before the first dose of study drug.
4. Subject has been previously enrolled in any clinical study involving TPOXX (tecovirimat).
5. Subject has a history of relevant drug and/or food allergies (ie, allergy to tecovirimat or excipients, or any significant food allergy that could preclude a standard diet in the study site).
6. Subject has any condition possibly affecting drug absorption (eg, previous surgery on the gastrointestinal tract, including removal of parts of the stomach, bowel, liver, gallbladder, or pancreas, with the exception of appendectomy).
7. Subject has evidence or history of clinically significant allergic (except for untreated, asymptomatic, seasonal allergies at time of the first dose of study drug), hematological, endocrine, pulmonary, gastrointestinal, cardiovascular, hepatic, psychiatric, or neurological disease. Exceptions to these criteria (eg, stable, mild joint disease

unassociated with collagen vascular disease) may be made following discussions with the medical monitor.

8. Subject has a history of cardiac disease, symptomatic or asymptomatic arrhythmias, syncopal episodes, or risk factors for torsades de pointes (eg, heart failure, hypokalemia).
9. Subject has a family history of sudden cardiac death, not clearly due to acute myocardial infarction.
10. Subject has a seizure disorder or history of seizures (does not include childhood febrile seizures) or a past history that increases seizure risks such as significant head injury that caused loss of consciousness or other changes in the subject's daily function, concussion, stroke, central nervous system infection or disease, or alcohol or drug abuse or family history of idiopathic seizures.
11. Subject has a history of a peptic ulcer or significant gastrointestinal bleed.
12. Subject has a bleeding disorder diagnosed by a doctor (eg, factor deficiency, coagulopathy, or platelet disorder requiring special precautions) or significant bruising or bleeding difficulties with blood draws.
13. Subject has a malignancy that is active, or treated malignancy for which there is not reasonable assurance of sustained cure, or malignancy that is likely to recur during the period of the study (subject should be in complete remission for at least 5 years).
14. Subject has neutropenia or other blood dyscrasia determined to be clinically significant by the investigator.
15. Subject has used any of the following prohibited medications from within 7 days (or 5 half-lives, whichever is longer) before the first dose of study drug: antidiabetic medication; anticoagulants; anticonvulsants; substrates of the breast cancer resistance protein transporter including methotrexate, mitoxantrone, imatinib, irinotecan, lapatinib, rosuvastatin, sulfasalazine, and topotecan; substrates of CYP2C8 including repaglinide, paclitaxel, Montelukast, pioglitazone, rosiglitazone; and substrates of CYP2C19 including S-mephenytoin, clobazam, diazepam, rabeprazole, voriconazole, lansoprazole, and omeprazole. Medications not listed here that are known (or thought) to be CYP3A4 substrates may be allowed at the investigator's discretion, after consultation with the medical monitor, if administration poses little to no risk to the subject.
16. Subject has a history of drug or alcohol abuse or dependency within the last year before screening.
17. Subject has a history of an eating disorder.
18. Subject has a current or recent (<30 days before screening) history of clinically significant bacterial, fungal, or mycobacterial infection.
19. Subject has a current clinically significant viral infection.
20. Subject has a known clinically significant chronic viral infection (eg, human T cell lymphotropic virus I or II).
21. Subject has consumed grapefruit or grapefruit juice, Seville orange or Seville orange-containing products (eg, marmalade), or caffeine- or xanthine-containing products within 48 hours before the first dose of study drug or throughout the study.

22. Subject has used any prescription (excluding hormonal birth control) or over-the-counter medication (including herbal or nutritional supplements) within 14 days before the first dose of study drug.
23. Subject demonstrates long-term use (≥14 consecutive days) of glucocorticoids including oral or parenteral prednisone or equivalent (>20 mg total dose per day) or high-dose inhaled steroids (>800 mcg/day of beclomethasone dipropionate or equivalent) within the preceding 1 month (low-dose [≤800 mcg/day of beclomethasone dipropionate or equivalent] inhaled and topical steroids are allowed).
24. Subject has donated >450 mL blood or blood components within 30 days before the first dose of study drug. The investigator should instruct subjects who participate in this study to not donate blood or blood components for 4 weeks after the completion of the study.
25. Subject is a smoker or has used nicotine or nicotine-containing products (eg, cigarettes, electronic vapor cigarettes, cigars, chewing tobacco, snuff, nicotine patches, or nicotine gum) within 6 months before the first dose of study drug.
26. Subject has consumed pomegranate or pomegranate juice, pomelo fruits or pomelo juice, or alcohol within 72 hours before the first dose of study drug.
27. Subject reports participation in strenuous activity or contact sports within 24 hours before the first dose of study drug.
28. Subject has known hepatitis B or C infection or positive test for hepatitis B surface antigen, hepatitis C virus antibody, or human immunodeficiency virus type 1 or 2 antibodies at screening.
29. Subject has a positive test result for amphetamines (including methamphetamines and ecstasy/methylenedioxymethamphetamine), barbiturates, benzodiazepines, cannabinoids (including tetrahydrocannabinol), cocaine metabolites, opiates (including heroin, codeine, and oxycodone), or alcohol at screening or check-in.
30. Subject has any of the following laboratory test results within 28 days before the first dose of study drug:
    - Estimated serum creatinine clearance (Cockcroft-Gault) <90 mL/min
    - Creatinine in males >1.7 mg/dL and in females >1.4 mg/dL (1.3 times the upper central laboratory reference range)
    - Hemoglobin ≤10% of the lower central laboratory reference range
    - White blood cell count not within the central laboratory reference range
    - Absolute neutrophil count <1000 cells/mm^3
    - Platelets not within ±10% of central laboratory reference range
    - Alanine aminotransferase >1.5 times above the upper central laboratory reference range
    - Aspartate aminotransferase >1.5 times above the upper central laboratory reference range
    - Alkaline phosphatase >20% above the upper central laboratory reference range
    - Hemoglobin A1c ≥7.0%

- Cholesterol ≥300 mg/dL and low-density lipoprotein ≥190 mg/dL.

31. Subject has a sustained sitting systolic blood pressure >140 mm Hg or <100 mm Hg or a diastolic blood pressure >90 mm Hg at screening. Blood pressure may be retested twice in the sitting position at 5-minute intervals. The pressure elevation is considered sustained if either the systolic or the diastolic pressure exceeds the stated limits on all 3 assessments.
32. Subject has a resting heart rate of <40 beats per minute or >100 beats per minute at screening.
33. Subject has an abnormal ECG at screening that is determined by the investigator to be clinically significant.
34. Male subject has a QTcF >450 ms or female subject has a QTcF >470 ms at screening or Day –1.
35. In the opinion of the investigator, the subject is not suitable for entry into the study.

EVALUATION PROCEDURES:

Pharmacokinetic Assessments:

Blood samples for PK analysis of TPOXX will be collected from all subjects on Day 1 before study drug administration (0 hour), at 0.5, 1, 2, 4, 6, 8, 12 (before the PM dose), 14, 16, 18, 20, and 24 hours (before the AM dose on Day 2), on Day 6 (before the AM dose and 4 hours after the AM dose), on Day 7 before the AM dose (0 hour), at 0.5, 1, 2, 4, 6, 8, 12 (before the PM dose), 14, 16, 18, 20, and 24 hours (Day 8, 24 hours after the AM dose on Day 7), and on Day 9 (48 hours after the AM dose on Day 7).

For PK samples, the acceptable window for collection from the scheduled collection time point will be as follows: ±5 minutes for the time points from 1 to 8 hours and ±15 minutes for the 12- to 48-hour time points.

The following plasma PK parameters will be calculated for TPOXX using actual sampling times rather than scheduled sampling times and will include but are not limited to:

- Area under the plasma concentration-time curve (AUC) from time 0 to the last quantifiable measurement (AUC_{0-t})
- AUC from time 0 extrapolated to infinity ($AUC_{0-\infty}$)
- AUC from time 0 to 24 hours (AUC_{0-24})
- AUC during the first dosing interval (tau = 12 hours) (AUC_{0-tau})
- Maximum drug concentration in plasma (C_{max})
- Time to C_{max} (T_{max})
- Apparent volume of distribution (V_d/F)
- Apparent total body clearance (CL/F)
- Concentration observed prior to the next dose administration (C_{trough})
- Terminal elimination half-life ($t_{1/2}$)
- Terminal elimination rate constant (λ_z)

- Percentage of $AUC_{0-\infty}$ extrapolated from the last quantifiable measurement to infinity ($\%AUC_{extrap}$).

Safety Assessments:
Safety and tolerability will be assessed by monitoring and recording of AEs, clinical laboratory test results (hematology, serum chemistry, pregnancy, and urinalysis), vital sign measurements (systolic and diastolic blood pressures, heart rate, respiratory rate, and body temperature), 12-lead ECG results, and physical examination findings.

STUDY DRUG, DOSAGE, AND ROUTE OF ADMINISTRATION:
TPOXX, 600 mg (3 × 200-mg capsules), will be administered orally twice daily, approximately 12 hours (±30 minutes) apart, on Days 1 through 7.

STATISTICAL METHODS:
Complete, detailed statistical methods will be described in the statistical analysis plan.

Sample Size:
The sample size (N = 36 [to allow at least 32 enrolled subjects to complete]) for this study is based on clinical and practical considerations and not on a formal statistical power calculation. The sample size is considered sufficient to effectively assess the PK and safety profiles of TPOXX.

Analysis Populations:

- The Safety Population will include all subjects who receive at least 1 dose of study drug.
- The PK Population will include subjects who receive study drug and have sufficient concentration data to facilitate the calculation of PK variables.

Pharmacokinetic Analyses:
Individual plasma concentration and time deviation data will be presented in a data listing. Plasma concentration data will be listed and summarized using the following descriptive statistics: number of subjects, arithmetic mean, standard deviation (SD), coefficient of variation (CV), geometric mean, geometric CV, median, minimum, and maximum. Individual and mean plasma concentration versus time profiles will be presented in figures on both linear and semilogarithmic scales.

The PK parameters of TPOXX will be analyzed based on the actual sampling times. All parameters will be determined using noncompartmental methods using Phoenix® WinNonlin® Version 8.0 or higher (Certara, L.P., Princeton, New Jersey) or SAS® Version 9.4 or higher (SAS Institute Inc., Cary, North Carolina).

The individual PK parameters and weight-normalized PK parameters will be presented in data listings and summarized using the following descriptive statistics: number of subjects, arithmetic mean, SD, CV, median, minimum, maximum, geometric mean, geometric SD, and geometric CV.

Safety Analyses:
Adverse events will be coded by preferred term and system organ class using the latest version of the Medical Dictionary for Regulatory Activities and summarized overall. All AE data will be presented in a data listing. Treatment-emergent AEs will be summarized overall,

as well as by severity and relationship to study drug. Serious AEs and AEs leading to discontinuation of study drug will also be presented in the data listings and summarized overall.

Actual values and changes from baseline for clinical laboratory test results, vital sign measurements, and 12-lead ECG results will be summarized at each time point using descriptive statistics (number of subjects, mean, SD, median, minimum, and maximum). Shift tables will be generated for clinical laboratory test results. Clinical laboratory data, vital sign measurements, 12-lead ECG results, and physical examination findings will be presented in data listings.

DATE OF PROTOCOL: 19 February 2019

1. INTRODUCTION

1.1 BACKGROUND

Historically, variola virus (VARV), the etiologic agent of smallpox, has been one of the more important human pathogens. Smallpox is highly communicable and carries exceptionally high morbidity. Secondary attack rates from 30% to 80% have been reported among unvaccinated members of households.[1] Mortality rates range from 1% for variola minor to 30% for variola major.[1] With the advent of biowarfare as an instrument of terrorism, smallpox can no longer be thought of as a disease only of historic impact.

In July 2018, the FDA approved the oral formulation of TPOXX for the treatment of patients with human smallpox disease caused by VARV.

1.2 RATIONALE FOR STUDY

This study is being conducted as an FDA post marketing commitment to the approved New Drug Application for TPOXX. SIGA is required to conduct a study to determine the pharmacokinetic (PK) profile of TPOXX in subjects with a body weight greater than 120 kilograms (>120 kg) to determine if a change in dosing regimen would be needed in these patients.

1.3 POTENTIAL RISKS AND BENEFITS

1.3.1 Potential Risks

The effect of TPOXX on a fetus or nursing baby is not yet known; therefore, women of childbearing potential participating in this study will be required to agree to use an acceptable means of birth control from 30 days before the first dose of study drug and continuing through 30 days after the last dose of study drug. Pregnancy testing will be performed at the screening visit and checked by the investigator for negative pregnancy before administration of study drug on Day –1. Women who are pregnant or lactating or plan to become pregnant within 3 months after study drug administration will be excluded from the study; if a female subject becomes pregnant during study participation, study drug dosing will be discontinued, and the subject will be withdrawn from the study (Section 6.2.1.9).

As with all drugs, there is potential risk of an allergic reaction. At this time, there is no definitive information on the allergic activity of TPOXX. Headache and nausea have been the most common AEs in clinical studies completed to date. There may be other side effects

of TPOXX that are not yet known. Full details can be found in the TPOXX full prescribing information.[2]

1.3.2 Known Potential Benefits

As this study will be conducted in subjects free from smallpox, no direct health benefits from taking the study drug are expected. Study subjects may benefit from receiving the laboratory testing, ECGs, and physical examinations. Others may benefit from knowledge gained in this study that may aid in the development of a drug for the treatment of smallpox.

2. STUDY OBJECTIVES

2.1 PRIMARY OBJECTIVE

The primary objective of this study is to determine the PK profile of 600 mg oral TPOXX (3 × 200-mg capsules) administered twice daily (BID) for 7 days in adult subjects weighing more than 120 kg to determine if a change in dosing regimen would be needed in these patients.

2.2 SECONDARY OBJECTIVE

The secondary objective of this study is to evaluate the safety and tolerability of 600 mg oral TPOXX administered BID for 7 days in adult subjects weighing more than 120 kg.

3. STUDY DESIGN

This is an open-label, multiple-dose study to assess the safety, tolerability, and PK of TPOXX 600 mg BID when administered orally for 7 days to adult subjects weighing more than 120 kg. A total of 36 subjects, ages 18 to 50, inclusive, will be enrolled. The study will consist of a screening period (Day –28 to Day –2), a treatment and confinement period (Days –1 to 9), a follow-up telephone call or visit (Day 14 [+2 days]), and a follow-up telephone call (Day 37 [+2 days]).

Subjects will undergo screening evaluations to determine eligibility within 28 days before study drug administration. Subjects will be admitted to the study site on Day –1 to complete baseline assessments; results of these assessments must be reviewed by the investigator before dosing. Starting in the morning of Day 1, subjects will receive 600 mg oral TPOXX BID for 7 days (Days 1 through 7).

All subjects will be provided meals (consisting of approximately 600 calories and 25 g fat) 30 minutes prior to study drug administration and subjects must fast for 2 hours after taking study drug. Subjects should eat this meal within 30 minutes or less of taking study drug. Study drug and meals must be taken with water only, and no other beverage except water should be ingested within 3 hours before or 3 hours after study drug administration.

Subjects will remain confined to the study site for collection of PK samples and will be carefully monitored for safety and tolerability until discharge on Day 9. Subjects who have abnormal physical examination findings or an ongoing adverse event (AE)/serious adverse event (SAE) on Day 9 that is deemed related to study drug or per investigator or SIGA discretion will return to the study site on Day 14 (+2 days) for a follow-up visit. All other subjects will have the Day 14 (+2 days) follow-up via telephone. All subjects will have a follow-up telephone call 30 days after administration of the last dose of study drug (Day 37 [+2 days]) to report any SAEs. At the time of discharge from the clinical research unit, subjects will be instructed to notify the investigator of any SAEs that occur within 30 days after administration of the last dose of study drug. Serious AEs will be followed until the SAE is stable or until resolution as determined by the investigator and/or medical monitor.

The total duration of the study for each subject, including the screening period, treatment period, and the Day 37 (+2 days) follow-up telephone call, will be approximately 65 days.

4. STUDY POPULATION

Approximately 36 male and female subjects will be enrolled at a single center in the United States to achieve at least 32 evaluable enrolled subjects.

4.1 INCLUSION CRITERIA

Each subject must meet all the following criteria to be enrolled in this study:

1. Subject is male or female between 18 and 50 years of age, inclusive.
2. Subject has a body weight >120 kg at screening, at check-in on Day -1, and prior to dosing on Day 1.
3. Women of childbearing potential, have a negative β human chorionic gonadotropin pregnancy test (serum) at the screening visit and a confirmatory negative serum pregnancy test on Day –1 before receipt of study drug, and meet 1 of the following criteria:

a. The subject or their partner has undergone surgical sterilization

b. The subject is postmenopausal, defined as 12 consecutive months with no menses without an alternative medical cause and has a documented plasma follicle-stimulating hormone level >40 IU/mL

c. The subject agrees to be abstinent (ie, heterosexually inactive or women in a religious order)

d. The subject agrees to consistently use 1 of the following methods of contraception from the beginning of screening (which they had been consistently using for at least 30 days before the first dose of study drug) through 30 days after the last dose of study drug:

   i. Condoms, male or female, with a spermicide

      NOTE: For male subjects, condoms must be used for 90 days after the last dose of study drug.

   ii. Diaphragm or cervical cap with spermicide

   iii. Intrauterine device with spermicide

   iv. Oral contraceptives or other hormonal methods

      NOTE: Subject must agree to use an additional nonhormonal method of contraception in conjunction with oral contraceptives.

   v. Male sexual partner who had undergone a vasectomy at least 3 months before screening.

4. Male subjects must agree to not donate sperm from the first dose of study drug through 90 days after the last dose of study drug.

5. Subject is considered by the investigator to be in good general health as determined by medical history (no hospitalizations for chronic medical conditions in the previous 2 years), clinical laboratory results, vital sign measurements, 12-lead ECG results, and physical examination findings at screening.

6. Subject agrees to comply with all protocol requirements.

7. Subject is able to provide written informed consent.

8. Subject agrees to comply with the dietary requirements.

9. Subject does not intend to lose weight (diet or weight loss) from the screening visit and throughout the study.

4.2 EXCLUSION CRITERIA

Subjects meeting any of the following criteria will be excluded from the study:

1. Subject is a female who is pregnant or breastfeeding or planning to become pregnant within 3 months after the last dose of study drug.
2. Subject has a history of any clinically significant conditions including:
   - Asthma treated with oral systemic steroids within the past 6 months
   - Diabetes mellitus (type 1 or 2), with the exception of gestational diabetes
   - Hypertension that is poorly controlled (repeat readings >140 mm Hg systolic and/or >90 mm Hg diastolic)
   - Thyroidectomy or thyroid disease that required medication within the past 12 months
   - Serious angioedema episodes within the previous 3 years or requiring medication in the previous 2 years
   - Head trauma resulting in a diagnosis of traumatic brain injury other than concussion
   - Frequent episodes of headache.
3. Subject has received treatment in another clinical study of an investigational drug (or medical device) within 30 days or 5 half-lives (whichever is longer) before the first dose of study drug.
4. Subject has been previously enrolled in any clinical study involving TPOXX (tecovirimat).
5. Subject has a history of relevant drug and/or food allergies (ie, allergy to tecovirimat or excipients, or any significant food allergy that could preclude a standard diet in the study site).
6. Subject has any condition possibly affecting drug absorption (eg, previous surgery on the gastrointestinal tract, including removal of parts of the stomach, bowel, liver, gallbladder, or pancreas, with the exception of appendectomy).
7. Subject has evidence or history of clinically significant allergic (except for untreated, asymptomatic, seasonal allergies at time of the first dose of study drug), hematological, endocrine, pulmonary, gastrointestinal, cardiovascular, hepatic, psychiatric, or neurological disease. Exceptions to these criteria (eg, stable, mild joint disease unassociated with collagen vascular disease) may be made following discussions with the medical monitor.

8. Subject has a history of cardiac disease, symptomatic or asymptomatic arrhythmias, syncopal episodes, or risk factors for torsades de pointes (eg, heart failure, hypokalemia).
9. Subject has a family history of sudden cardiac death not clearly due to acute myocardial infarction.
10. Subject has a seizure disorder or history of seizures (does not include childhood febrile seizures) or a past history that increases seizure risks such as significant head injury that caused loss of consciousness or other changes in the subject's daily function, concussion, stroke, central nervous system infection or disease, or alcohol or drug abuse or family history of idiopathic seizures.
11. Subject has a history of a peptic ulcer or significant gastrointestinal bleed.
12. Subject has a bleeding disorder diagnosed by a doctor (eg, factor deficiency, coagulopathy, or platelet disorder requiring special precautions) or significant bruising or bleeding difficulties with blood draws.
13. Subject has a malignancy that is active, or treated malignancy for which there is not reasonable assurance of sustained cure, or malignancy that is likely to recur during the period of the study (subject should be in complete remission for at least 5 years).
14. Subject has neutropenia or other blood dyscrasia determined to be clinically significant by the investigator.
15. Subject has used any of the following prohibited medications from within 7 days (or 5 half-lives, whichever is longer) before the first dose of study drug: antidiabetic medication; anticoagulants; anticonvulsants; substrates of the BCRP transporter including methotrexate, mitoxantrone, imatinib, irinotecan, lapatinib, rosuvastatin, sulfasalazine, and topotecan; substrates of CYP2C8 including repaglinide, paclitaxel, Montelukast, pioglitazone, rosiglitazone; and substrates of CYP2C19 including S-mephenytoin, clobazam, diazepam, rabeprazole, voriconazole, lansoprazole, and omeprazole. Medications not listed here that are known (or thought) to be CYP3A4 substrates may be allowed at the investigator's discretion, after consultation with the medical monitor, if administration poses little to no risk to the subject.
16. Subject has a history of drug or alcohol abuse or dependency within the last year before screening.
17. Subject has a history of an eating disorder.

18. Subject has a current or recent (<30 days before screening) history of clinically significant bacterial, fungal, or mycobacterial infection.
19. Subject has a current clinically significant viral infection.
20. Subject has a known clinically significant chronic viral infection (eg, human T cell lymphotropic virus I or II).
21. Subject has consumed grapefruit or grapefruit juice, Seville orange or Seville orange-containing products (eg, marmalade), or caffeine- or xanthine-containing products within 48 hours before the first dose of study drug or throughout the study.
22. Subject has used any prescription (excluding hormonal birth control) or over-the-counter medication (including herbal or nutritional supplements) within 14 days before the first dose of study drug.
23. Subject demonstrates long-term use (≥14 consecutive days) of glucocorticoids including oral or parenteral prednisone or equivalent (>20 mg total dose per day) or high-dose inhaled steroids (>800 mcg/day of beclomethasone dipropionate or equivalent) within the preceding 1 month (low-dose [≤800 mcg/day of beclomethasone dipropionate or equivalent] inhaled and topical steroids are allowed).
24. Subject has donated >450 mL blood or blood components within 30 days before the first dose of study drug. The investigator should instruct subjects who participate in this study to not donate blood or blood components for 4 weeks after the completion of the study.
25. Subject is a smoker or has used nicotine or nicotine-containing products (eg, cigarettes, electronic vapor cigarettes, cigars, chewing tobacco, snuff, nicotine patches, or nicotine gum) within 6 months before the first dose of study drug.
26. Subject has consumed pomegranate or pomegranate juice, pomelo fruits or pomelo juice, or alcohol within 72 hours before the first dose of study drug.
27. Subject reports participation in strenuous activity or contact sports within 24 hours before the first dose of study drug.
28. Subject has known hepatitis B or C infection or positive test for hepatitis B surface antigen, hepatitis C virus antibody, or human immunodeficiency virus type 1 or 2 antibodies at screening.
29. Subject has a positive test result for amphetamines (including methamphetamines and ecstasy/methylenedioxymethamphetamine), barbiturates, benzodiazepines,

cannabinoids (including tetrahydrocannabinol), cocaine metabolites, opiates (including heroin, codeine, and oxycodone), or alcohol at screening or check-in.

30. Subject has any of the following laboratory test results within 28 days before the first dose of study drug:
    - Estimated serum creatinine clearance (Cockcroft-Gault) <90 mL/min
    - Creatinine in males >1.7 mg/dL and in females >1.4 mg/dL (1.3 times the upper central laboratory reference range)
    - Hemoglobin ≤10% of the lower central laboratory reference range
    - White blood cell count not within the central laboratory reference range
    - Absolute neutrophil count <1000 cells/mm^3
    - Platelets not within ±10% of central laboratory reference range
    - Alanine aminotransferase >1.5 times above the upper central laboratory reference range
    - Aspartate aminotransferase >1.5 times above the upper central laboratory reference range
    - Alkaline phosphatase >20% above the upper central laboratory reference range
    - Hemoglobin A1c ≥7.0%
    - Cholesterol ≥300 mg/dL and low-density lipoprotein ≥190 mg/dL.
31. Subject has a sustained sitting systolic blood pressure >140 mm Hg or <100 mm Hg or a diastolic blood pressure >90 mm Hg at screening. Blood pressure may be retested twice in the sitting position at 5-minute intervals. The pressure elevation is considered sustained if either the systolic or the diastolic pressure exceeds the stated limits on all 3 assessments.
32. Subject has a resting heart rate of <40 beats per minute or >100 beats per minute at screening.
33. Subject has an abnormal ECG at screening that is determined by the investigator to be clinically significant.
34. Male subject has a QTcF >450 ms or female subject has a QTcF >470 ms at screening or Day –1.
35. In the opinion of the investigator, the subject is not suitable for entry into the study.

4.3 OTHER SCREENING CONSIDERATIONS

4.3.1 Subject Restrictions During the Study

- Subjects must be willing to remain confined at the study site from check-in (Day –1) until safety assessments are completed on Day 9.
- Subjects who have abnormal physical examination findings or an ongoing AE/SAE on Day 9 that is deemed related to study drug or per investigator or SIGA discretion will return to the study site on Day 14 (+2 days) for a follow-up visit.

4.4 WITHDRAWAL OF SUBJECTS FROM THE STUDY

4.4.1 Reasons for Withdrawal

Subjects can withdraw consent and discontinue from the study at any time, for any reason, without prejudice to further treatment.

The investigator may withdraw a subject from the study for any of the following:

- The subject is in violation of the protocol.
- The subject experiences a serious or intolerable AE.
- The subject becomes pregnant.
- The subject is noncompliant.
- The subject has laboratory abnormalities for assessments listed in Sections 4.1 or 4.2 that meet Grade 3 or Grade 4 on the Division of Acquired Immune Deficiency Syndrome (DAIDS) AE Grading Table Version 2.1 July 2017, any other Grade 3 or Grade 4 AE; or a Grade 2 or higher rash considered by the investigator to be possibly, probably, or definitely related to study drug.
- The subject develops, during the course of the study, symptoms or conditions listed in the exclusion criteria.
- The subject requires a medication prohibited by the protocol.
- The subject requests an early discontinuation for any reason.
- The subject′s primary care provider requests that the subject be withdrawn.

- The independent safety monitor (ISM), SIGA, or the FDA requests subject withdrawal based on study safety findings.

The investigator can also withdraw a subject upon the request of SIGA or if SIGA terminates the study. Upon occurrence of a SAE or intolerable AE, the investigator will confer with SIGA. If a subject is discontinued because of an AE, the event will be followed until it is resolved or stabilized as determined by the investigator and/or the medical monitor.

4.4.2 Handling of Withdrawals

Subjects are free to withdraw from the study at any time upon request. Subject participation in the study may be stopped at any time at the discretion of the investigator or at the request of SIGA.

When a subject withdraws from the study, the reason(s) for withdrawal will be recorded by the investigator in the electronic case report form (eCRF). Whenever possible, any subject who withdraws from the study prematurely will undergo all Day 9/early discontinuation assessments (Table 9-1). Any subject who fails to return for final assessments will be contacted by the study site personnel in an attempt to have them comply with the protocol. The status of subjects who fail to complete final assessments will be documented in the eCRF.

4.4.3 Halting Rules

The medical monitor, investigator, SIGA, and ISM will review all AEs. All AEs determined by the investigator to be severe and possibly, probably, or definitely related to study drug, as well as all clinical assessments, laboratory test results, ECG results, or vital sign measurements that meet Grade 3 criteria on the DAIDS AE Grading Table will be assessed by the medical monitor, who will make a recommendation as to whether or not halting of the study should occur. At the discretion of the medical monitor, depending on the assessment of the severity of the event, the recommendation to halt the study may be made after consultation with the investigator, SIGA, and the ISM.

The study will be temporarily halted (no new enrollments and no further study drug administration) by the investigator and the medical monitor, SIGA, and the ISM will be promptly notified according to the following criteria:

- One subject experiences a Grade 4 AE assessed as possibly, probably, or definitely related to study drug.

- There is a subject death assessed as possibly, probably, or definitely related to study drug.
- One subject experiences a seizure assessed as possibly, probably, or definitely related to study drug.
- Two or more subjects experience the same or similar SAEs that are possibly, probably, or definitely related to the study drug.
- Three or more subjects experience the same or similar AEs that are Grade 3 or above and are possibly, probably, or definitely related to the study drug.

Study enrollment and study drug administration would resume if review of the AEs that caused the halt resulted in a recommendation to permit further continuation. In such an instance, SIGA, with participation by the investigator and the medical monitor, would consult with the ISM to conduct the review of all AEs that meet the criteria for halting the study. The study would remain suspended until the events were reviewed by the ISM and a recommendation was made as to whether the study should be continued or stopped. This constitutes a minimum criterion, and the decision to halt the study may be made based on any other criteria that, in the judgment of the investigator, with agreement of the medical monitor and ISM, indicate a potentially serious safety concern. The investigator will advise SIGA immediately if any of the halting rules are met.

4.4.4 Replacements

At the discretion of the investigator, and after consultation with the medical monitor, any subject who withdraws before completing the study may be replaced to retain the target of 32 evaluable enrolled subjects.

5. STUDY TREATMENT

5.1 TREATMENT ADMINISTERED

On Days 1 to 7, all subjects will receive an oral dose of TPOXX 600 mg (3 × 200-mg capsules) BID, approximately 12 hours (±30 minutes) apart, for 7 days.

All subjects will be provided meals consisting of approximately 600 calories and 25 g fat, 30 minutes before study drug administration. Subjects should eat this meal within 30 minutes or less of taking study drug. Study drug will be administered approximately 30 minutes after the start of the meal. All doses of study drug will be administered to subjects by study site personnel with approximately 240 mL of water. Subjects must fast 2 hours after taking study

drug. Study drug and meals must be taken with water only, and no other beverage except water should be ingested within 3 hours before or 3 hours after study drug administration.

5.2 STUDY DRUG

TPOXX will be supplied as 200-mg capsules containing tecovirimat monohydrate as the active pharmaceutical ingredient. The TPOXX capsules are immediate release, size 0, orange and black, hard gelatin capsules containing white to off white powder. All inactive ingredients/excipients are generally recognized as safe and are United States Pharmacopeia/National Formulary grade. The TPOXX excipients are shown in Table 5-1.

Table 5-1 Excipients of TPOXX Capsules

Component	Quality Designation
Microcrystalline cellulose	NF[a]
Lactose monohydrate	NF
Croscarmellose sodium	NF[a]
Colloidal silicon dioxide	NF
Hydroxypropyl methylcellulose	USP
Sodium lauryl sulfate	NF
Purified water[b]	USP
Magnesium stearate	NF

Abbreviations: NF, National Formulary; USP, United States Pharmacopeia.

[a] Microcrystalline cellulose and croscarmellose sodium are added as intragranular and extragranular excipients.

[b] Removed during processing.

Compendial components are tested and released in accordance with full compendial methods and specifications before their use in clinical formulations. TPOXX 200-mg capsules are manufactured and analyzed for clinical use in accordance with Current Good Manufacturing Practices.

TPOXX capsules are manufactured by:
Catalent Pharma Solutions
1100 Enterprise Drive
Winchester, KY 40391.

Further information on TPOXX can be found in the TPOXX full prescribing information.[2]

5.2.1 Study Drug Packaging and Storage

TPOXX capsules are packaged, labeled, distributed, and placed on stability testing in accordance with Current Good Manufacturing Practice and International Council for Harmonisation (ICH) guidelines.

The 200-mg TPOXX capsules are supplied in 75-mL high density polyethylene bottles fitted with a heat induction seal and child-resistant screw cap closure system. Each bottle of study drug will contain 42 capsules and will be labeled with the drug name, SIGA's name, a space to fill in the protocol number, and a space to fill in the bottle number.

SIGA (or designee) will provide the investigator and study site with adequate quantities of TPOXX.

All study drug must be stored in a secure area (eg, a locked cabinet), protected from moisture and light, and stored at 15°C to 30°C (59°F to 86°F). Study drug should not be refrigerated or used beyond the expiration dates provided by the manufacturer. The study site will be required to keep a temperature log to establish a record of compliance with these study drug storage conditions. All study drug will be kept in a secure cabinet or room with access restricted to necessary study site personnel.

5.2.2 Study Drug Accountability

The investigator will maintain accurate records of receipt of all study drug, including dates of receipt. Accurate records will be kept regarding when and how much study drug is dispensed and used by each subject in the study. Reasons for departure from the expected dispensing regimen must also be recorded. Study drug accountability will be recorded in the subject source documentation, entered into the eCRF, and should be reviewed by the monitor during each monitoring visit. On a regular basis and at the completion of the study, to satisfy regulatory requirements regarding drug accountability, all study drug will be reconciled and retained or destroyed according to applicable regulations.

5.3 TREATMENT COMPLIANCE

All doses of the study drug will be administered in the study site under direct observation of study site personnel and recorded in the eCRF. Per standard clinic procedure, study site personnel will perform a mouth check and inspect all dose containers to ensure that the entire dose was administered. Following completion of dosing procedures and return of dosing containers to the pharmacy by team members, pharmacy staff will follow standard clinic

procedures for study drug reconciliation. SIGA will provide information to PPD for destruction of returned used and unused study drug and study drug bottles.

The date and time of study drug dosing will be captured and recorded on the appropriate page of the eCRF. If a subject is not administered study drug, the reason for the missed dose will be recorded.

5.3.1 Prior and Concomitant Medications

Restrictions for prior and concomitant medications and therapies are provided in Sections 4.1 and 4.2. Prior and concomitant medications and therapies will be coded using the latest version of the World Health Organization Drug Dictionary.

5.3.1.1 Prior Medications

Information regarding prior medications taken by the subject within the 30 days before signing the informed consent form (ICF) will be recorded in the subject's eCRF.

5.3.1.2 Concomitant Medications

Any concomitant medication deemed necessary for the welfare of the subject during the study may be given at the discretion of the investigator. If a concomitant medication listed in Section 4.2 is taken it will be documented as a protocol deviation and a joint decision will be made by the investigator and SIGA to continue or discontinue the subject based on the time the medication was administered, its pharmacology and PK, and whether the use of the medication will compromise the safety of the subject or the interpretation of the data. The investigator is responsible for ensuring that details regarding the medication are adequately recorded in both the subject's source document and the eCRF.

6. STUDY PROCEDURES

Before performing any study procedures, all potential subjects will sign an ICF as outlined in Section 9.3.2.3. Subjects will undergo study procedures at the time points specified in the schedule of events (Table 9-1).

The total amount of blood collected from each subject over the duration of the study, including any extra assessments that may be required, will not exceed 500 mL.

6.1 PHARMACOKINETIC ASSESSMENTS AND ENDPOINTS

Blood samples for PK analysis of TPOXX will be collected from all subjects Day 1 before study drug administration (0 hour), at 0.5, 1, 2, 4, 6, 8, 12 (before the PM dose), 14, 16, 18, 20, and 24 hours (before the AM dose on Day 2), on Day 6 (before the AM dose and 4 hours after the AM dose), on Day 7 before the AM dose (0 hour), at 0.5, 1, 2, 4, 6, 8, 12 (before the PM dose), 14, 16, 18, 20, and 24 hours (Day 8, 24 hours after the AM dose on Day 7), and on Day 9 (48 hours after the AM dose on Day 7).

For PK samples, the acceptable window for collection from the scheduled collection time point will be as follows: ±5 minutes for the time points from 1 to 8 hours and ±15 minutes for the 12- to 48-hour time points.

The following plasma PK parameters will be calculated for TPOXX using actual sampling times rather than scheduled sampling times and will include but are not limited to:

- Area under the plasma concentration-time curve (AUC) from time 0 to the last quantifiable measurement (AUC_{0-t})
- AUC from time 0 extrapolated to infinity ($AUC_{0-\infty}$)
- AUC from time 0 to 24 hour (AUC_{0-24})
- AUC during the first dosing interval (tau = 12 hours) (AUC_{0-tau})
- Maximum drug concentration in plasma (C_{max})
- Time to C_{max} (T_{max})
- Apparent volume of distribution (V_d/F)
- Apparent total body clearance (CL/F)
- Concentration observed prior to the next dose administration (C_{trough})
- Terminal elimination half-life ($t_{1/2}$)
- Terminal elimination rate constant (λ_z)
- Percentage of $AUC_{0-\infty}$ extrapolated from the last quantifiable measurement to infinity ($\%AUC_{extrap}$).

6.1.1 Pharmacokinetic Sample Collection, Shipping, and Storage

Blood samples (approximately 5 mL) for the determination of plasma concentrations of TPOXX will be collected in 5-mL lavender-topped K_3EDTA Vacutainer® tubes using a 21 gauge or larger needle, or from an indwelling intravenous catheter using a vacutainer tube. Blood samples should be placed on wet ice or equivalent (approximately 4°C to 8°C) and kept at this temperature until processed to separate plasma.

The exact time and date of sample collection will be recorded for each sample by the investigator or designee on the subject's eCRF, the vacutainer and cryovial labels, and the specimen shipping log. In addition, the time of study drug administration before PK sampling will be recorded on the subject's eCRF. Labels will be created by the site and should contain the protocol number, matrix (plasma), subject number, date, and time drawn. For information that is not preprinted on the label, a fine tipped indelible marking pen is to be used to complete the entry.

The 5-mL blood sample will be centrifuged in a refrigerated centrifuge immediately, if possible, or within 60 minutes of collection at 1000 to 1200 × *g* (2000 to 3000 rpm) for 10 minutes to separate plasma. Each plasma sample should be transferred via pipette into 2 cryovials labeled as described previously and should be capped tightly. The second tube will be a duplicate and retained at the site as a backup sample. If red blood cells are inadvertently drawn into the plasma, the sample should be re-centrifuged as soon as possible. Adequate space between the solution and the tube cap should be allowed for expansion during freezing.

Cryovial tubes containing plasma samples must be frozen at –70°C or below until shipment in a freezer equipped with a temperature monitor and temperature-activated alarm. Uncentrifuged specimens should not be frozen.

The study site will batch ship sets of frozen plasma samples. A log sheet listing the samples being shipped will be included in each shipment. The samples will be sent on dry ice via courier to Alturas Analytics (Moscow, ID). The back-up sets will remain at the site until confirmation that the first sets have been received. After receipt confirmation is received from Alturas Analytics, the back-up sets should be shipped. The site will contact Alturas Analytics and coordinate the shipment prior to sending the samples. Shipments before weekends or holidays must be avoided.

The samples will be shipped for analysis to:

Alturas Analytics
1324 Alturas Drive
Moscow, ID 83843

The bioanalytical laboratory will store all plasma samples at –70°C until analysis for tecovirimat is complete. SIGA will advise Alturas to destroy any remaining plasma samples after regulatory review is complete or the samples have met their applicable length of stability, whichever comes sooner.

6.1.2 Pharmacokinetic Sample Analysis

Pharmacokinetic samples will be analyzed by Alturas Analytics using a validated liquid chromatography coupled with tandem mass spectrometry assay for tecovirimat in human plasma method in accordance with the US FDA Guidance for Industry on Bioanalytical Method Validation.[3]

6.2 SAFETY ASSESSMENTS AND ENDPOINTS

Safety and tolerability will be assessed by monitoring and recording of AEs, clinical laboratory test results (hematology, serum chemistry, pregnancy, and urinalysis), vital sign measurements (systolic and diastolic blood pressures, heart rate, respiratory rate, and body temperature), 12-lead ECG results, and physical examination findings. Adverse events will be assessed from the time of the first dose of study drug until the follow-up telephone call on Day 37 (+2 days).

6.2.1 Adverse Events

6.2.1.1 Adverse Event Definitions

The investigator is responsible for reporting all AEs that are observed or reported during the study, regardless of their relationship to study drug or clinical significance. If there is any doubt as to whether a clinical observation is an AE, the event should be reported.

An AE is any event or other untoward medical occurrence, including those AEs that result from dosing errors, which may present during administration of a study drug or during a reasonable follow-up period and which does not necessarily have a causal relationship with this treatment. An AE is any unfavorable and unintended sign (eg, a clinically significant

abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal product, whether or not considered to be related to the medicinal product. All AEs will be followed until the AE is resolved or stabilized as determined by the investigator and/or the medical monitor.

A treatment-emergent AE (TEAE) is defined as any event not present before exposure to study drug or any event already present that worsens in intensity or frequency after exposure to study drug.

An adverse reaction is any AE caused by a drug. Adverse reactions are a subset of all suspected adverse reactions for which there are reasons to conclude that the drug caused the event.

A suspected adverse reaction is any AE for which there is a reasonable possibility that the study drug caused the AE. For the purposes of IND safety reporting, "reasonable possibility" means that there is evidence to suggest a causal relationship between the drug and the AE. A suspected adverse reaction implies a lesser degree of certainty about causality than adverse reaction, which means any AE caused by a study drug.

An AE or suspected adverse reaction is considered "unexpected" if it is not listed in the TPOXX full prescribing information or at the specificity or severity that has been observed with the study drug being tested. For example, under this definition, hepatic necrosis would be unexpected (by virtue of greater severity) if the TPOXX full prescribing information referred only to elevated hepatic enzymes or hepatitis. Similarly, cerebral thromboembolism and cerebral vasculitis would be unexpected (by virtue of greater specificity) if the TPOXX full prescribing information listed only cerebral vascular accidents. "Unexpected," as used in this definition, also refers to AEs or suspected adverse reactions that are mentioned in the TPOXX full prescribing information as occurring with a class of drugs or as anticipated from the pharmacological properties of the drug, but are not specifically mentioned as occurring with the particular drug under investigation.

An AE or suspected adverse reaction is considered an SAE if, in the view of either the investigator or SIGA, it results in any of the following outcomes:

- Results in death.
- Is life threatening (subject is at immediate risk of death at the time of the event).
- Requires inpatient hospitalization or prolongation of existing hospitalization, other than elective hospitalization, during the period of protocol defined surveillance.

- Results in congenital anomaly or birth defect.
- Results in a persistent or significant disability/incapacity.
- Any other important medical event that may not result in death, be life threatening, or requires hospitalization may be considered an SAE when, based on appropriate medical judgment, the event may jeopardize the subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition or is otherwise considered to be medically significant.

Important medical events that may not result in death, be life threatening, or require hospitalization may be considered serious when, based upon appropriate medical judgement, they may jeopardize the subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. Examples of such medical events include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse.

An AE or suspected adverse reaction is considered “life-threatening” if, in the view of either the investigator or SIGA, its occurrence places the subject at immediate risk of death. It does not include an AE or suspected adverse reaction that, had it occurred in a more severe form, might have caused death.

Serious AEs will be followed until the SAE is stable or until resolution as determined by the investigator and/or the medical monitor.

6.2.1.2 Eliciting and Documenting Adverse Events

The investigator is responsible for ensuring that all AEs and SAEs are recorded in the eCRF and reported to SIGA by PPD. Adverse events and SAEs will be assessed from the first dose of study drug through the telephone call on Day 37 (+2 days).

At every study visit or assessment, subjects will be asked a standard question to elicit any medically related changes in their well-being. They will also be asked if they have been hospitalized, had any accidents, used any new medications, or changed concomitant medication regimens (both prescription and over-the-counter medications).

In addition to subject observations, AEs will be documented from any data collected on the AE page of the eCRF (eg, laboratory values, physical examination findings, and ECG changes) or other documents that are relevant to subject safety.

6.2.1.3 Reporting Adverse Events

All AEs reported or observed from the first dose of study drug through the follow-up telephone call on Day 37 (+2 days) will be recorded on the AE page of the eCRF. Information to be collected includes drug treatment, type of event, date and time of onset, investigator-specified assessment of severity and relationship to study drug, date and time of resolution of the event, seriousness, as well as any required treatment or evaluations, and outcome. Adverse events resulting from concurrent illnesses, reactions to concurrent illnesses, reactions to concurrent medications, or progression of disease states must also be reported.

All AEs will be followed until they are resolved or stabilized as determined by the investigator and/or medical monitor. These data will be reviewed on an ongoing basis by the study coordinator, the investigator, the medical monitor, and the ISM. This requirement indicates that for some events, follow-up may be required after the subject has completed study participation. These events will be reported by SIGA, as required, to the FDA.

Any medical condition that is present at the time that the subject is screened but does not deteriorate should not be reported as an AE. However, if it deteriorates at any time during the study, it should be recorded as an AE. Prior to this, medical conditions reported by subjects are considered medical history.

6.2.1.4 Reporting of Serious Adverse Events

Any AE considered serious by the investigator or which meets SAE criteria (Section 6.2.1.1), or any other event or condition regardless of grade, which in their judgment represents a reportable event, must be reported to the medical monitor and SIGA as soon as the investigator becomes aware of the event. In addition, the event must be reported to PPD via the SAE hotline. The PPD SAE Report Form must be submitted within 24 hours of knowledge of the event. SIGA (or designee) will be responsible for notifying the relevant regulatory authorities of any SAE as outlined in US Title 21 Code of Federal Regulations (CFR) Parts 312 and 320. The investigator is responsible for notifying the institutional review board (IRB) directly.

In addition, the investigator (or designee) must report any Grade 3 (severe) AE that they deem possibly, probably, or definitely related to study drug to the medical monitor and SIGA within 24 hours after becoming aware of the event.

After notification from the investigator, SIGA will report all study drug-related and unexpected SAEs (those not listed in the TPOXX full prescribing information) to the FDA within 15 calendar days of first knowledge. Fatalities or life-threatening events assessed as related and unexpected will be reported to the FDA within 7 calendar days of first knowledge. The ISM will also receive these reports.

The following contact information is to be used for SAE reporting:

PPD Medical Monitor: Rahul Bhatnagar, MD
PPD Phase I Clinic
7551 Metro Center Drive, Suite 300
Austin, TX 78744
Telephone: 888-483-7729

PPD SAE Hotline: 888-483-7729
PPD SAE Fax line: 888-529-3580

The collection and monitoring period for SAEs is 30 days after administration of the last dose of study drug. At the time of discharge or early termination from the study site, the subject will be instructed to notify the investigator of any SAEs that occur within 30 days after the last dose of study drug.

All subjects will have a follow-up telephone call 30 days after administration of the last dose of study drug (Day 37 [+2 days]) to report any SAEs.

6.2.1.5 Assessment of Severity

All AEs will be graded for intensity according to the current DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events Version 2.1 July 2017.

Any laboratory or clinical AE that is not listed on the DAIDS Table will be assessed for severity and classified into 1 of 5 clearly defined categories as follows:

- Grade 1 (Mild): Events require minimal or no treatment and do not interfere with the subject's daily activities.
- Grade 2 (Moderate): Events result in a low level of inconvenience or concern with the therapeutic measures and may cause some interference with normal functioning.

- Grade 3 (Severe): Events interrupt a subject's usual daily activity, may require systemic drug therapy or other treatment, and are usually incapacitating.

- Grade 4 (Life-threatening): Event that, in the opinion of the investigator, places the subject at immediate risk of death from the reaction as it occurred (ie, it does not include a reaction that, had it occurred in a more severe form, might have caused death).

- Grade 5 (Death).

Changes in the severity of an AE should be documented to allow an assessment of the duration of the event at each level of intensity to be performed. An AE characterized as intermittent requires documentation of onset and duration of each episode.

6.2.1.6 Assessment of Causality

Any occurrence of an AE will be assessed for relationship to the study drug. A causal relationship means that the study drug caused (or is reasonably likely to have caused) the AE. This usually implies a relationship in time between the drug and the AE; for example, the AE occurred shortly after the subject received the study drug.

The investigator who examines and evaluates the subject will determine AE causality based on the temporal relationship to administration of the study drug, the pharmacology of the study drug, and their clinical judgment. Terms used to describe the degree of causality between a study drug and an AE are definitely related, probably related, possibly related, unlikely related, or not related.

The best estimate at the time of reporting of an event and the degree of certainty about the causal relationship between the study drug administration and the AE will be graded as follows:

Associated

- Definitely Related: The AE and administration of study drug are related in time, and a direct association can be demonstrated (eg, the event disappears or decreases with reduction in dose or cessation of study drug and recurs with re-exposure).

- Probably Related: The AE and administration of study drug are reasonably related in time and/or follow a known pattern of response, and the AE is more likely explained by study drug than other causes.

- Possibly Related: The AE and administration of study drug are reasonably related in time and/or follow a known pattern of response, but the AE can be explained equally well by causes other than study drug (eg, could readily have been produced by the subject's clinical state or could have been due to environmental or other interventions).

Not Associated

- Unlikely Related: A potential relationship between study drug and the AE could exist (ie, the possibility cannot be excluded), but the AE is most likely explained by causes other than the study drug (eg, could readily have been produced by the subject's clinical state or could have been due to environmental or other interventions).

- Not Related: The AE is clearly due to extraneous causes (eg, underlying disease, environment) or exposure to the study drug has not occurred. Such events MUST have an alternative, definitive etiology documented in the subject's medical record.

6.2.1.7 Follow-up of Adverse Events

All AEs must be reported in detail on the appropriate page of the eCRF and followed until they are resolved or stabilized as determined by the investigator and/or medical monitor.

6.2.1.8 Reactogenicity

At this time, there is no definitive information on allergic activity of TPOXX. Reactogenicity will be monitored in subjects during the study treatment period. The study site personnel will observe the subjects for signs of allergic reaction for at least 1 hour after the study drug is ingested.

6.2.1.9 Reporting of Pregnancy

Pregnant women are not eligible to participate in the study. Subjects must be counseled regarding prevention of pregnancy and encouraged to make every effort to avoid pregnancy during study participation. If a female subject becomes pregnant during study participation, study drug dosing will be discontinued, and the subject will be withdrawn from the study. The pregnancy itself is not considered an SAE. However, the investigator must complete the pregnancy report form and fax it to PPD Pharmacovigilance within 24 hours of knowledge of the pregnancy. After delivery or termination of pregnancy, the follow-up pregnancy report form should be completed and submitted via fax to PPD Pharmacovigilance. Spontaneous abortions should always be reported as SAEs. Pregnancy data will be captured and followed

by PPD. All pregnancies and outcomes will be tracked. The case will not be closed until after the child is followed for 3 months.

If there are complications during the pregnancy, the complications will be recorded as AEs in the usual manner. The subject will be asked to report the outcome of the pregnancy. If there is a congenital anomaly in the infant, this will be recorded as an SAE in the data forms for the mother (ie, the study subject).

If a subject becomes pregnant during the study after receiving the study drug, all safety evaluations will be collected as per protocol. In addition, at the time that the pregnancy is reported, consent will be requested to contact the subject and her physician in the postpartum period to assess delivery and health status of the neonate.

If the partner of a male subject becomes pregnant, the partner will be asked for consent to allow her treating physician to provide SIGA or its designee with follow-up information regarding the pregnancy and its outcome.

6.2.2 Clinical Laboratory Testing

Clinical laboratory tests will be performed by the PPD Central Laboratory. Blood samples will be collected at the time points indicated in the schedule of events (Table 9-1) and will be prepared using standard procedures.

Repeat clinical laboratory tests may be performed at the discretion of the investigator, if necessary, to evaluate inclusion and exclusion criteria or clinical laboratory abnormalities. PPD central laboratory will provide the reference ranges for all clinical laboratory safety parameters.

The following clinical laboratory assessments will be performed:

Hematology	Hematocrit, hemoglobin, mean corpuscular hemoglobin, mean corpuscular hemoglobin concentration, total and differential leukocyte count (basophils, eosinophils, lymphocytes, monocytes, neutrophils), mean corpuscular volume, platelet count, red blood cell count, and red cell distribution width
Serum Chemistry	Alanine aminotransferase, albumin, alkaline phosphatase, anion gap, aspartate aminotransferase, bilirubin (total), blood urea nitrogen, calcium, carbon dioxide, chloride, creatinine clearance (calculated[a]), gamma-glutamyltransferase, globulin, glucose, lactate dehydrogenase, phosphorus, potassium, sodium, total protein, and uric acid

Urinalysis	Appearance, bilirubin, blood, color, glucose, ketones, leukocytes, microscopy (performed if dipstick is ≥1+; includes bacteria, cast, crystals, epithelial cells, red blood cells, and white blood cells), nitrates, pH, protein, specific gravity, turbidity, and urobilinogen

[a] Creatinine clearance (CLcr) will be calculated using the Cockcroft-Gault formula:

$$CLcr\ (mL/min) = \frac{[140 - age(years)] \times weight\ (kg)}{72\ \times serum\ creatinine\ (mg/dL)}\{\times 0.85\ if\ female\}$$

Glycosylated hemoglobin A1c and a fasting lipid panel including cholesterol (total, high-density lipoprotein, calculated low-density lipoprotein, and triglycerides) will be performed at screening.

Serum pregnancy test (β human chorionic gonadotropin) for women of childbearing potential will be performed at screening and on Day –1.

A serum follicle-stimulating hormone test for postmenopausal women will be performed at screening.

Human immunodeficiency virus (type 1 and 2) antibodies, hepatitis B surface antigen, and hepatitis C virus antibody will be assessed at screening only.

A urine drug screen for alcohol, amphetamines (including methamphetamines and ecstasy/methylenedioxymethamphetamine), barbiturates, benzodiazepines, cannabinoids (including tetrahydrocannabinol), cocaine metabolites, and opiates (including heroin, codeine, and oxycodone) will be performed at screening and on Day –1.

Abnormal clinical laboratory values will be flagged as either high or low (or normal or abnormal) based on the reference ranges for each laboratory parameter. The investigator will determine whether any of the abnormally high or low results are clinically significant or not clinically significant. Clinical significance is defined as any variation in results that has medical relevance and may result in an alteration in medical care (eg, active observation, diagnostic measures, or therapeutic measures). If a clinically significant change from the screening value is noted, the clinically significant value and reason for clinical significance will be documented on the AE page of the eCRF. The investigator will continue to monitor the subject with additional assessments until the values have reached the reference range or the values at screening or until the investigator determines that follow-up is no longer medically necessary.

6.2.3 Medical History

A complete medical history will be obtained, including a review of systems, recreational and prescription drug use, over-the-counter drug use, nicotine and alcohol use, and past hospitalizations.

6.2.4 Vital Sign Measurements

Vital signs will be measured after the subject has been seated for at least 5 minutes at the time points indicated in the schedule of events (Table 9-1).

Vital sign measurements will include systolic and diastolic blood pressures, heart rate, respiratory rate, and body temperature.

When procedures are overlapping and occurring at the same time point, the order of procedures should be ECG, vital sign measurements, and then blood collection, with the blood collection scheduled to occur at the nominal time point, unless dictated by other study events happening at that time, such as dosing requirements.

The investigator will determine whether any of the vital sign measurements are clinically significant or not clinically significant. Clinical significance is defined as any variation in results that has medical relevance and may result in an alteration in medical care (eg, active observation, diagnostic measures, or therapeutic measures). If a clinically significant change from the screening values is noted, the clinically significant value and reason for clinical significance will be documented on the AE page of the subject's eCRF. The investigator will continue to monitor the subject with additional assessments until the value has reached the reference range or the value at screening or until the investigator determines that follow up is no longer medically necessary.

6.2.5 Electrocardiograms

A 12-lead ECG will be obtained after the subject has been in the supine position for at least 10 minutes at the time points indicated in the schedule of events (Table 9-1). On Days 1, 4, and 7, an ECG will be recorded 4 hours after the AM study drug administration. The acceptable window for collection from the scheduled collection time point will ±15 minutes.

Electrocardiogram assessments will include comments on whether the tracings are normal or abnormal, rhythm, presence of arrhythmia or conduction defects, morphology, any evidence of myocardial infarction, or ST segment, T wave, and U wave abnormalities. In addition, the

following parameters will be measured and reported: heart rate; PR, RR, and QT intervals; QTcF; QT interval corrected using Bazett's formula; and QRS duration. All ECGs must be performed by an experienced ECG technician.

The investigator will determine whether any of the 12-lead ECG results are clinically significant or not clinically significant. Clinical significance is defined as any variation in results that has medical relevance and may result in an alteration in medical care (eg, active observation, diagnostic measures, or therapeutic measures). If a clinically significant change from screening is noted, the clinically significant value and reason for clinical significance will be documented on the AE page of the subject's eCRF. The investigator will continue to monitor the subject with additional assessments until either the values have reached reference range or the values at screening or until the investigator determines that follow-up is no longer medically necessary.

6.2.6 Physical Examinations

A full physical examination will be performed at the time points indicated in the schedule of events (Table 9-1) and will include assessment of the following body systems: head, ears, eyes, nose, and throat; cardiac (including auscultation of heart); pulmonary (chest) auscultation of lungs; abdomen; skin; musculoskeletal system; lymphatic system; and neurologic system (cranial nerves, sensation, motor function, coordination, reflexes, and mental status).

A symptom-directed physical examination will be performed at the time points indicated in the schedule of events (Table 9-1) (for those subjects who require it), and at unscheduled visits as necessary. This examination will include an assessment of the heart, lungs, abdomen, a neurologic review, and a review of symptoms for assessments and/or follow-up of reported or potential AEs.

Weight will be measured without shoes and in light clothing at screening and without shoes and in hospital gowns at all other time points indicated in the schedule of events (Table 9-1). The scales should be calibrated, and the same weight scale should be used throughout the study starting with Screening through Day 9. Weight measurements will be rounded to one decimal place.

6.2.7 Unscheduled Visits

Subjects will be provided with the contact information for the study site personnel. Subjects are free to contact study site personnel at any time, and the site may require an unscheduled

visit for the purpose of physical examinations, laboratory tests, etc. Unscheduled visits will be documented by the site personnel in the source documents. Unscheduled procedures and laboratory tests and results will also be recorded in the eCRF.

7. STATISTICAL ANALYSIS PLANS

7.1 SAMPLE SIZE CALCULATIONS

The sample size (N = 36 [to allow at least 32 enrolled subjects to complete]) for this study is based on clinical and practical considerations and not on a formal statistical power calculation. The sample size is considered sufficient to effectively assess the PK and safety profiles of TPOXX.

7.2 ANALYSIS POPULATIONS

The Safety Population will include all subjects who receive at least 1 dose of study drug.

The PK Population will include subjects who receive study drug and have sufficient concentration data to facilitate the calculation of PK variables.

7.3 STATISTICAL ANALYSIS

Details of all statistical analyses will be described in a statistical analysis plan. All data collected will be presented in data listings. Data from subjects excluded from an analysis population will be presented in the data listings, but not included in the calculation of summary statistics.

For categorical variables, frequencies and percentages will be presented. Continuous variables will be summarized using descriptive statistics (number of subjects, mean, median, standard deviation [SD], minimum, and maximum).

Baseline demographic and background variables will be summarized overall for all subjects. The number of subjects who enroll in the study and the number and percentage of subjects who complete the study will be presented. Frequency and percentage of subjects who withdraw or discontinue from the study, and the reason for withdrawal or discontinuation, will also be summarized.

7.3.1 Pharmacokinetic Analyses

Individual plasma concentration and time deviation data will be presented in a data listing. Plasma concentration data will be listed and summarized using the following descriptive statistics: number of subjects, arithmetic mean, SD, coefficient of variation (CV), geometric mean, geometric CV, median, minimum, and maximum. Individual and mean plasma concentration versus time profiles will be presented in figures on both linear and semilogarithmic scales.

The PK parameters of TPOXX will be analyzed based on the actual sampling times. All parameters will be determined using noncompartmental methods using Phoenix® WinNonlin® Version 8.0 or higher (Certara, L.P., Princeton, New Jersey) or SAS® Version 9.4 or higher (SAS Institute Inc., Cary, North Carolina).

The individual PK parameters and body weight-normalized PK parameters will be presented in data listings and summarized using the following descriptive statistics: number of subjects, arithmetic mean, SD, CV, median, minimum, maximum, geometric mean, geometric SD, and geometric CV.

7.3.2 Safety Analyses

Adverse events will be coded by preferred term and system organ class using the latest version of the Medical Dictionary for Regulatory Activities and summarized overall. All AE data will be presented in a data listing. Treatment-emergent AEs will be summarized overall, as well as by severity and relationship to study drug. Serious AEs and AEs leading to discontinuation of study drug will also be presented in the data listings and summarized overall.

Actual values and changes from baseline for clinical laboratory test results, vital sign measurements, and 12-lead ECG results will be summarized at each time point using descriptive statistics (number of subjects, mean, SD, median, minimum, and maximum). Shift tables will be generated for clinical laboratory test results. Clinical laboratory data, vital sign measurements, 12-lead ECG results, and physical examination findings will be presented in data listings.

7.4 HANDLING OF BELOW THE LIMIT OF QUANTIFICATION AND MISSING DATA

Plasma concentrations that are below the limit of quantification (BLQ) will be treated as zero for descriptive statistics. Geometric mean values will not be calculated or displayed when zero is the minimal value. Mean BLQ concentrations will be presented as BLQ, and the SD and CV will be reported as not applicable. Missing concentrations will be excluded from the calculations.

7.5 INTERIM ANALYSES

No formal interim safety analyses will be performed in this study.

8. REFERENCE LIST

1. Breman JG, Henderson DA. Diagnosis and management of smallpox. N Engl J Med. 2002;346(17):1300-8.

2. TPOXX (tecovirimat) [full prescribing information]. SIGA Technologies, Inc. Corvallis (OR); 2018. 18 p.

3. Department of Health and Human Services, Food and Drug Administration (US). Guidance for Industry. Bioanalytical Method Validation. May 2018. Available from: https://www.fda.gov/files/drugs/published/Bioanalytical-Method-Validation-Guidance-for-Industry.pdf.

9. APPENDICES

9.1 APPENDIX 1: LIST OF ABBREVIATIONS

Abbreviation	Term
$\%AUC_{extrap}$	percentage of $AUC_{0-\infty}$ extrapolated from the last quantifiable measurement to infinity
λ_z	terminal elimination rate constant
AE	adverse event
AUC	area under the plasma concentration-time curve
AUC_{0-24}	area under the plasma concentration-time curve from time 0 to 24 hours
$AUC_{0-\infty}$	area under the plasma concentration-time curve from time 0 extrapolated to infinity
AUC_{0-t}	area under the plasma concentration-time curve from time 0 to the last quantifiable measurement
AUC_{0-tau}	area under the plasma concentration-time curve during the first dosing interval
BCRP	breast cancer resistance protein
BID	twice daily
BLQ	below the limit of quantification
CFR	Code of Federal Regulations
CL/F	apparent total body clearance
C_{max}	maximum drug concentration in plasma
C_{trough}	concentration observed prior to the next dose administration
CRA	clinical research associate
CV	coefficient of variation
CYP	cytochrome P450
DAIDS	Division of Acquired Immune Deficiency Syndrome
ECG	electrocardiogram
eCRF	electronic case report form
FDA	Food and Drug Administration
ICF	informed consent form
ICH	International Council for Harmonisation
IRB	institutional review board
ISM	independent safety monitor
MedDRA	Medical Dictionary for Regulatory Activities
PK	pharmacokinetic(s)
QTcF	QT interval corrected using Fridericia's formula
SAE	serious adverse event
SD	standard deviation
SOP	standard operating procedures
$t_{1/2}$	terminal elimination half-life
TEAE	treatment-emergent adverse event

Abbreviation	Term
T_{max}	time to maximum drug concentration in plasma
UGT	uridine diphosphate-glucuronosyltransferase
VARV	variola virus
V_d/F	apparent volume of distribution

9.2 APPENDIX 2: SCHEDULE OF EVENTS

Table 9-1 Schedule of Events

	Screening	Check-in	Treatment Period									Telephone Call or Follow-up Visit[a]	Follow-up Telephone Call[b]
Procedure[c] Day	**–28 to –2**	**–1**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9 or Early Discontinuation**	**14 (+2)**	**37 (+2)**
Admission to clinic		X											
Discharge from clinic[d]											X		
Informed consent	X												
Inclusion/exclusion criteria	X	X											
Medical history[e]	X	X											
Complete physical examination[f]	X	X							X		X		
Weight[g]	X	X	X[h]								X		
Vital sign measurements[i]	X	X	X[j]			X[j]			X[j]	X	X	X[k]	
Glycosylated hemoglobin (HbA1c)	X												
Fasting lipid panel[l]	X												
Clinical laboratory testing[m]	X[n]	X				X				X[o]	X[n]		
Serum follicle-stimulating hormone[p]	X												
Serum pregnancy test[q]	X	X											
Urine drug/alcohol screen[r]	X	X											
Serology (HBsAg, HCV, and HIV)	X												
12-Lead ECG[s]	X	X	X			X			X		X		
TPOXX administration[t]			X	X	X	X	X	X	X				
Pharmacokinetic sampling[u]			X	X				X	X	X	X		
Symptom-directed physical examination[v]				X	X	X	X	X				X[k]	
Reactogenicity[w]			X	X	X	X	X	X	X				
Adverse events			←	←	←	←	←	←	←	←	X →		
Prior/concomitant medications	←	←	←	←	←	←	←	←	←	←	X →		

Abbreviations: AE, adverse event; ECG, electrocardiogram; HBsAg, hepatitis B surface antigen; HCV, hepatitis C virus; HIV, human immunodeficiency virus; PK, pharmacokinetic; SAE, serious adverse event.

Notes:

[a] The follow-up visit or telephone call will occur on Day 14 (+2 days), 7 days after the last dose of study drug. Subjects who have abnormal physical examination findings or an ongoing AE/SAE on Day 9 that is deemed related to study drug or per investigator or SIGA discretion will return to the study site on Day 14 (+2 days) for a follow-up visit. All other subjects will have the Day 14 (+2 days) follow-up via telephone.

[b] The follow-up telephone call will be made 30 days after the last dose of study drug (Day 37 [+2 days]).

[c] When procedures are overlapping and occurring at the same time point, the order of procedures should be ECG, vital sign measurements, and then blood collection, with the blood collection scheduled to occur at the nominal time point, unless dictated by other study events happening at that time, such as dosing requirements.

[d] Discharge following collection of all safety assessments.

[e] Including a review of systems; recreational, prescription, and over-the-counter drug use; nicotine and alcohol use; and past hospitalizations.

[f] Including assessment of the following body systems: head, ears, eyes, nose, and throat; cardiac (including auscultation of heart); pulmonary (chest) auscultation of lungs; abdomen; skin; musculoskeletal system; lymphatic system; and neurologic system (cranial nerves, sensation, motor function, coordination, reflexes, and mental status).

[g] Weight will be measured without shoes and in light clothing at screening and without shoes and in hospital gowns at all other time points. The scales should be calibrated and the same weight scale should be used throughout the study starting with Screening through Day 9. Weight measurements will be rounded to one decimal place.

[h] Weight will be collected prior to dosing.

[i] Vital sign measurements will include systolic and diastolic blood pressures, heart rate, respiratory rate, and body temperature. Vital signs will be measured after the subject has been seated for at least 5 minutes.

[j] Vital sign measurements will be performed before dosing and 4 hours after the AM study drug administration on Days 1 and 7 and 4 hours after the AM study drug administration on Day 4. The acceptable window for collection from the scheduled collection time point is ±15 minutes.

[k] Collected only if subjects are required to return to the study site on Day 14 (+2 days) for a follow-up visit.

[l] Including cholesterol (total, high-density lipoprotein, calculated low-density lipoprotein, and triglycerides).

[m] Clinical laboratory testing will include hematology and serum chemistry.

[n] Clinical laboratory testing at screening and at Day 9 or early discontinuation will include hematology, serum chemistry, and urinalysis.

[o] Collect 12 hours after the PM study drug administration on Day 7.

[p] For postmenopausal women, a serum follicle-stimulating hormone test will be performed at screening.

[q] Women of childbearing potential only.

[r] Includes alcohol, amphetamines (including methamphetamines and ecstasy/methylenedioxymethamphetamine), barbiturates, benzodiazepines, cannabinoids (including tetrahydrocannabinol), cocaine metabolites, and opiates (including heroin, codeine, and oxycodone).

[s] A 12-lead ECG will be collected after the subject has been in the supine position for at least 10 minutes. On Days 1, 4, and 7, an ECG will be recorded 4 hours after the AM study drug administration. The acceptable window for collection from the scheduled collection time point is ±15 minutes.

[t] TPOXX, 600 mg (3 × 200-mg capsules) will be administered orally twice daily, approximately 12 hours (± 30 minutes) apart on Days 1 through 7. All subjects will be provided meals consisting of approximately 600 calories and 25 g fat, which will start 30 minutes before study drug administration. Subjects should eat this meal within 30 minutes or less of taking study drug. Study drug will be administered approximately 30 minutes after the start of the meal. All doses of study drug will be administered to subjects by study site personnel with approximately 240 mL of water. Subjects must fast 2 hours after taking study drug. Study drug and meals must be taken with water only, and no other beverage except water should be ingested within 3 hours before or 3 hours after study drug administration.

[u] Blood samples for PK analysis of TPOXX will be collected from all subjects at the following tome points: on Day 1 before study drug administration (0 hour), at 0.5, 1, 2, 4, 6, 8, 12 (before the PM dose), 14, 16, 18, 20, and 24 hours (before the AM dose on Day 2), on Day 6 (before the AM dose and 4 hours after the AM dose), on Day 7 before the AM dose (0 hour), at 0.5, 1, 2, 4, 6, 8, 12 (before the PM dose), 14, 16, 18, 20, and 24 hours (Day 8, 24 hours after the AM dose on Day 7), and on Day 9 (48 hours after the AM dose on Day 7). For PK blood samples, the acceptable window for collection from the scheduled collection time point will be as follows: ±5 minutes for the time points from 1 to 8 hours and ±15 minutes for the 12- to 48-hour time points.

[v] Including assessment of heart, lungs, abdomen, a neurologic review, and a review of symptoms for assessment and/or follow-up of reported or potential adverse events.

[w] The study site personnel will observe the subjects for signs of allergic reaction for at least 1 hour after the study drug is ingested.

9.3 APPENDIX 3: STUDY GOVERNANCE

9.3.1 Data Quality Assurance

This study will be conducted using the quality processes described in applicable procedural documents. The quality management approach to be implemented will be documented and will comply with current ICH guidance on quality and risk management. All aspects of the study will be monitored for compliance with applicable government regulatory requirements, current Good Clinical Practice, the protocol, and standard operating procedures (SOPs). The monitor will maintain current personal knowledge of the study through observation, review of study records and source documentation, and discussion of the conduct of the study with the investigator and staff. Electronic CRFs and electronic data capture will be utilized. The electronic data capture system is validated and compliant with US Title 21 CFR Part 11. Each person involved with the study will have an individual identification code and password that allows for record traceability. There may be an internal quality review audit of the data and additional reviews by the clinical monitor.

Steps to be taken to ensure the accuracy and reliability of data include, but are not limited to: selection of qualified investigator and appropriate study center, protocol training and review of protocol procedures with the investigator and study site personnel before the start of the study, site initiation and periodic interim monitoring visits by SIGA or PPD, and direct transmission of safety laboratory data into the PPD study database for all clinical safety laboratory tests performed. The eCRF will be reviewed for accuracy and completeness by PPD Clinical research associate (CRA) remotely and during on-site monitoring visits. Discrepancies will be resolved with the investigator or designees, as appropriate. The data will be entered into the clinical study database and validated for accuracy. During on-site monitoring visits, 100% of the data will be verified using source documentation. SIGA or Biomedical Advanced Research and Development Authority representatives may accompany the PPD CRA on any scheduled site visit. The investigator will be informed in advance of any visitors to the study site in addition to the PPD CRA.

Representatives of SIGA’s Quality Assurance department (or designee) may visit the site to carry out an audit of the study in compliance with regulatory guidelines and PPD policy. Such audits will require access to all study records, including source documents, for inspection and source document verification with the eCRF. Subject privacy must, however, be respected. Sufficient prior notice will be provided to allow the investigator to prepare properly for the audit. Similar auditing procedures may also be conducted by any regulatory body reviewing the results of this study in support of a Licensing Application. The

investigator will immediately notify SIGA if they are contacted by a regulatory agency requesting a site inspection.

9.3.2 Investigator Obligations

The following administrative items are meant to guide the investigator in the conduct of the study and may be subject to change based on industry and government SOPs, working practice documents, or guidelines. Changes will be reported to the IRB but will not result in protocol amendments.

9.3.2.1 Confidentiality

All laboratory specimens, evaluation forms, reports, and other records will be identified in a manner designed to maintain subject confidentiality. All records will be kept in a secure storage area with limited access. Subjects will not be identified by name in any reports in this study. All records will be kept confidential to the extent provided by federal, state, and local law. Medical records are made available for review when required by the FDA or other authorized users only under the guidelines set by the Federal Privacy Act. Direct access, as defined in the Federal Privacy Act, includes examining, analyzing, verifying, and reproducing any records and reports that are important to the evaluation of the study. The investigator is obligated to inform the subjects that these representatives may review their study-related records without violating the confidentiality of the subjects. The requirement to maintain subject confidentiality is included in the study informed consent document.

The investigator and all employees and coworkers involved with this study may not disclose or use for any purpose other than performance of the study, any data, record, or other unpublished, confidential information disclosed to those individuals for the purpose of the study. Prior written agreement from SIGA or its designee must be obtained for the disclosure of any said confidential information to other parties.

9.3.2.2 Institutional Review

Federal regulations and ICH guidelines require that approval be obtained from an IRB before participation of human subjects in research studies. Before study onset, the protocol, ICF, advertisements to be used for the recruitment of study subjects, and any other written information regarding this study to be provided to the subject or the subject's legal guardian must be approved by the IRB. Documentation of all IRB approvals and of the IRB

compliance with the ICH harmonised tripartite guideline E6(R2): Good Clinical Practice will be maintained by the site and will be available for review by SIGA or its designee.

All IRB approvals should be signed by the IRB chairman or designee and must identify the IRB name and address, the clinical protocol by title or protocol number or both, and the date approval or a favorable opinion was granted.

9.3.2.3 Subject Consent

Written documentation of informed consent in compliance with US Title 21 CFR Part 50 shall be obtained from each subject before any study-related procedures are performed and study drug is administered. If any institution-specific modifications to study-related procedures are proposed or made by the site, the consent should be reviewed by SIGA or its designee or both before IRB submission. Once reviewed, the investigator will submit the ICF to the IRB for review and approval before the start of the study. If the ICF is revised during the course of the study, all active participating subjects must sign the revised ICF.

Before recruitment and enrollment, each prospective subject or his/her legal guardian will be given a full explanation of the study and will be asked to read and review the approved ICF. Once the investigator is assured that the subject/legal guardian understands the implications of participating in the study, the subject/legal guardian will be asked to give his or her consent to participate in the study by signing the ICF. A copy of the ICF will be provided to the subject/legal guardian.

9.3.2.4 Exclusion of Children

Effort will be made to include women and minorities in proportions similar to that of the community from which they are recruited. Because this study is designed to establish safety of the study drug in adults, enrollment will be limited to persons at least 18 years of age, and no older than 50 years. Children are excluded from participation in this clinical study because it does not meet the Department of Health and Human Services' guidelines (45 CFR 46, Subpart D, 401-409) for inclusion of children in research. These guidelines provide guidance for the protection of children in research. Generally, healthy children can be studied when the research is considered as "not greater than minimal risk." Children can be involved in research with greater than minimal risk only when it presents the prospect of direct benefit to the individual child or is likely to yield generalizable knowledge about the child's disorder or condition.

9.3.2.5 Study Reporting Requirements

By participating in this study, the investigator agrees to submit reports of SAEs according to the time line and method outlined in this protocol. In addition, the investigator agrees to submit annual reports to his or her IRB as appropriate.

9.3.2.6 Financial Disclosure and Obligations

The investigator is required to provide financial disclosure information to allow SIGA to submit the complete and accurate certification or disclosure statements required under US Title 21 CFR Part 54. In addition, the investigator must provide to SIGA a commitment to promptly update this information if any relevant changes occur during the course of the investigation and for 1 year following the completion of the study.

Neither SIGA nor PPD is financially responsible for further testing or treatment of any medical condition that may be detected during the screening process. In addition, in the absence of specific arrangements, neither SIGA nor PPD is financially responsible for further treatment of the disease under study.

9.3.2.7 Investigator Documentation

Prior to beginning the study, the investigator will be asked to comply with ICH E6(R2) Section 8.2 and US Title 21 of the CFR by providing essential documents, including but not limited to, the following:

- IRB approval.
- An original investigator-signed investigator agreement page of the protocol.
- Form FDA 1572, fully executed, and all updates on a new fully executed Form FDA 1572.
- Curriculum vitae for the principal investigator and each subinvestigator listed on Form FDA 1572. Current licensure must be noted on the curriculum vitae. Curriculum vitae will be signed and dated by the principal investigators and subinvestigators at study start-up, indicating that they are accurate and current.
- Financial disclosure information to allow SIGA to submit complete and accurate certification or disclosure statements required under US Title 21 CFR Part 54. In addition, the investigators must provide to SIGA a commitment to promptly update this

information if any relevant changes occur during the course of the investigation and for 1 year after the completion of the study.

- An IRB-approved ICF, samples of site advertisements for recruitment for this study, and any other written information about this study that is to be provided to the subject or legal guardians.

- Laboratory certifications and reference ranges for any local laboratories used by the site, in accordance with US Title 42 CFR Part 493.

9.3.2.8 Study Conduct

The investigator agrees to perform all aspects of this study in accordance with the ethical principles that have their origin in the Declaration of Helsinki, ICH E6(R2): Good Clinical Practice; the protocol; and all national, state, and local laws or regulations.

9.3.2.9 Case Report Forms and Source Documents

Site personnel will maintain source documentation, enter subject data into the eCRF as accurately as possible, and will rapidly respond to any reported discrepancies.

Electronic CRFs and electronic data capture will be utilized. The electronic data capture system is validated and compliant with US Title 21 CFR Part 11. Each person involved with the study will have an individual identification code and password that allows for record traceability. Thus, the system, and any subsequent investigative reviews, can identify coordinators, investigators, and individuals who have entered or modified records, as well as the time and date of any modifications. There may be an internal quality review audit of the data and additional reviews by PPD's CRA.

Each eCRF is presented as an electronic copy, allowing data entry by site personnel, who can add and edit data, add new subjects, identify and resolve discrepancies, and view records. This system provides immediate direct data transfer to the database, as well as immediate detection of discrepancies, enabling site coordinators to resolve and manage discrepancies in a timely manner.

Paper copies of the eCRFs and other database reports may be printed and signed by the investigator. This system provides site personnel, PPD CRAs, and reviewers with access to hardcopy audits, discrepancy reviews, and investigator comment information.

9.3.2.10 Adherence to Protocol

The investigator agrees to conduct the study as outlined in this protocol, in accordance with ICH E6(R2) and all applicable guidelines and regulations.

9.3.2.11 Reporting Adverse Events

By participating in this study, the investigator agrees to submit reports of SAEs according to the timeline and method outlined in this protocol. In addition, the investigator agrees to submit annual reports to his or her IRB as appropriate. The investigator also agrees to provide SIGA with an adequate report, if applicable, shortly after completion of the investigator's participation in the study.

9.3.2.12 Investigator's Final Report

Upon completion of the study, the investigator, where applicable, should inform the institution; the investigator/institution should provide the IRB with a summary of the study's outcome and SIGA and regulatory authorities with any reports required.

9.3.2.13 Records Retention

Essential documents should be retained until at least 2 years after the last approval of a marketing application in an ICH region and until there are no pending or contemplated marketing applications in an ICH region or until at least 2 years have elapsed since the formal discontinuation of clinical development of the study drug. These documents should be retained for a longer period, however, if required by applicable regulatory requirements or by an agreement with SIGA. SIGA is responsible for informing the investigator/institution when these documents no longer need to be retained.

9.3.2.14 Publications

All information concerning TPOXX, SIGA operations, patent application, formulas, manufacturing processes, basic scientific data, and formula information, supplied by SIGA to the investigator and not previously published, is considered confidential and remains the sole property of SIGA. The investigator agrees to use this information only to accomplish this study and will not use it for other purposes without SIGA's written consent. The investigator understands that the information developed in the clinical study will be used by SIGA, in connection with the continued development of TPOXX, and thus may be disclosed as required to other clinical investigators or government regulatory agencies. To permit the

information derived from the clinical studies to be used, the investigator is obligated to provide SIGA with all data obtained in the study. Any publication or other public presentation of results from this study, including manuscripts and materials for presentation at scientific meetings, should be provided to SIGA at least 30 working days before abstract or other relevant submission deadlines. Authorship of publications resulting from this study will be determined at the discretion of SIGA.

9.3.3 Study Management

9.3.3.1 Monitoring

9.3.3.1.1 Monitoring of the Study

Site monitoring for safety is conducted to ensure that human subject protection, study procedures, and laboratory, study drug dosing, and data collection processes are of high quality and meet SIGA, GCP/ICH, and regulatory guidelines. PPD CRA(s) will conduct site monitoring visits as detailed in the monitoring plan.

Site investigators will allow the CRA(s), the designated IRB, SIGA or its designee and the FDA to review, audit, and inspect study documents (eg, ICFs, drug accountability and distribution forms, eCRF), pertinent hospital and site records, and source documentation for verification of the study data.

Clinical research associates will conduct site visits in accordance with PPD SOPs to monitor the following: study operations, the quality of data collected in the research records, the accuracy and timeliness of data entered in the database, and to determine that all process and regulatory requirements are met. Study monitoring visits will occur at initiation of the study site, at intervals determined by SIGA during conduct of the study, and at completion of the study.

The CRA will maintain current personal knowledge of the study through observation, review of study records and source documentation, and discussion of the conduct of the study with the investigator and staff. During the routine monitoring visits, the CRA will perform a 100% source document verification of all subject data entered into the eCRF. Discrepancies, if any, will be clarified with the study site coordinator and investigator, and corrected at the site by the study coordinator. Any questions or required data clarifications will be sent to the study site electronically.

9.3.4 Safety Monitoring Plan

Close cooperation between the designated members of the study team will occur to evaluate and respond to individual AEs in a timely manner. Designated team members (investigator, subinvestigators, study coordinator, and other designated study clinicians) will review the subject safety information and data (laboratory test results, ECGs, AEs, and concomitant medications) and update the PPD project team and the ISM on the status of all enrolled subjects at their site on a weekly basis (or more frequently if required because of an unexpected safety issue) through completion of each subject's final study visit.

9.3.5 Medical Monitor

The medical monitor, or their qualified designee, will receive reports within 24 hours of study site awareness of all SAEs and within 7 days of study site awareness of all other AEs. The safety monitors will review all safety data and alert the medical monitor of SAEs and AEs of interest. The medical monitor may make a request for data to the investigator as necessary for safety evaluations.

The medical monitor will review each significant AE in a timely fashion and ensure that appropriate management is initiated and completed. Drug safety representatives and the medical monitor will have direct contact with the investigators and follow all significant events as needed.

9.3.6 Safety Oversite (Independent Safety Monitor)

In addition to the investigator's ongoing review of the safety data, the ISM will review the protocol for any major concerns and will be involved in data review in coordination with the investigator. The primary role of the ISM will be to evaluate the study safety and tolerability data. The ISM will provide independent safety monitoring in a timely fashion, which will include reviewing individual SAE reports and a review of periodic cumulative AE reports. Clinical safety and laboratory data, clinical records, and other safety study-related records will be made available for the ISM to review. Based on review of this data, the ISM may make recommendations regarding the safe continuation of the study. Specific details will be outlined in the Safety and Medical Management Plan.

9.3.6.1 Inspection of Records

The investigator and study site involved in the study will permit study-related monitoring, audits, IRB review, and regulatory inspections by providing direct access to all study records.

In the event of an audit, the investigator agrees to allow SIGA, their representatives, the FDA, or other regulatory agencies access to all study records.

The investigator should promptly notify SIGA and study site of any audits scheduled by any regulatory authorities and promptly forward copies of any audit reports received to SIGA.

9.3.6.2 Management of Protocol Amendments and Deviations

9.3.6.2.1 Modification of the Protocol

Any changes in this research activity, except those necessary to remove an apparent immediate hazard to the subject, must be reviewed and approved by SIGA or designee. Amendments to the protocol must be submitted in writing to the IRB for approval before subjects are enrolled into an amended protocol.

9.3.6.2.2 Protocol Deviations

The investigator or designee must document and explain in the subject's source documentation any deviation from the approved protocol. The investigator may implement a deviation from, or a change to, the protocol to eliminate an immediate hazard to study subjects without prior IRB approval. As soon as possible after such an occurrence, the implemented deviation or change, the reasons for it, and any proposed protocol amendments should be submitted to the IRB for review and approval, to SIGA for agreement, and to the regulatory authorities, if required.

A *protocol deviation* is any change, divergence, or departure from the study design or procedures defined in the protocol. An *important protocol deviation* (sometimes referred to as a protocol violation or a major protocol deviation) is a subset of protocol deviations that might significantly affect the reliability of the study data or that might significantly affect a subject's safety. An important deviation can include nonadherence to inclusion or exclusion criteria or nonadherence to FDA regulations or ICH E6(R2) guidelines.

Protocol deviations will be documented by the clinical monitor throughout the course of monitoring visits. The investigator will be notified in writing by the monitor of deviations. The IRB should be notified of all protocol deviations, if appropriate, in a timely manner.

9.3.6.3 Study Termination

Although SIGA has every intention of completing the study, they reserve the right to discontinue it at any time for clinical or administrative reasons.

An initiative for closure of the clinical investigative site or termination of the study can be taken at any time either by SIGA, PPD, or the investigator provided there is reasonable cause and sufficient notice is given in advance of the intended termination. Reasons for such action include, but are not limited to:

- Study site closure
    - Inadequate site recruitment/enrollment of subjects
    - Failure of an investigator to comply with the protocol, PPD SOPs, GCP guidelines, or applicable federal regulations
- Termination of enrollment
    - Enrollment of the required estimated number of subjects for the study
- Study termination
    - Completion of the study
    - Safety concerns

In addition, the ISM and FDA have the prerogative to delay or terminate the study.

The end of the study is defined as the date on which the last subject completes the last visit (includes the follow-up visit and the follow-up telephone call). Any additional long-term follow-up that is required for monitoring of the resolution of an AE or finding may be reported through an amendment to the clinical study report.

9.3.6.4 Final Report

Whether the study is completed or prematurely terminated, SIGA will ensure that clinical study reports are prepared and provided to regulatory agency(ies) as required by the applicable regulatory requirement(s). SIGA will also ensure that clinical study reports in marketing applications meet the standards of the ICH harmonised tripartite guideline E3: Structure and content of clinical study reports.

Upon completion of the clinical study report, the investigator will be provided with the final approved clinical study report, as appropriate.

9.4 APPENDIX 4: CHANGE HISTORY

9.4.1 Protocol Amendment 1

Protocol Amendment 1 was issued to clarify the weight requirements for qualified subjects on Day -1 and Day 1, clarify that the same scale will be used in Screening and how rounding procedures will be used, update Reference 3 to cite the current FDA Guidance, remove the ±2 day window for the Day 9 / Early Discontinuation visit, and remove symptom-directed physical examination from Day 7. The changes to Protocol Amendment 1 are outlined as follows:

Protocol Section	**Change**	**Rationale**
Synopsis and Section 4.1 Inclusion Criteria	Clarified subjects need to weigh >120 kg at check-in on Day -1, and prior to dosing on Day 1, in addition to weighing >120 kg at Screening.	In order to obtain accurate pharmacokinetic data in subjects weighing >120 kg, subjects participating in this study need to meet the weight requirement during dosing.
Section 6.2.6 Physical Examinations and Section 9.2 Appendix 2: Schedule of Events	Clarified the scale should be used throughout the entire study including Screening. Clarified rounding should occur by adding the following text: *Weight measurements will be rounded to one decimal place.*	The same scale should be used for the screening of subjects as will be used in the study to ensure weight measurement consistency. Scales at the site measure weight to two decimal places.
Section 8 Reference List	Updated reference 3 to cite the May 2018 Bioanalytical Method Validation Guidance for Industry	An updated Guidance was published in May of 2018.
Section 9.2 Appendix 2: Schedule of Events	Removal of (±2) from Day 9 or Early Discontinuation visit header	The ±2 day visit window was included in error. Subjects will check out on day 9 or will undergo Early Discontinuation Procedures on the day they discontinue. There is no window for these visits.
Section 9.2 Appendix 2: Schedule of Events	Removal of Day 7 symptom-directed physical examination from schedule.	A complete physical exam is already being conducted on Day 7.

SIGA

PROTOCOL ADMINISTRATIVE LETTER

TO:	Rebecca Wood-Horrall, MD – Principal Investigator
FROM:	SIGA Technologies, Inc.
STUDY:	SIGA-246-022 "A Post Marketing Study of the Safety, Tolerability, and Pharmacokinetic of TPOXX in Adult Subjects Weighing More Than 120 kg"
RE:	Collection of "Height" data point for all subjects on Study Day -1 Check-in Visit
DATE:	19 July 2019
CC:	SIGA-246-022 Trial Master File ADVARRA IRB

Dear Dr. Wood and Staff:

Per our discussion at the SIGA-246-022 study site initiation visit with the PPD team on 16 July 2019, please add "Height" to the Study Day -1 Check-in Visit procedures.

The protocol will not be amended at this time; however, per ADVARRA's request, should the protocol be amended in the future, this change will be included.

Kady M Honeychurch

19 July 2019

Kady M. Honeychurch
Associate Director, Project Management
SIGA Technologies, Inc.

Date

CLINICAL STUDY PROTOCOL AMENDMENT 2
IND 69,019

A POST MARKETING STUDY OF THE SAFETY, TOLERABILITY, AND PHARMACOKINETICS OF TPOXX® IN ADULT SUBJECTS WEIGHING MORE THAN 120 KG

Post Marketing Commitment: 3417-4

SIGA-246-022

Sponsor:	SIGA Technologies, Inc. 4575 SW Research Way, Suite 110 Corvallis, OR 97333
Sponsor Contact:	Kady Honeychurch, PhD, PMP SIGA Technologies, Inc. 4575 SW Research Way, Suite 110 Corvallis, OR 97333
Medical Monitor:	Rahul Bhatnagar, MD PPD Phase I Clinic 7551 Metro Center Drive, Suite 300 Austin, TX 78744
Version of Protocol:	Final 3.0
Date of Protocol:	02 August 2019

CONFIDENTIAL

The study will be conducted according to the International Council for Harmonisation Guideline E6(R2): Good Clinical Practice.

SIGNATURE PAGE

PROTOCOL TITLE: A Post Marketing Study of the Safety, Tolerability, and Pharmacokinetics of TPOXX® in Adult Subjects Weighing More Than 120 kg

PROTOCOL NUMBER: SIGA-246-022

Dennis E. Hruby

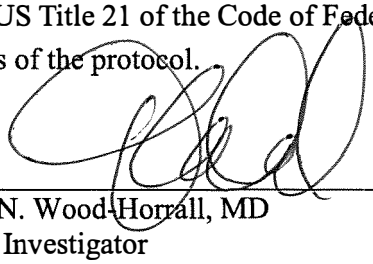
06 Aug 2019

Dennis E. Hruby, PhD
Chief Scientific Officer
SIGA Technologies, Inc.

Date

INVESTIGATOR PROTOCOL AGREEMENT PAGE

I agree to conduct the study as outlined in the protocol titled "A Post Marketing Study of the Safety, Tolerability, and Pharmacokinetics of TPOXX® in Adult Subjects Weighing More Than 120 kg" in accordance with the guidelines and all applicable government regulations, including US Title 21 of the Code of Federal Regulations Part 54. I have read and understand all sections of the protocol.



Rebecca N. Wood-Horrall, MD
Principal Investigator
PPD

05 AUG 2019
Date

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PROTOCOL SYNOPSIS

PROTOCOL NO.: SIGA-246-022

TITLE: A Post Marketing Study of the Safety, Tolerability, and Pharmacokinetics of TPOXX® in Adult Subjects Weighing More Than 120 kg

STUDY PHASE: 4 Post Marketing Study

STUDY SITE: PPD Phase I Clinic, 7551 Metro Center Drive, Suite 200, Austin, TX 78744, USA.

OBJECTIVES:

Primary:

The primary objective of this study is to determine the pharmacokinetic (PK) profile of 600 mg oral TPOXX (3 × 200-mg capsules) administered twice daily (BID) for 7 days in adult subjects weighing more than 120 kg to determine if a change in dosing regimen would be needed in these patients.

Secondary:

The secondary objective of this study is to evaluate the safety and tolerability of 600 mg oral TPOXX administered BID for 7 days in healthy adult subjects weighing more than 120 kg.

STUDY DESIGN AND METHODOLOGY:

This is an open-label, multiple-dose study to assess the safety, tolerability, and PK of TPOXX 600 mg BID when administered orally for 7 days to adult subjects weighing more than 120 kg. A total of 36 subjects, ages 18 to 50, inclusive, will be enrolled. The study will consist of a screening period (Day –28 to Day –2), a treatment and confinement period (Days –1 to 9), a follow-up telephone call or visit (Day 14 [+2 days]), and a follow-up telephone call (Day 37 [+2 days]).

Subjects will undergo screening evaluations to determine eligibility within 28 days before study drug administration. Subjects will be admitted to the study site on Day –1 to complete baseline assessments; results of these assessments must be reviewed by the investigator before dosing. Starting in the morning of Day 1, subjects will receive 600 mg oral TPOXX BID for 7 days (Days 1 through 7).

All subjects will be provided meals (consisting of approximately 600 calories and 25 g fat) 30 minutes prior to study drug administration and subjects must fast for 2 hours after taking study drug. Subjects should eat this meal within 30 minutes or less of taking study drug. Study drug and meals must be taken with water only, and no other beverage except water should be ingested within 3 hours before or 3 hours after study drug administration.

Subjects will remain confined to the study site for collection of PK samples and will be carefully monitored for safety and tolerability until discharge on Day 9. Subjects who have abnormal physical examination findings or an ongoing adverse event (AE)/serious adverse event (SAE) on Day 9 that is deemed related to study drug or per investigator or SIGA discretion will return to the study site on Day 14 (+2 days) for a follow-up visit. All other subjects will have the Day 14 (+2 days) follow-up via telephone. All subjects will have a

follow-up telephone call 30 days after administration of the last dose of study drug (Day 37 [+2 days]) to report any SAEs. At the time of discharge from the clinical research unit, subjects will be instructed to notify the investigator of any SAEs that occur within 30 days after administration of the last dose of study drug. Serious AEs will be followed until the SAE is stable or until resolution as determined by the investigator and/or medical monitor.

The total duration of the study for each subject, including the screening period, treatment period, and the Day 37 (+2 days) follow-up telephone call, will be approximately 65 days.

STUDY POPULATION:

Inclusion Criteria:

Each subject must meet all the following criteria to be enrolled in this study:

1. Subject is male or female between 18 and 50 years of age, inclusive.
2. Subject has a body weight >120 kg at screening, at check-in on Day -1, and prior to dosing on Day 1.
3. Women of childbearing potential, have a negative β human chorionic gonadotropin pregnancy test (serum) at the screening visit and a confirmatory negative serum pregnancy test on Day –1 before receipt of study drug, and meet 1 of the following criteria:
   a. The subject or their partner has undergone surgical sterilization
   b. The subject is postmenopausal, defined as 12 consecutive months with no menses without an alternative medical cause and has a documented plasma follicle-stimulating hormone level >40 IU/mL
   c. The subject agrees to be abstinent (ie, heterosexually inactive or women in a religious order)
   d. The subject agrees to consistently use 1 of the following methods of contraception from the beginning of screening (which they had been consistently using for at least 30 days before the first dose of study drug) through 30 days after the last dose of study drug:
      i. Condoms, male or female, with a spermicide

         NOTE: For male subjects, condoms must be used for 90 days after the last dose of study drug.
      ii. Diaphragm or cervical cap with spermicide
      iii. Intrauterine device with spermicide
      iv. Oral contraceptives or other hormonal methods

         NOTE: Subject must agree to use an additional nonhormonal method of contraception in conjunction with oral contraceptives.
      v. Male sexual partner who had undergone a vasectomy at least 3 months before screening
4. Male subjects must agree to not donate sperm from the first dose of study drug through 90 days after the last dose of study drug.

5. Subject is considered by the investigator to be in good general health as determined by medical history (no hospitalizations for chronic medical conditions in the previous 2 years), clinical laboratory results, vital sign measurements, 12-lead electrocardiogram (ECG) results, and physical examination findings at screening.
6. Subject agrees to comply with all protocol requirements.
7. Subject is able to provide written informed consent.
8. Subject agrees to comply with the dietary requirements.
9. Subject does not intend to lose weight (diet or weight loss) from the screening visit and throughout the study.

EXCLUSION CRITERIA:
Subjects meeting any of the following criteria will be excluded from the study:

1. Subject is a female who is pregnant or breastfeeding or planning to become pregnant within 3 months after the last dose of study drug.
2. Subject has a history of any clinically significant conditions including:
   - Asthma treated with oral systemic steroids within the past 6 months
   - Diabetes mellitus (type 1 or 2), with the exception of gestational diabetes
   - Thyroidectomy or thyroid disease that required medication within the past 12 months
   - Serious angioedema episodes within the previous 3 years or requiring medication in the previous 2 years
   - Head trauma resulting in a diagnosis of traumatic brain injury other than concussion
   - Frequent episodes of headache.
3. Subject has received treatment in another clinical study of an investigational drug (or medical device) within 30 days or 5 half-lives (whichever is longer) before the first dose of study drug.
4. Subject has been previously enrolled in any clinical study involving TPOXX (tecovirimat).
5. Subject has a history of relevant drug and/or food allergies (ie, allergy to tecovirimat or excipients, or any significant food allergy that could preclude a standard diet in the study site).
6. Subject has any condition possibly affecting drug absorption (eg, previous surgery on the gastrointestinal tract, including removal of parts of the stomach, bowel, liver, gallbladder, or pancreas, with the exception of appendectomy).
7. Subject has evidence or history of clinically significant allergic (except for untreated, asymptomatic, seasonal allergies at time of the first dose of study drug), hematological, endocrine, pulmonary, gastrointestinal, cardiovascular, hepatic, psychiatric, or neurological disease. Exceptions to these criteria (eg, stable, mild joint disease unassociated with collagen vascular disease) may be made following discussions with the medical monitor.

8. Subject has a history of cardiac disease, symptomatic or asymptomatic arrhythmias, syncopal episodes, or risk factors for torsades de pointes (eg, heart failure, hypokalemia).
9. Subject has a family history of sudden cardiac death, not clearly due to acute myocardial infarction.
10. Subject has a seizure disorder or history of seizures (does not include childhood febrile seizures) or a past history that increases seizure risks such as significant head injury that caused loss of consciousness or other changes in the subject's daily function, concussion, stroke, central nervous system infection or disease, or alcohol or drug abuse or family history of idiopathic seizures.
11. Subject has a history of a peptic ulcer or significant gastrointestinal bleed.
12. Subject has a bleeding disorder diagnosed by a doctor (eg, factor deficiency, coagulopathy, or platelet disorder requiring special precautions) or significant bruising or bleeding difficulties with blood draws.
13. Subject has a malignancy that is active, or treated malignancy for which there is not reasonable assurance of sustained cure, or malignancy that is likely to recur during the period of the study (subject should be in complete remission for at least 5 years).
14. Subject has neutropenia or other blood dyscrasia determined to be clinically significant by the investigator.
15. Subject has used any of the following prohibited medications from within 7 days (or 5 half-lives, whichever is longer) before the first dose of study drug: antidiabetic medication; anticoagulants; anticonvulsants; substrates of the breast cancer resistance protein transporter including methotrexate, mitoxantrone, imatinib, irinotecan, lapatinib, rosuvastatin, sulfasalazine, and topotecan; substrates of CYP2C8 including repaglinide, paclitaxel, Montelukast, pioglitazone, rosiglitazone; and substrates of CYP2C19 including S-mephenytoin, clobazam, diazepam, rabeprazole, voriconazole, lansoprazole, and omeprazole. Medications not listed here that are known (or thought) to be CYP3A4 substrates may be allowed at the investigator's discretion, after consultation with the medical monitor, if administration poses little to no risk to the subject.
16. Subject has a history of drug or alcohol abuse or dependency within the last year before screening.
17. Subject has a history of an eating disorder.
18. Subject has a current or recent (<30 days before screening) history of clinically significant bacterial, fungal, or mycobacterial infection.
19. Subject has a current clinically significant viral infection.
20. Subject has a known clinically significant chronic viral infection (eg, human T cell lymphotropic virus I or II).
21. Subject has consumed grapefruit or grapefruit juice, Seville orange or Seville orange-containing products (eg, marmalade), or caffeine- or xanthine-containing products within 48 hours before the first dose of study drug or throughout the study.
22. Subject has used any prescription (excluding hormonal birth control) or over-the-counter medication (including herbal or nutritional supplements) within 14 days before the first dose of study drug.

23. Subject demonstrates long-term use (≥14 consecutive days) of glucocorticoids including oral or parenteral prednisone or equivalent (>20 mg total dose per day) or high-dose inhaled steroids (>800 mcg/day of beclomethasone dipropionate or equivalent) within the preceding 1 month (low-dose [≤800 mcg/day of beclomethasone dipropionate or equivalent] inhaled and topical steroids are allowed).
24. Subject has donated >450 mL blood or blood components within 30 days before the first dose of study drug. The investigator should instruct subjects who participate in this study to not donate blood or blood components for 4 weeks after the completion of the study.
25. Subject is a smoker or has used nicotine or nicotine-containing products (eg, cigarettes, electronic vapor cigarettes, cigars, chewing tobacco, snuff, nicotine patches, or nicotine gum) within 6 months before the first dose of study drug.
26. Subject has consumed pomegranate or pomegranate juice, pomelo fruits or pomelo juice, or alcohol within 72 hours before the first dose of study drug.
27. Subject reports participation in strenuous activity or contact sports within 24 hours before the first dose of study drug.
28. Subject has known hepatitis B or C infection or positive test for hepatitis B surface antigen, hepatitis C virus antibody, or human immunodeficiency virus type 1 or 2 antibodies at screening.
29. Subject has a positive test result for amphetamines (including methamphetamines and ecstasy/methylenedioxymethamphetamine), barbiturates, benzodiazepines, cannabinoids (including tetrahydrocannabinol), cocaine metabolites, opiates (including heroin, codeine, and oxycodone), or alcohol at screening or check-in.
30. Subject has any of the following laboratory test results within 28 days before the first dose of study drug:
    - Estimated serum creatinine clearance (Cockcroft-Gault) <90 mL/min
    - Creatinine in males >1.7 mg/dL and in females >1.4 mg/dL (1.3 times the upper central laboratory reference range)
    - Hemoglobin ≤10% of the lower central laboratory reference range
    - White blood cell count not within the central laboratory reference range
    - Absolute neutrophil count <1000 cells/mm^3
    - Platelets not within ±10% of central laboratory reference range
    - Alanine aminotransferase >1.5 times above the upper central laboratory reference range
    - Aspartate aminotransferase >1.5 times above the upper central laboratory reference range
    - Alkaline phosphatase >20% above the upper central laboratory reference range
    - Hemoglobin A1c ≥7.0%
    - Cholesterol ≥300 mg/dL and low-density lipoprotein ≥190 mg/dL.
31. Subject has a blood pressure considered to be clinically significant by the investigator. Blood pressure may be retested twice in the sitting position at 5-minute intervals.

32. Subject has a resting heart rate of <40 beats per minute or >100 beats per minute at screening.
33. Subject has an abnormal ECG at screening that is determined by the investigator to be clinically significant.
34. Male subject has a QTcF >450 ms or female subject has a QTcF >470 ms at screening or Day –1.
35. In the opinion of the investigator, the subject is not suitable for entry into the study.

EVALUATION PROCEDURES:

Pharmacokinetic Assessments:

Blood samples for PK analysis of TPOXX will be collected from all subjects on Day 1 before study drug administration (0 hour), at 0.5, 1, 2, 4, 6, 8, 12 (before the PM dose), 14, 16, 18, 20, and 24 hours (before the AM dose on Day 2), on Day 6 (before the AM dose and 4 hours after the AM dose), on Day 7 before the AM dose (0 hour), at 0.5, 1, 2, 4, 6, 8, 12 (before the PM dose), 14, 16, 18, 20, and 24 hours (Day 8, 24 hours after the AM dose on Day 7), and on Day 9 (48 hours after the AM dose on Day 7).

For PK samples, the acceptable window for collection from the scheduled collection time point will be as follows: ±5 minutes for the time points from 1 to 8 hours and ±15 minutes for the 12- to 48-hour time points.

The following plasma PK parameters will be calculated for TPOXX using actual sampling times rather than scheduled sampling times and will include but are not limited to:

- Area under the plasma concentration-time curve (AUC) from time 0 to the last quantifiable measurement (AUC_{0-t})
- AUC from time 0 extrapolated to infinity ($AUC_{0-\infty}$)
- AUC from time 0 to 24 hours (AUC_{0-24})
- AUC during the first dosing interval (tau = 12 hours) (AUC_{0-tau})
- Maximum drug concentration in plasma (C_{max})
- Time to C_{max} (T_{max})
- Apparent volume of distribution (V_d/F)
- Apparent total body clearance (CL/F)
- Concentration observed prior to the next dose administration (C_{trough})
- Terminal elimination half-life ($t_{1/2}$)
- Terminal elimination rate constant (λ_z)
- Percentage of $AUC_{0-\infty}$ extrapolated from the last quantifiable measurement to infinity ($\%AUC_{extrap}$).

Safety Assessments:
Safety and tolerability will be assessed by monitoring and recording of AEs, clinical laboratory test results (hematology, serum chemistry, pregnancy, and urinalysis), vital sign measurements (systolic and diastolic blood pressures, heart rate, respiratory rate, and body temperature), 12-lead ECG results, and physical examination findings.

STUDY DRUG, DOSAGE, AND ROUTE OF ADMINISTRATION:
TPOXX, 600 mg (3 × 200-mg capsules), will be administered orally twice daily, approximately 12 hours (±30 minutes) apart, on Days 1 through 7.

STATISTICAL METHODS:
Complete, detailed statistical methods will be described in the statistical analysis plan.

Sample Size:
The sample size (N = 36 [to allow at least 32 enrolled subjects to complete]) for this study is based on clinical and practical considerations and not on a formal statistical power calculation. The sample size is considered sufficient to effectively assess the PK and safety profiles of TPOXX.

Analysis Populations:
- The Safety Population will include all subjects who receive at least 1 dose of study drug.
- The PK Population will include subjects who receive study drug and have sufficient concentration data to facilitate the calculation of PK variables.

Pharmacokinetic Analyses:
Individual plasma concentration and time deviation data will be presented in a data listing. Plasma concentration data will be listed and summarized using the following descriptive statistics: number of subjects, arithmetic mean, standard deviation (SD), coefficient of variation (CV), geometric mean, geometric CV, median, minimum, and maximum. Individual and mean plasma concentration versus time profiles will be presented in figures on both linear and semilogarithmic scales.

The PK parameters of TPOXX will be analyzed based on the actual sampling times. All parameters will be determined using noncompartmental methods using Phoenix® WinNonlin® Version 8.0 or higher (Certara, L.P., Princeton, New Jersey) or SAS® Version 9.4 or higher (SAS Institute Inc., Cary, North Carolina).

The individual PK parameters and weight-normalized PK parameters will be presented in data listings and summarized using the following descriptive statistics: number of subjects, arithmetic mean, SD, CV, median, minimum, maximum, geometric mean, geometric SD, and geometric CV.

Safety Analyses:
Adverse events will be coded by preferred term and system organ class using the latest version of the Medical Dictionary for Regulatory Activities and summarized overall. All AE data will be presented in a data listing. Treatment-emergent AEs will be summarized overall, as well as by severity and relationship to study drug. Serious AEs and AEs leading to

discontinuation of study drug will also be presented in the data listings and summarized overall.

Actual values and changes from baseline for clinical laboratory test results, vital sign measurements, and 12-lead ECG results will be summarized at each time point using descriptive statistics (number of subjects, mean, SD, median, minimum, and maximum). Shift tables will be generated for clinical laboratory test results. Clinical laboratory data, vital sign measurements, 12-lead ECG results, and physical examination findings will be presented in data listings.

DATE OF PROTOCOL: 02 August 2019

1. INTRODUCTION

1.1 BACKGROUND

Historically, variola virus (VARV), the etiologic agent of smallpox, has been one of the more important human pathogens. Smallpox is highly communicable and carries exceptionally high morbidity. Secondary attack rates from 30% to 80% have been reported among unvaccinated members of households.[1] Mortality rates range from 1% for variola minor to 30% for variola major.[1] With the advent of biowarfare as an instrument of terrorism, smallpox can no longer be thought of as a disease only of historic impact.

In July 2018, the FDA approved the oral formulation of TPOXX for the treatment of patients with human smallpox disease caused by VARV.

1.2 RATIONALE FOR STUDY

This study is being conducted as an FDA post marketing commitment to the approved New Drug Application for TPOXX. SIGA is required to conduct a study to determine the pharmacokinetic (PK) profile of TPOXX in subjects with a body weight greater than 120 kilograms (>120 kg) to determine if a change in dosing regimen would be needed in these patients.

1.3 POTENTIAL RISKS AND BENEFITS

1.3.1 Potential Risks

The effect of TPOXX on a fetus or nursing baby is not yet known; therefore, women of childbearing potential participating in this study will be required to agree to use an acceptable means of birth control from 30 days before the first dose of study drug and continuing through 30 days after the last dose of study drug. Pregnancy testing will be performed at the screening visit and checked by the investigator for negative pregnancy before administration of study drug on Day –1. Women who are pregnant or lactating or plan to become pregnant within 3 months after study drug administration will be excluded from the study; if a female subject becomes pregnant during study participation, study drug dosing will be discontinued, and the subject will be withdrawn from the study (Section 6.2.1.9).

As with all drugs, there is potential risk of an allergic reaction. At this time, there is no definitive information on the allergic activity of TPOXX. Headache and nausea have been the most common AEs in clinical studies completed to date. There may be other side effects

of TPOXX that are not yet known. Full details can be found in the TPOXX full prescribing information.[2]

1.3.2 Known Potential Benefits

As this study will be conducted in subjects free from smallpox, no direct health benefits from taking the study drug are expected. Study subjects may benefit from receiving the laboratory testing, ECGs, and physical examinations. Others may benefit from knowledge gained in this study that may aid in the development of a drug for the treatment of smallpox.

2. STUDY OBJECTIVES

2.1 PRIMARY OBJECTIVE

The primary objective of this study is to determine the PK profile of 600 mg oral TPOXX (3 × 200-mg capsules) administered twice daily (BID) for 7 days in adult subjects weighing more than 120 kg to determine if a change in dosing regimen would be needed in these patients.

2.2 SECONDARY OBJECTIVE

The secondary objective of this study is to evaluate the safety and tolerability of 600 mg oral TPOXX administered BID for 7 days in adult subjects weighing more than 120 kg.

3. STUDY POPULATION

Approximately 36 male and female subjects will be enrolled at a single center in the United States to achieve at least 32 evaluable enrolled subjects.

3.1 INCLUSION CRITERIA

Each subject must meet all the following criteria to be enrolled in this study:

1. Subject is male or female between 18 and 50 years of age, inclusive.
2. Subject has a body weight >120 kg at screening, at check-in on Day -1, and prior to dosing on Day 1.
3. Women of childbearing potential, have a negative β human chorionic gonadotropin pregnancy test (serum) at the screening visit and a confirmatory negative serum

pregnancy test on Day –1 before receipt of study drug, and meet 1 of the following criteria:

a. The subject or their partner has undergone surgical sterilization
b. The subject is postmenopausal, defined as 12 consecutive months with no menses without an alternative medical cause and has a documented plasma follicle-stimulating hormone level >40 IU/mL
c. The subject agrees to be abstinent (ie, heterosexually inactive or women in a religious order)
d. The subject agrees to consistently use 1 of the following methods of contraception from the beginning of screening (which they had been consistently using for at least 30 days before the first dose of study drug) through 30 days after the last dose of study drug:
    i. Condoms, male or female, with a spermicide

       NOTE: For male subjects, condoms must be used for 90 days after the last dose of study drug.
    ii. Diaphragm or cervical cap with spermicide
    iii. Intrauterine device with spermicide
    iv. Oral contraceptives or other hormonal methods

       NOTE: Subject must agree to use an additional nonhormonal method of contraception in conjunction with oral contraceptives.
    v. Male sexual partner who had undergone a vasectomy at least 3 months before screening.

4. Male subjects must agree to not donate sperm from the first dose of study drug through 90 days after the last dose of study drug.
5. Subject is considered by the investigator to be in good general health as determined by medical history (no hospitalizations for chronic medical conditions in the previous 2 years), clinical laboratory results, vital sign measurements, 12-lead ECG results, and physical examination findings at screening.
6. Subject agrees to comply with all protocol requirements.
7. Subject is able to provide written informed consent.
8. Subject agrees to comply with the dietary requirements.

9. Subject does not intend to lose weight (diet or weight loss) from the screening visit and throughout the study.

3.2 EXCLUSION CRITERIA

Subjects meeting any of the following criteria will be excluded from the study:

1. Subject is a female who is pregnant or breastfeeding or planning to become pregnant within 3 months after the last dose of study drug.
2. Subject has a history of any clinically significant conditions including:
   - Asthma treated with oral systemic steroids within the past 6 months
   - Diabetes mellitus (type 1 or 2), with the exception of gestational diabetes
   - Thyroidectomy or thyroid disease that required medication within the past 12 months
   - Serious angioedema episodes within the previous 3 years or requiring medication in the previous 2 years
   - Head trauma resulting in a diagnosis of traumatic brain injury other than concussion
   - Frequent episodes of headache.
3. Subject has received treatment in another clinical study of an investigational drug (or medical device) within 30 days or 5 half-lives (whichever is longer) before the first dose of study drug.
4. Subject has been previously enrolled in any clinical study involving TPOXX (tecovirimat).
5. Subject has a history of relevant drug and/or food allergies (ie, allergy to tecovirimat or excipients, or any significant food allergy that could preclude a standard diet in the study site).
6. Subject has any condition possibly affecting drug absorption (eg, previous surgery on the gastrointestinal tract, including removal of parts of the stomach, bowel, liver, gallbladder, or pancreas, with the exception of appendectomy).
7. Subject has evidence or history of clinically significant allergic (except for untreated, asymptomatic, seasonal allergies at time of the first dose of study drug), hematological, endocrine, pulmonary, gastrointestinal, cardiovascular, hepatic, psychiatric, or neurological disease. Exceptions to these criteria (eg, stable, mild

joint disease unassociated with collagen vascular disease) may be made following discussions with the medical monitor.

8. Subject has a history of cardiac disease, symptomatic or asymptomatic arrhythmias, syncopal episodes, or risk factors for torsades de pointes (eg, heart failure, hypokalemia).
9. Subject has a family history of sudden cardiac death not clearly due to acute myocardial infarction.
10. Subject has a seizure disorder or history of seizures (does not include childhood febrile seizures) or a past history that increases seizure risks such as significant head injury that caused loss of consciousness or other changes in the subject's daily function, concussion, stroke, central nervous system infection or disease, or alcohol or drug abuse or family history of idiopathic seizures.
11. Subject has a history of a peptic ulcer or significant gastrointestinal bleed.
12. Subject has a bleeding disorder diagnosed by a doctor (eg, factor deficiency, coagulopathy, or platelet disorder requiring special precautions) or significant bruising or bleeding difficulties with blood draws.
13. Subject has a malignancy that is active, or treated malignancy for which there is not reasonable assurance of sustained cure, or malignancy that is likely to recur during the period of the study (subject should be in complete remission for at least 5 years).
14. Subject has neutropenia or other blood dyscrasia determined to be clinically significant by the investigator.
15. Subject has used any of the following prohibited medications from within 7 days (or 5 half-lives, whichever is longer) before the first dose of study drug: antidiabetic medication; anticoagulants; anticonvulsants; substrates of the BCRP transporter including methotrexate, mitoxantrone, imatinib, irinotecan, lapatinib, rosuvastatin, sulfasalazine, and topotecan; substrates of CYP2C8 including repaglinide, paclitaxel, Montelukast, pioglitazone, rosiglitazone; and substrates of CYP2C19 including S-mephenytoin, clobazam, diazepam, rabeprazole, voriconazole, lansoprazole, and omeprazole. Medications not listed here that are known (or thought) to be CYP3A4 substrates may be allowed at the investigator's discretion, after consultation with the medical monitor, if administration poses little to no risk to the subject.

16. Subject has a history of drug or alcohol abuse or dependency within the last year before screening.
17. Subject has a history of an eating disorder.
18. Subject has a current or recent (<30 days before screening) history of clinically significant bacterial, fungal, or mycobacterial infection.
19. Subject has a current clinically significant viral infection.
20. Subject has a known clinically significant chronic viral infection (eg, human T cell lymphotropic virus I or II).
21. Subject has consumed grapefruit or grapefruit juice, Seville orange or Seville orange-containing products (eg, marmalade), or caffeine- or xanthine-containing products within 48 hours before the first dose of study drug or throughout the study.
22. Subject has used any prescription (excluding hormonal birth control) or over-the-counter medication (including herbal or nutritional supplements) within 14 days before the first dose of study drug.
23. Subject demonstrates long-term use (≥14 consecutive days) of glucocorticoids including oral or parenteral prednisone or equivalent (>20 mg total dose per day) or high-dose inhaled steroids (>800 mcg/day of beclomethasone dipropionate or equivalent) within the preceding 1 month (low-dose [≤800 mcg/day of beclomethasone dipropionate or equivalent] inhaled and topical steroids are allowed).
24. Subject has donated >450 mL blood or blood components within 30 days before the first dose of study drug. The investigator should instruct subjects who participate in this study to not donate blood or blood components for 4 weeks after the completion of the study.
25. Subject is a smoker or has used nicotine or nicotine-containing products (eg, cigarettes, electronic vapor cigarettes, cigars, chewing tobacco, snuff, nicotine patches, or nicotine gum) within 6 months before the first dose of study drug.
26. Subject has consumed pomegranate or pomegranate juice, pomelo fruits or pomelo juice, or alcohol within 72 hours before the first dose of study drug.
27. Subject reports participation in strenuous activity or contact sports within 24 hours before the first dose of study drug.

28. Subject has known hepatitis B or C infection or positive test for hepatitis B surface antigen, hepatitis C virus antibody, or human immunodeficiency virus type 1 or 2 antibodies at screening.
29. Subject has a positive test result for amphetamines (including methamphetamines and ecstasy/methylenedioxymethamphetamine), barbiturates, benzodiazepines, cannabinoids (including tetrahydrocannabinol), cocaine metabolites, opiates (including heroin, codeine, and oxycodone), or alcohol at screening or check-in.
30. Subject has any of the following laboratory test results within 28 days before the first dose of study drug:
    - Estimated serum creatinine clearance (Cockcroft-Gault) <90 mL/min
    - Creatinine in males >1.7 mg/dL and in females >1.4 mg/dL (1.3 times the upper central laboratory reference range)
    - Hemoglobin ≤10% of the lower central laboratory reference range
    - White blood cell count not within the central laboratory reference range
    - Absolute neutrophil count <1000 cells/mm^3
    - Platelets not within ±10% of central laboratory reference range
    - Alanine aminotransferase >1.5 times above the upper central laboratory reference range
    - Aspartate aminotransferase >1.5 times above the upper central laboratory reference range
    - Alkaline phosphatase >20% above the upper central laboratory reference range
    - Hemoglobin A1c ≥7.0%
    - Cholesterol ≥300 mg/dL and low-density lipoprotein ≥190 mg/dL.
31. Subject has a blood pressure considered to be clinically significant by the investigator. Blood pressure may be retested twice in the sitting position at 5-minute intervals.
32. Subject has a resting heart rate of <40 beats per minute or >100 beats per minute at screening.
33. Subject has an abnormal ECG at screening that is determined by the investigator to be clinically significant.
34. Male subject has a QTcF >450 ms or female subject has a QTcF >470 ms at screening or Day –1.
35. In the opinion of the investigator, the subject is not suitable for entry into the study.

3.3 OTHER SCREENING CONSIDERATIONS

3.3.1 Subject Restrictions During the Study

- Subjects must be willing to remain confined at the study site from check-in (Day –1) until safety assessments are completed on Day 9.
- Subjects who have abnormal physical examination findings or an ongoing AE/SAE on Day 9 that is deemed related to study drug or per investigator or SIGA discretion will return to the study site on Day 14 (+2 days) for a follow-up visit.

3.4 WITHDRAWAL OF SUBJECTS FROM THE STUDY

3.4.1 Reasons for Withdrawal

Subjects can withdraw consent and discontinue from the study at any time, for any reason, without prejudice to further treatment.

The investigator may withdraw a subject from the study for any of the following:

- The subject is in violation of the protocol.
- The subject experiences a serious or intolerable AE.
- The subject becomes pregnant.
- The subject is noncompliant.
- The subject has laboratory abnormalities for assessments listed in Sections 4.1 or 4.2 that meet Grade 3 or Grade 4 on the Division of Acquired Immune Deficiency Syndrome (DAIDS) AE Grading Table Version 2.1 July 2017, any other Grade 3 or Grade 4 AE; or a Grade 2 or higher rash considered by the investigator to be possibly, probably, or definitely related to study drug.
- The subject develops, during the course of the study, symptoms or conditions listed in the exclusion criteria.
- The subject requires a medication prohibited by the protocol.
- The subject requests an early discontinuation for any reason.
- The subject′s primary care provider requests that the subject be withdrawn.

- The independent safety monitor (ISM), SIGA, or the FDA requests subject withdrawal based on study safety findings.

The investigator can also withdraw a subject upon the request of SIGA or if SIGA terminates the study. Upon occurrence of a SAE or intolerable AE, the investigator will confer with SIGA. If a subject is discontinued because of an AE, the event will be followed until it is resolved or stabilized as determined by the investigator and/or the medical monitor.

3.4.2 Handling of Withdrawals

Subjects are free to withdraw from the study at any time upon request. Subject participation in the study may be stopped at any time at the discretion of the investigator or at the request of SIGA.

When a subject withdraws from the study, the reason(s) for withdrawal will be recorded by the investigator in the electronic case report form (eCRF). Whenever possible, any subject who withdraws from the study prematurely will undergo all Day 9/early discontinuation assessments (Table 9-1). Any subject who fails to return for final assessments will be contacted by the study site personnel in an attempt to have them comply with the protocol. The status of subjects who fail to complete final assessments will be documented in the eCRF.

3.4.3 Halting Rules

The medical monitor, investigator, SIGA, and ISM will review all AEs. All AEs determined by the investigator to be severe and possibly, probably, or definitely related to study drug, as well as all clinical assessments, laboratory test results, ECG results, or vital sign measurements that meet Grade 3 criteria on the DAIDS AE Grading Table will be assessed by the medical monitor, who will make a recommendation as to whether or not halting of the study should occur. At the discretion of the medical monitor, depending on the assessment of the severity of the event, the recommendation to halt the study may be made after consultation with the investigator, SIGA, and the ISM.

The study will be temporarily halted (no new enrollments and no further study drug administration) by the investigator and the medical monitor, SIGA, and the ISM will be promptly notified according to the following criteria:

- One subject experiences a Grade 4 AE assessed as possibly, probably, or definitely related to study drug.

- There is a subject death assessed as possibly, probably, or definitely related to study drug.
- One subject experiences a seizure assessed as possibly, probably, or definitely related to study drug.
- Two or more subjects experience the same or similar SAEs that are possibly, probably, or definitely related to the study drug.
- Three or more subjects experience the same or similar AEs that are Grade 3 or above and are possibly, probably, or definitely related to the study drug.

Study enrollment and study drug administration would resume if review of the AEs that caused the halt resulted in a recommendation to permit further continuation. In such an instance, SIGA, with participation by the investigator and the medical monitor, would consult with the ISM to conduct the review of all AEs that meet the criteria for halting the study. The study would remain suspended until the events were reviewed by the ISM and a recommendation was made as to whether the study should be continued or stopped. This constitutes a minimum criterion, and the decision to halt the study may be made based on any other criteria that, in the judgment of the investigator, with agreement of the medical monitor and ISM, indicate a potentially serious safety concern. The investigator will advise SIGA immediately if any of the halting rules are met.

4. STUDY DESIGN

This is an open-label, multiple-dose study to assess the safety, tolerability, and PK of TPOXX 600 mg BID when administered orally for 7 days to adult subjects weighing more than 120 kg. A total of 36 subjects, ages 18 to 50, inclusive, will be enrolled. The study will consist of a screening period (Day –28 to Day –2), a treatment and confinement period (Days –1 to 9), a follow-up telephone call or visit (Day 14 [+2 days]), and a follow-up telephone call (Day 37 [+2 days]).

Subjects will undergo screening evaluations to determine eligibility within 28 days before study drug administration. Subjects will be admitted to the study site on Day –1 to complete baseline assessments; results of these assessments must be reviewed by the investigator before dosing. Starting in the morning of Day 1, subjects will receive 600 mg oral TPOXX BID for 7 days (Days 1 through 7).

All subjects will be provided meals (consisting of approximately 600 calories and 25 g fat) 30 minutes prior to study drug administration and subjects must fast for 2 hours after taking

study drug. Subjects should eat this meal within 30 minutes or less of taking study drug. Study drug and meals must be taken with water only, and no other beverage except water should be ingested within 3 hours before or 3 hours after study drug administration.

Subjects will remain confined to the study site for collection of PK samples and will be carefully monitored for safety and tolerability until discharge on Day 9. Subjects who have abnormal physical examination findings or an ongoing adverse event (AE)/serious adverse event (SAE) on Day 9 that is deemed related to study drug or per investigator or SIGA discretion will return to the study site on Day 14 (+2 days) for a follow-up visit. All other subjects will have the Day 14 (+2 days) follow-up via telephone. All subjects will have a follow-up telephone call 30 days after administration of the last dose of study drug (Day 37 [+2 days]) to report any SAEs. At the time of discharge from the clinical research unit, subjects will be instructed to notify the investigator of any SAEs that occur within 30 days after administration of the last dose of study drug. Serious AEs will be followed until the SAE is stable or until resolution as determined by the investigator and/or medical monitor.

The total duration of the study for each subject, including the screening period, treatment period, and the Day 37 (+2 days) follow-up telephone call, will be approximately 65 days.

4.1.1 Replacements

At the discretion of the investigator, and after consultation with the medical monitor, any subject who withdraws before completing the study may be replaced to retain the target of 32 evaluable enrolled subjects.

5. STUDY TREATMENT

5.1 TREATMENT ADMINISTERED

On Days 1 to 7, all subjects will receive an oral dose of TPOXX 600 mg (3 × 200-mg capsules) BID, approximately 12 hours (±30 minutes) apart, for 7 days.

All subjects will be provided meals consisting of approximately 600 calories and 25 g fat, 30 minutes before study drug administration. Subjects should eat this meal within 30 minutes or less of taking study drug. Study drug will be administered approximately 30 minutes after the start of the meal. All doses of study drug will be administered to subjects by study site personnel with approximately 240 mL of water. Subjects must fast 2 hours after taking study

drug. Study drug and meals must be taken with water only, and no other beverage except water should be ingested within 3 hours before or 3 hours after study drug administration.

5.2 STUDY DRUG

TPOXX will be supplied as 200-mg capsules containing tecovirimat monohydrate as the active pharmaceutical ingredient. The TPOXX capsules are immediate release, size 0, orange and black, hard gelatin capsules containing white to off white powder. All inactive ingredients/excipients are generally recognized as safe and are United States Pharmacopeia/National Formulary grade. The TPOXX excipients are shown in Table 5-1.

Table 5-1 Excipients of TPOXX Capsules

Component	Quality Designation
Microcrystalline cellulose	NF[a]
Lactose monohydrate	NF
Croscarmellose sodium	NF[a]
Colloidal silicon dioxide	NF
Hydroxypropyl methylcellulose	USP
Sodium lauryl sulfate	NF
Purified water[b]	USP
Magnesium stearate	NF

Abbreviations: NF, National Formulary; USP, United States Pharmacopeia.

[a] Microcrystalline cellulose and croscarmellose sodium are added as intragranular and extragranular excipients.

[b] Removed during processing.

Compendial components are tested and released in accordance with full compendial methods and specifications before their use in clinical formulations. TPOXX 200-mg capsules are manufactured and analyzed for clinical use in accordance with Current Good Manufacturing Practices.

TPOXX capsules are manufactured by:
Catalent Pharma Solutions
1100 Enterprise Drive
Winchester, KY 40391.

Further information on TPOXX can be found in the TPOXX full prescribing information.[2]

5.2.1 Study Drug Packaging and Storage

TPOXX capsules are packaged, labeled, distributed, and placed on stability testing in accordance with Current Good Manufacturing Practice and International Council for Harmonisation (ICH) guidelines.

The 200-mg TPOXX capsules are supplied in 75-mL high density polyethylene bottles fitted with a heat induction seal and child-resistant screw cap closure system. Each bottle of study drug will contain 42 capsules and will be labeled with the drug name, SIGA's name, a space to fill in the protocol number, and a space to fill in the bottle number.

SIGA (or designee) will provide the investigator and study site with adequate quantities of TPOXX.

All study drug must be stored in a secure area (eg, a locked cabinet), protected from moisture and light, and stored at 15°C to 30°C (59°F to 86°F). Study drug should not be refrigerated or used beyond the expiration dates provided by the manufacturer. The study site will be required to keep a temperature log to establish a record of compliance with these study drug storage conditions. All study drug will be kept in a secure cabinet or room with access restricted to necessary study site personnel.

5.2.2 Study Drug Accountability

The investigator will maintain accurate records of receipt of all study drug, including dates of receipt. Accurate records will be kept regarding when and how much study drug is dispensed and used by each subject in the study. Reasons for departure from the expected dispensing regimen must also be recorded. Study drug accountability will be recorded in the subject source documentation, entered into the eCRF, and should be reviewed by the monitor during each monitoring visit. On a regular basis and at the completion of the study, to satisfy regulatory requirements regarding drug accountability, all study drug will be reconciled and retained or destroyed according to applicable regulations.

5.3 TREATMENT COMPLIANCE

All doses of the study drug will be administered in the study site under direct observation of study site personnel and recorded in the eCRF. Per standard clinic procedure, study site personnel will perform a mouth check and inspect all dose containers to ensure that the entire dose was administered. Following completion of dosing procedures and return of dosing containers to the pharmacy by team members, pharmacy staff will follow standard clinic

procedures for study drug reconciliation. SIGA will provide information to PPD for destruction of returned used and unused study drug and study drug bottles.

The date and time of study drug dosing will be captured and recorded on the appropriate page of the eCRF. If a subject is not administered study drug, the reason for the missed dose will be recorded.

5.3.1 Prior and Concomitant Medications

Restrictions for prior and concomitant medications and therapies are provided in Sections 4.1 and 4.2. Prior and concomitant medications and therapies will be coded using the latest version of the World Health Organization Drug Dictionary.

5.3.1.1 Prior Medications

Information regarding prior medications taken by the subject within the 30 days before signing the informed consent form (ICF) will be recorded in the subject's eCRF.

5.3.1.2 Concomitant Medications

Any concomitant medication deemed necessary for the welfare of the subject during the study may be given at the discretion of the investigator. If a concomitant medication listed in Section 4.2 is taken it will be documented as a protocol deviation and a joint decision will be made by the investigator and SIGA to continue or discontinue the subject based on the time the medication was administered, its pharmacology and PK, and whether the use of the medication will compromise the safety of the subject or the interpretation of the data. The investigator is responsible for ensuring that details regarding the medication are adequately recorded in both the subject's source document and the eCRF.

6. STUDY PROCEDURES

Before performing any study procedures, all potential subjects will sign an ICF as outlined in Section 9.3.2.3. Subjects will undergo study procedures at the time points specified in the schedule of events (Table 9-1).

The total amount of blood collected from each subject over the duration of the study, including any extra assessments that may be required, will not exceed 500 mL.

6.1 PHARMACOKINETIC ASSESSMENTS AND ENDPOINTS

Blood samples for PK analysis of TPOXX will be collected from all subjects Day 1 before study drug administration (0 hour), at 0.5, 1, 2, 4, 6, 8, 12 (before the PM dose), 14, 16, 18, 20, and 24 hours (before the AM dose on Day 2), on Day 6 (before the AM dose and 4 hours after the AM dose), on Day 7 before the AM dose (0 hour), at 0.5, 1, 2, 4, 6, 8, 12 (before the PM dose), 14, 16, 18, 20, and 24 hours (Day 8, 24 hours after the AM dose on Day 7), and on Day 9 (48 hours after the AM dose on Day 7).

For PK samples, the acceptable window for collection from the scheduled collection time point will be as follows: ±5 minutes for the time points from 1 to 8 hours and ±15 minutes for the 12- to 48-hour time points.

The following plasma PK parameters will be calculated for TPOXX using actual sampling times rather than scheduled sampling times and will include but are not limited to:

- Area under the plasma concentration-time curve (AUC) from time 0 to the last quantifiable measurement (AUC_{0-t})
- AUC from time 0 extrapolated to infinity ($AUC_{0-\infty}$)
- AUC from time 0 to 24 hour (AUC_{0-24})
- AUC during the first dosing interval (tau = 12 hours) (AUC_{0-tau})
- Maximum drug concentration in plasma (C_{max})
- Time to C_{max} (T_{max})
- Apparent volume of distribution (V_d/F)
- Apparent total body clearance (CL/F)
- Concentration observed prior to the next dose administration (C_{trough})
- Terminal elimination half-life ($t_{1/2}$)
- Terminal elimination rate constant (λ_z)
- Percentage of $AUC_{0-\infty}$ extrapolated from the last quantifiable measurement to infinity ($\%AUC_{extrap}$).

6.1.1 Pharmacokinetic Sample Collection, Shipping, and Storage

Blood samples (approximately 5 mL) for the determination of plasma concentrations of TPOXX will be collected in 5-mL lavender-topped K_3EDTA Vacutainer® tubes using a 21 gauge or larger needle, or from an indwelling intravenous catheter using a vacutainer tube. Blood samples should be placed on wet ice or equivalent (approximately 4°C to 8°C) and kept at this temperature until processed to separate plasma.

The exact time and date of sample collection will be recorded for each sample by the investigator or designee on the subject's eCRF, the vacutainer and cryovial labels, and the specimen shipping log. In addition, the time of study drug administration before PK sampling will be recorded on the subject's eCRF. Labels will be created by the site and should contain the protocol number, matrix (plasma), subject number, date, and time drawn. For information that is not preprinted on the label, a fine tipped indelible marking pen is to be used to complete the entry.

The 5-mL blood sample will be centrifuged in a refrigerated centrifuge immediately, if possible, or within 60 minutes of collection at 1000 to 1200 × *g* (2000 to 3000 rpm) for 10 minutes to separate plasma. Each plasma sample should be transferred via pipette into 2 cryovials labeled as described previously and should be capped tightly. The second tube will be a duplicate and retained at the site as a backup sample. If red blood cells are inadvertently drawn into the plasma, the sample should be re-centrifuged as soon as possible. Adequate space between the solution and the tube cap should be allowed for expansion during freezing.

Cryovial tubes containing plasma samples must be frozen at –70°C or below until shipment in a freezer equipped with a temperature monitor and temperature-activated alarm. Uncentrifuged specimens should not be frozen.

The study site will batch ship sets of frozen plasma samples. A log sheet listing the samples being shipped will be included in each shipment. The samples will be sent on dry ice via courier to Alturas Analytics (Moscow, ID). The back-up sets will remain at the site until confirmation that the first sets have been received. After receipt confirmation is received from Alturas Analytics, the back-up sets should be shipped. The site will contact Alturas Analytics and coordinate the shipment prior to sending the samples. Shipments before weekends or holidays must be avoided.

The samples will be shipped for analysis to:

Alturas Analytics
1324 Alturas Drive
Moscow, ID 83843

The bioanalytical laboratory will store all plasma samples at –70°C until analysis for tecovirimat is complete. SIGA will advise Alturas to destroy any remaining plasma samples after regulatory review is complete or the samples have met their applicable length of stability, whichever comes sooner.

6.1.2 Pharmacokinetic Sample Analysis

Pharmacokinetic samples will be analyzed by Alturas Analytics using a validated liquid chromatography coupled with tandem mass spectrometry assay for tecovirimat in human plasma method in accordance with the US FDA Guidance for Industry on Bioanalytical Method Validation.[3]

6.2 SAFETY ASSESSMENTS AND ENDPOINTS

Safety and tolerability will be assessed by monitoring and recording of AEs, clinical laboratory test results (hematology, serum chemistry, pregnancy, and urinalysis), vital sign measurements (systolic and diastolic blood pressures, heart rate, respiratory rate, and body temperature), 12-lead ECG results, and physical examination findings. Adverse events will be assessed from the time of the first dose of study drug until the follow-up telephone call on Day 37 (+2 days).

6.2.1 Adverse Events

6.2.1.1 Adverse Event Definitions

The investigator is responsible for reporting all AEs that are observed or reported during the study, regardless of their relationship to study drug or clinical significance. If there is any doubt as to whether a clinical observation is an AE, the event should be reported.

An AE is any event or other untoward medical occurrence, including those AEs that result from dosing errors, which may present during administration of a study drug or during a reasonable follow-up period and which does not necessarily have a causal relationship with this treatment. An AE is any unfavorable and unintended sign (eg, a clinically significant

abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal product, whether or not considered to be related to the medicinal product. All AEs will be followed until the AE is resolved or stabilized as determined by the investigator and/or the medical monitor.

A treatment-emergent AE (TEAE) is defined as any event not present before exposure to study drug or any event already present that worsens in intensity or frequency after exposure to study drug.

An adverse reaction is any AE caused by a drug. Adverse reactions are a subset of all suspected adverse reactions for which there are reasons to conclude that the drug caused the event.

A suspected adverse reaction is any AE for which there is a reasonable possibility that the study drug caused the AE. For the purposes of IND safety reporting, "reasonable possibility" means that there is evidence to suggest a causal relationship between the drug and the AE. A suspected adverse reaction implies a lesser degree of certainty about causality than adverse reaction, which means any AE caused by a study drug.

An AE or suspected adverse reaction is considered "unexpected" if it is not listed in the TPOXX full prescribing information or at the specificity or severity that has been observed with the study drug being tested. For example, under this definition, hepatic necrosis would be unexpected (by virtue of greater severity) if the TPOXX full prescribing information referred only to elevated hepatic enzymes or hepatitis. Similarly, cerebral thromboembolism and cerebral vasculitis would be unexpected (by virtue of greater specificity) if the TPOXX full prescribing information listed only cerebral vascular accidents. "Unexpected," as used in this definition, also refers to AEs or suspected adverse reactions that are mentioned in the TPOXX full prescribing information as occurring with a class of drugs or as anticipated from the pharmacological properties of the drug, but are not specifically mentioned as occurring with the particular drug under investigation.

An AE or suspected adverse reaction is considered an SAE if, in the view of either the investigator or SIGA, it results in any of the following outcomes:

- Results in death.
- Is life threatening (subject is at immediate risk of death at the time of the event).
- Requires inpatient hospitalization or prolongation of existing hospitalization, other than elective hospitalization, during the period of protocol defined surveillance.

- Results in congenital anomaly or birth defect.
- Results in a persistent or significant disability/incapacity.
- Any other important medical event that may not result in death, be life threatening, or requires hospitalization may be considered an SAE when, based on appropriate medical judgment, the event may jeopardize the subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition or is otherwise considered to be medically significant.

Important medical events that may not result in death, be life threatening, or require hospitalization may be considered serious when, based upon appropriate medical judgement, they may jeopardize the subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. Examples of such medical events include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse.

An AE or suspected adverse reaction is considered “life-threatening” if, in the view of either the investigator or SIGA, its occurrence places the subject at immediate risk of death. It does not include an AE or suspected adverse reaction that, had it occurred in a more severe form, might have caused death.

Serious AEs will be followed until the SAE is stable or until resolution as determined by the investigator and/or the medical monitor.

6.2.1.2 Eliciting and Documenting Adverse Events

The investigator is responsible for ensuring that all AEs and SAEs are recorded in the eCRF and reported to SIGA by PPD. Adverse events and SAEs will be assessed from the first dose of study drug through the telephone call on Day 37 (+2 days).

At every study visit or assessment, subjects will be asked a standard question to elicit any medically related changes in their well-being. They will also be asked if they have been hospitalized, had any accidents, used any new medications, or changed concomitant medication regimens (both prescription and over-the-counter medications).

In addition to subject observations, AEs will be documented from any data collected on the AE page of the eCRF (eg, laboratory values, physical examination findings, and ECG changes) or other documents that are relevant to subject safety.

6.2.1.3 Reporting Adverse Events

All AEs reported or observed from the first dose of study drug through the follow-up telephone call on Day 37 (+2 days) will be recorded on the AE page of the eCRF. Information to be collected includes drug treatment, type of event, date and time of onset, investigator-specified assessment of severity and relationship to study drug, date and time of resolution of the event, seriousness, as well as any required treatment or evaluations, and outcome. Adverse events resulting from concurrent illnesses, reactions to concurrent illnesses, reactions to concurrent medications, or progression of disease states must also be reported.

All AEs will be followed until they are resolved or stabilized as determined by the investigator and/or medical monitor. These data will be reviewed on an ongoing basis by the study coordinator, the investigator, the medical monitor, and the ISM. This requirement indicates that for some events, follow-up may be required after the subject has completed study participation. These events will be reported by SIGA, as required, to the FDA.

Any medical condition that is present at the time that the subject is screened but does not deteriorate should not be reported as an AE. However, if it deteriorates at any time during the study, it should be recorded as an AE. Prior to this, medical conditions reported by subjects are considered medical history.

6.2.1.4 Reporting of Serious Adverse Events

Any AE considered serious by the investigator or which meets SAE criteria (Section 6.2.1.1), or any other event or condition regardless of grade, which in their judgment represents a reportable event, must be reported to the medical monitor and SIGA as soon as the investigator becomes aware of the event. In addition, the event must be reported to PPD via the SAE hotline. The PPD SAE Report Form must be submitted within 24 hours of knowledge of the event. SIGA (or designee) will be responsible for notifying the relevant regulatory authorities of any SAE as outlined in US Title 21 Code of Federal Regulations (CFR) Parts 312 and 320. The investigator is responsible for notifying the institutional review board (IRB) directly.

In addition, the investigator (or designee) must report any Grade 3 (severe) AE that they deem possibly, probably, or definitely related to study drug to the medical monitor and SIGA within 24 hours after becoming aware of the event.

After notification from the investigator, SIGA will report all study drug-related and unexpected SAEs (those not listed in the TPOXX full prescribing information) to the FDA within 15 calendar days of first knowledge. Fatalities or life-threatening events assessed as related and unexpected will be reported to the FDA within 7 calendar days of first knowledge. The ISM will also receive these reports.

The following contact information is to be used for SAE reporting:

PPD Medical Monitor: Rahul Bhatnagar, MD
PPD Phase I Clinic
7551 Metro Center Drive, Suite 300
Austin, TX 78744
Telephone: 888-483-7729

PPD SAE Hotline: 888-483-7729
PPD SAE Fax line: 888-529-3580

The collection and monitoring period for SAEs is 30 days after administration of the last dose of study drug. At the time of discharge or early termination from the study site, the subject will be instructed to notify the investigator of any SAEs that occur within 30 days after the last dose of study drug.

All subjects will have a follow-up telephone call 30 days after administration of the last dose of study drug (Day 37 [+2 days]) to report any SAEs.

6.2.1.5 Assessment of Severity

All AEs will be graded for intensity according to the current DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events Version 2.1 July 2017.

Any laboratory or clinical AE that is not listed on the DAIDS Table will be assessed for severity and classified into 1 of 5 clearly defined categories as follows:

- Grade 1 (Mild): Events require minimal or no treatment and do not interfere with the subject's daily activities.
- Grade 2 (Moderate): Events result in a low level of inconvenience or concern with the therapeutic measures and may cause some interference with normal functioning.

- Grade 3 (Severe): Events interrupt a subject's usual daily activity, may require systemic drug therapy or other treatment, and are usually incapacitating.

- Grade 4 (Life-threatening): Event that, in the opinion of the investigator, places the subject at immediate risk of death from the reaction as it occurred (ie, it does not include a reaction that, had it occurred in a more severe form, might have caused death).

- Grade 5 (Death).

Changes in the severity of an AE should be documented to allow an assessment of the duration of the event at each level of intensity to be performed. An AE characterized as intermittent requires documentation of onset and duration of each episode.

6.2.1.6 Assessment of Causality

Any occurrence of an AE will be assessed for relationship to the study drug. A causal relationship means that the study drug caused (or is reasonably likely to have caused) the AE. This usually implies a relationship in time between the drug and the AE; for example, the AE occurred shortly after the subject received the study drug.

The investigator who examines and evaluates the subject will determine AE causality based on the temporal relationship to administration of the study drug, the pharmacology of the study drug, and their clinical judgment. Terms used to describe the degree of causality between a study drug and an AE are definitely related, probably related, possibly related, unlikely related, or not related.

The best estimate at the time of reporting of an event and the degree of certainty about the causal relationship between the study drug administration and the AE will be graded as follows:

<u>Associated</u>

- Definitely Related: The AE and administration of study drug are related in time, and a direct association can be demonstrated (eg, the event disappears or decreases with reduction in dose or cessation of study drug and recurs with re-exposure).

- Probably Related: The AE and administration of study drug are reasonably related in time and/or follow a known pattern of response, and the AE is more likely explained by study drug than other causes.

- Possibly Related: The AE and administration of study drug are reasonably related in time and/or follow a known pattern of response, but the AE can be explained equally well by causes other than study drug (eg, could readily have been produced by the subject's clinical state or could have been due to environmental or other interventions).

Not Associated

- Unlikely Related: A potential relationship between study drug and the AE could exist (ie, the possibility cannot be excluded), but the AE is most likely explained by causes other than the study drug (eg, could readily have been produced by the subject's clinical state or could have been due to environmental or other interventions).

- Not Related: The AE is clearly due to extraneous causes (eg, underlying disease, environment) or exposure to the study drug has not occurred. Such events MUST have an alternative, definitive etiology documented in the subject's medical record.

6.2.1.7 Follow-up of Adverse Events

All AEs must be reported in detail on the appropriate page of the eCRF and followed until they are resolved or stabilized as determined by the investigator and/or medical monitor.

6.2.1.8 Reactogenicity

At this time, there is no definitive information on allergic activity of TPOXX. Reactogenicity will be monitored in subjects during the study treatment period.

6.2.1.9 Reporting of Pregnancy

Pregnant women are not eligible to participate in the study. Subjects must be counseled regarding prevention of pregnancy and encouraged to make every effort to avoid pregnancy during study participation. If a female subject becomes pregnant during study participation, study drug dosing will be discontinued, and the subject will be withdrawn from the study. The pregnancy itself is not considered an SAE. However, the investigator must complete the pregnancy report form and fax it to PPD Pharmacovigilance within 24 hours of knowledge of the pregnancy. After delivery or termination of pregnancy, the follow-up pregnancy report form should be completed and submitted via fax to PPD Pharmacovigilance. Spontaneous abortions should always be reported as SAEs. Pregnancy data will be captured and followed by PPD. All pregnancies and outcomes will be tracked. The case will not be closed until after the child is followed for 3 months.

If there are complications during the pregnancy, the complications will be recorded as AEs in the usual manner. The subject will be asked to report the outcome of the pregnancy. If there is a congenital anomaly in the infant, this will be recorded as an SAE in the data forms for the mother (ie, the study subject).

If a subject becomes pregnant during the study after receiving the study drug, all safety evaluations will be collected as per protocol. In addition, at the time that the pregnancy is reported, consent will be requested to contact the subject and her physician in the postpartum period to assess delivery and health status of the neonate.

If the partner of a male subject becomes pregnant, the partner will be asked for consent to allow her treating physician to provide SIGA or its designee with follow-up information regarding the pregnancy and its outcome.

6.2.2 Clinical Laboratory Testing

Clinical laboratory tests will be performed by the PPD Central Laboratory. Blood samples will be collected at the time points indicated in the schedule of events (Table 9-1) and will be prepared using standard procedures.

Repeat clinical laboratory tests may be performed at the discretion of the investigator, if necessary, to evaluate inclusion and exclusion criteria or clinical laboratory abnormalities. PPD central laboratory will provide the reference ranges for all clinical laboratory safety parameters.

The following clinical laboratory assessments will be performed:

Hematology	Hematocrit, hemoglobin, mean corpuscular hemoglobin, mean corpuscular hemoglobin concentration, total and differential leukocyte count (basophils, eosinophils, lymphocytes, monocytes, neutrophils), mean corpuscular volume, platelet count, red blood cell count, and red cell distribution width
Serum Chemistry	Alanine aminotransferase, albumin, alkaline phosphatase, anion gap, aspartate aminotransferase, bilirubin (total), blood urea nitrogen, calcium, carbon dioxide, chloride, creatinine clearance (calculated[a]), gamma-glutamyltransferase, globulin, glucose, lactate dehydrogenase, phosphorus, potassium, sodium, total protein, and uric acid

Urinalysis	Appearance, bilirubin, blood, color, glucose, ketones, leukocytes, microscopy (performed if dipstick is ≥1+; includes bacteria, cast, crystals, epithelial cells, red blood cells, and white blood cells), nitrates, pH, protein, specific gravity, turbidity, and urobilinogen

[a] Creatinine clearance (CLcr) will be calculated using the Cockcroft-Gault formula:

$$CLcr\ (mL/min) = \frac{[140 - age(years)] \times weight\ (kg)}{72\ \times serum\ creatinine\ (mg/dL)}\{\times 0.85\ if\ female\}$$

Glycosylated hemoglobin A1c and a fasting lipid panel including cholesterol (total, high-density lipoprotein, calculated low-density lipoprotein, and triglycerides) will be performed at screening.

Serum pregnancy test (β human chorionic gonadotropin) for women of childbearing potential will be performed at screening and on Day –1.

A serum follicle-stimulating hormone test for postmenopausal women will be performed at screening.

Human immunodeficiency virus (type 1 and 2) antibodies, hepatitis B surface antigen, and hepatitis C virus antibody will be assessed at screening only.

A urine drug screen for alcohol, amphetamines (including methamphetamines and ecstasy/methylenedioxymethamphetamine), barbiturates, benzodiazepines, cannabinoids (including tetrahydrocannabinol), cocaine metabolites, and opiates (including heroin, codeine, and oxycodone) will be performed at screening and on Day –1.

Abnormal clinical laboratory values will be flagged as either high or low (or normal or abnormal) based on the reference ranges for each laboratory parameter. The investigator will determine whether any of the abnormally high or low results are clinically significant or not clinically significant. Clinical significance is defined as any variation in results that has medical relevance and may result in an alteration in medical care (eg, active observation, diagnostic measures, or therapeutic measures). If a clinically significant change from the screening value is noted, the clinically significant value and reason for clinical significance will be documented on the AE page of the eCRF. The investigator will continue to monitor the subject with additional assessments until the values have reached the reference range or the values at screening or until the investigator determines that follow-up is no longer medically necessary.

6.2.3 Medical History

A complete medical history will be obtained, including a review of systems, recreational and prescription drug use, over-the-counter drug use, nicotine and alcohol use, and past hospitalizations.

6.2.4 Vital Sign Measurements

Vital signs will be measured after the subject has been seated for at least 5 minutes at the time points indicated in the schedule of events (Table 9-1).

Vital sign measurements will include systolic and diastolic blood pressures, heart rate, respiratory rate, and body temperature.

When procedures are overlapping and occurring at the same time point, the order of procedures should be ECG, vital sign measurements, and then blood collection, with the blood collection scheduled to occur at the nominal time point, unless dictated by other study events happening at that time, such as dosing requirements.

The investigator will determine whether any of the vital sign measurements are clinically significant or not clinically significant. Clinical significance is defined as any variation in results that has medical relevance and may result in an alteration in medical care (eg, active observation, diagnostic measures, or therapeutic measures). If a clinically significant change from the screening values is noted, the clinically significant value and reason for clinical significance will be documented on the AE page of the subject's eCRF. The investigator will continue to monitor the subject with additional assessments until the value has reached the reference range or the value at screening or until the investigator determines that follow up is no longer medically necessary.

6.2.5 Electrocardiograms

A 12-lead ECG will be obtained after the subject has been in the supine position for at least 10 minutes at the time points indicated in the schedule of events (Table 9-1). On Days 1, 4, and 7, an ECG will be recorded 4 hours after the AM study drug administration. The acceptable window for collection from the scheduled collection time point will ±15 minutes.

Electrocardiogram assessments will include comments on whether the tracings are normal or abnormal, rhythm, presence of arrhythmia or conduction defects, morphology, any evidence of myocardial infarction, or ST segment, T wave, and U wave abnormalities. In addition, the

following parameters will be measured and reported: heart rate; PR, RR, and QT intervals; QTcF; QT interval corrected using Bazett's formula; and QRS duration. All ECGs must be performed by an experienced ECG technician.

The investigator will determine whether any of the 12-lead ECG results are clinically significant or not clinically significant. Clinical significance is defined as any variation in results that has medical relevance and may result in an alteration in medical care (eg, active observation, diagnostic measures, or therapeutic measures). If a clinically significant change from screening is noted, the clinically significant value and reason for clinical significance will be documented on the AE page of the subject's eCRF. The investigator will continue to monitor the subject with additional assessments until either the values have reached reference range or the values at screening or until the investigator determines that follow-up is no longer medically necessary.

6.2.6 Physical Examinations

A full physical examination will be performed at the time points indicated in the schedule of events (Table 9-1) and will include assessment of the following body systems: head, ears, eyes, nose, and throat; cardiac (including auscultation of heart); pulmonary (chest) auscultation of lungs; abdomen; skin; musculoskeletal system; lymphatic system; and neurologic system (cranial nerves, sensation, motor function, coordination, reflexes, and mental status).

A symptom-directed physical examination will be performed at the time points indicated in the schedule of events (Table 9-1) (for those subjects who require it), and at unscheduled visits as necessary. This examination will include an assessment of the heart, lungs, abdomen, a neurologic review, and a review of symptoms for assessments and/or follow-up of reported or potential AEs.

Weight will be measured without shoes and in light clothing at screening and without shoes and in hospital gowns at all other time points indicated in the schedule of events (Table 9-1). The scales should be calibrated, and the same weight scale should be used throughout the study starting with Screening through Day 9. Weight measurements will be rounded to one decimal place.

Height will be measured at Check-in on Day -1.

6.2.7 Unscheduled Visits

Subjects will be provided with the contact information for the study site personnel. Subjects are free to contact study site personnel at any time, and the site may require an unscheduled visit for the purpose of physical examinations, laboratory tests, etc. Unscheduled visits will be documented by the site personnel in the source documents. Unscheduled procedures and laboratory tests and results will also be recorded in the eCRF.

7. STATISTICAL ANALYSIS PLANS

7.1 SAMPLE SIZE CALCULATIONS

The sample size (N = 36 [to allow at least 32 enrolled subjects to complete]) for this study is based on clinical and practical considerations and not on a formal statistical power calculation. The sample size is considered sufficient to effectively assess the PK and safety profiles of TPOXX.

7.2 ANALYSIS POPULATIONS

The Safety Population will include all subjects who receive at least 1 dose of study drug.

The PK Population will include subjects who receive study drug and have sufficient concentration data to facilitate the calculation of PK variables.

7.3 STATISTICAL ANALYSIS

Details of all statistical analyses will be described in a statistical analysis plan. All data collected will be presented in data listings. Data from subjects excluded from an analysis population will be presented in the data listings, but not included in the calculation of summary statistics.

For categorical variables, frequencies and percentages will be presented. Continuous variables will be summarized using descriptive statistics (number of subjects, mean, median, standard deviation [SD], minimum, and maximum).

Baseline demographic and background variables will be summarized overall for all subjects. The number of subjects who enroll in the study and the number and percentage of subjects who complete the study will be presented. Frequency and percentage of subjects who withdraw or discontinue from the study, and the reason for withdrawal or discontinuation, will also be summarized.

7.3.1 Pharmacokinetic Analyses

Individual plasma concentration and time deviation data will be presented in a data listing. Plasma concentration data will be listed and summarized using the following descriptive statistics: number of subjects, arithmetic mean, SD, coefficient of variation (CV), geometric mean, geometric CV, median, minimum, and maximum. Individual and mean plasma concentration versus time profiles will be presented in figures on both linear and semilogarithmic scales.

The PK parameters of TPOXX will be analyzed based on the actual sampling times. All parameters will be determined using noncompartmental methods using Phoenix® WinNonlin® Version 8.0 or higher (Certara, L.P., Princeton, New Jersey) or SAS® Version 9.4 or higher (SAS Institute Inc., Cary, North Carolina).

The individual PK parameters and body weight-normalized PK parameters will be presented in data listings and summarized using the following descriptive statistics: number of subjects, arithmetic mean, SD, CV, median, minimum, maximum, geometric mean, geometric SD, and geometric CV.

7.3.2 Safety Analyses

Adverse events will be coded by preferred term and system organ class using the latest version of the Medical Dictionary for Regulatory Activities and summarized overall. All AE data will be presented in a data listing. Treatment-emergent AEs will be summarized overall, as well as by severity and relationship to study drug. Serious AEs and AEs leading to discontinuation of study drug will also be presented in the data listings and summarized overall.

Actual values and changes from baseline for clinical laboratory test results, vital sign measurements, and 12-lead ECG results will be summarized at each time point using descriptive statistics (number of subjects, mean, SD, median, minimum, and maximum). Shift tables will be generated for clinical laboratory test results. Clinical laboratory data, vital sign measurements, 12-lead ECG results, and physical examination findings will be presented in data listings.

7.4 HANDLING OF BELOW THE LIMIT OF QUANTIFICATION AND MISSING DATA

Plasma concentrations that are below the limit of quantification (BLQ) will be treated as zero for descriptive statistics. Geometric mean values will not be calculated or displayed when zero is the minimal value. Mean BLQ concentrations will be presented as BLQ, and the SD and CV will be reported as not applicable. Missing concentrations will be excluded from the calculations.

7.5 INTERIM ANALYSES

No formal interim safety analyses will be performed in this study.

8. REFERENCE LIST

1. Breman JG, Henderson DA. Diagnosis and management of smallpox. N Engl J Med. 2002;346(17):1300-8.

2. TPOXX (tecovirimat) [full prescribing information]. SIGA Technologies, Inc. Corvallis (OR); 2018. 18 p.

3. Department of Health and Human Services, Food and Drug Administration (US). Guidance for Industry. Bioanalytical Method Validation. May 2018. Available from: https://www.fda.gov/files/drugs/published/Bioanalytical-Method-Validation-Guidance-for-Industry.pdf.

9. APPENDICES

9.1 APPENDIX 1: LIST OF ABBREVIATIONS

Abbreviation	Term
$\%AUC_{extrap}$	percentage of $AUC_{0-\infty}$ extrapolated from the last quantifiable measurement to infinity
λ_z	terminal elimination rate constant
AE	adverse event
AUC	area under the plasma concentration-time curve
AUC_{0-24}	area under the plasma concentration-time curve from time 0 to 24 hours
$AUC_{0-\infty}$	area under the plasma concentration-time curve from time 0 extrapolated to infinity
AUC_{0-t}	area under the plasma concentration-time curve from time 0 to the last quantifiable measurement
AUC_{0-tau}	area under the plasma concentration-time curve during the first dosing interval
BCRP	breast cancer resistance protein
BID	twice daily
BLQ	below the limit of quantification
CFR	Code of Federal Regulations
CL/F	apparent total body clearance
C_{max}	maximum drug concentration in plasma
C_{trough}	concentration observed prior to the next dose administration
CRA	clinical research associate
CV	coefficient of variation
CYP	cytochrome P450
DAIDS	Division of Acquired Immune Deficiency Syndrome
ECG	electrocardiogram
eCRF	electronic case report form
FDA	Food and Drug Administration
ICF	informed consent form
ICH	International Council for Harmonisation
IRB	institutional review board
ISM	independent safety monitor
MedDRA	Medical Dictionary for Regulatory Activities
PK	pharmacokinetic(s)
QTcF	QT interval corrected using Fridericia's formula
SAE	serious adverse event
SD	standard deviation
SOP	standard operating procedures
$t_{1/2}$	terminal elimination half-life
TEAE	treatment-emergent adverse event

Abbreviation	Term
T_{max}	time to maximum drug concentration in plasma
UGT	uridine diphosphate-glucuronosyltransferase
VARV	variola virus
V_d/F	apparent volume of distribution

9.2 APPENDIX 2: SCHEDULE OF EVENTS

Table 9-1 Schedule of Events

	Screening	Check-in	Treatment Period									Telephone Call or Follow-up Visit[a]	Follow-up Telephone Call[b]
Procedure[c] Day	**–28 to –2**	**–1**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9 or Early Discontinuation**	**14 (+2)**	**37 (+2)**
Admission to clinic		X											
Discharge from clinic[d]											X		
Informed consent	X												
Inclusion/exclusion criteria	X	X											
Medical history[e]	X	X											
Complete physical examination[f]	X	X							X		X		
Weight[g]	X	X	X[h]								X		
Height		X											
Vital sign measurements[i]	X	X	X[j]			X[j]			X[j]	X	X	X[k]	
Glycosylated hemoglobin (HbA1c)	X												
Fasting lipid panel[l]	X												
Clinical laboratory testing[m]	X[n]	X				X				X[o]	X[n]		
Serum follicle-stimulating hormone[p]	X												
Serum pregnancy test[q]	X	X											
Urine drug/alcohol screen[r]	X	X											
Serology (HBsAg, HCV, and HIV)	X												
12-Lead ECG[s]	X	X	X			X			X		X		
TPOXX administration[t]			X	X	X	X	X	X	X				
Pharmacokinetic sampling[u]			X	X				X	X	X	X		
Symptom-directed physical examination[v]				X	X	X	X	X				X[k]	
Adverse events			◄	———	———	———	———	———	———	———	X	———	►
Prior/concomitant medications	◄	———	———	———	———	———	———	———	X	———	———	———	►

Abbreviations: AE, adverse event; ECG, electrocardiogram; HBsAg, hepatitis B surface antigen; HCV, hepatitis C virus; HIV, human immunodeficiency virus; PK, pharmacokinetic; SAE, serious adverse event.

Notes:

[a] The follow-up visit or telephone call will occur on Day 14 (+2 days), 7 days after the last dose of study drug. Subjects who have abnormal physical examination findings or an ongoing AE/SAE on Day 9 that is deemed related to study drug or per investigator or SIGA discretion will return to the study site on Day 14 (+2 days) for a follow-up visit. All other subjects will have the Day 14 (+2 days) follow-up via telephone.

[b] The follow-up telephone call will be made 30 days after the last dose of study drug (Day 37 [+2 days]).

[c] When procedures are overlapping and occurring at the same time point, the order of procedures should be ECG, vital sign measurements, and then blood collection, with the blood collection scheduled to occur at the nominal time point, unless dictated by other study events happening at that time, such as dosing requirements.

[d] Discharge following collection of all safety assessments.

[e] Including a review of systems; recreational, prescription, and over-the-counter drug use; nicotine and alcohol use; and past hospitalizations.

[f] Including assessment of the following body systems: head, ears, eyes, nose, and throat; cardiac (including auscultation of heart); pulmonary (chest) auscultation of lungs; abdomen; skin; musculoskeletal system; lymphatic system; and neurologic system (cranial nerves, sensation, motor function, coordination, reflexes, and mental status).

[g] Weight will be measured without shoes and in light clothing at screening and without shoes and in hospital gowns at all other time points. The scales should be calibrated and the same weight scale should be used throughout the study starting with Screening through Day 9. Weight measurements will be rounded to one decimal place.

[h] Weight will be collected prior to dosing.

[i] Vital sign measurements will include systolic and diastolic blood pressures, heart rate, respiratory rate, and body temperature. Vital signs will be measured after the subject has been seated for at least 5 minutes.

[j] Vital sign measurements will be performed before dosing and 4 hours after the AM study drug administration on Days 1 and 7 and 4 hours after the AM study drug administration on Day 4. The acceptable window for collection from the scheduled collection time point is ±15 minutes.

[k] Collected only if subjects are required to return to the study site on Day 14 (+2 days) for a follow-up visit.

[l] Including cholesterol (total, high-density lipoprotein, calculated low-density lipoprotein, and triglycerides).

[m] Clinical laboratory testing will include hematology and serum chemistry.

[n] Clinical laboratory testing at screening and at Day 9 or early discontinuation will include hematology, serum chemistry, and urinalysis.

[o] Collect 12 hours after the PM study drug administration on Day 7.

[p] For postmenopausal women, a serum follicle-stimulating hormone test will be performed at screening.

[q] Women of childbearing potential only.

[r] Includes alcohol, amphetamines (including methamphetamines and ecstasy/methylenedioxymethamphetamine), barbiturates, benzodiazepines, cannabinoids (including tetrahydrocannabinol), cocaine metabolites, and opiates (including heroin, codeine, and oxycodone).

[s] A 12-lead ECG will be collected after the subject has been in the supine position for at least 10 minutes. On Days 1, 4, and 7, an ECG will be recorded 4 hours after the AM study drug administration. The acceptable window for collection from the scheduled collection time point is ±15 minutes.

[t] TPOXX, 600 mg (3 × 200-mg capsules) will be administered orally twice daily, approximately 12 hours (± 30 minutes) apart on Days 1 through 7. All subjects will be provided meals consisting of approximately 600 calories and 25 g fat, which will start 30 minutes before study drug administration. Subjects should eat this meal within 30 minutes or less of taking study drug. Study drug will be administered approximately 30 minutes after the start of the meal. All doses of study drug will be administered to subjects by study site personnel with approximately 240 mL of water. Subjects must fast 2 hours after taking study drug. Study drug and meals must be taken with water only, and no other beverage except water should be ingested within 3 hours before or 3 hours after study drug administration.

[u] Blood samples for PK analysis of TPOXX will be collected from all subjects at the following tome points: on Day 1 before study drug administration (0 hour), at 0.5, 1, 2, 4, 6, 8, 12 (before the PM dose), 14, 16, 18, 20, and 24 hours (before the AM dose on Day 2), on Day 6 (before the AM dose and 4 hours after the AM dose), on Day 7 before the AM dose (0 hour), at 0.5, 1, 2, 4, 6, 8, 12 (before the PM dose), 14, 16, 18, 20, and 24 hours (Day 8, 24 hours after the AM dose on Day 7), and on Day 9 (48 hours after the AM dose on Day 7). For PK blood samples, the acceptable window for collection from the scheduled collection time point will be as follows: ±5 minutes for the time points from 1 to 8 hours and ±15 minutes for the 12- to 48-hour time points.

[v] Including assessment of heart, lungs, abdomen, a neurologic review, and a review of symptoms for assessment and/or follow-up of reported or potential adverse events.

9.3 APPENDIX 3: STUDY GOVERNANCE

9.3.1 Data Quality Assurance

This study will be conducted using the quality processes described in applicable procedural documents. The quality management approach to be implemented will be documented and will comply with current ICH guidance on quality and risk management. All aspects of the study will be monitored for compliance with applicable government regulatory requirements, current Good Clinical Practice, the protocol, and standard operating procedures (SOPs). The monitor will maintain current personal knowledge of the study through observation, review of study records and source documentation, and discussion of the conduct of the study with the investigator and staff. Electronic CRFs and electronic data capture will be utilized. The electronic data capture system is validated and compliant with US Title 21 CFR Part 11. Each person involved with the study will have an individual identification code and password that allows for record traceability. There may be an internal quality review audit of the data and additional reviews by the clinical monitor.

Steps to be taken to ensure the accuracy and reliability of data include, but are not limited to: selection of qualified investigator and appropriate study center, protocol training and review of protocol procedures with the investigator and study site personnel before the start of the study, site initiation and periodic interim monitoring visits by SIGA or PPD, and direct transmission of safety laboratory data into the PPD study database for all clinical safety laboratory tests performed. The eCRF will be reviewed for accuracy and completeness by PPD Clinical research associate (CRA) remotely and during on-site monitoring visits. Discrepancies will be resolved with the investigator or designees, as appropriate. The data will be entered into the clinical study database and validated for accuracy. During on-site monitoring visits, 100% of the data will be verified using source documentation. SIGA or Biomedical Advanced Research and Development Authority representatives may accompany the PPD CRA on any scheduled site visit. The investigator will be informed in advance of any visitors to the study site in addition to the PPD CRA.

Representatives of SIGA’s Quality Assurance department (or designee) may visit the site to carry out an audit of the study in compliance with regulatory guidelines and PPD policy. Such audits will require access to all study records, including source documents, for inspection and source document verification with the eCRF. Subject privacy must, however, be respected. Sufficient prior notice will be provided to allow the investigator to prepare properly for the audit. Similar auditing procedures may also be conducted by any regulatory body reviewing the results of this study in support of a Licensing Application. The

investigator will immediately notify SIGA if they are contacted by a regulatory agency requesting a site inspection.

9.3.2 Investigator Obligations

The following administrative items are meant to guide the investigator in the conduct of the study and may be subject to change based on industry and government SOPs, working practice documents, or guidelines. Changes will be reported to the IRB but will not result in protocol amendments.

9.3.2.1 Confidentiality

All laboratory specimens, evaluation forms, reports, and other records will be identified in a manner designed to maintain subject confidentiality. All records will be kept in a secure storage area with limited access. Subjects will not be identified by name in any reports in this study. All records will be kept confidential to the extent provided by federal, state, and local law. Medical records are made available for review when required by the FDA or other authorized users only under the guidelines set by the Federal Privacy Act. Direct access, as defined in the Federal Privacy Act, includes examining, analyzing, verifying, and reproducing any records and reports that are important to the evaluation of the study. The investigator is obligated to inform the subjects that these representatives may review their study-related records without violating the confidentiality of the subjects. The requirement to maintain subject confidentiality is included in the study informed consent document.

The investigator and all employees and coworkers involved with this study may not disclose or use for any purpose other than performance of the study, any data, record, or other unpublished, confidential information disclosed to those individuals for the purpose of the study. Prior written agreement from SIGA or its designee must be obtained for the disclosure of any said confidential information to other parties.

9.3.2.2 Institutional Review

Federal regulations and ICH guidelines require that approval be obtained from an IRB before participation of human subjects in research studies. Before study onset, the protocol, ICF, advertisements to be used for the recruitment of study subjects, and any other written information regarding this study to be provided to the subject or the subject’s legal guardian must be approved by the IRB. Documentation of all IRB approvals and of the IRB

compliance with the ICH harmonised tripartite guideline E6(R2): Good Clinical Practice will be maintained by the site and will be available for review by SIGA or its designee.

All IRB approvals should be signed by the IRB chairman or designee and must identify the IRB name and address, the clinical protocol by title or protocol number or both, and the date approval or a favorable opinion was granted.

9.3.2.3 Subject Consent

Written documentation of informed consent in compliance with US Title 21 CFR Part 50 shall be obtained from each subject before any study-related procedures are performed and study drug is administered. If any institution-specific modifications to study-related procedures are proposed or made by the site, the consent should be reviewed by SIGA or its designee or both before IRB submission. Once reviewed, the investigator will submit the ICF to the IRB for review and approval before the start of the study. If the ICF is revised during the course of the study, all active participating subjects must sign the revised ICF.

Before recruitment and enrollment, each prospective subject or his/her legal guardian will be given a full explanation of the study and will be asked to read and review the approved ICF. Once the investigator is assured that the subject/legal guardian understands the implications of participating in the study, the subject/legal guardian will be asked to give his or her consent to participate in the study by signing the ICF. A copy of the ICF will be provided to the subject/legal guardian.

9.3.2.4 Exclusion of Children

Effort will be made to include women and minorities in proportions similar to that of the community from which they are recruited. Because this study is designed to establish safety of the study drug in adults, enrollment will be limited to persons at least 18 years of age, and no older than 50 years. Children are excluded from participation in this clinical study because it does not meet the Department of Health and Human Services' guidelines (45 CFR 46, Subpart D, 401-409) for inclusion of children in research. These guidelines provide guidance for the protection of children in research. Generally, healthy children can be studied when the research is considered as "not greater than minimal risk." Children can be involved in research with greater than minimal risk only when it presents the prospect of direct benefit to the individual child or is likely to yield generalizable knowledge about the child's disorder or condition.

9.3.2.5 Study Reporting Requirements

By participating in this study, the investigator agrees to submit reports of SAEs according to the time line and method outlined in this protocol. In addition, the investigator agrees to submit annual reports to his or her IRB as appropriate.

9.3.2.6 Financial Disclosure and Obligations

The investigator is required to provide financial disclosure information to allow SIGA to submit the complete and accurate certification or disclosure statements required under US Title 21 CFR Part 54. In addition, the investigator must provide to SIGA a commitment to promptly update this information if any relevant changes occur during the course of the investigation and for 1 year following the completion of the study.

Neither SIGA nor PPD is financially responsible for further testing or treatment of any medical condition that may be detected during the screening process. In addition, in the absence of specific arrangements, neither SIGA nor PPD is financially responsible for further treatment of the disease under study.

9.3.2.7 Investigator Documentation

Prior to beginning the study, the investigator will be asked to comply with ICH E6(R2) Section 8.2 and US Title 21 of the CFR by providing essential documents, including but not limited to, the following:

- IRB approval.
- An original investigator-signed investigator agreement page of the protocol.
- Form FDA 1572, fully executed, and all updates on a new fully executed Form FDA 1572.
- Curriculum vitae for the principal investigator and each subinvestigator listed on Form FDA 1572. Current licensure must be noted on the curriculum vitae. Curriculum vitae will be signed and dated by the principal investigators and subinvestigators at study start-up, indicating that they are accurate and current.
- Financial disclosure information to allow SIGA to submit complete and accurate certification or disclosure statements required under US Title 21 CFR Part 54. In addition, the investigators must provide to SIGA a commitment to promptly update this

information if any relevant changes occur during the course of the investigation and for 1 year after the completion of the study.

- An IRB-approved ICF, samples of site advertisements for recruitment for this study, and any other written information about this study that is to be provided to the subject or legal guardians.

- Laboratory certifications and reference ranges for any local laboratories used by the site, in accordance with US Title 42 CFR Part 493.

9.3.2.8 Study Conduct

The investigator agrees to perform all aspects of this study in accordance with the ethical principles that have their origin in the Declaration of Helsinki, ICH E6(R2): Good Clinical Practice; the protocol; and all national, state, and local laws or regulations.

9.3.2.9 Case Report Forms and Source Documents

Site personnel will maintain source documentation, enter subject data into the eCRF as accurately as possible, and will rapidly respond to any reported discrepancies.

Electronic CRFs and electronic data capture will be utilized. The electronic data capture system is validated and compliant with US Title 21 CFR Part 11. Each person involved with the study will have an individual identification code and password that allows for record traceability. Thus, the system, and any subsequent investigative reviews, can identify coordinators, investigators, and individuals who have entered or modified records, as well as the time and date of any modifications. There may be an internal quality review audit of the data and additional reviews by PPD's CRA.

Each eCRF is presented as an electronic copy, allowing data entry by site personnel, who can add and edit data, add new subjects, identify and resolve discrepancies, and view records. This system provides immediate direct data transfer to the database, as well as immediate detection of discrepancies, enabling site coordinators to resolve and manage discrepancies in a timely manner.

Paper copies of the eCRFs and other database reports may be printed and signed by the investigator. This system provides site personnel, PPD CRAs, and reviewers with access to hardcopy audits, discrepancy reviews, and investigator comment information.

9.3.2.10 Adherence to Protocol

The investigator agrees to conduct the study as outlined in this protocol, in accordance with ICH E6(R2) and all applicable guidelines and regulations.

9.3.2.11 Reporting Adverse Events

By participating in this study, the investigator agrees to submit reports of SAEs according to the timeline and method outlined in this protocol. In addition, the investigator agrees to submit annual reports to his or her IRB as appropriate. The investigator also agrees to provide SIGA with an adequate report, if applicable, shortly after completion of the investigator's participation in the study.

9.3.2.12 Investigator's Final Report

Upon completion of the study, the investigator, where applicable, should inform the institution; the investigator/institution should provide the IRB with a summary of the study's outcome and SIGA and regulatory authorities with any reports required.

9.3.2.13 Records Retention

Essential documents should be retained until at least 2 years after the last approval of a marketing application in an ICH region and until there are no pending or contemplated marketing applications in an ICH region or until at least 2 years have elapsed since the formal discontinuation of clinical development of the study drug. These documents should be retained for a longer period, however, if required by applicable regulatory requirements or by an agreement with SIGA. SIGA is responsible for informing the investigator/institution when these documents no longer need to be retained.

9.3.2.14 Publications

All information concerning TPOXX, SIGA operations, patent application, formulas, manufacturing processes, basic scientific data, and formula information, supplied by SIGA to the investigator and not previously published, is considered confidential and remains the sole property of SIGA. The investigator agrees to use this information only to accomplish this study and will not use it for other purposes without SIGA's written consent. The investigator understands that the information developed in the clinical study will be used by SIGA, in connection with the continued development of TPOXX, and thus may be disclosed as required to other clinical investigators or government regulatory agencies. To permit the

information derived from the clinical studies to be used, the investigator is obligated to provide SIGA with all data obtained in the study. Any publication or other public presentation of results from this study, including manuscripts and materials for presentation at scientific meetings, should be provided to SIGA at least 30 working days before abstract or other relevant submission deadlines. Authorship of publications resulting from this study will be determined at the discretion of SIGA.

9.3.3 Study Management

9.3.3.1 Monitoring

9.3.3.1.1 Monitoring of the Study

Site monitoring for safety is conducted to ensure that human subject protection, study procedures, and laboratory, study drug dosing, and data collection processes are of high quality and meet SIGA, GCP/ICH, and regulatory guidelines. PPD CRA(s) will conduct site monitoring visits as detailed in the monitoring plan.

Site investigators will allow the CRA(s), the designated IRB, SIGA or its designee and the FDA to review, audit, and inspect study documents (eg, ICFs, drug accountability and distribution forms, eCRF), pertinent hospital and site records, and source documentation for verification of the study data.

Clinical research associates will conduct site visits in accordance with PPD SOPs to monitor the following: study operations, the quality of data collected in the research records, the accuracy and timeliness of data entered in the database, and to determine that all process and regulatory requirements are met. Study monitoring visits will occur at initiation of the study site, at intervals determined by SIGA during conduct of the study, and at completion of the study.

The CRA will maintain current personal knowledge of the study through observation, review of study records and source documentation, and discussion of the conduct of the study with the investigator and staff. During the routine monitoring visits, the CRA will perform a 100% source document verification of all subject data entered into the eCRF. Discrepancies, if any, will be clarified with the study site coordinator and investigator, and corrected at the site by the study coordinator. Any questions or required data clarifications will be sent to the study site electronically.

9.3.4 Safety Monitoring Plan

Close cooperation between the designated members of the study team will occur to evaluate and respond to individual AEs in a timely manner. Designated team members (investigator, subinvestigators, study coordinator, and other designated study clinicians) will review the subject safety information and data (laboratory test results, ECGs, AEs, and concomitant medications) and update the PPD project team and the ISM on the status of all enrolled subjects at their site on a weekly basis (or more frequently if required because of an unexpected safety issue) through completion of each subject's final study visit.

9.3.5 Medical Monitor

The medical monitor, or their qualified designee, will receive reports within 24 hours of study site awareness of all SAEs and within 7 days of study site awareness of all other AEs. The safety monitors will review all safety data and alert the medical monitor of SAEs and AEs of interest. The medical monitor may make a request for data to the investigator as necessary for safety evaluations.

The medical monitor will review each significant AE in a timely fashion and ensure that appropriate management is initiated and completed. Drug safety representatives and the medical monitor will have direct contact with the investigators and follow all significant events as needed.

9.3.6 Safety Oversite (Independent Safety Monitor)

In addition to the investigator's ongoing review of the safety data, the ISM will review the protocol for any major concerns and will be involved in data review in coordination with the investigator. The primary role of the ISM will be to evaluate the study safety and tolerability data. The ISM will provide independent safety monitoring in a timely fashion, which will include reviewing individual SAE reports and a review of periodic cumulative AE reports. Clinical safety and laboratory data, clinical records, and other safety study-related records will be made available for the ISM to review. Based on review of this data, the ISM may make recommendations regarding the safe continuation of the study. Specific details will be outlined in the Safety and Medical Management Plan.

9.3.6.1 Inspection of Records

The investigator and study site involved in the study will permit study-related monitoring, audits, IRB review, and regulatory inspections by providing direct access to all study records.

In the event of an audit, the investigator agrees to allow SIGA, their representatives, the FDA, or other regulatory agencies access to all study records.

The investigator should promptly notify SIGA and study site of any audits scheduled by any regulatory authorities and promptly forward copies of any audit reports received to SIGA.

9.3.6.2 Management of Protocol Amendments and Deviations

9.3.6.2.1 Modification of the Protocol

Any changes in this research activity, except those necessary to remove an apparent immediate hazard to the subject, must be reviewed and approved by SIGA or designee. Amendments to the protocol must be submitted in writing to the IRB for approval before subjects are enrolled into an amended protocol.

9.3.6.2.2 Protocol Deviations

The investigator or designee must document and explain in the subject's source documentation any deviation from the approved protocol. The investigator may implement a deviation from, or a change to, the protocol to eliminate an immediate hazard to study subjects without prior IRB approval. As soon as possible after such an occurrence, the implemented deviation or change, the reasons for it, and any proposed protocol amendments should be submitted to the IRB for review and approval, to SIGA for agreement, and to the regulatory authorities, if required.

A *protocol deviation* is any change, divergence, or departure from the study design or procedures defined in the protocol. An *important protocol deviation* (sometimes referred to as a protocol violation or a major protocol deviation) is a subset of protocol deviations that might significantly affect the reliability of the study data or that might significantly affect a subject's safety. An important deviation can include nonadherence to inclusion or exclusion criteria or nonadherence to FDA regulations or ICH E6(R2) guidelines.

Protocol deviations will be documented by the clinical monitor throughout the course of monitoring visits. The investigator will be notified in writing by the monitor of deviations. The IRB should be notified of all protocol deviations, if appropriate, in a timely manner.

9.3.6.3 Study Termination

Although SIGA has every intention of completing the study, they reserve the right to discontinue it at any time for clinical or administrative reasons.

An initiative for closure of the clinical investigative site or termination of the study can be taken at any time either by SIGA, PPD, or the investigator provided there is reasonable cause and sufficient notice is given in advance of the intended termination. Reasons for such action include, but are not limited to:

- Study site closure
    - Inadequate site recruitment/enrollment of subjects
    - Failure of an investigator to comply with the protocol, PPD SOPs, GCP guidelines, or applicable federal regulations
- Termination of enrollment
    - Enrollment of the required estimated number of subjects for the study
- Study termination
    - Completion of the study
    - Safety concerns

In addition, the ISM and FDA have the prerogative to delay or terminate the study.

The end of the study is defined as the date on which the last subject completes the last visit (includes the follow-up visit and the follow-up telephone call). Any additional long-term follow-up that is required for monitoring of the resolution of an AE or finding may be reported through an amendment to the clinical study report.

9.3.6.4 Final Report

Whether the study is completed or prematurely terminated, SIGA will ensure that clinical study reports are prepared and provided to regulatory agency(ies) as required by the applicable regulatory requirement(s). SIGA will also ensure that clinical study reports in marketing applications meet the standards of the ICH harmonised tripartite guideline E3: Structure and content of clinical study reports.

Upon completion of the clinical study report, the investigator will be provided with the final approved clinical study report, as appropriate.

9.4 APPENDIX 4: CHANGE HISTORY

9.4.1 Protocol Amendment 1

Protocol Amendment 1 was issued to clarify the weight requirements for qualified subjects on Day -1 and Day 1, clarify that the same scale will be used in Screening and how rounding procedures will be used, update Reference 3 to cite the current FDA Guidance, remove the ±2 day window for the Day 9 / Early Discontinuation visit, and remove symptom-directed physical examination from Day 7. The changes to Protocol Amendment 1 are outlined as follows:

Protocol Section	Change	Rationale
Synopsis and Section 3.1 Inclusion Criteria	Clarified subjects need to weigh >120 kg at check-in on Day -1, and prior to dosing on Day 1, in addition to weighing >120 kg at Screening.	In order to obtain accurate pharmacokinetic data in subjects weighing >120 kg, subjects participating in this study need to meet the weight requirement during dosing.
Section 6.2.6 Physical Examinations and Section 9.2 Appendix 2: Schedule of Events	Clarified the scale should be used throughout the entire study including Screening. Clarified rounding should occur by adding the following text: *Weight measurements will be rounded to one decimal place.*	The same scale should be used for the screening of subjects as will be used in the study to ensure weight measurement consistency. Scales at the site measure weight to two decimal places.
Section 8 Reference List	Updated reference 3 to cite the May 2018 Bioanalytical Method Validation Guidance for Industry	An updated Guidance was published in May of 2018.
Section 9.2 Appendix 2: Schedule of Events	Removal of (±2) from Day 9 or Early Discontinuation visit header	The ±2 day visit window was included in error. Subjects will check out on day 9 or will undergo Early Discontinuation Procedures on the day they discontinue. There is no window for these visits.
Section 9.2 Appendix 2: Schedule of Events	Removal of Day 7 symptom-directed physical examination from schedule.	A complete physical exam is already being conducted on Day 7.

9.4.2 Protocol Amendment 2

Protocol Amendment 2 was issued to revise Exclusion Criteria 31; to remove redundant Exclusion Criteria; to add the measurement of height to the Day -1 Check-in procedures; and to remove the one hour observation period for allergic reaction following dosing. The changes to Protocol Amendment 2 are outlined as follows:

Protocol Section	Change	Rationale
Synopsis and Section 3.2 Exclusion Criteria	Removed bullet point 3 from Exclusion Criteria 2, which stated: *Hypertension that is poorly controlled (repeat readings >140 mm Hg systolic and/or >90 mm Hg diastolic)* and revised Exclusion Criteria 31 from *Subject has a sustained sitting systolic blood pressure >140 mm Hg or <100 mm Hg or a diastolic blood pressure >90 mm Hg at screening. Blood pressure may be retested twice in the sitting position at 5-minute intervals. The pressure elevation is considered sustained if either the systolic or the diastolic pressure exceeds the stated limits on all 3 assessments* to *Subject has a blood pressure considered to be clinically significant by the investigator. Blood pressure may be retested twice in the sitting position at 5-minute intervals.*	Bullet point 3 was removed as it was redundant with Exclusion Criteria 31. Exclusion Criteria 31 was revised to allow the investigator to determine clinical significance of blood pressure for study inclusion or exclusion.
Section 6.2.6 Physical Examinations and Section 9.2 Appendix 2: Schedule of Events	Added height to Day -1 Check-in procedures	This measurement was previously unintentionally omitted from the study assessments.
Section 6.2.1.8 Reactogenicity and Section 9.2 Appendix 2: Schedule of Events	Removed specific mention of a one hour observation period for allergic reaction following dosing from Section 6.2.1.8 and removed reactogenicity from the Schedule of Events.	Subjects are required to stay at the clinical site throughout the entire dosing period and are continually under observation by site staff.

16.1.2 Sample Case Report Form (Unique Pages Only)

This section contains the following document:

Sample case report form dated 16 December 2019

Subject Case Report Forms

PROD_16DEC2019_3.00 - UNIQUE

Generated On: 31 Jan 2020 12:45:03

PROD_16DEC2019_3.00: UNIQUE
Project Name: SGSIGA246022
Form: Subject Enrollment
Generated On: 31 Jan 2020 12:45:03

What is the site identifier? _____

What is the subject identifier? _____

What is the Visit Date? (dd-mon-yyyy) _____

Select all assessments performed at the Unscheduled Visit.

Vital Signs	
Electrocardiogram	
Central Laboratory	
Physical Examination	
Pharmacokinetic Blood Collection	

To which period of the trial does this disposition refer?	SCREENING ■ BASELINE ☐ FOLLOW-UP ☐
Protocol Milestone	INFORMED CONSENT OBTAINED ■ ELIGIBILITY CRITERIA MET ☐
What is the date informed consent was signed? (dd-mon-yyyy)	_____

What is the subject's date of birth? (dd-mon-yyyy)	_____
What is the sex of the subject?	MALE ☐ FEMALE ☐
What is the ethnicity of the subject?	HISPANIC OR LATINO ☐ NOT HISPANIC OR LATINO ☐ NOT REPORTED ☐ UNKNOWN ☐
Race Not Reported	NOT REPORTED..... ☐
Race: Choose all that apply	
AMERICAN INDIAN OR ALASKA NATIVE: A person having origins in any of the original peoples of North and South America (including Central America), and who maintains tribal affiliation or community attachment. (FDA)	AMERICAN INDIAN OR ALASKA NATIVE..... ☐
ASIAN: A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam. (FDA)	ASIAN..... ☐
BLACK OR AFRICAN AMERICAN: A person having origins in any of the black racial groups of Africa. Terms such as "Haitian" or "Negro" can be used in addition to "Black or African American." (FDA)	BLACK OR AFRICAN AMERICAN..... ☐

NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER: Denotes a person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands. The term covers particularly people who identify themselves as part-Hawaiian, Native Hawaiian, Guamanian or Chamorro, Carolinian, Samoan, Chuu. (FDA)	NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER ☐
WHITE: Denotes a person with European, Middle Eastern, or North African ancestral origin who identifies, or is identified, as White. (FDA)	WHITE..... ..... ☐

Protocol Milestone	INFORMED CONSENT OBTAINED ☐ ELIGIBILITY CRITERIA MET ■
What is the protocol version and date?	AMENDMENT 1, VERSION 2.0, 27-JUN-2019 ☐ AMENDMENT 2, VERSION 3.0, 02-AUG-2019 ☐
Did the subject meet all eligibility criteria?	YES ☐ NO ☐

If the subject did not meet all eligibility criteria, please specify criterion type and number below.

What was the category of the criterion?	INCLUSION ☐ EXCLUSION ☐
What is the identifier of the criterion the subject did not meet?	IN01 ☐ IN02 ☐ IN03 ☐ IN04 ☐ IN05 ☐ IN06 ☐ IN07 ☐ IN08 ☐ IN09 ☐ EX01 ☐ EX02 ☐ EX03 ☐ EX04 ☐

EX05 ☐
EX06 ☐
EX07 ☐
EX08 ☐
EX09 ☐
EX10 ☐
EX11 ☐
EX12 ☐
EX13 ☐
EX14 ☐
EX15 ☐
EX16 ☐
EX17 ☐
EX18 ☐
EX19 ☐
EX20 ☐
EX21 ☐
EX22 ☐
EX23 ☐
EX24 ☐
EX25 ☐
EX26 ☐
EX27 ☐
EX28 ☐
EX29 ☐
EX30 ☐
EX31 ☐
EX32 ☐
EX33 ☐
EX34 ☐
EX35 ☐

Protocol Milestone	INFORMED CONSENT OBTAINED ☐ ELIGIBILITY CRITERIA MET ■
What is the protocol version and date?	AMENDMENT 1, VERSION 2.0, 27-JUN-2019 ☐ AMENDMENT 2, VERSION 3.0, 02-AUG-2019 ☐
Did the subject meet all eligibility criteria?	YES ☐ NO ☐

On what date were the measurements performed? (dd-mon-yyyy)	
Any collections: DERIVED	YES ☐ NO ☐
Current Date/Time (Hidden field for CF use)	
In what position was the subject during the measurement?	SITTING ■
Were Vital Signs collected?	YES ☐ NO ☐
If No, provide reason	
At what time were the measurements performed? (00:00-23:59)	
Systolic Blood Pressure	**mmHg** ☐
Diastolic Blood Pressure	**mmHg** ☐
Heart Rate	**beats/min** ☐
Respiratory Rate	**breaths/min** ☐
Temperature	**C** ☐

Vital Date/Time: DERIVED (dd-mon-yyyy 00:00-23:59) _____

On what date were the measurements performed? (dd-mon-yyyy)	
Any collections: DERIVED	YES ☐ NO ☐
Current Date/Time (Hidden field for CF use)	
In what position was the subject during the measurement?	SITTING ■
Were Vital Signs collected?	YES ☐ NO ☐
If No, provide reason	
At what time were the measurements performed? (00:00-23:59)	
Systolic Blood Pressure	**mmHg** ☐
Diastolic Blood Pressure	**mmHg** ☐
Heart Rate	**beats/min** ☐
Respiratory Rate	**breaths/min** ☐
Temperature	**C** ☐

Vital Date/Time: DERIVED (dd-mon-yyyy 00:00-23:59) _____

On what date were the measurements performed? (dd-mon-yyyy) _____

Any collections: DERIVED

- [ ] YES
- [ ] NO

Current Date/Time (Hidden field for CF use) _____

What is the planned time point for this measurement?

- [x] PREDOSE
- [ ] 4 HOUR POSTDOSE

In what position was the subject during the measurement?

- [x] SITTING

Were Vital Signs collected?

- [ ] YES
- [ ] NO

If No, provide reason _____

At what time were the measurements performed? (00:00-23:59) _____

Systolic Blood Pressure **mmHg** _____

Diastolic Blood Pressure **mmHg** _____

Heart Rate **beats/min** _____

Respiratory Rate	**breaths/min** ☐
Temperature	**C** ☐
Vital Date/Time: DERIVED (dd-mon-yyyy 00:00-23:59)	_____
What is the planned time point for this measurement?	PREDOSE ☐ 4 HOUR POSTDOSE ■
In what position was the subject during the measurement?	SITTING ■
Were Vital Signs collected?	YES ☐ NO ☐
If No, provide reason	_____
At what time were the measurements performed? (00:00-23:59)	_____
Systolic Blood Pressure	**mmHg** ☐
Diastolic Blood Pressure	**mmHg** ☐
Heart Rate	**beats/min** ☐
Respiratory Rate	**breaths/min** ☐

Temperature **C** ☐

Vital Date/Time: DERIVED (dd-mon-yyyy 00:00-23:59) _____

On what date were the measurements performed? (dd-mon-yyyy)	
Any collections: DERIVED	YES ☐ NO ☐
Current Date/Time (Hidden field for CF use)	
What is the planned time point for this measurement?	PREDOSE ☐ 4 HOUR POSTDOSE ■
In what position was the subject during the measurement?	SITTING ■
Were Vital Signs collected?	YES ☐ NO ☐
If No, provide reason	
At what time were the measurements performed? (00:00-23:59)	
Systolic Blood Pressure	**mmHg** ☐
Diastolic Blood Pressure	**mmHg** ☐
Heart Rate	**beats/min** ☐

Respiratory Rate	**breaths/min** ☐
Temperature	**C** ☐
Vital Date/Time: DERIVED (dd-mon-yyyy 00:00-23:59)	_____

On what date were the measurements performed? (dd-mon-yyyy)	
Any collections: DERIVED	YES ☐ NO ☐
Current Date/Time (Hidden field for CF use)	
What is the planned time point for this measurement?	PREDOSE ■ 4 HOUR POSTDOSE ☐
In what position was the subject during the measurement?	SITTING ■
Were Vital Signs collected?	YES ☐ NO ☐
If No, provide reason	
At what time were the measurements performed? (00:00-23:59)	
Systolic Blood Pressure	**mmHg** ☐
Diastolic Blood Pressure	**mmHg** ☐
Heart Rate	**beats/min** ☐

Respiratory Rate	**breaths/min** ☐
Temperature	**C** ☐
Vital Date/Time: DERIVED (dd-mon-yyyy 00:00-23:59)	_____
What is the planned time point for this measurement?	PREDOSE ☐ 4 HOUR POSTDOSE ■
In what position was the subject during the measurement?	SITTING ■
Were Vital Signs collected?	YES ☐ NO ☐
If No, provide reason	_____
At what time were the measurements performed? (00:00-23:59)	_____
Systolic Blood Pressure	**mmHg** ☐
Diastolic Blood Pressure	**mmHg** ☐
Heart Rate	**beats/min** ☐
Respiratory Rate	**breaths/min** ☐

Temperature **C** ☐

Vital Date/Time: DERIVED (dd-mon-yyyy 00:00-23:59) _____

On what date were the measurements performed? (dd-mon-yyyy)	
Any collections: DERIVED	YES ☐ NO ☐
Current Date/Time (Hidden field for CF use)	
In what position was the subject during the measurement?	SITTING ■
Were Vital Signs collected?	YES ☐ NO ☐
If No, provide reason	
At what time were the measurements performed? (00:00-23:59)	
Systolic Blood Pressure	**mmHg** ☐
Diastolic Blood Pressure	**mmHg** ☐
Heart Rate	**beats/min** ☐
Respiratory Rate	**breaths/min** ☐
Temperature	**C** ☐

Vital Date/Time: DERIVED (dd-mon-yyyy 00:00-23:59) _____

On what date were the measurements performed? (dd-mon-yyyy) _____

At what time were the measurements performed? (00:00-23:59) _____

Height **cm** ☐

Weight **kg** ☐

On what date were the measurements performed? (dd-mon-yyyy) _____

At what time were the measurements performed? (00:00-23:59) _____

Weight **kg** ☐

What was the method used to measure ECG?

- [ ] 10 LEAD STANDARD
- [ ] 12 LEAD 1 LEAD MISSING
- [ ] 12 LEAD CABRERA
- [ ] 12 LEAD CONTINUOUS ECG
- [ ] 12 LEAD EASI DOWER TRANSFORMATION
- [ ] 12 LEAD ECG EXTRACTED FROM 12 LEAD CONTINUOUS ECG RECORDING
- [ ] 12 LEAD MASON LIKAR
- [ ] 12 LEAD MODIFIED MASON LIKAR
- [ ] 12 LEAD NON-STANDARD
- [ ] 12 LEAD RIGHT-SIDED PRECORDIAL LEADS
- [ ] 12 LEAD SINGLE PAD
- [x] 12 LEAD STANDARD
- [ ] 12 LEAD UNSPECIFIED
- [ ] 6 LEAD NEHB-SPORI
- [ ] 6 LEAD STANDARD
- [ ] 8 LEAD STANDARD
- [ ] BIPOLAR UNCORRECTED XYZ LEAD SYSTEM
- [ ] CONTINUOUS AMBULATORY ECG
- [ ] CUBE LEAD SYSTEM
- [ ] FRANK LEAD SYSTEM
- [ ] HOLTER CONTINUOUS ECG RECORDING
- [ ] MCFEE-PARUNGAO LEAD SYSTEM
- [ ] PSEUDO-ORTHOGONAL XYZ LEAD SYSTEM
- [ ] STANDARD 12-LEAD AND CC5-CM5-ML

STANDARD 12-LEAD AND CM5-CC5-CH5 ☐
STANDARD 12-LEAD EXTENDED LEFT ☐
STANDARD 12-LEAD EXTENDED RIGHT ☐
STANDARD LEADS FOR BICYCLE EXERCISE ☐
STANDARD LEADS ONE INTERCOSTAL SPACE HIGHER ☐
VECTORCARDIOGRAPH CORRECTED ☐
VECTORCARDIOGRAPH UNCORRECTED ☐

What was the ECG date? (dd-mon-yyyy) _____

Any Collections: DERIVED _____

Current Date/Time (Hidden field for CF use) _____

What was the position of the subject during ECG measurement?

DECUBITUS ☐
FOWLERS ☐
LATERAL DECUBITUS ☐
LEFT LATERAL DECUBITUS ☐
PRONE ☐
REVERSE TRENDELENBURG ☐
RIGHT LATERAL DECUBITUS ☐
SEMI-FOWLERS ☐
SEMI-RECUMBENT ☐
SITTING ☐

	SLING ☐ STANDING ☐ SUPINE ■ TRENDELENBURG ☐ UNCONSTRAINED ☐
Was an ECG performed?	YES ☐ NO ☐
If No, provide reason	_____
What was the ECG time? (00:00-23:59)	_____
Heart Rate	**beats/min** ☐
PR Interval	**msec** ☐
QRS Duration	**msec** ☐
QTcB Interval	**msec** ☐
QTcF Interval	**msec** ☐
RR Interval	**msec** ☐
Interpretation	NORMAL ☐ ABNORMAL ☐

	INDETERMINATE ☐
	NOT EVALUABLE ☐
	UNKNOWN ☐
If abnormal, was the interpretation considered clinically significant?	YES ☐
	NO ☐
Abnormal findings	
Date/Time DERIVED (dd-mon-yyyy 00:00-23:59)	

What was the method used to measure ECG?

- [ ] 10 LEAD STANDARD
- [ ] 12 LEAD 1 LEAD MISSING
- [ ] 12 LEAD CABRERA
- [ ] 12 LEAD CONTINUOUS ECG
- [ ] 12 LEAD EASI DOWER TRANSFORMATION
- [ ] 12 LEAD ECG EXTRACTED FROM 12 LEAD CONTINUOUS ECG RECORDING
- [ ] 12 LEAD MASON LIKAR
- [ ] 12 LEAD MODIFIED MASON LIKAR
- [ ] 12 LEAD NON-STANDARD
- [ ] 12 LEAD RIGHT-SIDED PRECORDIAL LEADS
- [ ] 12 LEAD SINGLE PAD
- [x] 12 LEAD STANDARD
- [ ] 12 LEAD UNSPECIFIED
- [ ] 6 LEAD NEHB-SPORI
- [ ] 6 LEAD STANDARD
- [ ] 8 LEAD STANDARD
- [ ] BIPOLAR UNCORRECTED XYZ LEAD SYSTEM
- [ ] CONTINUOUS AMBULATORY ECG
- [ ] CUBE LEAD SYSTEM
- [ ] FRANK LEAD SYSTEM
- [ ] HOLTER CONTINUOUS ECG RECORDING
- [ ] MCFEE-PARUNGAO LEAD SYSTEM
- [ ] PSEUDO-ORTHOGONAL XYZ LEAD SYSTEM
- [ ] STANDARD 12-LEAD AND CC5-CM5-ML

	STANDARD 12-LEAD AND CM5-CC5-CH5 ☐ STANDARD 12-LEAD EXTENDED LEFT ☐ STANDARD 12-LEAD EXTENDED RIGHT ☐ STANDARD LEADS FOR BICYCLE EXERCISE ☐ STANDARD LEADS ONE INTERCOSTAL SPACE HIGHER ☐ VECTORCARDIOGRAPH CORRECTED ☐ VECTORCARDIOGRAPH UNCORRECTED ☐
What was the ECG date? (dd-mon-yyyy)	
Any Collections: DERIVED	
Current Date/Time (Hidden field for CF use)	
What was the planned time point of the measurement?	4 HOUR POSTDOSE ■
What was the position of the subject during ECG measurement?	DECUBITUS ☐ FOWLERS ☐ LATERAL DECUBITUS ☐ LEFT LATERAL DECUBITUS ☐ PRONE ☐ REVERSE TRENDELENBURG ☐ RIGHT LATERAL DECUBITUS ☐

	SEMI-FOWLERS ☐
	SEMI-RECUMBENT ☐
	SITTING ☐
	SLING ☐
	STANDING ☐
	SUPINE ■
	TRENDELENBURG ☐
	UNCONSTRAINED ☐
Was an ECG performed?	YES ☐
	NO ☐
If No, provide reason	_____
What was the ECG time? (00:00-23:59)	_____
Heart Rate	**beats/min** ☐
PR Interval	**msec** ☐
QRS Duration	**msec** ☐
QTcB Interval	**msec** ☐
QTcF Interval	**msec** ☐
RR Interval	**msec** ☐

Interpretation	NORMAL ☐ ABNORMAL ☐ INDETERMINATE ☐ NOT EVALUABLE ☐ UNKNOWN ☐
If abnormal, was the interpretation considered clinically significant?	YES ☐ NO ☐
Abnormal findings	_____
Date/Time DERIVED (dd-mon-yyyy 00:00-23:59)	_____

Any Collections: DERIVED

Current Date/Time (Hidden field for CF use)

What was the lab panel name?

- [x] HEMATOLOGY
- [ ] CHEMISTRY
- [ ] SEROLOGY
- [ ] SPECIAL CHEMISTRY
- [ ] URINALYSIS
- [ ] URINE DRUG SCREEN
- [ ] SERUM HUMAN CHORIONIC GONADOTROPIN
- [ ] SERUM CHEMISTRY

Was the sample collected?

- [ ] YES
- [ ] NO
- [ ] NOT APPLICABLE

If No, provide reason

What was the lab specimen collection date? (dd-mon-yyyy)

What was the lab specimen collection time? (00:00-23:59)

Date/Time DERIVED (dd-mon-yyyy 00:00-23:59)

What was the lab panel name?

- HEMATOLOGY ☐
- CHEMISTRY ■
- SEROLOGY ☐
- SPECIAL CHEMISTRY ☐
- URINALYSIS ☐
- URINE DRUG SCREEN ☐
- SERUM HUMAN CHORIONIC GONADOTROPIN ☐
- SERUM CHEMISTRY ☐

Was the sample collected?

- YES ☐
- NO ☐
- NOT APPLICABLE ☐

If No, provide reason _____

What was the lab specimen collection date? (dd-mon-yyyy) _____

What was the lab specimen collection time? (00:00-23:59) _____

Date/Time DERIVED (dd-mon-yyyy 00:00-23:59) _____

What was the lab panel name?

- HEMATOLOGY ☐
- CHEMISTRY ☐
- SEROLOGY ■
- SPECIAL CHEMISTRY ☐
- URINALYSIS ☐
- URINE DRUG SCREEN ☐

SERUM HUMAN CHORIONIC GONADOTROPIN ☐
SERUM CHEMISTRY ☐

Was the sample collected?

YES ☐
NO ☐
NOT APPLICABLE ☐

If No, provide reason _____

What was the lab specimen collection date? (dd-mon-yyyy) _____

What was the lab specimen collection time? (00:00-23:59) _____

Date/Time DERIVED (dd-mon-yyyy 00:00-23:59) _____

What was the lab panel name?

HEMATOLOGY ☐
CHEMISTRY ☐
SEROLOGY ☐
SPECIAL CHEMISTRY ■
URINALYSIS ☐
URINE DRUG SCREEN ☐
SERUM HUMAN CHORIONIC GONADOTROPIN ☐
SERUM CHEMISTRY ☐

Was the sample collected?

YES ☐
NO ☐

NOT APPLICABLE ☐

If No, provide reason _____

What was the lab specimen collection date? (dd-mon-yyyy) _____

What was the lab specimen collection time? (00:00-23:59) _____

Date/Time DERIVED (dd-mon-yyyy 00:00-23:59) _____

What was the lab panel name?

HEMATOLOGY ☐
CHEMISTRY ☐
SEROLOGY ☐
SPECIAL CHEMISTRY ☐
URINALYSIS ■
URINE DRUG SCREEN ☐
SERUM HUMAN CHORIONIC GONADOTROPIN ☐
SERUM CHEMISTRY ☐

Was the sample collected?

YES ☐
NO ☐
NOT APPLICABLE ☐

If No, provide reason _____

What was the lab specimen collection date? (dd-mon-yyyy) _____

What was the lab specimen collection time? (00:00-23:59) _____

Date/Time DERIVED (dd-mon-yyyy 00:00-23:59) _____

What was the lab panel name?

- HEMATOLOGY ☐
- CHEMISTRY ☐
- SEROLOGY ☐
- SPECIAL CHEMISTRY ☐
- URINALYSIS ☐
- URINE DRUG SCREEN ■
- SERUM HUMAN CHORIONIC GONADOTROPIN ☐
- SERUM CHEMISTRY ☐

Was the sample collected?

- YES ☐
- NO ☐
- NOT APPLICABLE ☐

If No, provide reason _____

What was the lab specimen collection date? (dd-mon-yyyy) _____

What was the lab specimen collection time? (00:00-23:59) _____

Date/Time DERIVED (dd-mon-yyyy 00:00-23:59) _____

What was the lab panel name?

- HEMATOLOGY ☐
- CHEMISTRY ☐
- SEROLOGY ☐
- SPECIAL CHEMISTRY ☐
- URINALYSIS ☐
- URINE DRUG SCREEN ☐
- SERUM HUMAN CHORIONIC GONADOTROPIN ■
- SERUM CHEMISTRY ☐

Was the sample collected?

- YES ☐
- NO ☐
- NOT APPLICABLE ☐

If No, provide reason _____

What was the lab specimen collection date? (dd-mon-yyyy) _____

What was the lab specimen collection time? (00:00-23:59) _____

Date/Time DERIVED (dd-mon-yyyy 00:00-23:59) _____

What was the lab panel name?

- HEMATOLOGY ☐
- CHEMISTRY ☐
- SEROLOGY ☐
- SPECIAL CHEMISTRY ☐
- URINALYSIS ☐
- URINE DRUG SCREEN ☐

	SERUM HUMAN CHORIONIC GONADOTROPIN ☐ SERUM CHEMISTRY ■
Was the sample collected?	YES ☐ NO ☐ NOT APPLICABLE ☐
If No, provide reason	
What was the lab specimen collection date? (dd-mon-yyyy)	
What was the lab specimen collection time? (00:00-23:59)	
Date/Time DERIVED (dd-mon-yyyy 00:00-23:59)	

What was the lab specimen collection date? (dd-mon-yyyy) _____

Any Collections: DERIVED _____

Current Date/Time (Hidden field for CF use) _____

What was the lab panel name?

- [x] HEMATOLOGY
- [ ] CHEMISTRY
- [ ] SEROLOGY
- [ ] SPECIAL CHEMISTRY
- [ ] URINALYSIS
- [ ] URINE DRUG SCREEN
- [ ] SERUM HUMAN CHORIONIC GONADOTROPIN
- [ ] SERUM CHEMISTRY

Was the sample collected?

- [ ] YES
- [ ] NO
- [ ] NOT APPLICABLE

If No, provide reason _____

What was the lab specimen collection time? (00:00-23:59) _____

Date/Time DERIVED (dd-mon-yyyy 00:00-23:59) _____

What was the lab panel name?

- HEMATOLOGY ☐
- CHEMISTRY ☐
- SEROLOGY ☐
- SPECIAL CHEMISTRY ☐
- URINALYSIS ☐
- URINE DRUG SCREEN ☐
- SERUM HUMAN CHORIONIC GONADOTROPIN ■
- SERUM CHEMISTRY ☐

Was the sample collected?

- YES ☐
- NO ☐
- NOT APPLICABLE ☐

If No, provide reason _____

What was the lab specimen collection time? (00:00-23:59) _____

Date/Time DERIVED (dd-mon-yyyy 00:00-23:59) _____

What was the lab panel name?

- HEMATOLOGY ☐
- CHEMISTRY ☐
- SEROLOGY ☐
- SPECIAL CHEMISTRY ☐
- URINALYSIS ☐
- URINE DRUG SCREEN ☐
- SERUM HUMAN CHORIONIC GONADOTROPIN ☐
- SERUM CHEMISTRY ■

Was the sample collected?

- YES ☐
- NO ☐
- NOT APPLICABLE ☐

If No, provide reason _____

What was the lab specimen collection time? (00:00-23:59) _____

Date/Time DERIVED (dd-mon-yyyy 00:00-23:59) _____

What was the lab panel name?

- HEMATOLOGY ☐
- CHEMISTRY ☐
- SEROLOGY ☐
- SPECIAL CHEMISTRY ☐
- URINALYSIS ☐
- URINE DRUG SCREEN ■
- SERUM HUMAN CHORIONIC GONADOTROPIN ☐
- SERUM CHEMISTRY ☐

Was the sample collected?

- YES ☐
- NO ☐
- NOT APPLICABLE ☐

If No, provide reason _____

What was the lab specimen collection time? (00:00-23:59) _____

Date/Time DERIVED (dd-mon-yyyy 00:00-23:59) _____

What was the lab specimen collection date? (dd-mon-yyyy) _____

Any Collections: DERIVED _____

Current Date/Time (Hidden field for CF use) _____

What was the lab panel name?

- [x] HEMATOLOGY
- [ ] CHEMISTRY
- [ ] SEROLOGY
- [ ] SPECIAL CHEMISTRY
- [ ] URINALYSIS
- [ ] URINE DRUG SCREEN
- [ ] SERUM HUMAN CHORIONIC GONADOTROPIN
- [ ] SERUM CHEMISTRY

Was the sample collected?

- [ ] YES
- [ ] NO
- [ ] NOT APPLICABLE

If No, provide reason _____

What was the lab specimen collection time? (00:00-23:59) _____

Date/Time DERIVED (dd-mon-yyyy 00:00-23:59) _____

What was the lab panel name?

- HEMATOLOGY ☐
- CHEMISTRY ☐
- SEROLOGY ☐
- SPECIAL CHEMISTRY ☐
- URINALYSIS ☐
- URINE DRUG SCREEN ☐
- SERUM HUMAN CHORIONIC GONADOTROPIN ☐
- SERUM CHEMISTRY ■

Was the sample collected?

- YES ☐
- NO ☐
- NOT APPLICABLE ☐

If No, provide reason _____

What was the lab specimen collection time? (00:00-23:59) _____

Date/Time DERIVED (dd-mon-yyyy 00:00-23:59) _____

What was the lab specimen collection date? (dd-mon-yyyy)	
Any Collections: DERIVED	
Current Date/Time (Hidden field for CF use)	
What was the lab panel name?	HEMATOLOGY ■ CHEMISTRY ☐ SEROLOGY ☐ SPECIAL CHEMISTRY ☐ URINALYSIS ☐ URINE DRUG SCREEN ☐ SERUM HUMAN CHORIONIC GONADOTROPIN ☐ SERUM CHEMISTRY ☐
What was the planned time point of the lab?	12 HOURS POSTDOSE ■
Was the sample collected?	YES ☐ NO ☐ NOT APPLICABLE ☐
If No, provide reason	
What was the lab specimen collection time? (00:00-23:59)	
Date/Time DERIVED (dd-mon-yyyy 00:00-23:59)	

What was the lab panel name?	HEMATOLOGY ☐ CHEMISTRY ☐ SEROLOGY ☐ SPECIAL CHEMISTRY ☐ URINALYSIS ☐ URINE DRUG SCREEN ☐ SERUM HUMAN CHORIONIC GONADOTROPIN ☐ SERUM CHEMISTRY ■
What was the planned time point of the lab?	12 HOURS POSTDOSE ☐
Was the sample collected?	YES ☐ NO ☐ NOT APPLICABLE ☐
If No, provide reason	_____
What was the lab specimen collection time? (00:00-23:59)	_____
Date/Time DERIVED (dd-mon-yyyy 00:00-23:59)	_____

What was the lab specimen collection date? (dd-mon-yyyy) _____

Any Collections: DERIVED _____

Current Date/Time (Hidden field for CF use) _____

What was the lab panel name?

- [x] HEMATOLOGY
- [ ] CHEMISTRY
- [ ] SEROLOGY
- [ ] SPECIAL CHEMISTRY
- [ ] URINALYSIS
- [ ] URINE DRUG SCREEN
- [ ] SERUM HUMAN CHORIONIC GONADOTROPIN
- [ ] SERUM CHEMISTRY

Was the sample collected?

- [ ] YES
- [ ] NO
- [ ] NOT APPLICABLE

If No, provide reason _____

What was the lab specimen collection time? (00:00-23:59) _____

Date/Time DERIVED (dd-mon-yyyy 00:00-23:59) _____

What was the lab panel name?

- HEMATOLOGY ☐
- CHEMISTRY ☐
- SEROLOGY ☐
- SPECIAL CHEMISTRY ☐
- URINALYSIS ■
- URINE DRUG SCREEN ☐
- SERUM HUMAN CHORIONIC GONADOTROPIN ☐
- SERUM CHEMISTRY ☐

Was the sample collected?

- YES ☐
- NO ☐
- NOT APPLICABLE ☐

If No, provide reason _____

What was the lab specimen collection time? (00:00-23:59) _____

Date/Time DERIVED (dd-mon-yyyy 00:00-23:59) _____

What was the lab panel name?

- HEMATOLOGY ☐
- CHEMISTRY ☐
- SEROLOGY ☐
- SPECIAL CHEMISTRY ☐
- URINALYSIS ☐
- URINE DRUG SCREEN ☐
- SERUM HUMAN CHORIONIC GONADOTROPIN ☐
- SERUM CHEMISTRY ■

Was the sample collected?	YES ☐ NO ☐ NOT APPLICABLE ☐
If No, provide reason	
What was the lab specimen collection time? (00:00-23:59)	
Date/Time DERIVED (dd-mon-yyyy 00:00-23:59)	

Has the subject experienced any past and/or concomitant diseases or past surgeries?

YES ☐
NO ☐

If yes, record all significant findings on the Medical History form.

Has the subject reported any additional past medical history or concomitant medications since screening visit?

YES ☐
NO ☐

Please record any past or present medical conditions.

Medical History Category	GENERAL MEDICAL HISTORY ■
What is the verbatim term of the medical history condition/event?	
What was the date the medical history event or condition started? (dd-mon-yyyy)	
Is the medical history disease/condition or event still ongoing?	YES ☐ NO ☐
What was the date the medical history event or condition ended? (dd-mon-yyyy)	
MH Key Items: DERIVED	

Was the physical examination performed? YES ☐ NO ☐

If yes, record all significant findings on the Physical Examination form.

What was the physical examination date? (dd-mon-yyyy) _____

What was the body system examined?

- [x] SKIN
- [ ] HEENT
- [ ] PULMONARY
- [ ] CARDIOVASCULAR
- [ ] ABDOMEN
- [ ] LYMPH NODES
- [ ] MUSCULOSKELETAL
- [ ] NEUROLOGIC SYSTEM
- [ ] OTHER

What was the overall interpretation?

- [ ] NORMAL
- [ ] ABNORMAL
- [ ] NOT DONE

If the result was abnormal, what were the findings? _____

If abnormal, was the interpretation considered clinically significant?

- [ ] YES
- [ ] NO

What was the body system examined?

- [ ] SKIN
- [x] HEENT
- [ ] PULMONARY
- [ ] CARDIOVASCULAR
- [ ] ABDOMEN

LYMPH NODES ☐
MUSCULOSKELETAL ☐
NEUROLOGIC SYSTEM ☐
OTHER ☐

What was the overall interpretation?

NORMAL ☐
ABNORMAL ☐
NOT DONE ☐

If the result was abnormal, what were the findings? _____

If abnormal, was the interpretation considered clinically significant?

YES ☐
NO ☐

What was the body system examined?

SKIN ☐
HEENT ☐
PULMONARY ■
CARDIOVASCULAR ☐
ABDOMEN ☐
LYMPH NODES ☐
MUSCULOSKELETAL ☐
NEUROLOGIC SYSTEM ☐
OTHER ☐

What was the overall interpretation?

NORMAL ☐
ABNORMAL ☐
NOT DONE ☐

If the result was abnormal, what were the findings? _____

If abnormal, was the interpretation considered clinically significant?
- YES ☐
- NO ☐

What was the body system examined?
- SKIN ☐
- HEENT ☐
- PULMONARY ☐
- CARDIOVASCULAR ■
- ABDOMEN ☐
- LYMPH NODES ☐
- MUSCULOSKELETAL ☐
- NEUROLOGIC SYSTEM ☐
- OTHER ☐

What was the overall interpretation?
- NORMAL ☐
- ABNORMAL ☐
- NOT DONE ☐

If the result was abnormal, what were the findings? _____

If abnormal, was the interpretation considered clinically significant?
- YES ☐
- NO ☐

What was the body system examined?
- SKIN ☐
- HEENT ☐

PULMONARY ☐
CARDIOVASCULAR ☐
ABDOMEN ■
LYMPH NODES ☐
MUSCULOSKELETAL ☐
NEUROLOGIC SYSTEM ☐
OTHER ☐

What was the overall interpretation?

NORMAL ☐
ABNORMAL ☐
NOT DONE ☐

If the result was abnormal, what were the findings? _____

If abnormal, was the interpretation considered clinically significant?

YES ☐
NO ☐

What was the body system examined?

SKIN ☐
HEENT ☐
PULMONARY ☐
CARDIOVASCULAR ☐
ABDOMEN ☐
LYMPH NODES ■
MUSCULOSKELETAL ☐
NEUROLOGIC SYSTEM ☐
OTHER ☐

What was the overall interpretation?

- NORMAL ☐
- ABNORMAL ☐
- NOT DONE ☐

If the result was abnormal, what were the findings? _____

If abnormal, was the interpretation considered clinically significant?

- YES ☐
- NO ☐

What was the body system examined?

- SKIN ☐
- HEENT ☐
- PULMONARY ☐
- CARDIOVASCULAR ☐
- ABDOMEN ☐
- LYMPH NODES ☐
- MUSCULOSKELETAL ■
- NEUROLOGIC SYSTEM ☐
- OTHER ☐

What was the overall interpretation?

- NORMAL ☐
- ABNORMAL ☐
- NOT DONE ☐

If the result was abnormal, what were the findings? _____

If abnormal, was the interpretation considered clinically significant?

- YES ☐
- NO ☐

What was the body system examined?

- [ ] SKIN
- [ ] HEENT
- [ ] PULMONARY
- [ ] CARDIOVASCULAR
- [ ] ABDOMEN
- [ ] LYMPH NODES
- [ ] MUSCULOSKELETAL
- [x] NEUROLOGIC SYSTEM
- [ ] OTHER

What was the overall interpretation?

- [ ] NORMAL
- [ ] ABNORMAL
- [ ] NOT DONE

If the result was abnormal, what were the findings? _____

If abnormal, was the interpretation considered clinically significant?

- [ ] YES
- [ ] NO

What was the body system examined?

- [ ] SKIN
- [ ] HEENT
- [ ] PULMONARY
- [ ] CARDIOVASCULAR
- [ ] ABDOMEN
- [ ] LYMPH NODES
- [ ] MUSCULOSKELETAL
- [ ] NEUROLOGIC SYSTEM
- [x] OTHER

What was the overall interpretation?

- NORMAL ☐
- ABNORMAL ☐
- NOT DONE ☐

If the result was abnormal, what were the findings? _____

If abnormal, was the interpretation considered clinically significant?

- YES ☐
- NO ☐

What is the subject's child bearing potential?	STERILE ☐ POST-MENOPAUSAL ☐ POTENTIALLY ABLE TO BEAR CHILDREN ☐
Birth Control Test	BIRTH CONTROL METHOD
Birth Control Test Code	BCMETHOD

Select all methods of birth control used.

What kind of birth control was used?	BARRIER WITH SPERMICIDE ☐ ORAL CONTRACEPTIVES ☐ DEPOT CONTRACEPTIVES (IMPLANTS/ INJECTABLES) ☐ IUD ☐ OTHER ☐
Other, specify	_____

Is treatment data available? YES ☐ NO ☐

If yes, record dosing information on Exposure form.

What was the study treatment?	TPOXX
What was the planned time point for the study treatment?	AM PM
What was the treatment date? (dd-mon-yyyy)	
What was the treatment time? (00:00-23:59)	
What was the planned dose per administration?	600
What were the units for the dose?	mg ug mL IU TABLET g CAPSULE PUFF
What was the total amount administered?	200 400 600
What were the units for the amount administered?	mg
What was the frequency of the study treatment dosing?	QD

	QOD ☐
	BID ■
	TID ☐
	QID ☐
	PRN ☐
	QM ☐
	ONCE ☐
	UNKNOWN ☐

What was the route of administration for the study treatment?	INTRALESIONAL ☐
	INTRAOCULAR ☐
	INTRAPERITONEAL ☐
	RESPIRATORY (INHALATION) ☐
	ORAL ■
	TOPICAL ☐
	SUBCUTANEOUS ☐
	INTRAMUSCULAR ☐
	RECTAL ☐
	VAGINAL ☐
	NASAL ☐
	TRANSDERMAL ☐

Was the dose adjusted from planned?	YES ☐
	NO ☐

What was the reason the dose was adjusted?	ADVERSE EVENT ☐
	DOSING ERROR ☐
	OTHER ☐

Specify other reason	
Date/Time DERIVED (dd-mon-yyyy 00:00-23:59)	
What was the study treatment?	TPOXX
What was the planned time point for the study treatment?	AM PM
What was the treatment date? (dd-mon-yyyy)	
What was the treatment time? (00:00-23:59)	
What was the planned dose per administration?	600
What were the units for the dose?	mg ug mL IU TABLET g CAPSULE PUFF
What was the total amount administered?	200 400 600

What were the units for the amount administered?

- [x] mg

What was the frequency of the study treatment dosing?

- [ ] QD
- [ ] QOD
- [x] BID
- [ ] TID
- [ ] QID
- [ ] PRN
- [ ] QM
- [ ] ONCE
- [ ] UNKNOWN

What was the route of administration for the study treatment?

- [ ] INTRALESIONAL
- [ ] INTRAOCULAR
- [ ] INTRAPERITONEAL
- [ ] RESPIRATORY (INHALATION)
- [x] ORAL
- [ ] TOPICAL
- [ ] SUBCUTANEOUS
- [ ] INTRAMUSCULAR
- [ ] RECTAL
- [ ] VAGINAL
- [ ] NASAL
- [ ] TRANSDERMAL

Was the dose adjusted from planned?

- [ ] YES
- [ ] NO

What was the reason the dose was adjusted?	ADVERSE EVENT ☐ DOSING ERROR ☐ OTHER ☐
Specify other reason	
Date/Time DERIVED (dd-mon-yyyy 00:00-23:59)	

What was the planned time point for the meal?	PREDOSE ■
What was the meal type?	BREAKFAST ■ DINNER ☐
What was the date of the meal? (dd-mon-yyyy)	
What was the start time of the meal? (00:00-23:59)	
What was the end time of the meal? (00:00-23:59)	
What was the percentage (%) of meal eaten?	0 ☐ 25 ☐ 50 ☐ 75 ☐ 100 ☐
Start Date/Time DERIVED (dd-mon-yyyy 00:00-23:59)	
End Date/Time DERIVED (dd-mon-yyyy 00:00-23:59)	

What was the planned time point for the meal?	PREDOSE ☐
What was the meal type?	BREAKFAST ☐ DINNER ■

What was the date of the meal? (dd-mon-yyyy) _____

What was the start time of the meal? (00:00-23:59) _____

What was the end time of the meal? (00:00-23:59) _____

What was the percentage (%) of meal eaten?

- 0 ☐
- 25 ☐
- 50 ☐
- 75 ☐
- 100 ☐

Start Date/Time DERIVED (dd-mon-yyyy 00:00-23:59) _____

End Date/Time DERIVED (dd-mon-yyyy 00:00-23:59) _____

Any Collections: DERIVED

Current Date/Time (Hidden field for CF use)

What was the sample date? (dd-mon-yyyy)

What was the planned time point of the sample?

- [x] PREDOSE
- [ ] 0.5 HOUR POSTDOSE
- [ ] 1 HOUR POSTDOSE
- [ ] 2 HOUR POSTDOSE
- [ ] 4 HOUR POSTDOSE
- [ ] 6 HOUR POSTDOSE
- [ ] 8 HOUR POSTDOSE
- [ ] 12 HOUR POSTDOSE
- [ ] 14 HOUR POSTDOSE
- [ ] 16 HOUR POSTDOSE
- [ ] 18 HOUR POSTDOSE
- [ ] 20 HOUR POSTDOSE
- [ ] 24 HOUR POSTDOSE
- [ ] 48 HOUR POSTDOSE

Was the sample collected?

- [ ] YES
- [ ] NO

If No, provide reason

What was the sample time? (00:00-23:59)

Date/Time DERIVED (dd-mon-yyyy 00:00-23:59) _____

What was the sample date? (dd-mon-yyyy) _____

What was the planned time point of the sample?

- PREDOSE ☐
- 0.5 HOUR POSTDOSE ■
- 1 HOUR POSTDOSE ☐
- 2 HOUR POSTDOSE ☐
- 4 HOUR POSTDOSE ☐
- 6 HOUR POSTDOSE ☐
- 8 HOUR POSTDOSE ☐
- 12 HOUR POSTDOSE ☐
- 14 HOUR POSTDOSE ☐
- 16 HOUR POSTDOSE ☐
- 18 HOUR POSTDOSE ☐
- 20 HOUR POSTDOSE ☐
- 24 HOUR POSTDOSE ☐
- 48 HOUR POSTDOSE ☐

Was the sample collected?

- YES ☐
- NO ☐

If No, provide reason _____

What was the sample time? (00:00-23:59) _____

Date/Time DERIVED (dd-mon-yyyy 00:00-23:59) _____

What was the sample date? (dd-mon-yyyy) _____

What was the planned time point of the sample?

- PREDOSE ☐
- 0.5 HOUR POSTDOSE ☐
- 1 HOUR POSTDOSE ■
- 2 HOUR POSTDOSE ☐
- 4 HOUR POSTDOSE ☐
- 6 HOUR POSTDOSE ☐
- 8 HOUR POSTDOSE ☐
- 12 HOUR POSTDOSE ☐
- 14 HOUR POSTDOSE ☐
- 16 HOUR POSTDOSE ☐
- 18 HOUR POSTDOSE ☐
- 20 HOUR POSTDOSE ☐
- 24 HOUR POSTDOSE ☐
- 48 HOUR POSTDOSE ☐

Was the sample collected?

- YES ☐
- NO ☐

If No, provide reason _____

What was the sample time? (00:00-23:59) _____

Date/Time DERIVED (dd-mon-yyyy 00:00-23:59) _____

What was the sample date? (dd-mon-yyyy) _____

What was the planned time point of the sample?

- PREDOSE ☐
- 0.5 HOUR POSTDOSE ☐
- 1 HOUR POSTDOSE ☐
- 2 HOUR POSTDOSE ■
- 4 HOUR POSTDOSE ☐
- 6 HOUR POSTDOSE ☐
- 8 HOUR POSTDOSE ☐
- 12 HOUR POSTDOSE ☐
- 14 HOUR POSTDOSE ☐
- 16 HOUR POSTDOSE ☐
- 18 HOUR POSTDOSE ☐
- 20 HOUR POSTDOSE ☐
- 24 HOUR POSTDOSE ☐
- 48 HOUR POSTDOSE ☐

Was the sample collected?

- YES ☐
- NO ☐

If No, provide reason _____

What was the sample time? (00:00-23:59) _____

Date/Time DERIVED (dd-mon-yyyy 00:00-23:59) _____

What was the sample date? (dd-mon-yyyy) _____

What was the planned time point of the sample?

- PREDOSE ☐
- 0.5 HOUR POSTDOSE ☐

1 HOUR POSTDOSE ☐
2 HOUR POSTDOSE ☐
4 HOUR POSTDOSE ■
6 HOUR POSTDOSE ☐
8 HOUR POSTDOSE ☐
12 HOUR POSTDOSE ☐
14 HOUR POSTDOSE ☐
16 HOUR POSTDOSE ☐
18 HOUR POSTDOSE ☐
20 HOUR POSTDOSE ☐
24 HOUR POSTDOSE ☐
48 HOUR POSTDOSE ☐

Was the sample collected? YES ☐ NO ☐

If No, provide reason _____

What was the sample time? (00:00-23:59) _____

Date/Time DERIVED (dd-mon-yyyy 00:00-23:59) _____

What was the sample date? (dd-mon-yyyy) _____

What was the planned time point of the sample?
PREDOSE ☐
0.5 HOUR POSTDOSE ☐
1 HOUR POSTDOSE ☐
2 HOUR POSTDOSE ☐

	4 HOUR POSTDOSE ☐ 6 HOUR POSTDOSE ■ 8 HOUR POSTDOSE ☐ 12 HOUR POSTDOSE ☐ 14 HOUR POSTDOSE ☐ 16 HOUR POSTDOSE ☐ 18 HOUR POSTDOSE ☐ 20 HOUR POSTDOSE ☐ 24 HOUR POSTDOSE ☐ 48 HOUR POSTDOSE ☐
Was the sample collected?	YES ☐ NO ☐
If No, provide reason	_____
What was the sample time? (00:00-23:59)	_____
Date/Time DERIVED (dd-mon-yyyy 00:00-23:59)	_____
What was the sample date? (dd-mon-yyyy)	_____
What was the planned time point of the sample?	PREDOSE ☐ 0.5 HOUR POSTDOSE ☐ 1 HOUR POSTDOSE ☐ 2 HOUR POSTDOSE ☐ 4 HOUR POSTDOSE ☐ 6 HOUR POSTDOSE ☐

	8 HOUR POSTDOSE ■
	12 HOUR POSTDOSE ☐
	14 HOUR POSTDOSE ☐
	16 HOUR POSTDOSE ☐
	18 HOUR POSTDOSE ☐
	20 HOUR POSTDOSE ☐
	24 HOUR POSTDOSE ☐
	48 HOUR POSTDOSE ☐
Was the sample collected?	YES ☐
	NO ☐
If No, provide reason	_____
What was the sample time? (00:00-23:59)	_____
Date/Time DERIVED (dd-mon-yyyy 00:00-23:59)	_____
What was the sample date? (dd-mon-yyyy)	_____
What was the planned time point of the sample?	PREDOSE ☐
	0.5 HOUR POSTDOSE ☐
	1 HOUR POSTDOSE ☐
	2 HOUR POSTDOSE ☐
	4 HOUR POSTDOSE ☐
	6 HOUR POSTDOSE ☐
	8 HOUR POSTDOSE ☐
	12 HOUR POSTDOSE ■

	14 HOUR POSTDOSE ☐ 16 HOUR POSTDOSE ☐ 18 HOUR POSTDOSE ☐ 20 HOUR POSTDOSE ☐ 24 HOUR POSTDOSE ☐ 48 HOUR POSTDOSE ☐
Was the sample collected?	YES ☐ NO ☐
If No, provide reason	_____
What was the sample time? (00:00-23:59)	_____
Date/Time DERIVED (dd-mon-yyyy 00:00-23:59)	_____
What was the sample date? (dd-mon-yyyy)	_____
What was the planned time point of the sample?	PREDOSE ☐ 0.5 HOUR POSTDOSE ☐ 1 HOUR POSTDOSE ☐ 2 HOUR POSTDOSE ☐ 4 HOUR POSTDOSE ☐ 6 HOUR POSTDOSE ☐ 8 HOUR POSTDOSE ☐ 12 HOUR POSTDOSE ☐ 14 HOUR POSTDOSE ■ 16 HOUR POSTDOSE ☐

18 HOUR POSTDOSE ☐
20 HOUR POSTDOSE ☐
24 HOUR POSTDOSE ☐
48 HOUR POSTDOSE ☐

Was the sample collected? YES ☐ NO ☐

If No, provide reason _____

What was the sample time? (00:00-23:59) _____

Date/Time DERIVED (dd-mon-yyyy 00:00-23:59) _____

Any Collections: DERIVED

Current Date/Time (Hidden field for CF use)

What was the sample date? (dd-mon-yyyy)

What was the planned time point of the sample?

- PREDOSE ☐
- 0.5 HOUR POSTDOSE ☐
- 1 HOUR POSTDOSE ☐
- 2 HOUR POSTDOSE ☐
- 4 HOUR POSTDOSE ☐
- 6 HOUR POSTDOSE ☐
- 8 HOUR POSTDOSE ☐
- 12 HOUR POSTDOSE ☐
- 14 HOUR POSTDOSE ☐
- 16 HOUR POSTDOSE ■
- 18 HOUR POSTDOSE ☐
- 20 HOUR POSTDOSE ☐
- 24 HOUR POSTDOSE ☐
- 48 HOUR POSTDOSE ☐

Was the sample collected?

- YES ☐
- NO ☐

If No, provide reason

What was the sample time? (00:00-23:59)

Date/Time DERIVED (dd-mon-yyyy 00:00-23:59) _____

What was the sample date? (dd-mon-yyyy) _____

What was the planned time point of the sample?

- PREDOSE ☐
- 0.5 HOUR POSTDOSE ☐
- 1 HOUR POSTDOSE ☐
- 2 HOUR POSTDOSE ☐
- 4 HOUR POSTDOSE ☐
- 6 HOUR POSTDOSE ☐
- 8 HOUR POSTDOSE ☐
- 12 HOUR POSTDOSE ☐
- 14 HOUR POSTDOSE ☐
- 16 HOUR POSTDOSE ☐
- 18 HOUR POSTDOSE ■
- 20 HOUR POSTDOSE ☐
- 24 HOUR POSTDOSE ☐
- 48 HOUR POSTDOSE ☐

Was the sample collected?

- YES ☐
- NO ☐

If No, provide reason _____

What was the sample time? (00:00-23:59) _____

Date/Time DERIVED (dd-mon-yyyy 00:00-23:59) _____

What was the sample date? (dd-mon-yyyy) _____

What was the planned time point of the sample?

- PREDOSE ☐
- 0.5 HOUR POSTDOSE ☐
- 1 HOUR POSTDOSE ☐
- 2 HOUR POSTDOSE ☐
- 4 HOUR POSTDOSE ☐
- 6 HOUR POSTDOSE ☐
- 8 HOUR POSTDOSE ☐
- 12 HOUR POSTDOSE ☐
- 14 HOUR POSTDOSE ☐
- 16 HOUR POSTDOSE ☐
- 18 HOUR POSTDOSE ☐
- 20 HOUR POSTDOSE ■
- 24 HOUR POSTDOSE ☐
- 48 HOUR POSTDOSE ☐

Was the sample collected?

- YES ☐
- NO ☐

If No, provide reason _____

What was the sample time? (00:00-23:59) _____

Date/Time DERIVED (dd-mon-yyyy 00:00-23:59) _____

What was the sample date? (dd-mon-yyyy) _____

What was the planned time point of the sample?

- PREDOSE ☐
- 0.5 HOUR POSTDOSE ☐
- 1 HOUR POSTDOSE ☐
- 2 HOUR POSTDOSE ☐
- 4 HOUR POSTDOSE ☐
- 6 HOUR POSTDOSE ☐
- 8 HOUR POSTDOSE ☐
- 12 HOUR POSTDOSE ☐
- 14 HOUR POSTDOSE ☐
- 16 HOUR POSTDOSE ☐
- 18 HOUR POSTDOSE ☐
- 20 HOUR POSTDOSE ☐
- 24 HOUR POSTDOSE ■
- 48 HOUR POSTDOSE ☐

Was the sample collected?

- YES ☐
- NO ☐

If No, provide reason _____

What was the sample time? (00:00-23:59) _____

Date/Time DERIVED (dd-mon-yyyy 00:00-23:59) _____

What was the sample date? (dd-mon-yyyy) _____

Any Collections: DERIVED _____

Current Date/Time (Hidden field for CF use) _____

What was the planned time point of the sample?

- PREDOSE ☐
- 0.5 HOUR POSTDOSE ☐
- 1 HOUR POSTDOSE ☐
- 2 HOUR POSTDOSE ☐
- 4 HOUR POSTDOSE ☐
- 6 HOUR POSTDOSE ☐
- 8 HOUR POSTDOSE ☐
- 12 HOUR POSTDOSE ☐
- 14 HOUR POSTDOSE ☐
- 16 HOUR POSTDOSE ☐
- 18 HOUR POSTDOSE ☐
- 20 HOUR POSTDOSE ☐
- 24 HOUR POSTDOSE ☐
- 48 HOUR POSTDOSE ■

Was the sample collected?

- YES ☐
- NO ☐

If No, provide reason _____

What was the sample time? (00:00-23:59) _____

Date/Time DERIVED (dd-mon-yyyy 00:00-23:59) _____

What was the sample date? (dd-mon-yyyy) _____

Any Collections: DERIVED _____

Current Date/Time (Hidden field for CF use) _____

What was the planned time point of the sample?

- [x] PREDOSE
- [ ] 0.5 HOUR POSTDOSE
- [ ] 1 HOUR POSTDOSE
- [ ] 2 HOUR POSTDOSE
- [ ] 4 HOUR POSTDOSE
- [ ] 6 HOUR POSTDOSE
- [ ] 8 HOUR POSTDOSE
- [ ] 12 HOUR POSTDOSE
- [ ] 14 HOUR POSTDOSE
- [ ] 16 HOUR POSTDOSE
- [ ] 18 HOUR POSTDOSE
- [ ] 20 HOUR POSTDOSE
- [ ] 24 HOUR POSTDOSE
- [ ] 48 HOUR POSTDOSE

Was the sample collected?

- [ ] YES
- [ ] NO

If No, provide reason _____

What was the sample time? (00:00-23:59) _____

Date/Time DERIVED (dd-mon-yyyy 00:00-23:59) _____

What was the planned time point of the sample?

- PREDOSE ☐
- 0.5 HOUR POSTDOSE ☐
- 1 HOUR POSTDOSE ☐
- 2 HOUR POSTDOSE ☐
- 4 HOUR POSTDOSE ■
- 6 HOUR POSTDOSE ☐
- 8 HOUR POSTDOSE ☐
- 12 HOUR POSTDOSE ☐
- 14 HOUR POSTDOSE ☐
- 16 HOUR POSTDOSE ☐
- 18 HOUR POSTDOSE ☐
- 20 HOUR POSTDOSE ☐
- 24 HOUR POSTDOSE ☐
- 48 HOUR POSTDOSE ☐

Was the sample collected?

- YES ☐
- NO ☐

If No, provide reason _____

What was the sample time? (00:00-23:59) _____

Date/Time DERIVED (dd-mon-yyyy 00:00-23:59) _____

What was the sample date? (dd-mon-yyyy)	
Was the sample collected?	YES ☐ NO ☐
If No, provide reason	
What was the sample time? (00:00-23:59)	
Date/Time DERIVED (dd-mon-yyyy 00:00-23:59)	
Any Collections: DERIVED	
Current Date/Time (Hidden field for CF use)	

Was the visit performed?	YES ☐ NO ☐
Was the visit completed in-person or remotely?	Remotely ☐ In-Person ☐
If Site Visit, what is the reason?	ABNORMAL PE ☐ ABNORMAL RESULT ☐ ONGOING AE/SAE ☐ INVESTIGATOR DISCRETION ☐ SIGA DISCRETION ☐
Did the subject experience any adverse events since the last visit?	YES ☐ NO ☐
Did the subject use any medications related to an AE?	YES ☐ NO ☐

Please select one status for the follow-up contact	CONTACT MADE ☐ CONTACT NOT MADE ☐
If contact was not made, what was the reason?	_____
Date of Contact or Contact Attempt (dd-mon-yyyy)	_____
Did the subject experience any adverse events since the last visit?	YES ☐ NO ☐
Did the subject use any medications related to an AE?	YES ☐ NO ☐

Were any adverse events experienced? YES ☐ NO ☐

If yes, please complete Adverse Events form.

What is the adverse event term? _____

What is the date the adverse event started? (dd-mon-yyyy) _____

At what time did the adverse event start? (00:00-23:59) _____

Check if start time is unknown _____

Is the adverse event still ongoing?

- YES ☐
- NO ☐

What date did the adverse event end? (dd-mon-yyyy) _____

At what time did the adverse event end? (00:00-23:59) _____

Check if end time is unknown _____

What was the severity of the adverse event?

- Grade 1 (MILD) ☐
- Grade 2 (MODERATE) ☐
- Grade 3 (SEVERE) ☐
- Grade 4 (LIFE THREATENING) ☐
- Grade 5 (DEATH) ☐

What was the outcome of this adverse event?

- FATAL ☐
- NOT RECOVERED/NOT RESOLVED ☐
- RECOVERED/RESOLVED ☐
- RECOVERED/RESOLVED WITH SEQUELAE ☐
- RECOVERING/RESOLVING ☐

	UNKNOWN ☐
What was the frequency of the adverse event?	CONTINUOUS ☐ INTERMITTENT ☐
Did the adverse event cause the subject to be discontinued from the study?	YES ☐ NO ☐
Is this event related to study treatment XXXX?	NOT RELATED ☐ UNLIKELY RELATED ☐ POSSIBLY RELATED ☐ PROBABLY RELATED ☐ DEFINITELY RELATED ☐
What action was taken with study treatment?	DOSE NOT CHANGED ☐ DRUG WITHDRAWN ☐ NOT APPLICABLE ☐
What other action was taken in response to the adverse event?	_____
Was the adverse event serious?	YES ☐ NO ☐
What was the ID of the medication/therapy that was taken for the adverse event? (If applicable)	_____
What was the ID of second medication/therapy that was taken for the adverse event? (If applicable)	_____

What was the ID of third medication/therapy that was taken for the adverse event? (If applicable)	
Start Date/Time DERIVED (dd-mon-yyyy 00:00-23:59)	
End Date/Time DERIVED (dd-mon-yyyy 00:00-23:59)	
AE Key Items: DERIVED	

Were any medications taken? YES ☐ NO ☐

If yes, please complete Prior/Concomitant Medications form.

What was the term for the medication/therapy taken? _____

For what indication was the medication/therapy taken? _____

What was the individual dose of the medication/therapy? _____

What was the total daily dose of the medication/therapy? _____

What was the unit of the medication/therapy?

- ☐ APPLICATION
- ☐ CALORIES
- ☐ CAPSULES
- ☐ Centigram (cg)
- ☐ Dram (dr)
- ☐ GTT (DROPS)
- ☐ Femtogram (fg)
- ☐ Grain (gr)
- ☐ GRAMS
- ☐ RING, HORMONAL CONTRACEPTIVE
- ☐ I.U. (INTERNATIONAL UNITS)
- ☐ KG (KILOGRAMS)
- ☐ LITERS
- ☐ MCG (MICROGRAMS)
- ☐ mEq (Milliequivalent)
- ☐ MG (MILLIGRAMS)
- ☐ ML (MILLILITERS)
- ☐ Moles (mol)
- ☐ Nanograms (ng)
- ☐ OZ (OUNCES)
- ☐ PATCH

Picograms (pg) ☐
PUFF ☐
SPRAY ☐
TBS (TABLESPOON) ☐
TABLETS ☐
TSP (TEASPOON) ☐
OTHER ☐
UNKNOWN ☐

Specify other dose unit _____

What was the frequency of the medication/therapy?

ONCE ☐
PRN (AS NEEDED) ☐
CONTINUOUS ☐
QD (DAILY) ☐
QOD (EVERY OTHER DAY) ☐
BID (TWICE PER DAY) ☐
TID (THREE TIMES PER DAY) ☐
QID (FOUR TIMES PER DAY) ☐
QH (EVERY HOUR) ☐
Q2H (EVERY TWO HOURS) ☐
Q3H (EVERY THREE HOURS) ☐
Q4H (EVERY FOUR HOURS) ☐
Q5H (EVERY FIVE HOURS) ☐
Q6H (EVERY SIX HOURS) ☐
Q8H (EVERY EIGHT HOURS) ☐
Q12H (EVERY TWELVE HOURS) ☐
Q18H (EVERY EIGHTEEN HOURS) ☐

1XWK (ONE TIME PER WEEK) ☐
2XWK (TWICE PER WEEK) ☐
3XWK (THREE TIMES PER WEEK) ☐
Q1WK (EVERY WEEK) ☐
Q2WK (EVERY TWO WEEKS) ☐
Q3WK (EVERY THREE WEEKS) ☐
Q4WK (EVERY FOUR WEEKS) ☐
Q5WK (EVERY FIVE WEEKS) ☐
QM (MONTHLY) ☐
6 TIMES PER YEAR (EVERY TWO MONTHS) ☐
4 TIMES PER YEAR (EVERY THREE MONTHS) ☐
OTHER ☐

Specify other dose frequency _____

What was the route of administration of the medication/therapy?

ORAL ☐
TOPICAL ☐
SUBCUTANEOUS ☐
INTRAMUSCULAR ☐
INTRAVENOUS ☐
RECTAL ☐
AURICULAR (OTIC) ☐
INTRADERMAL ☐
RESPIRATORY (INHALATION) ☐
INTRAUTERINE ☐
TRANSDERMAL ☐
OTHER ☐

Specify other dose route	
What was the start date of the medication/therapy? (dd-mon-yyyy)	
What was the start time of the medication/therapy? (00:00-23:59)	
Check if start time is unknown	
Is the medication/therapy still ongoing?	YES ☐ NO ☐
What was the end date of the medication/therapy? (dd-mon-yyyy)	
What was the end time of the medication/therapy? (00:00-23:59)	
Check if end time is unknown	
Was the medication/therapy taken prior to the study?	YES ☐ NO ☐
What was the ID for the adverse event for which the medication was taken? (If applicable)	
What was the ID for the second adverse event for which the medication was taken? (If applicable)	
What was the ID for the third adverse event for which the medication was taken? (If applicable)	

What was the ID of the medical history condition(s) for which the medication was taken? (If applicable)	
What was the ID of the second medical history condition(s) for which the medication was taken? (If applicable)	
What was the ID of the third medical history condition(s) for which the medication was taken? (If applicable)	
Start Date/Time DERIVED (dd-mon-yyyy 00:00-23:59)	
End Date/Time DERIVED (dd-mon-yyyy 00:00-23:59)	
CM Key Items: DERIVED	

Has the subject had any medical or surgical treatment procedures? YES ☐ NO ☐

If yes, please complete the Medical/Surgical Treatment procedure form.

What was the medical or surgical treatment procedure?	
For what indication was the medical or surgical treatment procedure taken?	Adverse Event ☐ Other ☐
Other, specify	
What was the ID for the adverse event for which the treatment was taken?	
What was the start date of the treatment/procedure? (dd-mon-yyyy)	
Is the treatment/procedure still ongoing?	YES ☐ NO ☐
What was the end date of the treatment/procedure? (dd-mon-yyyy)	

On what date were the measurements performed? (dd-mon-yyyy) _____

Status (If Repeat, please specify original period/day/visit)

- REPEAT ☐
- UNSCHEDULED ☐

Original Period/Day/Visit

- Screening ☐
- Check-in ☐
- Day 1 ☐
- Day 4 ☐
- Day 7 ☐
- Day 8 ☐
- Day 9 ☐
- Early Term ☐
- Follow-up (D14) ☐
- Follow-up (D37) ☐

What is the planned time point for this measurement?

- PREDOSE ☐
- 4 HOUR POSTDOSE ☐

In what position was the subject during the measurement?

- SITTING ■

At what time were the measurements performed? (00:00-23:59) _____

Systolic Blood Pressure **mmHg** ☐

Diastolic Blood Pressure **mmHg** ☐

Heart Rate	**beats/min** ☐
Respiratory Rate	**breaths/min** ☐
Temperature	**C** ☐
Vital Date/Time: DERIVED (dd-mon-yyyy 00:00-23:59)	_____

Status (If Repeat, please specify original period/day/visit)

- [ ] REPEAT
- [ ] UNSCHEDULED

Original Period/Day/Visit

- [ ] Screening
- [ ] Check-in
- [ ] Day 1
- [ ] Day 4
- [ ] Day 7
- [ ] Day 9
- [ ] Early Term

What was the method used to measure ECG?

- [ ] 10 LEAD STANDARD
- [ ] 12 LEAD 1 LEAD MISSING
- [ ] 12 LEAD CABRERA
- [ ] 12 LEAD CONTINUOUS ECG
- [ ] 12 LEAD EASI DOWER TRANSFORMATION
- [ ] 12 LEAD ECG EXTRACTED FROM 12 LEAD CONTINUOUS ECG RECORDING
- [ ] 12 LEAD MASON LIKAR
- [ ] 12 LEAD MODIFIED MASON LIKAR
- [ ] 12 LEAD NON-STANDARD
- [ ] 12 LEAD RIGHT-SIDED PRECORDIAL LEADS
- [ ] 12 LEAD SINGLE PAD
- [x] 12 LEAD STANDARD
- [ ] 12 LEAD UNSPECIFIED
- [ ] 6 LEAD NEHB-SPORI
- [ ] 6 LEAD STANDARD

	8 LEAD STANDARD ☐
	BIPOLAR UNCORRECTED XYZ LEAD SYSTEM ☐
	CONTINUOUS AMBULATORY ECG ☐
	CUBE LEAD SYSTEM ☐
	FRANK LEAD SYSTEM ☐
	HOLTER CONTINUOUS ECG RECORDING ☐
	MCFEE-PARUNGAO LEAD SYSTEM ☐
	PSEUDO-ORTHOGONAL XYZ LEAD SYSTEM ☐
	STANDARD 12-LEAD AND CC5-CM5-ML ☐
	STANDARD 12-LEAD AND CM5-CC5-CH5 ☐
	STANDARD 12-LEAD EXTENDED LEFT ☐
	STANDARD 12-LEAD EXTENDED RIGHT ☐
	STANDARD LEADS FOR BICYCLE EXERCISE ☐
	STANDARD LEADS ONE INTERCOSTAL SPACE HIGHER ☐
	VECTORCARDIOGRAPH CORRECTED ☐
	VECTORCARDIOGRAPH UNCORRECTED ☐
What was the ECG date? (dd-mon-yyyy)	_____
What was the planned time point of the measurement?	4 HOUR POSTDOSE ☐

What was the position of the subject during ECG measurement?

- DECUBITUS ☐
- FOWLERS ☐
- LATERAL DECUBITUS ☐
- LEFT LATERAL DECUBITUS ☐
- PRONE ☐
- REVERSE TRENDELENBURG ☐
- RIGHT LATERAL DECUBITUS ☐
- SEMI-FOWLERS ☐
- SEMI-RECUMBENT ☐
- SITTING ☐
- SLING ☐
- STANDING ☐
- SUPINE ■
- TRENDELENBURG ☐
- UNCONSTRAINED ☐

What was the ECG time? (00:00-23:59) _____

Heart Rate **beats/min** ☐

PR Interval **msec** ☐

QRS Duration **msec** ☐

QTcB Interval **msec** ☐

QTcF Interval **msec** ☐

RR Interval **msec** ☐

Interpretation
- NORMAL ☐
- ABNORMAL ☐
- INDETERMINATE ☐
- NOT EVALUABLE ☐
- UNKNOWN ☐

If abnormal, was the interpretation considered clinically significant?
- YES ☐
- NO ☐

Abnormal findings _____

Date/Time DERIVED (dd-mon-yyyy 00:00-23:59) _____

What was the lab specimen collection date? (dd-mon-yyyy) _____

Status (If Repeat, please specify original period/day/visit)

- REPEAT ☐
- UNSCHEDULED ☐

Original Period/Day/Visit

- Screening ☐
- Check-in ☐
- Day 4 ☐
- Day 8 ☐
- Day 9 ☐
- Early Term ☐
- Follow-up (D14) ☐
- Follow-up (D37) ☐

What was the lab panel name?

- HEMATOLOGY ☐
- CHEMISTRY ☐
- SEROLOGY ☐
- SPECIAL CHEMISTRY ☐
- URINALYSIS ☐
- URINE DRUG SCREEN ☐
- SERUM HUMAN CHORIONIC GONADOTROPIN ☐
- SERUM CHEMISTRY ☐

Was the sample collected?

- YES ☐
- NO ☐
- NOT APPLICABLE ☐

What was the planned time point of the lab?

- 12 HOURS POSTDOSE ☐

What was the lab specimen collection time? (00:00-23:59)	
Date/Time DERIVED (dd-mon-yyyy 00:00-23:59)	

Status (If Repeat, please specify original period/day/visit)

- [ ] REPEAT
- [ ] UNSCHEDULED

Original Period/Day/Visit

- [ ] Screening
- [ ] Check-in
- [ ] Day 7
- [ ] Day 9
- [ ] Early Term

What was the physical examination date? (dd-mon-yyyy) _____

What was the body system examined?

- [x] SKIN
- [ ] HEENT
- [ ] PULMONARY
- [ ] CARDIOVASCULAR
- [ ] ABDOMEN
- [ ] LYMPH NODES
- [ ] MUSCULOSKELETAL
- [ ] NEUROLOGIC SYSTEM
- [ ] OTHER

What was the overall interpretation?

- [ ] NORMAL
- [ ] ABNORMAL
- [ ] NOT DONE

If the result was abnormal, what were the findings? _____

If abnormal, was the interpretation considered clinically significant?

- [ ] YES
- [ ] NO

What was the body system examined?

- [ ] SKIN
- [x] HEENT
- [ ] PULMONARY
- [ ] CARDIOVASCULAR
- [ ] ABDOMEN
- [ ] LYMPH NODES
- [ ] MUSCULOSKELETAL
- [ ] NEUROLOGIC SYSTEM
- [ ] OTHER

What was the overall interpretation?

- [ ] NORMAL
- [ ] ABNORMAL
- [ ] NOT DONE

If the result was abnormal, what were the findings? _____

If abnormal, was the interpretation considered clinically significant?

- [ ] YES
- [ ] NO

What was the body system examined?

- [ ] SKIN
- [ ] HEENT
- [x] PULMONARY
- [ ] CARDIOVASCULAR

ABDOMEN ☐
LYMPH NODES ☐
MUSCULOSKELETAL ☐
NEUROLOGIC SYSTEM ☐
OTHER ☐

What was the overall interpretation?

NORMAL ☐
ABNORMAL ☐
NOT DONE ☐

If the result was abnormal, what were the findings? _____

If abnormal, was the interpretation considered clinically significant?

YES ☐
NO ☐

What was the body system examined?

SKIN ☐
HEENT ☐
PULMONARY ☐
CARDIOVASCULAR ■
ABDOMEN ☐
LYMPH NODES ☐
MUSCULOSKELETAL ☐
NEUROLOGIC SYSTEM ☐
OTHER ☐

What was the overall interpretation?

NORMAL ☐
ABNORMAL ☐

NOT DONE ☐

If the result was abnormal, what were the findings? _____

If abnormal, was the interpretation considered clinically significant?
YES ☐
NO ☐

What was the body system examined?
SKIN ☐
HEENT ☐
PULMONARY ☐
CARDIOVASCULAR ☐
ABDOMEN ■
LYMPH NODES ☐
MUSCULOSKELETAL ☐
NEUROLOGIC SYSTEM ☐
OTHER ☐

What was the overall interpretation?
NORMAL ☐
ABNORMAL ☐
NOT DONE ☐

If the result was abnormal, what were the findings? _____

If abnormal, was the interpretation considered clinically significant?
YES ☐
NO ☐

What was the body system examined?

- [ ] SKIN
- [ ] HEENT
- [ ] PULMONARY
- [ ] CARDIOVASCULAR
- [ ] ABDOMEN
- [x] LYMPH NODES
- [ ] MUSCULOSKELETAL
- [ ] NEUROLOGIC SYSTEM
- [ ] OTHER

What was the overall interpretation?

- [ ] NORMAL
- [ ] ABNORMAL
- [ ] NOT DONE

If the result was abnormal, what were the findings? _____

If abnormal, was the interpretation considered clinically significant?

- [ ] YES
- [ ] NO

What was the body system examined?

- [ ] SKIN
- [ ] HEENT
- [ ] PULMONARY
- [ ] CARDIOVASCULAR
- [ ] ABDOMEN
- [ ] LYMPH NODES
- [x] MUSCULOSKELETAL
- [ ] NEUROLOGIC SYSTEM
- [ ] OTHER

What was the overall interpretation?

- NORMAL ☐
- ABNORMAL ☐
- NOT DONE ☐

If the result was abnormal, what were the findings? _____

If abnormal, was the interpretation considered clinically significant?

- YES ☐
- NO ☐

What was the body system examined?

- SKIN ☐
- HEENT ☐
- PULMONARY ☐
- CARDIOVASCULAR ☐
- ABDOMEN ☐
- LYMPH NODES ☐
- MUSCULOSKELETAL ☐
- NEUROLOGIC SYSTEM ■
- OTHER ☐

What was the overall interpretation?

- NORMAL ☐
- ABNORMAL ☐
- NOT DONE ☐

If the result was abnormal, what were the findings? _____

If abnormal, was the interpretation considered clinically significant?

- YES ☐
- NO ☐

What was the body system examined?

- SKIN ☐
- HEENT ☐
- PULMONARY ☐
- CARDIOVASCULAR ☐
- ABDOMEN ☐
- LYMPH NODES ☐
- MUSCULOSKELETAL ☐
- NEUROLOGIC SYSTEM ☐
- OTHER ■

What was the overall interpretation?

- NORMAL ☐
- ABNORMAL ☐
- NOT DONE ☐

If the result was abnormal, what were the findings? _____

If abnormal, was the interpretation considered clinically significant?

- YES ☐
- NO ☐

What was the sample date? (dd-mon-yyyy)	
What was the sample time? (00:00-23:59)	
Date/Time DERIVED (dd-mon-yyyy 00:00-23:59)	

To which period of the trial does this disposition refer?

- SCREENING ☐
- BASELINE ☐
- FOLLOW-UP ■

To which category does the disposition refer?

- PROTOCOL MILESTONE ☐
- OTHER EVENT ☐
- DISPOSITION EVENT ■

What was the subject's status?

- ADVERSE EVENT ☐
- COMPLETED ☐
- DEATH ☐
- FAILURE TO MEET INCLUSION/EXCLUSION CRITERIA ☐
- LOST TO FOLLOW-UP ☐
- NON-COMPLIANCE WITH STUDY DRUG ☐
- INVESTIGATOR DECISION ☐
- PREGNANCY ☐
- STUDY TERMINATED BY SPONSOR ☐
- WITHDRAWAL BY SUBJECT ☐
- PROTOCOL VIOLATION ☐
- OTHER ☐

Other Specify Status _____

What was the date of study completion or discontinuation? (dd-mon-yyyy) _____

If AE, specify Corresponding AE _____

16.1.3 IRB (Plus the Name of the Committee Chair if Required by the Regulatory Authority) and Representative Written Information for Subject and Sample Consent Forms

Information for the investigator who used a central IRB/IEC is provided below:

Investigator	**IRB/IEC Name and Address**
Wood-Horrall, MD	Advarra 6940 Columbia Gateway Drive, Suite 110 Columbia, MD 21046 United States Chairperson name: Harnish, Sara, JD

The sample informed consent form is provided on the following pages:

Site Specific ICF Version 1.0 dated 13 June 2019

Site Specific ICF Version 2.0 dated 23 July 2019

Site Specific ICF Version 3.0 dated 23 September 2019

AN AGREEMENT TO BE IN A RESEARCH STUDY
INFORMED CONSENT DOCUMENT

Sponsor / Study Title:	**SIGA Technologies, Inc. / "A Post Marketing Study of the Safety, Tolerability, and Pharmacokinetics of TPOXX® in Adult Subjects Weighing More Than 120 kg"**
Protocol Number:	**SIGA-246-022**
Principal Investigator: (Study Doctor)	**Rebecca Wood-Horrall, M.D.**
Additional Contact (Study Staff):	**Lucy Flores**
Telephone:	**512-447-2985 (24 Hours)**
Address:	**PPD Development, LP** **7551 Metro Center Drive** **Suite 200** **Austin, TX 78744**

INTRODUCTION

You are being asked to volunteer and take part in a medical research study. Before you decide to take part in this study, you must read, sign, and date this form. This form, called an informed consent document, explains the study. Please ask as many questions as you need to help you decide whether you want to be in the study. This consent document may contain words that you do not understand. Please ask the study doctor or the study staff to explain any words or anything else that you do not clearly understand before you sign and date this consent document.

To be in this research study, you cannot already be in another medical research study anywhere or have been in any other research study within 30 days before taking the study drug in this study.

You must be honest with the study doctor and study staff about your health history or you may harm yourself by being in this study. It is very important that you give complete and truthful answers to all questions that you are asked during the study. The answers will help the study staff to decide if you can be in the study or stay in the study. If you do not wish to answer a question, tell the study doctor or study staff that you do not want to answer the question. Not answering some questions may mean that you cannot be in the study.

The study doctor is being paid by SIGA Technologies, Inc., the sponsor (the company paying for this study), to run this study. Also, the Biomedical Advanced Research and Development Authority (BARDA), an organization with the United States Department of Health and Human Services, is contributing to the funding of the study.

Please read this form carefully. Take your time to ask the study doctor or study staff as many questions about the study as you would like. The study doctor or study staff can explain words or information that you do not understand. Reading this form and talking to the study doctor or study staff may help you decide whether to take part or not. If you decide to take part in this study, you must sign your name at the end of this form and date it.

PURPOSE OF THE STUDY

In July 2018, TPOXX was approved by the United States Food and Drug Administration (FDA) for the treatment of smallpox (variola virus).

The FDA has asked SIGA Technologies to also do a research study in people that weigh more than 120 kilograms (264.5 pounds), which is this study.

In this document, you may see the terms "study drug", "study treatment", and "study treatment period"; these are terms used in research studies as mentioned above, and this does not mean that you will be receiving medical treatment for any condition. These terms apply to the study drug and parts of the study where you will be receiving this study drug.

The purpose(s) of this study are:

- To measure the amount of TPOXX in the blood
- To see how safe TPOXX is, and how well you tolerate it

The dose(s) you will receive are as follows:

- An oral dose of 600 mg (3 x 200 mg capsules) of TPOXX twice a day for 7 days (Days 1 through 7)

Meals of about 600 calories and 25 grams of fat will be given to you by the study staff 30 minutes before taking study drug. You should eat this entire meal within 30 minutes before taking the study drug. Study drug will be given to you about 30 minutes after you start eating your meal and with about 240 mL (1 cup) of water. You will be told not to eat anything after taking study drug for 2 hours after dosing. In addition, you will be asked not to drink anything (except water) 3 hours before and after taking the study drug.

NEW FINDINGS

If there is new information or any significant new findings that could relate to your willingness to continue participation we will tell you. You can then decide if you still want to be in the study.

If the FDA or the sponsor makes changes to the study before the study starts, the study staff will try to notify you before you check-in. If changes are made after the study has started, the study staff will tell you about them as soon as they have been approved. You can use this information to decide if you want to stay in the study.

WHAT WILL HAPPEN DURING THE STUDY

Before you are asked to do any study-related tests or procedures you will be asked to read, sign, and date this consent document. The following screening tests and procedures will then be performed to determine if you can take part in this study.

You will have medical tests and procedures to help the study doctor decide if you can be in the study. This is called "screening" and will take place between 28 to 2 days before the day you start taking study drug.

Screening does not mean that you will be in the study. Whether you can be in the study will depend upon the results of your lab tests, study specific guidelines, and the decision of the study doctor. Even if your screening tests are okay, there is a chance that you will not be able to participate.

There may be other reasons why you cannot be in the study. The study doctor and/or the study staff will discuss this with you. You will not be paid for your screening visit(s).

You will need to have at least two visits to the research facility for screening tests. After your first screening results have been reviewed, at least one more screening visit will be scheduled by the study staff.

Screening for this study includes:

- A talk about your medical history (including recreational, prescription, and over-the-counter drug use; nicotine and alcohol use; and past hospitalizations)
- Physical exam
- Measurement of your weight
- Your vital signs (temperature, breathing rate, blood pressure and heart rate) after at least 5 minutes sitting
- Your blood and urine will be collected for clinical lab testing (after not eating for at least 8 hours)
- If you are a post-menopausal female, you will have a blood Follicle Stimulating Hormone (FSH) test done
- If female, you will have a blood pregnancy test done
- A urine sample to screen for drugs of abuse, including alcohol (must be negative to participate in the study) will be collected
- You will have blood collected for HIV and hepatitis B and C (these tests must be negative in order for you to be in the study). The study doctor may be required by law to report the result of these tests to the local health authority
- An Electrocardiogram (ECG - measures the electrical activity of the heart) after lying down for at least 10 minutes will be done
- The study doctor will review your nicotine/tobacco and alcohol use

One of the study staff will talk with you about your medical history, draw blood, and collect urine for lab tests.

For screening, the amount of blood taken from you will be a little over 2 teaspoons (11 mL). It may be necessary to try more than one time if the needed amount cannot be collected. A new needle will be used for each blood draw.

A urine test will be done to check for drugs of abuse such as:

- Amphetamines (including methamphetamines and ecstasy/methylenedioxymethamphetamine)
- Barbiturates
- Benzodiazepines
- Cannabinoids (including tetrahydrocannabinol)
- Cocaine
- Opiates (including heroin, codeine, and oxycodone)
- Alcohol

Day -1 (Check-in)

If you are eligible to be in the study, you will be admitted to the research facility on Day -1 (check-in), the day before you start taking study drug. You will remain in the research facility overnight for 9 nights.

At check-in, a blood sample of a little less than 2 teaspoons (9 mL) and urine sample will be taken from you for lab testing and to test for drugs of abuse to see if you can still be in the study.

If you have a positive urine drug test including alcohol, you will not be allowed to take part or to stay in the study. All results of drug tests will remain private.

You will be asked questions regarding your general health and any medication you may have taken since your screening visit to see if you can still be in the study. Vital signs will be taken (temperature, blood pressure, heart rate and breathing rate) after sitting for at least 5 minutes, measurement of weight, physical exam, blood pregnancy test (if female), and ECG performed (after lying down for at least 10 minutes).

Day 1 will be the first day that you take study drug. The following will happen on study days 1 through Day 8.

Days 1 - 8

- Vital signs taken (temperature, breathing rate, blood pressure and heart rate) after sitting for at least 5 minutes (Days 1, 4, 7, and 8)
- Measurement of your weight (Day 1)
- Blood sample for clinical labs (Days 4 and 8)
- Physical exam (Day 7)
- ECG after lying down for at least 10 minutes (Days 1, 4, and 7)
- Blood samples of about 1 teaspoon (5 ml) will be collected before the morning dose and 30 minutes, 1, 2, 4, 6, 8, 12 (before the afternoon dose), 14, 16, 18, 20, and 24 hours after dosing on Days 1 and 7, to measure the amount of study drug in your blood
- Blood samples of about 1 teaspoon (5 ml) will be collected before and 4 hours after the morning dose on Day 6, to measure the amount of study drug in your blood
- Review of current medications and side effects

Day 9 (Study Discharge)

- Physical exam
- Measurement of your weight
- Vital signs (temperature, breathing rate, blood pressure and heart rate) after sitting for at least 5 minutes
- Blood and urine sample for clinical labs
- ECG after lying down for at least 10 minutes
- Blood samples of about 1 teaspoon (5 ml) will be collected 48 hours after the morning dose on Day 7, to measure the amount of study drug in your blood
- Review of current medications and side effects

Before exiting the study, a blood sample of a little less than 2 teaspoons (9 mL) and a urine sample will be collected for clinical lab tests. For your safety, if lab test results are not normal, more blood and/or urine samples may be collected.

You can leave the research facility after all study tests and procedures on Day 9 have been completed. If you have ongoing side effects or abnormal findings on your physical exam on Day 9, you will be asked to return to the research facility five days later, on Day 14.

If you do not have any abnormal findings on your physical exam, the study staff will call you by phone on Day 14 to check on your wellbeing.

You will be contacted by telephone about 30 days after the last dose of study drug (Day 37) to see how you are feeling. You should also contact PPD during this time if you are experiencing any side effects.

A small needle with a thin plastic tube covering it (like a small straw) called a "cannula" may be inserted into a vein in your arm or hand to make blood draws easier. A study staff member puts the needle with the cannula over it into a vein in your arm or hand, and then slides the cannula over the needle into your arm or hand vein. The cannula stays in your arm or hand vein, and the needle is taken out. You will need to keep your arm very still for the period while the needle is in place. Use of a cannula is optional and the study doctor will decide if it is needed. Very small amounts of saline (salt water) will be injected into this cannula to prevent clogging. This procedure may cause pain, swelling and redness at the place where the cannula is put into your vein. When a cannula is used for blood collected, the study staff will take about an extra 1 mL of blood. The cannula will be left in for as long as it is needed to help with blood collections, but not for longer than about 72 hours.

If you take part in this study, you will have your blood drawn about 32 times during this study. About less than 1 cup (187 mL) of blood will be taken from you during this study. You may want to know that the standard blood donation is about 2 cups (480 mL) of blood.

Signing and dating this consent form means that you agree to allow PPD, the sponsor, or other laboratories involved in this study to store and test any used or unused blood samples or plasma samples (taken from the blood samples, for study related testing) until all research on the study drug is stopped. When all research is stopped, all blood or plasma samples will be destroyed. If you do not agree to this, you will not be enrolled in the study.

After Study Treatment:

Because this is a research study, the study drug will be given to you only during this study and not after the study is over.

HIV AND HEPATITIS TESTING

As required by the study and if any person is exposed to your blood, you must be tested for the hepatitis viruses and for HIV (Human Immunodeficiency Virus). HIV is the virus that causes AIDS (Acquired Immunodeficiency Syndrome). If you have a positive HIV or hepatitis test, you cannot remain in the study.

If the HIV test is positive, a follow-up test will be done. If the follow-up test is also positive, you will be given the results in private and will also be given information about counseling.

It may take weeks or months after being infected with HIV for the test to be positive. The HIV test is not always right.

Positive HIV and hepatitis test results must be reported to the Department of Health, and the law may require that your name be reported. Although this testing is supposed to be private, this cannot be guaranteed. For example, it is possible for a court of law to get medical or study records without your permission.

LENGTH OF THE STUDY AND NUMBER OF SUBJECTS EXPECTED TO PARTICIPATE

About 36 male and female subjects, ages 18 to 50, will be in this study. You will be in this study up to 65 days; this begins with your screening visit and continues until your last study visit. You will be confined to the research facility continuously for 9 nights and 10 days, during this period.

RESTRICTIONS

- You must not have participated in another clinical research trial where you received any other study drug in a previous study within 30 days before the first dose of study drug.
- You must not have been in any other clinical research study with the study drug TPOXX (also known as tecovirimat).
- You should not have donated more than 450 mL of blood or blood components within 30 days before the first dose of study drug. You should not donate blood or blood components for 4 weeks after the completion of the study.
- You may not consume any food or drink containing grapefruit or grapefruit juice, Seville orange or Seville orange-containing products (for example, marmalade) within 48 hours before the first dose of study drug or throughout the study.
- You may not consume caffeine- or xanthine-containing beverages within 48 hours before the first dose of study drug or throughout the study.
- You may not consume pomegranate or pomegranate juice, pomelo fruits or pomelo juice within 72 hours before the first dose of study drug.
- You may not consume alcohol-containing beverages within 72 hours before the first dose of study drug.
- You must not have used nicotine or nicotine-containing products (for example, cigarettes, electronic vapor cigarettes, cigars, chewing tobacco, snuff, nicotine patches, or nicotine gum) within 6 months before the first dose of study drug and throughout the duration of the study.
- You must refrain from strenuous exercise or contact sports within 24 hours before first dose of study drug until study discharge.
- You must not have used any herbal or nutritional supplements, prescription, or over-the-counter medications within 14 days before the first dose of study drug.
- You must not intend to lose weight (diet or weight loss) from screening and throughout the study.
- The following medications are not allowed to be taken within 7 days before receiving study drug on study Day 1 through check out (Day 9):
    - antidiabetic medications
    - anticoagulants
    - anticonvulsants
    - substrates of the breast cancer resistance protein transporter including
        - methotrexate, mitoxantrone, imatinib, irinotecan, lapatinib, rosuvastatin, sulfasalazine, and topotecan;
    - substrates of cytochrome P450 (CYP) 2C8 including
        - repaglinide, paclitaxel, Montelukast, pioglitazone, rosiglitazone; and
    - substrates of CYP2C19 including
        - S-mephenytoin, clobazam, diazepam, rabeprazole, voriconazole, lansoprazole, and omeprazole

If you are on any of these medications, do not stop taking them without first consulting your personal doctor.

You must not use any drugs (over-the-counter, prescription, or illegal) without approval from the study doctor. Oral birth control pills or other hormonal birth control methods are allowed. Taking other drugs or drinking alcohol could result in serious and even life-threatening reactions. If you decide to take any medication without approval from the study doctor, you may not be allowed to continue in the study. You must inform the study staff of any prescription birth control you are using including intrauterine devices (IUDs).

Taking other drugs or alcohol could result in serious and even life-threatening reactions. If you decide to take any medication without approval from the study doctor you may not be allowed to continue in the study.

RISKS, SIDE EFFECTS, AND/OR DISCOMFORTS

It is very important that you tell the study staff right away about any side effects. It is also very important that you do not talk to other people participating in this study about your side effects or theirs.

If you do not tell the study staff about a side effect, or if you talk to other people in the study with you about your side effects, you may be removed from this study. In addition to being removed from the current study, your payment may be reduced, and you may not be allowed to take part in future studies for PPD.

All side effects or changes in your normal health must be reported, even those changes you might not consider to be important. Some examples may include:

- Headache
- Tooth pain
- Bruising
- Hiccups
- Changes in your eating or sleeping patterns

If you have any changes in your health/medical history after signing and dating this consent document, please tell your study doctor or study staff.

One of the reasons for this study is to learn more about the possible side effects of the study drug. It is important that you tell the study staff about possible side effects. Contact PPD if you experience any side effects through the follow-up phone call on Day 37.

Rare or unknown side effects could possibly occur, including allergic reactions, and life-threatening reactions.

You may harm yourself by taking part in this study if you are not fully truthful about any side effect with the study doctor and study staff.

The most common side effects of TPOXX include:

- Headache (12%)
- Nausea (5%)
- Abdominal Pain (2%)
- Vomiting (2%)
- Diarrhea

- Dizziness

If you do not understand what any of these side effects mean, please ask the study doctor or study staff to explain these terms to you.

In animal studies, seizures were seen in dogs, but not any other species. The significance of this for humans is unknown. You may not participate in the study if you have a history of seizures and you will be monitored for any signs of seizure.

ADDITIONAL RISKS OR DISCOMFORTS

Until you know how the study drug will affect you, you should use caution by avoiding stairs, not driving a car or working with machinery. If you later feel that the study drug has affected your ability to perform these things, stop doing them.

Blood Samples:

There may be side effects of having blood taken such as:

- Fainting
- Redness
- Swelling of the vein
- Pain
- Bruising
- Bleeding

There is also a slight possibility of infection or nerve damage.

If you feel faint tell the study staff or study doctor right away.

Scarring can occur at the sites of repetitive blood draws. If you have a "cannula" or intravenous catheter, you could also have pain, swelling, and redness of the vein, which may not go away quickly.

Electrocardiogram (ECG):

The ECG test is a recording of the electrical activity of your heart. The sticky pads used may be cold when applied and sometimes cause some discomfort such as redness or itching. If the hair under the patches needs to be shaved, irritation from shaving also could occur.

Other Risks

PPD requires that you agree to have pictures taken of your skin if you develop a side effect such as a rash. The picture(s) are only for the use of the study doctor and study sponsor.

Since as with any drug, there may be other risks that are unknown.

BIRTH CONTROL, DANGERS OF PREGNANCY AND BREASTFEEDING

The effects of the study drug on an unborn or breastfed baby are unknown, but could be a risk. If you are pregnant or breastfeeding, you cannot be in this study.

It is **very** important that you not become pregnant or breastfeed during this study or within 3 months after the last dose of study drug. Not having sex is the only certain way to prevent pregnancy. If you are a woman who is able to become pregnant, and choose to have sex, you must agree to use one of the methods of birth control listed below for at least 30 days before first dose through 30 days after last dose of study drug.

The only birth control methods that can be used during this study include:

- Condom, male or female, with spermicide (male and female condoms must NOT be used together)
- Diaphragm or cervical cap with spermicide
- Intrauterine device (IUD) with spermicide
- Oral contraceptives or other hormonal methods with another nonhormonal method
- Male sexual partner who had undergone a vasectomy at least 3 months before screening
- Not having sex (abstinence)*****

*Abstinence

You must understand that sexual abstinence means heterosexual sexual intercourse for medical, psychological, legal, social, financial, philosophical, moral or religious reasons. Heterosexual sexual activity refers to sexual activity between a male and a female. Any types of heterosexual activity where any amount of male semen (or ejaculate) could be present are to be strictly avoided, without exception.

This does not mean periodic abstinence (for example, calendar, ovulation, profession of abstinence for entry into a clinical trial).

Abstinence must be your preferred and usual lifestyle. By agreeing to this you affirm (commit) that this has been your lifestyle for at least the past 6 months and this will be true until the specified amount of time required for the study has been met.

If there is a possibility that you will engage in any heterosexual activity at any time during the study time requirement, you must not choose sexual abstinence as your method of birth control.

If you choose abstinence as your method of contraception and become pregnant/father a child during participation in this study, you will be excluded from all future participation in PPD studies.

If you cannot have children because of a surgery (for example if you have had a hysterectomy [removal of the uterus] or tubal ligation [tubes tied]), or if you are postmenopausal for at least 12 months, you can participate in this study without using additional forms of contraception.

Even if you use a medically acceptable birth control method, you could still become pregnant.

There is a chance that a pregnancy test could indicate that you are not pregnant, even though you are. **If it is early enough in your pregnancy, a pregnancy test may not be able to detect that you are pregnant.**

If you are pregnant, become pregnant or breastfeed during the study, the study drug or procedures may involve risks to the unborn or breastfed baby, which are currently unforeseeable.

If you are a man, there may be risks to an unborn baby if you father a child during the study. Men must agree to use a condom throughout the study and for 90 days after you take the last dose of study drug.

Men must agree not to donate sperm from the first dose of study drug through 90 days after the last dose of study drug.

Even if you and your partner use birth control, you or your partner could become pregnant. If you or your partner are pregnant, become pregnant, or breastfeed during the study, the study drug may involve risks to the unborn or breastfed baby, which we are not aware of at this time.

In the event you (if you are female) or your partner (if you are male) become pregnant during the course of the study, you (or your partner) may be requested to sign and date a separate informed consent form to allow PPD study staff to contact you throughout the course of the pregnancy to get updates on how the pregnancy is progressing, and for 3 months after the birth. PPD and the sponsor are required to attempt to collect and report information about any pregnancy that occurs in a subject who is participating in a study. They may also be required to attempt to collect and report this information if the female partner of a male subject who is participating in a study becomes pregnant and could have been exposed to study drug through the male subject's semen.

If you are female, and you have had sex without using a medically acceptable method of birth control during the three weeks before the start of the study, you must not be in this study.

COSTS

All study tests are being done for research only and are not replacements for medical care. There will be no charge to you for your participation in this study. The study drug, study-related procedures, and testing supplies, as well as study visits will be provided at no charge to you or your insurance company. While confined to the research facility all your meals, snacks and beverages will be provided.

POSSIBLE BENEFITS OF THE STUDY

This study is for research purposes only. There is no direct benefit to you from your participation in the study. Information learned from the study may help other people in the future.

ALTERNATIVES TO PARTICIPATING

This research study is for research purposes only. The only alternative is to not participate in this study.

PAYMENT FOR PARTICIPATION

For the current study, you will receive:

- $225.00/night for each night that you spend at the research facility ($225.00/night x 9 nights)
- $125.00/visit for each outpatient visit/phone call to the research facility ($125.00/visit x 2 outpatient visit/phone call)

If you successfully complete the study, you will receive an additional $725.00 making your total payment $3,000.00. You will receive payment within 3 weeks of your last study visit or your study completion.

If you have a side effect linked to the study drug and the study doctor thinks that this may harm your safety, you will be taken out of the study. You may be paid in full, including the study completion bonus, at the discretion of the study doctor.

However full payment is not guaranteed. If you have a side effect linked to the study drug and you leave the study when the study doctor does not think your safety is at risk, your pay will be lower. You will receive a pro-rated payment and pro-rated study completion bonus based on the days you were in the study. If the study doctor releases you from the study and it is non-drug related, you will receive a pro-rated payment and pro-rated study completion bonus based on the number of days you were in the study.

If you are a backup subject who is required to stay in the facility overnight you will be paid $75.00. If you are not required to stay overnight you will be paid $25.00. If you are required to stay for additional nights for safety procedures or observation, then you will be paid $200.00 for the additional night(s).

You will be paid an amount based on the extent of your participation, if:

- You are unable to complete the study
- You miss multiple outpatient visits (your completion bonus will be reduced accordingly)
- You voluntarily leave the study
- The study doctor withdraws you early from the study
- The study is stopped early
- You are qualified but not chosen to participate

You will be expected to read and follow the Phase 1 Clinic Subject Rules and Regulations, available at http://www.ppdi.com, while participating in the study. If you do not have access to the internet, let a PPD study staff member know and you will be provided with a printed version to review. The study staff will be available to answer any questions or clarify any information you do not understand. You will be asked to confirm whether you have fully read the Rules and Regulations document, acknowledge that you have been given the opportunity to ask questions and that you have received satisfactory answers. If you do not read and acknowledge the Rules and Regulations document, you will not be able to participate in the study. If you do not follow the Rules and Regulations of the Phase I Clinic during your participation in the study, you may not be paid as stated above.

If at any time you test positive for drugs or substances other than the study drug or if you engage in disruptive behavior, you may not be paid as stated above. Disruptive behavior includes, but is not limited to:

- Destruction of property
- Stealing
- Verbal abuse or profanity
- Bodily or verbal threats
- Sexual harassment

If you engage in disruptive behavior, or if you test positive for drugs or substances other than the study drug, you will be paid $2.00 per night and/or outpatient visit for the time you were in the study. You will immediately be dropped from the study. Also, you may not be allowed to take part in other studies for PPD.

If you feel that the payment listed may interfere with your making a good decision about whether or not you should volunteer to be in this study, you should not agree to participate.

You may be required to report the payment received for this study to the Internal Revenue Service as taxable income.

You have to provide your social security number because the IRS may be told how much you were paid to take part in this study.

IN CASE OF AN INJURY RELATED TO THIS RESEARCH STUDY

If you have any adverse reaction (side effect) to the study drug or changes in your physical or mental condition during the course of the study, you should tell the study doctor or study staff right away at the phone number listed on the first page of this document.

The study doctor will treat you as needed, at no cost, for any physical injury caused directly by this study. The study doctor will not offer to cover the medical care costs for injuries or illnesses that are not caused directly by the study.

If you become injured during this study and your injury is a direct result of the study drug or the administration of the study drug or properly performed study procedures according to the study directions, medical treatment will be available to you. The costs of treatment will be paid by SIGA Technologies, Inc. to the extent they are not covered by your health insurance. SIGA Technologies, Inc. does not plan to make further compensation for research-related injury available to you.

Be aware that your health care payer/insurance provider might not cover the costs of study-related injuries or illnesses.

You do not give up any of your legal rights by signing and dating this form. Further information regarding medical treatment for research-related injuries can be obtained from the study doctor or other authorized personnel. You must notify the study doctor immediately of any research related injury.

When the sponsor is going to pay for treatment for your injury, the sponsor or its representatives may need to collect certain personal information about you, such as your name, date of birth, gender, social security number, and Medicare identification number (if you have one). The sponsor needs this information to comply with a Medicare reporting obligation. This information may be collected directly from you, or from researchers, physicians or other healthcare providers who treated your problem or injury. This information and also information about your injury or other health problems may be shared with others, including sponsor representatives, the sponsor's insurance company, and the Centers for Medicare & Medicaid Services.

Public Readiness and Emergency Preparedness Act (PREP Act)

This clinical trial is covered by the PREP Act.
If you are physically injured by taking part in this study, the study doctor will provide immediate medical treatment. The study doctor will also refer you to the health care facilities that can best treat your injury. No financial compensation by the study doctors that gave you the study drug will be offered for any discomfort caused by your taking part in this study.

This clinical trial involves the use of TPOXX, which is covered by the Public Readiness and Emergency Preparedness (PREP) Act. The PREP Act limits your ability to sue under U.S. law from any harm that may result from your use of TPOXX unless the harm is caused by willful misconduct (certain types of intentional acts). A federal program called the Countermeasures Injury Compensation Program (CICP) has been created to provide compensation for some types of serious injuries or death directly caused by medical products covered by the PREP Act. If you are injured by TPOXX and meet all of the CICP's eligibility requirements, you may be able to receive compensation under this program. Information about the CICP, including how to file a claim follows.

What is the PREP Act?
The PREP Act was passed in December 2005. With regard to clinical trials, it provides compensation to subjects in the event of serious physical injury or death directly caused by a drug, device, or biological product, including a vaccine, against certain pandemic, epidemic, biological, chemical, radiological, or nuclear threats, and liability protection for persons conducting the clinical trial and the manufacturer. This coverage becomes effective only when the Secretary of HHS issues a Declaration covering that category or health threat or condition.

What does the PREP Act do?
The PREP Act protects those who make, test, develop, distribute and/or use the product covered by the Declaration. Those protected may not be sued for an adverse event related to the covered product, except for willful misconduct. However, the PREP Act authorizes the Countermeasures Injury Compensation Program (CICP) to provide compensation to eligible individuals for serious physical injury or death determined to be directly caused by administration or use of the covered product. This compensation may include out-of-pocket medical expenses, lost employment income and/or survivor death benefits. Claims must be filed within one calendar year of receiving the covered vaccine or drug.

What do I do if I am injured as a result of being in this clinical trial?
If you believe that your injury may be covered by the PREP Act, or you are representing someone who has died, and wish to file a request for benefits with the CICP, your request form must be postmarked within one year of receipt of the covered vaccine or drug. The request for benefits form and instructions on how to file a claim are available online at:
http://www.hrsa.gov/gethealthcare/conditions/countermeasurescomp/howtofile.html.

A paper copy of the request for benefits form may be obtained by calling 1 (855) 266-2427.

Send the letter by mail or a commercial carrier or courier service to:

Health Resources and Services Administration
Countermeasures Injury Compensation Program
5600 Fishers Lane, Room 11C-06
Rockville, MD 20857

For additional information, please refer to these websites:

HRSA Countermeasures Injury Compensation Program https://www.hrsa.gov/cicp/

CICP Administrative Final Rule
http://www.phe.gov/Preparedness/legal/prepact/Pages/default.aspx

While you should understand the impact of the PREP Act and how it may limit your rights if you are injured during the research, by signing and dating this form you are not giving up any legal rights that you may otherwise have.

WHOM TO CONTACT ABOUT THIS STUDY

During this study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study, please contact the Investigator at the telephone number listed on the first page of this consent document. If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

If you are unable to reach anyone at the facility and you need medical attention, please go to the nearest emergency room. If you feel this emergency may be life-threatening, call 911 before contacting PPD.

An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, contact**:**

- By mail:
  Study Subject Adviser
  Advarra IRB
  6940 Columbia Gateway Drive, Suite 110
  Columbia, MD 21046
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00035974.

Advarra has approved the information in this consent document and has given approval for the study doctor to do the study. This does not mean Advarra has approved you being in the study. You must consider the information in this consent document for yourself and decide if you want to be in this study.

YOUR PARTICIPATION IN THE STUDY

Your decision to participate in this study is voluntary. You may choose to not participate or you may withdraw from the study for any reason without penalty or loss of benefits to which you are otherwise entitled and without any effect on your future medical care. However, please note that the FDA requires that any information collected up to the point of your withdrawal cannot be removed from the study.

It is your choice if you want to be in the study. No one can force you to be in the study. You can leave the study at any time. You will not be punished for leaving the study.

If you believe it is in your best interest to leave the study, you must withdraw, even if that means you will be paid less.

If you wish to leave this study, please call the study staff at the phone number listed on the first page of this document.

Your part in this study may be stopped at any time without you being asked. The following people can stop your participation:

- The study doctor
- Advarra IRB
- The United States Food and Drug Administration (FDA)
- The sponsor company

You may be taken out of the study without your permission at any time for the following reasons:

- If you do not follow the study requirements
- If you do not follow the study doctor's instructions

- If it is discovered that you do not meet the study requirements (including any requirements in this consent document)
- If the study is cancelled
- If it becomes harmful to your health
- If you are not truthful

If you leave the study or if you are taken out of the study, you may be asked to return for a final visit to have some end of study evaluations or tests. If information generated from this study is published or presented, your identity will not be revealed. If you leave the study, no more information about you will be collected for this study. However, all of the information you gave us before you left the study will still be used.

Certain effects of the study may exist that while under a controlled environment normally do not pose a threat to a subject's safety, but which without proper control such as is found in the PPD facility, may be hazardous to your health.

If you decide to leave the PPD facility against the advice of the study doctor you will be asked to sign a release form acknowledging so.

RELEASE OF MEDICAL RECORDS AND PRIVACY

Your records of being in this study will be kept private except when ordered by law. The following people will have access to your study records:

- Study doctor and study staff
- Study Monitor
- SIGA Technologies, Inc. [including monitor(s) and auditor(s)]
- The United States Food and Drug Administration (FDA)
- Other country, state or federal regulatory agencies including the Biomedical Advanced Research and Development Authority (BARDA)
- Advarra IRB

In the event you require emergency treatment at a medical facility other than PPD during the study, PPD may need to provide your study records, which may include demographic and/or personal information, to the healthcare provider involved in your care or treatment. The information disclosed may include records/reports including but not limited to clinical lab reports, ECGs, vital sign measurements and information related to ongoing side effects and/or concomitant medications.

The Independent Review Board (IRB), Advarra, and accrediting agencies, may inspect and copy your records, which may have your name on them. Therefore, total confidentiality cannot be guaranteed. If the study results are presented at meetings or printed in publications, your name will not be used.

If you require medical care outside of the PPD Phase I Clinic, the study doctor may ask for your approval to obtain health records of any hospitalizations or medical visits. The health records will become part of your research record.

If PPD is notified that you have participated in a research study at another research facility while also participating in a research study at PPD, it may be necessary for PPD to share certain details about your study participation with the other research facility.

Identification Photo

Prior to screening for the study, you may be required to have your photo taken by a study staff member. Your photo will be used as a means of verifying your identification and will be saved in PPD's internal database for future reference. Only the study doctor and study staff who have access to the database will be able to view your photo.

Electronic Surveillance

The facility is equipped with electronic surveillance and your activities may be monitored.

CONSENT

I have read and understand the information in this informed consent document. I have had an opportunity to ask questions and all of my questions have been answered to my satisfaction. I voluntarily agree to participate in this study until I decide otherwise. I do not give up any of my legal rights by signing and dating this consent document. I will receive a copy of this signed and dated consent document.

IF YOU DO NOT AGREE WITH THE STATEMENT ABOVE, YOU SHOULD NOT SIGN OR DATE THIS INFORMED CONSENT DOCUMENT.

AN AGREEMENT TO BE IN A RESEARCH STUDY
INFORMED CONSENT DOCUMENT

Sponsor / Study Title:	**SIGA Technologies, Inc. / "A Post Marketing Study of the Safety, Tolerability, and Pharmacokinetics of TPOXX® in Adult Subjects Weighing More Than 120 kg"**
Protocol Number:	**SIGA-246-022**
Principal Investigator: (Study Doctor)	**Rebecca Wood-Horrall, M.D.**
Additional Contact (Study Staff):	**Lucy Flores**
Telephone:	**512-447-2985 (24 Hours)**
Address:	**PPD Development, LP** **7551 Metro Center Drive** **Suite 200** **Austin, TX 78744**

INTRODUCTION

You are being asked to volunteer and take part in a medical research study. Before you decide to take part in this study, you must read, sign, and date this form. This form, called an informed consent document, explains the study. Please ask as many questions as you need to help you decide whether you want to be in the study. This consent document may contain words that you do not understand. Please ask the study doctor or the study staff to explain any words or anything else that you do not clearly understand before you sign and date this consent document.

To be in this research study, you cannot already be in another medical research study anywhere or have been in any other research study within 30 days before taking the study drug in this study.

You must be honest with the study doctor and study staff about your health history or you may harm yourself by being in this study. It is very important that you give complete and truthful answers to all questions that you are asked during the study. The answers will help the study staff to decide if you can be in the study or stay in the study. If you do not wish to answer a question, tell the study doctor or study staff that you do not want to answer the question. Not answering some questions may mean that you cannot be in the study.

The study doctor is being paid by SIGA Technologies, Inc., the sponsor (the company paying for this study), to run this study. Also, the Biomedical Advanced Research and Development Authority (BARDA), an organization with the United States Department of Health and Human Services, is contributing to the funding of the study.

Please read this form carefully. Take your time to ask the study doctor or study staff as many questions about the study as you would like. The study doctor or study staff can explain words or information that you do not understand. Reading this form and talking to the study doctor or study staff may help you decide whether to take part or not. If you decide to take part in this study, you must sign your name at the end of this form and date it.

PURPOSE OF THE STUDY

In July 2018, TPOXX was approved by the United States Food and Drug Administration (FDA) for the treatment of smallpox (variola virus).

The FDA has asked SIGA Technologies to also do a research study in people that weigh more than 120 kilograms (264.5 pounds), which is this study.

In this document, you may see the terms "study drug", "study treatment", and "study treatment period"; these are terms used in research studies as mentioned above, and this does not mean that you will be receiving medical treatment for any condition. These terms apply to the study drug and parts of the study where you will be receiving this study drug.

The purpose(s) of this study are:

- To measure the amount of TPOXX in the blood
- To see how safe TPOXX is, and how well you tolerate it

The dose(s) you will receive are as follows:

- An oral dose of 600 mg (3 x 200 mg capsules) of TPOXX twice a day for 7 days (Days 1 through 7)

Meals of about 600 calories and 25 grams of fat will be given to you by the study staff 30 minutes before taking study drug. You should eat this entire meal within 30 minutes before taking the study drug. Study drug will be given to you about 30 minutes after you start eating your meal and with about 240 mL (1 cup) of water. You will be told not to eat anything after taking study drug for 2 hours after dosing. In addition, you will be asked not to drink anything (except water) 3 hours before and after taking the study drug.

NEW FINDINGS

If there is new information or any significant new findings that could relate to your willingness to continue participation we will tell you. You can then decide if you still want to be in the study.

If the FDA or the sponsor makes changes to the study before the study starts, the study staff will try to notify you before you check-in. If changes are made after the study has started, the study staff will tell you about them as soon as they have been approved. You can use this information to decide if you want to stay in the study.

WHAT WILL HAPPEN DURING THE STUDY

Before you are asked to do any study-related tests or procedures you will be asked to read, sign, and date this consent document. The following screening tests and procedures will then be performed to determine if you can take part in this study.

You will have medical tests and procedures to help the study doctor decide if you can be in the study. This is called "screening" and will take place between 28 to 2 days before the day you start taking study drug.

Screening does not mean that you will be in the study. Whether you can be in the study will depend upon the results of your lab tests, study specific guidelines, and the decision of the study doctor. Even if your screening tests are okay, there is a chance that you will not be able to participate.

There may be other reasons why you cannot be in the study. The study doctor and/or the study staff will discuss this with you. You will not be paid for your screening visit(s).

You will need to have at least two visits to the research facility for screening tests. After your first screening results have been reviewed, at least one more screening visit will be scheduled by the study staff.

Screening for this study includes:

- A talk about your medical history (including recreational, prescription, and over-the-counter drug use; nicotine and alcohol use; and past hospitalizations)
- Physical exam
- Measurement of your weight
- Your vital signs (temperature, breathing rate, blood pressure and heart rate) after at least 5 minutes sitting
- Your blood and urine will be collected for clinical lab testing (after not eating for at least 8 hours)
- If you are a post-menopausal female, you will have a blood Follicle Stimulating Hormone (FSH) test done
- If female, you will have a blood pregnancy test done
- A urine sample to screen for drugs of abuse, including alcohol (must be negative to participate in the study) will be collected
- You will have blood collected for HIV and hepatitis B and C (these tests must be negative in order for you to be in the study). The study doctor may be required by law to report the result of these tests to the local health authority
- An Electrocardiogram (ECG - measures the electrical activity of the heart) after lying down for at least 10 minutes will be done
- The study doctor will review your nicotine/tobacco and alcohol use

One of the study staff will talk with you about your medical history, draw blood, and collect urine for lab tests.

For screening, the amount of blood taken from you will be a little over 2 teaspoons (11 mL). It may be necessary to try more than one time if the needed amount cannot be collected. A new needle will be used for each blood draw.

A urine test will be done to check for drugs of abuse such as:

- Amphetamines (including methamphetamines and ecstasy/methylenedioxymethamphetamine)
- Barbiturates
- Benzodiazepines
- Cannabinoids (including tetrahydrocannabinol)
- Cocaine
- Opiates (including heroin, codeine, and oxycodone)
- Alcohol

Day -1 (Check-in)

If you are eligible to be in the study, you will be admitted to the research facility on Day -1 (check-in), the day before you start taking study drug. You will remain in the research facility overnight for 9 nights.

At check-in, a blood sample of a little less than 2 teaspoons (9 mL) and urine sample will be taken from you for lab testing and to test for drugs of abuse to see if you can still be in the study.

If you have a positive urine drug test including alcohol, you will not be allowed to take part or to stay in the study. All results of drug tests will remain private.

You will be asked questions regarding your general health and any medication you may have taken since your screening visit to see if you can still be in the study. Vital signs will be taken (temperature, blood pressure, heart rate and breathing rate) after sitting for at least 5 minutes, measurement of weight and height, physical exam, blood pregnancy test (if female), and ECG performed (after lying down for at least 10 minutes).

Day 1 will be the first day that you take study drug. The following will happen on study days 1 through Day 8.

Days 1 - 8

- Vital signs taken (temperature, breathing rate, blood pressure and heart rate) after sitting for at least 5 minutes (Days 1, 4, 7, and 8)
- Measurement of your weight (Day 1)
- Blood sample for clinical labs (Days 4 and 8)
- Physical exam (Day 7)
- ECG after lying down for at least 10 minutes (Days 1, 4, and 7)
- Blood samples of about 1 teaspoon (5 ml) will be collected before the morning dose and 30 minutes, 1, 2, 4, 6, 8, 12 (before the afternoon dose), 14, 16, 18, 20, and 24 hours after dosing on Days 1 and 7, to measure the amount of study drug in your blood
- Blood samples of about 1 teaspoon (5 ml) will be collected before and 4 hours after the morning dose on Day 6, to measure the amount of study drug in your blood
- Review of current medications and side effects

Day 9 (Study Discharge)

- Physical exam
- Measurement of your weight
- Vital signs (temperature, breathing rate, blood pressure and heart rate) after sitting for at least 5 minutes
- Blood and urine sample for clinical labs
- ECG after lying down for at least 10 minutes
- Blood samples of about 1 teaspoon (5 ml) will be collected 48 hours after the morning dose on Day 7, to measure the amount of study drug in your blood
- Review of current medications and side effects

Before exiting the study, a blood sample of a little less than 2 teaspoons (9 mL) and a urine sample will be collected for clinical lab tests. For your safety, if lab test results are not normal, more blood and/or urine samples may be collected.

You can leave the research facility after all study tests and procedures on Day 9 have been completed. If you have ongoing side effects or abnormal findings on your physical exam on Day 9, you will be asked to return to the research facility five days later, on Day 14.

If you do not have any abnormal findings on your physical exam, the study staff will call you by phone on Day 14 to check on your wellbeing.

You will be contacted by telephone about 30 days after the last dose of study drug (Day 37) to see how you are feeling. You should also contact PPD during this time if you are experiencing any side effects.

A small needle with a thin plastic tube covering it (like a small straw) called a "cannula" may be inserted into a vein in your arm or hand to make blood draws easier. A study staff member puts the needle with the cannula over it into a vein in your arm or hand, and then slides the cannula over the needle into your arm or hand vein. The cannula stays in your arm or hand vein, and the needle is taken out. You will need to keep your arm very still for the period while the needle is in place. Use of a cannula is optional and the study doctor will decide if it is needed. Very small amounts of saline (salt water) will be injected into this cannula to prevent clogging. This procedure may cause pain, swelling and redness at the place where the cannula is put into your vein. When a cannula is used for blood collected, the study staff will take about an extra 1 mL of blood. The cannula will be left in for as long as it is needed to help with blood collections, but not for longer than about 72 hours.

If you take part in this study, you will have your blood drawn about 32 times during this study. About less than 1 cup (187 mL) of blood will be taken from you during this study. You may want to know that the standard blood donation is about 2 cups (480 mL) of blood.

Signing and dating this consent form means that you agree to allow PPD, the sponsor, or other laboratories involved in this study to store and test any used or unused blood samples or plasma samples (taken from the blood samples, for study related testing) until all research on the study drug is stopped. When all research is stopped, all blood or plasma samples will be destroyed. If you do not agree to this, you will not be enrolled in the study.

After Study Treatment:

Because this is a research study, the study drug will be given to you only during this study and not after the study is over.

HIV AND HEPATITIS TESTING

As required by the study and if any person is exposed to your blood, you must be tested for the hepatitis viruses and for HIV (Human Immunodeficiency Virus). HIV is the virus that causes AIDS (Acquired Immunodeficiency Syndrome). If you have a positive HIV or hepatitis test, you cannot remain in the study.

If the HIV test is positive, a follow-up test will be done. If the follow-up test is also positive, you will be given the results in private and will also be given information about counseling.

It may take weeks or months after being infected with HIV for the test to be positive. The HIV test is not always right.

Positive HIV and hepatitis test results must be reported to the Department of Health, and the law may require that your name be reported. Although this testing is supposed to be private, this cannot be guaranteed. For example, it is possible for a court of law to get medical or study records without your permission.

LENGTH OF THE STUDY AND NUMBER OF SUBJECTS EXPECTED TO PARTICIPATE

About 36 male and female subjects, ages 18 to 50, will be in this study. You will be in this study up to 65 days; this begins with your screening visit and continues until your last study visit. You will be confined to the research facility continuously for 9 nights and 10 days, during this period.

RESTRICTIONS

- You must not have participated in another clinical research trial where you received any other study drug in a previous study within 30 days before the first dose of study drug.
- You must not have been in any other clinical research study with the study drug TPOXX (also known as tecovirimat).
- You should not have donated more than 450 mL of blood or blood components within 30 days before the first dose of study drug. You should not donate blood or blood components for 4 weeks after the completion of the study.
- You may not consume any food or drink containing grapefruit or grapefruit juice, Seville orange or Seville orange-containing products (for example, marmalade) within 48 hours before the first dose of study drug or throughout the study.
- You may not consume caffeine- or xanthine-containing beverages within 48 hours before the first dose of study drug or throughout the study.
- You may not consume pomegranate or pomegranate juice, pomelo fruits or pomelo juice within 72 hours before the first dose of study drug.
- You may not consume alcohol-containing beverages within 72 hours before the first dose of study drug.
- You must not have used nicotine or nicotine-containing products (for example, cigarettes, electronic vapor cigarettes, cigars, chewing tobacco, snuff, nicotine patches, or nicotine gum) within 6 months before the first dose of study drug and throughout the duration of the study.
- You must refrain from strenuous exercise or contact sports within 24 hours before first dose of study drug until study discharge.
- You must not have used any herbal or nutritional supplements, prescription, or over-the-counter medications within 14 days before the first dose of study drug.
- You must not intend to lose weight (diet or weight loss) from screening and throughout the study.
- The following medications are not allowed to be taken within 7 days before receiving study drug on study Day 1 through check out (Day 9):
    - antidiabetic medications
    - anticoagulants
    - anticonvulsants
    - substrates of the breast cancer resistance protein transporter including
        - methotrexate, mitoxantrone, imatinib, irinotecan, lapatinib, rosuvastatin, sulfasalazine, and topotecan;
    - substrates of cytochrome P450 (CYP) 2C8 including
        - repaglinide, paclitaxel, Montelukast, pioglitazone, rosiglitazone; and
    - substrates of CYP2C19 including
        - S-mephenytoin, clobazam, diazepam, rabeprazole, voriconazole, lansoprazole, and omeprazole

If you are on any of these medications, do not stop taking them without first consulting your personal doctor.

You must not use any drugs (over-the-counter, prescription, or illegal) without approval from the study doctor. Oral birth control pills or other hormonal birth control methods are allowed. Taking other drugs or drinking alcohol could result in serious and even life-threatening reactions. If you decide to take any medication without approval from the study doctor, you may not be allowed to continue in the study. You must inform the study staff of any prescription birth control you are using including intrauterine devices (IUDs).

Taking other drugs or alcohol could result in serious and even life-threatening reactions. If you decide to take any medication without approval from the study doctor you may not be allowed to continue in the study.

RISKS, SIDE EFFECTS, AND/OR DISCOMFORTS

It is very important that you tell the study staff right away about any side effects. It is also very important that you do not talk to other people participating in this study about your side effects or theirs.

If you do not tell the study staff about a side effect, or if you talk to other people in the study with you about your side effects, you may be removed from this study. In addition to being removed from the current study, your payment may be reduced, and you may not be allowed to take part in future studies for PPD.

All side effects or changes in your normal health must be reported, even those changes you might not consider to be important. Some examples may include:

- Headache
- Tooth pain
- Bruising
- Hiccups
- Changes in your eating or sleeping patterns

If you have any changes in your health/medical history after signing and dating this consent document, please tell your study doctor or study staff.

One of the reasons for this study is to learn more about the possible side effects of the study drug. It is important that you tell the study staff about possible side effects. Contact PPD if you experience any side effects through the follow-up phone call on Day 37.

Rare or unknown side effects could possibly occur, including allergic reactions, and life-threatening reactions.

You may harm yourself by taking part in this study if you are not fully truthful about any side effect with the study doctor and study staff.

The most common side effects of TPOXX include:

- Headache (12%)
- Nausea (5%)
- Abdominal Pain (2%)
- Vomiting (2%)
- Diarrhea

- Dizziness

If you do not understand what any of these side effects mean, please ask the study doctor or study staff to explain these terms to you.

In animal studies, seizures were seen in dogs, but not any other species. The significance of this for humans is unknown. You may not participate in the study if you have a history of seizures and you will be monitored for any signs of seizure.

ADDITIONAL RISKS OR DISCOMFORTS

Until you know how the study drug will affect you, you should use caution by avoiding stairs, not driving a car or working with machinery. If you later feel that the study drug has affected your ability to perform these things, stop doing them.

Blood Samples:

There may be side effects of having blood taken such as:

- Fainting
- Redness
- Swelling of the vein
- Pain
- Bruising
- Bleeding

There is also a slight possibility of infection or nerve damage.

If you feel faint tell the study staff or study doctor right away.

Scarring can occur at the sites of repetitive blood draws. If you have a "cannula" or intravenous catheter, you could also have pain, swelling, and redness of the vein, which may not go away quickly.

Electrocardiogram (ECG):

The ECG test is a recording of the electrical activity of your heart. The sticky pads used may be cold when applied and sometimes cause some discomfort such as redness or itching. If the hair under the patches needs to be shaved, irritation from shaving also could occur.

Other Risks

PPD requires that you agree to have pictures taken of your skin if you develop a side effect such as a rash. The picture(s) are only for the use of the study doctor and study sponsor.

Since as with any drug, there may be other risks that are unknown.

BIRTH CONTROL, DANGERS OF PREGNANCY AND BREASTFEEDING

The effects of the study drug on an unborn or breastfed baby are unknown, but could be a risk. If you are pregnant or breastfeeding, you cannot be in this study.

It is **very** important that you not become pregnant or breastfeed during this study or within 3 months after the last dose of study drug. Not having sex is the only certain way to prevent pregnancy. If you are a woman who is able to become pregnant, and choose to have sex, you must agree to use one of the methods of birth control listed below for at least 30 days before first dose through 30 days after last dose of study drug.

The only birth control methods that can be used during this study include:

- Condom, male or female, with spermicide (male and female condoms must NOT be used together)
- Diaphragm or cervical cap with spermicide
- Intrauterine device (IUD) with spermicide
- Oral contraceptives or other hormonal methods with another nonhormonal method
- Male sexual partner who had undergone a vasectomy at least 3 months before screening
- Not having sex (abstinence)*****

*Abstinence

You must understand that sexual abstinence means heterosexual sexual intercourse for medical, psychological, legal, social, financial, philosophical, moral or religious reasons. Heterosexual sexual activity refers to sexual activity between a male and a female. Any types of heterosexual activity where any amount of male semen (or ejaculate) could be present are to be strictly avoided, without exception.

This does not mean periodic abstinence (for example, calendar, ovulation, profession of abstinence for entry into a clinical trial).

Abstinence must be your preferred and usual lifestyle. By agreeing to this you affirm (commit) that this has been your lifestyle for at least the past 6 months and this will be true until the specified amount of time required for the study has been met.

If there is a possibility that you will engage in any heterosexual activity at any time during the study time requirement, you must not choose sexual abstinence as your method of birth control.

If you choose abstinence as your method of contraception and become pregnant/father a child during participation in this study, you will be excluded from all future participation in PPD studies.

If you cannot have children because of a surgery (for example if you have had a hysterectomy [removal of the uterus] or tubal ligation [tubes tied]), or if you are postmenopausal for at least 12 months, you can participate in this study without using additional forms of contraception.

Even if you use a medically acceptable birth control method, you could still become pregnant.

There is a chance that a pregnancy test could indicate that you are not pregnant, even though you are. **If it is early enough in your pregnancy, a pregnancy test may not be able to detect that you are pregnant.**

If you are pregnant, become pregnant or breastfeed during the study, the study drug or procedures may involve risks to the unborn or breastfed baby, which are currently unforeseeable.

If you are a man, there may be risks to an unborn baby if you father a child during the study. Men must agree to use a condom throughout the study and for 90 days after you take the last dose of study drug.

Men must agree not to donate sperm from the first dose of study drug through 90 days after the last dose of study drug.

Even if you and your partner use birth control, you or your partner could become pregnant. If you or your partner are pregnant, become pregnant, or breastfeed during the study, the study drug may involve risks to the unborn or breastfed baby, which we are not aware of at this time.

In the event you (if you are female) or your partner (if you are male) become pregnant during the course of the study, you (or your partner) may be requested to sign and date a separate informed consent form to allow PPD study staff to contact you throughout the course of the pregnancy to get updates on how the pregnancy is progressing, and for 3 months after the birth. PPD and the sponsor are required to attempt to collect and report information about any pregnancy that occurs in a subject who is participating in a study. They may also be required to attempt to collect and report this information if the female partner of a male subject who is participating in a study becomes pregnant and could have been exposed to study drug through the male subject's semen.

If you are female, and you have had sex without using a medically acceptable method of birth control during the three weeks before the start of the study, you must not be in this study.

COSTS

All study tests are being done for research only and are not replacements for medical care. There will be no charge to you for your participation in this study. The study drug, study-related procedures, and testing supplies, as well as study visits will be provided at no charge to you or your insurance company. While confined to the research facility all your meals, snacks and beverages will be provided.

POSSIBLE BENEFITS OF THE STUDY

This study is for research purposes only. There is no direct benefit to you from your participation in the study. Information learned from the study may help other people in the future.

ALTERNATIVES TO PARTICIPATING

This research study is for research purposes only. The only alternative is to not participate in this study.

PAYMENT FOR PARTICIPATION

For the current study, you will receive:

- $225.00/night for each night that you spend at the research facility ($225.00/night x 9 nights)
- $125.00/visit for each outpatient visit/phone call to the research facility ($125.00/visit x 2 outpatient visit/phone call)

If you successfully complete the study, you will receive an additional $725.00 making your total payment $3,000.00. You will receive payment within 3 weeks of your last study visit or your study completion.

If you have a side effect linked to the study drug and the study doctor thinks that this may harm your safety, you will be taken out of the study. You may be paid in full, including the study completion bonus, at the discretion of the study doctor.

However full payment is not guaranteed. If you have a side effect linked to the study drug and you leave the study when the study doctor does not think your safety is at risk, your pay will be lower. You will receive a pro-rated payment and pro-rated study completion bonus based on the days you were in the study. If the study doctor releases you from the study and it is non-drug related, you will receive a pro-rated payment and pro-rated study completion bonus based on the number of days you were in the study.

If you are a backup subject who is required to stay in the facility overnight you will be paid $75.00. If you are not required to stay overnight you will be paid $25.00. If you are required to stay for additional nights for safety procedures or observation, then you will be paid $200.00 for the additional night(s).

You will be paid an amount based on the extent of your participation, if:

- You are unable to complete the study
- You miss multiple outpatient visits (your completion bonus will be reduced accordingly)
- You voluntarily leave the study
- The study doctor withdraws you early from the study
- The study is stopped early
- You are qualified but not chosen to participate

You will be expected to read and follow the Phase 1 Clinic Subject Rules and Regulations, available at http://www.ppdi.com, while participating in the study. If you do not have access to the internet, let a PPD study staff member know and you will be provided with a printed version to review. The study staff will be available to answer any questions or clarify any information you do not understand. You will be asked to confirm whether you have fully read the Rules and Regulations document, acknowledge that you have been given the opportunity to ask questions and that you have received satisfactory answers. If you do not read and acknowledge the Rules and Regulations document, you will not be able to participate in the study. If you do not follow the Rules and Regulations of the Phase I Clinic during your participation in the study, you may not be paid as stated above.

If at any time you test positive for drugs or substances other than the study drug or if you engage in disruptive behavior, you may not be paid as stated above. Disruptive behavior includes, but is not limited to:

- Destruction of property
- Stealing
- Verbal abuse or profanity
- Bodily or verbal threats
- Sexual harassment

If you engage in disruptive behavior, or if you test positive for drugs or substances other than the study drug, you will be paid $2.00 per night and/or outpatient visit for the time you were in the study. You will immediately be dropped from the study. Also, you may not be allowed to take part in other studies for PPD.

If you feel that the payment listed may interfere with your making a good decision about whether or not you should volunteer to be in this study, you should not agree to participate.

You may be required to report the payment received for this study to the Internal Revenue Service as taxable income.

You have to provide your social security number because the IRS may be told how much you were paid to take part in this study.

IN CASE OF AN INJURY RELATED TO THIS RESEARCH STUDY

If you have any adverse reaction (side effect) to the study drug or changes in your physical or mental condition during the course of the study, you should tell the study doctor or study staff right away at the phone number listed on the first page of this document.

The study doctor will treat you as needed, at no cost, for any physical injury caused directly by this study. The study doctor will not offer to cover the medical care costs for injuries or illnesses that are not caused directly by the study.

If you become injured during this study and your injury is a direct result of the study drug or the administration of the study drug or properly performed study procedures according to the study directions, medical treatment will be available to you. The costs of treatment will be paid by SIGA Technologies, Inc. to the extent they are not covered by your health insurance. SIGA Technologies, Inc. does not plan to make further compensation for research-related injury available to you.

Be aware that your health care payer/insurance provider might not cover the costs of study-related injuries or illnesses.

You do not give up any of your legal rights by signing and dating this form. Further information regarding medical treatment for research-related injuries can be obtained from the study doctor or other authorized personnel. You must notify the study doctor immediately of any research related injury.

When the sponsor is going to pay for treatment for your injury, the sponsor or its representatives may need to collect certain personal information about you, such as your name, date of birth, gender, social security number, and Medicare identification number (if you have one). The sponsor needs this information to comply with a Medicare reporting obligation. This information may be collected directly from you, or from researchers, physicians or other healthcare providers who treated your problem or injury. This information and also information about your injury or other health problems may be shared with others, including sponsor representatives, the sponsor's insurance company, and the Centers for Medicare & Medicaid Services.

Public Readiness and Emergency Preparedness Act (PREP Act)

This clinical trial is covered by the PREP Act.
If you are physically injured by taking part in this study, the study doctor will provide immediate medical treatment. The study doctor will also refer you to the health care facilities that can best treat your injury. No financial compensation by the study doctors that gave you the study drug will be offered for any discomfort caused by your taking part in this study.

This clinical trial involves the use of TPOXX, which is covered by the Public Readiness and Emergency Preparedness (PREP) Act. The PREP Act limits your ability to sue under U.S. law from any harm that may result from your use of TPOXX unless the harm is caused by willful misconduct (certain types of intentional acts). A federal program called the Countermeasures Injury Compensation Program (CICP) has been created to provide compensation for some types of serious injuries or death directly caused by medical products covered by the PREP Act. If you are injured by TPOXX and meet all of the CICP's eligibility requirements, you may be able to receive compensation under this program. Information about the CICP, including how to file a claim follows.

What is the PREP Act?
The PREP Act was passed in December 2005. With regard to clinical trials, it provides compensation to subjects in the event of serious physical injury or death directly caused by a drug, device, or biological product, including a vaccine, against certain pandemic, epidemic, biological, chemical, radiological, or nuclear threats, and liability protection for persons conducting the clinical trial and the manufacturer. This coverage becomes effective only when the Secretary of HHS issues a Declaration covering that category or health threat or condition.

What does the PREP Act do?
The PREP Act protects those who make, test, develop, distribute and/or use the product covered by the Declaration. Those protected may not be sued for an adverse event related to the covered product, except for willful misconduct. However, the PREP Act authorizes the Countermeasures Injury Compensation Program (CICP) to provide compensation to eligible individuals for serious physical injury or death determined to be directly caused by administration or use of the covered product. This compensation may include out-of-pocket medical expenses, lost employment income and/or survivor death benefits. Claims must be filed within one calendar year of receiving the covered vaccine or drug.

What do I do if I am injured as a result of being in this clinical trial?
If you believe that your injury may be covered by the PREP Act, or you are representing someone who has died, and wish to file a request for benefits with the CICP, your request form must be postmarked within one year of receipt of the covered vaccine or drug. The request for benefits form and instructions on how to file a claim are available online at:
http://www.hrsa.gov/gethealthcare/conditions/countermeasurescomp/howtofile.html.

A paper copy of the request for benefits form may be obtained by calling 1 (855) 266-2427.

Send the letter by mail or a commercial carrier or courier service to:

Health Resources and Services Administration
Countermeasures Injury Compensation Program
5600 Fishers Lane, Room 11C-06
Rockville, MD 20857

For additional information, please refer to these websites:

HRSA Countermeasures Injury Compensation Program https://www.hrsa.gov/cicp/

CICP Administrative Final Rule
http://www.phe.gov/Preparedness/legal/prepact/Pages/default.aspx

While you should understand the impact of the PREP Act and how it may limit your rights if you are injured during the research, by signing and dating this form you are not giving up any legal rights that you may otherwise have.

WHOM TO CONTACT ABOUT THIS STUDY

During this study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study, please contact the Investigator at the telephone number listed on the first page of this consent document. If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

If you are unable to reach anyone at the facility and you need medical attention, please go to the nearest emergency room. If you feel this emergency may be life-threatening, call 911 before contacting PPD.

An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, contact**:**

- By mail:
  Study Subject Adviser
  Advarra IRB
  6940 Columbia Gateway Drive, Suite 110
  Columbia, MD 21046
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00035974.

Advarra has approved the information in this consent document and has given approval for the study doctor to do the study. This does not mean Advarra has approved you being in the study. You must consider the information in this consent document for yourself and decide if you want to be in this study.

YOUR PARTICIPATION IN THE STUDY

Your decision to participate in this study is voluntary. You may choose to not participate or you may withdraw from the study for any reason without penalty or loss of benefits to which you are otherwise entitled and without any effect on your future medical care. However, please note that the FDA requires that any information collected up to the point of your withdrawal cannot be removed from the study.

It is your choice if you want to be in the study. No one can force you to be in the study. You can leave the study at any time. You will not be punished for leaving the study.

If you believe it is in your best interest to leave the study, you must withdraw, even if that means you will be paid less.

If you wish to leave this study, please call the study staff at the phone number listed on the first page of this document.

Your part in this study may be stopped at any time without you being asked. The following people can stop your participation:

- The study doctor
- Advarra IRB
- The United States Food and Drug Administration (FDA)
- The sponsor company

You may be taken out of the study without your permission at any time for the following reasons:

- If you do not follow the study requirements
- If you do not follow the study doctor's instructions

- If it is discovered that you do not meet the study requirements (including any requirements in this consent document)
- If the study is cancelled
- If it becomes harmful to your health
- If you are not truthful

If you leave the study or if you are taken out of the study, you may be asked to return for a final visit to have some end of study evaluations or tests. If information generated from this study is published or presented, your identity will not be revealed. If you leave the study, no more information about you will be collected for this study. However, all of the information you gave us before you left the study will still be used.

Certain effects of the study may exist that while under a controlled environment normally do not pose a threat to a subject's safety, but which without proper control such as is found in the PPD facility, may be hazardous to your health.

If you decide to leave the PPD facility against the advice of the study doctor you will be asked to sign a release form acknowledging so.

RELEASE OF MEDICAL RECORDS AND PRIVACY

Your records of being in this study will be kept private except when ordered by law. The following people will have access to your study records:

- Study doctor and study staff
- Study Monitor
- SIGA Technologies, Inc. [including monitor(s) and auditor(s)]
- The United States Food and Drug Administration (FDA)
- Other country, state or federal regulatory agencies including the Biomedical Advanced Research and Development Authority (BARDA)
- Advarra IRB

In the event you require emergency treatment at a medical facility other than PPD during the study, PPD may need to provide your study records, which may include demographic and/or personal information, to the healthcare provider involved in your care or treatment. The information disclosed may include records/reports including but not limited to clinical lab reports, ECGs, vital sign measurements and information related to ongoing side effects and/or concomitant medications.

The Independent Review Board (IRB), Advarra, and accrediting agencies, may inspect and copy your records, which may have your name on them. Therefore, total confidentiality cannot be guaranteed. If the study results are presented at meetings or printed in publications, your name will not be used.

If you require medical care outside of the PPD Phase I Clinic, the study doctor may ask for your approval to obtain health records of any hospitalizations or medical visits. The health records will become part of your research record.

If PPD is notified that you have participated in a research study at another research facility while also participating in a research study at PPD, it may be necessary for PPD to share certain details about your study participation with the other research facility.

Identification Photo

Prior to screening for the study, you may be required to have your photo taken by a study staff member. Your photo will be used as a means of verifying your identification and will be saved in PPD's internal database for future reference. Only the study doctor and study staff who have access to the database will be able to view your photo.

Electronic Surveillance

The facility is equipped with electronic surveillance and your activities may be monitored.

CONSENT

I have read and understand the information in this informed consent document. I have had an opportunity to ask questions and all of my questions have been answered to my satisfaction. I voluntarily agree to participate in this study until I decide otherwise. I do not give up any of my legal rights by signing and dating this consent document. I will receive a copy of this signed and dated consent document.

IF YOU DO NOT AGREE WITH THE STATEMENT ABOVE, YOU SHOULD NOT SIGN OR DATE THIS INFORMED CONSENT DOCUMENT.

AN AGREEMENT TO BE IN A RESEARCH STUDY
INFORMED CONSENT DOCUMENT

Sponsor / Study Title:	**SIGA Technologies, Inc. / "A Post Marketing Study of the Safety, Tolerability, and Pharmacokinetics of TPOXX® in Adult Subjects Weighing More Than 120 kg"**
Protocol Number:	**SIGA-246-022**
Principal Investigator: (Study Doctor)	**Rebecca Wood-Horrall, M.D.**
Additional Contact (Study Staff):	**Lucy Flores**
Telephone:	**512-447-2985 (24 Hours)**
Address:	**PPD Development, LP** **7551 Metro Center Drive** **Suite 200** **Austin, TX 78744**

INTRODUCTION

You are being asked to volunteer and take part in a medical research study. Before you decide to take part in this study, you must read, sign, and date this form. This form, called an informed consent document, explains the study. Please ask as many questions as you need to help you decide whether you want to be in the study. This consent document may contain words that you do not understand. Please ask the study doctor or the study staff to explain any words or anything else that you do not clearly understand before you sign and date this consent document.

To be in this research study, you cannot already be in another medical research study anywhere or have been in any other research study within 30 days before taking the study drug in this study.

You must be honest with the study doctor and study staff about your health history or you may harm yourself by being in this study. It is very important that you give complete and truthful answers to all questions that you are asked during the study. The answers will help the study staff to decide if you can be in the study or stay in the study. If you do not wish to answer a question, tell the study doctor or study staff that you do not want to answer the question. Not answering some questions may mean that you cannot be in the study.

The study doctor is being paid by SIGA Technologies, Inc., the sponsor (the company paying for this study), to run this study. Also, the Biomedical Advanced Research and Development Authority (BARDA), an organization with the United States Department of Health and Human Services, is contributing to the funding of the study.

Please read this form carefully. Take your time to ask the study doctor or study staff as many questions about the study as you would like. The study doctor or study staff can explain words or information that you do not understand. Reading this form and talking to the study doctor or study staff may help you decide whether to take part or not. If you decide to take part in this study, you must sign your name at the end of this form and date it.

PURPOSE OF THE STUDY

In July 2018, TPOXX was approved by the United States Food and Drug Administration (FDA) for the treatment of smallpox (variola virus).

The FDA has asked SIGA Technologies to also do a research study in people that weigh more than 120 kilograms (264.5 pounds), which is this study.

In this document, you may see the terms "study drug", "study treatment", and "study treatment period"; these are terms used in research studies as mentioned above, and this does not mean that you will be receiving medical treatment for any condition. These terms apply to the study drug and parts of the study where you will be receiving this study drug.

The purpose(s) of this study are:

- To measure the amount of TPOXX in the blood
- To see how safe TPOXX is, and how well you tolerate it

The dose(s) you will receive are as follows:

- An oral dose of 600 mg (3 x 200 mg capsules) of TPOXX twice a day for 7 days (Days 1 through 7)

Meals of about 600 calories and 25 grams of fat will be given to you by the study staff 30 minutes before taking study drug. You should eat this entire meal within 30 minutes before taking the study drug. Study drug will be given to you about 30 minutes after you start eating your meal and with about 240 mL (1 cup) of water. You will be told not to eat anything after taking study drug for 2 hours after dosing. In addition, you will be asked not to drink anything (except water) 3 hours before and after taking the study drug.

NEW FINDINGS

If there is new information or any significant new findings that could relate to your willingness to continue participation we will tell you. You can then decide if you still want to be in the study.

If the FDA or the sponsor makes changes to the study before the study starts, the study staff will try to notify you before you check-in. If changes are made after the study has started, the study staff will tell you about them as soon as they have been approved. You can use this information to decide if you want to stay in the study.

WHAT WILL HAPPEN DURING THE STUDY

Before you are asked to do any study-related tests or procedures you will be asked to read, sign, and date this consent document. The following screening tests and procedures will then be performed to determine if you can take part in this study.

You will have medical tests and procedures to help the study doctor decide if you can be in the study. This is called "screening" and will take place between 28 to 2 days before the day you start taking study drug.

Screening does not mean that you will be in the study. Whether you can be in the study will depend upon the results of your lab tests, study specific guidelines, and the decision of the study doctor. Even if your screening tests are okay, there is a chance that you will not be able to participate.

There may be other reasons why you cannot be in the study. The study doctor and/or the study staff will discuss this with you. You will not be paid for your screening visit(s).

You will need to have at least two visits to the research facility for screening tests. After your first screening results have been reviewed, at least one more screening visit will be scheduled by the study staff.

Screening for this study includes:

- A talk about your medical history (including recreational, prescription, and over-the-counter drug use; nicotine and alcohol use; and past hospitalizations)
- Physical exam
- Measurement of your weight
- Your vital signs (temperature, breathing rate, blood pressure and heart rate) after at least 5 minutes sitting
- Your blood and urine will be collected for clinical lab testing (after not eating for at least 8 hours)
- If you are a post-menopausal female, you will have a blood Follicle Stimulating Hormone (FSH) test done
- If female, you will have a blood pregnancy test done
- A urine sample to screen for drugs of abuse, including alcohol (must be negative to participate in the study) will be collected
- You will have blood collected for HIV and hepatitis B and C (these tests must be negative in order for you to be in the study). The study doctor may be required by law to report the result of these tests to the local health authority
- An Electrocardiogram (ECG - measures the electrical activity of the heart) after lying down for at least 10 minutes will be done
- The study doctor will review your nicotine/tobacco and alcohol use

One of the study staff will talk with you about your medical history, draw blood, and collect urine for lab tests.

For screening, the amount of blood taken from you will be a little over 2 teaspoons (11 mL). It may be necessary to try more than one time if the needed amount cannot be collected. A new needle will be used for each blood draw.

A urine test will be done to check for drugs of abuse such as:

- Amphetamines (including methamphetamines and ecstasy/methylenedioxymethamphetamine)
- Barbiturates
- Benzodiazepines
- Cannabinoids (including tetrahydrocannabinol)
- Cocaine
- Opiates (including heroin, codeine, and oxycodone)
- Alcohol

Day -1 (Check-in)

If you are eligible to be in the study, you will be admitted to the research facility on Day -1 (check-in), the day before you start taking study drug. You will remain in the research facility overnight for 9 nights.

At check-in, a blood sample of a little less than 2 teaspoons (9 mL) and urine sample will be taken from you for lab testing and to test for drugs of abuse to see if you can still be in the study.

If you have a positive urine drug test including alcohol, you will not be allowed to take part or to stay in the study. All results of drug tests will remain private.

You will be asked questions regarding your general health and any medication you may have taken since your screening visit to see if you can still be in the study. Vital signs will be taken (temperature, blood pressure, heart rate and breathing rate) after sitting for at least 5 minutes, measurement of weight and height, physical exam, blood pregnancy test (if female), and ECG performed (after lying down for at least 10 minutes).

Day 1 will be the first day that you take study drug. The following will happen on study days 1 through Day 8.

Days 1 - 8

- Vital signs taken (temperature, breathing rate, blood pressure and heart rate) after sitting for at least 5 minutes (Days 1, 4, 7, and 8)
- Measurement of your weight (Day 1)
- Blood sample for clinical labs (Days 4 and 8)
- Physical exam (Day 7)
- ECG after lying down for at least 10 minutes (Days 1, 4, and 7)
- Blood samples of about 1 teaspoon (5 ml) will be collected before the morning dose and 30 minutes, 1, 2, 4, 6, 8, 12 (before the afternoon dose), 14, 16, 18, 20, and 24 hours after dosing on Days 1 and 7, to measure the amount of study drug in your blood
- Blood samples of about 1 teaspoon (5 ml) will be collected before and 4 hours after the morning dose on Day 6, to measure the amount of study drug in your blood
- Review of current medications and side effects

Day 9 (Study Discharge)

- Physical exam
- Measurement of your weight
- Vital signs (temperature, breathing rate, blood pressure and heart rate) after sitting for at least 5 minutes
- Blood and urine sample for clinical labs
- ECG after lying down for at least 10 minutes
- Blood samples of about 1 teaspoon (5 ml) will be collected 48 hours after the morning dose on Day 7, to measure the amount of study drug in your blood
- Review of current medications and side effects

Before exiting the study, a blood sample of a little less than 2 teaspoons (9 mL) and a urine sample will be collected for clinical lab tests. For your safety, if lab test results are not normal, more blood and/or urine samples may be collected.

You can leave the research facility after all study tests and procedures on Day 9 have been completed. If you have ongoing side effects or abnormal findings on your physical exam on Day 9, you will be asked to return to the research facility five days later, on Day 14.

If you do not have any abnormal findings on your physical exam, the study staff will call you by phone on Day 14 to check on your wellbeing.

You will be contacted by telephone about 30 days after the last dose of study drug (Day 37) to see how you are feeling. You should also contact PPD during this time if you are experiencing any side effects.

A small needle with a thin plastic tube covering it (like a small straw) called a "cannula" may be inserted into a vein in your arm or hand to make blood draws easier. A study staff member puts the needle with the cannula over it into a vein in your arm or hand, and then slides the cannula over the needle into your arm or hand vein. The cannula stays in your arm or hand vein, and the needle is taken out. You will need to keep your arm very still for the period while the needle is in place. Use of a cannula is optional and the study doctor will decide if it is needed. Very small amounts of saline (salt water) will be injected into this cannula to prevent clogging. This procedure may cause pain, swelling and redness at the place where the cannula is put into your vein. When a cannula is used for blood collected, the study staff will take about an extra 1 mL of blood. The cannula will be left in for as long as it is needed to help with blood collections, but not for longer than about 72 hours.

If you take part in this study, you will have your blood drawn about 32 times during this study. About less than 1 cup (187 mL) of blood will be taken from you during this study. You may want to know that the standard blood donation is about 2 cups (480 mL) of blood.

Signing and dating this consent form means that you agree to allow PPD, the sponsor, or other laboratories involved in this study to store and test any used or unused blood samples or plasma samples (taken from the blood samples, for study related testing) until all research on the study drug is stopped. When all research is stopped, all blood or plasma samples will be destroyed. If you do not agree to this, you will not be enrolled in the study.

After Study Treatment:

Because this is a research study, the study drug will be given to you only during this study and not after the study is over.

HIV AND HEPATITIS TESTING

As required by the study and if any person is exposed to your blood, you must be tested for the hepatitis viruses and for HIV (Human Immunodeficiency Virus). HIV is the virus that causes AIDS (Acquired Immunodeficiency Syndrome). If you have a positive HIV or hepatitis test, you cannot remain in the study.

If the HIV test is positive, a follow-up test will be done. If the follow-up test is also positive, you will be given the results in private and will also be given information about counseling.

It may take weeks or months after being infected with HIV for the test to be positive. The HIV test is not always right.

Positive HIV and hepatitis test results must be reported to the Department of Health, and the law may require that your name be reported. Although this testing is supposed to be private, this cannot be guaranteed. For example, it is possible for a court of law to get medical or study records without your permission.

LENGTH OF THE STUDY AND NUMBER OF SUBJECTS EXPECTED TO PARTICIPATE

About 36 male and female subjects, ages 18 to 50, will be in this study. You will be in this study up to 65 days; this begins with your screening visit and continues until your last study visit. You will be confined to the research facility continuously for 9 nights and 10 days, during this period.

RESTRICTIONS

- You must not have participated in another clinical research trial where you received any other study drug in a previous study within 30 days before the first dose of study drug.
- You must not have been in any other clinical research study with the study drug TPOXX (also known as tecovirimat).
- You should not have donated more than 450 mL of blood or blood components within 30 days before the first dose of study drug. You should not donate blood or blood components for 4 weeks after the completion of the study.
- You may not consume any food or drink containing grapefruit or grapefruit juice, Seville orange or Seville orange-containing products (for example, marmalade) within 48 hours before the first dose of study drug or throughout the study.
- You may not consume caffeine- or xanthine-containing beverages within 48 hours before the first dose of study drug or throughout the study.
- You may not consume pomegranate or pomegranate juice, pomelo fruits or pomelo juice within 72 hours before the first dose of study drug.
- You may not consume alcohol-containing beverages within 72 hours before the first dose of study drug.
- You must not have used nicotine or nicotine-containing products (for example, cigarettes, electronic vapor cigarettes, cigars, chewing tobacco, snuff, nicotine patches, or nicotine gum) within 6 months before the first dose of study drug and throughout the duration of the study.
- You must refrain from strenuous exercise or contact sports within 24 hours before first dose of study drug until study discharge.
- You must not have used any herbal or nutritional supplements, prescription, or over-the-counter medications within 14 days before the first dose of study drug.
- You must not intend to lose weight (diet or weight loss) from screening and throughout the study.
- The following medications are not allowed to be taken within 7 days before receiving study drug on study Day 1 through check out (Day 9):
    - antidiabetic medications
    - anticoagulants
    - anticonvulsants
    - substrates of the breast cancer resistance protein transporter including
        - methotrexate, mitoxantrone, imatinib, irinotecan, lapatinib, rosuvastatin, sulfasalazine, and topotecan;
    - substrates of cytochrome P450 (CYP) 2C8 including
        - repaglinide, paclitaxel, Montelukast, pioglitazone, rosiglitazone; and
    - substrates of CYP2C19 including
        - S-mephenytoin, clobazam, diazepam, rabeprazole, voriconazole, lansoprazole, and omeprazole

If you are on any of these medications, do not stop taking them without first consulting your personal doctor.

You must not use any drugs (over-the-counter, prescription, or illegal) without approval from the study doctor. Oral birth control pills or other hormonal birth control methods are allowed. Taking other drugs or drinking alcohol could result in serious and even life-threatening reactions. If you decide to take any medication without approval from the study doctor, you may not be allowed to continue in the study. You must inform the study staff of any prescription birth control you are using including intrauterine devices (IUDs).

Taking other drugs or alcohol could result in serious and even life-threatening reactions. If you decide to take any medication without approval from the study doctor you may not be allowed to continue in the study.

RISKS, SIDE EFFECTS, AND/OR DISCOMFORTS

It is very important that you tell the study staff right away about any side effects. It is also very important that you do not talk to other people participating in this study about your side effects or theirs.

If you do not tell the study staff about a side effect, or if you talk to other people in the study with you about your side effects, you may be removed from this study. In addition to being removed from the current study, your payment may be reduced, and you may not be allowed to take part in future studies for PPD.

All side effects or changes in your normal health must be reported, even those changes you might not consider to be important. Some examples may include:

- Headache
- Tooth pain
- Bruising
- Hiccups
- Changes in your eating or sleeping patterns

If you have any changes in your health/medical history after signing and dating this consent document, please tell your study doctor or study staff.

One of the reasons for this study is to learn more about the possible side effects of the study drug. It is important that you tell the study staff about possible side effects. Contact PPD if you experience any side effects through the follow-up phone call on Day 37.

Rare or unknown side effects could possibly occur, including allergic reactions, and life-threatening reactions.

You may harm yourself by taking part in this study if you are not fully truthful about any side effect with the study doctor and study staff.

The most common side effects of TPOXX include:

- Headache (12%)
- Nausea (5%)
- Abdominal Pain (2%)
- Vomiting (2%)
- Diarrhea

- Dizziness

If you do not understand what any of these side effects mean, please ask the study doctor or study staff to explain these terms to you.

In animal studies, seizures were seen in dogs, but not any other species. The significance of this for humans is unknown. You may not participate in the study if you have a history of seizures and you will be monitored for any signs of seizure.

ADDITIONAL RISKS OR DISCOMFORTS

Until you know how the study drug will affect you, you should use caution by avoiding stairs, not driving a car or working with machinery. If you later feel that the study drug has affected your ability to perform these things, stop doing them.

Blood Samples:

There may be side effects of having blood taken such as:

- Fainting
- Redness
- Swelling of the vein
- Pain
- Bruising
- Bleeding

There is also a slight possibility of infection or nerve damage.

If you feel faint tell the study staff or study doctor right away.

Scarring can occur at the sites of repetitive blood draws. If you have a "cannula" or intravenous catheter, you could also have pain, swelling, and redness of the vein, which may not go away quickly.

Electrocardiogram (ECG):

The ECG test is a recording of the electrical activity of your heart. The sticky pads used may be cold when applied and sometimes cause some discomfort such as redness or itching. If the hair under the patches needs to be shaved, irritation from shaving also could occur.

Other Risks

PPD requires that you agree to have pictures taken of your skin if you develop a side effect such as a rash. The picture(s) are only for the use of the study doctor and study sponsor.

Since as with any drug, there may be other risks that are unknown.

BIRTH CONTROL, DANGERS OF PREGNANCY AND BREASTFEEDING

The effects of the study drug on an unborn or breastfed baby are unknown, but could be a risk. If you are pregnant or breastfeeding, you cannot be in this study.

It is **very** important that you not become pregnant or breastfeed during this study or within 3 months after the last dose of study drug. Not having sex is the only certain way to prevent pregnancy. If you are a woman who is able to become pregnant, and choose to have sex, you must agree to use one of the methods of birth control listed below for at least 30 days before first dose through 30 days after last dose of study drug.

The only birth control methods that can be used during this study include:

- Condom, male or female, with spermicide (male and female condoms must NOT be used together)
- Diaphragm or cervical cap with spermicide
- Intrauterine device (IUD) with spermicide
- Oral contraceptives or other hormonal methods with another nonhormonal method
- Male sexual partner who had undergone a vasectomy at least 3 months before screening
- Not having sex (abstinence)*****

*Abstinence

You must understand that sexual abstinence means heterosexual sexual intercourse for medical, psychological, legal, social, financial, philosophical, moral or religious reasons. Heterosexual sexual activity refers to sexual activity between a male and a female. Any types of heterosexual activity where any amount of male semen (or ejaculate) could be present are to be strictly avoided, without exception.

This does not mean periodic abstinence (for example, calendar, ovulation, profession of abstinence for entry into a clinical trial).

Abstinence must be your preferred and usual lifestyle. By agreeing to this you affirm (commit) that this has been your lifestyle for at least the past 6 months and this will be true until the specified amount of time required for the study has been met.

If there is a possibility that you will engage in any heterosexual activity at any time during the study time requirement, you must not choose sexual abstinence as your method of birth control.

If you choose abstinence as your method of contraception and become pregnant/father a child during participation in this study, you will be excluded from all future participation in PPD studies.

If you cannot have children because of a surgery (for example if you have had a hysterectomy [removal of the uterus] or tubal ligation [tubes tied]), or if you are postmenopausal for at least 12 months, you can participate in this study without using additional forms of contraception.

Even if you use a medically acceptable birth control method, you could still become pregnant.

There is a chance that a pregnancy test could indicate that you are not pregnant, even though you are. **If it is early enough in your pregnancy, a pregnancy test may not be able to detect that you are pregnant.**

If you are pregnant, become pregnant or breastfeed during the study, the study drug or procedures may involve risks to the unborn or breastfed baby, which are currently unforeseeable.

If you are a man, there may be risks to an unborn baby if you father a child during the study. Men must agree to use a condom throughout the study and for 90 days after you take the last dose of study drug.

Men must agree not to donate sperm from the first dose of study drug through 90 days after the last dose of study drug.

Even if you and your partner use birth control, you or your partner could become pregnant. If you or your partner are pregnant, become pregnant, or breastfeed during the study, the study drug may involve risks to the unborn or breastfed baby, which we are not aware of at this time.

In the event you (if you are female) or your partner (if you are male) become pregnant during the course of the study, you (or your partner) may be requested to sign and date a separate informed consent form to allow PPD study staff to contact you throughout the course of the pregnancy to get updates on how the pregnancy is progressing, and for 3 months after the birth. PPD and the sponsor are required to attempt to collect and report information about any pregnancy that occurs in a subject who is participating in a study. They may also be required to attempt to collect and report this information if the female partner of a male subject who is participating in a study becomes pregnant and could have been exposed to study drug through the male subject's semen.

If you are female, and you have had sex without using a medically acceptable method of birth control during the three weeks before the start of the study, you must not be in this study.

COSTS

All study tests are being done for research only and are not replacements for medical care. There will be no charge to you for your participation in this study. The study drug, study-related procedures, and testing supplies, as well as study visits will be provided at no charge to you or your insurance company. While confined to the research facility all your meals, snacks and beverages will be provided.

POSSIBLE BENEFITS OF THE STUDY

This study is for research purposes only. There is no direct benefit to you from your participation in the study. Information learned from the study may help other people in the future.

ALTERNATIVES TO PARTICIPATING

This research study is for research purposes only. The only alternative is to not participate in this study.

PAYMENT FOR PARTICIPATION

For the current study, you will receive:

- $75.00 for screening
- $225.00/night for each night that you spend at the research facility ($225.00/night x 9 nights)
- $125.00/visit for each outpatient visit/phone call to the research facility ($125.00/visit x 2 outpatient visit/phone call)

If you successfully complete the study, you will receive an additional $650.00 making your total payment $3,000.00. You will receive payment within 3 weeks of your last study visit or your study completion.

If you have a side effect linked to the study drug and the study doctor thinks that this may harm your safety, you will be taken out of the study. You may be paid in full, including the study completion bonus, at the discretion of the study doctor.

However full payment is not guaranteed. If you have a side effect linked to the study drug and you leave the study when the study doctor does not think your safety is at risk, your pay will be lower. You will receive a pro-rated payment and pro-rated study completion bonus based on the days you were in the study. If the study doctor releases you from the study and it is non-drug related, you will receive a pro-rated payment and pro-rated study completion bonus based on the number of days you were in the study.

If you are a backup subject who is required to stay in the facility overnight you will be paid $75.00. If you are not required to stay overnight you will be paid $25.00. If you are required to stay for additional nights for safety procedures or observation, then you will be paid $200.00 for the additional night(s).

You will be paid an amount based on the extent of your participation, if:

- You are unable to complete the study
- You miss multiple outpatient visits (your completion bonus will be reduced accordingly)
- You voluntarily leave the study
- The study doctor withdraws you early from the study
- The study is stopped early
- You are qualified but not chosen to participate

You will be expected to read and follow the Phase 1 Clinic Subject Rules and Regulations, available at http://www.ppdi.com, while participating in the study. If you do not have access to the internet, let a PPD study staff member know and you will be provided with a printed version to review. The study staff will be available to answer any questions or clarify any information you do not understand. You will be asked to confirm whether you have fully read the Rules and Regulations document, acknowledge that you have been given the opportunity to ask questions and that you have received satisfactory answers. If you do not read and acknowledge the Rules and Regulations document, you will not be able to participate in the study. If you do not follow the Rules and Regulations of the Phase I Clinic during your participation in the study, you may not be paid as stated above.

If at any time you test positive for drugs or substances other than the study drug or if you engage in disruptive behavior, you may not be paid as stated above. Disruptive behavior includes, but is not limited to:

- Destruction of property
- Stealing
- Verbal abuse or profanity
- Bodily or verbal threats
- Sexual harassment

If you engage in disruptive behavior, or if you test positive for drugs or substances other than the study drug, you will be paid $2.00 per night and/or outpatient visit for the time you were in the study. You will immediately be dropped from the study. Also, you may not be allowed to take part in other studies for PPD.

If you feel that the payment listed may interfere with your making a good decision about whether or not you should volunteer to be in this study, you should not agree to participate.

You may be required to report the payment received for this study to the Internal Revenue Service as taxable income.

You have to provide your social security number because the IRS may be told how much you were paid to take part in this study.

IN CASE OF AN INJURY RELATED TO THIS RESEARCH STUDY

If you have any adverse reaction (side effect) to the study drug or changes in your physical or mental condition during the course of the study, you should tell the study doctor or study staff right away at the phone number listed on the first page of this document.

The study doctor will treat you as needed, at no cost, for any physical injury caused directly by this study. The study doctor will not offer to cover the medical care costs for injuries or illnesses that are not caused directly by the study.

If you become injured during this study and your injury is a direct result of the study drug or the administration of the study drug or properly performed study procedures according to the study directions, medical treatment will be available to you. The costs of treatment will be paid by SIGA Technologies, Inc. to the extent they are not covered by your health insurance. SIGA Technologies, Inc. does not plan to make further compensation for research-related injury available to you.

Be aware that your health care payer/insurance provider might not cover the costs of study-related injuries or illnesses.

You do not give up any of your legal rights by signing and dating this form. Further information regarding medical treatment for research-related injuries can be obtained from the study doctor or other authorized personnel. You must notify the study doctor immediately of any research related injury.

When the sponsor is going to pay for treatment for your injury, the sponsor or its representatives may need to collect certain personal information about you, such as your name, date of birth, gender, social security number, and Medicare identification number (if you have one). The sponsor needs this information to comply with a Medicare reporting obligation. This information may be collected directly from you, or from researchers, physicians or other healthcare providers who treated your problem or injury. This information and also information about your injury or other health problems may be shared with others, including sponsor representatives, the sponsor's insurance company, and the Centers for Medicare & Medicaid Services.

Public Readiness and Emergency Preparedness Act (PREP Act)

This clinical trial is covered by the PREP Act.
If you are physically injured by taking part in this study, the study doctor will provide immediate medical treatment. The study doctor will also refer you to the health care facilities that can best treat your injury. No financial compensation by the study doctors that gave you the study drug will be offered for any discomfort caused by your taking part in this study.

This clinical trial involves the use of TPOXX, which is covered by the Public Readiness and Emergency Preparedness (PREP) Act. The PREP Act limits your ability to sue under U.S. law from any harm that may result from your use of TPOXX unless the harm is caused by willful misconduct (certain types of intentional acts).

A federal program called the Countermeasures Injury Compensation Program (CICP) has been created to provide compensation for some types of serious injuries or death directly caused by medical products covered by the PREP Act. If you are injured by TPOXX and meet all of the CICP's eligibility requirements, you may be able to receive compensation under this program. Information about the CICP, including how to file a claim follows.

What is the PREP Act?
The PREP Act was passed in December 2005. With regard to clinical trials, it provides compensation to subjects in the event of serious physical injury or death directly caused by a drug, device, or biological product, including a vaccine, against certain pandemic, epidemic, biological, chemical, radiological, or nuclear threats, and liability protection for persons conducting the clinical trial and the manufacturer. This coverage becomes effective only when the Secretary of HHS issues a Declaration covering that category or health threat or condition.

What does the PREP Act do?
The PREP Act protects those who make, test, develop, distribute and/or use the product covered by the Declaration. Those protected may not be sued for an adverse event related to the covered product, except for willful misconduct. However, the PREP Act authorizes the Countermeasures Injury Compensation Program (CICP) to provide compensation to eligible individuals for serious physical injury or death determined to be directly caused by administration or use of the covered product. This compensation may include out-of-pocket medical expenses, lost employment income and/or survivor death benefits. Claims must be filed within one calendar year of receiving the covered vaccine or drug.

What do I do if I am injured as a result of being in this clinical trial?
If you believe that your injury may be covered by the PREP Act, or you are representing someone who has died, and wish to file a request for benefits with the CICP, your request form must be postmarked within one year of receipt of the covered vaccine or drug. The request for benefits form and instructions on how to file a claim are available online at:
http://www.hrsa.gov/gethealthcare/conditions/countermeasurescomp/howtofile.html.

A paper copy of the request for benefits form may be obtained by calling 1 (855) 266-2427.

Send the letter by mail or a commercial carrier or courier service to:

Health Resources and Services Administration
Countermeasures Injury Compensation Program
5600 Fishers Lane, Room 11C-06
Rockville, MD 20857

For additional information, please refer to these websites:

HRSA Countermeasures Injury Compensation Program https://www.hrsa.gov/cicp/

CICP Administrative Final Rule
http://www.phe.gov/Preparedness/legal/prepact/Pages/default.aspx

While you should understand the impact of the PREP Act and how it may limit your rights if you are injured during the research, by signing and dating this form you are not giving up any legal rights that you may otherwise have.

WHOM TO CONTACT ABOUT THIS STUDY

During this study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study, please contact the Investigator at the telephone number listed on the first page of this consent document. If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

If you are unable to reach anyone at the facility and you need medical attention, please go to the nearest emergency room. If you feel this emergency may be life-threatening, call 911 before contacting PPD.

An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, contact**:**

- By mail:
  Study Subject Adviser
  Advarra IRB
  6940 Columbia Gateway Drive, Suite 110
  Columbia, MD 21046
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00035974.

Advarra has approved the information in this consent document and has given approval for the study doctor to do the study. This does not mean Advarra has approved you being in the study. You must consider the information in this consent document for yourself and decide if you want to be in this study.

YOUR PARTICIPATION IN THE STUDY

Your decision to participate in this study is voluntary. You may choose to not participate or you may withdraw from the study for any reason without penalty or loss of benefits to which you are otherwise entitled and without any effect on your future medical care. However, please note that the FDA requires that any information collected up to the point of your withdrawal cannot be removed from the study.

It is your choice if you want to be in the study. No one can force you to be in the study. You can leave the study at any time. You will not be punished for leaving the study.

If you believe it is in your best interest to leave the study, you must withdraw, even if that means you will be paid less.

If you wish to leave this study, please call the study staff at the phone number listed on the first page of this document.

Your part in this study may be stopped at any time without you being asked. The following people can stop your participation:

- The study doctor
- Advarra IRB

- The United States Food and Drug Administration (FDA)
- The sponsor company

You may be taken out of the study without your permission at any time for the following reasons:

- If you do not follow the study requirements
- If you do not follow the study doctor's instructions
- If it is discovered that you do not meet the study requirements (including any requirements in this consent document)
- If the study is cancelled
- If it becomes harmful to your health
- If you are not truthful

If you leave the study or if you are taken out of the study, you may be asked to return for a final visit to have some end of study evaluations or tests. If information generated from this study is published or presented, your identity will not be revealed. If you leave the study, no more information about you will be collected for this study. However, all of the information you gave us before you left the study will still be used.

Certain effects of the study may exist that while under a controlled environment normally do not pose a threat to a subject's safety, but which without proper control such as is found in the PPD facility, may be hazardous to your health.

If you decide to leave the PPD facility against the advice of the study doctor you will be asked to sign a release form acknowledging so.

RELEASE OF MEDICAL RECORDS AND PRIVACY

Your records of being in this study will be kept private except when ordered by law. The following people will have access to your study records:

- Study doctor and study staff
- Study Monitor
- SIGA Technologies, Inc. [including monitor(s) and auditor(s)]
- The United States Food and Drug Administration (FDA)
- Other country, state or federal regulatory agencies including the Biomedical Advanced Research and Development Authority (BARDA)
- Advarra IRB

In the event you require emergency treatment at a medical facility other than PPD during the study, PPD may need to provide your study records, which may include demographic and/or personal information, to the healthcare provider involved in your care or treatment. The information disclosed may include records/reports including but not limited to clinical lab reports, ECGs, vital sign measurements and information related to ongoing side effects and/or concomitant medications.

The Independent Review Board (IRB), Advarra, and accrediting agencies, may inspect and copy your records, which may have your name on them. Therefore, total confidentiality cannot be guaranteed. If the study results are presented at meetings or printed in publications, your name will not be used.

If you require medical care outside of the PPD Phase I Clinic, the study doctor may ask for your approval to obtain health records of any hospitalizations or medical visits. The health records will become part of your research record.

If PPD is notified that you have participated in a research study at another research facility while also participating in a research study at PPD, it may be necessary for PPD to share certain details about your study participation with the other research facility.

Identification Photo

Prior to screening for the study, you may be required to have your photo taken by a study staff member. Your photo will be used as a means of verifying your identification and will be saved in PPD's internal database for future reference. Only the study doctor and study staff who have access to the database will be able to view your photo.

Electronic Surveillance

The facility is equipped with electronic surveillance and your activities may be monitored.

CONSENT

I have read and understand the information in this informed consent document. I have had an opportunity to ask questions and all of my questions have been answered to my satisfaction. I voluntarily agree to participate in this study until I decide otherwise. I do not give up any of my legal rights by signing and dating this consent document. I will receive a copy of this signed and dated consent document.

IF YOU DO NOT AGREE WITH THE STATEMENT ABOVE, YOU SHOULD NOT SIGN OR DATE THIS INFORMED CONSENT DOCUMENT.

16.1.4 List and Description of Investigators and Other Important Participants in the Study, Including Brief Curriculum Vitae or Equivalent Summaries of Training and Experience Relevant to the Performance of the Study

Investigator	Site #	Sub-investigator	Address
Rebecca N. Wood-Horrall, MD	001	Lu Ann Bundrant, MD Theresa T. Pham, MD Antonia M. Davidson, MD Gregg H. Lucksinger, MD	PPD Development, LP 7551 Metro Center Drive, Suite 200 Austin, TX 78744 United States

A CV for the principal investigator is provided on the following pages.

CURRICULUM VITAE

FULL NAME

Rebecca N. Wood-Horrall, M.D.

OFFICE ADDRESS

PPD Development, LP
7551 Metro Center Drive
Suite 200
Austin, Texas 78744
(512) 447-2985

EDUCATION

Christus Spohn Memorial Hospital
Corpus Christi, Texas
Emergency Medicine Residency
2010-2013

University of Texas Medical Branch
Galveston, Texas
M.D.
2006-2010

Central Texas College
Burnet, Texas
EMT-Intermediate Certification
Fall 2002

Texas A&M University
College Station, Texas
B.S., Psychology
May 1997

Texas A&M University
College Station, Texas
B.A., Sociology
May 1996

LICENSURE

Texas: P6553

EXPERIENCE

2014 to Present	PPD Development, LP Austin, Texas Principal Investigator
2013 to 2015	Emergency Service Partners Emergency Medicine Physician Austin, TX
2010 to 2013	Christus Spohn Memorial Hospital Corpus Christi, Texas Emergency Medicine Resident
2004 to 2010	PPD Development, LP Austin, Texas Paramedic
2002 to 2003	Seton Premiere Staffing, Seton Hospital Network Austin, Texas Clinical Assistant II
2001 to 2003	North Hays County EMS EMT-B then EMT-1
1994 to 1997	Texas A&M University College Station, Texas Research Assistant

PROFESSIONAL MEMBERSHIPS

2010-2013	American College of Emergency Physicians Emergency Medicine Residency Association
2006-current	Texas Medical Association Travis County Medical Society
2006-2010	AMA/TMA UTMB Student Chapter *Vice President* *First Year Membership Representative*

1997-current	Alpha Phi Omega Life Member *Region VII Service Chair* *National Service and Communication Committee* *Vice President* *National Voting Delegate*

Employee confirms CV is accurate and acknowledges responsibilities outlined in the job description applicable to the current job title, posted on the PPD employee intranet.

SIGNATURE: _____ **DATE:** 03 JAN 2019

16.1.5 Signature of Principal Investigator

Please refer to page 2 of the study report for the signature of the Principal Investigator.

16.1.6 Listing of Subjects Receiving Test Drug/Investigational Product(s) From Specific Batches, Where More Than 1 Batch was Used

Only one batch of study drug was used in this study.

Name of Drug/Investigational Product	Formulation	Lot Number
Tecovirimat (TPOXX®)	200 mg capsule	24601069BS

16.1.7 Randomization Scheme and Codes (Subject Identification and Treatment Assigned)

This was an open-label study.

16.1.8 Audit Certificates

No audits certificates are included for this study.

16.1.9 Documentation of Statistical Methods

This section contains the following documents:

Statistical analysis plan version 1.0 dated 11 October 2019

SIGA Technologies, Inc.

SIGA-246-022

A POST MARKETING STUDY OF THE SAFETY, TOLERABILITY, AND PHARMACOKINETICS OF TPOXX® IN ADULT SUBJECTS WEIGHING MORE THAN 120 KG

Post Marketing Commitment: 3417-4

11OCT2019

Statistical Analysis Plan

Version 1.0

Prepared by:

PPD
3900 Paramount Parkway
Morrisville, NC 27560 USA

TABLE OF CONTENTS

List of Abbreviations

λ_z	terminal elimination rate constant
$\%AUC_{extrap}$	percentage of $AUC_{0-\infty}$ extrapolated from the last quantifiable measurement to infinity
AE	adverse event
AUC	area under the plasma concentration-time curve
AUC_{0-24}	area under the plasma concentration-time curve from time 0 to 24 hours
$AUC_{0-\infty}$	area under the plasma concentration-time curve from time 0 extrapolated to infinity
AUC_{0-t}	AUC from time 0 to the last measurable concentration in plasma
AUC_{0-tau}	area under the plasma concentration-time curve during the first dosing interval
BID	twice daily
BLQ	below the limit of quantification
C_{avg}	average plasma concentration
CL/F	apparent total body clearance
C_{max}	maximum drug concentration in plasma
C_{trough}	concentration observed prior to the next dose administration
CSR	clinical study report
CV	coefficient of variation
DAIDS	Division of Acquired Immune Deficiency Syndrome
ECG	electrocardiogram
eCRF	electronic case report form
FDA	Food and Drug Administration
MedDRA	Medical Dictionary for Regulatory Activities
PK	pharmacokinetic(s)
PT	preferred term
SAE	serious adverse event
SD	standard deviation
SOC	system organ class
$t_{1/2}$	terminal elimination half-life
TRAE	treatment-related adverse event
T_{max}	time to maximum drug concentration in plasma
V_d/F	apparent volume of distribution

1. Introduction

This document outlines the statistical methods to be implemented during the analysis of data collected within the scope of SIGA Technologies, Inc., protocol SIGA-246-022 (A Post Marketing Study of the Safety, Tolerability, and Pharmacokinetics of TPOXX® in Adult Subjects Weighing More Than 120 kg), Version 2.0, 27 Jun 2019. The SIGA-246-022 clinical study is being conducted as a Food and Drug Administration (FDA) post marketing commitment (3417-4) to the approved New Drug Application for TPOXX. SIGA is required to conduct a study to determine the pharmacokinetic (PK) profile of TPOXX in subjects with a body weight greater than 120 kilograms (>120 kg) to determine if a change in dosing regimen would be needed in these patients.

The purpose of this statistical analysis plan is to define the planned statistical analysis of the study data consistent with the study objectives.

2. Objectives

2.1. Primary Objectives

The primary objective of this study is to determine the PK profile of 600 mg oral TPOXX (3 × 200-mg capsules) administered twice daily (BID) for 7 days in adult subjects weighing more than 120 kg to determine if a change in dosing regimen would be needed in these patients.

2.2. Secondary Objectives

The secondary objective of this study is to evaluate the safety and tolerability of 600 mg oral TPOXX administered BID for 7 days in adult subjects weighing more than 120 kg.

3. Investigational Plan

3.1. Overall Study Design and Plan

This is an open-label, multiple-dose study to assess the safety, tolerability, and PK of TPOXX 600 mg BID when administered orally for 7 days to adult subjects weighing more than 120 kg. A total of 36 subjects, ages 18 to 50, inclusive, will be enrolled. The study will consist of a screening period (Day –28 to Day –2), a treatment and confinement period (Days –1 to 9), a follow-up telephone call or visit (Day 14 [+2 days]), and a follow-up telephone call (Day 37 [+2 days]).

Subjects will undergo screening evaluations to determine eligibility within 28 days before study drug administration. Subjects will be admitted to the study site on Day –1 to complete baseline assessments; results of these assessments must be reviewed by the

investigator before dosing. Starting in the morning of Day 1, subjects will receive 600 mg oral TPOXX BID for 7 days (Days 1 through 7).

All subjects will be provided meals (consisting of approximately 600 calories and 25 g fat) 30 minutes prior to study drug administration and subjects must fast for 2 hours after taking study drug. Subjects should eat this meal within 30 minutes or less of taking study drug. Study drug and meals must be taken with water only, and no other beverage except water should be ingested within 3 hours before or 3 hours after study drug administration.

Subjects will remain confined to the study site for collection of PK samples and will be carefully monitored for safety and tolerability until discharge on Day 9. Subjects who have abnormal physical examination findings or an ongoing adverse event (AE)/serious adverse event (SAE) on Day 9 that is deemed related to study drug or per investigator or SIGA discretion will return to the study site on Day 14 (+2 days) for a follow-up visit. All other subjects will have the Day 14 (+2 days) follow-up via telephone. All subjects will have a follow-up telephone call 30 days after administration of the last dose of study drug (Day 37 [+2 days]) to report any SAEs. At the time of discharge from the clinical research unit, subjects will be instructed to notify the investigator of any SAEs that occur within 30 days after administration of the last dose of study drug. Serious AEs will be followed until the SAE is stable or until resolution as determined by the investigator and/or medical monitor.

The total duration of the study for each subject, including the screening period, treatment period, and the Day 37 (+2 days) follow-up telephone call, will be approximately 65 days. The schedule of events is presented in Appendix 12.1.

3.2. Study Endpoints

3.2.1. Pharmacokinetic Endpoints

Blood samples for PK analysis of TPOXX will be collected from all subjects Day 1 before study drug administration (0 hour), at 0.5, 1, 2, 4, 6, 8, 12 (before the PM dose), 14, 16, 18, 20, and 24 hours (before the AM dose on Day 2), on Day 6 (before the AM dose and 4 hours after the AM dose), on Day 7 before the AM dose (0 hour), at 0.5, 1, 2, 4, 6, 8, 12 (before the PM dose), 14, 16, 18, 20, and 24 hours (Day 8, 24 hours after the AM dose on Day 7), and on Day 9 (48 hours after the AM dose on Day 7).

For PK samples, the acceptable window for collection from the scheduled collection time point will be as follows: ±5 minutes for the time points from 1 to 8 hours and ±15 minutes for the 12- to 48-hour time points.

Pharmacokinetic endpoints include but are not limited to the following:

- Area under the plasma concentration-time curve (AUC) from time 0 to the last quantifiable measurement (AUC_{0-t})
- AUC from time 0 extrapolated to infinity ($AUC_{0-\infty}$)
- AUC from time 0 to 24 hour (AUC_{0-24})
- AUC during the first dosing interval (tau = 12 hours) (AUC_{0-tau})
- Maximum drug concentration in plasma (C_{max})
- Time to C_{max} (T_{max})
- Apparent volume of distribution (V_d/F)
- Apparent total body clearance (CL/F)
- Concentration observed prior to the next dose administration (C_{trough})
- Terminal elimination half-life ($t_{1/2}$)
- Terminal elimination rate constant (λ_z)
- Percentage of $AUC_{0-\infty}$ extrapolated from the last quantifiable measurement to infinity ($\%AUC_{extrap}$).

3.2.2. Safety Endpoints

Safety and tolerability will be assessed by monitoring and recording of AEs, clinical laboratory test results (hematology, serum chemistry, pregnancy, and urinalysis), vital sign measurements (systolic and diastolic blood pressures, heart rate, respiratory rate, and body temperature), 12-lead electrocardiogram (ECG) results, and physical examination findings. Adverse events will be assessed from the time of the first dose of study drug until the follow-up telephone call on Day 37 (+2 days).

4. General Statistical Considerations

All data collected will be presented in data listings. Data from subjects excluded from an analysis population will be presented in the data listings but not included in the calculation of summary statistics.

For categorical variables, frequencies and percentages will be presented. Continuous variables will be summarized using descriptive statistics (number of subjects, mean, median, standard deviation [SD], minimum, and maximum).

During the analysis and reporting process, any deviations from the statistical plan designed for this protocol will be described and justified in the clinical study report.

Unless specified otherwise, baseline will be defined as the last non-missing assessment prior to dosing for each study period. Unscheduled visits will be used in determining baseline.

4.1. Sample Size

The sample size (N = 36 [to allow at least 32 enrolled subjects to complete]) for this study is based on clinical and practical considerations and not on a formal statistical power calculation. The sample size is considered sufficient to effectively assess the PK and safety profiles of TPOXX.

4.2. Analysis Populations

The Safety Population will include all subjects who receive at least 1 dose of study drug.

The PK Population will include subjects who receive study drug and have sufficient concentration data to facilitate the calculation of PK variables.

5. Subject Disposition, Protocol Deviations, and Follow-up

5.1. Disposition

Subject disposition will be summarized overall for all subjects.

The number of subjects who enroll in the study and the number and percentage of subjects who complete the study will be presented. Frequency and percentage of subjects who withdraw or discontinue from the study, and the reason for withdrawal or discontinuation, will also be summarized.

Subject disposition data and analysis populations will be presented in data listings.

5.2. Protocol Deviations

A protocol deviation is any change, divergence, or departure from the study design or procedures defined in the protocol. An important protocol deviation (sometimes referred to as a protocol violation or a major protocol deviation) is a subset of protocol deviations that might significantly affect the reliability of the study data or that might significantly affect a subject's safety. An important deviation can include nonadherence to inclusion or exclusion criteria or nonadherence to FDA regulations or International Council for Harmonisation E6(R2) guidelines.

Protocol deviations will be documented by the clinical monitor throughout the course of monitoring visits. The investigator will be notified in writing by the monitor of deviations. The institutional review board should be notified of all protocol deviations, if appropriate, in a timely manner.

Major protocol deviations will be summarized overall. All protocol deviations will be presented in a data listing, including the categorization of the deviation as major or minor.

6. Demographics and Baseline Characteristics

6.1. Demographics

Baseline demographic and background variables will be summarized overall for all subjects.

The demographic characteristics consist of age (years), sex, race, and ethnicity. The baseline characteristics consist of baseline weight (kg) and height (cm). A subject's age in years is calculated using the date of the informed consent and date of birth. Age (years) and baseline weight (kg) will be summarized using descriptive statistics. The number and percentage of subjects by race (American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, and White), ethnicity (Hispanic or Latino, Not Hispanic or Latino), and reproductive status (for females only; Sterile, Post-Menopausal, Potentially Able to Bear Children) will also be reported. Percentages will be based on the total number of subjects in the Safety population.

Subject demographic and baseline characteristics will be presented in a data listing.

6.1.1. General Medical History

A complete medical history will be obtained, including recreational, prescription drug use, over-the-counter drug use, nicotine and alcohol use, and past hospitalizations.
Medical history will be coded using the Medical Dictionary for Regulatory Activities (MedDRA, version to be delineated in the clinical study report [CSR]).

Medical history will be presented in a data listing.

6.2. Inclusion and Exclusion Criteria

All inclusion/exclusion criteria deviations recorded in the electronic case report form (eCRF) will be presented in a data listing.

7. Treatments, Medications, and Meals

7.1. Prior and Concomitant Medications

A prior medication is defined as any medication that is taken within 30 days before signing the informed consent form. A concomitant medication is defined as any medication that has a start date on or after date of first dose.

Prior and concomitant medications and therapies will be coded using the latest version of the World Health Organization Drug Dictionary.

All prior and concomitant medications will be presented in a data listing.

7.2. Medical and Surgical Treatment Procedures

All medical and surgical treatment procedures will be coded using the MedDRA (version to be delineated in the CSR). All medical and surgical treatment procedures will be presented in a data listing.

7.3. Study Drug Administration

All doses of study drug will be administered at the study site under direct observation of site personnel and recorded in the eCRF. Study site personnel will confirm that the subject has received the dose of study drug. The date, time, and amount of study drug dosing will be recorded on the appropriate page of the eCRF. If a subject does not receive study drug, the reason for the missed dose will be recorded.

A summary of study drug administration data will be presented. The summary will include the number and percentage of subjects dosed, as well as summary statistics of the number of complete doses received and the number and percentage of subjects who receive all 14 doses.

All study drug administration data will be presented in a data listing.

7.4. Meals

Meal data will be presented in a data listing.

8. Pharmacokinetic Analysis

8.1. Pharmacokinetic Sample Concentrations

Individual plasma concentrations, actual time, and deviation from the scheduled time will be presented in a data listing by subject, study day and nominal time point. Plasma concentration data will be summarized by day and time point using the following descriptive statistics: sample size (n), arithmetic mean, geometric mean, SD, geometric SD, coefficient of variation (CV), geometric CV (calculated as sqrt [exp [variance for log transformed data]-1]*100), median, minimum, and maximum.

If the minimum value is zero, the geometric mean will not be calculated and displayed. If the mean concentration values are below the limit of quantification (BLQ), they will be displayed as BLQ; in this case the SD and CV will be reported as NA (not applicable). Plasma concentrations that are BLQ will be treated as zero for descriptive statistics. Missing concentrations will be excluded from the calculations.

Individual and mean (±SD) and trough (±SD) plasma TPOXX concentration versus time profiles will be presented in figures on both linear and semi-logarithmic scales. Mean plasma concentration versus time profiles will be presented using nominal time and individual plasma concentration versus time profiles will be presented using actual time.

8.2. Pharmacokinetic Parameters

The individual plasma concentration versus actual time data for TPOXX will be used to derive the following PK parameters, by noncompartmental methods using Phoenix® WinNonlin® Version 8.0 or higher (Certara USA, Inc., Princeton, NJ).

Parameter	Day	Definition
AUC_{0-t}	1, 7	AUC versus time curve from time 0 to the last quantifiable measurement, calculated using the linear trapezoidal rule. $AUC_{0-t} = \sum_{i=1}^{n} \frac{(C_i + C_{i-1})}{2}(t_i - t_{i-1})$, where C_i and C_{i-1} is the plasma concentration at t_i and t_{i-1}, respectively, and t_i-t_{i-1} is the time interval.
AUC_{0-24}	1, 7	AUC versus time curve from time 0 to 24 hours postdose, calculated using the linear trapezoidal rule.
AUC_{0-tau}	1, 7	AUC during the first dosing interval (tau = 12 hours)
$AUC_{0-\infty}$	7	AUC versus time curve from time 0 extrapolated to infinity, calculated using the linear trapezoidal rule, $AUC_{0-\infty} = AUC_{0-t} + C_{last}/\lambda_z$, where C_{last} is the last quantifiable plasma drug concentration and λ_z is the terminal elimination rate constant.
$\%AUC_{extrap}$	7	Percentage of $AUC_{0-\infty}$ extrapolated from the last quantifiable measurement to infinity
C_{max}	1, 7	Maximum observed plasma drug concentration
T_{max}	1, 7	Time to reach C_{max}
λ_z	1, 7	Terminal elimination rate constant
$t_{1/2}$	1, 7	Terminal elimination half-life, calculated as $t_{1/2} = \ln 2/\lambda_z$
CL/F	7	Apparent total body clearance, calculated as: $Dose/AUC_{0-\infty}$

V_d/F	7	Apparent volume of distribution, calculated as: $CL/F/\lambda_z$
C_{trough}	1, 2, 6, 7	Concentration observed prior to the next dose administration

No concentration estimates will be imputed for missing sample values. Any sample with a missing value will be treated as if the sample had not been scheduled for collection and will be ignored when calculating mean concentrations or PK parameters. For the purpose of calculating the PK parameters only, all plasma concentrations that are BLQ prior to the first measurable concentration will be set to zero and treated as missing thereafter.

For the calculation of λ_z and all associated parameters, at least 3 time points (excluding C_{max}) are required, and the correlation coefficient (r^2) must be ≥ 0.80.

Actual sampling times, rather than scheduled sampling times, will be used in the computation of PK parameters. However, for ease of presentation, scheduled sampling times will be used to present results in summary tables. The individual PK parameters of TPOXX will be presented in a data listing. The PK parameters will be summarized by day using the following descriptive statistics: n, arithmetic mean, geometric mean, SD, CV, geometric SD, geometric CV, median, minimum, and maximum. For T_{max}, only n, median, minimum, and maximum will be included in descriptive statistics. Geometric mean, geometric SD, and geometric CV will be included for the AUCs and C_{max}.

9. Safety Analysis

Safety and tolerability will be assessed by monitoring and recording of AEs, clinical laboratory test results (hematology, serum chemistry, and urinalysis), vital sign measurements (systolic and diastolic blood pressures, heart rate, respiratory rate, and temperature), 12-lead ECG results, and physical examination findings.

All safety summaries and analyses will be conducted for the Safety population. Safety data will be presented in listings.

9.1. Adverse Events

An AE is any event or other untoward medical occurrence, including those AEs that result from dosing errors, which may present during administration of a study drug or during a reasonable follow-up period and which does not necessarily have a causal relationship with this treatment. An AE is any unfavorable and unintended sign (e.g., a clinically significant abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal product, whether or not considered to be related to the medicinal product.
A treatment-emergent AE is defined as any event not present before exposure to study drug or any event already present that worsens in intensity or frequency after exposure to study drug.

Adverse events will be coded by preferred term (PT) and system organ class (SOC) using MedDRA (version to be delineated in the CSR).

An overall summary of all AEs will be presented. The number and percentage of subjects, as well as the number of AEs will be presented for each of the following categories: any AE; any grade 2, grade 3, grade 4, and grade 5 AE; any treatment-related AE (TRAE); any grade 2, grade 3, grade 4, and grade 5 TRAE; any SAE; any serious TRAE, and any AE leading to discontinuation of study drug. In addition, the table will include a summary of the time to first AE and the time to first AE of grade 3 or higher. Time to first AE will be calculated for each period of the study in days as the date of the first AE in the period – the date of first dose of study drug in the period + 1. Time to first AE of grade 3 or higher will be computed similarly. These times will be summarized overall.

All AEs will be presented in a data listing.

9.1.1. Incidence of Adverse Events

Adverse events will be summarized by SOC and PT and by PT alone, including the total number of AEs and the number and percentage of subjects with at least one AE. At each level of subject summarization, a subject is counted once if the subject reported one or more events. Percentages will be calculated out of the number of subjects in the Safety population.

9.1.2. Relationship of Adverse Events to Study Drug

A summary of AEs by relationship to study drug will be presented in a table by incidence of occurrence. The investigator will provide an assessment of the relationship of the event to the study drug. The possible relationships are “Not Related”, “Unlikely Related”, “Possibly Related”, “Probably Related”, and “Definitely Related”. In the summary of AEs by relationship, if a subject reports multiple occurrence of the same AE, only the most closely related occurrence will be presented. Adverse events that are missing a relationship will be presented in the summary table as “Definitely Related” but will be presented in the data listing with a missing relationship. Percentages will be calculated based on the number of subjects in the Safety Population.

An AE is considered treatment-related if it is assessed as probably, possibly, or definitely related by the investigator. Treatment-related AEs will be presented in a data listing.

9.1.3. Severity of Adverse Event

All AEs will be graded for severity according to the current Division of Acquired Immunodeficiency Syndrome (DAIDS) Table for Grading the Severity of Adult and

Pediatric Adverse Events, version 2.1. Any laboratory or clinical AE that is not listed on the DAIDS table will be assessed for severity and classified into 1 of 5 clearly defined categories as follows:

- Grade 1 (Mild): Events require minimal or no treatment and do not interfere with the subject's daily activities
- Grade 2 (Moderate): Events result in a low level of inconvenience or concern with the therapeutic measures and may cause some interference with normal functioning
- Grade 3 (Severe): Events interrupt a subject's usual daily activity, may require systemic drug therapy or other treatment, and are usually incapacitating
- Grade 4 (Life-threatening): Event that, in the opinion of the investigator, places the subject at immediate risk of death from the reaction as it occurred (i.e., it does not include a reaction that, had it occurred in a more severe form, might have caused death)
- Grade 5 (Death)

A summary of AEs by severity will be presented in a table. The severity that will be presented represents the most extreme severity captured on the eCRF page. In this summary, if a subject reported multiple occurrences of the same AE, only the most severe will be presented. Adverse events that are missing severity will be presented in tables as Grade 3 but will be presented in the data listing with a missing severity. Percentages will be calculated out of the number of subjects in the Safety Population.

9.1.4. Serious Adverse Events

An AE is considered an SAE if, in the view of either the investigator or sponsor, it results in any of the following outcomes:

- Results in death
- Is life threatening (subject is at immediate risk of death at the time of the event)
- Requires inpatient hospitalization or prolongation of existing hospitalization, other than elective hospitalization, during the period of protocol defined surveillance
- Results in congenital anomaly or birth defect
- Results in a persistent or significant disability/incapacity
- Any other important medical event that may not result in death, be life threatening, or requires hospitalization may be considered an SAE when, based on appropriate medical judgment, the event may jeopardize the subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition or is otherwise considered to be medically significant.

The seriousness of an AE should be assessed by the investigator independently from the severity of the AE.

All SAEs will be presented in a data listing.

9.1.5. Adverse Events Leading to Study Drug Discontinuation

An AE where the answer to "What action was taken with study treatment?" is "Drug Withdrawn" will be considered an AE leading to study drug discontinuation.

All AEs leading to study drug discontinuation will be presented in a data listing.

9.2. Clinical Laboratory Evaluations

Abnormal clinical laboratory values will be flagged as either high or low (or normal or abnormal) based on the reference ranges for each laboratory parameter. The investigator will determine whether any of the abnormally high or low results are clinically significant or not clinically significant. Clinical significance is defined as any variation in results that has medical relevance and may result in an alteration in medical care (e.g., active observation, diagnostic measures, or therapeutic measures). If a clinically significant change from the screening value is noted, the clinically significant value and reason for clinical significance will be documented on the AE page in the eCRF. The investigator will continue to monitor the subject with additional assessments until the values have reached the reference range or the values at screening or until the investigator determines that follow-up is no longer medically necessary.

Where possible, abnormal clinical laboratory values will be graded for severity according to the DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, version 2.1.

9.2.1. Hematology

The following clinical laboratory hematology assessments will be performed: hematocrit, hemoglobin, mean corpuscular hemoglobin, mean corpuscular hemoglobin concentration, total and differential leukocyte count (basophils, eosinophils, lymphocytes, monocytes, neutrophils), mean corpuscular volume, platelet count, red blood cell count, and red cell distribution width.

Summary tables presenting observed values and changes from baseline will be presented for hematology laboratory tests with numeric values for subjects in the Safety Population. Changes from baseline to each scheduled post-baseline visit will be presented.

Changes in low, normal, high, and abnormal classifications will be summarized in shift tables comparing the results at each scheduled post-baseline visit with those at the baseline visit.

The maximum increase in DAIDS grade post-baseline (including both scheduled and unscheduled visits) will be summarized.

All hematology laboratory data will be presented in a data listing.

9.2.2. Serum Chemistry

The following clinical laboratory serum chemistry assessments will be performed: alanine aminotransferase, albumin, alkaline phosphatase, anion gap, aspartate aminotransferase, bilirubin (total), blood urea nitrogen, calcium, carbon dioxide, chloride, creatinine clearance (calculated), gamma-glutamyl transferase, globulin, glucose, lactate dehydrogenase, phosphorus, potassium, sodium, total protein, and uric acid.

Creatinine clearance will be calculated using the Cockcroft-Gault formula:

$$CLcr\ (mL/min)\ = \frac{[140 - age(years)] \times weight(kg)}{72 \times serum\ creatinine(mg/dL)} \{\times 0.85\ if\ female\}$$

Summary tables presenting observed values and changes from baseline will be presented for serum chemistry laboratory tests with numeric values for subjects in the Safety Population. Changes from baseline to each scheduled post-baseline visit will be presented.

Changes in low, normal, high, and abnormal classifications will be summarized in shift tables comparing the results at each scheduled post-baseline visit with those at the baseline visit. Shift tables will be presented for subjects in the Safety Population.

The maximum increase in DAIDS grade post-baseline (including both scheduled and unscheduled visits) will be summarized.

All serum chemistry laboratory data will be presented in a data listing.

9.2.3. Urinalysis

The following clinical laboratory urinalysis assessments will be performed: appearance (scored using nephelometry as clear, slightly cloudy, cloudy, or turbid), bilirubin, blood, color, glucose, ketones, leukocytes, microscopy (performed if dipstick is ≥1+; includes bacteria, cast, crystals, epithelial cells, red blood cells, and white blood cells), nitrates, pH, protein, specific gravity, turbidity, and urobilinogen.

Summary tables presenting observed values and changes from baseline will be presented for urinalysis laboratory tests with numeric values for subjects in the Safety Population. Changes from baseline to each scheduled post-baseline visit will be presented.

Changes in low, normal, high, and abnormal classifications will be summarized in shift tables comparing the results at each scheduled post-baseline visit with those at the baseline visit. Shift tables will be presented for subjects in the Safety Population.

The maximum increase in DAIDS grade post-baseline (including both scheduled and unscheduled visits) will be summarized.

Microscopy data will not be included in the summaries.

All urinalysis laboratory data will be presented in a data listing.

9.2.4. Other Clinical Laboratory Assessments

Glycosylated hemoglobin A1c and a fasting lipid panel including cholesterol (total, high-density lipoprotein, calculated low-density lipoprotein, and triglycerides) will be performed at screening.

Serum pregnancy test (β human chorionic gonadotropin) for women of childbearing potential will be performed at screening and on Day –1.

A serum follicle-stimulating hormone test for postmenopausal women will be performed at screening.

Human immunodeficiency virus (type 1 and 2) antibodies, hepatitis B surface antigen, and hepatitis C virus antibody will be assessed at screening only.

A urine drug screen for alcohol, amphetamines (including methamphetamines and ecstasy/methylenedioxymethamphetamine), barbiturates, benzodiazepines, cannabinoids (including tetrahydrocannabinol), cocaine metabolites, and opiates (including heroin, codeine, and oxycodone) will be performed at screening and on Day –1.

The results of these assessments will be presented in a data listing.

9.3. Vital Sign Measurements

Vital signs will be measured after the subject has been seated for at least 5 minutes at the time points indicated in the schedule of events (Appendix 12.1).

Vital sign measurements will include systolic and diastolic blood pressures, heart rate, respiratory rate, and body temperature.

The investigator will determine whether any of the vital sign measurements are clinically significant or not clinically significant. Clinical significance is defined as any variation in

results that has medical relevance and may result in an alteration in medical care (e.g., active observation, diagnostic measures, or therapeutic measures). If a clinically significant change from the screening values is noted, the clinically significant value and reason for clinical significance will be documented on the AE page of the subject's eCRF. The investigator will continue to monitor the subject with additional assessments until the value has reached the reference range or the value at screening or until the investigator determines that follow up is no longer medically necessary.

Summary tables presenting observed values and changes from baseline will be presented for vital sign data for subjects in the Safety Population. Changes from baseline to each scheduled post-baseline visit will be presented.

All vital sign data will be presented in a data listing.

9.4. Electrocardiograms

A 12-lead ECG will be obtained after the subject has been in the supine position for at least 10 minutes at the time points indicated in the schedule of events (Appendix 12.1).

Electrocardiogram assessments will include comments on whether the tracings are normal or abnormal, rhythm, presence of arrhythmia or conduction defects, morphology, any evidence of myocardial infarction, or ST segment, T wave, and U wave abnormalities. In addition, the following parameters will be measured and reported: heart rate; PR, RR, and QT intervals; QT interval corrected using Fridericia's formula (QTcF); QT interval corrected using Bazett's formula (QTcB); and QRS duration. All ECGs must be performed by an experienced ECG technician.

The investigator will determine whether any of the 12-lead ECG results are clinically significant or not clinically significant. Clinical significance is defined as any variation in results that has medical relevance and may result in an alteration in medical care (e.g., active observation, diagnostic measures, or therapeutic measures). If a clinically significant change from screening is noted, the clinically significant value and reason for clinical significance will be documented on the AE page of the subject's eCRF. The investigator will continue to monitor the subject with additional assessments until either the values have reached reference range or the values at screening or until the investigator determines that follow-up is no longer medically necessary.

Summary tables presenting observed values and changes from baseline will be presented for ECG numeric results for subjects in the Safety population. Changes from baseline to each scheduled post baseline visit will be presented.

All ECG data will be presented in a data listing.

9.5. Physical Measurements

Physical measurements (height and weight) will be performed at the time points indicated in the schedule of events (Appendix 12.1).

Height and weight data will be presented in a data listing.

9.6. Physical Examination

A full physical examination will be performed at the time points indicated in the schedule of events (Appendix 12.1) and will include assessment of the following body systems:

- Head, ears, eyes, nose and throat
- Cardiac (including auscultation of heart)
- Pulmonary (chest) auscultation of lungs
- Abdomen
- Skin
- Musculoskeletal system
- Lymphatic system
- Neurologic system (cranial nerves, sensation, motor function, coordination, reflexes, and mental status).

A symptom-directed physical examination will be performed at the time points indicated in the schedule of events (Appendix 12.1) (for those subjects who require it), and at unscheduled visits as necessary. This examination will include an assessment of the heart, lungs, abdomen, a neurologic review, and a review of symptoms for assessments and/or follow-up of reported or potential AEs.

Physical examination results will be presented in a data listing.

9.7. Follow-up Visit/Call

Follow-up visit and follow-up call data will be presented in a data listing.

10. Interim Analysis

No formal interim safety analyses will be performed in this study.

11. Changes to the Planned Analysis

Per FDA request, clinical laboratory values will be graded for severity according to the DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, version 2.1. Summary tables for the maximum increase in DAIDS grade post-baseline (including both scheduled and unscheduled visits) have been added.

No other changes were made from the planned analysis in the protocol.

12. Appendices

12.1. Schedule of Events

	Screening	Check-in	Treatment Period								Telephone Call or Follow-up Visit[a]	Follow-up Telephone Call[b]
Procedure[c] Day	**–28 to –2**	**–1**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9 or Early Discontinuation (±2)**	**14 (+2)**	**37 (+2)**
Admission to clinic		X											
Discharge from clinic[d]											X		
Informed consent	X												
Inclusion/exclusion criteria	X	X											
Medical history[e]	X	X											
Complete physical examination[f]	X	X							X		X		
Weight[g]	X	X	X[h]								X		
Height		X											
Vital sign measurements[i]	X	X	X[j]			X[j]			X[j]	X	X	X[k]	
Glycosylated hemoglobin (HbA1c)	X												
Fasting lipid panel[l]	X												
Clinical laboratory testing[m]	X[n]	X				X				X[o]	X[n]		
Serum follicle-stimulating hormone[p]	X												
Serum pregnancy test[q]	X	X											
Urine drug/alcohol screen[r]	X	X											
Serology (HBsAg, HCV, and HIV)	X												

12-Lead ECG[s]	X	X	X			X			X		X		
TPOXX administration[t]			X	X	X	X	X	X	X				
Pharmacokinetic sampling[u]			X	X				X	X	X	X		
Symptom-directed physical examination[v]				X	X	X	X	X	X			X[k]	
Adverse events			◄	———	———	———	———	———	———	———	X	———	►
Prior/concomitant medications	◄	———	———	———	———	———	———	———	———	X	———	———	►

Abbreviations: AE, adverse event; ECG, electrocardiogram; HBsAg, hepatitis B surface antigen; HCV, hepatitis C virus; HIV, human immunodeficiency virus; PK, pharmacokinetic; SAE, serious adverse event.

Notes:

[a] The follow-up visit, or telephone call will occur on Day 14 (+2 days), 7 days after the last dose of study drug. Subjects who have abnormal physical examination findings or an ongoing AE/SAE on Day 9 that is deemed related to study drug or per investigator or SIGA discretion will return to the study site on Day 14 (+2 days) for a follow-up visit. All other subjects will have the Day 14 (+2 days) follow-up via telephone.

[b] The follow-up telephone call will be made 30 days after the last dose of study drug (Day 37 [+2 days]).

[c] When procedures are overlapping and occurring at the same time point, the order of procedures should be ECG, vital sign measurements, and then blood collection, with the blood collection scheduled to occur at the nominal time point, unless dictated by other study events happening at that time, such as dosing requirements.

[d] Discharge following collection of all safety assessments.

[e] Including a review of systems; recreational, prescription, and over-the-counter drug use; nicotine and alcohol use; and past hospitalizations.

[f] Including assessment of the following body systems: head, ears, eyes, nose, and throat; cardiac (including auscultation of heart); pulmonary (chest) auscultation of lungs; abdomen; skin; musculoskeletal system; lymphatic system; and neurologic system (cranial nerves, sensation, motor function, coordination, reflexes, and mental status).

[g] Weight will be measured without shoes and in light clothing at screening and without shoes and in hospital gowns at all other time points. The scales should be calibrated, and the same weight scale should be used throughout the study starting on Day –1.

[h] Weight will be collected prior to dosing.

[i] Vital sign measurements will include systolic and diastolic blood pressures, heart rate, respiratory rate, and body temperature. Vital signs will be measured after the subject has been seated for at least 5 minutes.

[j] Vital sign measurements will be performed before dosing and 4 hours after the AM study drug administration on Days 1 and 7 and 4 hours after the AM study drug administration on Day 4. The acceptable window for collection from the scheduled collection time point is ±15 minutes.

[k] Collected only if subjects are required to return to the study site on Day 14 (+2 days) for a follow-up visit.

[l] Including cholesterol (total, high-density lipoprotein, calculated low-density lipoprotein, and triglycerides).

[m] Clinical laboratory testing will include hematology and serum chemistry.

[n] Clinical laboratory testing at screening and at Day 9 or early discontinuation will include hematology, serum chemistry, and urinalysis.

[o] Collect 12 hours after the PM study drug administration on Day 7.

[p] For postmenopausal women, a serum follicle-stimulating hormone test will be performed at screening.

[q] Women of childbearing potential only.

[r] Includes alcohol, amphetamines (including methamphetamines and ecstasy/methylenedioxymethamphetamine), barbiturates, benzodiazepines, cannabinoids (including tetrahydrocannabinol), cocaine metabolites, and opiates (including heroin, codeine, and oxycodone).

[s] A 12-lead ECG will be collected after the subject has been in the supine position for at least 10 minutes. On Days 1, 4, and 7, an ECG will be recorded 4 hours after the AM study drug administration. The acceptable window for collection from the scheduled collection time point is ±15 minutes.

(t) TPOXX, 600 mg (3 × 200-mg capsules) will be administered orally twice daily, approximately 12 hours (± 30 minutes) apart on Days 1 through 7. All subjects will be provided meals consisting of approximately 600 calories and 25 g fat, which will start 30 minutes before study drug administration. Subjects should eat this meal within 30 minutes or less of taking study drug. Study drug will be administered approximately 30 minutes after the start of the meal. All doses of study drug will be administered to subjects by study site personnel with approximately 240 mL of water. Subjects must fast 2 hours after taking study drug. Study drug and meals must be taken with water only, and no other beverage except water should be ingested within 3 hours before or 3 hours after study drug administration.

(u) Blood samples for PK analysis of TPOXX will be collected from all subjects at the following tome points: on Day 1 before study drug administration (0 hour), at 0.5, 1, 2, 4, 6, 8, 12 (before the PM dose), 14, 16, 18, 20, and 24 hours (before the AM dose on Day 2), on Day 6 (before the AM dose and 4 hours after the AM dose), on Day 7 before the AM dose (0 hour), at 0.5, 1, 2, 4, 6, 8, 12 (before the PM dose), 14, 16, 18, 20, and 24 hours (Day 8, 24 hours after the AM dose on Day 7), and on Day 9 (48 hours after the AM dose on Day 7). For PK blood samples, the acceptable window for collection from the scheduled collection time point will be as follows: ±5 minutes for the time points from 1 to 8 hours and ±15 minutes for the 12- to 48-hour time points.

(v) Including assessment of heart, lungs, abdomen, a neurologic review, and a review of symptoms for assessment and/or follow-up of reported or potential adverse events.

PPD	PPD Biostatistics and Programming
	Statistical Analysis Plan (SAP) Client Approval Form

Client:	**SIGA Technologies, Inc.**
Protocol Number:	**SIGA-246-022**

Document Description:	Final Statistical Analysis Plan
SAP Title:	A Post Marketing Study of the Safety, Tolerability, and Pharmacokinetics of TPOXX® in Adult Subjects Weighing More Than 120 kg
SAP Version Number:	1.0
Effective Date:	11OCT2019

Author(s):

For PPD: Rebekah Hahn, Sr. Biostatistician; Nancy Zheng, Pharmacokineticist

Approved by:

Kady Honeychurch, Associate Director
Project Management, SIGA Technologies, Inc.

11 Oct 2019
Date *(DD-MMM-YYYY)*

Rebekah Hahn
Senior Biostatistician
I approve this document
11 Oct 2019 17:38:05 -05:00

Rebekah Hahn, Senior Biostatistician
Early Development Services, PPD

Date *(DD-MMM-YYYY)*

Nancy N. Zheng
Pharmacokineticist
I approve this document
Oct 11 2019 4:18 PM

Nancy Zheng, Pharmacokineticist
Clinical Pharmacology, PPD

Date *(DD-MMM-YYYY)*

16.1.10 Documentation of Interlaboratory Standardization Methods and Quality Assurance Procedures if Used

The following laboratories were used in the study:

Clinical Laboratory:

PPD Austin Central Laboratory
7551 Metro Center Drive, Suite 200
Austin, TX 78744
USA

Bioanalytical Laboratory:

Alturas Analytics, Inc.
1324 Alturas Drive
Moscow, ID 83843
USA

Laboratory ranges can be found in Listings 16.2.8.1, 16.2.8.2, 16.2.8.3, 16.2.8.4 and 16.2.8.5.

16.1.11 Publications Based on the Study

There were no publications based on the study.

16.1.12 Important Publications Referenced in the Report

Please refer to Section 15 of the study report for the complete reference list.

16.2 DATA LISTINGS

16.2.1 Discontinued Subjects

Listing 16.2.1.1
Disposition
Enrolled Population

Subject ID	Age(yrs)/ Sex/Race	Informed Consent Date	First Dose Date/ Last Dose Date (Day)	Completed Study?	Discontinuation	
					Date (Day)	Reason
9001	41/M/BL	19JUL2019	14AUG2019/ 20AUG2019 (7)	Yes		
9002	48/M/W	19JUL2019	14AUG2019/ 20AUG2019 (7)	Yes		
9005	40/M/W	23JUL2019	14AUG2019/ 20AUG2019 (7)	Yes		
9009	21/F/BL	31JUL2019	14AUG2019/ 20AUG2019 (7)	Yes		
9012	34/M/BL	06AUG2019	14AUG2019/ 20AUG2019 (7)	Yes		
9015	29/M/BL	12AUG2019	14AUG2019/ 20AUG2019 (7)	Yes		
9016	48/F/W	12AUG2019	04SEP2019/ 10SEP2019 (7)	Yes		
9019	41/M/BL	15AUG2019	04SEP2019/ 10SEP2019 (7)	Yes		

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.1.1
Disposition
Enrolled Population

Subject ID	Age(yrs)/ Sex/Race	Informed Consent Date	First Dose Date/ Last Dose Date (Day)	Completed Study?	Discontinuation	
					Date (Day)	Reason
9020	47/F/BL	21AUG2019	04SEP2019/ 10SEP2019 (7)	Yes		
9021	39/F/BL	21AUG2019	04SEP2019/ 10SEP2019 (7)	Yes		
9022	31/M/W	21AUG2019	04SEP2019/ 10SEP2019 (7)	Yes		
9024	20/M/BL	23AUG2019	04SEP2019/ 10SEP2019 (7)	Yes		
9025	50/M/W	23AUG2019	18SEP2019/ 24SEP2019 (7)	Yes		
9033	32/M/W	29AUG2019	04SEP2019/ 10SEP2019 (7)	Yes		
9043	22/M/BL	11SEP2019	18SEP2019/ 24SEP2019 (7)	Yes		
9046	34/M/BL	13SEP2019	18SEP2019/ 24SEP2019 (7)	Yes		

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.1.1
Disposition
Enrolled Population

Subject ID	Age(yrs)/ Sex/Race	Informed Consent Date	First Dose Date/ Last Dose Date (Day)	Completed Study?	Discontinuation	
					Date (Day)	Reason
9051	34/M/BL	19SEP2019	02OCT2019/ 08OCT2019 (7)	Yes		
9052	42/M/BL	21SEP2019	02OCT2019/ 08OCT2019 (7)	Yes		
9056	31/F/BL	24SEP2019	02OCT2019/ 08OCT2019 (7)	Yes		
9057	29/F/W	25SEP2019	02OCT2019/ 08OCT2019 (7)	Yes		
9058	32/M/W	26SEP2019	16OCT2019/ 22OCT2019 (7)	Yes		
9061	21/F/BL	26SEP2019	16OCT2019/ 22OCT2019 (7)	Yes		
9062	33/M/BL	30SEP2019	02OCT2019/ 08OCT2019 (7)	Yes		
9063	35/M/W	30SEP2019	02OCT2019/ 08OCT2019 (7)	Yes		

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.1.1
Disposition
Enrolled Population

Subject ID	Age(yrs)/ Sex/Race	Informed Consent Date	First Dose Date/ Last Dose Date (Day)	Completed Study?	Discontinuation	
					Date (Day)	Reason
9069	41/F/BL	30SEP2019	16OCT2019/ 22OCT2019 (7)	Yes		
9073	40/M/BL	04OCT2019	16OCT2019/ 22OCT2019 (7)	Yes		
9077	37/F/W	05OCT2019	16OCT2019/ 22OCT2019 (7)	Yes		
9080	41/F/BL	08OCT2019	16OCT2019/ 22OCT2019 (7)	Yes		
9081	49/M/BL	10OCT2019	30OCT2019/ 05NOV2019 (7)	Yes		
9086	36/M/BL	11OCT2019	16OCT2019/ 22OCT2019 (7)	Yes		
9087	34/F/BL	11OCT2019	16OCT2019/ 22OCT2019 (7)	Yes		
9089	29/M/BL	14OCT2019	16OCT2019/ 22OCT2019 (7)	Yes		

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.1.1
Disposition
Enrolled Population

Subject ID	Age(yrs)/ Sex/Race	Informed Consent Date	First Dose Date/ Last Dose Date (Day)	Completed Study?	Discontinuation	
					Date (Day)	Reason
9092	24/M/W	14OCT2019	16OCT2019/ 22OCT2019 (7)	Yes		
9095	42/M/W	17OCT2019	30OCT2019/ 05NOV2019 (7)	Yes		

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.1.2
Analysis Sets
Enrolled Population

Subject ID	Age(yrs)/Sex/Race	Safety Population/Reason Excluded	PK Population/Reason Excluded
9001	41/M/BL	Yes	Yes
9002	48/M/W	Yes	Yes
9005	40/M/W	Yes	Yes
9009	21/F/BL	Yes	Yes
9012	34/M/BL	Yes	Yes
9015	29/M/BL	Yes	Yes
9016	48/F/W	Yes	Yes
9019	41/M/BL	Yes	Yes
9020	47/F/BL	Yes	Yes
9021	39/F/BL	Yes	Yes
9022	31/M/W	Yes	Yes
9024	20/M/BL	Yes	Yes
9025	50/M/W	Yes	Yes

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Note: The Safety population includes all subjects who receive at least 1 dose of study drug.
The PK population includes all subjects who receive study drug and have sufficient concentration data to facilitate the calculation of PK variables.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.1.2
Analysis Sets
Enrolled Population

Subject ID	Age(yrs)/Sex/Race	Safety Population/Reason Excluded	PK Population/Reason Excluded
9033	32/M/W	Yes	Yes
9043	22/M/BL	Yes	Yes
9046	34/M/BL	Yes	Yes
9051	34/M/BL	Yes	Yes
9052	42/M/BL	Yes	Yes
9056	31/F/BL	Yes	Yes
9057	29/F/W	Yes	Yes
9058	32/M/W	Yes	Yes
9061	21/F/BL	Yes	Yes
9062	33/M/BL	Yes	Yes
9063	35/M/W	Yes	Yes
9069	41/F/BL	Yes	Yes
9073	40/M/BL	Yes	Yes

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Note: The Safety population includes all subjects who receive at least 1 dose of study drug.
The PK population includes all subjects who receive study drug and have sufficient concentration data to facilitate the calculation of PK variables.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.1.2
Analysis Sets
Enrolled Population

Subject ID	Age(yrs)/Sex/Race	Safety Population/Reason Excluded	PK Population/Reason Excluded
9077	37/F/W	Yes	Yes
9080	41/F/BL	Yes	Yes
9081	49/M/BL	Yes	Yes
9086	36/M/BL	Yes	Yes
9087	34/F/BL	Yes	Yes
9089	29/M/BL	Yes	Yes
9092	24/M/W	Yes	Yes
9095	42/M/W	Yes	Yes

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Note: The Safety population includes all subjects who receive at least 1 dose of study drug.
The PK population includes all subjects who receive study drug and have sufficient concentration data to facilitate the calculation of PK variables.
TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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16.2.2 Protocol Deviations

Listing 16.2.2.1
Protocol Deviations
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Deviation Date/ Visit	Type	Category	Protocol Deviation
9001	41/M/BL	15AUG2019/ Day 2	MINOR	Study Procedures/Assessments	Subject 9001/105 - Period 1 Day 2 AM dose was administered 34 minutes after start of meal.
			MINOR	Study Procedures/Assessments	Subject R105/S9001 Day 2 Breakfast did not begin within 30 mins of dose due to late dose; Subject began meal 34 mins prior to dose; 4 mins outside of protocol window
		17AUG2019/ Day 4	MINOR	Study Treatment Admin/Dispense	Subject R105/S9001 - Day 4 AM dose 1 min late due to late breakfast; adjusted in error
			MINOR	Study Treatment Admin/Dispense	Subject R105/S9001 Day 4 AM dose 1 min late due to late breakfast; adjusted in error
9002	48/M/W	14AUG2019/ Day 1	MINOR	Study Procedures/Assessments	Subject 9002/101 - Period 1 Day 1 4HR PK was collected 18 minutes late; 13 mins outside of protocol window
		15AUG2019/ Day 2	MINOR	Study Procedures/Assessments	Subject 9002/101 - Period 1 Day 2 AM dose was administered 32 minutes after the start of the AM meal "breakfast".
			MINOR	Study Treatment Admin/Dispense	Subject R101/S9002 - Day 2 AM dose 2 mins late due to AE confirmation

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.2.1
Protocol Deviations
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Deviation Date/ Visit	Type	Category	Protocol Deviation
9002	48/M/W	17AUG2019/ Day 4	MINOR	Other GCP Deviation	Subject R101/S9002 - Day 4 4Hr Vital signs Subject had three total out of range vital signs, including original timepoint and two repeats; 3rd repeat performed by paramedic with result of 162/100 outs ide of systolic range 90-160 and diastolic range 40-96. No PI assessment documented.
			MINOR	Study Treatment Admin/Dispense	Subject R101/S9002 - Day 4 AM dose 1 min late due to late breakfast; adjusted in error
		19AUG2019/ Day 6	MAJOR	Missing Endpoint Assessments	(P17:01: Missing endpoint assessments) - R101/S9002 Day 6 4Hr Pk sample hemolyzed
			MINOR	Study Procedures/Assessments	Subject R101/S9002 Day 6 Breakfast did not begin within 30 mins of dose due to late dose; Subject began meal 37 mins prior to dose; 7 mins outside of protocol window
			MINOR	Study Treatment Admin/Dispense	Subject R101/S9002 Day 6 AM dose 6 mins late late to difficulty collecting blood at previous procedure

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.2.1
Protocol Deviations
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Deviation Date/ Visit	Type	Category	Protocol Deviation
9002	48/M/W	20AUG2019/ Day 7	MINOR	Study Procedures/Assessments	(P13:01: PK sample not per protocol requirements) - R101/S9002 Day 7 2Hr PK sample drawn 9 mins late due to restick; 4 mins outside of protocol window
			MINOR	Study Procedures/Assessments	(P13:01: PK sample not per protocol requirements) - R101/S9002 Day 7 6Hr PK sample drawn 8 mins late due to restick; 3 mins outside of protocol window
			MINOR	Study Procedures/Assessments	(P13:01: PK sample not per protocol requirements) - R101/S9002 Day 7 8Hr PK sample drawn 30 mins late due to restick; 25 mins outside of protocol window
			MINOR	Study Procedures/Assessments	Subject R101/S9002 Day 7 Breakfast did not begin within 30 mins of dose due to late dose; Subject began meal 33 mins prior to dose; 3 mins outside of protocol window
			MINOR	Study Treatment Admin/Dispense	Subject R101/S9002 Day 7 AM dose 3 mins late late to difficulty collecting blood at previous procedure
9009	21/F/BL	14AUG2019/ Day 1	MAJOR	Study Procedures/Assessments	P07:01 - Subject 9009/104 - Period 1 Day 1 8HR PK sample was not able to be obtained.

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.2.1
Protocol Deviations
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Deviation Date/ Visit	Type	Category	Protocol Deviation
9009	21/F/BL	14AUG2019/ Day 1	MINOR	Study Procedures/Assessments	Subject 9009/104 - Period 1 Day 1 4HR PK was collected 8 minutes late; 3 mins outside of protocol window
9012	34/M/BL	15AUG2019/ Day 2	MINOR	Study Treatment Admin/Dispense	Subject R106/S9012 - Day 2 AM dose 4 mins late due to late breakfast; adjusted in error
9015	29/M/BL	14AUG2019/ Day 1	MINOR	Study Procedures/Assessments	Subject R103/S9015 Day 1 Breakfast did not begin within 30 mins of dose due to late dose; Subject began meal 34 mins prior to dose; 4 mins outside of protocol window
9019	41/M/BL	04SEP2019/ Day 1	MINOR	Study Procedures/Assessments	(P13:01: PK sample not per protocol requirements) - R108/S9019 Day 1 .5Hr PK sample drawn 1 min late; no window given per protocol; 1 min outside of planned protocol time
			MINOR	Study Procedures/Assessments	(P13:01: PK sample not per protocol requirements) - R108/S9019 Day 1 8Hr PK sample respun for 3 mins

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.2.1
Protocol Deviations
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Deviation Date/ Visit	Type	Category	Protocol Deviation
9019	41/M/BL	05SEP2019/ Day 2	MINOR	Study Procedures/Assessments	Subject R108/S9019 Day 2 Breakfast did not begin within 30 mins of dose due to late dose; Subject began meal 36 mins prior to dose; 6 mins outside of protocol window
			MINOR	Study Treatment Admin/Dispense	Subject R108/S9019 - Day 1 PM dose 3 mins late due to late dinner; adjusted in error
			MINOR	Study Treatment Admin/Dispense	Subject R108/S9019 Day 2 AM dose 6 mins late late to difficulty collecting blood at previous procedure
		07SEP2019/ Day 4	MINOR	Study Treatment Admin/Dispense	Subject R108/S9019 - Day 4 AM dose 6 mins late due to late breakfast; adjusted in error
9021	39/F/BL	05SEP2019/ Day 2	MINOR	Study Treatment Admin/Dispense	Subject R110/S9021 - Day 2 AM dose 3 mins late due to late breakfast; adjusted in error
9022	31/M/W	07SEP2019/ Day 4	MINOR	Study Treatment Admin/Dispense	Subject R111/S9022 - Day 4 AM dose 6 mins late due to late breakfast; adjusted in error

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.2.1
Protocol Deviations
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Deviation Date/ Visit	Type	Category	Protocol Deviation
9024	20/M/BL	04SEP2019/ Day 1	MAJOR	Missing Endpoint Assessments	(P17:01: Missing endpoint assessments) - R112/S9024 Day 1 1Hr Pk sample hemolyzed
			MAJOR	Missing Endpoint Assessments	(P17:01: Missing endpoint assessments) - R112/S9024 Day 1 4Hr Pk sample hemolyzed
9025	50/M/W	22SEP2019/ Day 5	MINOR	Study Procedures/Assessments	Subject R114/S9025 Day 5 Dinner did not begin within 30 mins of dose due to late dose; Subject began meal 35 mins prior to dose; 5 mins outside of protocol window
			MINOR	Study Treatment Admin/Dispense	Subject R114/S9025 - Day 5 PM dose 5 mins late
9033	32/M/W	05SEP2019/ Day 2	MINOR	Study Procedures/Assessments	(P13:01: PK sample not per protocol requirements) - R113/S9033 Day 2 18Hr PK sample drawn 34 mins late due to restick; 19 mins outside of protocol window
			MINOR	Study Treatment Admin/Dispense	Subject R113/S9033 - Day 2 AM dose 1 min late due to late breakfast; adjusted in error
		07SEP2019/ Day 4	MINOR	Study Treatment Admin/Dispense	Subject R113/S9033 - Day 4 AM dose 3 mins late due to late breakfast; adjusted in error

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.2.1
Protocol Deviations
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Deviation Date/ Visit	Type	Category	Protocol Deviation
9033	32/M/W	10SEP2019/ Day 7	MINOR	Study Procedures/Assessments	(P13:01: PK sample not per protocol requirements) - R113/S9033 Day 7 .5Hr PK sample drawn 1 min late; no window given per protocol; 1 min outside of planned protocol time
9043	22/M/BL	18SEP2019/ Day 1	MAJOR	Missing Endpoint Assessments	(P17:01: Missing endpoint assessments) - R115/S9043 Day 1 12Hr PK sample not collected due to unable to obtain
			MINOR	Study Procedures/Assessments	(P13:01: PK sample not per protocol requirements) - R115/S9043 Day 1 14Hr PK sample drawn 33 mins late due to adjusted for late PM dose; 18 mins outside of protocol window
			MINOR	Study Procedures/Assessments	(P13:01: PK sample not per protocol requirements) - R115/S9043 Day 1 2Hr PK sample drawn 6 mins late due to restick; 1 min outside of protocol window
			MINOR	Study Procedures/Assessments	Subject R115/S9043 Day 1 Dinner did not begin within 30 mins of dose due to late dose; Subject began meal 1 Hr 3 mins prior to dose; 33 mins outside of protocol window

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.2.1
Protocol Deviations
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Deviation Date/ Visit	Type	Category	Protocol Deviation
9043	22/M/BL	18SEP2019/ Day 1	MINOR	Study Treatment Admin/Dispense	Subject R115/S9043 - Day 1 PM dose 33 min late due to previous procedure
		19SEP2019/ Day 2	MINOR	Study Procedures/Assessments	(P13:01: PK sample not per protocol requirements) - R115/S9043 Day 2 16Hr PK sample drawn 33 mins late due to adjusted for late PM dose; 18 mins outside of protocol window
			MINOR	Study Procedures/Assessments	(P13:01: PK sample not per protocol requirements) - R115/S9043 Day 2 18Hr PK sample drawn 49 mins late due to adjusted for late PM dose and restick; 34 mins outside of protocol window
			MINOR	Study Procedures/Assessments	(P13:01: PK sample not per protocol requirements) - R115/S9043 Day 2 20Hr PK sample drawn 33 mins late due to adjusted for late PM dose; 18 mins outside of protocol window
			MINOR	Study Treatment Admin/Dispense	Subject R115/S9043 - Day 2 PM dose 5 mins late due to previous procedure

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.2.1
Protocol Deviations
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Deviation Date/ Visit	Type	Category	Protocol Deviation
9043	22/M/BL	22SEP2019/ Day 5	MINOR	Study Procedures/Assessments	Subject R115/S9043 Day 5 Dinner did not begin within 30 mins of dose due to late dose; Subject began meal 33 mins prior to dose; 3 mins outside of protocol window
			MINOR	Study Treatment Admin/Dispense	Subject R115/S9043 - Day 5 PM dose 3 mins late due to previous subject
		24SEP2019/ Day 7	MINOR	Study Procedures/Assessments	(P13:01: PK sample not per protocol requirements) - R115/S9043 Day 7 .5Hr PK sample drawn 1 min late; no window given per protocol; 1 min outside of planned protocol time
			MINOR	Study Procedures/Assessments	(P13:01: PK sample not per protocol requirements) - R115/S9043 Day 7 8Hr PK sample drawn 15 mins late due to restick; 10 mins outside of protocol window
		25SEP2019/ Day 8	MINOR	Study Procedures/Assessments	Subject R115/S9043 Day 8 24Hr clinical labs drawn 29 mins late due to additional time needed

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.2.1
Protocol Deviations
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Deviation Date/ Visit	Type	Category	Protocol Deviation
9046	34/M/BL	22SEP2019/ Day 5	MINOR	Study Procedures/Assessments	Subject R116/S9046 Day 2 dinner did not begin within 30 mins of dose due to late dose; Subject began meal 31 mins prior to dose; 1 min outside of protocol window
			MINOR	Study Treatment Admin/Dispense	Subject R116/S9046 - Day 5 PM dose 1 min late
		24SEP2019/ Day 7	MINOR	Study Procedures/Assessments	(P13:01: PK sample not per protocol requirements) - R116/S9046 Day 7 .5Hr PK sample drawn 1 min late; no window given per protocol; 1 min outside of planned protocol time
9052	42/M/BL	02OCT2019/ Day 1	MINOR	Study Treatment Admin/Dispense	Subject R121/S9052 - Day 1 AM dose 7 min late due to late breakfast; adjusted in error
9056	31/F/BL	08OCT2019/ Day 7	MINOR	Study Procedures/Assessments	(P13:01: PK sample not per protocol requirements) - R117/S9056 Day 7 .5Hr PK sample drawn 5 mins late; no window given per protocol; 5 mins outside of planned protocol time

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.2.1
Protocol Deviations
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Deviation Date/ Visit	Type	Category	Protocol Deviation
9056	31/F/BL	08OCT2019/ Day 7	MINOR	Study Procedures/Assessments	(P13:01: PK sample not per protocol requirements) - R117/S9056 Day 7 6Hr PK sample drawn 6 mins late; 1 min outside of protocol window
		09OCT2019/ Day 8	MINOR	Study Procedures/Assessments	Subject R117/S9056 Day 8 24Hr clinical labs drawn 3 mins late
9058	32/M/W	16OCT2019/ Day 1	MAJOR	Missing Endpoint Assessments	(P17:01: Missing endpoint assessments) - R123/S9058 Day 1 .5Hr Pk sample hemolyzed
			MAJOR	Missing Endpoint Assessments	(P17:01: Missing endpoint assessments) - R123/S9058 Day 1 1Hr Pk sample hemolyzed
			MINOR	Study Procedures/Assessments	Subject R123/S9058 Day 1 Breakfast did not begin within 30 mins of dose due to late dose; Subject began meal 37 mins prior to dose; 7 mins outside of protocol window
			MINOR	Study Treatment Admin/Dispense	Subject R123/S9058 - Day 1 AM dose 7 min late due to restick

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.2.1
Protocol Deviations
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Deviation Date/ Visit	Type	Category	Protocol Deviation
9058	32/M/W	22OCT2019/ Day 7	MINOR	Study Procedures/Assessments	(P13:01: PK sample not per protocol requirements) - R123/S9058 Day 7 8Hr PK sample drawn 13 mins late due to restick; 8 mins outside of protocol window
			MINOR	Study Procedures/Assessments	Subject R123/S9058 Day 7 Dinner did not begin within 30 mins of dose due to late dose; Subject began meal 40 mins prior to dose; 10 mins outside of protocol window
			MINOR	Study Treatment Admin/Dispense	Subject R123/S9058 - Day 7 PM dose 10 mins late due to previous procedure difficulty obtaining blood
		23OCT2019/ Day 8	MINOR	Study Procedures/Assessments	(P13:01: PK sample not per protocol requirements) - R123/S9058 Day 8 24Hr PK sample drawn 22 mins late due to restick; 7 mins outside of protocol window
		24OCT2019/ Day 9	MINOR	Study Procedures/Assessments	(P13: Other deviations) - R123/S9058 Day 9 48Hr clinical BC drawn 1 min late due to additional time needed

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.2.1
Protocol Deviations
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Deviation Date/ Visit	Type	Category	Protocol Deviation
9061	21/F/BL	16OCT2019/ Day 1	MINOR	Study Procedures/Assessments	(P13:01: PK sample not per protocol requirements) - R124/S9061 Day 1 .5Hr PK sample drawn 1 min late; no window given per protocol; 1 min outside of planned protocol time
			MINOR	Study Procedures/Assessments	(P13:01: PK sample not per protocol requirements) - R124/S9061 Day 1 .5Hr PK sample drawn 2 mins late; no window given per protocol; 2 mins outside of planned protocol time
			MINOR	Study Procedures/Assessments	(P13:01: PK sample not per protocol requirements) - R124/S9061 Day 1 1Hr PK sample drawn 7 mins late due to restick; 2 mins outside of protocol window
			MINOR	Study Procedures/Assessments	(P13:01: PK sample not per protocol requirements) - R124/S9061 Day 1 8Hr PK sample drawn 32 mins late due to restick; 27 mins outside of protocol window
		17OCT2019/ Day 2	MAJOR	Missing Endpoint Assessments	(P17:01: Missing endpoint assessments) - R124/S9061 Day 2 18Hr PK sample not collected due to unable to obtain

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.2.1
Protocol Deviations
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Deviation Date/ Visit	Type	Category	Protocol Deviation
9061	21/F/BL	17OCT2019/ Day 2	MAJOR	Missing Endpoint Assessments	(P17:01: Missing endpoint assessments) - R124/S9061 Day 2 20Hr PK sample not collected due to unable to obtain
		22OCT2019/ Day 7	MINOR	Study Procedures/Assessments	Subject R124/S9061 Day 7 Dinner did not begin within 30 mins of dose; Subject began meal 31 mins prior to dose; 1 min outside of protocol window
		23OCT2019/ Day 8	MINOR	Study Procedures/Assessments	Subject R124/S9061 Day 8 24Hr clinical labs drawn 3 mins late due to restick
9069	41/F/BL	16OCT2019/ Day 1	MINOR	Study Procedures/Assessments	(P13:01: PK sample not per protocol requirements) - R125/S9069 Day 1 .5Hr PK sample drawn 18 mins late; no window given per protocol; 18 mins outside of planned protocol time
			MINOR	Study Procedures/Assessments	(P13:01: PK sample not per protocol requirements) - R125/S9069 Day 1 14Hr PK sample drawn 16 mins late due to late dose adjusted; 1 min outside of protocol window

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.2.1
Protocol Deviations
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Deviation Date/ Visit	Type	Category	Protocol Deviation
9069	41/F/BL	16OCT2019/ Day 1	MINOR	Study Procedures/Assessments	(P13:01: PK sample not per protocol requirements) - R125/S9069 Day 1 4Hr PK sample drawn 6 mins late due to previous VS procedure; 1 min outside of protocol window
			MINOR	Study Procedures/Assessments	Subject R125/S9069 Day 1 Dinner did not begin within 30 mins of dose due to late dose; Subject began meal 46 mins prior to dose; 16 mins outside of protocol window
			MINOR	Study Treatment Admin/Dispense	Subject R125/S9069 Day 1 PM dose 16 mins late due to subject late
		17OCT2019/ Day 2	MINOR	Study Procedures/Assessments	(P13:01: PK sample not per protocol requirements) - R125/S9069 Day 2 16Hr PK sample drawn 17 mins late due to late dose adjusted; 2 mins outside of protocol window
			MINOR	Study Procedures/Assessments	(P13:01: PK sample not per protocol requirements) - R125/S9069 Day 2 18Hr PK sample drawn 16 mins late due to late dose adjusted; 1 min outside of protocol window

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.2.1
Protocol Deviations
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Deviation Date/ Visit	Type	Category	Protocol Deviation
9069	41/F/BL	17OCT2019/ Day 2	MINOR	Study Procedures/Assessments	(P13:01: PK sample not per protocol requirements) - R125/S9069 Day 2 20Hr PK sample drawn 16 mins late due to late dose adjusted; 1 min outside of protocol window
			MINOR	Study Treatment Admin/Dispense	Subject R125/S9069 - Day 2 AM dose 4 min late due to late breakfast; adjusted in error
			MINOR	Study Treatment Admin/Dispense	Subject R125/S9069 - Day 2 AM dose 4 mins late due to late breakfast; adjusted in error
		23OCT2019/ Day 8	MINOR	Study Procedures/Assessments	(P13: Other deviations) - R125/S9069 Day 8 24Hr clinical BC drawn 9 mins late due to restick
9073	40/M/BL	16OCT2019/ Day 1	MINOR	Study Procedures/Assessments	(P13:01: PK sample not per protocol requirements) - R126/S9073 Day 1 .5Hr PK sample drawn 5 mins late; no window given per protocol; 5 mins outside of planned protocol time

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.2.1
Protocol Deviations
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Deviation Date/ Visit	Type	Category	Protocol Deviation
9073	40/M/BL	16OCT2019/ Day 1	MINOR	Study Procedures/Assessments	(P13:01: PK sample not per protocol requirements) - R126/S9073 Day 1 6Hr PK sample drawn 6 mins late due to restick; 1 mins outside of protocol window
			MINOR	Study Procedures/Assessments	Subject R126/S9073 - Day 1 breakfast not started within 30 mins of dose due to late dose; breakfast started 37 mins mins prior to dose; 7 mins outsode of protocol window
			MINOR	Study Treatment Admin/Dispense	Subject R126/S9073 - Day 1 AM dose 7 min late due to restick
9077	37/F/W	22OCT2019/ Day 7	MINOR	Study Procedures/Assessments	(P13:01: PK sample not per protocol requirements) - R127/S9077 Day 7 4Hr PK sample drawn 19 mins late due to restick; 14 mins outside of protocol window
			MINOR	Study Procedures/Assessments	R127/S9077 Day 7 4Hr VS collected 16 mins late; 1 min ouside of protocol window
9080	41/F/BL	23OCT2019/ Day 8	MAJOR	Missing Endpoint Assessments	(P17:01: Missing endpoint assessments) - R130/S9080 Day 8 18Hr PK sample not collected due to unable to obtain

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.2.1
Protocol Deviations
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Deviation Date/ Visit	Type	Category	Protocol Deviation
9081	49/M/BL	06NOV2019/ Day 7	MINOR	Study Procedures/Assessments	(P13:01: PK sample not per protocol requirements) - R133/S9081 Day 7 .5Hr PK sample drawn 1 mins late; 1 min outside of planned protocol time; no allowable window given
		07NOV2019/ Day 9	MINOR	Study Procedures/Assessments	(P13:01: PK sample not per protocol requirements) - R133/S9081 Day 9 48Hr PK sample re-spun for 3 mins
9086	36/M/BL	21OCT2019/ Day 6	MINOR	Study Procedures/Assessments	Subject R128/S9086 - Day 6 breakfast not started within 30 mins prior to dose due to late dose; breakfast started 33 mins prior to dose; 3 mins outside of protocol window
			MINOR	Study Treatment Admin/Dispense	Subject R128/S9086 - Day 6 AM dose 3 mins late due to additional time needed
9089	29/M/BL	24OCT2019/ Day 9	MINOR	Study Procedures/Assessments	(P13:01: PK sample not per protocol requirements) - R131/S9089 Day 9 48Hr PK sample re-spun for 3 mins

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.2.2
Inclusion/Exclusion Criteria Deviations
Safety Population

Subject ID	Age(yrs)/Sex/Race	Protocol Version	Inclusion Criteria Not Met	Exclusion Criteria Met

No data to display

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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16.2.3 Subjects Excluded From the Analyses

Not Applicable

16.2.4 Demographic Data

Listing 16.2.4.1
Demographics
Safety Population

Subject ID	Age(yrs)/ Sex/Race	Birth Date	Ethnicity	Weight (kg)	Height (cm)	Reproductive Status/ Methods of Birth Control [1]
9001	41/M/BL	21MAR1978	NOT HISPANIC OR LATINO	129.9	174.3	
9002	48/M/W	07MAR1971	NOT HISPANIC OR LATINO	159.7	178.5	
9005	40/M/W	21JAN1979	NOT HISPANIC OR LATINO	141.9	176.8	
9009	21/F/BL	03JAN1998	NOT HISPANIC OR LATINO	137.2	174.0	POTENTIALLY ABLE TO BEAR CHILDREN/ ABSTINENCE
9012	34/M/BL	02JUN1985	NOT HISPANIC OR LATINO	130.4	177.0	
9015	29/M/BL	01NOV1989	NOT HISPANIC OR LATINO	120.4	195.3	
9016	48/F/W	15DEC1970	HISPANIC OR LATINO	144.9	173.6	POTENTIALLY ABLE TO BEAR CHILDREN/ ABSTINENCE
9019	41/M/BL	07OCT1977	NOT HISPANIC OR LATINO	133.5	181.6	
9020	47/F/BL	25JUL1972	NOT HISPANIC OR LATINO	135.0	164.8	STERILE/ BARRIER WITH SPERMICIDE

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] Reproductive status and methods of birth control are presented for female subjects only.
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Listing 16.2.4.1
Demographics
Safety Population

Subject ID	Age(yrs)/ Sex/Race	Birth Date	Ethnicity	Weight (kg)	Height (cm)	Reproductive Status/ Methods of Birth Control [1]
9021	39/F/BL	09JUL1980	NOT HISPANIC OR LATINO	123.4	172.8	POTENTIALLY ABLE TO BEAR CHILDREN/ BARRIER WITH SPERMICIDE
9022	31/M/W	24JUL1988	HISPANIC OR LATINO	172.1	177.3	
9024	20/M/BL	08MAR1999	NOT HISPANIC OR LATINO	133.3	186.4	
9025	50/M/W	28APR1969	NOT HISPANIC OR LATINO	123.5	175.5	
9033	32/M/W	10DEC1986	HISPANIC OR LATINO	148.0	172.7	
9043	22/M/BL	19MAR1997	NOT HISPANIC OR LATINO	158.9	186.4	
9046	34/M/BL	19FEB1985	NOT HISPANIC OR LATINO	121.3	190.4	
9051	34/M/BL	23JUN1985	NOT HISPANIC OR LATINO	130.0	182.0	
9052	42/M/BL	31JUL1977	NOT HISPANIC OR LATINO	121.6	179.4	
9056	31/F/BL	23OCT1987	NOT HISPANIC OR LATINO	120.9	171.0	POTENTIALLY ABLE TO BEAR CHILDREN/ BARRIER WITH SPERMICIDE

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] Reproductive status and methods of birth control are presented for female subjects only.
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Listing 16.2.4.1
Demographics
Safety Population

Subject ID	Age(yrs)/ Sex/Race	Birth Date	Ethnicity	Weight (kg)	Height (cm)	Reproductive Status/ Methods of Birth Control [1]
9057	29/F/W	30MAY1990	HISPANIC OR LATINO	127.6	151.2	POTENTIALLY ABLE TO BEAR CHILDREN/ BARRIER WITH SPERMICIDE
9058	32/M/W	31MAY1987	NOT HISPANIC OR LATINO	121.3	185.9	
9061	21/F/BL	11APR1998	NOT HISPANIC OR LATINO	127.2	169.8	POTENTIALLY ABLE TO BEAR CHILDREN/ ABSTINENCE
9062	33/M/BL	09MAY1986	NOT HISPANIC OR LATINO	131.9	173.5	
9063	35/M/W	22APR1984	NOT HISPANIC OR LATINO	120.3	189.0	
9069	41/F/BL	14JAN1978	NOT HISPANIC OR LATINO	151.4	160.0	STERILE
9073	40/M/BL	11SEP1979	NOT HISPANIC OR LATINO	161.5	182.5	
9077	37/F/W	31DEC1981	NOT HISPANIC OR LATINO	125.7	167.4	POTENTIALLY ABLE TO BEAR CHILDREN/ BARRIER WITH SPERMICIDE
9080	41/F/BL	19MAR1978	NOT HISPANIC OR LATINO	121.2	161.8	STERILE
9081	49/M/BL	19FEB1970	NOT HISPANIC OR LATINO	220.4	192.0	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] Reproductive status and methods of birth control are presented for female subjects only.
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Listing 16.2.4.1
Demographics
Safety Population

Subject ID	Age(yrs)/ Sex/Race	Birth Date	Ethnicity	Weight (kg)	Height (cm)	Reproductive Status/ Methods of Birth Control [1]
9086	36/M/BL	26SEP1983	NOT HISPANIC OR LATINO	139.9	186.4	
9087	34/F/BL	14AUG1985	NOT HISPANIC OR LATINO	123.0	167.2	POTENTIALLY ABLE TO BEAR CHILDREN/ ABSTINENCE
9089	29/M/BL	30SEP1990	NOT HISPANIC OR LATINO	122.0	167.9	
9092	24/M/W	29JAN1995	HISPANIC OR LATINO	168.6	176.5	
9095	42/M/W	18AUG1977	NOT HISPANIC OR LATINO	148.6	176.6	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] Reproductive status and methods of birth control are presented for female subjects only.
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Listing 16.2.4.2
Medical History
Safety Population

Subject ID	Age(yrs)/ Sex/Race	MH ID	System Organ Class/ Preferred Term / Verbatim term of Medical Condition(s)	Start Date	End date	Ongoing
9002	48/M/W	1	Infections and infestations/ Tinea versicolour/ TINEA VERSICOLOR	2017		Yes
9012	34/M/BL	1	Surgical and medical procedures/ Open reduction of fracture/ LEFT FEMUR FRACTURE OPEN REDUCTION AND INTERNAL FIXATION	MAY1998	MAY1998	No
		2	Injury, poisoning and procedural complications/ Femur fracture/ LEFT FEMUR FRACTURE	MAY1998	MAY1998	No
		3	Surgical and medical procedures/ Vasectomy/ VASECTOMY	07FEB2019	07FEB2019	No
9016	48/F/W	1	Injury, poisoning and procedural complications/ Ankle fracture/ LEFT BROKEN ANKLE	OCT2011	OCT2011	No

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other. Medical History was coded using MedDRA version 22.0.
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.4.2
Medical History
Safety Population

Subject ID	Age(yrs)/ Sex/Race	MH ID	System Organ Class/ Preferred Term / Verbatim term of Medical Condition(s)	Start Date	End date	Ongoing
9016	48/F/W	2	Surgical and medical procedures/ Open reduction of fracture/ LEFT ANKLE OPEN REDUCTION AND INTERNAL FIXATION	OCT2011	OCT2011	No
9019	41/M/BL	1	Musculoskeletal and connective tissue disorders/ Osteoarthritis/ MILD RIGHT KNEE OSTEOARTHRITIS	03SEP2019	11SEP2019	No
9020	47/F/BL	1	Surgical and medical procedures/ Hysterectomy/ HYSTERECTOMY	2017	2017	No
9022	31/M/W	1	Surgical and medical procedures/ Ligament operation/ RIGHT ANTERIOR CRUCIATE LIGAMENT REPAIR	MAY2010	MAY2010	No
		2	Injury, poisoning and procedural complications/ Ligament rupture/ RIGHT ANTERIOR CRUCIATE LIGAMENT TEAR	MAY2010	MAY2010	No

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other. Medical History was coded using MedDRA version 22.0.
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.4.2
Medical History
Safety Population

Subject ID	Age(yrs)/ Sex/Race	MH ID	System Organ Class/ Preferred Term / Verbatim term of Medical Condition(s)	Start Date	End date	Ongoing
9025	50/M/W	1	Skin and subcutaneous tissue disorders/ Eczema/ REMOTE ECZEMA	2004	2004	No
		2	Investigations/ Medical observation/ OVERNIGHT OBSERVATION-NEGATIVE WORKUP FOR MENINGITIS	1993	1993	No
		3	Immune system disorders/ Seasonal allergy/ SEASONAL ALLERGIES	1994		Yes
9043	22/M/BL	1	Infections and infestations/ Meningitis/ IMMEDIATE POSTNATAL PERIOD HOSPITALIZATION FOR MENINGITIS	19MAR1997	19MAR1997	No
9046	34/M/BL	1	Investigations/ Arthroscopy/ LEFT KNEE ARTHROSCOPY	APR2005	APR2005	No
		2	Surgical and medical procedures/ Tenoplasty/ RIGHT INDEX FINGER TENDON REPAIR	JAN2011	JAN2011	No

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other. Medical History was coded using MedDRA version 22.0.
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.4.2
Medical History
Safety Population

Subject ID	Age(yrs)/ Sex/Race	MH ID	System Organ Class/ Preferred Term / Verbatim term of Medical Condition(s)	Start Date	End date	Ongoing
9046	34/M/BL	3	Investigations/ Arthroscopy/ LEFT KNEE ARTHROSCOPY	OCT2005	OCT2005	No
9056	31/F/BL	1	Surgical and medical procedures/ Caesarean section/ CESAREAN SECTION	11DEC2008	11DEC2008	No
9057	29/F/W	1	Surgical and medical procedures/ Appendicectomy/ APPENDECTOMY	SEP2001	SEP2001	No
		2	Infections and infestations/ Appendicitis/ APPENDICITIS	SEP2001	SEP2001	No
		3	Reproductive system and breast disorders/ Menstruation irregular/ IRREGULAR MENSTRUAL CYCLES	OCT2013		Yes
9069	41/F/BL	1	Surgical and medical procedures/ Caesarean section/ CESAREAN SECTION	31MAR2008	31MAR2008	No

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other. Medical History was coded using MedDRA version 22.0.
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.4.2
Medical History
Safety Population

Subject ID	Age(yrs)/ Sex/Race	MH ID	System Organ Class/ Preferred Term / Verbatim term of Medical Condition(s)	Start Date	End date	Ongoing
9069	41/F/BL	2	Surgical and medical procedures/ Female sterilisation/ BILATERAL TUBAL LIGATION	31MAR2008	31MAR2008	No
		3	Skin and subcutaneous tissue disorders/ Drug eruption/ RASH WITH ORAL FLAGYL	MAY2001		Yes
		4	Musculoskeletal and connective tissue disorders/ Back pain/ BACK PAIN	MAY2018	FEB2019	No
9077	37/F/W	1	Surgical and medical procedures/ Caesarean section/ CESAREAN SECTION	19JAN2010	19JAN2010	No
		2	Surgical and medical procedures/ Caesarean section/ CESAREAN SECTION	27DEC2010	27DEC2010	No
9080	41/F/BL	1	Surgical and medical procedures/ Female sterilisation/ BILATERAL TUBAL LIGATION	AUG2001	AUG2001	No

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other. Medical History was coded using MedDRA version 22.0.
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.4.2
Medical History
Safety Population

Subject ID	Age(yrs)/ Sex/Race	MH ID	System Organ Class/ Preferred Term / Verbatim term of Medical Condition(s)	Start Date	End date	Ongoing
9080	41/F/BL	2	Surgical and medical procedures/ Endometrial ablation/ UTERINE ABLATION	MAY2005	MAY2005	No
		3	Reproductive system and breast disorders/ Menorrhagia/ MENORRHAGIA	AUG2001	MAY2005	No
9081	49/M/BL	1	Surgical and medical procedures/ Knee arthroplasty/ LEFT KNEE RECONSTRUCTION	FEB2014	FEB2014	No
		2	Surgical and medical procedures/ Appendicectomy/ APPENDECTOMY	1982	1982	No
		3	Infections and infestations/ Appendicitis/ APPENDICITIS	1982	1982	No
		4	Surgical and medical procedures/ Knee operation/ REPAIR OF PATELLA	FEB2014	FEB2014	No

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other. Medical History was coded using MedDRA version 22.0.
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.4.2
Medical History
Safety Population

Subject ID	Age(yrs)/ Sex/Race	MH ID	System Organ Class/ Preferred Term / Verbatim term of Medical Condition(s)	Start Date	End date	Ongoing
9081	49/M/BL	5	Surgical and medical procedures/ Peripheral nerve operation/ REPAIR OF FOOT DROP	FEB2014	FEB2014	No
		6	Musculoskeletal and connective tissue disorders/ Arthralgia/ LEFT KNEE PAIN	11OCT2019	11OCT2019	No
		7	Vascular disorders/ Lymphoedema/ LEFT LEG LYMPHEDEMA 2/2 ORTHOPEDIC SURGERY TO THAT LIMB	FEB2014		Yes
9086	36/M/BL	1	Surgical and medical procedures/ Cyst removal/ REMOVAL OF BENIGN CYST FROM RIGHT CHEST WALL FOR COSMETIC REASONS	1991	1991	No
		2	Musculoskeletal and connective tissue disorders/ Chest wall cyst/ BENIGN CYST ON RIGHT CHEST WALL	1991	1991	No

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other. Medical History was coded using MedDRA version 22.0.
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.4.2
Medical History
Safety Population

Subject ID	Age(yrs)/ Sex/Race	MH ID	System Organ Class/ Preferred Term / Verbatim term of Medical Condition(s)	Start Date	End date	Ongoing
9095	42/M/W	1	Immune system disorders/ Seasonal allergy/ SEASONAL ALLERGIES	SEP2012		Yes

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other. Medical History was coded using MedDRA version 22.0.
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.4.3
Prior and Concomitant Medications
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	CM ID	ATC Level 4 [1]/ Preferred Term/ Medication Reported/ Indication	Prior to Study	Start Date Time (Day)/ Stop Date Time (Day)	Ongoing/ Dose	Route/ Freq	Assoc. AE/ MH IDs [2]
9005	40/M/W	1	VITAMIN D AND ANALOGUES/ COLECALCIFEROL/ VITAMIN D3/ IMPROVE BODY	YES	04JUN2019 (-71)/ 30JUL2019 (-15)	NO/ 2 UNKNOWN	ORAL/ QD	
		2	OTHER PLAIN VITAMIN PREPARATIONS/ BIOTIN/ BIOTIN/ IMPROVE HAIR, SKIN	YES	04JUN2019 (-71)/ 30JUL2019 (-15)	NO/ 3000 ug	ORAL/ QD	
9016	48/F/W	1	PROPIONIC ACID DERIVATIVES/ IBUPROFEN/ IBUPROFEN/ MENSTRUAL SYMPTOMS	YES	05AUG2019 (-30)/ 09AUG2019 (-26)	NO/ 800 mg	ORAL/ QD	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Prior and concomitant medications were coded with the WHODD version March 2019 Global B3.
Day = The presented date — First dose date + 1
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] If ATC Level 4 description is not available, ATC Level 3 will be used. If ATC Level 3 is also not available, ATC Level 2 will be used.
[2] Associated adverse events or medical history conditions for which the medication was taken. Assoc.=Associated, AE=Adverse event, MH=Medical history, ID=Identification.
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Listing 16.2.4.3
Prior and Concomitant Medications
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	CM ID	ATC Level 4 [1]/ Preferred Term/ Medication Reported/ Indication	Prior to Study	Start Date Time (Day)/ Stop Date Time (Day)	Ongoing/ Dose	Route/ Freq	Assoc. AE/ MH IDs [2]
9021	39/F/BL	1	UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE/ PRUNUS SPP./ PRUNE JUICE/ DECREASED FREQUENCY OF BOWEL MOVEMENT	NO	10SEP2019 15:06 (7)/ 10SEP2019 15:06 (7)	NO/ 1 oz	ORAL/ ONCE	AE ID:3
		2	UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE/ PRUNUS SPP./ PRUNE JUICE/ DECREASED FREQUENCY OF BOWEL MOVEMENT	NO	10SEP2019 15:50 (7)/ 11SEP2019 17:41 (8)	NO/ 1 oz	ORAL/ PRN	AE ID:3
9025	50/M/W	1	SUBSTITUTED ALKYLAMINES/ CHLORPHENAMINE MALEATE/ CHLORTRIMETON/ ALLERGIES	YES	FEB2019/ 21AUG2019 (-28)	NO/ 4 mg	ORAL/ BID	MH ID:3

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Prior and concomitant medications were coded with the WHODD version March 2019 Global B3.
Day = The presented date − First dose date + 1
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] If ATC Level 4 description is not available, ATC Level 3 will be used. If ATC Level 3 is also not available, ATC Level 2 will be used.
[2] Associated adverse events or medical history conditions for which the medication was taken. Assoc.=Associated, AE=Adverse event, MH=Medical history, ID=Identification.
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Listing 16.2.4.3
Prior and Concomitant Medications
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	CM ID	ATC Level 4 [1]/ Preferred Term/ Medication Reported/ Indication	Prior to Study	Start Date Time (Day)/ Stop Date Time (Day)	Ongoing/ Dose	Route/ Freq	Assoc. AE/ MH IDs [2]
9025	50/M/W	2	AMINO ACIDS, INCL. COMBINATIONS WITH POLYPEPTIDES/ LYSINE/ LYSINE/ SUPPLEMENT	YES	FEB2019/ 21AUG2019 (-28)	NO/ 500 mg	ORAL/ QD	
		3	PROPIONIC ACID DERIVATIVES/ IBUPROFEN/ IBUPROFEN/ HEADACHE	YES	FEB2019/ 21APR2019 (-150)	NO/ 400 mg	ORAL/ PRN	
		4	SUBSTITUTED ALKYLAMINES/ CHLORPHENAMINE MALEATE/ CHLORTRIMETON/ SEASONAL ALLERGIES	NO	28SEP2019 07:00 (11)/	YES/ 4 mg	ORAL/ BID	MH ID:3

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Prior and concomitant medications were coded with the WHODD version March 2019 Global B3.
Day = The presented date − First dose date + 1
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] If ATC Level 4 description is not available, ATC Level 3 will be used. If ATC Level 3 is also not available, ATC Level 2 will be used.
[2] Associated adverse events or medical history conditions for which the medication was taken. Assoc.=Associated, AE=Adverse event, MH=Medical history, ID=Identification.
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Listing 16.2.4.3
Prior and Concomitant Medications
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	CM ID	ATC Level 4 [1]/ Preferred Term/ Medication Reported/ Indication	Prior to Study	Start Date Time (Day)/ Stop Date Time (Day)	Ongoing/ Dose	Route/ Freq	Assoc. AE/ MH IDs [2]
9058	32/M/W	1	OTHER DERMATOLOGICALS/ FINASTERIDE/ FINASTERIDE/ PROPHLAXIS HAIR GROWTH	YES	01DEC2017 (-684)/ 22SEP2019 (-24)	NO/ 1 mg	ORAL/ QD	
9061	21/F/BL	1	ANILIDES/ PARACETAMOL/ TYLENOL/ MENSTRUAL CRAMPS	YES	21SEP2019 (-25)/ 21SEP2019 (-25)	NO/ 200 mg	ORAL/ ONCE	
		2	NITROFURAN DERIVATIVES/ NITROFURANTOIN/ NITROFURANTOIN-MON O/ URINARY TRACT INFECTION	NO	04NOV2019 00:00 (20)/ 11NOV2019 12:00 (27)	NO/ 1 CAPSULE	ORAL/ Q12H	AE ID:1

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Prior and concomitant medications were coded with the WHODD version March 2019 Global B3.
Day = The presented date — First dose date + 1
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] If ATC Level 4 description is not available, ATC Level 3 will be used. If ATC Level 3 is also not available, ATC Level 2 will be used.
[2] Associated adverse events or medical history conditions for which the medication was taken. Assoc.=Associated, AE=Adverse event, MH=Medical history, ID=Identification.
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Listing 16.2.4.3
Prior and Concomitant Medications
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	CM ID	ATC Level 4 [1]/ Preferred Term/ Medication Reported/ Indication	Prior to Study	Start Date Time (Day)/ Stop Date Time (Day)	Ongoing/ Dose	Route/ Freq	Assoc. AE/ MH IDs [2]
9069	41/F/BL	1	OTHER OPIOIDS/ TRAMADOL/ TRAMADOL/ BACK PAIN	YES	29SEP2019 (-17)/ 29SEP2019 (-17)	NO/ 35 mg	ORAL/ ONCE	MH ID:4
9081	49/M/BL	1	MULTIVITAMINS WITH MINERALS/ MINERALS NOS;VITAMINS NOS/ CENTRUM 1 A DAY/ HEALTH	YES	26SEP2019 (-34)/ 06OCT2019 (-24)	NO/ 220 mg	ORAL/ QD	
		2	PROPIONIC ACID DERIVATIVES/ NAPROXEN SODIUM/ ALEVE/ LEFT KNEE PAIN	NO	11OCT2019 (-19)/ 11OCT2019 (-19)	NO/ 200 mg	ORAL/ ONCE	MH ID:6

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Prior and concomitant medications were coded with the WHODD version March 2019 Global B3.
Day = The presented date — First dose date + 1
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] If ATC Level 4 description is not available, ATC Level 3 will be used. If ATC Level 3 is also not available, ATC Level 2 will be used.
[2] Associated adverse events or medical history conditions for which the medication was taken. Assoc.=Associated, AE=Adverse event, MH=Medical history, ID=Identification.
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Listing 16.2.4.3
Prior and Concomitant Medications
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	CM ID	ATC Level 4 [1]/ Preferred Term/ Medication Reported/ Indication	Prior to Study	Start Date Time (Day)/ Stop Date Time (Day)	Ongoing/ Dose	Route/ Freq	Assoc. AE/ MH IDs [2]
9095	42/M/W	1	OTHER ANTIHISTAMINES FOR SYSTEMIC USE/ LORATADINE/ LORATADINE/ SEASONAL ALLERGIES	NO	10NOV2019 22:00 (12)/ 04DEC2019 22:00 (36)	NO/ 5 mg	ORAL/ QD	MH ID:1

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Prior and concomitant medications were coded with the WHODD version March 2019 Global B3.
Day = The presented date − First dose date + 1
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] If ATC Level 4 description is not available, ATC Level 3 will be used. If ATC Level 3 is also not available, ATC Level 2 will be used.
[2] Associated adverse events or medical history conditions for which the medication was taken. Assoc.=Associated, AE=Adverse event, MH=Medical history, ID=Identification.
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Listing 16.2.4.4
Medical and Surgical Treatment Procedures
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment Procedure	Indication	AE ID	Start Date	End Date	Ongoing
9025	50/M/W	AD HOC SAFETY - OBSERVATION	Other: FREQUENT PVCS		18SEP2019	19SEP2019	NO
		RHYTHM STRIPS	Other: ASSESS FREQUENCY OF PVC'S		18SEP2019	18SEP2019	NO

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart. Medical and Surgical Treatment Procedures were coded using MedDRA version 22.0.
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16.2.5 Compliance and/or Drug Concentration Data

Listing 16.2.5.1
Study Drug Administration
Safety Population

Subject ID/ Age(yrs)/ Sex/Race	Visit - Timepoint	Treatment Date/Time (Day)	Dose (Units)	Route/Freq	Dose Adjusted/ Reason
9001/ 41/M/BL	Day 1-AM	14AUG2019 09:25 (1)	600 (mg)	ORAL/BID	NO
	Day 1-PM	14AUG2019 21:25 (1)	600 (mg)	ORAL/BID	NO
	Day 2-AM	15AUG2019 09:29 (2)	600 (mg)	ORAL/BID	NO
	Day 2-PM	15AUG2019 21:25 (2)	600 (mg)	ORAL/BID	NO
	Day 3-AM	16AUG2019 09:25 (3)	600 (mg)	ORAL/BID	NO
	Day 3-PM	16AUG2019 21:25 (3)	600 (mg)	ORAL/BID	NO
	Day 4-AM	17AUG2019 09:26 (4)	600 (mg)	ORAL/BID	NO
	Day 4-PM	17AUG2019 21:25 (4)	600 (mg)	ORAL/BID	NO
	Day 5-AM	18AUG2019 09:25 (5)	600 (mg)	ORAL/BID	NO
	Day 5-PM	18AUG2019 21:25 (5)	600 (mg)	ORAL/BID	NO
	Day 6-AM	19AUG2019 09:25 (6)	600 (mg)	ORAL/BID	NO
	Day 6-PM	19AUG2019 21:25 (6)	600 (mg)	ORAL/BID	NO
	Day 7-AM	20AUG2019 09:25 (7)	600 (mg)	ORAL/BID	NO
	Day 7-PM	20AUG2019 21:25 (7)	600 (mg)	ORAL/BID	NO
9002/ 48/M/W	Day 1-AM	14AUG2019 09:24 (1)	600 (mg)	ORAL/BID	NO
	Day 1-PM	14AUG2019 21:24 (1)	600 (mg)	ORAL/BID	NO
	Day 2-AM	15AUG2019 09:26 (2)	600 (mg)	ORAL/BID	NO
	Day 2-PM	15AUG2019 21:24 (2)	600 (mg)	ORAL/BID	NO
	Day 3-AM	16AUG2019 09:24 (3)	600 (mg)	ORAL/BID	NO
	Day 3-PM	16AUG2019 21:24 (3)	600 (mg)	ORAL/BID	NO

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Freq=Frequency;
Day = The presented date — First dose date + 1
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.5.1
Study Drug Administration
Safety Population

Subject ID/ Age(yrs)/ Sex/Race	Visit - Timepoint	Treatment Date/Time (Day)	Dose (Units)	Route/Freq	Dose Adjusted/ Reason
9002/ 48/M/W	Day 4-AM	17AUG2019 09:25 (4)	600 (mg)	ORAL/BID	NO
	Day 4-PM	17AUG2019 21:24 (4)	600 (mg)	ORAL/BID	NO
	Day 5-AM	18AUG2019 09:24 (5)	600 (mg)	ORAL/BID	NO
	Day 5-PM	18AUG2019 21:24 (5)	600 (mg)	ORAL/BID	NO
	Day 6-AM	19AUG2019 09:31 (6)	600 (mg)	ORAL/BID	NO
	Day 6-PM	19AUG2019 21:24 (6)	600 (mg)	ORAL/BID	NO
	Day 7-AM	20AUG2019 09:27 (7)	600 (mg)	ORAL/BID	NO
	Day 7-PM	20AUG2019 21:24 (7)	600 (mg)	ORAL/BID	NO
9005/ 40/M/W	Day 1-AM	14AUG2019 09:02 (1)	600 (mg)	ORAL/BID	NO
	Day 1-PM	14AUG2019 21:02 (1)	600 (mg)	ORAL/BID	NO
	Day 2-AM	15AUG2019 09:02 (2)	600 (mg)	ORAL/BID	NO
	Day 2-PM	15AUG2019 21:02 (2)	600 (mg)	ORAL/BID	NO
	Day 3-AM	16AUG2019 09:02 (3)	600 (mg)	ORAL/BID	NO
	Day 3-PM	16AUG2019 21:02 (3)	600 (mg)	ORAL/BID	NO
	Day 4-AM	17AUG2019 09:02 (4)	600 (mg)	ORAL/BID	NO
	Day 4-PM	17AUG2019 21:02 (4)	600 (mg)	ORAL/BID	NO
	Day 5-AM	18AUG2019 09:02 (5)	600 (mg)	ORAL/BID	NO
	Day 5-PM	18AUG2019 21:02 (5)	600 (mg)	ORAL/BID	NO
	Day 6-AM	19AUG2019 09:02 (6)	600 (mg)	ORAL/BID	NO
	Day 6-PM	19AUG2019 21:02 (6)	600 (mg)	ORAL/BID	NO

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Freq=Frequency;
Day = The presented date — First dose date + 1
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.5.1
Study Drug Administration
Safety Population

Subject ID/ Age(yrs)/ Sex/Race	Visit - Timepoint	Treatment Date/Time (Day)	Dose (Units)	Route/Freq	Dose Adjusted/ Reason
9005/ 40/M/W	Day 7-AM	20AUG2019 09:02 (7)	600 (mg)	ORAL/BID	NO
	Day 7-PM	20AUG2019 21:02 (7)	600 (mg)	ORAL/BID	NO
9009/ 21/F/BL	Day 1-AM	14AUG2019 09:06 (1)	600 (mg)	ORAL/BID	NO
	Day 1-PM	14AUG2019 21:06 (1)	600 (mg)	ORAL/BID	NO
	Day 2-AM	15AUG2019 09:06 (2)	600 (mg)	ORAL/BID	NO
	Day 2-PM	15AUG2019 21:06 (2)	600 (mg)	ORAL/BID	NO
	Day 3-AM	16AUG2019 09:06 (3)	600 (mg)	ORAL/BID	NO
	Day 3-PM	16AUG2019 21:06 (3)	600 (mg)	ORAL/BID	NO
	Day 4-AM	17AUG2019 09:06 (4)	600 (mg)	ORAL/BID	NO
	Day 4-PM	17AUG2019 21:06 (4)	600 (mg)	ORAL/BID	NO
	Day 5-AM	18AUG2019 09:06 (5)	600 (mg)	ORAL/BID	NO
	Day 5-PM	18AUG2019 21:06 (5)	600 (mg)	ORAL/BID	NO
	Day 6-AM	19AUG2019 09:06 (6)	600 (mg)	ORAL/BID	NO
	Day 6-PM	19AUG2019 21:06 (6)	600 (mg)	ORAL/BID	NO
	Day 7-AM	20AUG2019 09:06 (7)	600 (mg)	ORAL/BID	NO
	Day 7-PM	20AUG2019 21:06 (7)	600 (mg)	ORAL/BID	NO
9012/ 34/M/BL	Day 1-AM	14AUG2019 09:10 (1)	600 (mg)	ORAL/BID	NO
	Day 1-PM	14AUG2019 21:10 (1)	600 (mg)	ORAL/BID	NO

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Freq=Frequency;
Day = The presented date — First dose date + 1
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.5.1
Study Drug Administration
Safety Population

Subject ID/ Age(yrs)/ Sex/Race	Visit - Timepoint	Treatment Date/Time (Day)	Dose (Units)	Route/Freq	Dose Adjusted/ Reason
9012/ 34/M/BL	Day 2-AM	15AUG2019 09:14 (2)	600 (mg)	ORAL/BID	NO
	Day 2-PM	15AUG2019 21:10 (2)	600 (mg)	ORAL/BID	NO
	Day 3-AM	16AUG2019 09:10 (3)	600 (mg)	ORAL/BID	NO
	Day 3-PM	16AUG2019 21:10 (3)	600 (mg)	ORAL/BID	NO
	Day 4-AM	17AUG2019 09:10 (4)	600 (mg)	ORAL/BID	NO
	Day 4-PM	17AUG2019 21:10 (4)	600 (mg)	ORAL/BID	NO
	Day 5-AM	18AUG2019 09:10 (5)	600 (mg)	ORAL/BID	NO
	Day 5-PM	18AUG2019 21:10 (5)	600 (mg)	ORAL/BID	NO
	Day 6-AM	19AUG2019 09:10 (6)	600 (mg)	ORAL/BID	NO
	Day 6-PM	19AUG2019 21:10 (6)	600 (mg)	ORAL/BID	NO
	Day 7-AM	20AUG2019 09:10 (7)	600 (mg)	ORAL/BID	NO
	Day 7-PM	20AUG2019 21:10 (7)	600 (mg)	ORAL/BID	NO
9015/ 29/M/BL	Day 1-AM	14AUG2019 09:08 (1)	600 (mg)	ORAL/BID	NO
	Day 1-PM	14AUG2019 21:08 (1)	600 (mg)	ORAL/BID	NO
	Day 2-AM	15AUG2019 09:08 (2)	600 (mg)	ORAL/BID	NO
	Day 2-PM	15AUG2019 21:08 (2)	600 (mg)	ORAL/BID	NO
	Day 3-AM	16AUG2019 09:08 (3)	600 (mg)	ORAL/BID	NO
	Day 3-PM	16AUG2019 21:08 (3)	600 (mg)	ORAL/BID	NO
	Day 4-AM	17AUG2019 09:08 (4)	600 (mg)	ORAL/BID	NO
	Day 4-PM	17AUG2019 21:08 (4)	600 (mg)	ORAL/BID	NO

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Freq=Frequency;
Day = The presented date — First dose date + 1
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.5.1
Study Drug Administration
Safety Population

Subject ID/ Age(yrs)/ Sex/Race	Visit - Timepoint	Treatment Date/Time (Day)	Dose (Units)	Route/Freq	Dose Adjusted/ Reason
9015/ 29/M/BL	Day 5-AM	18AUG2019 09:08 (5)	600 (mg)	ORAL/BID	NO
	Day 5-PM	18AUG2019 21:08 (5)	600 (mg)	ORAL/BID	NO
	Day 6-AM	19AUG2019 09:08 (6)	600 (mg)	ORAL/BID	NO
	Day 6-PM	19AUG2019 21:08 (6)	600 (mg)	ORAL/BID	NO
	Day 7-AM	20AUG2019 09:08 (7)	600 (mg)	ORAL/BID	NO
	Day 7-PM	20AUG2019 21:08 (7)	600 (mg)	ORAL/BID	NO
9016/ 48/F/W	Day 1-AM	04SEP2019 08:00 (1)	600 (mg)	ORAL/BID	NO
	Day 1-PM	04SEP2019 20:00 (1)	600 (mg)	ORAL/BID	NO
	Day 2-AM	05SEP2019 08:00 (2)	600 (mg)	ORAL/BID	NO
	Day 2-PM	05SEP2019 20:00 (2)	600 (mg)	ORAL/BID	NO
	Day 3-AM	06SEP2019 08:00 (3)	600 (mg)	ORAL/BID	NO
	Day 3-PM	06SEP2019 20:00 (3)	600 (mg)	ORAL/BID	NO
	Day 4-AM	07SEP2019 08:00 (4)	600 (mg)	ORAL/BID	NO
	Day 4-PM	07SEP2019 20:00 (4)	600 (mg)	ORAL/BID	NO
	Day 5-AM	08SEP2019 08:00 (5)	600 (mg)	ORAL/BID	NO
	Day 5-PM	08SEP2019 20:00 (5)	600 (mg)	ORAL/BID	NO
	Day 6-AM	09SEP2019 08:00 (6)	600 (mg)	ORAL/BID	NO
	Day 6-PM	09SEP2019 20:00 (6)	600 (mg)	ORAL/BID	NO
	Day 7-AM	10SEP2019 08:00 (7)	600 (mg)	ORAL/BID	NO
	Day 7-PM	10SEP2019 20:00 (7)	600 (mg)	ORAL/BID	NO

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Freq=Frequency;
Day = The presented date — First dose date + 1
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.5.1
Study Drug Administration
Safety Population

Subject ID/ Age(yrs)/ Sex/Race	Visit - Timepoint	Treatment Date/Time (Day)	Dose (Units)	Route/Freq	Dose Adjusted/ Reason
9019/ 41/M/BL	Day 1-AM	04SEP2019 08:03 (1)	600 (mg)	ORAL/BID	NO
	Day 1-PM	04SEP2019 20:03 (1)	600 (mg)	ORAL/BID	NO
	Day 2-AM	05SEP2019 08:09 (2)	600 (mg)	ORAL/BID	NO
	Day 2-PM	05SEP2019 20:06 (2)	600 (mg)	ORAL/BID	NO
	Day 3-AM	06SEP2019 08:03 (3)	600 (mg)	ORAL/BID	NO
	Day 3-PM	06SEP2019 20:03 (3)	600 (mg)	ORAL/BID	NO
	Day 4-AM	07SEP2019 08:09 (4)	600 (mg)	ORAL/BID	NO
	Day 4-PM	07SEP2019 20:03 (4)	600 (mg)	ORAL/BID	NO
	Day 5-AM	08SEP2019 08:03 (5)	600 (mg)	ORAL/BID	NO
	Day 5-PM	08SEP2019 20:03 (5)	600 (mg)	ORAL/BID	NO
	Day 6-AM	09SEP2019 08:03 (6)	600 (mg)	ORAL/BID	NO
	Day 6-PM	09SEP2019 20:03 (6)	600 (mg)	ORAL/BID	NO
	Day 7-AM	10SEP2019 08:03 (7)	600 (mg)	ORAL/BID	NO
	Day 7-PM	10SEP2019 20:03 (7)	600 (mg)	ORAL/BID	NO
9020/ 47/F/BL	Day 1-AM	04SEP2019 08:06 (1)	600 (mg)	ORAL/BID	NO
	Day 1-PM	04SEP2019 20:06 (1)	600 (mg)	ORAL/BID	NO
	Day 2-AM	05SEP2019 08:06 (2)	600 (mg)	ORAL/BID	NO
	Day 2-PM	05SEP2019 20:06 (2)	600 (mg)	ORAL/BID	NO
	Day 3-AM	06SEP2019 08:06 (3)	600 (mg)	ORAL/BID	NO
	Day 3-PM	06SEP2019 20:06 (3)	600 (mg)	ORAL/BID	NO

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Freq=Frequency;
Day = The presented date — First dose date + 1
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.5.1
Study Drug Administration
Safety Population

Subject ID/ Age(yrs)/ Sex/Race	Visit - Timepoint	Treatment Date/Time (Day)	Dose (Units)	Route/Freq	Dose Adjusted/ Reason
9020/ 47/F/BL	Day 4-AM	07SEP2019 08:06 (4)	600 (mg)	ORAL/BID	NO
	Day 4-PM	07SEP2019 20:06 (4)	600 (mg)	ORAL/BID	NO
	Day 5-AM	08SEP2019 08:06 (5)	600 (mg)	ORAL/BID	NO
	Day 5-PM	08SEP2019 20:06 (5)	600 (mg)	ORAL/BID	NO
	Day 6-AM	09SEP2019 08:06 (6)	600 (mg)	ORAL/BID	NO
	Day 6-PM	09SEP2019 20:06 (6)	600 (mg)	ORAL/BID	NO
	Day 7-AM	10SEP2019 08:06 (7)	600 (mg)	ORAL/BID	NO
	Day 7-PM	10SEP2019 20:06 (7)	600 (mg)	ORAL/BID	NO
9021/ 39/F/BL	Day 1-AM	04SEP2019 08:09 (1)	600 (mg)	ORAL/BID	NO
	Day 1-PM	04SEP2019 20:09 (1)	600 (mg)	ORAL/BID	NO
	Day 2-AM	05SEP2019 08:12 (2)	600 (mg)	ORAL/BID	NO
	Day 2-PM	05SEP2019 20:09 (2)	600 (mg)	ORAL/BID	NO
	Day 3-AM	06SEP2019 08:09 (3)	600 (mg)	ORAL/BID	NO
	Day 3-PM	06SEP2019 20:09 (3)	600 (mg)	ORAL/BID	NO
	Day 4-AM	07SEP2019 08:09 (4)	600 (mg)	ORAL/BID	NO
	Day 4-PM	07SEP2019 20:09 (4)	600 (mg)	ORAL/BID	NO
	Day 5-AM	08SEP2019 08:09 (5)	600 (mg)	ORAL/BID	NO
	Day 5-PM	08SEP2019 20:09 (5)	600 (mg)	ORAL/BID	NO
	Day 6-AM	09SEP2019 08:09 (6)	600 (mg)	ORAL/BID	NO
	Day 6-PM	09SEP2019 20:09 (6)	600 (mg)	ORAL/BID	NO

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Freq=Frequency;
Day = The presented date — First dose date + 1
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.5.1
Study Drug Administration
Safety Population

Subject ID/ Age(yrs)/ Sex/Race	Visit - Timepoint	Treatment Date/Time (Day)	Dose (Units)	Route/Freq	Dose Adjusted/ Reason
9021/ 39/F/BL	Day 7-AM	10SEP2019 08:09 (7)	600 (mg)	ORAL/BID	NO
	Day 7-PM	10SEP2019 20:09 (7)	600 (mg)	ORAL/BID	NO
9022/ 31/M/W	Day 1-AM	04SEP2019 08:12 (1)	600 (mg)	ORAL/BID	NO
	Day 1-PM	04SEP2019 20:12 (1)	600 (mg)	ORAL/BID	NO
	Day 2-AM	05SEP2019 08:12 (2)	600 (mg)	ORAL/BID	NO
	Day 2-PM	05SEP2019 20:12 (2)	600 (mg)	ORAL/BID	NO
	Day 3-AM	06SEP2019 08:12 (3)	600 (mg)	ORAL/BID	NO
	Day 3-PM	06SEP2019 20:12 (3)	600 (mg)	ORAL/BID	NO
	Day 4-AM	07SEP2019 08:18 (4)	600 (mg)	ORAL/BID	NO
	Day 4-PM	07SEP2019 20:12 (4)	600 (mg)	ORAL/BID	NO
	Day 5-AM	08SEP2019 08:12 (5)	600 (mg)	ORAL/BID	NO
	Day 5-PM	08SEP2019 20:12 (5)	600 (mg)	ORAL/BID	NO
	Day 6-AM	09SEP2019 08:12 (6)	600 (mg)	ORAL/BID	NO
	Day 6-PM	09SEP2019 20:12 (6)	600 (mg)	ORAL/BID	NO
	Day 7-AM	10SEP2019 08:12 (7)	600 (mg)	ORAL/BID	NO
	Day 7-PM	10SEP2019 20:12 (7)	600 (mg)	ORAL/BID	NO
9024/ 20/M/BL	Day 1-AM	04SEP2019 08:15 (1)	600 (mg)	ORAL/BID	NO
	Day 1-PM	04SEP2019 20:15 (1)	600 (mg)	ORAL/BID	NO

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Freq=Frequency;
Day = The presented date — First dose date + 1
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.5.1
Study Drug Administration
Safety Population

Subject ID/ Age(yrs)/ Sex/Race	Visit - Timepoint	Treatment Date/Time (Day)	Dose (Units)	Route/Freq	Dose Adjusted/ Reason
9024/ 20/M/BL	Day 2-AM	05SEP2019 08:15 (2)	600 (mg)	ORAL/BID	NO
	Day 2-PM	05SEP2019 20:15 (2)	600 (mg)	ORAL/BID	NO
	Day 3-AM	06SEP2019 08:15 (3)	600 (mg)	ORAL/BID	NO
	Day 3-PM	06SEP2019 20:15 (3)	600 (mg)	ORAL/BID	NO
	Day 4-AM	07SEP2019 08:15 (4)	600 (mg)	ORAL/BID	NO
	Day 4-PM	07SEP2019 20:15 (4)	600 (mg)	ORAL/BID	NO
	Day 5-AM	08SEP2019 08:15 (5)	600 (mg)	ORAL/BID	NO
	Day 5-PM	08SEP2019 20:15 (5)	600 (mg)	ORAL/BID	NO
	Day 6-AM	09SEP2019 08:15 (6)	600 (mg)	ORAL/BID	NO
	Day 6-PM	09SEP2019 20:15 (6)	600 (mg)	ORAL/BID	NO
	Day 7-AM	10SEP2019 08:15 (7)	600 (mg)	ORAL/BID	NO
	Day 7-PM	10SEP2019 20:15 (7)	600 (mg)	ORAL/BID	NO
9025/ 50/M/W	Day 1-AM	18SEP2019 08:00 (1)	600 (mg)	ORAL/BID	NO
	Day 1-PM	18SEP2019 20:00 (1)	600 (mg)	ORAL/BID	NO
	Day 2-AM	19SEP2019 08:00 (2)	600 (mg)	ORAL/BID	NO
	Day 2-PM	19SEP2019 20:00 (2)	600 (mg)	ORAL/BID	NO
	Day 3-AM	20SEP2019 08:00 (3)	600 (mg)	ORAL/BID	NO
	Day 3-PM	20SEP2019 20:00 (3)	600 (mg)	ORAL/BID	NO
	Day 4-AM	21SEP2019 08:00 (4)	600 (mg)	ORAL/BID	NO
	Day 4-PM	21SEP2019 20:00 (4)	600 (mg)	ORAL/BID	NO

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Freq=Frequency;
Day = The presented date — First dose date + 1
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.5.1
Study Drug Administration
Safety Population

Subject ID/ Age(yrs)/ Sex/Race	Visit - Timepoint	Treatment Date/Time (Day)	Dose (Units)	Route/Freq	Dose Adjusted/ Reason
9025/ 50/M/W	Day 5-AM	22SEP2019 08:00 (5)	600 (mg)	ORAL/BID	NO
	Day 5-PM	22SEP2019 20:05 (5)	600 (mg)	ORAL/BID	NO
	Day 6-AM	23SEP2019 08:00 (6)	600 (mg)	ORAL/BID	NO
	Day 6-PM	23SEP2019 20:00 (6)	600 (mg)	ORAL/BID	NO
	Day 7-AM	24SEP2019 08:00 (7)	600 (mg)	ORAL/BID	NO
	Day 7-PM	24SEP2019 20:00 (7)	600 (mg)	ORAL/BID	NO
9033/ 32/M/W	Day 1-AM	04SEP2019 08:18 (1)	600 (mg)	ORAL/BID	NO
	Day 1-PM	04SEP2019 20:18 (1)	600 (mg)	ORAL/BID	NO
	Day 2-AM	05SEP2019 08:19 (2)	600 (mg)	ORAL/BID	NO
	Day 2-PM	05SEP2019 20:18 (2)	600 (mg)	ORAL/BID	NO
	Day 3-AM	06SEP2019 08:18 (3)	600 (mg)	ORAL/BID	NO
	Day 3-PM	06SEP2019 20:18 (3)	600 (mg)	ORAL/BID	NO
	Day 4-AM	07SEP2019 08:21 (4)	600 (mg)	ORAL/BID	NO
	Day 4-PM	07SEP2019 20:18 (4)	600 (mg)	ORAL/BID	NO
	Day 5-AM	08SEP2019 08:18 (5)	600 (mg)	ORAL/BID	NO
	Day 5-PM	08SEP2019 20:18 (5)	600 (mg)	ORAL/BID	NO
	Day 6-AM	09SEP2019 08:18 (6)	600 (mg)	ORAL/BID	NO
	Day 6-PM	09SEP2019 20:18 (6)	600 (mg)	ORAL/BID	NO
	Day 7-AM	10SEP2019 08:18 (7)	600 (mg)	ORAL/BID	NO
	Day 7-PM	10SEP2019 20:18 (7)	600 (mg)	ORAL/BID	NO

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Freq=Frequency;
Day = The presented date — First dose date + 1
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.5.1
Study Drug Administration
Safety Population

Subject ID/ Age(yrs)/ Sex/Race	Visit - Timepoint	Treatment Date/Time (Day)	Dose (Units)	Route/Freq	Dose Adjusted/ Reason
9043/ 22/M/BL	Day 1-AM	18SEP2019 08:03 (1)	600 (mg)	ORAL/BID	NO
	Day 1-PM	18SEP2019 20:36 (1)	600 (mg)	ORAL/BID	NO
	Day 2-AM	19SEP2019 08:03 (2)	600 (mg)	ORAL/BID	NO
	Day 2-PM	19SEP2019 20:08 (2)	600 (mg)	ORAL/BID	NO
	Day 3-AM	20SEP2019 08:03 (3)	600 (mg)	ORAL/BID	NO
	Day 3-PM	20SEP2019 20:03 (3)	600 (mg)	ORAL/BID	NO
	Day 4-AM	21SEP2019 08:03 (4)	600 (mg)	ORAL/BID	NO
	Day 4-PM	21SEP2019 20:03 (4)	600 (mg)	ORAL/BID	NO
	Day 5-AM	22SEP2019 08:03 (5)	600 (mg)	ORAL/BID	NO
	Day 5-PM	22SEP2019 20:06 (5)	600 (mg)	ORAL/BID	NO
	Day 6-AM	23SEP2019 08:03 (6)	600 (mg)	ORAL/BID	NO
	Day 6-PM	23SEP2019 20:03 (6)	600 (mg)	ORAL/BID	NO
	Day 7-AM	24SEP2019 08:03 (7)	600 (mg)	ORAL/BID	NO
	Day 7-PM	24SEP2019 20:03 (7)	600 (mg)	ORAL/BID	NO
9046/ 34/M/BL	Day 1-AM	18SEP2019 08:06 (1)	600 (mg)	ORAL/BID	NO
	Day 1-PM	18SEP2019 20:06 (1)	600 (mg)	ORAL/BID	NO
	Day 2-AM	19SEP2019 08:06 (2)	600 (mg)	ORAL/BID	NO
	Day 2-PM	19SEP2019 20:06 (2)	600 (mg)	ORAL/BID	NO
	Day 3-AM	20SEP2019 08:06 (3)	600 (mg)	ORAL/BID	NO
	Day 3-PM	20SEP2019 20:06 (3)	600 (mg)	ORAL/BID	NO

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Freq=Frequency;
Day = The presented date — First dose date + 1
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.5.1
Study Drug Administration
Safety Population

Subject ID/ Age(yrs)/ Sex/Race	Visit - Timepoint	Treatment Date/Time (Day)	Dose (Units)	Route/Freq	Dose Adjusted/ Reason
9046/ 34/M/BL	Day 4-AM	21SEP2019 08:06 (4)	600 (mg)	ORAL/BID	NO
	Day 4-PM	21SEP2019 20:06 (4)	600 (mg)	ORAL/BID	NO
	Day 5-AM	22SEP2019 08:06 (5)	600 (mg)	ORAL/BID	NO
	Day 5-PM	22SEP2019 20:07 (5)	600 (mg)	ORAL/BID	NO
	Day 6-AM	23SEP2019 08:06 (6)	600 (mg)	ORAL/BID	NO
	Day 6-PM	23SEP2019 20:06 (6)	600 (mg)	ORAL/BID	NO
	Day 7-AM	24SEP2019 08:06 (7)	600 (mg)	ORAL/BID	NO
	Day 7-PM	24SEP2019 20:06 (7)	600 (mg)	ORAL/BID	NO
9051/ 34/M/BL	Day 1-AM	02OCT2019 08:15 (1)	600 (mg)	ORAL/BID	NO
	Day 1-PM	02OCT2019 20:15 (1)	600 (mg)	ORAL/BID	NO
	Day 2-AM	03OCT2019 08:15 (2)	600 (mg)	ORAL/BID	NO
	Day 2-PM	03OCT2019 20:15 (2)	600 (mg)	ORAL/BID	NO
	Day 3-AM	04OCT2019 08:15 (3)	600 (mg)	ORAL/BID	NO
	Day 3-PM	04OCT2019 20:15 (3)	600 (mg)	ORAL/BID	NO
	Day 4-AM	05OCT2019 08:15 (4)	600 (mg)	ORAL/BID	NO
	Day 4-PM	05OCT2019 20:15 (4)	600 (mg)	ORAL/BID	NO
	Day 5-AM	06OCT2019 08:15 (5)	600 (mg)	ORAL/BID	NO
	Day 5-PM	06OCT2019 20:15 (5)	600 (mg)	ORAL/BID	NO
	Day 6-AM	07OCT2019 08:15 (6)	600 (mg)	ORAL/BID	NO
	Day 6-PM	07OCT2019 20:15 (6)	600 (mg)	ORAL/BID	NO

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Freq=Frequency;
Day = The presented date — First dose date + 1
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.5.1
Study Drug Administration
Safety Population

Subject ID/ Age(yrs)/ Sex/Race	Visit - Timepoint	Treatment Date/Time (Day)	Dose (Units)	Route/Freq	Dose Adjusted/ Reason
9051/ 34/M/BL	Day 7-AM	08OCT2019 08:15 (7)	600 (mg)	ORAL/BID	NO
	Day 7-PM	08OCT2019 20:15 (7)	600 (mg)	ORAL/BID	NO
9052/ 42/M/BL	Day 1-AM	02OCT2019 08:19 (1)	600 (mg)	ORAL/BID	NO
	Day 1-PM	02OCT2019 20:19 (1)	600 (mg)	ORAL/BID	NO
	Day 2-AM	03OCT2019 08:19 (2)	600 (mg)	ORAL/BID	NO
	Day 2-PM	03OCT2019 20:19 (2)	600 (mg)	ORAL/BID	NO
	Day 3-AM	04OCT2019 08:19 (3)	600 (mg)	ORAL/BID	NO
	Day 3-PM	04OCT2019 20:19 (3)	600 (mg)	ORAL/BID	NO
	Day 4-AM	05OCT2019 08:19 (4)	600 (mg)	ORAL/BID	NO
	Day 4-PM	05OCT2019 20:19 (4)	600 (mg)	ORAL/BID	NO
	Day 5-AM	06OCT2019 08:19 (5)	600 (mg)	ORAL/BID	NO
	Day 5-PM	06OCT2019 20:19 (5)	600 (mg)	ORAL/BID	NO
	Day 6-AM	07OCT2019 08:19 (6)	600 (mg)	ORAL/BID	NO
	Day 6-PM	07OCT2019 20:19 (6)	600 (mg)	ORAL/BID	NO
	Day 7-AM	08OCT2019 08:19 (7)	600 (mg)	ORAL/BID	NO
	Day 7-PM	08OCT2019 20:19 (7)	600 (mg)	ORAL/BID	NO
9056/ 31/F/BL	Day 1-AM	02OCT2019 08:00 (1)	600 (mg)	ORAL/BID	NO
	Day 1-PM	02OCT2019 20:00 (1)	600 (mg)	ORAL/BID	NO

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Freq=Frequency;
Day = The presented date — First dose date + 1
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.5.1
Study Drug Administration
Safety Population

Subject ID/ Age(yrs)/ Sex/Race	Visit - Timepoint	Treatment Date/Time (Day)	Dose (Units)	Route/Freq	Dose Adjusted/ Reason
9056/ 31/F/BL	Day 2-AM	03OCT2019 08:00 (2)	600 (mg)	ORAL/BID	NO
	Day 2-PM	03OCT2019 20:00 (2)	600 (mg)	ORAL/BID	NO
	Day 3-AM	04OCT2019 08:00 (3)	600 (mg)	ORAL/BID	NO
	Day 3-PM	04OCT2019 20:00 (3)	600 (mg)	ORAL/BID	NO
	Day 4-AM	05OCT2019 08:00 (4)	600 (mg)	ORAL/BID	NO
	Day 4-PM	05OCT2019 20:00 (4)	600 (mg)	ORAL/BID	NO
	Day 5-AM	06OCT2019 08:00 (5)	600 (mg)	ORAL/BID	NO
	Day 5-PM	06OCT2019 20:00 (5)	600 (mg)	ORAL/BID	NO
	Day 6-AM	07OCT2019 08:00 (6)	600 (mg)	ORAL/BID	NO
	Day 6-PM	07OCT2019 20:00 (6)	600 (mg)	ORAL/BID	NO
	Day 7-AM	08OCT2019 08:00 (7)	600 (mg)	ORAL/BID	NO
	Day 7-PM	08OCT2019 20:00 (7)	600 (mg)	ORAL/BID	NO
9057/ 29/F/W	Day 1-AM	02OCT2019 08:03 (1)	600 (mg)	ORAL/BID	NO
	Day 1-PM	02OCT2019 20:03 (1)	600 (mg)	ORAL/BID	NO
	Day 2-AM	03OCT2019 08:03 (2)	600 (mg)	ORAL/BID	NO
	Day 2-PM	03OCT2019 20:03 (2)	600 (mg)	ORAL/BID	NO
	Day 3-AM	04OCT2019 08:03 (3)	600 (mg)	ORAL/BID	NO
	Day 3-PM	04OCT2019 20:03 (3)	600 (mg)	ORAL/BID	NO
	Day 4-AM	05OCT2019 08:03 (4)	600 (mg)	ORAL/BID	NO
	Day 4-PM	05OCT2019 20:03 (4)	600 (mg)	ORAL/BID	NO

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Freq=Frequency;
Day = The presented date — First dose date + 1
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.5.1
Study Drug Administration
Safety Population

Subject ID/ Age(yrs)/ Sex/Race	Visit - Timepoint	Treatment Date/Time (Day)	Dose (Units)	Route/Freq	Dose Adjusted/ Reason
9057/ 29/F/W	Day 5-AM	06OCT2019 08:03 (5)	600 (mg)	ORAL/BID	NO
	Day 5-PM	06OCT2019 20:03 (5)	600 (mg)	ORAL/BID	NO
	Day 6-AM	07OCT2019 08:03 (6)	600 (mg)	ORAL/BID	NO
	Day 6-PM	07OCT2019 20:03 (6)	600 (mg)	ORAL/BID	NO
	Day 7-AM	08OCT2019 08:03 (7)	600 (mg)	ORAL/BID	NO
	Day 7-PM	08OCT2019 20:03 (7)	600 (mg)	ORAL/BID	NO
9058/ 32/M/W	Day 1-AM	16OCT2019 08:07 (1)	600 (mg)	ORAL/BID	NO
	Day 1-PM	16OCT2019 20:07 (1)	600 (mg)	ORAL/BID	NO
	Day 2-AM	17OCT2019 08:07 (2)	600 (mg)	ORAL/BID	NO
	Day 2-PM	17OCT2019 20:07 (2)	600 (mg)	ORAL/BID	NO
	Day 3-AM	18OCT2019 08:07 (3)	600 (mg)	ORAL/BID	NO
	Day 3-PM	18OCT2019 20:07 (3)	600 (mg)	ORAL/BID	NO
	Day 4-AM	19OCT2019 08:07 (4)	600 (mg)	ORAL/BID	NO
	Day 4-PM	19OCT2019 20:07 (4)	600 (mg)	ORAL/BID	NO
	Day 5-AM	20OCT2019 08:07 (5)	600 (mg)	ORAL/BID	NO
	Day 5-PM	20OCT2019 20:07 (5)	600 (mg)	ORAL/BID	NO
	Day 6-AM	21OCT2019 08:07 (6)	600 (mg)	ORAL/BID	NO
	Day 6-PM	21OCT2019 20:07 (6)	600 (mg)	ORAL/BID	NO
	Day 7-AM	22OCT2019 08:07 (7)	600 (mg)	ORAL/BID	NO
	Day 7-PM	22OCT2019 20:17 (7)	600 (mg)	ORAL/BID	NO

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Freq=Frequency;
Day = The presented date — First dose date + 1
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.5.1
Study Drug Administration
Safety Population

Subject ID/ Age(yrs)/ Sex/Race	Visit - Timepoint	Treatment Date/Time (Day)	Dose (Units)	Route/Freq	Dose Adjusted/ Reason
9061/ 21/F/BL	Day 1-AM	16OCT2019 08:03 (1)	600 (mg)	ORAL/BID	NO
	Day 1-PM	16OCT2019 20:03 (1)	600 (mg)	ORAL/BID	NO
	Day 2-AM	17OCT2019 08:03 (2)	600 (mg)	ORAL/BID	NO
	Day 2-PM	17OCT2019 20:03 (2)	600 (mg)	ORAL/BID	NO
	Day 3-AM	18OCT2019 08:03 (3)	600 (mg)	ORAL/BID	NO
	Day 3-PM	18OCT2019 20:03 (3)	600 (mg)	ORAL/BID	NO
	Day 4-AM	19OCT2019 08:03 (4)	600 (mg)	ORAL/BID	NO
	Day 4-PM	19OCT2019 20:03 (4)	600 (mg)	ORAL/BID	NO
	Day 5-AM	20OCT2019 08:03 (5)	600 (mg)	ORAL/BID	NO
	Day 5-PM	20OCT2019 20:03 (5)	600 (mg)	ORAL/BID	NO
	Day 6-AM	21OCT2019 08:03 (6)	600 (mg)	ORAL/BID	NO
	Day 6-PM	21OCT2019 20:03 (6)	600 (mg)	ORAL/BID	NO
	Day 7-AM	22OCT2019 08:03 (7)	600 (mg)	ORAL/BID	NO
	Day 7-PM	22OCT2019 20:03 (7)	600 (mg)	ORAL/BID	NO
9062/ 33/M/BL	Day 1-AM	02OCT2019 08:06 (1)	600 (mg)	ORAL/BID	NO
	Day 1-PM	02OCT2019 20:06 (1)	600 (mg)	ORAL/BID	NO
	Day 2-AM	03OCT2019 08:06 (2)	600 (mg)	ORAL/BID	NO
	Day 2-PM	03OCT2019 20:06 (2)	600 (mg)	ORAL/BID	NO
	Day 3-AM	04OCT2019 08:06 (3)	600 (mg)	ORAL/BID	NO
	Day 3-PM	04OCT2019 20:06 (3)	600 (mg)	ORAL/BID	NO

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Freq=Frequency;
Day = The presented date — First dose date + 1
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.5.1
Study Drug Administration
Safety Population

Subject ID/ Age(yrs)/ Sex/Race	Visit - Timepoint	Treatment Date/Time (Day)	Dose (Units)	Route/Freq	Dose Adjusted/ Reason
9062/ 33/M/BL	Day 4-AM	05OCT2019 08:06 (4)	600 (mg)	ORAL/BID	NO
	Day 4-PM	05OCT2019 20:06 (4)	600 (mg)	ORAL/BID	NO
	Day 5-AM	06OCT2019 08:06 (5)	600 (mg)	ORAL/BID	NO
	Day 5-PM	06OCT2019 20:06 (5)	600 (mg)	ORAL/BID	NO
	Day 6-AM	07OCT2019 08:06 (6)	600 (mg)	ORAL/BID	NO
	Day 6-PM	07OCT2019 20:06 (6)	600 (mg)	ORAL/BID	NO
	Day 7-AM	08OCT2019 08:06 (7)	600 (mg)	ORAL/BID	NO
	Day 7-PM	08OCT2019 20:06 (7)	600 (mg)	ORAL/BID	NO
9063/ 35/M/W	Day 1-AM	02OCT2019 08:09 (1)	600 (mg)	ORAL/BID	NO
	Day 1-PM	02OCT2019 20:09 (1)	600 (mg)	ORAL/BID	NO
	Day 2-AM	03OCT2019 08:09 (2)	600 (mg)	ORAL/BID	NO
	Day 2-PM	03OCT2019 20:09 (2)	600 (mg)	ORAL/BID	NO
	Day 3-AM	04OCT2019 08:09 (3)	600 (mg)	ORAL/BID	NO
	Day 3-PM	04OCT2019 20:09 (3)	600 (mg)	ORAL/BID	NO
	Day 4-AM	05OCT2019 08:09 (4)	600 (mg)	ORAL/BID	NO
	Day 4-PM	05OCT2019 20:09 (4)	600 (mg)	ORAL/BID	NO
	Day 5-AM	06OCT2019 08:09 (5)	600 (mg)	ORAL/BID	NO
	Day 5-PM	06OCT2019 20:09 (5)	600 (mg)	ORAL/BID	NO
	Day 6-AM	07OCT2019 08:09 (6)	600 (mg)	ORAL/BID	NO
	Day 6-PM	07OCT2019 20:09 (6)	600 (mg)	ORAL/BID	NO

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Freq=Frequency;
Day = The presented date — First dose date + 1
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.5.1
Study Drug Administration
Safety Population

Subject ID/ Age(yrs)/ Sex/Race	Visit - Timepoint	Treatment Date/Time (Day)	Dose (Units)	Route/Freq	Dose Adjusted/ Reason
9063/ 35/M/W	Day 7-AM	08OCT2019 08:09 (7)	600 (mg)	ORAL/BID	NO
	Day 7-PM	08OCT2019 20:09 (7)	600 (mg)	ORAL/BID	NO
9069/ 41/F/BL	Day 1-AM	16OCT2019 08:06 (1)	600 (mg)	ORAL/BID	NO
	Day 1-PM	16OCT2019 20:22 (1)	600 (mg)	ORAL/BID	NO
	Day 2-AM	17OCT2019 08:10 (2)	600 (mg)	ORAL/BID	NO
	Day 2-PM	17OCT2019 20:06 (2)	600 (mg)	ORAL/BID	NO
	Day 3-AM	18OCT2019 08:06 (3)	600 (mg)	ORAL/BID	NO
	Day 3-PM	18OCT2019 20:06 (3)	600 (mg)	ORAL/BID	NO
	Day 4-AM	19OCT2019 08:06 (4)	600 (mg)	ORAL/BID	NO
	Day 4-PM	19OCT2019 20:06 (4)	600 (mg)	ORAL/BID	NO
	Day 5-AM	20OCT2019 08:06 (5)	600 (mg)	ORAL/BID	NO
	Day 5-PM	20OCT2019 20:06 (5)	600 (mg)	ORAL/BID	NO
	Day 6-AM	21OCT2019 08:06 (6)	600 (mg)	ORAL/BID	NO
	Day 6-PM	21OCT2019 20:06 (6)	600 (mg)	ORAL/BID	NO
	Day 7-AM	22OCT2019 08:06 (7)	600 (mg)	ORAL/BID	NO
	Day 7-PM	22OCT2019 20:06 (7)	600 (mg)	ORAL/BID	NO
9073/ 40/M/BL	Day 1-AM	16OCT2019 08:16 (1)	600 (mg)	ORAL/BID	NO
	Day 1-PM	16OCT2019 20:16 (1)	600 (mg)	ORAL/BID	NO

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Freq=Frequency;
Day = The presented date — First dose date + 1
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.5.1
Study Drug Administration
Safety Population

Subject ID/ Age(yrs)/ Sex/Race	Visit - Timepoint	Treatment Date/Time (Day)	Dose (Units)	Route/Freq	Dose Adjusted/ Reason
9073/ 40/M/BL	Day 2-AM	17OCT2019 08:16 (2)	600 (mg)	ORAL/BID	NO
	Day 2-PM	17OCT2019 20:16 (2)	600 (mg)	ORAL/BID	NO
	Day 3-AM	18OCT2019 08:16 (3)	600 (mg)	ORAL/BID	NO
	Day 3-PM	18OCT2019 20:16 (3)	600 (mg)	ORAL/BID	NO
	Day 4-AM	19OCT2019 08:16 (4)	600 (mg)	ORAL/BID	NO
	Day 4-PM	19OCT2019 20:16 (4)	600 (mg)	ORAL/BID	NO
	Day 5-AM	20OCT2019 08:16 (5)	600 (mg)	ORAL/BID	NO
	Day 5-PM	20OCT2019 20:16 (5)	600 (mg)	ORAL/BID	NO
	Day 6-AM	21OCT2019 08:16 (6)	600 (mg)	ORAL/BID	NO
	Day 6-PM	21OCT2019 20:16 (6)	600 (mg)	ORAL/BID	NO
	Day 7-AM	22OCT2019 08:16 (7)	600 (mg)	ORAL/BID	NO
	Day 7-PM	22OCT2019 20:16 (7)	600 (mg)	ORAL/BID	NO
9077/ 37/F/W	Day 1-AM	16OCT2019 08:12 (1)	600 (mg)	ORAL/BID	NO
	Day 1-PM	16OCT2019 20:12 (1)	600 (mg)	ORAL/BID	NO
	Day 2-AM	17OCT2019 08:12 (2)	600 (mg)	ORAL/BID	NO
	Day 2-PM	17OCT2019 20:12 (2)	600 (mg)	ORAL/BID	NO
	Day 3-AM	18OCT2019 08:12 (3)	600 (mg)	ORAL/BID	NO
	Day 3-PM	18OCT2019 20:12 (3)	600 (mg)	ORAL/BID	NO
	Day 4-AM	19OCT2019 08:12 (4)	600 (mg)	ORAL/BID	NO
	Day 4-PM	19OCT2019 20:12 (4)	600 (mg)	ORAL/BID	NO

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Freq=Frequency;
Day = The presented date — First dose date + 1
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.5.1
Study Drug Administration
Safety Population

Subject ID/ Age(yrs)/ Sex/Race	Visit - Timepoint	Treatment Date/Time (Day)	Dose (Units)	Route/Freq	Dose Adjusted/ Reason
9077/ 37/F/W	Day 5-AM	20OCT2019 08:12 (5)	600 (mg)	ORAL/BID	NO
	Day 5-PM	20OCT2019 20:12 (5)	600 (mg)	ORAL/BID	NO
	Day 6-AM	21OCT2019 08:12 (6)	600 (mg)	ORAL/BID	NO
	Day 6-PM	21OCT2019 20:12 (6)	600 (mg)	ORAL/BID	NO
	Day 7-AM	22OCT2019 08:12 (7)	600 (mg)	ORAL/BID	NO
	Day 7-PM	22OCT2019 20:12 (7)	600 (mg)	ORAL/BID	NO
9080/ 41/F/BL	Day 1-AM	16OCT2019 08:21 (1)	600 (mg)	ORAL/BID	NO
	Day 1-PM	16OCT2019 20:21 (1)	600 (mg)	ORAL/BID	NO
	Day 2-AM	17OCT2019 08:21 (2)	600 (mg)	ORAL/BID	NO
	Day 2-PM	17OCT2019 20:21 (2)	600 (mg)	ORAL/BID	NO
	Day 3-AM	18OCT2019 08:21 (3)	600 (mg)	ORAL/BID	NO
	Day 3-PM	18OCT2019 20:21 (3)	600 (mg)	ORAL/BID	NO
	Day 4-AM	19OCT2019 08:21 (4)	600 (mg)	ORAL/BID	NO
	Day 4-PM	19OCT2019 20:21 (4)	600 (mg)	ORAL/BID	NO
	Day 5-AM	20OCT2019 08:21 (5)	600 (mg)	ORAL/BID	NO
	Day 5-PM	20OCT2019 20:21 (5)	600 (mg)	ORAL/BID	NO
	Day 6-AM	21OCT2019 08:21 (6)	600 (mg)	ORAL/BID	NO
	Day 6-PM	21OCT2019 20:21 (6)	600 (mg)	ORAL/BID	NO
	Day 7-AM	22OCT2019 08:21 (7)	600 (mg)	ORAL/BID	NO
	Day 7-PM	22OCT2019 20:21 (7)	600 (mg)	ORAL/BID	NO

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Freq=Frequency;
Day = The presented date — First dose date + 1
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.5.1
Study Drug Administration
Safety Population

Subject ID/ Age(yrs)/ Sex/Race	Visit - Timepoint	Treatment Date/Time (Day)	Dose (Units)	Route/Freq	Dose Adjusted/ Reason
9081/ 49/M/BL	Day 1-AM	30OCT2019 08:00 (1)	600 (mg)	ORAL/BID	NO
	Day 1-PM	30OCT2019 20:00 (1)	600 (mg)	ORAL/BID	NO
	Day 2-AM	31OCT2019 08:00 (2)	600 (mg)	ORAL/BID	NO
	Day 2-PM	31OCT2019 20:00 (2)	600 (mg)	ORAL/BID	NO
	Day 3-AM	01NOV2019 08:00 (3)	600 (mg)	ORAL/BID	NO
	Day 3-PM	01NOV2019 20:00 (3)	600 (mg)	ORAL/BID	NO
	Day 4-AM	02NOV2019 08:00 (4)	600 (mg)	ORAL/BID	NO
	Day 4-PM	02NOV2019 20:00 (4)	600 (mg)	ORAL/BID	NO
	Day 5-AM	03NOV2019 07:00 (5)	600 (mg)	ORAL/BID	NO
	Day 5-PM	03NOV2019 19:00 (5)	600 (mg)	ORAL/BID	NO
	Day 6-AM	04NOV2019 07:00 (6)	600 (mg)	ORAL/BID	NO
	Day 6-PM	04NOV2019 19:00 (6)	600 (mg)	ORAL/BID	NO
	Day 7-AM	05NOV2019 07:00 (7)	600 (mg)	ORAL/BID	NO
	Day 7-PM	05NOV2019 19:00 (7)	600 (mg)	ORAL/BID	NO
9086/ 36/M/BL	Day 1-AM	16OCT2019 08:15 (1)	600 (mg)	ORAL/BID	NO
	Day 1-PM	16OCT2019 20:15 (1)	600 (mg)	ORAL/BID	NO
	Day 2-AM	17OCT2019 08:15 (2)	600 (mg)	ORAL/BID	NO
	Day 2-PM	17OCT2019 20:15 (2)	600 (mg)	ORAL/BID	NO
	Day 3-AM	18OCT2019 08:15 (3)	600 (mg)	ORAL/BID	NO
	Day 3-PM	18OCT2019 20:15 (3)	600 (mg)	ORAL/BID	NO

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Freq=Frequency;
Day = The presented date — First dose date + 1
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.5.1
Study Drug Administration
Safety Population

Subject ID/ Age(yrs)/ Sex/Race	Visit - Timepoint	Treatment Date/Time (Day)	Dose (Units)	Route/Freq	Dose Adjusted/ Reason
9086/ 36/M/BL	Day 4-AM	19OCT2019 08:15 (4)	600 (mg)	ORAL/BID	NO
	Day 4-PM	19OCT2019 20:15 (4)	600 (mg)	ORAL/BID	NO
	Day 5-AM	20OCT2019 08:15 (5)	600 (mg)	ORAL/BID	NO
	Day 5-PM	20OCT2019 20:15 (5)	600 (mg)	ORAL/BID	NO
	Day 6-AM	21OCT2019 08:18 (6)	600 (mg)	ORAL/BID	NO
	Day 6-PM	21OCT2019 20:15 (6)	600 (mg)	ORAL/BID	NO
	Day 7-AM	22OCT2019 08:15 (7)	600 (mg)	ORAL/BID	NO
	Day 7-PM	22OCT2019 20:15 (7)	600 (mg)	ORAL/BID	NO
9087/ 34/F/BL	Day 1-AM	16OCT2019 08:18 (1)	600 (mg)	ORAL/BID	NO
	Day 1-PM	16OCT2019 20:18 (1)	600 (mg)	ORAL/BID	NO
	Day 2-AM	17OCT2019 08:18 (2)	600 (mg)	ORAL/BID	NO
	Day 2-PM	17OCT2019 20:18 (2)	600 (mg)	ORAL/BID	NO
	Day 3-AM	18OCT2019 08:18 (3)	600 (mg)	ORAL/BID	NO
	Day 3-PM	18OCT2019 20:18 (3)	600 (mg)	ORAL/BID	NO
	Day 4-AM	19OCT2019 08:18 (4)	600 (mg)	ORAL/BID	NO
	Day 4-PM	19OCT2019 20:18 (4)	600 (mg)	ORAL/BID	NO
	Day 5-AM	20OCT2019 08:18 (5)	600 (mg)	ORAL/BID	NO
	Day 5-PM	20OCT2019 20:18 (5)	600 (mg)	ORAL/BID	NO
	Day 6-AM	21OCT2019 08:18 (6)	600 (mg)	ORAL/BID	NO
	Day 6-PM	21OCT2019 20:18 (6)	600 (mg)	ORAL/BID	NO

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Freq=Frequency;
Day = The presented date — First dose date + 1
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.5.1
Study Drug Administration
Safety Population

Subject ID/ Age(yrs)/ Sex/Race	Visit - Timepoint	Treatment Date/Time (Day)	Dose (Units)	Route/Freq	Dose Adjusted/ Reason
9087/ 34/F/BL	Day 7-AM	22OCT2019 08:18 (7)	600 (mg)	ORAL/BID	NO
	Day 7-PM	22OCT2019 20:18 (7)	600 (mg)	ORAL/BID	NO
9089/ 29/M/BL	Day 1-AM	16OCT2019 08:24 (1)	600 (mg)	ORAL/BID	NO
	Day 1-PM	16OCT2019 20:24 (1)	600 (mg)	ORAL/BID	NO
	Day 2-AM	17OCT2019 08:24 (2)	600 (mg)	ORAL/BID	NO
	Day 2-PM	17OCT2019 20:24 (2)	600 (mg)	ORAL/BID	NO
	Day 3-AM	18OCT2019 08:24 (3)	600 (mg)	ORAL/BID	NO
	Day 3-PM	18OCT2019 20:24 (3)	600 (mg)	ORAL/BID	NO
	Day 4-AM	19OCT2019 08:24 (4)	600 (mg)	ORAL/BID	NO
	Day 4-PM	19OCT2019 20:24 (4)	600 (mg)	ORAL/BID	NO
	Day 5-AM	20OCT2019 08:24 (5)	600 (mg)	ORAL/BID	NO
	Day 5-PM	20OCT2019 20:24 (5)	600 (mg)	ORAL/BID	NO
	Day 6-AM	21OCT2019 08:24 (6)	600 (mg)	ORAL/BID	NO
	Day 6-PM	21OCT2019 20:24 (6)	600 (mg)	ORAL/BID	NO
	Day 7-AM	22OCT2019 08:24 (7)	600 (mg)	ORAL/BID	NO
	Day 7-PM	22OCT2019 20:24 (7)	600 (mg)	ORAL/BID	NO
9092/ 24/M/W	Day 1-AM	16OCT2019 08:27 (1)	600 (mg)	ORAL/BID	NO
	Day 1-PM	16OCT2019 20:27 (1)	600 (mg)	ORAL/BID	NO

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Freq=Frequency;
Day = The presented date — First dose date + 1
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.5.1
Study Drug Administration
Safety Population

Subject ID/ Age(yrs)/ Sex/Race	Visit - Timepoint	Treatment Date/Time (Day)	Dose (Units)	Route/Freq	Dose Adjusted/ Reason
9092/ 24/M/W	Day 2-AM	17OCT2019 08:27 (2)	600 (mg)	ORAL/BID	NO
	Day 2-PM	17OCT2019 20:27 (2)	600 (mg)	ORAL/BID	NO
	Day 3-AM	18OCT2019 08:27 (3)	600 (mg)	ORAL/BID	NO
	Day 3-PM	18OCT2019 20:27 (3)	600 (mg)	ORAL/BID	NO
	Day 4-AM	19OCT2019 08:27 (4)	600 (mg)	ORAL/BID	NO
	Day 4-PM	19OCT2019 20:27 (4)	600 (mg)	ORAL/BID	NO
	Day 5-AM	20OCT2019 08:27 (5)	600 (mg)	ORAL/BID	NO
	Day 5-PM	20OCT2019 20:27 (5)	600 (mg)	ORAL/BID	NO
	Day 6-AM	21OCT2019 08:27 (6)	600 (mg)	ORAL/BID	NO
	Day 6-PM	21OCT2019 20:27 (6)	600 (mg)	ORAL/BID	NO
	Day 7-AM	22OCT2019 08:27 (7)	600 (mg)	ORAL/BID	NO
	Day 7-PM	22OCT2019 20:27 (7)	600 (mg)	ORAL/BID	NO
9095/ 42/M/W	Day 1-AM	30OCT2019 08:06 (1)	600 (mg)	ORAL/BID	NO
	Day 1-PM	30OCT2019 20:06 (1)	600 (mg)	ORAL/BID	NO
	Day 2-AM	31OCT2019 08:06 (2)	600 (mg)	ORAL/BID	NO
	Day 2-PM	31OCT2019 20:06 (2)	600 (mg)	ORAL/BID	NO
	Day 3-AM	01NOV2019 08:06 (3)	600 (mg)	ORAL/BID	NO
	Day 3-PM	01NOV2019 20:06 (3)	600 (mg)	ORAL/BID	NO
	Day 4-AM	02NOV2019 08:06 (4)	600 (mg)	ORAL/BID	NO
	Day 4-PM	02NOV2019 20:06 (4)	600 (mg)	ORAL/BID	NO

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Freq=Frequency;
Day = The presented date — First dose date + 1
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.5.1
Study Drug Administration
Safety Population

Subject ID/ Age(yrs)/ Sex/Race	Visit - Timepoint	Treatment Date/Time (Day)	Dose (Units)	Route/Freq	Dose Adjusted/ Reason
9095/ 42/M/W	Day 5-AM	03NOV2019 07:06 (5)	600 (mg)	ORAL/BID	NO
	Day 5-PM	03NOV2019 19:06 (5)	600 (mg)	ORAL/BID	NO
	Day 6-AM	04NOV2019 07:06 (6)	600 (mg)	ORAL/BID	NO
	Day 6-PM	04NOV2019 19:06 (6)	600 (mg)	ORAL/BID	NO
	Day 7-AM	05NOV2019 07:06 (7)	600 (mg)	ORAL/BID	NO
	Day 7-PM	05NOV2019 19:06 (7)	600 (mg)	ORAL/BID	NO

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Freq=Frequency;
Day = The presented date — First dose date + 1
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.5.2
Meals
Safety Population

Subject ID	Age(yrs)/ Sex/Race	Visit	Meal Type	Meal Date (Day)	Start/Stop Time	Percent Consumed
9001	41/M/BL	Day 1	BREAKFAST	14AUG2019 (1)	08:55/09:00	100
		Day 1	DINNER	14AUG2019 (1)	20:55/21:00	100
		Day 2	BREAKFAST	15AUG2019 (2)	08:55/08:58	100
		Day 2	DINNER	15AUG2019 (2)	20:55/21:00	100
		Day 3	BREAKFAST	16AUG2019 (3)	08:55/09:02	100
		Day 3	DINNER	16AUG2019 (3)	20:55/21:02	100
		Day 4	BREAKFAST	17AUG2019 (4)	08:56/09:01	100
		Day 4	DINNER	17AUG2019 (4)	20:55/21:01	100
		Day 5	BREAKFAST	18AUG2019 (5)	08:55/08:58	100
		Day 5	DINNER	18AUG2019 (5)	20:55/21:00	100
		Day 6	BREAKFAST	19AUG2019 (6)	08:55/09:00	100
		Day 6	DINNER	19AUG2019 (6)	20:55/21:01	25
		Day 7	BREAKFAST	20AUG2019 (7)	08:55/09:01	100
		Day 7	DINNER	20AUG2019 (7)	20:55/20:59	100
9002	48/M/W	Day 1	BREAKFAST	14AUG2019 (1)	08:54/09:03	100
		Day 1	DINNER	14AUG2019 (1)	20:54/21:04	100
		Day 2	BREAKFAST	15AUG2019 (2)	08:54/09:02	100
		Day 2	DINNER	15AUG2019 (2)	20:54/21:03	100
		Day 3	BREAKFAST	16AUG2019 (3)	08:54/09:04	100
		Day 3	DINNER	16AUG2019 (3)	20:54/21:00	75
		Day 4	BREAKFAST	17AUG2019 (4)	08:55/09:03	100
		Day 4	DINNER	17AUG2019 (4)	20:54/21:03	100
		Day 5	BREAKFAST	18AUG2019 (5)	08:54/08:59	100

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart. Subject 9020 did not eat onions in the dinner on Day 3.
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Listing 16.2.5.2
Meals
Safety Population

Subject ID	Age(yrs)/ Sex/Race	Visit	Meal Type	Meal Date (Day)	Start/Stop Time	Percent Consumed
9002	48/M/W	Day 5	DINNER	18AUG2019 (5)	20:54/21:02	100
		Day 6	BREAKFAST	19AUG2019 (6)	08:54/09:05	100
		Day 6	DINNER	19AUG2019 (6)	20:54/21:04	75
		Day 7	BREAKFAST	20AUG2019 (7)	08:54/09:05	100
		Day 7	DINNER	20AUG2019 (7)	20:54/21:00	100
9005	40/M/W	Day 1	BREAKFAST	14AUG2019 (1)	08:32/08:41	100
		Day 1	DINNER	14AUG2019 (1)	20:33/20:46	100
		Day 2	BREAKFAST	15AUG2019 (2)	08:32/08:48	75
		Day 2	DINNER	15AUG2019 (2)	20:32/20:44	100
		Day 3	BREAKFAST	16AUG2019 (3)	08:32/08:47	100
		Day 3	DINNER	16AUG2019 (3)	20:32/20:44	100
		Day 4	BREAKFAST	17AUG2019 (4)	08:32/08:44	100
		Day 4	DINNER	17AUG2019 (4)	20:32/20:48	100
		Day 5	BREAKFAST	18AUG2019 (5)	08:32/08:38	100
		Day 5	DINNER	18AUG2019 (5)	20:32/20:48	100
		Day 6	BREAKFAST	19AUG2019 (6)	08:32/08:46	100
		Day 6	DINNER	19AUG2019 (6)	20:32/20:45	100
		Day 7	BREAKFAST	20AUG2019 (7)	08:32/08:45	100
		Day 7	DINNER	20AUG2019 (7)	20:32/20:40	100
9009	21/F/BL	Day 1	BREAKFAST	14AUG2019 (1)	08:36/08:42	100
		Day 1	DINNER	14AUG2019 (1)	20:36/20:46	100
		Day 2	BREAKFAST	15AUG2019 (2)	08:36/08:46	100

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart. Subject 9020 did not eat onions in the dinner on Day 3.
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Listing 16.2.5.2
Meals
Safety Population

Subject ID	Age(yrs)/ Sex/Race	Visit	Meal Type	Meal Date (Day)	Start/Stop Time	Percent Consumed
9009	21/F/BL	Day 2	DINNER	15AUG2019 (2)	20:36/20:47	100
		Day 3	BREAKFAST	16AUG2019 (3)	08:36/08:48	100
		Day 3	DINNER	16AUG2019 (3)	20:36/20:56	100
		Day 4	BREAKFAST	17AUG2019 (4)	08:36/08:49	100
		Day 4	DINNER	17AUG2019 (4)	20:36/20:49	100
		Day 5	BREAKFAST	18AUG2019 (5)	08:36/08:42	100
		Day 5	DINNER	18AUG2019 (5)	20:36/20:49	100
		Day 6	BREAKFAST	19AUG2019 (6)	08:36/08:48	100
		Day 6	DINNER	19AUG2019 (6)	20:36/20:48	100
		Day 7	BREAKFAST	20AUG2019 (7)	08:36/08:47	100
		Day 7	DINNER	20AUG2019 (7)	20:36/20:45	100
9012	34/M/BL	Day 1	BREAKFAST	14AUG2019 (1)	08:40/08:45	100
		Day 1	DINNER	14AUG2019 (1)	20:40/20:48	100
		Day 2	BREAKFAST	15AUG2019 (2)	08:48/08:55	100
		Day 2	DINNER	15AUG2019 (2)	20:40/20:49	100
		Day 3	BREAKFAST	16AUG2019 (3)	08:40/08:49	100
		Day 3	DINNER	16AUG2019 (3)	20:40/20:49	100
		Day 4	BREAKFAST	17AUG2019 (4)	08:40/08:47	100
		Day 4	DINNER	17AUG2019 (4)	20:40/20:50	100
		Day 5	BREAKFAST	18AUG2019 (5)	08:40/08:45	100
		Day 5	DINNER	18AUG2019 (5)	20:40/20:51	100
		Day 6	BREAKFAST	19AUG2019 (6)	08:40/08:50	100
		Day 6	DINNER	19AUG2019 (6)	20:40/20:50	100

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart. Subject 9020 did not eat onions in the dinner on Day 3.
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Listing 16.2.5.2
Meals
Safety Population

Subject ID	Age(yrs)/ Sex/Race	Visit	Meal Type	Meal Date (Day)	Start/Stop Time	Percent Consumed
9012	34/M/BL	Day 7	BREAKFAST	20AUG2019 (7)	08:40/08:50	100
		Day 7	DINNER	20AUG2019 (7)	20:40/20:46	100
9015	29/M/BL	Day 1	BREAKFAST	14AUG2019 (1)	08:34/08:42	100
		Day 1	DINNER	14AUG2019 (1)	20:38/20:48	100
		Day 2	BREAKFAST	15AUG2019 (2)	08:38/08:47	100
		Day 2	DINNER	15AUG2019 (2)	20:38/20:48	100
		Day 3	BREAKFAST	16AUG2019 (3)	08:38/08:49	100
		Day 3	DINNER	16AUG2019 (3)	20:38/20:49	100
		Day 4	BREAKFAST	17AUG2019 (4)	08:38/08:46	100
		Day 4	DINNER	17AUG2019 (4)	20:38/20:47	100
		Day 5	BREAKFAST	18AUG2019 (5)	08:38/08:47	100
		Day 5	DINNER	18AUG2019 (5)	20:38/20:48	100
		Day 6	BREAKFAST	19AUG2019 (6)	08:38/08:48	100
		Day 6	DINNER	19AUG2019 (6)	20:38/20:47	100
		Day 7	BREAKFAST	20AUG2019 (7)	08:38/08:48	100
		Day 7	DINNER	20AUG2019 (7)	20:38/20:44	100
9016	48/F/W	Day 1	BREAKFAST	04SEP2019 (1)	07:30/07:40	100
		Day 1	DINNER	04SEP2019 (1)	19:30/19:44	100
		Day 2	BREAKFAST	05SEP2019 (2)	07:30/07:38	100
		Day 2	DINNER	05SEP2019 (2)	19:30/19:41	100
		Day 3	BREAKFAST	06SEP2019 (3)	07:30/07:46	100
		Day 3	DINNER	06SEP2019 (3)	19:30/19:41	100

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart. Subject 9020 did not eat onions in the dinner on Day 3.
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Listing 16.2.5.2
Meals
Safety Population

Subject ID	Age(yrs)/ Sex/Race	Visit	Meal Type	Meal Date (Day)	Start/Stop Time	Percent Consumed
9016	48/F/W	Day 4	BREAKFAST	07SEP2019 (4)	07:30/07:38	100
		Day 4	DINNER	07SEP2019 (4)	19:30/19:42	100
		Day 5	BREAKFAST	08SEP2019 (5)	07:30/07:39	100
		Day 5	DINNER	08SEP2019 (5)	19:30/19:40	100
		Day 6	BREAKFAST	09SEP2019 (6)	07:30/07:39	100
		Day 6	DINNER	09SEP2019 (6)	19:30/19:44	100
		Day 7	BREAKFAST	10SEP2019 (7)	07:30/07:39	100
		Day 7	DINNER	10SEP2019 (7)	19:30/19:38	100
9019	41/M/BL	Day 1	BREAKFAST	04SEP2019 (1)	07:33/07:48	100
		Day 1	DINNER	04SEP2019 (1)	19:33/19:45	100
		Day 2	BREAKFAST	05SEP2019 (2)	07:33/07:43	100
		Day 2	DINNER	05SEP2019 (2)	19:36/19:47	100
		Day 3	BREAKFAST	06SEP2019 (3)	07:33/07:46	100
		Day 3	DINNER	06SEP2019 (3)	19:33/19:44	100
		Day 4	BREAKFAST	07SEP2019 (4)	07:39/07:47	100
		Day 4	DINNER	07SEP2019 (4)	19:33/19:44	100
		Day 5	BREAKFAST	08SEP2019 (5)	07:33/07:40	100
		Day 5	DINNER	08SEP2019 (5)	19:33/19:42	100
		Day 6	BREAKFAST	09SEP2019 (6)	07:33/07:41	100
		Day 6	DINNER	09SEP2019 (6)	19:33/19:46	100
		Day 7	BREAKFAST	10SEP2019 (7)	07:33/07:43	100
		Day 7	DINNER	10SEP2019 (7)	19:33/19:43	100

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart. Subject 9020 did not eat onions in the dinner on Day 3.
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Listing 16.2.5.2
Meals
Safety Population

Subject ID	Age(yrs)/ Sex/Race	Visit	Meal Type	Meal Date (Day)	Start/Stop Time	Percent Consumed
9020	47/F/BL	Day 1	BREAKFAST	04SEP2019 (1)	07:36/07:52	100
		Day 1	DINNER	04SEP2019 (1)	19:36/19:53	100
		Day 2	BREAKFAST	05SEP2019 (2)	07:36/07:53	100
		Day 2	DINNER	05SEP2019 (2)	19:36/19:53	100
		Day 3	BREAKFAST	06SEP2019 (3)	07:36/07:51	50
		Day 3	DINNER	06SEP2019 (3)	19:36/19:52	
		Day 4	BREAKFAST	07SEP2019 (4)	07:36/07:49	100
		Day 4	DINNER	07SEP2019 (4)	19:36/19:52	100
		Day 5	BREAKFAST	08SEP2019 (5)	07:36/07:46	100
		Day 5	DINNER	08SEP2019 (5)	19:36/19:52	100
		Day 6	BREAKFAST	09SEP2019 (6)	07:36/07:50	100
		Day 6	DINNER	09SEP2019 (6)	19:36/19:51	25
		Day 7	BREAKFAST	10SEP2019 (7)	07:36/07:49	100
		Day 7	DINNER	10SEP2019 (7)	19:36/19:48	100
9021	39/F/BL	Day 1	BREAKFAST	04SEP2019 (1)	07:39/07:52	100
		Day 1	DINNER	04SEP2019 (1)	19:39/19:54	100
		Day 2	BREAKFAST	05SEP2019 (2)	07:42/07:54	100
		Day 2	DINNER	05SEP2019 (2)	19:39/19:57	100
		Day 3	BREAKFAST	06SEP2019 (3)	07:39/07:58	100
		Day 3	DINNER	06SEP2019 (3)	19:39/19:55	100
		Day 4	BREAKFAST	07SEP2019 (4)	07:39/07:53	100
		Day 4	DINNER	07SEP2019 (4)	19:39/19:54	100
		Day 5	BREAKFAST	08SEP2019 (5)	07:39/07:52	100

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart. Subject 9020 did not eat onions in the dinner on Day 3.
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Listing 16.2.5.2
Meals
Safety Population

Subject ID	Age(yrs)/ Sex/Race	Visit	Meal Type	Meal Date (Day)	Start/Stop Time	Percent Consumed
9021	39/F/BL	Day 5	DINNER	08SEP2019 (5)	19:39/19:54	100
		Day 6	BREAKFAST	09SEP2019 (6)	07:39/07:55	100
		Day 6	DINNER	09SEP2019 (6)	19:39/19:57	100
		Day 7	BREAKFAST	10SEP2019 (7)	07:39/07:55	100
		Day 7	DINNER	10SEP2019 (7)	19:39/19:51	100
9022	31/M/W	Day 1	BREAKFAST	04SEP2019 (1)	07:42/07:48	100
		Day 1	DINNER	04SEP2019 (1)	19:42/19:50	100
		Day 2	BREAKFAST	05SEP2019 (2)	07:42/07:47	100
		Day 2	DINNER	05SEP2019 (2)	19:42/19:52	100
		Day 3	BREAKFAST	06SEP2019 (3)	07:42/07:53	100
		Day 3	DINNER	06SEP2019 (3)	19:42/19:54	100
		Day 4	BREAKFAST	07SEP2019 (4)	07:48/07:56	100
		Day 4	DINNER	07SEP2019 (4)	19:42/19:50	100
		Day 5	BREAKFAST	08SEP2019 (5)	07:42/07:44	100
		Day 5	DINNER	08SEP2019 (5)	19:42/19:48	100
		Day 6	BREAKFAST	09SEP2019 (6)	07:42/07:53	100
		Day 6	DINNER	09SEP2019 (6)	19:42/19:53	100
		Day 7	BREAKFAST	10SEP2019 (7)	07:42/07:52	100
		Day 7	DINNER	10SEP2019 (7)	19:42/19:49	100
9024	20/M/BL	Day 1	BREAKFAST	04SEP2019 (1)	07:45/07:55	100
		Day 1	DINNER	04SEP2019 (1)	19:45/19:54	100
		Day 2	BREAKFAST	05SEP2019 (2)	07:45/07:55	100

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart. Subject 9020 did not eat onions in the dinner on Day 3.
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Listing 16.2.5.2
Meals
Safety Population

Subject ID	Age(yrs)/ Sex/Race	Visit	Meal Type	Meal Date (Day)	Start/Stop Time	Percent Consumed
9024	20/M/BL	Day 2	DINNER	05SEP2019 (2)	19:45/19:55	100
		Day 3	BREAKFAST	06SEP2019 (3)	07:45/07:56	100
		Day 3	DINNER	06SEP2019 (3)	19:45/19:53	100
		Day 4	BREAKFAST	07SEP2019 (4)	07:45/07:52	75
		Day 4	DINNER	07SEP2019 (4)	19:45/19:53	100
		Day 5	BREAKFAST	08SEP2019 (5)	07:45/07:50	100
		Day 5	DINNER	08SEP2019 (5)	19:45/19:55	100
		Day 6	BREAKFAST	09SEP2019 (6)	07:45/07:54	100
		Day 6	DINNER	09SEP2019 (6)	19:45/19:54	100
		Day 7	BREAKFAST	10SEP2019 (7)	07:45/07:59	100
		Day 7	DINNER	10SEP2019 (7)	19:45/19:52	100
9025	50/M/W	Day 1	BREAKFAST	18SEP2019 (1)	07:30/07:38	100
		Day 1	DINNER	18SEP2019 (1)	19:30/19:41	100
		Day 2	BREAKFAST	19SEP2019 (2)	07:30/07:39	100
		Day 2	DINNER	19SEP2019 (2)	19:30/19:40	100
		Day 3	BREAKFAST	20SEP2019 (3)	07:30/07:39	100
		Day 3	DINNER	20SEP2019 (3)	19:30/19:39	75
		Day 4	BREAKFAST	21SEP2019 (4)	07:30/07:37	100
		Day 4	DINNER	21SEP2019 (4)	19:30/19:39	100
		Day 5	BREAKFAST	22SEP2019 (5)	07:30/07:34	100
		Day 5	DINNER	22SEP2019 (5)	19:30/19:41	100
		Day 6	BREAKFAST	23SEP2019 (6)	07:30/07:42	100
		Day 6	DINNER	23SEP2019 (6)	19:30/19:41	100

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart. Subject 9020 did not eat onions in the dinner on Day 3.
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Listing 16.2.5.2
Meals
Safety Population

Subject ID	Age(yrs)/ Sex/Race	Visit	Meal Type	Meal Date (Day)	Start/Stop Time	Percent Consumed
9025	50/M/W	Day 7	BREAKFAST	24SEP2019 (7)	07:30/07:37	100
		Day 7	DINNER	24SEP2019 (7)	19:30/19:35	100
9033	32/M/W	Day 1	BREAKFAST	04SEP2019 (1)	07:48/07:54	100
		Day 1	DINNER	04SEP2019 (1)	19:48/19:53	100
		Day 2	BREAKFAST	05SEP2019 (2)	07:49/07:54	100
		Day 2	DINNER	05SEP2019 (2)	19:48/19:55	100
		Day 3	BREAKFAST	06SEP2019 (3)	07:48/07:54	100
		Day 3	DINNER	06SEP2019 (3)	19:48/19:54	100
		Day 4	BREAKFAST	07SEP2019 (4)	07:51/07:55	100
		Day 4	DINNER	07SEP2019 (4)	19:48/19:54	100
		Day 5	BREAKFAST	08SEP2019 (5)	07:48/07:52	100
		Day 5	DINNER	08SEP2019 (5)	19:48/19:54	100
		Day 6	BREAKFAST	09SEP2019 (6)	07:48/07:53	100
		Day 6	DINNER	09SEP2019 (6)	19:48/19:55	100
		Day 7	BREAKFAST	10SEP2019 (7)	07:48/07:57	100
		Day 7	DINNER	10SEP2019 (7)	19:48/19:54	100
9043	22/M/BL	Day 1	BREAKFAST	18SEP2019 (1)	07:33/07:39	100
		Day 1	DINNER	18SEP2019 (1)	19:33/19:42	100
		Day 2	BREAKFAST	19SEP2019 (2)	07:33/07:40	100
		Day 2	DINNER	19SEP2019 (2)	19:38/19:44	100
		Day 3	BREAKFAST	20SEP2019 (3)	07:33/07:40	100
		Day 3	DINNER	20SEP2019 (3)	19:33/19:38	100

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart. Subject 9020 did not eat onions in the dinner on Day 3.
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Listing 16.2.5.2
Meals
Safety Population

Subject ID	Age(yrs)/ Sex/Race	Visit	Meal Type	Meal Date (Day)	Start/Stop Time	Percent Consumed
9043	22/M/BL	Day 4	BREAKFAST	21SEP2019 (4)	07:33/07:38	100
		Day 4	DINNER	21SEP2019 (4)	19:33/19:38	100
		Day 5	BREAKFAST	22SEP2019 (5)	07:33/07:36	100
		Day 5	DINNER	22SEP2019 (5)	19:33/19:38	100
		Day 6	BREAKFAST	23SEP2019 (6)	07:33/07:41	100
		Day 6	DINNER	23SEP2019 (6)	19:33/19:40	100
		Day 7	BREAKFAST	24SEP2019 (7)	07:33/07:39	100
		Day 7	DINNER	24SEP2019 (7)	19:33/19:37	100
9046	34/M/BL	Day 1	BREAKFAST	18SEP2019 (1)	07:36/07:42	100
		Day 1	DINNER	18SEP2019 (1)	19:36/19:49	100
		Day 2	BREAKFAST	19SEP2019 (2)	07:36/07:46	100
		Day 2	DINNER	19SEP2019 (2)	19:36/19:44	100
		Day 3	BREAKFAST	20SEP2019 (3)	07:36/07:45	100
		Day 3	DINNER	20SEP2019 (3)	19:36/19:43	100
		Day 4	BREAKFAST	21SEP2019 (4)	07:36/07:45	100
		Day 4	DINNER	21SEP2019 (4)	19:36/19:46	100
		Day 5	BREAKFAST	22SEP2019 (5)	07:36/07:42	100
		Day 5	DINNER	22SEP2019 (5)	19:36/19:44	100
		Day 6	BREAKFAST	23SEP2019 (6)	07:36/07:49	100
		Day 6	DINNER	23SEP2019 (6)	19:36/19:44	100
		Day 7	BREAKFAST	24SEP2019 (7)	07:36/07:45	100
		Day 7	DINNER	24SEP2019 (7)	19:36/19:43	100

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart. Subject 9020 did not eat onions in the dinner on Day 3.
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Listing 16.2.5.2
Meals
Safety Population

Subject ID	Age(yrs)/ Sex/Race	Visit	Meal Type	Meal Date (Day)	Start/Stop Time	Percent Consumed
9051	34/M/BL	Day 1	BREAKFAST	02OCT2019 (1)	07:45/07:51	100
		Day 1	DINNER	02OCT2019 (1)	19:45/19:54	100
		Day 2	BREAKFAST	03OCT2019 (2)	07:45/07:52	100
		Day 2	DINNER	03OCT2019 (2)	19:45/19:53	100
		Day 3	BREAKFAST	04OCT2019 (3)	07:45/07:53	100
		Day 3	DINNER	04OCT2019 (3)	19:45/19:54	100
		Day 4	BREAKFAST	05OCT2019 (4)	07:45/07:51	100
		Day 4	DINNER	05OCT2019 (4)	19:45/19:53	100
		Day 5	BREAKFAST	06OCT2019 (5)	07:45/07:48	100
		Day 5	DINNER	06OCT2019 (5)	19:45/19:52	100
		Day 6	BREAKFAST	07OCT2019 (6)	07:45/07:53	100
		Day 6	DINNER	07OCT2019 (6)	19:45/19:55	100
		Day 7	BREAKFAST	08OCT2019 (7)	07:45/07:51	100
		Day 7	DINNER	08OCT2019 (7)	19:45/19:52	100
9052	42/M/BL	Day 1	BREAKFAST	02OCT2019 (1)	07:49/07:54	100
		Day 1	DINNER	02OCT2019 (1)	19:49/19:57	100
		Day 2	BREAKFAST	03OCT2019 (2)	07:49/07:55	100
		Day 2	DINNER	03OCT2019 (2)	19:49/19:58	100
		Day 3	BREAKFAST	04OCT2019 (3)	07:49/08:00	100
		Day 3	DINNER	04OCT2019 (3)	19:49/19:57	100
		Day 4	BREAKFAST	05OCT2019 (4)	07:49/07:56	100
		Day 4	DINNER	05OCT2019 (4)	19:49/19:58	100
		Day 5	BREAKFAST	06OCT2019 (5)	07:49/07:55	100

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart. Subject 9020 did not eat onions in the dinner on Day 3.
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Listing 16.2.5.2
Meals
Safety Population

Subject ID	Age(yrs)/ Sex/Race	Visit	Meal Type	Meal Date (Day)	Start/Stop Time	Percent Consumed
9052	42/M/BL	Day 5	DINNER	06OCT2019 (5)	19:49/19:56	100
		Day 6	BREAKFAST	07OCT2019 (6)	07:49/07:58	100
		Day 6	DINNER	07OCT2019 (6)	19:49/20:00	100
		Day 7	BREAKFAST	08OCT2019 (7)	07:49/07:57	100
		Day 7	DINNER	08OCT2019 (7)	19:49/19:56	100
9056	31/F/BL	Day 1	BREAKFAST	02OCT2019 (1)	07:30/07:38	100
		Day 1	DINNER	02OCT2019 (1)	19:30/19:45	100
		Day 2	BREAKFAST	03OCT2019 (2)	07:30/07:45	100
		Day 2	DINNER	03OCT2019 (2)	19:30/19:45	100
		Day 3	BREAKFAST	04OCT2019 (3)	07:30/07:47	100
		Day 3	DINNER	04OCT2019 (3)	19:30/19:43	100
		Day 4	BREAKFAST	05OCT2019 (4)	07:30/07:44	100
		Day 4	DINNER	05OCT2019 (4)	19:30/19:43	100
		Day 5	BREAKFAST	06OCT2019 (5)	07:30/07:44	100
		Day 5	DINNER	06OCT2019 (5)	19:30/19:46	100
		Day 6	BREAKFAST	07OCT2019 (6)	07:30/07:44	100
		Day 6	DINNER	07OCT2019 (6)	19:30/19:47	100
		Day 7	BREAKFAST	08OCT2019 (7)	07:30/07:44	100
		Day 7	DINNER	08OCT2019 (7)	19:30/19:40	100
9057	29/F/W	Day 1	BREAKFAST	02OCT2019 (1)	07:33/07:47	100
		Day 1	DINNER	02OCT2019 (1)	19:33/19:51	100
		Day 2	BREAKFAST	03OCT2019 (2)	07:33/07:52	100

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart. Subject 9020 did not eat onions in the dinner on Day 3.
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Listing 16.2.5.2
Meals
Safety Population

Subject ID	Age(yrs)/ Sex/Race	Visit	Meal Type	Meal Date (Day)	Start/Stop Time	Percent Consumed
9057	29/F/W	Day 2	DINNER	03OCT2019 (2)	19:33/19:46	100
		Day 3	BREAKFAST	04OCT2019 (3)	07:33/07:52	100
		Day 3	DINNER	04OCT2019 (3)	19:33/19:44	100
		Day 4	BREAKFAST	05OCT2019 (4)	07:33/07:45	100
		Day 4	DINNER	05OCT2019 (4)	19:33/19:45	100
		Day 5	BREAKFAST	06OCT2019 (5)	07:33/07:46	100
		Day 5	DINNER	06OCT2019 (5)	19:33/19:50	100
		Day 6	BREAKFAST	07OCT2019 (6)	07:33/07:49	100
		Day 6	DINNER	07OCT2019 (6)	19:33/19:46	100
		Day 7	BREAKFAST	08OCT2019 (7)	07:33/07:48	100
		Day 7	DINNER	08OCT2019 (7)	19:33/19:43	100
9058	32/M/W	Day 1	BREAKFAST	16OCT2019 (1)	07:30/07:36	100
		Day 1	DINNER	16OCT2019 (1)	19:37/19:44	100
		Day 2	BREAKFAST	17OCT2019 (2)	07:37/07:43	100
		Day 2	DINNER	17OCT2019 (2)	19:37/19:44	100
		Day 3	BREAKFAST	18OCT2019 (3)	07:37/07:44	100
		Day 3	DINNER	18OCT2019 (3)	19:37/19:44	100
		Day 4	BREAKFAST	19OCT2019 (4)	07:40/07:46	100
		Day 4	DINNER	19OCT2019 (4)	19:37/19:42	100
		Day 5	BREAKFAST	20OCT2019 (5)	07:37/07:40	100
		Day 5	DINNER	20OCT2019 (5)	19:37/19:47	100
		Day 6	BREAKFAST	21OCT2019 (6)	07:37/07:43	100
		Day 6	DINNER	21OCT2019 (6)	19:37/19:48	100

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart. Subject 9020 did not eat onions in the dinner on Day 3.
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Listing 16.2.5.2
Meals
Safety Population

Subject ID	Age(yrs)/ Sex/Race	Visit	Meal Type	Meal Date (Day)	Start/Stop Time	Percent Consumed
9058	32/M/W	Day 7	BREAKFAST	22OCT2019 (7)	07:37/07:45	100
		Day 7	DINNER	22OCT2019 (7)	19:37/19:41	100
9061	21/F/BL	Day 1	BREAKFAST	16OCT2019 (1)	07:33/07:40	100
		Day 1	DINNER	16OCT2019 (1)	19:33/19:46	100
		Day 2	BREAKFAST	17OCT2019 (2)	07:38/07:52	100
		Day 2	DINNER	17OCT2019 (2)	19:33/19:43	100
		Day 3	BREAKFAST	18OCT2019 (3)	07:33/07:45	100
		Day 3	DINNER	18OCT2019 (3)	19:33/19:45	100
		Day 4	BREAKFAST	19OCT2019 (4)	07:40/07:46	100
		Day 4	DINNER	19OCT2019 (4)	19:33/19:44	100
		Day 5	BREAKFAST	20OCT2019 (5)	07:33/07:38	75
		Day 5	DINNER	20OCT2019 (5)	19:33/19:44	100
		Day 6	BREAKFAST	21OCT2019 (6)	07:33/07:44	100
		Day 6	DINNER	21OCT2019 (6)	19:33/19:53	100
		Day 7	BREAKFAST	22OCT2019 (7)	07:33/07:44	100
		Day 7	DINNER	22OCT2019 (7)	19:32/19:41	100
9062	33/M/BL	Day 1	BREAKFAST	02OCT2019 (1)	07:36/07:42	100
		Day 1	DINNER	02OCT2019 (1)	19:36/19:42	100
		Day 2	BREAKFAST	03OCT2019 (2)	07:36/07:43	100
		Day 2	DINNER	03OCT2019 (2)	19:36/19:43	100
		Day 3	BREAKFAST	04OCT2019 (3)	07:36/07:45	100
		Day 3	DINNER	04OCT2019 (3)	19:36/19:42	100

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart. Subject 9020 did not eat onions in the dinner on Day 3.
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Listing 16.2.5.2
Meals
Safety Population

Subject ID	Age(yrs)/ Sex/Race	Visit	Meal Type	Meal Date (Day)	Start/Stop Time	Percent Consumed
9062	33/M/BL	Day 4	BREAKFAST	05OCT2019 (4)	07:36/07:43	100
		Day 4	DINNER	05OCT2019 (4)	19:36/19:42	100
		Day 5	BREAKFAST	06OCT2019 (5)	07:36/07:42	100
		Day 5	DINNER	06OCT2019 (5)	19:36/19:44	100
		Day 6	BREAKFAST	07OCT2019 (6)	07:36/07:43	100
		Day 6	DINNER	07OCT2019 (6)	19:36/19:45	100
		Day 7	BREAKFAST	08OCT2019 (7)	07:36/07:43	100
		Day 7	DINNER	08OCT2019 (7)	19:36/19:40	100
9063	35/M/W	Day 1	BREAKFAST	02OCT2019 (1)	07:39/07:45	100
		Day 1	DINNER	02OCT2019 (1)	19:39/19:46	100
		Day 2	BREAKFAST	03OCT2019 (2)	07:39/07:44	100
		Day 2	DINNER	03OCT2019 (2)	19:39/19:44	100
		Day 3	BREAKFAST	04OCT2019 (3)	07:39/07:46	100
		Day 3	DINNER	04OCT2019 (3)	19:39/19:43	100
		Day 4	BREAKFAST	05OCT2019 (4)	07:39/07:44	100
		Day 4	DINNER	05OCT2019 (4)	19:39/19:43	100
		Day 5	BREAKFAST	06OCT2019 (5)	07:39/07:44	100
		Day 5	DINNER	06OCT2019 (5)	19:39/19:44	100
		Day 6	BREAKFAST	07OCT2019 (6)	07:39/07:44	100
		Day 6	DINNER	07OCT2019 (6)	19:39/19:45	100
		Day 7	BREAKFAST	08OCT2019 (7)	07:39/07:44	100
		Day 7	DINNER	08OCT2019 (7)	19:39/19:42	100

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart. Subject 9020 did not eat onions in the dinner on Day 3.
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Listing 16.2.5.2
Meals
Safety Population

Subject ID	Age(yrs)/ Sex/Race	Visit	Meal Type	Meal Date (Day)	Start/Stop Time	Percent Consumed
9069	41/F/BL	Day 1	BREAKFAST	16OCT2019 (1)	07:36/07:42	100
		Day 1	DINNER	16OCT2019 (1)	19:36/19:45	100
		Day 2	BREAKFAST	17OCT2019 (2)	07:40/07:51	100
		Day 2	DINNER	17OCT2019 (2)	19:36/19:47	100
		Day 3	BREAKFAST	18OCT2019 (3)	07:36/07:47	100
		Day 3	DINNER	18OCT2019 (3)	19:36/19:45	100
		Day 4	BREAKFAST	19OCT2019 (4)	07:38/07:46	100
		Day 4	DINNER	19OCT2019 (4)	19:36/19:44	100
		Day 5	BREAKFAST	20OCT2019 (5)	07:36/07:40	100
		Day 5	DINNER	20OCT2019 (5)	19:36/19:44	100
		Day 6	BREAKFAST	21OCT2019 (6)	07:36/07:46	100
		Day 6	DINNER	21OCT2019 (6)	19:36/19:50	100
		Day 7	BREAKFAST	22OCT2019 (7)	07:36/07:47	100
		Day 7	DINNER	22OCT2019 (7)	19:36/19:42	100
9073	40/M/BL	Day 1	BREAKFAST	16OCT2019 (1)	07:39/07:46	100
		Day 1	DINNER	16OCT2019 (1)	19:46/19:56	100
		Day 2	BREAKFAST	17OCT2019 (2)	07:46/07:54	100
		Day 2	DINNER	17OCT2019 (2)	19:46/19:55	100
		Day 3	BREAKFAST	18OCT2019 (3)	07:46/07:56	100
		Day 3	DINNER	18OCT2019 (3)	19:46/19:55	100
		Day 4	BREAKFAST	19OCT2019 (4)	07:46/07:52	100
		Day 4	DINNER	19OCT2019 (4)	19:46/19:54	100
		Day 5	BREAKFAST	20OCT2019 (5)	07:46/07:50	100

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart. Subject 9020 did not eat onions in the dinner on Day 3.
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Listing 16.2.5.2
Meals
Safety Population

Subject ID	Age(yrs)/ Sex/Race	Visit	Meal Type	Meal Date (Day)	Start/Stop Time	Percent Consumed
9073	40/M/BL	Day 5	DINNER	20OCT2019 (5)	19:46/19:54	100
		Day 6	BREAKFAST	21OCT2019 (6)	07:46/07:54	100
		Day 6	DINNER	21OCT2019 (6)	19:46/19:58	100
		Day 7	BREAKFAST	22OCT2019 (7)	07:46/07:55	100
		Day 7	DINNER	22OCT2019 (7)	19:46/19:53	100
9077	37/F/W	Day 1	BREAKFAST	16OCT2019 (1)	07:42/07:49	75
		Day 1	DINNER	16OCT2019 (1)	19:42/19:51	100
		Day 2	BREAKFAST	17OCT2019 (2)	07:42/07:52	100
		Day 2	DINNER	17OCT2019 (2)	19:42/19:51	100
		Day 3	BREAKFAST	18OCT2019 (3)	07:42/07:56	100
		Day 3	DINNER	18OCT2019 (3)	19:42/19:54	100
		Day 4	BREAKFAST	19OCT2019 (4)	07:42/07:52	100
		Day 4	DINNER	19OCT2019 (4)	19:42/19:55	100
		Day 5	BREAKFAST	20OCT2019 (5)	07:42/07:47	100
		Day 5	DINNER	20OCT2019 (5)	19:42/19:53	100
		Day 6	BREAKFAST	21OCT2019 (6)	07:42/07:52	100
		Day 6	DINNER	21OCT2019 (6)	19:42/20:01	100
		Day 7	BREAKFAST	22OCT2019 (7)	07:42/07:54	100
		Day 7	DINNER	22OCT2019 (7)	19:42/19:50	100
9080	41/F/BL	Day 1	BREAKFAST	16OCT2019 (1)	07:51/08:04	100
		Day 1	DINNER	16OCT2019 (1)	19:51/20:08	100
		Day 2	BREAKFAST	17OCT2019 (2)	07:51/08:09	100

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart. Subject 9020 did not eat onions in the dinner on Day 3.
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Listing 16.2.5.2
Meals
Safety Population

Subject ID	Age(yrs)/ Sex/Race	Visit	Meal Type	Meal Date (Day)	Start/Stop Time	Percent Consumed
9080	41/F/BL	Day 2	DINNER	17OCT2019 (2)	19:51/20:07	75
		Day 3	BREAKFAST	18OCT2019 (3)	07:51/08:07	75
		Day 3	DINNER	18OCT2019 (3)	19:51/20:05	100
		Day 4	BREAKFAST	19OCT2019 (4)	07:51/08:07	100
		Day 4	DINNER	19OCT2019 (4)	19:51/20:10	75
		Day 5	BREAKFAST	20OCT2019 (5)	07:51/08:02	100
		Day 5	DINNER	20OCT2019 (5)	19:51/20:09	100
		Day 6	BREAKFAST	21OCT2019 (6)	07:51/08:11	100
		Day 6	DINNER	21OCT2019 (6)	19:51/20:13	100
		Day 7	BREAKFAST	22OCT2019 (7)	07:51/08:07	100
		Day 7	DINNER	22OCT2019 (7)	19:51/20:05	100
9081	49/M/BL	Day 1	BREAKFAST	30OCT2019 (1)	07:30/07:35	100
		Day 1	DINNER	30OCT2019 (1)	19:47/19:53	100
		Day 2	BREAKFAST	31OCT2019 (2)	07:30/07:38	100
		Day 2	DINNER	31OCT2019 (2)	19:30/19:40	100
		Day 3	BREAKFAST	01NOV2019 (3)	07:30/07:41	100
		Day 3	DINNER	01NOV2019 (3)	19:30/19:44	100
		Day 4	BREAKFAST	02NOV2019 (4)	07:30/07:38	100
		Day 4	DINNER	02NOV2019 (4)	19:30/19:39	100
		Day 5	BREAKFAST	03NOV2019 (5)	06:30/06:39	100
		Day 5	DINNER	03NOV2019 (5)	18:30/18:38	100
		Day 6	BREAKFAST	04NOV2019 (6)	06:30/06:45	100
		Day 6	DINNER	04NOV2019 (6)	18:30/18:40	100

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart. Subject 9020 did not eat onions in the dinner on Day 3.
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Listing 16.2.5.2
Meals
Safety Population

Subject ID	Age(yrs)/ Sex/Race	Visit	Meal Type	Meal Date (Day)	Start/Stop Time	Percent Consumed
9081	49/M/BL	Day 7	BREAKFAST	05NOV2019 (7)	06:30/06:40	100
		Day 7	DINNER	05NOV2019 (7)	18:30/18:34	100
9086	36/M/BL	Day 1	BREAKFAST	16OCT2019 (1)	07:45/07:53	100
		Day 1	DINNER	16OCT2019 (1)	19:45/19:55	100
		Day 2	BREAKFAST	17OCT2019 (2)	07:45/08:15	100
		Day 2	DINNER	17OCT2019 (2)	19:45/19:55	100
		Day 3	BREAKFAST	18OCT2019 (3)	07:45/07:57	100
		Day 3	DINNER	18OCT2019 (3)	19:45/19:59	100
		Day 4	BREAKFAST	19OCT2019 (4)	07:45/07:56	100
		Day 4	DINNER	19OCT2019 (4)	19:45/19:57	100
		Day 5	BREAKFAST	20OCT2019 (5)	07:45/07:50	100
		Day 5	DINNER	20OCT2019 (5)	19:45/19:58	100
		Day 6	BREAKFAST	21OCT2019 (6)	07:45/07:56	100
		Day 6	DINNER	21OCT2019 (6)	19:45/20:04	100
		Day 7	BREAKFAST	22OCT2019 (7)	07:45/07:58	100
		Day 7	DINNER	22OCT2019 (7)	19:45/19:54	100
9087	34/F/BL	Day 1	BREAKFAST	16OCT2019 (1)	07:48/07:54	100
		Day 1	DINNER	16OCT2019 (1)	19:48/20:00	100
		Day 2	BREAKFAST	17OCT2019 (2)	07:48/08:00	100
		Day 2	DINNER	17OCT2019 (2)	19:48/19:58	100
		Day 3	BREAKFAST	18OCT2019 (3)	07:48/08:05	100
		Day 3	DINNER	18OCT2019 (3)	19:18/20:01	100

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart. Subject 9020 did not eat onions in the dinner on Day 3.
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Listing 16.2.5.2
Meals
Safety Population

Subject ID	Age(yrs)/ Sex/Race	Visit	Meal Type	Meal Date (Day)	Start/Stop Time	Percent Consumed
9087	34/F/BL	Day 4	BREAKFAST	19OCT2019 (4)	07:48/07:58	100
		Day 4	DINNER	19OCT2019 (4)	19:48/20:01	100
		Day 5	BREAKFAST	20OCT2019 (5)	07:48/07:54	100
		Day 5	DINNER	20OCT2019 (5)	19:48/20:00	100
		Day 6	BREAKFAST	21OCT2019 (6)	07:48/08:06	100
		Day 6	DINNER	21OCT2019 (6)	19:48/20:06	100
		Day 7	BREAKFAST	22OCT2019 (7)	07:48/07:59	100
		Day 7	DINNER	22OCT2019 (7)	19:48/19:59	100
9089	29/M/BL	Day 1	BREAKFAST	16OCT2019 (1)	07:54/08:02	100
		Day 1	DINNER	16OCT2019 (1)	19:54/20:03	100
		Day 2	BREAKFAST	17OCT2019 (2)	07:54/08:07	100
		Day 2	DINNER	17OCT2019 (2)	19:54/20:08	75
		Day 3	BREAKFAST	18OCT2019 (3)	07:54/08:08	75
		Day 3	DINNER	18OCT2019 (3)	19:54/20:03	100
		Day 4	BREAKFAST	19OCT2019 (4)	07:54/08:08	100
		Day 4	DINNER	19OCT2019 (4)	19:54/20:07	100
		Day 5	BREAKFAST	20OCT2019 (5)	07:54/08:02	100
		Day 5	DINNER	20OCT2019 (5)	19:54/20:08	100
		Day 6	BREAKFAST	21OCT2019 (6)	07:54/08:09	100
		Day 6	DINNER	21OCT2019 (6)	19:54/20:13	100
		Day 7	BREAKFAST	22OCT2019 (7)	07:54/08:08	100
		Day 7	DINNER	22OCT2019 (7)	19:54/20:05	100

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart. Subject 9020 did not eat onions in the dinner on Day 3.
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Listing 16.2.5.2
Meals
Safety Population

Subject ID	Age(yrs)/ Sex/Race	Visit	Meal Type	Meal Date (Day)	Start/Stop Time	Percent Consumed
9092	24/M/W	Day 1	BREAKFAST	16OCT2019 (1)	07:57/08:05	100
		Day 1	DINNER	16OCT2019 (1)	19:57/20:08	100
		Day 2	BREAKFAST	17OCT2019 (2)	07:57/08:08	100
		Day 2	DINNER	17OCT2019 (2)	19:57/20:09	100
		Day 3	BREAKFAST	18OCT2019 (3)	07:57/08:08	100
		Day 3	DINNER	18OCT2019 (3)	19:57/20:06	100
		Day 4	BREAKFAST	19OCT2019 (4)	07:57/08:04	100
		Day 4	DINNER	19OCT2019 (4)	19:57/20:05	100
		Day 5	BREAKFAST	20OCT2019 (5)	07:57/08:03	100
		Day 5	DINNER	20OCT2019 (5)	19:57/20:08	100
		Day 6	BREAKFAST	21OCT2019 (6)	07:57/08:06	100
		Day 6	DINNER	21OCT2019 (6)	19:57/20:11	100
		Day 7	BREAKFAST	22OCT2019 (7)	07:57/08:07	100
		Day 7	DINNER	22OCT2019 (7)	19:57/20:06	100
9095	42/M/W	Day 1	BREAKFAST	30OCT2019 (1)	07:36/07:41	100
		Day 1	DINNER	30OCT2019 (1)	19:47/19:56	100
		Day 2	BREAKFAST	31OCT2019 (2)	07:36/07:46	100
		Day 2	DINNER	31OCT2019 (2)	19:36/19:46	100
		Day 3	BREAKFAST	01NOV2019 (3)	07:36/07:45	100
		Day 3	DINNER	01NOV2019 (3)	19:36/19:45	100
		Day 4	BREAKFAST	02NOV2019 (4)	07:36/07:43	100
		Day 4	DINNER	02NOV2019 (4)	19:36/19:45	100
		Day 5	BREAKFAST	03NOV2019 (5)	06:36/06:41	100

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart. Subject 9020 did not eat onions in the dinner on Day 3.
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Listing 16.2.5.2
Meals
Safety Population

Subject ID	Age(yrs)/ Sex/Race	Visit	Meal Type	Meal Date (Day)	Start/Stop Time	Percent Consumed
9095	42/M/W	Day 5	DINNER	03NOV2019 (5)	18:36/18:44	100
		Day 6	BREAKFAST	04NOV2019 (6)	06:36/06:45	100
		Day 6	DINNER	04NOV2019 (6)	18:36/18:46	100
		Day 7	BREAKFAST	05NOV2019 (7)	06:36/06:44	100
		Day 7	DINNER	05NOV2019 (7)	18:36/18:41	100

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart. Subject 9020 did not eat onions in the dinner on Day 3.
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16.2.6 Individual Pharmacokinetic Response Data

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
1	9001	PREDOSE	14AUG2019/09:20	.	BLQ	
		0.5	14AUG2019/09:55	0.00	10.8	
		1	14AUG2019/10:25	0.00	104	
		2	14AUG2019/11:25	0.00	469	
		4	14AUG2019/13:25	0.00	1100	
		6	14AUG2019/15:25	0.00	759	
		8	14AUG2019/17:27	2.00	397	
		12	14AUG2019/21:22	-3.00	240	
		14	14AUG2019/23:28	3.00	173	
		16	15AUG2019/01:25	0.00	485	
		18	15AUG2019/03:25	0.00	688	
		20	15AUG2019/05:26	1.00	695	
		24	15AUG2019/09:25	0.00	455	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
1	9002	PREDOSE	14AUG2019/09:22	.	BLQ	
		0.5	14AUG2019/09:54	0.00	BLQ	
		1	14AUG2019/10:24	0.00	33.4	
		2	14AUG2019/11:24	0.00	323	
		4	14AUG2019/13:42	18.00	717	
		6	14AUG2019/15:28	4.00	548	
		8	14AUG2019/17:25	1.00	355	
		12	14AUG2019/21:23	-1.00	216	
		14	14AUG2019/23:24	0.00	273	
		16	15AUG2019/01:28	4.00	471	
		18	15AUG2019/03:28	4.00	674	
		20	15AUG2019/05:24	0.00	865	
		24	15AUG2019/09:19	-5.00	637	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
1	9005	PREDOSE	14AUG2019/08:57	.	BLQ	
		0.5	14AUG2019/09:32	0.00	22.2	
		1	14AUG2019/10:02	0.00	164	
		2	14AUG2019/11:02	0.00	840	
		4	14AUG2019/13:02	0.00	1080	
		6	14AUG2019/15:02	0.00	578	
		8	14AUG2019/17:02	0.00	360	
		12	14AUG2019/20:57	-5.00	233	
		14	14AUG2019/23:02	0.00	579	
		16	15AUG2019/01:02	0.00	1110	
		18	15AUG2019/03:02	0.00	1190	
		20	15AUG2019/05:02	0.00	811	
		24	15AUG2019/08:57	-5.00	555	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
1	9009	PREDOSE	14AUG2019/09:01	.	BLQ	
		0.5	14AUG2019/09:36	0.00	BLQ	
		1	14AUG2019/10:06	0.00	BLQ	
		2	14AUG2019/11:06	0.00	72.3	
		4	14AUG2019/13:14	8.00	523	
		6	14AUG2019/15:06	0.00	378	
		12	14AUG2019/21:01	-5.00	274	
		14	14AUG2019/23:06	0.00	346	
		16	15AUG2019/01:06	0.00	899	
		18	15AUG2019/03:06	0.00	1520	
		20	15AUG2019/05:10	4.00	935	
		24	15AUG2019/09:01	-5.00	550	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
1	9012	PREDOSE	14AUG2019/09:05	.	BLQ	
		0.5	14AUG2019/09:40	0.00	10.7	
		1	14AUG2019/10:10	0.00	78.9	
		2	14AUG2019/11:10	0.00	683	
		4	14AUG2019/13:10	0.00	757	
		6	14AUG2019/15:10	0.00	657	
		8	14AUG2019/17:10	0.00	367	
		12	14AUG2019/21:05	-5.00	193	
		14	14AUG2019/23:10	0.00	265	
		16	15AUG2019/01:10	0.00	667	
		18	15AUG2019/03:10	0.00	648	
		20	15AUG2019/05:10	0.00	685	
		24	15AUG2019/09:05	-5.00	451	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
1	9015	PREDOSE	14AUG2019/08:59	.	BLQ	
		0.5	14AUG2019/09:38	0.00	5.35	
		1	14AUG2019/10:08	0.00	69.1	
		2	14AUG2019/11:08	0.00	212	
		4	14AUG2019/13:08	0.00	331	
		6	14AUG2019/15:08	0.00	900	
		8	14AUG2019/17:08	0.00	544	
		12	14AUG2019/21:03	-5.00	256	
		14	14AUG2019/23:08	0.00	246	
		16	15AUG2019/01:08	0.00	393	
		18	15AUG2019/03:08	0.00	642	
		20	15AUG2019/05:08	0.00	741	
		24	15AUG2019/09:03	-5.00	507	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
1	9016	PREDOSE	04SEP2019/07:55	.	BLQ	
		0.5	04SEP2019/08:30	0.00	BLQ	
		1	04SEP2019/09:00	0.00	91.5	
		2	04SEP2019/10:00	0.00	205	
		4	04SEP2019/12:00	0.00	711	
		6	04SEP2019/14:00	0.00	547	
		8	04SEP2019/16:00	0.00	408	
		12	04SEP2019/19:55	-5.00	327	
		14	04SEP2019/22:00	0.00	321	
		16	05SEP2019/00:00	0.00	528	
		18	05SEP2019/02:00	0.00	624	
		20	05SEP2019/04:00	0.00	613	
		24	05SEP2019/07:55	-5.00	534	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
1	9019	PREDOSE	04SEP2019/07:59	.	BLQ	
		0.5	04SEP2019/08:34	1.00	BLQ	
		1	04SEP2019/09:03	0.00	16.6	
		2	04SEP2019/10:03	0.00	641	
		4	04SEP2019/12:03	0.00	922	
		6	04SEP2019/14:07	4.00	771	
		8	04SEP2019/16:07	4.00	511	
		12	04SEP2019/19:58	-5.00	271	
		14	04SEP2019/22:03	0.00	225	
		16	05SEP2019/00:03	0.00	493	
		18	05SEP2019/02:03	0.00	568	
		20	05SEP2019/04:03	0.00	761	
		24	05SEP2019/08:06	3.00	417	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
1	9020	PREDOSE	04SEP2019/08:01	.	BLQ	
		0.5	04SEP2019/08:36	0.00	BLQ	
		1	04SEP2019/09:06	0.00	BLQ	
		2	04SEP2019/10:06	0.00	25.6	
		4	04SEP2019/12:06	0.00	740	
		6	04SEP2019/14:06	0.00	684	
		8	04SEP2019/16:06	0.00	740	
		12	04SEP2019/20:01	-5.00	444	
		14	04SEP2019/22:15	9.00	334	
		16	05SEP2019/00:06	0.00	603	
		18	05SEP2019/02:06	0.00	801	
		20	05SEP2019/04:06	0.00	721	
		24	05SEP2019/08:02	-4.00	429	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
1	9021	PREDOSE	04SEP2019/08:04	.	BLQ	
		0.5	04SEP2019/08:39	0.00	BLQ	
		1	04SEP2019/09:09	0.00	21.9	
		2	04SEP2019/10:09	0.00	774	
		4	04SEP2019/12:11	2.00	890	
		6	04SEP2019/14:09	0.00	511	
		8	04SEP2019/16:10	1.00	292	
		12	04SEP2019/20:04	-5.00	272	
		14	04SEP2019/22:09	0.00	722	
		16	05SEP2019/00:09	0.00	748	
		18	05SEP2019/02:09	0.00	713	
		20	05SEP2019/04:09	0.00	714	
		24	05SEP2019/08:04	-5.00	336	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
1	9022	PREDOSE	04SEP2019/08:07	.	BLQ	
		0.5	04SEP2019/08:42	0.00	BLQ	
		1	04SEP2019/09:12	0.00	40.6	
		2	04SEP2019/10:12	0.00	309	
		4	04SEP2019/12:12	0.00	624	
		6	04SEP2019/14:12	0.00	648	
		8	04SEP2019/16:12	0.00	396	
		12	04SEP2019/20:07	-5.00	304	
		14	04SEP2019/22:12	0.00	402	
		16	05SEP2019/00:12	0.00	668	
		18	05SEP2019/02:12	0.00	632	
		20	05SEP2019/04:12	0.00	637	
		24	05SEP2019/08:07	-5.00	513	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
1	9024	PREDOSE	04SEP2019/08:13	.	BLQ	
		0.5	04SEP2019/08:45	0.00	BLQ	
		1	04SEP2019/09:17	2.00	23.5	
		2	04SEP2019/10:15	0.00	251	
		4	04SEP2019/12:15	0.00	840	
		6	04SEP2019/14:15	0.00	885	
		8	04SEP2019/16:15	0.00	845	
		12	04SEP2019/20:10	-5.00	456	
		14	04SEP2019/22:15	0.00	328	
		16	05SEP2019/00:15	0.00	835	
		18	05SEP2019/02:15	0.00	647	
		20	05SEP2019/04:15	0.00	1070	
		24	05SEP2019/08:10	-5.00	630	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
1	9025	PREDOSE	18SEP2019/07:55	.	BLQ	
		0.5	18SEP2019/08:30	0.00	BLQ	
		1	18SEP2019/09:00	0.00	BLQ	
		2	18SEP2019/10:00	0.00	50.1	
		4	18SEP2019/12:00	0.00	192	
		6	18SEP2019/14:00	0.00	628	
		8	18SEP2019/16:01	1.00	1330	
		12	18SEP2019/19:55	-5.00	758	
		14	18SEP2019/22:00	0.00	554	
		16	19SEP2019/00:00	0.00	1050	
		18	19SEP2019/02:00	0.00	936	
		20	19SEP2019/04:00	0.00	958	
		24	19SEP2019/07:55	-5.00	1110	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
1	9033	PREDOSE	04SEP2019/08:16	.	BLQ	
		0.5	04SEP2019/08:48	0.00	15.5	
		1	04SEP2019/09:18	0.00	129	
		2	04SEP2019/10:18	0.00	497	
		4	04SEP2019/12:18	0.00	574	
		6	04SEP2019/14:22	4.00	347	
		8	04SEP2019/16:18	0.00	191	
		12	04SEP2019/20:13	-5.00	160	
		14	04SEP2019/22:18	0.00	339	
		16	05SEP2019/00:18	0.00	631	
		18	05SEP2019/02:52	34.00	528	
		20	05SEP2019/04:18	0.00	467	
		24	05SEP2019/08:13	-5.00	292	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
1	9043	PREDOSE	18SEP2019/07:58	.	BLQ	
		0.5	18SEP2019/08:33	0.00	BLQ	
		1	18SEP2019/09:03	0.00	14.9	
		2	18SEP2019/10:09	6.00	711	
		4	18SEP2019/12:04	1.00	909	
		6	18SEP2019/14:03	0.00	571	
		8	18SEP2019/16:05	2.00	361	
		14	18SEP2019/22:36	33.00	269	
		16	19SEP2019/00:36	33.00	421	
		18	19SEP2019/02:52	49.00	635	
		20	19SEP2019/04:36	33.00	1100	
		24	19SEP2019/07:58	-5.00	504	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
1	9046	PREDOSE	18SEP2019/08:01	.	BLQ	
		0.5	18SEP2019/08:36	0.00	BLQ	
		1	18SEP2019/09:06	0.00	11.8	
		2	18SEP2019/10:06	0.00	370	
		4	18SEP2019/12:06	0.00	1030	
		6	18SEP2019/14:06	0.00	498	
		8	18SEP2019/16:06	0.00	331	
		12	18SEP2019/20:02	-4.00	265	
		14	18SEP2019/22:06	0.00	535	
		16	19SEP2019/00:06	0.00	1090	
		18	19SEP2019/02:06	0.00	951	
		20	19SEP2019/04:06	0.00	832	
		24	19SEP2019/08:01	-5.00	506	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
1	9051	PREDOSE	02OCT2019/08:10	.	BLQ	
		0.5	02OCT2019/08:45	0.00	BLQ	
		1	02OCT2019/09:15	0.00	26.7	
		2	02OCT2019/10:15	0.00	453	
		4	02OCT2019/12:15	0.00	811	
		6	02OCT2019/14:15	0.00	232	
		8	02OCT2019/16:15	0.00	136	
		12	02OCT2019/20:10	-5.00	149	
		14	02OCT2019/22:15	0.00	171	
		16	03OCT2019/00:15	0.00	553	
		18	03OCT2019/02:15	0.00	475	
		20	03OCT2019/04:15	0.00	409	
		24	03OCT2019/08:10	-5.00	294	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
1	9052	PREDOSE	02OCT2019/08:14	.	BLQ	
		0.5	02OCT2019/08:49	0.00	15.0	
		1	02OCT2019/09:19	0.00	54.2	
		2	02OCT2019/10:19	0.00	256	
		4	02OCT2019/12:19	0.00	556	
		6	02OCT2019/14:19	0.00	941	
		8	02OCT2019/16:19	0.00	522	
		12	02OCT2019/20:14	-5.00	346	
		14	02OCT2019/22:19	0.00	458	
		16	03OCT2019/00:19	0.00	1040	
		18	03OCT2019/02:19	0.00	1040	
		20	03OCT2019/04:19	0.00	958	
		24	03OCT2019/08:14	-5.00	705	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
1	9056	PREDOSE	02OCT2019/07:55	.	BLQ	
		0.5	02OCT2019/08:30	0.00	9.22	
		1	02OCT2019/09:00	0.00	33.0	
		2	02OCT2019/10:02	2.00	123	
		4	02OCT2019/12:00	0.00	938	
		6	02OCT2019/14:00	0.00	519	
		8	02OCT2019/16:00	0.00	327	
		12	02OCT2019/19:59	-1.00	213	
		14	02OCT2019/22:00	0.00	158	
		16	03OCT2019/00:00	0.00	398	
		18	03OCT2019/02:03	3.00	1140	
		20	03OCT2019/04:00	0.00	916	
		24	03OCT2019/07:55	-5.00	555	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
1	9057	PREDOSE	02OCT2019/07:58	.	BLQ	
		0.5	02OCT2019/08:33	0.00	BLQ	
		1	02OCT2019/09:03	0.00	45.8	
		2	02OCT2019/10:03	0.00	239	
		4	02OCT2019/12:03	0.00	489	
		6	02OCT2019/14:03	0.00	557	
		8	02OCT2019/16:03	0.00	362	
		12	02OCT2019/19:58	-5.00	210	
		14	02OCT2019/22:03	0.00	178	
		16	03OCT2019/00:03	0.00	457	
		18	03OCT2019/02:03	0.00	451	
		20	03OCT2019/04:03	0.00	504	
		24	03OCT2019/07:58	-5.00	472	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
1	9058	PREDOSE	16OCT2019/08:03	.	BLQ	
		0.5	16OCT2019/08:37	0.00	14.0	
		1	16OCT2019/09:12	5.00	355	
		2	16OCT2019/10:07	0.00	894	
		4	16OCT2019/12:07	0.00	881	
		6	16OCT2019/14:09	2.00	623	
		8	16OCT2019/16:08	1.00	359	
		12	16OCT2019/20:02	-5.00	192	
		14	16OCT2019/22:07	0.00	248	
		16	17OCT2019/00:07	0.00	513	
		18	17OCT2019/02:07	0.00	588	
		20	17OCT2019/04:07	0.00	702	
		24	17OCT2019/08:02	-5.00	746	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
1	9061	PREDOSE	16OCT2019/07:58	.	BLQ	
		0.5	16OCT2019/08:35	2.00	5.77	
		1	16OCT2019/09:10	7.00	288	
		2	16OCT2019/10:06	3.00	940	
		4	16OCT2019/12:03	0.00	965	
		6	16OCT2019/14:08	5.00	440	
		8	16OCT2019/16:35	32.00	311	
		12	16OCT2019/19:58	-5.00	325	
		14	16OCT2019/22:03	0.00	745	
		16	17OCT2019/00:04	1.00	833	
		24	17OCT2019/07:59	-4.00	448	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
1	9062	PREDOSE	02OCT2019/08:01	.	BLQ	
		0.5	02OCT2019/08:36	0.00	14.3	
		1	02OCT2019/09:06	0.00	127	
		2	02OCT2019/10:06	0.00	609	
		4	02OCT2019/12:06	0.00	583	
		6	02OCT2019/14:06	0.00	368	
		8	02OCT2019/16:06	0.00	232	
		12	02OCT2019/20:01	-5.00	157	
		14	02OCT2019/22:06	0.00	245	
		16	03OCT2019/00:06	0.00	467	
		18	03OCT2019/02:06	0.00	407	
		20	03OCT2019/04:06	0.00	441	
		24	03OCT2019/08:01	-5.00	370	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
1	9063	PREDOSE	02OCT2019/08:04	.	BLQ	
		0.5	02OCT2019/08:39	0.00	10.2	
		1	02OCT2019/09:09	0.00	41.2	
		2	02OCT2019/10:10	1.00	455	
		4	02OCT2019/12:09	0.00	762	
		6	02OCT2019/14:09	0.00	571	
		8	02OCT2019/16:09	0.00	382	
		12	02OCT2019/20:04	-5.00	170	
		14	02OCT2019/22:09	0.00	200	
		16	03OCT2019/00:09	0.00	653	
		18	03OCT2019/02:09	0.00	674	
		20	03OCT2019/04:09	0.00	761	
		24	03OCT2019/08:04	-5.00	469	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
1	9069	PREDOSE	16OCT2019/08:01	.	BLQ	
		0.5	16OCT2019/08:54	18.00	73.2	
		1	16OCT2019/09:06	0.00	102	
		2	16OCT2019/10:06	0.00	537	
		4	16OCT2019/12:12	6.00	957	
		6	16OCT2019/14:06	0.00	402	
		8	16OCT2019/16:06	0.00	331	
		12	16OCT2019/20:17	11.00	283	
		14	16OCT2019/22:22	16.00	629	
		16	17OCT2019/00:23	17.00	933	
		18	17OCT2019/02:22	16.00	831	
		20	17OCT2019/04:22	16.00	592	
		24	17OCT2019/08:01	-5.00	407	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
1	9073	PREDOSE	16OCT2019/08:13	.	BLQ	
		0.5	16OCT2019/08:51	5.00	11.1	
		1	16OCT2019/09:16	0.00	127	
		2	16OCT2019/10:19	3.00	702	
		4	16OCT2019/12:16	0.00	630	
		6	16OCT2019/14:22	6.00	237	
		8	16OCT2019/16:18	2.00	225	
		12	16OCT2019/20:14	-2.00	164	
		14	16OCT2019/22:16	0.00	208	
		16	17OCT2019/00:21	5.00	504	
		18	17OCT2019/02:27	11.00	540	
		20	17OCT2019/04:20	4.00	452	
		24	17OCT2019/08:11	-5.00	294	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
1	9077	PREDOSE	16OCT2019/08:07	.	BLQ	
		0.5	16OCT2019/08:42	0.00	BLQ	
		1	16OCT2019/09:12	0.00	15.2	
		2	16OCT2019/10:12	0.00	586	
		4	16OCT2019/12:12	0.00	1310	
		6	16OCT2019/14:12	0.00	810	
		8	16OCT2019/16:12	0.00	436	
		12	16OCT2019/20:07	-5.00	343	
		14	16OCT2019/22:12	0.00	694	
		16	17OCT2019/00:12	0.00	1220	
		18	17OCT2019/02:12	0.00	1060	
		20	17OCT2019/04:12	0.00	1100	
		24	17OCT2019/08:07	-5.00	1170	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
1	9080	PREDOSE	16OCT2019/08:19	.	BLQ	
		0.5	16OCT2019/08:51	0.00	5.31	
		1	16OCT2019/09:21	0.00	75.1	
		2	16OCT2019/10:21	0.00	454	
		4	16OCT2019/12:21	0.00	1130	
		6	16OCT2019/14:21	0.00	771	
		8	16OCT2019/16:21	0.00	494	
		12	16OCT2019/20:20	-1.00	407	
		14	16OCT2019/22:21	0.00	269	
		16	17OCT2019/00:22	1.00	382	
		18	17OCT2019/02:23	2.00	538	
		20	17OCT2019/04:21	0.00	771	
		24	17OCT2019/08:17	-4.00	584	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
1	9081	PREDOSE	30OCT2019/07:57	.	BLQ	
		0.5	30OCT2019/08:30	0.00	31.4	
		1	30OCT2019/09:00	0.00	105	
		2	30OCT2019/10:00	0.00	628	
		4	30OCT2019/12:05	5.00	527	
		6	30OCT2019/14:00	0.00	361	
		8	30OCT2019/16:00	0.00	223	
		12	30OCT2019/19:55	-5.00	152	
		14	30OCT2019/22:00	0.00	258	
		16	31OCT2019/00:00	0.00	471	
		18	31OCT2019/02:00	0.00	473	
		20	31OCT2019/04:00	0.00	496	
		24	31OCT2019/07:55	-5.00	340	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
1	9086	PREDOSE	16OCT2019/08:10	.	BLQ	
		0.5	16OCT2019/08:45	0.00	BLQ	
		1	16OCT2019/09:15	0.00	21.9	
		2	16OCT2019/10:15	0.00	215	
		4	16OCT2019/12:15	0.00	634	
		6	16OCT2019/14:15	0.00	324	
		8	16OCT2019/16:15	0.00	154	
		12	16OCT2019/20:12	-3.00	121	
		14	16OCT2019/22:15	0.00	148	
		16	17OCT2019/00:15	0.00	240	
		18	17OCT2019/02:12	-3.00	382	
		20	17OCT2019/04:15	0.00	395	
		24	17OCT2019/08:10	-5.00	215	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
1	9087	PREDOSE	16OCT2019/08:15	.	BLQ	
		0.5	16OCT2019/08:48	0.00	BLQ	
		1	16OCT2019/09:18	0.00	23.4	
		2	16OCT2019/10:18	0.00	304	
		4	16OCT2019/12:18	0.00	1160	
		6	16OCT2019/14:18	0.00	557	
		8	16OCT2019/16:18	0.00	296	
		12	16OCT2019/20:13	-5.00	177	
		14	16OCT2019/22:18	0.00	173	
		16	17OCT2019/00:21	3.00	478	
		18	17OCT2019/02:29	11.00	867	
		20	17OCT2019/04:19	1.00	704	
		24	17OCT2019/08:13	-5.00	436	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
1	9089	PREDOSE	16OCT2019/08:19	.	BLQ	
		0.5	16OCT2019/08:54	0.00	BLQ	
		1	16OCT2019/09:24	0.00	65.9	
		2	16OCT2019/10:24	0.00	237	
		4	16OCT2019/12:24	0.00	802	
		6	16OCT2019/14:24	0.00	649	
		8	16OCT2019/16:24	0.00	407	
		12	16OCT2019/20:19	-5.00	241	
		14	16OCT2019/22:24	0.00	252	
		16	17OCT2019/00:24	0.00	513	
		18	17OCT2019/02:24	0.00	638	
		20	17OCT2019/04:24	0.00	698	
		24	17OCT2019/08:19	-5.00	457	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
1	9092	PREDOSE	16OCT2019/08:22	.	BLQ	
		0.5	16OCT2019/08:57	0.00	26.8	
		1	16OCT2019/09:27	0.00	196	
		2	16OCT2019/10:27	0.00	596	
		4	16OCT2019/12:27	0.00	521	
		6	16OCT2019/14:27	0.00	439	
		8	16OCT2019/16:28	1.00	217	
		12	16OCT2019/20:22	-5.00	160	
		14	16OCT2019/22:27	0.00	300	
		16	17OCT2019/00:27	0.00	442	
		18	17OCT2019/02:27	0.00	427	
		20	17OCT2019/04:27	0.00	484	
		24	17OCT2019/08:22	-5.00	370	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
1	9095	PREDOSE	30OCT2019/08:01	.	BLQ	
		0.5	30OCT2019/08:36	0.00	BLQ	
		1	30OCT2019/09:06	0.00	13.3	
		2	30OCT2019/10:06	0.00	178	
		4	30OCT2019/12:06	0.00	697	
		6	30OCT2019/14:06	0.00	612	
		8	30OCT2019/16:06	0.00	396	
		12	30OCT2019/20:01	-5.00	331	
		14	30OCT2019/22:06	0.00	266	
		16	31OCT2019/00:06	0.00	554	
		18	31OCT2019/02:06	0.00	549	
		20	31OCT2019/04:06	0.00	582	
		24	31OCT2019/08:01	-5.00	810	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
6	9001	PREDOSE	19AUG2019/09:20	.	630	
		4	19AUG2019/13:25	0.00	1580	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
6	9002	PREDOSE	19AUG2019/09:30	.	537	
		4	19AUG2019/13:31	0.00	1180	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
6	9005	PREDOSE	19AUG2019/08:57	.	827	
		4	19AUG2019/13:03	1.00	1800	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
6	9009	PREDOSE	19AUG2019/09:01	.	750	
		4	19AUG2019/13:06	0.00	1620	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
6	9012	PREDOSE	19AUG2019/09:05	.	815	
		4	19AUG2019/13:10	0.00	982	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
6	9015	PREDOSE	19AUG2019/09:03	.	563	
		4	19AUG2019/13:08	0.00	1320	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
6	9016	PREDOSE	09SEP2019/07:55	.	831	
		4	09SEP2019/12:00	0.00	1700	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
6	9019	PREDOSE	09SEP2019/08:01	.	555	
		4	09SEP2019/12:03	0.00	1210	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
6	9020	PREDOSE	09SEP2019/08:01	.	550	
		4	09SEP2019/12:06	0.00	1090	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
6	9021	PREDOSE	09SEP2019/08:04	.	434	
		4	09SEP2019/12:09	0.00	1330	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
6	9022	PREDOSE	09SEP2019/08:07	.	511	
		4	09SEP2019/12:12	0.00	1150	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
6	9024	PREDOSE	09SEP2019/08:10	.	921	
		4	09SEP2019/12:15	0.00	1940	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
6	9025	PREDOSE	23SEP2019/07:55	.	1200	
		4	23SEP2019/12:00	0.00	1440	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
6	9033	PREDOSE	09SEP2019/08:13	.	356	
		4	09SEP2019/12:18	0.00	1590	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
6	9043	PREDOSE	23SEP2019/07:58	.	958	
		4	23SEP2019/12:03	0.00	1100	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
6	9046	PREDOSE	23SEP2019/08:01	.	702	
		4	23SEP2019/12:06	0.00	1440	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
6	9051	PREDOSE	07OCT2019/08:10	.	241	
		4	07OCT2019/12:15	0.00	816	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
6	9052	PREDOSE	07OCT2019/08:14	.	632	
		4	07OCT2019/12:19	0.00	1470	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
6	9056	PREDOSE	07OCT2019/07:55	.	738	
		4	07OCT2019/12:00	0.00	1140	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
6	9057	PREDOSE	07OCT2019/07:58	.	618	
		4	07OCT2019/12:03	0.00	940	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
6	9058	PREDOSE	21OCT2019/08:02	.	573	
		4	21OCT2019/12:07	0.00	1400	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
6	9061	PREDOSE	21OCT2019/07:59	.	415	
		4	21OCT2019/12:03	0.00	1020	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
6	9062	PREDOSE	07OCT2019/08:01	.	438	
		4	07OCT2019/12:06	0.00	997	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
6	9063	PREDOSE	07OCT2019/08:04	.	532	
		4	07OCT2019/12:09	0.00	1800	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
6	9069	PREDOSE	21OCT2019/08:01	.	634	
		4	21OCT2019/12:06	0.00	1220	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
6	9073	PREDOSE	21OCT2019/08:11	.	599	
		4	21OCT2019/12:20	4.00	1290	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
6	9077	PREDOSE	21OCT2019/08:07	.	1010	
		4	21OCT2019/12:12	0.00	2000	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
6	9080	PREDOSE	21OCT2019/08:16	.	724	
		4	21OCT2019/12:23	2.00	1360	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
6	9081	PREDOSE	04NOV2019/06:55	.	471	
		4	04NOV2019/11:00	0.00	982	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
6	9086	PREDOSE	21OCT2019/08:15	.	227	
		4	21OCT2019/12:18	0.00	633	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
6	9087	PREDOSE	21OCT2019/08:13	.	474	
		4	21OCT2019/12:18	0.00	744	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
6	9089	PREDOSE	21OCT2019/08:19	.	468	
		4	21OCT2019/12:24	0.00	941	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
6	9092	PREDOSE	21OCT2019/08:22	.	442	
		4	21OCT2019/12:27	0.00	1200	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
6	9095	PREDOSE	04NOV2019/07:01	.	717	
		4	04NOV2019/11:06	0.00	1040	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
7	9001	PREDOSE	20AUG2019/09:20	.	555	
		0.5	20AUG2019/09:55	0.00	387	
		1	20AUG2019/10:25	0.00	345	
		2	20AUG2019/11:25	0.00	603	
		4	20AUG2019/13:25	0.00	1600	
		6	20AUG2019/15:25	0.00	1270	
		8	20AUG2019/17:25	0.00	691	
		12	20AUG2019/21:20	-5.00	481	
		14	20AUG2019/23:25	0.00	568	
		16	21AUG2019/01:25	0.00	1020	
		18	21AUG2019/03:29	4.00	1070	
		20	21AUG2019/05:25	0.00	717	
		24	21AUG2019/09:25	0.00	488	
		48	22AUG2019/09:25	0.00	121	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
7	9002	PREDOSE	20AUG2019/09:25	.	533	
		0.5	20AUG2019/09:57	0.00	429	
		1	20AUG2019/10:27	0.00	410	
		2	20AUG2019/11:36	9.00	907	
		4	20AUG2019/13:27	0.00	1290	
		6	20AUG2019/15:35	8.00	839	
		8	20AUG2019/17:57	30.00	509	
		12	20AUG2019/21:19	-8.00	567	
		14	20AUG2019/23:24	-3.00	854	
		16	21AUG2019/01:24	-3.00	1140	
		18	21AUG2019/03:24	-3.00	934	
		20	21AUG2019/05:24	-3.00	862	
		24	21AUG2019/09:24	-3.00	624	
		48	22AUG2019/09:27	0.00	203	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
7	9005	PREDOSE	20AUG2019/08:57	.	719	
		0.5	20AUG2019/09:32	0.00	655	
		1	20AUG2019/10:02	0.00	572	
		2	20AUG2019/11:02	0.00	1410	
		4	20AUG2019/13:02	0.00	2270	
		6	20AUG2019/15:02	0.00	1170	
		8	20AUG2019/17:02	0.00	748	
		12	20AUG2019/21:01	-1.00	607	
		14	20AUG2019/23:02	0.00	1270	
		16	21AUG2019/01:02	0.00	1660	
		18	21AUG2019/03:02	0.00	1490	
		20	21AUG2019/05:02	0.00	997	
		24	21AUG2019/09:02	0.00	810	
		48	22AUG2019/09:02	0.00	314	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
7	9009	PREDOSE	20AUG2019/09:04	.	650	
		0.5	20AUG2019/09:36	0.00	516	
		1	20AUG2019/10:06	0.00	471	
		2	20AUG2019/11:06	0.00	630	
		4	20AUG2019/13:06	0.00	1190	
		6	20AUG2019/15:06	0.00	1030	
		8	20AUG2019/17:06	0.00	860	
		12	20AUG2019/21:01	-5.00	922	
		14	20AUG2019/23:07	1.00	962	
		16	21AUG2019/01:06	0.00	1260	
		18	21AUG2019/03:06	0.00	1350	
		20	21AUG2019/05:06	0.00	1070	
		24	21AUG2019/09:06	0.00	849	
		48	22AUG2019/09:07	1.00	273	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
7	9012	PREDOSE	20AUG2019/09:05	.	490	
		0.5	20AUG2019/09:40	0.00	435	
		1	20AUG2019/10:10	0.00	354	
		2	20AUG2019/11:10	0.00	334	
		4	20AUG2019/13:10	0.00	810	
		6	20AUG2019/15:10	0.00	1060	
		8	20AUG2019/17:10	0.00	662	
		12	20AUG2019/21:05	-5.00	424	
		14	20AUG2019/23:10	0.00	481	
		16	21AUG2019/01:10	0.00	675	
		18	21AUG2019/03:10	0.00	979	
		20	21AUG2019/05:10	0.00	1180	
		24	21AUG2019/09:10	0.00	603	
		48	22AUG2019/09:13	3.00	131	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
7	9015	PREDOSE	20AUG2019/09:03	.	727	
		0.5	20AUG2019/09:38	0.00	612	
		1	20AUG2019/10:08	0.00	524	
		2	20AUG2019/11:08	0.00	618	
		4	20AUG2019/13:08	0.00	878	
		6	20AUG2019/15:10	2.00	858	
		8	20AUG2019/17:08	0.00	612	
		12	20AUG2019/21:03	-5.00	305	
		14	20AUG2019/23:08	0.00	632	
		16	21AUG2019/01:08	0.00	746	
		18	21AUG2019/03:08	0.00	865	
		20	21AUG2019/05:08	0.00	742	
		24	21AUG2019/09:08	0.00	471	
		48	22AUG2019/09:10	2.00	107	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
7	9016	PREDOSE	10SEP2019/07:55	.	773	
		0.5	10SEP2019/08:30	0.00	569	
		1	10SEP2019/09:00	0.00	621	
		2	10SEP2019/10:00	0.00	870	
		4	10SEP2019/12:00	0.00	1750	
		6	10SEP2019/14:00	0.00	1430	
		8	10SEP2019/16:00	0.00	913	
		12	10SEP2019/19:55	-5.00	811	
		14	10SEP2019/22:00	0.00	739	
		16	11SEP2019/00:00	0.00	1090	
		18	11SEP2019/02:00	0.00	992	
		20	11SEP2019/04:00	0.00	1180	
		24	11SEP2019/08:00	0.00	1020	
		48	12SEP2019/08:05	5.00	205	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
7	9019	PREDOSE	10SEP2019/08:00	.	526	
		0.5	10SEP2019/08:33	0.00	465	
		1	10SEP2019/09:03	0.00	406	
		2	10SEP2019/10:03	0.00	617	
		4	10SEP2019/12:03	0.00	950	
		6	10SEP2019/14:03	0.00	1130	
		8	10SEP2019/16:03	0.00	846	
		12	10SEP2019/19:58	-5.00	557	
		14	10SEP2019/22:03	0.00	650	
		16	11SEP2019/00:03	0.00	992	
		18	11SEP2019/02:03	0.00	1020	
		20	11SEP2019/04:04	1.00	920	
		24	11SEP2019/08:03	0.00	574	
		48	12SEP2019/08:08	5.00	130	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
7	9020	PREDOSE	10SEP2019/08:01	.	506	
		0.5	10SEP2019/08:36	0.00	506	
		1	10SEP2019/09:06	0.00	450	
		2	10SEP2019/10:06	0.00	498	
		4	10SEP2019/12:06	0.00	1060	
		6	10SEP2019/14:08	2.00	1110	
		8	10SEP2019/16:06	0.00	678	
		12	10SEP2019/20:01	-5.00	627	
		14	10SEP2019/22:06	0.00	610	
		16	11SEP2019/00:12	6.00	920	
		18	11SEP2019/02:06	0.00	1010	
		20	11SEP2019/04:06	0.00	886	
		24	11SEP2019/08:06	0.00	601	
		48	12SEP2019/08:13	7.00	245	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
7	9021	PREDOSE	10SEP2019/08:04	.	247	
		0.5	10SEP2019/08:39	0.00	192	
		1	10SEP2019/09:09	0.00	157	
		2	10SEP2019/10:09	0.00	451	
		4	10SEP2019/12:09	0.00	1050	
		6	10SEP2019/14:09	0.00	459	
		8	10SEP2019/16:09	0.00	288	
		12	10SEP2019/20:04	-5.00	527	
		14	10SEP2019/22:09	0.00	638	
		16	11SEP2019/00:16	7.00	663	
		18	11SEP2019/02:09	0.00	670	
		20	11SEP2019/04:09	0.00	532	
		24	11SEP2019/08:09	0.00	307	
		48	12SEP2019/08:09	0.00	58.0	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
7	9022	PREDOSE	10SEP2019/08:07	.	669	
		0.5	10SEP2019/08:42	0.00	582	
		1	10SEP2019/09:12	0.00	581	
		2	10SEP2019/10:12	0.00	920	
		4	10SEP2019/12:12	0.00	1170	
		6	10SEP2019/14:12	0.00	1200	
		8	10SEP2019/16:12	0.00	727	
		12	10SEP2019/20:07	-5.00	577	
		14	10SEP2019/22:12	0.00	839	
		16	11SEP2019/00:12	0.00	1350	
		18	11SEP2019/02:12	0.00	1300	
		20	11SEP2019/04:12	0.00	931	
		24	11SEP2019/08:12	0.00	582	
		48	12SEP2019/08:12	0.00	148	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
7	9024	PREDOSE	10SEP2019/08:10	.	862	
		0.5	10SEP2019/08:45	0.00	711	
		1	10SEP2019/09:15	0.00	621	
		2	10SEP2019/10:15	0.00	774	
		4	10SEP2019/12:15	0.00	1860	
		6	10SEP2019/14:15	0.00	1440	
		8	10SEP2019/16:15	0.00	902	
		12	10SEP2019/20:10	-5.00	733	
		14	10SEP2019/22:15	0.00	1090	
		16	11SEP2019/00:15	0.00	1300	
		18	11SEP2019/02:15	0.00	1430	
		20	11SEP2019/04:15	0.00	1300	
		24	11SEP2019/08:15	0.00	804	
		48	12SEP2019/08:15	0.00	271	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
7	9025	PREDOSE	24SEP2019/07:55	.	1090	
		0.5	24SEP2019/08:30	0.00	978	
		1	24SEP2019/09:02	2.00	728	
		2	24SEP2019/10:01	1.00	884	
		4	24SEP2019/12:00	0.00	1200	
		6	24SEP2019/14:00	0.00	1480	
		8	24SEP2019/16:00	0.00	1210	
		12	24SEP2019/19:57	-3.00	760	
		14	24SEP2019/22:00	0.00	1060	
		16	25SEP2019/00:00	0.00	1510	
		18	25SEP2019/02:01	1.00	1300	
		20	25SEP2019/04:00	0.00	1170	
		24	25SEP2019/08:00	0.00	815	
		48	26SEP2019/08:00	0.00	236	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
7	9033	PREDOSE	10SEP2019/08:13	.	365	
		0.5	10SEP2019/08:50	2.00	283	
		1	10SEP2019/09:18	0.00	402	
		2	10SEP2019/10:18	0.00	701	
		4	10SEP2019/12:19	1.00	1160	
		6	10SEP2019/14:18	0.00	845	
		8	10SEP2019/16:18	0.00	535	
		12	10SEP2019/20:13	-5.00	463	
		14	10SEP2019/22:18	0.00	1020	
		16	11SEP2019/00:19	1.00	916	
		18	11SEP2019/02:18	0.00	844	
		20	11SEP2019/04:18	0.00	612	
		24	11SEP2019/08:18	0.00	411	
		48	12SEP2019/08:18	0.00	117	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
7	9043	PREDOSE	24SEP2019/07:59	.	840	
		0.5	24SEP2019/08:34	1.00	451	
		1	24SEP2019/09:03	0.00	442	
		2	24SEP2019/10:03	0.00	1050	
		4	24SEP2019/12:03	0.00	1640	
		6	24SEP2019/14:03	0.00	1020	
		8	24SEP2019/16:18	15.00	543	
		12	24SEP2019/19:58	-5.00	501	
		14	24SEP2019/22:03	0.00	468	
		16	25SEP2019/00:06	3.00	1120	
		18	25SEP2019/02:08	5.00	960	
		20	25SEP2019/04:05	2.00	859	
		24	25SEP2019/08:05	2.00	570	
		48	26SEP2019/08:11	8.00	237	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
7	9046	PREDOSE	24SEP2019/08:01	.	909	
		0.5	24SEP2019/08:37	1.00	694	
		1	24SEP2019/09:08	2.00	629	
		2	24SEP2019/10:06	0.00	721	
		4	24SEP2019/12:09	3.00	1350	
		6	24SEP2019/14:07	1.00	833	
		8	24SEP2019/16:06	0.00	567	
		12	24SEP2019/20:01	-5.00	523	
		14	24SEP2019/22:06	0.00	1330	
		16	25SEP2019/00:09	3.00	1470	
		18	25SEP2019/02:06	0.00	1170	
		20	25SEP2019/04:07	1.00	1070	
		24	25SEP2019/08:06	0.00	802	
		48	26SEP2019/08:06	0.00	264	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
7	9051	PREDOSE	08OCT2019/08:10	.	282	
		0.5	08OCT2019/08:45	0.00	239	
		1	08OCT2019/09:15	0.00	449	
		2	08OCT2019/10:15	0.00	937	
		4	08OCT2019/12:15	0.00	1020	
		6	08OCT2019/14:15	0.00	513	
		8	08OCT2019/16:15	0.00	285	
		12	08OCT2019/20:10	-5.00	352	
		14	08OCT2019/22:15	0.00	512	
		16	09OCT2019/00:15	0.00	641	
		18	09OCT2019/02:15	0.00	539	
		20	09OCT2019/04:15	0.00	322	
		24	09OCT2019/08:15	0.00	284	
		48	10OCT2019/08:15	0.00	27.9	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
7	9052	PREDOSE	08OCT2019/08:14	.	575	
		0.5	08OCT2019/08:49	0.00	440	
		1	08OCT2019/09:19	0.00	450	
		2	08OCT2019/10:19	0.00	745	
		4	08OCT2019/12:19	0.00	1930	
		6	08OCT2019/14:19	0.00	1160	
		8	08OCT2019/16:19	0.00	750	
		12	08OCT2019/20:14	-5.00	494	
		14	08OCT2019/22:19	0.00	890	
		16	09OCT2019/00:19	0.00	1850	
		18	09OCT2019/02:19	0.00	1310	
		20	09OCT2019/04:19	0.00	909	
		24	09OCT2019/08:19	0.00	622	
		48	10OCT2019/08:19	0.00	146	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
7	9056	PREDOSE	08OCT2019/07:55	.	653	
		0.5	08OCT2019/08:35	5.00	458	
		1	08OCT2019/09:00	0.00	384	
		2	08OCT2019/10:03	3.00	323	
		4	08OCT2019/12:03	3.00	901	
		6	08OCT2019/14:06	6.00	1130	
		8	08OCT2019/16:04	4.00	794	
		12	08OCT2019/19:57	-3.00	1220	
		14	08OCT2019/22:00	0.00	853	
		16	09OCT2019/00:05	5.00	1210	
		18	09OCT2019/02:00	0.00	1020	
		20	09OCT2019/04:00	0.00	894	
		24	09OCT2019/08:03	3.00	707	
		48	10OCT2019/08:00	0.00	257	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
7	9057	PREDOSE	08OCT2019/07:58	.	635	
		0.5	08OCT2019/08:33	0.00	421	
		1	08OCT2019/09:03	0.00	368	
		2	08OCT2019/10:03	0.00	512	
		4	08OCT2019/12:03	0.00	1270	
		6	08OCT2019/14:03	0.00	931	
		8	08OCT2019/16:03	0.00	760	
		12	08OCT2019/19:58	-5.00	761	
		14	08OCT2019/22:03	0.00	797	
		16	09OCT2019/00:03	0.00	977	
		18	09OCT2019/02:03	0.00	853	
		20	09OCT2019/04:03	0.00	913	
		24	09OCT2019/08:03	0.00	648	
		48	10OCT2019/08:03	0.00	182	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
7	9058	PREDOSE	22OCT2019/08:02	.	645	
		0.5	22OCT2019/08:37	0.00	488	
		1	22OCT2019/09:07	0.00	897	
		2	22OCT2019/10:07	0.00	1710	
		4	22OCT2019/12:12	5.00	1470	
		6	22OCT2019/14:07	0.00	1270	
		8	22OCT2019/16:20	13.00	837	
		12	22OCT2019/20:14	7.00	621	
		14	22OCT2019/22:17	10.00	481	
		16	23OCT2019/00:17	10.00	704	
		18	23OCT2019/02:17	10.00	854	
		20	23OCT2019/04:18	11.00	743	
		24	23OCT2019/08:29	22.00	742	
		48	24OCT2019/08:08	1.00	141	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
7	9061	PREDOSE	22OCT2019/07:58	.	572	
		0.5	22OCT2019/08:33	0.00	439	
		1	22OCT2019/09:05	2.00	413	
		2	22OCT2019/10:03	0.00	606	
		4	22OCT2019/12:07	4.00	1290	
		6	22OCT2019/14:03	0.00	1000	
		8	22OCT2019/16:03	0.00	603	
		12	22OCT2019/19:58	-5.00	554	
		14	22OCT2019/22:10	7.00	614	
		16	23OCT2019/00:03	0.00	888	
		18	23OCT2019/02:05	2.00	936	
		20	23OCT2019/04:05	2.00	734	
		24	23OCT2019/08:06	3.00	460	
		48	24OCT2019/08:03	0.00	129	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
7	9062	PREDOSE	08OCT2019/08:01	.	462	
		0.5	08OCT2019/08:36	0.00	386	
		1	08OCT2019/09:06	0.00	359	
		2	08OCT2019/10:06	0.00	692	
		4	08OCT2019/12:07	1.00	941	
		6	08OCT2019/14:06	0.00	1020	
		8	08OCT2019/16:06	0.00	736	
		12	08OCT2019/20:06	0.00	647	
		14	08OCT2019/22:06	0.00	561	
		16	09OCT2019/00:06	0.00	849	
		18	09OCT2019/02:06	0.00	901	
		20	09OCT2019/04:06	0.00	598	
		24	09OCT2019/08:06	0.00	381	
		48	10OCT2019/08:06	0.00	128	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
7	9063	PREDOSE	08OCT2019/08:04	.	687	
		0.5	08OCT2019/08:39	0.00	539	
		1	08OCT2019/09:09	0.00	721	
		2	08OCT2019/10:09	0.00	1860	
		4	08OCT2019/12:09	0.00	2180	
		6	08OCT2019/14:09	0.00	1450	
		8	08OCT2019/16:09	0.00	823	
		12	08OCT2019/20:04	-5.00	635	
		14	08OCT2019/22:09	0.00	962	
		16	09OCT2019/00:09	0.00	1440	
		18	09OCT2019/02:09	0.00	1150	
		20	09OCT2019/04:09	0.00	955	
		24	09OCT2019/08:09	0.00	690	
		48	10OCT2019/08:09	0.00	190	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
7	9069	PREDOSE	22OCT2019/08:01	.	689	
		0.5	22OCT2019/08:36	0.00	511	
		1	22OCT2019/09:06	0.00	472	
		2	22OCT2019/10:06	0.00	560	
		4	22OCT2019/12:06	0.00	1270	
		6	22OCT2019/14:06	0.00	709	
		8	22OCT2019/16:06	0.00	501	
		12	22OCT2019/20:01	-5.00	543	
		14	22OCT2019/22:06	0.00	987	
		16	23OCT2019/00:06	0.00	861	
		18	23OCT2019/02:06	0.00	772	
		20	23OCT2019/04:06	0.00	647	
		24	23OCT2019/08:17	11.00	517	
		48	24OCT2019/08:06	0.00	232	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
7	9073	PREDOSE	22OCT2019/08:11	.	502	
		0.5	22OCT2019/08:46	0.00	397	
		1	22OCT2019/09:16	0.00	350	
		2	22OCT2019/10:16	0.00	847	
		4	22OCT2019/12:16	0.00	1300	
		6	22OCT2019/14:16	0.00	931	
		8	22OCT2019/16:16	0.00	637	
		12	22OCT2019/20:11	-5.00	505	
		14	22OCT2019/22:16	0.00	1030	
		16	23OCT2019/00:16	0.00	959	
		18	23OCT2019/02:16	0.00	811	
		20	23OCT2019/04:18	2.00	696	
		24	23OCT2019/08:16	0.00	522	
		48	24OCT2019/08:16	0.00	195	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
7	9077	PREDOSE	22OCT2019/08:07	.	969	
		0.5	22OCT2019/08:42	0.00	739	
		1	22OCT2019/09:12	0.00	750	
		2	22OCT2019/10:12	0.00	847	
		4	22OCT2019/12:31	19.00	2120	
		6	22OCT2019/14:12	0.00	1230	
		8	22OCT2019/16:12	0.00	875	
		12	22OCT2019/20:07	-5.00	925	
		14	22OCT2019/22:12	0.00	1000	
		16	23OCT2019/00:12	0.00	1360	
		18	23OCT2019/02:12	0.00	1290	
		20	23OCT2019/04:12	0.00	1210	
		24	23OCT2019/08:12	0.00	1090	
		48	24OCT2019/08:12	0.00	381	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
7	9080	PREDOSE	22OCT2019/08:16	.	797	
		0.5	22OCT2019/08:51	0.00	613	
		1	22OCT2019/09:21	0.00	481	
		2	22OCT2019/10:21	0.00	474	
		4	22OCT2019/12:21	0.00	1120	
		6	22OCT2019/14:21	0.00	1370	
		8	22OCT2019/16:21	0.00	886	
		12	22OCT2019/20:16	-5.00	1280	
		14	22OCT2019/22:27	6.00	1110	
		16	23OCT2019/00:34	13.00	1500	
		20	23OCT2019/04:21	0.00	1290	
		24	23OCT2019/08:21	0.00	1030	
		48	24OCT2019/08:21	0.00	206	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
7	9081	PREDOSE	05NOV2019/06:55	.	491	
		0.5	05NOV2019/07:31	1.00	420	
		1	05NOV2019/08:00	0.00	409	
		2	05NOV2019/09:00	0.00	769	
		4	05NOV2019/11:00	0.00	1030	
		6	05NOV2019/13:00	0.00	906	
		8	05NOV2019/15:00	0.00	579	
		12	05NOV2019/18:55	-5.00	491	
		14	05NOV2019/21:00	0.00	851	
		16	05NOV2019/23:00	0.00	808	
		18	06NOV2019/01:00	0.00	708	
		20	06NOV2019/03:02	2.00	638	
		24	06NOV2019/07:00	0.00	461	
		48	07NOV2019/07:00	0.00	160	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
7	9086	PREDOSE	22OCT2019/08:10	.	339	
		0.5	22OCT2019/08:45	0.00	230	
		1	22OCT2019/09:15	0.00	357	
		2	22OCT2019/10:15	0.00	531	
		4	22OCT2019/12:15	0.00	690	
		6	22OCT2019/14:15	0.00	626	
		8	22OCT2019/16:15	0.00	286	
		12	22OCT2019/20:10	-5.00	265	
		14	22OCT2019/22:15	0.00	632	
		16	23OCT2019/00:15	0.00	654	
		18	23OCT2019/02:15	0.00	548	
		20	23OCT2019/04:15	0.00	391	
		24	23OCT2019/08:15	0.00	263	
		48	24OCT2019/08:15	0.00	114	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
7	9087	PREDOSE	22OCT2019/08:13	.	449	
		0.5	22OCT2019/08:48	0.00	364	
		1	22OCT2019/09:18	0.00	329	
		2	22OCT2019/10:18	0.00	291	
		4	22OCT2019/12:18	0.00	516	
		6	22OCT2019/14:18	0.00	751	
		8	22OCT2019/16:18	0.00	638	
		12	22OCT2019/20:17	-1.00	549	
		14	22OCT2019/22:18	0.00	712	
		16	23OCT2019/00:18	0.00	1010	
		18	23OCT2019/02:18	0.00	868	
		20	23OCT2019/04:18	0.00	782	
		24	23OCT2019/08:18	0.00	514	
		48	24OCT2019/08:18	0.00	121	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
7	9089	PREDOSE	22OCT2019/08:19	.	563	
		0.5	22OCT2019/08:54	0.00	450	
		1	22OCT2019/09:24	0.00	387	
		2	22OCT2019/10:24	0.00	355	
		4	22OCT2019/12:24	0.00	950	
		6	22OCT2019/14:24	0.00	972	
		8	22OCT2019/16:24	0.00	566	
		12	22OCT2019/20:19	-5.00	444	
		14	22OCT2019/22:24	0.00	439	
		16	23OCT2019/00:24	0.00	786	
		18	23OCT2019/02:24	0.00	998	
		20	23OCT2019/04:24	0.00	752	
		24	23OCT2019/08:24	0.00	480	
		48	24OCT2019/08:24	0.00	142	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
7	9092	PREDOSE	22OCT2019/08:22	.	460	
		0.5	22OCT2019/08:57	0.00	376	
		1	22OCT2019/09:27	0.00	590	
		2	22OCT2019/10:27	0.00	1530	
		4	22OCT2019/12:27	0.00	1390	
		6	22OCT2019/14:27	0.00	688	
		8	22OCT2019/16:27	0.00	444	
		12	22OCT2019/20:22	-5.00	598	
		14	22OCT2019/22:27	0.00	842	
		16	23OCT2019/00:27	0.00	960	
		18	23OCT2019/02:27	0.00	774	
		20	23OCT2019/04:27	0.00	638	
		24	23OCT2019/08:27	0.00	270	
		48	24OCT2019/08:27	0.00	129	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.1
Individual Plasma Collection Times and Concentrations of TPOXX
Safety Population

Day	Subject	Scheduled Time (hours)	Blood Collection Date/Time	Deviation From Scheduled Time (minutes)	Concentration (ng/mL)	Comment
7	9095	PREDOSE	05NOV2019/07:01	.	662	
		0.5	05NOV2019/07:36	0.00	579	
		1	05NOV2019/08:06	0.00	318	
		2	05NOV2019/09:06	0.00	527	
		4	05NOV2019/11:06	0.00	863	
		6	05NOV2019/13:06	0.00	1340	
		8	05NOV2019/15:06	0.00	1030	
		12	05NOV2019/19:01	-5.00	706	
		14	05NOV2019/21:06	0.00	905	
		16	05NOV2019/23:06	0.00	1300	
		18	06NOV2019/01:06	0.00	996	
		20	06NOV2019/03:06	0.00	976	
		24	06NOV2019/07:06	0.00	719	
		48	07NOV2019/07:06	0.00	252	

BLQ = Below the Limit of Quantification.
Note: The lower limit of quantification is 5.00 ng/mL.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Plasma concentration data and CRF data
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020601.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.2
Individual Plasma Pharmacokinetic Parameters of TPOXX — Day 1
Pharmacokinetic Population

Subject	Cmax (ng/mL)	AUC0-24 (h*ng/mL)	AUC0-t (h*ng/mL)	AUC0-tau (h*ng/mL)	Tmax (h)	t1/2 (h)	Lambda_z (1/h)
9001	1100	12100	12100	6180	4.00	9.35	0.0742
9002	717	11300	11300	4520	4.30	NC	NC
9005	1080	15700	15700	6250	4.00	NC	NC
9009	523	13100	13100	3460	4.13	NC	NC
9012	757	11700	11700	5400	4.00	NC	NC
9015	900	11000	11000	4970	6.00	NC	NC
9016	711	10900	10900	4770	4.00	NC	NC
9019	922	12400	12400	6460	4.00	NC	NC
9020	740	12900	12900	5980	4.00	NC	NC
9021	890	12800	12800	5410	4.03	5.09	0.1362
9022	648	11400	11400	4830	6.00	18.2	0.0380
9024	885	15700	15700	7270	6.00	NC	NC
9025	1330	18000	18000	7200	8.02	NC	NC
9033	574	8760	8760	3600	4.00	6.15	0.1127
9043	909	12500	12500	5690	4.02	NC	NC
9046	1030	14000	14000	5140	4.00	6.33	0.1095
9051	811	7830	7830	3490	4.00	8.50	0.0815
9052	941	15300	15300	5680	6.00	10.3	0.0674
9056	938	11900	11900	4520	4.00	NC	NC
9057	557	8780	8780	3980	6.00	NC	NC
9058	894	12500	12500	6050	2.00	NC	NC
9061	965	13800	13800	6000	4.00	NC	NC
9062	609	8350	8350	3920	2.00	NC	NC
9063	762	11300	11300	4860	4.00	NC	NC

NC = Not Calculated.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Listing 16.2.6.1
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020602.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.2
Individual Plasma Pharmacokinetic Parameters of TPOXX — Day 1
Pharmacokinetic Population

Subject	Cmax (ng/mL)	AUC0-24 (h*ng/mL)	AUC0-t (h*ng/mL)	AUC0-tau (h*ng/mL)	Tmax (h)	t1/2 (h)	Lambda_z (1/h)
9069	957	12800	12800	5190	4.10	5.62	0.1234
9073	702	8470	8470	3890	2.05	6.49	0.1069
9077	1310	19000	19000	7120	4.00	NC	NC
9080	1130	13000	13000	6840	4.00	NC	NC
9081	628	8490	8490	3790	2.00	11.3	0.0614
9086	634	6210	6210	2960	4.00	NC	NC
9087	1160	11300	11300	5140	4.00	5.76	0.1204
9089	802	11000	11000	5000	4.00	NC	NC
9092	596	8610	8610	3950	2.00	NC	NC
9095	697	11100	11100	4740	4.00	NC	NC

NC = Not Calculated.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Source Data: Listing 16.2.6.1
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020602.SAS Executed: 24JAN2020 08:05

Listing 16.2.6.3
Individual Plasma Pharmacokinetic Parameters of TPOXX — Day 7
Pharmacokinetic Population

Subject	Cmax (ng/mL)	AUC0-24 (h*ng/mL)	AUC0-t (h*ng/mL)	AUC0-tau (h*ng/mL)	AUC0-inf (h*ng/mL)	Tmax (h)	t1/2 (h)	Lambda_z (1/h)	CL/F (L/h)	Vz/F (L)	%AUCextrap (%)
9001	1600	19200	26500	10300	28500	4.00	11.2	0.0616	58.5	948	6.89
9002	1290	19200	29200	8990	33200	4.00	13.9	0.0499	66.7	1340	12.2
9005	2270	27500	40900	13400	48700	4.00	17.1	0.0406	44.8	1100	15.9
9009	1190	23600	37000	10600	42700	4.00	14.4	0.0482	56.7	1180	13.3
9012	1060	17100	25900	7670	NC	6.00	NC	NC	78.2	NC	NC
9015	878	15700	22600	7720	24200	4.00	10.4	0.0665	77.7	1170	6.64
9016	1750	25000	39700	13000	43000	4.00	10.9	0.0638	46.3	725	7.48
9019	1130	19200	27700	9390	29600	6.00	10.4	0.0669	63.9	955	6.56
9020	1110	18600	28800	9100	34600	6.03	16.2	0.0427	66.0	1540	16.6
9021	1050	12600	17000	5900	17700	4.00	9.15	0.0758	102	1340	4.32
9022	1200	21900	30600	10300	33000	6.00	11.1	0.0627	58.0	926	7.16
9024	1860	26900	39800	13000	44900	4.00	13.3	0.0523	46.3	885	11.5
9025	1480	26800	39400	13100	43700	6.00	12.5	0.0552	45.7	827	9.78
9033	1160	16800	23200	8120	25100	4.02	11.3	0.0614	73.9	1200	7.60
9043	1640	19700	29400	10400	34700	4.00	15.5	0.0448	57.9	1290	15.2
9046	1350	22600	35400	9250	40700	4.05	14.1	0.0493	64.9	1320	13.2
9051	1020	11800	15600	6560	15900	4.00	7.65	0.0906	91.5	1010	1.94
9052	1930	23800	33000	11200	35200	4.00	10.1	0.0685	53.4	781	6.07
9056	1220	21500	33100	10000	38800	11.95	15.4	0.0449	59.8	1330	14.7
9057	1270	19700	29600	9620	32900	4.00	12.4	0.0560	62.4	1110	9.89
9058	1710	21600	32100	13000	34300	2.00	11.0	0.0633	46.2	731	6.49
9061	1290	17600	24700	9060	26900	4.07	11.7	0.0590	66.2	1120	8.13
9062	1020	16900	23000	9040	25400	6.00	13.4	0.0517	66.4	1280	9.73
9063	2180	26800	37300	14800	40600	4.00	11.9	0.0583	40.6	698	8.04

NC = Not Calculated.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Note: AUC0-inf estimate is unreliable when %AUCextrap is greater than 20%. CL/F is calculated as Dose/AUC0-12. Vz/F is calculated as Dose/(AUC0-12*Lambda_z).
Source Data: Listing 16.2.6.1
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020603.SAS Executed: 24JAN2020 08:06

Listing 16.2.6.3
Individual Plasma Pharmacokinetic Parameters of TPOXX — Day 7
Pharmacokinetic Population

Subject	Cmax (ng/mL)	AUC0-24 (h*ng/mL)	AUC0-t (h*ng/mL)	AUC0-tau (h*ng/mL)	AUC0-inf (h*ng/mL)	Tmax (h)	t1/2 (h)	Lambda_z (1/h)	CL/F (L/h)	Vz/F (L)	%AUCextrap (%)
9069	1270	17100	26000	8170	32100	4.00	18.3	0.0379	73.4	1940	19.1
9073	1300	18500	27100	9240	31400	4.00	15.1	0.0458	65.0	1420	13.6
9077	2120	27600	45300	13600	54500	4.32	16.8	0.0413	44.2	1070	16.9
9080	1370	27000	41800	11800	44900	6.00	10.5	0.0661	50.9	770	6.94
9081	1030	16500	23900	8380	27200	4.00	14.2	0.0487	71.6	1470	12.1
9086	690	10900	15500	5280	17900	4.00	14.8	0.0468	114	2430	13.6
9087	751	15600	23200	6520	25100	6.00	10.6	0.0652	92.0	1410	7.39
9089	972	15700	23200	7610	25700	6.00	12.3	0.0565	78.8	1400	9.79
9092	1530	17900	22700	9730	25100	2.00	12.7	0.0546	61.7	1130	9.42
9095	1340	21900	33500	10400	38900	6.00	14.8	0.0467	57.8	1240	13.9

NC = Not Calculated.
Treatment: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
Note: AUC0-inf estimate is unreliable when %AUCextrap is greater than 20%. CL/F is calculated as Dose/AUC0-12. Vz/F is calculated as Dose/(AUC0-12*Lambda_z).
Source Data: Listing 16.2.6.1
Program path: \\\\wilbtib\wilbtib08\SIGA SGSIGA246022_PK\Trunk\TLF\l16020603.SAS Executed: 24JAN2020 08:06

16.2.7 Adverse Event Listings (Each Subject)

Listing 16.2.7.1
Adverse Events
Safety Population

Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day=The presented date — First dose date + 1
TEAE=Treatment-emergent Adverse Event
Duration (Days)=Stop date — Start date + 1
Time to AE (Days)=Start date — First dose date + 1
CM=Concomitant or Additional Treatment Given? ; CM ID=ID of medication/therapy taken for AE
Action=Action taken with study treatment
Relationship=Relationship to study treatment
Study Disc=Caused study discontinuation?
Adverse Events were coded using MedDRA, Version 22.0.
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.7.1
Adverse Events
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	AE ID	System Organ Class/ Preferred Term/ Adverse Event Term	Start Date/ Time (Day)/ Stop Date/ Time (Day)	TEAE/ Time to AE (Days)/ Duration (Days)	Frequency/ Outcome/ Serious	Severity/ Action/ Other Action Taken	Relationship/ Study Disc/ CM/CM ID
9002	48/M/W	1	Gastrointestinal disorders/ Nausea/ NAUSEA	15AUG2019 06:43 (2)/ 15AUG2019 23:00 (2)	Yes/ 2/ 1	CONTINUOUS/ RECOVERED/ RESOLVED/ No	Grade 1/ DOSE NOT CHANGED	UNLIKELY RELATED/ No/ No
		2	Nervous system disorders/ Headache/ HEADACHE	15AUG2019 06:43 (2)/ 15AUG2019 23:00 (2)	Yes/ 2/ 1	CONTINUOUS/ RECOVERED/ RESOLVED/ No	Grade 1/ DOSE NOT CHANGED	UNLIKELY RELATED/ No/ No
9005	40/M/W	1	Eye disorders/ Scleral hyperaemia/ INJECTED SCLERAE	16AUG2019 19:25 (3)/ 19AUG2019 08:30 (6)	Yes/ 3/ 4	CONTINUOUS/ RECOVERED/ RESOLVED/ No	Grade 1/ DOSE NOT CHANGED	UNLIKELY RELATED/ No/ No
9009	21/F/BL	1	Gastrointestinal disorders/ Lip dry/ DRY LIPS	15AUG2019 09:00 (2)/ 16AUG2019 17:00 (3)	Yes/ 2/ 2	CONTINUOUS/ RECOVERED/ RESOLVED/ No	Grade 1/ DOSE NOT CHANGED	NOT RELATED/ No/ No
9016	48/F/W	1	Skin and subcutaneous tissue disorders/ Dermatitis contact/ CONTACT DERMATITIS (R SHOULDER)	08SEP2019 20:00 (5)/ 11SEP2019 00:00 (8)	Yes/ 5/ 4	CONTINUOUS/ RECOVERED/ RESOLVED/ No	Grade 1/ DOSE NOT CHANGED	UNLIKELY RELATED/ No/ No

Note: Footnotes are listed on page 1.

Listing 16.2.7.1
Adverse Events
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	AE ID	System Organ Class/ Preferred Term/ Adverse Event Term	Start Date/ Time (Day)/ Stop Date/ Time (Day)	TEAE/ Time to AE (Days)/ Duration (Days)	Frequency/ Outcome/ Serious	Severity/ Action/ Other Action Taken	Relationship/ Study Disc/ CM/CM ID
9021	39/F/BL	1	Gastrointestinal disorders/ Nausea/ NAUSEA	05SEP2019 12:30 (2)/ 08SEP2019 12:00 (5)	Yes/ 2/ 4	INTERMITTENT/ RECOVERED/ RESOLVED/ No	Grade 1/ DOSE NOT CHANGED	POSSIBLY RELATED/ No/ No
		2	Musculoskeletal and connective tissue disorders/ Back pain/ BACK PAIN (MUSCULOSKELETAL)	06SEP2019 07:22 (3)/ 13SEP2019 08:00 (10)	Yes/ 3/ 8	INTERMITTENT/ RECOVERED/ RESOLVED/ No	Grade 1/ DOSE NOT CHANGED	NOT RELATED/ No/ No
		3	Gastrointestinal disorders/ Infrequent bowel movements/ DECREASED FREQUENCY OF BOWEL MOVEMENTS	06SEP2019 17:00 (3)/ 11SEP2019 20:30 (8)	Yes/ 3/ 6	CONTINUOUS/ RECOVERED/ RESOLVED/ No	Grade 1/ DOSE NOT CHANGED; NON DRUG THERAPY GIVEN	UNLIKELY RELATED/ No/ Yes/1,2
9033	32/M/W	1	Injury, poisoning and procedural complications/ Palate injury/ HARD PALATE TRAUMA	07SEP2019 07:00 (4)/ 09SEP2019 19:55 (6)	Yes/ 4/ 3	CONTINUOUS/ RECOVERED/ RESOLVED/ No	Grade 1/ DOSE NOT CHANGED	NOT RELATED/ No/ No
9043	22/M/BL	1	Renal and urinary disorders/ Dysuria/ DYSURIA	23SEP2019 08:30 (6)/ 23SEP2019 11:00 (6)	Yes/ 6/ 1	CONTINUOUS/ RECOVERED/ RESOLVED/ No	Grade 1/ DOSE NOT CHANGED	UNLIKELY RELATED/ No/ No

Note: Footnotes are listed on page 1.

Listing 16.2.7.1
Adverse Events
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	AE ID	System Organ Class/ Preferred Term/ Adverse Event Term	Start Date/ Time (Day)/ Stop Date/ Time (Day)	TEAE/ Time to AE (Days)/ Duration (Days)	Frequency/ Outcome/ Serious	Severity/ Action/ Other Action Taken	Relationship/ Study Disc/ CM/CM ID
9061	21/F/BL	1	Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	03NOV2019 22:00 (19)/ 11NOV2019 12:00 (27)	Yes/ 19/ 9	CONTINUOUS/ RECOVERED/ RESOLVED/ No	Grade 1/ NOT APPLICABLE; CON MED GIVEN	NOT RELATED/ No/ Yes/2
9089	29/M/BL	1	Nervous system disorders/ Headache/ HEADACHE	17OCT2019 15:03 (2)/ 17OCT2019 20:00 (2)	Yes/ 2/ 1	INTERMITTENT/ RECOVERED/ RESOLVED/ No	Grade 1/ DOSE NOT CHANGED	POSSIBLY RELATED/ No/ No

Note: Footnotes are listed on page 1.

Listing 16.2.7.2
Treatment-Related Adverse Events
Safety Population

Sex: M=Male, F=Female
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day=The presented date — First dose date + 1
TEAE=Treatment-emergent Adverse Event
Duration (Days)=Stop date — Start date + 1
Time to AE (Days)=Start date — First dose date + 1
CM=Concomitant or Additional Treatment Given?; CM ID=ID of medication/therapy taken for AE
Action=Action taken with study treatment
Relationship=Relationship to study treatment
Study Disc=Caused study discontinuation?
Adverse Events were coded using MedDRA, Version 22.0.
An adverse event is considered Treamtment-related if it is assessed as possibly, probably, or definitely related by the investigator.
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.7.2
Treatment-Related Adverse Events
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	AE ID	System Organ Class/ Preferred Term/ Adverse Event Term	Start Date/ Time (Day)/ Stop Date/ Time (Day)	TEAE/ Time to AE (Days)/ Duration (Days)	Frequency/ Outcome/ Serious	Severity/ Action/ Other Action Taken	Relationship/ Study Disc/ CM/CM ID
9021	39/F/BL	1	Gastrointestinal disorders/ Nausea/ NAUSEA	05SEP2019 12:30 (2)/ 08SEP2019 12:00 (5)	Yes/ 2/ 4	INTERMITTENT/ RECOVERED/ RESOLVED/ No	Grade 1/ DOSE NOT CHANGED	POSSIBLY RELATED/ No/ No
9089	29/M/BL	1	Nervous system disorders/ Headache/ HEADACHE	17OCT2019 15:03 (2)/ 17OCT2019 20:00 (2)	Yes/ 2/ 1	INTERMITTENT/ RECOVERED/ RESOLVED/ No	Grade 1/ DOSE NOT CHANGED	POSSIBLY RELATED/ No/ No

Note: Footnotes are listed on page 1.

Listing 16.2.7.3
Serious Adverse Events
Safety Population

Sex: M=Male, F=Female
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day=The presented date — First dose date + 1
TEAE=Treatment-emergent Adverse Event
Duration (Days)=Stop date — Start date + 1
Time to AE (Days)=Start date — First dose date + 1
CM=Concomitant or Additional Treatment Given?; CM ID=ID of medication/therapy taken for AE
Action=Action taken with study treatment
Relationship=Relationship to study treatment
Study Disc=Caused study discontinuation?
Adverse Events were coded using MedDRA, Version 22.0.
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.7.3
Serious Adverse Events
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	AE ID	System Organ Class/ Preferred Term/ Adverse Event Term	Start Date/ Time (Day)/ Stop Date/ Time (Day)	TEAE/ Time to AE (Days)/ Duration (Days)	Frequency/ Outcome/ Serious	Severity/ Action/ Other Action Taken	Relationship/ Study Disc/ CM/CM ID

No data to display

Note: Footnotes are listed on page 1.

Listing 16.2.7.4
Adverse Events Leading to Study Drug Discontinuation
Safety Population

Sex: M=Male, F=Female
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day=The presented date — First dose date + 1
TEAE=Treatment-emergent Adverse Event
Duration (Days)=Stop date — Start date + 1
Time to AE (Days)=Start date — First dose date + 1
CM=Concomitant or Additional Treatment Given?; CM ID=ID of medication/therapy taken for AE
Action=Action taken with study treatment
Relationship=Relationship to study treatment
Adverse Events were coded using MedDRA, Version 22.0.
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.7.4
Adverse Events Leading to Study Drug Discontinuation
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	AE ID	System Organ Class/ Preferred Term/ Adverse Event Term	Start Date/ Time (Day)/ Stop Date/ Time (Day)	TEAE/ Time to AE (Days)/ Duration (Days)	Frequency/ Outcome/ Serious	Severity/ Action/ Other Action Taken	Relationship/ CM/CM ID

No data to display

Note: Footnotes are listed on page 1.

16.2.8 Listing of Individual Laboratory Measurements by Subject

Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9001	41/M/BL		Screening	19JUL2019 12:06 (-26)	Basophils	0.04	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.8	%			0-1.4	
					Eosinophils	0.14	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	2.8	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	330	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	29.0	pg			25-33.6	
					Ery. Mean Corpuscular Volume	88.1	fL			76.5-97.5	
					Erythrocytes	5.18	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	15.3	%			11.8-15.5	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9001	41/M/BL		Screening	19JUL2019 12:06 (-26)	Hematocrit	0.457	fraction of 1			0.387-0.507	
					Hemoglobin	150	g/L			128-174	
					Leukocytes	5.0	10^9/L			3.1-9.7	
					Lymphocytes	1.59	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	31.5	%			13.9-48.3	
					Monocytes	0.37	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	7.4	%			3.3-12.1	
					Neutrophils	2.90	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	57.6	%			39.1-77.2	
					Platelets	227	10^9/L			140-400	
			Check-in	13AUG2019 09:44 (-1)	Basophils	0.04	10^9/L			0-0.08	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9001	41/M/BL		Check-in	13AUG2019 09:44 (-1)	Basophils/ Leukocytes	0.6	%			0-1.4	
					Eosinophils	0.14	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	2.2	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	340	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	30.0	pg			25-33.6	
					Ery. Mean Corpuscular Volume	88.3	fL			76.5-97.5	
					Erythrocytes	4.99	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	14.9	%			11.8-15.5	
					Hematocrit	0.441	fraction of 1			0.387-0.507	
					Hemoglobin	150	g/L			128-174	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9001	41/M/BL		Check-in	13AUG2019 09:44 (-1)	Leukocytes	6.4	10^9/L			3.1-9.7	
					Lymphocytes	1.50	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	23.4	%			13.9-48.3	
					Monocytes	0.39	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	6.0	%			3.3-12.1	
					Neutrophils	4.36	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	67.8	%			39.1-77.2	
					Platelets	261	10^9/L			140-400	
		TPOXX 600 mg	Day 4	17AUG2019 08:54 (4)	Basophils	0.04	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.5	%			0-1.4	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9001	41/M/BL	TPOXX 600 mg	Day 4	17AUG2019 08:54 (4)	Eosinophils	0.16	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	2.1	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	341	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	29.8	pg			25-33.6	
					Ery. Mean Corpuscular Volume	87.4	fL			76.5-97.5	
					Erythrocytes	5.03	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	14.6	%			11.8-15.5	
					Hematocrit	0.439	fraction of 1			0.387-0.507	
					Hemoglobin	150	g/L			128-174	
					Leukocytes	7.6	10^9/L			3.1-9.7	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9001	41/M/BL	TPOXX 600 mg	Day 4	17AUG2019 08:54 (4)	Lymphocytes	1.95	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	25.8	%			13.9-48.3	
					Monocytes	0.56	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	7.4	%			3.3-12.1	
					Neutrophils	4.85	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	64.2	%			39.1-77.2	
					Platelets	281	10^9/L			140-400	
			Day 8 - 12 Hours Postdose	21AUG2019 09:25 (8)	Basophils	0.04	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.5	%			0-1.4	

Sex: M=Male, F=Female;
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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9001	41/M/BL	TPOXX 600 mg	Day 8 - 12 Hours Postdose	21AUG2019 09:25 (8)	Eosinophils	0.12	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	1.5	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	338	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	29.5	pg			25-33.6	
					Ery. Mean Corpuscular Volume	87.2	fL			76.5-97.5	
					Erythrocytes	5.03	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	14.2	%			11.8-15.5	
					Hematocrit	0.439	fraction of 1			0.387-0.507	
					Hemoglobin	148	g/L			128-174	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9001	41/M/BL	TPOXX 600 mg	Day 8 - 12 Hours Postdose	21AUG2019 09:25 (8)	Leukocytes	7.9	10^9/L			3.1-9.7	
					Lymphocytes	2.10	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	26.6	%			13.9-48.3	
					Monocytes	0.59	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	7.5	%			3.3-12.1	
					Neutrophils	5.05	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	64.0	%			39.1-77.2	
					Platelets	274	10^9/L			140-400	
			Day 9	22AUG2019 09:25 (9)	Basophils	0.04	10^9/L			0-0.08	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9001	41/M/BL	TPOXX 600 mg	Day 9	22AUG2019 09:25 (9)	Basophils/ Leukocytes	0.6	%			0-1.4	
					Eosinophils	0.09	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	1.3	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	340	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	29.7	pg			25-33.6	
					Ery. Mean Corpuscular Volume	87.4	fL			76.5-97.5	
					Erythrocytes	4.93	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	14.5	%			11.8-15.5	
					Hematocrit	0.431	fraction of 1			0.387-0.507	
					Hemoglobin	146	g/L			128-174	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9001	41/M/BL	TPOXX 600 mg	Day 9	22AUG2019 09:25 (9)	Leukocytes	6.9	10^9/L			3.1-9.7	
					Lymphocytes	1.68	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	24.5	%			13.9-48.3	
					Monocytes	0.44	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	6.4	%			3.3-12.1	
					Neutrophils	4.61	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	67.2	%			39.1-77.2	
					Platelets	275	10^9/L			140-400	
9002	48/M/W		Screening	19JUL2019 12:02 (-26)	Basophils	0.07	10^9/L			0-0.08	
					Basophils/ Leukocytes	1.1	%			0-1.4	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9002	48/M/W		Screening	19JUL2019 12:02 (-26)	Eosinophils	0.09	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	1.5	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	336	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	29.6	pg			25-33.6	
					Ery. Mean Corpuscular Volume	87.9	fL			76.5-97.5	
					Erythrocytes	4.48	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	14.7	%			11.8-15.5	
					Hematocrit	0.394	fraction of 1			0.387-0.507	
					Hemoglobin	133	g/L			128-174	
					Leukocytes	6.2	10^9/L			3.1-9.7	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9002	48/M/W		Screening	19JUL2019 12:02 (-26)	Lymphocytes	1.94	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	31.4	%			13.9-48.3	
					Monocytes	0.67	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	10.8	%			3.3-12.1	
					Neutrophils	3.41	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	55.3	%			39.1-77.2	
					Platelets	336	10^9/L			140-400	
			Check-in	13AUG2019 10:01 (-1)	Basophils	0.06	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.9	%			0-1.4	
					Eosinophils	0.11	10^9/L			0-0.35	

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Day = The presented date — First dose date + 1
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Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9002	48/M/W		Check-in	13AUG2019 10:01 (-1)	Eosinophils/ Leukocytes	1.5	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	344	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	29.9	pg			25-33.6	
					Ery. Mean Corpuscular Volume	87.0	fL			76.5-97.5	
					Erythrocytes	4.31	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	14.3	%			11.8-15.5	
					Hematocrit	0.375	fraction of 1	L NCS		0.387-0.507	
					Hemoglobin	129	g/L			128-174	
					Leukocytes	7.4	10^9/L			3.1-9.7	
					Lymphocytes	1.67	10^9/L			0.8-2.91	

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Day = The presented date — First dose date + 1
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Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9002	48/M/W		Check-in	13AUG2019 10:01 (-1)	Lymphocytes/ Leukocytes	22.4	%			13.9-48.3	
					Monocytes	0.61	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	8.3	%			3.3-12.1	
					Neutrophils	4.99	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	67.0	%			39.1-77.2	
					Platelets	320	10^9/L			140-400	
		TPOXX 600 mg	Day 4	17AUG2019 08:49 (4)	Basophils	0.07	10^9/L			0-0.08	
					Basophils/ Leukocytes	1.0	%			0-1.4	
					Eosinophils	0.13	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	1.8	%			0-6.1	

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Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9002	48/M/W	TPOXX 600 mg	Day 4	17AUG2019 08:49 (4)	Ery. Mean Corpuscular HGB Concentration	341	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	29.6	pg			25-33.6	
					Ery. Mean Corpuscular Volume	86.8	fL			76.5-97.5	
					Erythrocytes	4.81	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	14.3	%			11.8-15.5	
					Hematocrit	0.418	fraction of 1			0.387-0.507	
					Hemoglobin	143	g/L			128-174	
					Leukocytes	7.5	10^9/L			3.1-9.7	
					Lymphocytes	2.46	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	33.0	%			13.9-48.3	
					Monocytes	0.64	10^9/L			0.15-0.75	

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Laboratory Results - Hematology
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Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9002	48/M/W	TPOXX 600 mg	Day 4	17AUG2019 08:49 (4)	Monocytes/ Leukocytes	8.6	%			3.3-12.1	
					Neutrophils	4.15	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	55.7	%			39.1-77.2	
					Platelets	349	10^9/L			140-400	
			Day 8 - 12 Hours Postdose	21AUG2019 09:24 (8)	Basophils	0.05	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.8	%			0-1.4	
					Eosinophils	0.12	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	1.7	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	352	g/L			320-354	

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Laboratory Results - Hematology
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Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9002	48/M/W	TPOXX 600 mg	Day 8 - 12 Hours Postdose	21AUG2019 09:24 (8)	Ery. Mean Corpuscular Hemoglobin	30.3	pg			25-33.6	
					Ery. Mean Corpuscular Volume	86.1	fL			76.5-97.5	
					Erythrocytes	4.74	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	14.4	%			11.8-15.5	
					Hematocrit	0.408	fraction of 1			0.387-0.507	
					Hemoglobin	144	g/L			128-174	
					Leukocytes	6.8	10^9/L			3.1-9.7	
					Lymphocytes	1.68	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	24.6	%			13.9-48.3	
					Monocytes	0.60	10^9/L			0.15-0.75	

Sex: M=Male, F=Female;
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Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9002	48/M/W	TPOXX 600 mg	Day 8 - 12 Hours Postdose	21AUG2019 09:24 (8)	Monocytes/ Leukocytes	8.8	%			3.3-12.1	
					Neutrophils	4.38	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	64.1	%			39.1-77.2	
					Platelets	349	10^9/L			140-400	
			Day 9	22AUG2019 09:27 (9)	Basophils	0.06	10^9/L			0-0.08	
					Basophils/ Leukocytes	1.0	%			0-1.4	
					Eosinophils	0.15	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	2.7	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	339	g/L			320-354	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
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Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9002	48/M/W	TPOXX 600 mg	Day 9	22AUG2019 09:27 (9)	Ery. Mean Corpuscular Hemoglobin	29.5	pg			25-33.6	
					Ery. Mean Corpuscular Volume	86.9	fL			76.5-97.5	
					Erythrocytes	4.62	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	14.0	%			11.8-15.5	
					Hematocrit	0.402	fraction of 1			0.387-0.507	
					Hemoglobin	136	g/L			128-174	
					Leukocytes	5.6	10^9/L			3.1-9.7	
					Lymphocytes	1.74	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	31.3	%			13.9-48.3	
					Monocytes	0.50	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	8.9	%			3.3-12.1	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9002	48/M/W	TPOXX 600 mg	Day 9	22AUG2019 09:27 (9)	Neutrophils	3.12	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	56.1	%			39.1-77.2	
					Platelets	337	10^9/L			140-400	
9005	40/M/W		Screening	23JUL2019 10:05 (-22)	Basophils	0.08	10^9/L			0-0.08	
					Basophils/ Leukocytes	1.0	%			0-1.4	
					Eosinophils	0.15	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	1.8	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	347	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	31.5	pg			25-33.6	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9005	40/M/W		Screening	23JUL2019 10:05 (-22)	Ery. Mean Corpuscular Volume	90.9	fL			76.5-97.5	
					Erythrocytes	4.99	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	13.5	%			11.8-15.5	
					Hematocrit	0.454	fraction of 1			0.387-0.507	
					Hemoglobin	157	g/L			128-174	
					Leukocytes	8.1	10^9/L			3.1-9.7	
					Lymphocytes	2.41	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	29.6	%			13.9-48.3	
					Monocytes	0.66	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	8.2	%			3.3-12.1	
					Neutrophils	4.84	10^9/L			1.5-6.75	

Sex: M=Male, F=Female;
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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9005	40/M/W		Screening	23JUL2019 10:05 (-22)	Neutrophils/ Leukocytes	59.5	%			39.1-77.2	
					Platelets	188	10^9/L			140-400	
			Check-in	13AUG2019 09:35 (-1)	Basophils	0.06	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.6	%			0-1.4	
					Eosinophils	0.21	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	2.2	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	350	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	31.7	pg			25-33.6	
					Ery. Mean Corpuscular Volume	90.7	fL			76.5-97.5	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9005	40/M/W		Check-in	13AUG2019 09:35 (-1)	Erythrocytes	5.04	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	13.4	%			11.8-15.5	
					Hematocrit	0.457	fraction of 1			0.387-0.507	
					Hemoglobin	160	g/L			128-174	
					Leukocytes	9.2	10^9/L			3.1-9.7	
					Lymphocytes	2.19	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	23.8	%			13.9-48.3	
					Monocytes	0.79	10^9/L	H NCS		0.15-0.75	
					Monocytes/ Leukocytes	8.5	%			3.3-12.1	
					Neutrophils	5.97	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	64.8	%			39.1-77.2	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9005	40/M/W		Check-in	13AUG2019 09:35 (-1)	Platelets	192	10^9/L			140-400	
		TPOXX 600 mg	Day 4	17AUG2019 08:27 (4)	Basophils	0.05	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.5	%			0-1.4	
					Eosinophils	0.17	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	1.7	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	351	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	31.7	pg			25-33.6	
					Ery. Mean Corpuscular Volume	90.3	fL			76.5-97.5	
					Erythrocytes	5.18	10^12/L			4.28-6.03	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9005	40/M/W	TPOXX 600 mg	Day 4	17AUG2019 08:27 (4)	Erythrocytes Distribution Width	13.0	%			11.8-15.5	
					Hematocrit	0.468	fraction of 1			0.387-0.507	
					Hemoglobin	164	g/L			128-174	
					Leukocytes	10.2	10^9/L	H NCS		3.1-9.7	
					Lymphocytes	2.61	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	25.5	%			13.9-48.3	
					Monocytes	0.91	10^9/L	H NCS		0.15-0.75	
					Monocytes/ Leukocytes	8.9	%			3.3-12.1	
					Neutrophils	6.49	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	63.5	%			39.1-77.2	
					Platelets	213	10^9/L			140-400	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9005	40/M/W	TPOXX 600 mg	Day 4	18AUG2019 05:21 (5), R	Basophils	0.07	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.7	%			0-1.4	
					Eosinophils	0.20	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	2.0	%			0-6.1	
					Leukocytes	10.1	10^9/L	H NCS		3.1-9.7	
					Lymphocytes	2.62	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	25.9	%			13.9-48.3	
					Monocytes	0.80	10^9/L	H NCS		0.15-0.75	
					Monocytes/ Leukocytes	7.9	%			3.3-12.1	
					Neutrophils	6.43	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	63.5	%			39.1-77.2	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9005	40/M/W	TPOXX 600 mg	Day 4	19AUG2019 07:06 (6), R	Basophils	0.07	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.7	%			0-1.4	
					Eosinophils	0.19	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	1.9	%			0-6.1	
					Leukocytes	9.9	10^9/L	H NCS		3.1-9.7	
					Lymphocytes	2.64	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	26.7	%			13.9-48.3	
					Monocytes	0.79	10^9/L	H NCS		0.15-0.75	
					Monocytes/ Leukocytes	8.0	%			3.3-12.1	
					Neutrophils	6.20	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	62.8	%			39.1-77.2	

Sex: M=Male, F=Female;
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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9005	40/M/W	TPOXX 600 mg	Day 8 - 12 Hours Postdose	21AUG2019 09:02 (8)	Basophils	0.04	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.5	%			0-1.4	
					Eosinophils	0.14	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	1.5	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	351	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	31.8	pg			25-33.6	
					Ery. Mean Corpuscular Volume	90.6	fL			76.5-97.5	
					Erythrocytes	4.98	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	13.2	%			11.8-15.5	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9005	40/M/W	TPOXX 600 mg	Day 8 - 12 Hours Postdose	21AUG2019 09:02 (8)	Hematocrit	0.452	fraction of 1			0.387-0.507	
					Hemoglobin	158	g/L			128-174	
					Leukocytes	9.3	10^9/L			3.1-9.7	
					Lymphocytes	1.99	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	21.5	%			13.9-48.3	
					Monocytes	0.81	10^9/L	H NCS		0.15-0.75	
					Monocytes/ Leukocytes	8.7	%			3.3-12.1	
					Neutrophils	6.30	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	67.9	%			39.1-77.2	
					Platelets	210	10^9/L			140-400	

Sex: M=Male, F=Female;
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Day = The presented date — First dose date + 1
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Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9005	40/M/W	TPOXX 600 mg	Day 9	22AUG2019 09:02 (9)	Basophils	0.06	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.6	%			0-1.4	
					Eosinophils	0.11	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	1.2	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	346	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	31.2	pg			25-33.6	
					Ery. Mean Corpuscular Volume	90.1	fL			76.5-97.5	
					Erythrocytes	4.83	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	13.0	%			11.8-15.5	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9005	40/M/W	TPOXX 600 mg	Day 9	22AUG2019 09:02 (9)	Hematocrit	0.435	fraction of 1			0.387-0.507	
					Hemoglobin	151	g/L			128-174	
					Leukocytes	9.0	10^9/L			3.1-9.7	
					Lymphocytes	2.33	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	26.0	%			13.9-48.3	
					Monocytes	0.75	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	8.4	%			3.3-12.1	
					Neutrophils	5.70	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	63.7	%			39.1-77.2	
					Platelets	199	10^9/L			140-400	
9009	21/F/BL		Screening	31JUL2019 10:20 (-14)	Basophils	0.04	10^9/L			0-0.08	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9009	21/F/BL		Screening	31JUL2019 10:20 (-14)	Basophils/ Leukocytes	0.7	%			0-1.4	
					Eosinophils	0.19	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	3.1	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	345	g/L			314-348	
					Ery. Mean Corpuscular Hemoglobin	28.9	pg			22.9-33.9	
					Ery. Mean Corpuscular Volume	84.0	fL			72.2-99.1	
					Erythrocytes	4.67	10^12/L			3.84-5.28	
					Erythrocytes Distribution Width	14.2	%			11.1-17.3	
					Hematocrit	0.392	fraction of 1			0.335-0.444	
					Hemoglobin	135	g/L			108-150	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9009	21/F/BL		Screening	31JUL2019 10:20 (-14)	Leukocytes	6.2	10^9/L			3.1-9.7	
					Lymphocytes	2.16	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	35.1	%			13.9-48.3	
					Monocytes	0.44	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	7.1	%			3.3-12.1	
					Neutrophils	3.34	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	54.1	%			39.1-77.2	
					Platelets	365	10^9/L			140-400	
			Check-in	13AUG2019 09:32 (-1)	Basophils	0.04	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.7	%			0-1.4	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9009	21/F/BL		Check-in	13AUG2019 09:32 (-1)	Eosinophils	0.13	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	2.2	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	351	g/L	H NCS		314-348	
					Ery. Mean Corpuscular Hemoglobin	29.3	pg			22.9-33.9	
					Ery. Mean Corpuscular Volume	83.5	fL			72.2-99.1	
					Erythrocytes	4.70	10^12/L			3.84-5.28	
					Erythrocytes Distribution Width	14.1	%			11.1-17.3	
					Hematocrit	0.392	fraction of 1			0.335-0.444	
					Hemoglobin	138	g/L			108-150	
					Leukocytes	5.9	10^9/L			3.1-9.7	

Sex: M=Male, F=Female;
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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9009	21/F/BL		Check-in	13AUG2019 09:32 (-1)	Lymphocytes	1.94	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	32.7	%			13.9-48.3	
					Monocytes	0.33	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	5.5	%			3.3-12.1	
					Neutrophils	3.50	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	59.0	%			39.1-77.2	
					Platelets	344	10^9/L			140-400	
		TPOXX 600 mg	Day 4	17AUG2019 08:31 (4)	Basophils	0.04	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.6	%			0-1.4	
					Eosinophils	0.22	10^9/L			0-0.35	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9009	21/F/BL	TPOXX 600 mg	Day 4	17AUG2019 08:31 (4)	Eosinophils/ Leukocytes	3.5	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	348	g/L			314-348	
					Ery. Mean Corpuscular Hemoglobin	28.9	pg			22.9-33.9	
					Ery. Mean Corpuscular Volume	83.2	fL			72.2-99.1	
					Erythrocytes	4.75	10^12/L			3.84-5.28	
					Erythrocytes Distribution Width	13.8	%			11.1-17.3	
					Hematocrit	0.395	fraction of 1			0.335-0.444	
					Hemoglobin	137	g/L			108-150	
					Leukocytes	6.2	10^9/L			3.1-9.7	
					Lymphocytes	2.53	10^9/L			0.8-2.91	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9009	21/F/BL	TPOXX 600 mg	Day 4	17AUG2019 08:31 (4)	Lymphocytes/ Leukocytes	40.6	%			13.9-48.3	
					Monocytes	0.53	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	8.6	%			3.3-12.1	
					Neutrophils	2.92	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	46.8	%			39.1-77.2	
					Platelets	359	10^9/L			140-400	
			Day 8 - 12 Hours Postdose	21AUG2019 09:06 (8)	Basophils	0.04	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.6	%			0-1.4	
					Eosinophils	0.21	10^9/L			0-0.35	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9009	21/F/BL	TPOXX 600 mg	Day 8 - 12 Hours Postdose	21AUG2019 09:06 (8)	Eosinophils/ Leukocytes	3.2	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	349	g/L	H NCS		314-348	
					Ery. Mean Corpuscular Hemoglobin	28.9	pg			22.9-33.9	
					Ery. Mean Corpuscular Volume	82.9	fL			72.2-99.1	
					Erythrocytes	4.52	10^12/L			3.84-5.28	
					Erythrocytes Distribution Width	14.0	%			11.1-17.3	
					Hematocrit	0.375	fraction of 1			0.335-0.444	
					Hemoglobin	131	g/L			108-150	
					Leukocytes	6.6	10^9/L			3.1-9.7	
					Lymphocytes	2.79	10^9/L			0.8-2.91	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9009	21/F/BL	TPOXX 600 mg	Day 8 - 12 Hours Postdose	21AUG2019 09:06 (8)	Lymphocytes/ Leukocytes	42.4	%			13.9-48.3	
					Monocytes	0.52	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	7.8	%			3.3-12.1	
					Neutrophils	3.03	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	46.1	%			39.1-77.2	
					Platelets	362	10^9/L			140-400	
			Day 9	22AUG2019 09:07 (9)	Basophils	0.03	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.5	%			0-1.4	
					Eosinophils	0.19	10^9/L			0-0.35	

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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9009	21/F/BL	TPOXX 600 mg	Day 9	22AUG2019 09:07 (9)	Eosinophils/ Leukocytes	3.2	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	346	g/L			314-348	
					Ery. Mean Corpuscular Hemoglobin	28.9	pg			22.9-33.9	
					Ery. Mean Corpuscular Volume	83.6	fL			72.2-99.1	
					Erythrocytes	4.52	10^12/L			3.84-5.28	
					Erythrocytes Distribution Width	14.1	%			11.1-17.3	
					Hematocrit	0.378	fraction of 1			0.335-0.444	
					Hemoglobin	131	g/L			108-150	
					Leukocytes	6.0	10^9/L			3.1-9.7	
					Lymphocytes	2.29	10^9/L			0.8-2.91	

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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9009	21/F/BL	TPOXX 600 mg	Day 9	22AUG2019 09:07 (9)	Lymphocytes/ Leukocytes	38.3	%			13.9-48.3	
					Monocytes	0.47	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	7.8	%			3.3-12.1	
					Neutrophils	2.99	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	50.1	%			39.1-77.2	
					Platelets	373	10^9/L			140-400	
9012	34/M/BL		Screening	06AUG2019 10:31 (-8)	Basophils	0.02	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.3	%			0-1.4	
					Eosinophils	0.10	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	1.9	%			0-6.1	

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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9012	34/M/BL		Screening	06AUG2019 10:31 (-8)	Ery. Mean Corpuscular HGB Concentration	342	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	30.5	pg			25-33.6	
					Ery. Mean Corpuscular Volume	89.3	fL			76.5-97.5	
					Erythrocytes	4.66	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	13.5	%			11.8-15.5	
					Hematocrit	0.416	fraction of 1			0.387-0.507	
					Hemoglobin	142	g/L			128-174	
					Leukocytes	5.5	10^9/L			3.1-9.7	
					Lymphocytes	2.71	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	49.3	%	H NCS		13.9-48.3	
					Monocytes	0.57	10^9/L			0.15-0.75	

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Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9012	34/M/BL		Screening	06AUG2019 10:31 (-8)	Monocytes/ Leukocytes	10.3	%			3.3-12.1	
					Neutrophils	2.10	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	38.2	%	L NCS		39.1-77.2	
					Platelets	226	10^9/L			140-400	
			Check-in	13AUG2019 09:53 (-1)	Basophils	0.02	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.3	%			0-1.4	
					Eosinophils	0.11	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	2.2	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	346	g/L			320-354	

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Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9012	34/M/BL		Check-in	13AUG2019 09:53 (-1)	Ery. Mean Corpuscular Hemoglobin	31.2	pg			25-33.6	
					Ery. Mean Corpuscular Volume	90.4	fL			76.5-97.5	
					Erythrocytes	4.61	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	13.1	%			11.8-15.5	
					Hematocrit	0.416	fraction of 1			0.387-0.507	
					Hemoglobin	144	g/L			128-174	
					Leukocytes	5.0	10^9/L			3.1-9.7	
					Lymphocytes	2.00	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	40.0	%			13.9-48.3	
					Monocytes	0.47	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	9.4	%			3.3-12.1	

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Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9012	34/M/BL		Check-in	13AUG2019 09:53 (-1)	Neutrophils	2.40	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	48.0	%			39.1-77.2	
					Platelets	202	10^9/L			140-400	
		TPOXX 600 mg	Day 4	17AUG2019 08:35 (4)	Basophils	0.02	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.3	%			0-1.4	
					Eosinophils	0.11	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	1.9	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	346	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	31.2	pg			25-33.6	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
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Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9012	34/M/BL	TPOXX 600 mg	Day 4	17AUG2019 08:35 (4)	Ery. Mean Corpuscular Volume	89.9	fL			76.5-97.5	
					Erythrocytes	5.14	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	13.0	%			11.8-15.5	
					Hematocrit	0.462	fraction of 1			0.387-0.507	
					Hemoglobin	160	g/L			128-174	
					Leukocytes	5.7	10^9/L			3.1-9.7	
					Lymphocytes	2.48	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	43.8	%			13.9-48.3	
					Monocytes	0.50	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	8.8	%			3.3-12.1	
					Neutrophils	2.55	10^9/L			1.5-6.75	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9012	34/M/BL	TPOXX 600 mg	Day 4	17AUG2019 08:35 (4)	Neutrophils/ Leukocytes	45.1	%			39.1-77.2	
					Platelets	223	10^9/L			140-400	
			Day 8 - 12 Hours Postdose	21AUG2019 09:10 (8)	Basophils	0.02	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.4	%			0-1.4	
					Eosinophils	0.10	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	2.1	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	345	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	30.9	pg			25-33.6	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9012	34/M/BL	TPOXX 600 mg	Day 8 - 12 Hours Postdose	21AUG2019 09:10 (8)	Ery. Mean Corpuscular Volume	89.4	fL			76.5-97.5	
					Erythrocytes	4.90	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	12.9	%			11.8-15.5	
					Hematocrit	0.438	fraction of 1			0.387-0.507	
					Hemoglobin	151	g/L			128-174	
					Leukocytes	4.7	10^9/L			3.1-9.7	
					Lymphocytes	2.23	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	47.4	%			13.9-48.3	
					Monocytes	0.47	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	9.9	%			3.3-12.1	
					Neutrophils	1.89	10^9/L			1.5-6.75	

Sex: M=Male, F=Female;
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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9012	34/M/BL	TPOXX 600 mg	Day 8 - 12 Hours Postdose	21AUG2019 09:10 (8)	Neutrophils/ Leukocytes	40.3	%			39.1-77.2	
					Platelets	229	10^9/L			140-400	
			Day 9	22AUG2019 09:13 (9)	Basophils	0.02	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.3	%			0-1.4	
					Eosinophils	0.10	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	2.0	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	349	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	31.5	pg			25-33.6	

Sex: M=Male, F=Female;
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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9012	34/M/BL	TPOXX 600 mg	Day 9	22AUG2019 09:13 (9)	Ery. Mean Corpuscular Volume	90.4	fL			76.5-97.5	
					Erythrocytes	4.75	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	12.7	%			11.8-15.5	
					Hematocrit	0.429	fraction of 1			0.387-0.507	
					Hemoglobin	150	g/L			128-174	
					Leukocytes	5.1	10^9/L			3.1-9.7	
					Lymphocytes	2.44	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	47.4	%			13.9-48.3	
					Monocytes	0.45	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	8.7	%			3.3-12.1	
					Neutrophils	2.14	10^9/L			1.5-6.75	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9012	34/M/BL	TPOXX 600 mg	Day 9	22AUG2019 09:13 (9)	Neutrophils/ Leukocytes	41.6	%			39.1-77.2	
					Platelets	225	10^9/L			140-400	
9015	29/M/BL		Screening	12AUG2019 11:07 (-2)	Basophils	0.05	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.6	%			0-1.4	
					Eosinophils	0.15	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	2.1	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	334	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	27.5	pg			25-33.6	
					Ery. Mean Corpuscular Volume	82.3	fL			76.5-97.5	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9015	29/M/BL		Screening	12AUG2019 11:07 (-2)	Erythrocytes	5.09	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	17.3	%	H NCS		11.8-15.5	
					Hematocrit	0.419	fraction of 1			0.387-0.507	
					Hemoglobin	140	g/L			128-174	
					Leukocytes	7.4	10^9/L			3.1-9.7	
					Lymphocytes	3.19	10^9/L	H NCS		0.8-2.91	
					Lymphocytes/ Leukocytes	43.2	%			13.9-48.3	
					Monocytes	0.42	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	5.6	%			3.3-12.1	
					Neutrophils	3.57	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	48.4	%			39.1-77.2	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9015	29/M/BL		Screening	12AUG2019 11:07 (-2)	Platelets	315	10^9/L			140-400	
			Check-in	13AUG2019 09:39 (-1)	Basophils	0.05	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.6	%			0-1.4	
					Eosinophils	0.23	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	2.7	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	337	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	27.9	pg			25-33.6	
					Ery. Mean Corpuscular Volume	82.9	fL			76.5-97.5	
					Erythrocytes	5.25	10^12/L			4.28-6.03	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9015	29/M/BL		Check-in	13AUG2019 09:39 (-1)	Erythrocytes Distribution Width	17.1	%	H NCS		11.8-15.5	
					Hematocrit	0.435	fraction of 1			0.387-0.507	
					Hemoglobin	147	g/L			128-174	
					Leukocytes	8.6	10^9/L			3.1-9.7	
					Lymphocytes	3.83	10^9/L	H NCS		0.8-2.91	
					Lymphocytes/ Leukocytes	44.7	%			13.9-48.3	
					Monocytes	0.44	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	5.1	%			3.3-12.1	
					Neutrophils	4.03	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	47.0	%			39.1-77.2	
					Platelets	326	10^9/L			140-400	

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Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9015	29/M/BL	TPOXX 600 mg	Day 4	17AUG2019 08:33 (4)	Basophils	0.04	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.5	%			0-1.4	
					Eosinophils	0.16	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	2.0	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	333	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	27.5	pg			25-33.6	
					Ery. Mean Corpuscular Volume	82.6	fL			76.5-97.5	
					Erythrocytes	5.29	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	17.4	%	H NCS		11.8-15.5	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
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Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9015	29/M/BL	TPOXX 600 mg	Day 4	17AUG2019 08:33 (4)	Hematocrit	0.437	fraction of 1			0.387-0.507	
					Hemoglobin	145	g/L			128-174	
					Leukocytes	8.0	10^9/L			3.1-9.7	
					Lymphocytes	3.68	10^9/L	H NCS		0.8-2.91	
					Lymphocytes/ Leukocytes	45.9	%			13.9-48.3	
					Monocytes	0.42	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	5.2	%			3.3-12.1	
					Neutrophils	3.72	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	46.4	%			39.1-77.2	
					Platelets	356	10^9/L			140-400	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9015	29/M/BL	TPOXX 600 mg	Day 8 - 12 Hours Postdose	21AUG2019 09:08 (8)	Basophils	0.04	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.5	%			0-1.4	
					Eosinophils	0.16	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	2.0	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	334	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	27.6	pg			25-33.6	
					Ery. Mean Corpuscular Volume	82.5	fL			76.5-97.5	
					Erythrocytes	5.29	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	16.9	%	H NCS		11.8-15.5	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
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Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Laboratory Results - Hematology
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Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9015	29/M/BL	TPOXX 600 mg	Day 8 - 12 Hours Postdose	21AUG2019 09:08 (8)	Hematocrit	0.437	fraction of 1			0.387-0.507	
					Hemoglobin	146	g/L			128-174	
					Leukocytes	8.4	10^9/L			3.1-9.7	
					Lymphocytes	4.05	10^9/L	H NCS		0.8-2.91	
					Lymphocytes/ Leukocytes	48.2	%			13.9-48.3	
					Monocytes	0.50	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	6.0	%			3.3-12.1	
					Neutrophils	3.64	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	43.4	%			39.1-77.2	
					Platelets	364	10^9/L			140-400	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9015	29/M/BL	TPOXX 600 mg	Day 9	22AUG2019 09:10 (9)	Basophils	0.05	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.7	%			0-1.4	
					Eosinophils	0.14	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	1.9	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	338	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	27.8	pg			25-33.6	
					Ery. Mean Corpuscular Volume	82.4	fL			76.5-97.5	
					Erythrocytes	5.24	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	16.3	%	H NCS		11.8-15.5	

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Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9015	29/M/BL	TPOXX 600 mg	Day 9	22AUG2019 09:10 (9)	Hematocrit	0.431	fraction of 1			0.387-0.507	
					Hemoglobin	146	g/L			128-174	
					Leukocytes	7.3	10^9/L			3.1-9.7	
					Lymphocytes	3.01	10^9/L	H NCS		0.8-2.91	
					Lymphocytes/ Leukocytes	41.4	%			13.9-48.3	
					Monocytes	0.42	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	5.8	%			3.3-12.1	
					Neutrophils	3.64	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	50.2	%			39.1-77.2	
					Platelets	350	10^9/L			140-400	
9016	48/F/W		Screening	12AUG2019 11:08 (-23)	Basophils	0.09	10^9/L	H NCS		0-0.08	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9016	48/F/W		Screening	12AUG2019 11:08 (-23)	Basophils/ Leukocytes	1.0	%			0-1.4	
					Eosinophils	0.10	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	1.2	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	325	g/L			314-348	
					Ery. Mean Corpuscular Hemoglobin	26.7	pg			22.9-33.9	
					Ery. Mean Corpuscular Volume	82.0	fL			72.2-99.1	
					Erythrocytes	5.09	10^12/L			3.84-5.28	
					Erythrocytes Distribution Width	15.2	%			11.1-17.3	
					Hematocrit	0.418	fraction of 1			0.335-0.444	
					Hemoglobin	136	g/L			108-150	

Sex: M=Male, F=Female;
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Day = The presented date — First dose date + 1
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Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9016	48/F/W		Screening	12AUG2019 11:08 (-23)	Leukocytes	8.6	10^9/L			3.1-9.7	
					Lymphocytes	1.59	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	18.5	%			13.9-48.3	
					Monocytes	0.38	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	4.4	%			3.3-12.1	
					Neutrophils	6.44	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	74.9	%			39.1-77.2	
					Platelets	312	10^9/L			140-400	
			Check-in	03SEP2019 09:04 (-1)	Basophils	0.08	10^9/L			0-0.08	
					Basophils/ Leukocytes	1.0	%			0-1.4	

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Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9016	48/F/W		Check-in	03SEP2019 09:04 (-1)	Eosinophils	0.15	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	1.8	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	331	g/L			314-348	
					Ery. Mean Corpuscular Hemoglobin	26.9	pg			22.9-33.9	
					Ery. Mean Corpuscular Volume	81.5	fL			72.2-99.1	
					Erythrocytes	4.96	10^12/L			3.84-5.28	
					Erythrocytes Distribution Width	15.2	%			11.1-17.3	
					Hematocrit	0.404	fraction of 1			0.335-0.444	
					Hemoglobin	134	g/L			108-150	
					Leukocytes	7.9	10^9/L			3.1-9.7	

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Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9016	48/F/W		Check-in	03SEP2019 09:04 (-1)	Lymphocytes	1.49	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	18.8	%			13.9-48.3	
					Monocytes	0.40	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	5.0	%			3.3-12.1	
					Neutrophils	5.81	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	73.4	%			39.1-77.2	
					Platelets	290	10^9/L			140-400	
		TPOXX 600 mg	Day 4	07SEP2019 07:25 (4)	Basophils	0.07	10^9/L			0-0.08	
					Basophils/ Leukocytes	1.0	%			0-1.4	
					Eosinophils	0.16	10^9/L			0-0.35	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9016	48/F/W	TPOXX 600 mg	Day 4	07SEP2019 07:25 (4)	Eosinophils/ Leukocytes	2.3	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	329	g/L			314-348	
					Ery. Mean Corpuscular Hemoglobin	27.0	pg			22.9-33.9	
					Ery. Mean Corpuscular Volume	82.2	fL			72.2-99.1	
					Erythrocytes	4.83	10^12/L			3.84-5.28	
					Erythrocytes Distribution Width	15.5	%			11.1-17.3	
					Hematocrit	0.397	fraction of 1			0.335-0.444	
					Hemoglobin	130	g/L			108-150	
					Leukocytes	6.8	10^9/L			3.1-9.7	
					Lymphocytes	1.74	10^9/L			0.8-2.91	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9016	48/F/W	TPOXX 600 mg	Day 4	07SEP2019 07:25 (4)	Lymphocytes/ Leukocytes	25.7	%			13.9-48.3	
					Monocytes	0.41	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	6.1	%			3.3-12.1	
					Neutrophils	4.38	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	64.9	%			39.1-77.2	
					Platelets	296	10^9/L			140-400	
			Day 8 - 12 Hours Postdose	11SEP2019 08:00 (8)	Basophils	0.06	10^9/L			0-0.08	
					Basophils/ Leukocytes	1.0	%			0-1.4	
					Eosinophils	0.15	10^9/L			0-0.35	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9016	48/F/W	TPOXX 600 mg	Day 8 - 12 Hours Postdose	11SEP2019 08:00 (8)	Eosinophils/ Leukocytes	2.5	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	325	g/L			314-348	
					Ery. Mean Corpuscular Hemoglobin	26.9	pg			22.9-33.9	
					Ery. Mean Corpuscular Volume	82.7	fL			72.2-99.1	
					Erythrocytes	4.99	10^12/L			3.84-5.28	
					Erythrocytes Distribution Width	15.6	%			11.1-17.3	
					Hematocrit	0.412	fraction of 1			0.335-0.444	
					Hemoglobin	134	g/L			108-150	
					Leukocytes	5.9	10^9/L			3.1-9.7	
					Lymphocytes	1.54	10^9/L			0.8-2.91	

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Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9016	48/F/W	TPOXX 600 mg	Day 8 - 12 Hours Postdose	11SEP2019 08:00 (8)	Lymphocytes/ Leukocytes	26.1	%			13.9-48.3	
					Monocytes	0.37	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	6.3	%			3.3-12.1	
					Neutrophils	3.78	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	64.2	%			39.1-77.2	
					Platelets	294	10^9/L			140-400	
			Day 9	12SEP2019 08:05 (9)	Basophils	0.08	10^9/L			0-0.08	
					Basophils/ Leukocytes	1.3	%			0-1.4	
					Eosinophils	0.14	10^9/L			0-0.35	

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Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9016	48/F/W	TPOXX 600 mg	Day 9	12SEP2019 08:05 (9)	Eosinophils/ Leukocytes	2.3	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	329	g/L			314-348	
					Ery. Mean Corpuscular Hemoglobin	27.2	pg			22.9-33.9	
					Ery. Mean Corpuscular Volume	82.8	fL			72.2-99.1	
					Erythrocytes	4.88	10^12/L			3.84-5.28	
					Erythrocytes Distribution Width	15.6	%			11.1-17.3	
					Hematocrit	0.404	fraction of 1			0.335-0.444	
					Hemoglobin	133	g/L			108-150	
					Leukocytes	6.0	10^9/L			3.1-9.7	
					Lymphocytes	1.53	10^9/L			0.8-2.91	

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Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9016	48/F/W	TPOXX 600 mg	Day 9	12SEP2019 08:05 (9)	Lymphocytes/ Leukocytes	25.7	%			13.9-48.3	
					Monocytes	0.37	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	6.2	%			3.3-12.1	
					Neutrophils	3.84	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	64.5	%			39.1-77.2	
					Platelets	304	10^9/L			140-400	
9019	41/M/BL		Screening	15AUG2019 17:21 (-20)	Basophils	0.05	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.6	%			0-1.4	
					Eosinophils	0.11	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	1.2	%			0-6.1	

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Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9019	41/M/BL		Screening	15AUG2019 17:21 (-20)	Ery. Mean Corpuscular HGB Concentration	328	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	29.8	pg			25-33.6	
					Ery. Mean Corpuscular Volume	90.9	fL			76.5-97.5	
					Erythrocytes	5.30	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	13.7	%			11.8-15.5	
					Hematocrit	0.481	fraction of 1			0.387-0.507	
					Hemoglobin	158	g/L			128-174	
					Leukocytes	8.8	10^9/L			3.1-9.7	
					Lymphocytes	2.82	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	32.2	%			13.9-48.3	
					Monocytes	0.66	10^9/L			0.15-0.75	

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Laboratory Results - Hematology
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Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9019	41/M/BL		Screening	15AUG2019 17:21 (-20)	Monocytes/ Leukocytes	7.5	%			3.3-12.1	
					Neutrophils	5.13	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	58.5	%			39.1-77.2	
					Platelets	270	10^9/L			140-400	
			Check-in	03SEP2019 11:40 (-1)	Basophils	0.05	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.7	%			0-1.4	
					Eosinophils	0.08	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	1.2	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	333	g/L			320-354	

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Laboratory Results - Hematology
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Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9019	41/M/BL		Check-in	03SEP2019 11:40 (-1)	Ery. Mean Corpuscular Hemoglobin	30.3	pg			25-33.6	
					Ery. Mean Corpuscular Volume	91.1	fL			76.5-97.5	
					Erythrocytes	5.05	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	13.8	%			11.8-15.5	
					Hematocrit	0.460	fraction of 1			0.387-0.507	
					Hemoglobin	153	g/L			128-174	
					Leukocytes	6.8	10^9/L			3.1-9.7	
					Lymphocytes	2.05	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	30.0	%			13.9-48.3	
					Monocytes	0.60	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	8.8	%			3.3-12.1	

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Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9019	41/M/BL		Check-in	03SEP2019 11:40 (-1)	Neutrophils	4.06	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	59.3	%			39.1-77.2	
					Platelets	264	10^9/L			140-400	
		TPOXX 600 mg	Day 4	07SEP2019 07:32 (4)	Basophils	0.05	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.8	%			0-1.4	
					Eosinophils	0.11	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	1.9	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	335	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	30.5	pg			25-33.6	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9019	41/M/BL	TPOXX 600 mg	Day 4	07SEP2019 07:32 (4)	Ery. Mean Corpuscular Volume	91.1	fL			76.5-97.5	
					Erythrocytes	4.97	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	13.2	%			11.8-15.5	
					Hematocrit	0.452	fraction of 1			0.387-0.507	
					Hemoglobin	151	g/L			128-174	
					Leukocytes	5.8	10^9/L			3.1-9.7	
					Lymphocytes	2.03	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	34.9	%			13.9-48.3	
					Monocytes	0.48	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	8.2	%			3.3-12.1	
					Neutrophils	3.15	10^9/L			1.5-6.75	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9019	41/M/BL	TPOXX 600 mg	Day 4	07SEP2019 07:32 (4)	Neutrophils/ Leukocytes	54.3	%			39.1-77.2	
					Platelets	261	10^9/L			140-400	
			Day 8 - 12 Hours Postdose	11SEP2019 08:03 (8)	Basophils	0.05	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.8	%			0-1.4	
					Eosinophils	0.12	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	1.9	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	331	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	30.0	pg			25-33.6	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9019	41/M/BL	TPOXX 600 mg	Day 8 - 12 Hours Postdose	11SEP2019 08:03 (8)	Ery. Mean Corpuscular Volume	90.7	fL			76.5-97.5	
					Erythrocytes	5.15	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	13.4	%			11.8-15.5	
					Hematocrit	0.467	fraction of 1			0.387-0.507	
					Hemoglobin	155	g/L			128-174	
					Leukocytes	6.2	10^9/L			3.1-9.7	
					Lymphocytes	2.08	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	33.3	%			13.9-48.3	
					Monocytes	0.50	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	8.1	%			3.3-12.1	
					Neutrophils	3.50	10^9/L			1.5-6.75	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9019	41/M/BL	TPOXX 600 mg	Day 8 - 12 Hours Postdose	11SEP2019 08:03 (8)	Neutrophils/ Leukocytes	56.0	%			39.1-77.2	
					Platelets	264	10^9/L			140-400	
			Day 9	12SEP2019 08:08 (9)	Basophils	0.06	10^9/L			0-0.08	
					Basophils/ Leukocytes	1.0	%			0-1.4	
					Eosinophils	0.11	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	1.7	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	335	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	30.2	pg			25-33.6	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
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Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9019	41/M/BL	TPOXX 600 mg	Day 9	12SEP2019 08:08 (9)	Ery. Mean Corpuscular Volume	90.2	fL			76.5-97.5	
					Erythrocytes	5.11	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	13.3	%			11.8-15.5	
					Hematocrit	0.461	fraction of 1			0.387-0.507	
					Hemoglobin	155	g/L			128-174	
					Leukocytes	6.6	10^9/L			3.1-9.7	
					Lymphocytes	2.09	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	31.9	%			13.9-48.3	
					Monocytes	0.55	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	8.4	%			3.3-12.1	
					Neutrophils	3.74	10^9/L			1.5-6.75	

Sex: M=Male, F=Female;
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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9019	41/M/BL	TPOXX 600 mg	Day 9	12SEP2019 08:08 (9)	Neutrophils/ Leukocytes	57.1	%			39.1-77.2	
					Platelets	277	10^9/L			140-400	
9020	47/F/BL		Screening	21AUG2019 10:37 (-14)	Basophils	0.05	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.9	%			0-1.4	
					Eosinophils	0.24	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	4.5	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	329	g/L			314-348	
					Ery. Mean Corpuscular Hemoglobin	31.9	pg			22.9-33.9	
					Ery. Mean Corpuscular Volume	96.9	fL			72.2-99.1	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9020	47/F/BL		Screening	21AUG2019 10:37 (-14)	Erythrocytes	3.85	10^12/L			3.84-5.28	
					Erythrocytes Distribution Width	15.0	%			11.1-17.3	
					Hematocrit	0.373	fraction of 1			0.335-0.444	
					Hemoglobin	123	g/L			108-150	
					Leukocytes	5.4	10^9/L			3.1-9.7	
					Lymphocytes	1.75	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	32.6	%			13.9-48.3	
					Monocytes	0.44	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	8.2	%			3.3-12.1	
					Neutrophils	2.89	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	53.9	%			39.1-77.2	

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Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9020	47/F/BL		Screening	21AUG2019 10:37 (-14)	Platelets	204	10^9/L			140-400	
			Check-in	03SEP2019 08:56 (-1)	Basophils	0.04	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.7	%			0-1.4	
					Eosinophils	0.20	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	3.5	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	336	g/L			314-348	
					Ery. Mean Corpuscular Hemoglobin	32.8	pg			22.9-33.9	
					Ery. Mean Corpuscular Volume	97.4	fL			72.2-99.1	
					Erythrocytes	3.76	10^12/L	L NCS		3.84-5.28	

Sex: M=Male, F=Female;
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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9020	47/F/BL		Check-in	03SEP2019 08:56 (-1)	Erythrocytes Distribution Width	14.5	%			11.1-17.3	
					Hematocrit	0.366	fraction of 1			0.335-0.444	
					Hemoglobin	123	g/L			108-150	
					Leukocytes	5.6	10^9/L			3.1-9.7	
					Lymphocytes	1.90	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	33.9	%			13.9-48.3	
					Monocytes	0.44	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	7.9	%			3.3-12.1	
					Neutrophils	3.03	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	54.1	%			39.1-77.2	
					Platelets	198	10^9/L			140-400	

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Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9020	47/F/BL	TPOXX 600 mg	Day 4	07SEP2019 07:31 (4)	Basophils	0.04	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.7	%			0-1.4	
					Eosinophils	0.22	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	4.1	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	334	g/L			314-348	
					Ery. Mean Corpuscular Hemoglobin	32.6	pg			22.9-33.9	
					Ery. Mean Corpuscular Volume	97.7	fL			72.2-99.1	
					Erythrocytes	3.79	10^12/L	L NCS		3.84-5.28	
					Erythrocytes Distribution Width	15.0	%			11.1-17.3	

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Day = The presented date — First dose date + 1
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9020	47/F/BL	TPOXX 600 mg	Day 4	07SEP2019 07:31 (4)	Hematocrit	0.370	fraction of 1			0.335-0.444	
					Hemoglobin	124	g/L			108-150	
					Leukocytes	5.2	10^9/L			3.1-9.7	
					Lymphocytes	1.67	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	31.8	%			13.9-48.3	
					Monocytes	0.43	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	8.2	%			3.3-12.1	
					Neutrophils	2.89	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	55.2	%			39.1-77.2	
					Platelets	197	10^9/L			140-400	

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Day = The presented date — First dose date + 1
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Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Laboratory Results - Hematology
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Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9020	47/F/BL	TPOXX 600 mg	Day 8 - 12 Hours Postdose	11SEP2019 08:06 (8)	Basophils	0.04	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.9	%			0-1.4	
					Eosinophils	0.18	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	3.9	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	329	g/L			314-348	
					Ery. Mean Corpuscular Hemoglobin	32.2	pg			22.9-33.9	
					Ery. Mean Corpuscular Volume	97.7	fL			72.2-99.1	
					Erythrocytes	3.80	10^12/L	L NCS		3.84-5.28	
					Erythrocytes Distribution Width	14.5	%			11.1-17.3	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
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Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Laboratory Results - Hematology
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Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9020	47/F/BL	TPOXX 600 mg	Day 8 - 12 Hours Postdose	11SEP2019 08:06 (8)	Hematocrit	0.372	fraction of 1			0.335-0.444	
					Hemoglobin	122	g/L			108-150	
					Leukocytes	4.7	10^9/L			3.1-9.7	
					Lymphocytes	1.27	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	27.3	%			13.9-48.3	
					Monocytes	0.37	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	7.9	%			3.3-12.1	
					Neutrophils	2.80	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	60.1	%			39.1-77.2	
					Platelets	211	10^9/L			140-400	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
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Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9020	47/F/BL	TPOXX 600 mg	Day 9	12SEP2019 08:13 (9)	Basophils	0.03	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.7	%			0-1.4	
					Eosinophils	0.18	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	3.6	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	331	g/L			314-348	
					Ery. Mean Corpuscular Hemoglobin	32.3	pg			22.9-33.9	
					Ery. Mean Corpuscular Volume	97.5	fL			72.2-99.1	
					Erythrocytes	3.78	10^12/L	L NCS		3.84-5.28	
					Erythrocytes Distribution Width	14.5	%			11.1-17.3	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9020	47/F/BL	TPOXX 600 mg	Day 9	12SEP2019 08:13 (9)	Hematocrit	0.369	fraction of 1			0.335-0.444	
					Hemoglobin	122	g/L			108-150	
					Leukocytes	4.9	10^9/L			3.1-9.7	
					Lymphocytes	1.64	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	33.2	%			13.9-48.3	
					Monocytes	0.42	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	8.4	%			3.3-12.1	
					Neutrophils	2.68	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	54.2	%			39.1-77.2	
					Platelets	209	10^9/L			140-400	
9021	39/F/BL		Screening	21AUG2019 10:44 (-14)	Basophils	0.07	10^9/L			0-0.08	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9021	39/F/BL		Screening	21AUG2019 10:44 (-14)	Basophils/ Leukocytes	0.8	%			0-1.4	
					Eosinophils	0.25	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	3.2	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	314	g/L			314-348	
					Ery. Mean Corpuscular Hemoglobin	23.7	pg			22.9-33.9	
					Ery. Mean Corpuscular Volume	75.6	fL			72.2-99.1	
					Erythrocytes	4.91	10^12/L			3.84-5.28	
					Erythrocytes Distribution Width	20.1	%	H NCS		11.1-17.3	
					Hematocrit	0.371	fraction of 1			0.335-0.444	
					Hemoglobin	116	g/L			108-150	

Sex: M=Male, F=Female;
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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9021	39/F/BL		Screening	21AUG2019 10:44 (-14)	Leukocytes	7.8	10^9/L			3.1-9.7	
					Lymphocytes	2.90	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	37.3	%			13.9-48.3	
					Monocytes	0.58	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	7.5	%			3.3-12.1	
					Neutrophils	3.97	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	51.1	%			39.1-77.2	
					Platelets	393	10^9/L			140-400	
			Check-in	03SEP2019 09:00 (-1)	Basophils	0.07	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.7	%			0-1.4	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9021	39/F/BL		Check-in	03SEP2019 09:00 (-1)	Eosinophils	0.26	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	2.6	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	319	g/L			314-348	
					Ery. Mean Corpuscular Hemoglobin	24.2	pg			22.9-33.9	
					Ery. Mean Corpuscular Volume	75.8	fL			72.2-99.1	
					Erythrocytes	4.78	10^12/L			3.84-5.28	
					Erythrocytes Distribution Width	20.4	%	H NCS		11.1-17.3	
					Hematocrit	0.362	fraction of 1			0.335-0.444	
					Hemoglobin	116	g/L			108-150	
					Leukocytes	9.7	10^9/L			3.1-9.7	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9021	39/F/BL		Check-in	03SEP2019 09:00 (-1)	Lymphocytes	3.78	10^9/L	H NCS		0.8-2.91	
					Lymphocytes/ Leukocytes	38.8	%			13.9-48.3	
					Monocytes	0.65	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	6.7	%			3.3-12.1	
					Neutrophils	4.96	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	51.1	%			39.1-77.2	
					Platelets	403	10^9/L	H NCS		140-400	
		TPOXX 600 mg	Day 4	07SEP2019 07:34 (4)	Basophils	0.09	10^9/L	H NCS		0-0.08	
					Basophils/ Leukocytes	1.1	%			0-1.4	
					Eosinophils	0.21	10^9/L			0-0.35	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9021	39/F/BL	TPOXX 600 mg	Day 4	07SEP2019 07:34 (4)	Eosinophils/ Leukocytes	2.5	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	322	g/L			314-348	
					Ery. Mean Corpuscular Hemoglobin	24.6	pg			22.9-33.9	
					Ery. Mean Corpuscular Volume	76.5	fL			72.2-99.1	
					Erythrocytes	4.88	10^12/L			3.84-5.28	
					Erythrocytes Distribution Width	20.9	%	H NCS		11.1-17.3	
					Hematocrit	0.373	fraction of 1			0.335-0.444	
					Hemoglobin	120	g/L			108-150	
					Leukocytes	8.2	10^9/L			3.1-9.7	
					Lymphocytes	3.20	10^9/L	H NCS		0.8-2.91	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9021	39/F/BL	TPOXX 600 mg	Day 4	07SEP2019 07:34 (4)	Lymphocytes/ Leukocytes	38.9	%			13.9-48.3	
					Monocytes	0.57	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	6.9	%			3.3-12.1	
					Neutrophils	4.17	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	50.6	%			39.1-77.2	
					Platelets	432	10^9/L	H NCS		140-400	
			Day 8 - 12 Hours Postdose	11SEP2019 08:09 (8)	Basophils	0.08	10^9/L			0-0.08	
					Basophils/ Leukocytes	1.1	%			0-1.4	
					Eosinophils	0.21	10^9/L			0-0.35	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9021	39/F/BL	TPOXX 600 mg	Day 8 - 12 Hours Postdose	11SEP2019 08:09 (8)	Eosinophils/ Leukocytes	3.0	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	317	g/L			314-348	
					Ery. Mean Corpuscular Hemoglobin	24.5	pg			22.9-33.9	
					Ery. Mean Corpuscular Volume	77.3	fL			72.2-99.1	
					Erythrocytes	4.77	10^12/L			3.84-5.28	
					Erythrocytes Distribution Width	21.1	%	H	NCS	11.1-17.3	
					Hematocrit	0.369	fraction of 1			0.335-0.444	
					Hemoglobin	117	g/L			108-150	
					Leukocytes	7.3	10^9/L			3.1-9.7	
					Lymphocytes	2.43	10^9/L			0.8-2.91	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9021	39/F/BL	TPOXX 600 mg	Day 8 - 12 Hours Postdose	11SEP2019 08:09 (8)	Lymphocytes/ Leukocytes	33.5	%			13.9-48.3	
					Monocytes	0.45	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	6.2	%			3.3-12.1	
					Neutrophils	4.08	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	56.3	%			39.1-77.2	
					Platelets	379	10^9/L			140-400	
			Day 9	12SEP2019 08:09 (9)	Basophils	0.09	10^9/L	H NCS		0-0.08	
					Basophils/ Leukocytes	1.2	%			0-1.4	
					Eosinophils	0.19	10^9/L			0-0.35	

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Day = The presented date — First dose date + 1
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Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9021	39/F/BL	TPOXX 600 mg	Day 9	12SEP2019 08:09 (9)	Eosinophils/ Leukocytes	2.6	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	323	g/L			314-348	
					Ery. Mean Corpuscular Hemoglobin	25.0	pg			22.9-33.9	
					Ery. Mean Corpuscular Volume	77.5	fL			72.2-99.1	
					Erythrocytes	4.86	10^12/L			3.84-5.28	
					Erythrocytes Distribution Width	21.2	%	H NCS		11.1-17.3	
					Hematocrit	0.376	fraction of 1			0.335-0.444	
					Hemoglobin	121	g/L			108-150	
					Leukocytes	7.4	10^9/L			3.1-9.7	
					Lymphocytes	2.15	10^9/L			0.8-2.91	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
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Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9021	39/F/BL	TPOXX 600 mg	Day 9	12SEP2019 08:09 (9)	Lymphocytes/ Leukocytes	29.1	%			13.9-48.3	
					Monocytes	0.45	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	6.1	%			3.3-12.1	
					Neutrophils	4.52	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	61.1	%			39.1-77.2	
					Platelets	382	10^9/L			140-400	
9022	31/M/W		Screening	21AUG2019 11:05 (-14)	Basophils	0.09	10^9/L	H NCS		0-0.08	
					Basophils/ Leukocytes	1.5	%	H NCS		0-1.4	
					Eosinophils	0.05	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	0.9	%			0-6.1	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9022	31/M/W		Screening	21AUG2019 11:05 (-14)	Ery. Mean Corpuscular HGB Concentration	341	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	28.0	pg			25-33.6	
					Ery. Mean Corpuscular Volume	82.2	fL			76.5-97.5	
					Erythrocytes	5.27	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	13.3	%			11.8-15.5	
					Hematocrit	0.433	fraction of 1			0.387-0.507	
					Hemoglobin	147	g/L			128-174	
					Leukocytes	5.9	10^9/L			3.1-9.7	
					Lymphocytes	2.43	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	41.0	%			13.9-48.3	
					Monocytes	0.61	10^9/L			0.15-0.75	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9022	31/M/W		Screening	21AUG2019 11:05 (-14)	Monocytes/ Leukocytes	10.3	%			3.3-12.1	
					Neutrophils	2.75	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	46.4	%			39.1-77.2	
					Platelets	264	10^9/L			140-400	
			Check-in	03SEP2019 09:54 (-1)	Basophils	0.06	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.7	%			0-1.4	
					Eosinophils	0.09	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	1.2	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	346	g/L			320-354	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9022	31/M/W		Check-in	03SEP2019 09:54 (-1)	Ery. Mean Corpuscular Hemoglobin	28.0	pg			25-33.6	
					Ery. Mean Corpuscular Volume	81.0	fL			76.5-97.5	
					Erythrocytes	5.06	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	13.4	%			11.8-15.5	
					Hematocrit	0.410	fraction of 1			0.387-0.507	
					Hemoglobin	142	g/L			128-174	
					Leukocytes	7.7	10^9/L			3.1-9.7	
					Lymphocytes	2.75	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	35.6	%			13.9-48.3	
					Monocytes	0.69	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	9.0	%			3.3-12.1	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9022	31/M/W		Check-in	03SEP2019 09:54 (-1)	Neutrophils	4.12	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	53.4	%			39.1-77.2	
					Platelets	254	10^9/L			140-400	
		TPOXX 600 mg	Day 4	07SEP2019 07:44 (4)	Basophils	0.06	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.8	%			0-1.4	
					Eosinophils	0.07	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	1.0	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	345	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	28.0	pg			25-33.6	

Sex: M=Male, F=Female;
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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9022	31/M/W	TPOXX 600 mg	Day 4	07SEP2019 07:44 (4)	Ery. Mean Corpuscular Volume	81.3	fL			76.5-97.5	
					Erythrocytes	5.49	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	13.3	%			11.8-15.5	
					Hematocrit	0.446	fraction of 1			0.387-0.507	
					Hemoglobin	154	g/L			128-174	
					Leukocytes	7.2	10^9/L			3.1-9.7	
					Lymphocytes	2.88	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	39.9	%			13.9-48.3	
					Monocytes	0.65	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	9.0	%			3.3-12.1	
					Neutrophils	3.55	10^9/L			1.5-6.75	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9022	31/M/W	TPOXX 600 mg	Day 4	07SEP2019 07:44 (4)	Neutrophils/ Leukocytes	49.2	%			39.1-77.2	
					Platelets	282	10^9/L			140-400	
			Day 8 - 12 Hours Postdose	11SEP2019 08:12 (8)	Basophils	0.07	10^9/L			0-0.08	
					Basophils/ Leukocytes	1.1	%			0-1.4	
					Eosinophils	0.07	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	1.0	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	341	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	27.9	pg			25-33.6	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9022	31/M/W	TPOXX 600 mg	Day 8 - 12 Hours Postdose	11SEP2019 08:12 (8)	Ery. Mean Corpuscular Volume	81.8	fL			76.5-97.5	
					Erythrocytes	5.45	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	13.3	%			11.8-15.5	
					Hematocrit	0.446	fraction of 1			0.387-0.507	
					Hemoglobin	152	g/L			128-174	
					Leukocytes	6.3	10^9/L			3.1-9.7	
					Lymphocytes	2.51	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	39.8	%			13.9-48.3	
					Monocytes	0.59	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	9.4	%			3.3-12.1	
					Neutrophils	3.07	10^9/L			1.5-6.75	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9022	31/M/W	TPOXX 600 mg	Day 8 - 12 Hours Postdose	11SEP2019 08:12 (8)	Neutrophils/ Leukocytes	48.7	%			39.1-77.2	
					Platelets	277	10^9/L			140-400	
			Day 9	12SEP2019 08:12 (9)	Basophils	0.07	10^9/L			0-0.08	
					Basophils/ Leukocytes	1.2	%			0-1.4	
					Eosinophils	0.06	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	1.1	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	345	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	28.1	pg			25-33.6	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9022	31/M/W	TPOXX 600 mg	Day 9	12SEP2019 08:12 (9)	Ery. Mean Corpuscular Volume	81.6	fL			76.5-97.5	
					Erythrocytes	5.24	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	13.3	%			11.8-15.5	
					Hematocrit	0.427	fraction of 1			0.387-0.507	
					Hemoglobin	147	g/L			128-174	
					Leukocytes	5.8	10^9/L			3.1-9.7	
					Lymphocytes	2.12	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	36.6	%			13.9-48.3	
					Monocytes	0.51	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	8.8	%			3.3-12.1	
					Neutrophils	3.02	10^9/L			1.5-6.75	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9022	31/M/W	TPOXX 600 mg	Day 9	12SEP2019 08:12 (9)	Neutrophils/ Leukocytes	52.3	%			39.1-77.2	
					Platelets	275	10^9/L			140-400	
9024	20/M/BL		Screening	23AUG2019 10:48 (-12)	Basophils	0.05	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.6	%			0-1.4	
					Eosinophils	0.12	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	1.4	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	336	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	29.7	pg			25-33.6	
					Ery. Mean Corpuscular Volume	88.4	fL			76.5-97.5	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9024	20/M/BL		Screening	23AUG2019 10:48 (-12)	Erythrocytes	5.28	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	13.8	%			11.8-15.5	
					Hematocrit	0.467	fraction of 1			0.387-0.507	
					Hemoglobin	157	g/L			128-174	
					Leukocytes	8.8	10^9/L			3.1-9.7	
					Lymphocytes	2.77	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	31.5	%			13.9-48.3	
					Monocytes	0.57	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	6.4	%			3.3-12.1	
					Neutrophils	5.27	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	60.1	%			39.1-77.2	

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R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9024	20/M/BL		Screening	23AUG2019 10:48 (-12)	Platelets	337	10^9/L			140-400	
			Check-in	03SEP2019 09:18 (-1)	Basophils	0.09	10^9/L	H NCS		0-0.08	
					Basophils/ Leukocytes	0.9	%			0-1.4	
					Eosinophils	0.10	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	1.1	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	346	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	30.5	pg			25-33.6	
					Ery. Mean Corpuscular Volume	88.1	fL			76.5-97.5	
					Erythrocytes	4.80	10^12/L			4.28-6.03	

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Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9024	20/M/BL		Check-in	03SEP2019 09:18 (-1)	Erythrocytes Distribution Width	13.9	%			11.8-15.5	
					Hematocrit	0.423	fraction of 1			0.387-0.507	
					Hemoglobin	146	g/L			128-174	
					Leukocytes	9.4	10^9/L			3.1-9.7	
					Lymphocytes	2.75	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	29.2	%			13.9-48.3	
					Monocytes	0.55	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	5.9	%			3.3-12.1	
					Neutrophils	5.91	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	62.9	%			39.1-77.2	
					Platelets	355	10^9/L			140-400	

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Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9024	20/M/BL	TPOXX 600 mg	Day 4	07SEP2019 07:40 (4)	Basophils	0.06	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.7	%			0-1.4	
					Eosinophils	0.16	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	1.9	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	343	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	30.5	pg			25-33.6	
					Ery. Mean Corpuscular Volume	89.1	fL			76.5-97.5	
					Erythrocytes	5.29	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	14.0	%			11.8-15.5	

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Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Laboratory Results - Hematology
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Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9024	20/M/BL	TPOXX 600 mg	Day 4	07SEP2019 07:40 (4)	Hematocrit	0.471	fraction of 1			0.387-0.507	
					Hemoglobin	161	g/L			128-174	
					Leukocytes	8.6	10^9/L			3.1-9.7	
					Lymphocytes	2.93	10^9/L	H NCS		0.8-2.91	
					Lymphocytes/ Leukocytes	34.0	%			13.9-48.3	
					Monocytes	0.72	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	8.3	%			3.3-12.1	
					Neutrophils	4.75	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	55.1	%			39.1-77.2	
					Platelets	371	10^9/L			140-400	

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Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9024	20/M/BL	TPOXX 600 mg	Day 8 - 12 Hours Postdose	11SEP2019 08:15 (8)	Basophils	0.07	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.9	%			0-1.4	
					Eosinophils	0.12	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	1.6	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	344	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	30.5	pg			25-33.6	
					Ery. Mean Corpuscular Volume	88.6	fL			76.5-97.5	
					Erythrocytes	5.06	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	13.6	%			11.8-15.5	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9024	20/M/BL	TPOXX 600 mg	Day 8 - 12 Hours Postdose	11SEP2019 08:15 (8)	Hematocrit	0.449	fraction of 1			0.387-0.507	
					Hemoglobin	154	g/L			128-174	
					Leukocytes	7.5	10^9/L			3.1-9.7	
					Lymphocytes	2.45	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	32.6	%			13.9-48.3	
					Monocytes	0.57	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	7.6	%			3.3-12.1	
					Neutrophils	4.32	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	57.4	%			39.1-77.2	
					Platelets	339	10^9/L			140-400	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9024	20/M/BL	TPOXX 600 mg	Day 9	12SEP2019 08:15 (9)	Basophils	0.07	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.9	%			0-1.4	
					Eosinophils	0.11	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	1.5	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	345	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	30.5	pg			25-33.6	
					Ery. Mean Corpuscular Volume	88.4	fL			76.5-97.5	
					Erythrocytes	5.18	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	13.6	%			11.8-15.5	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9024	20/M/BL	TPOXX 600 mg	Day 9	12SEP2019 08:15 (9)	Hematocrit	0.458	fraction of 1			0.387-0.507	
					Hemoglobin	158	g/L			128-174	
					Leukocytes	7.2	10^9/L			3.1-9.7	
					Lymphocytes	2.22	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	30.9	%			13.9-48.3	
					Monocytes	0.57	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	8.0	%			3.3-12.1	
					Neutrophils	4.24	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	58.8	%			39.1-77.2	
					Platelets	350	10^9/L			140-400	
9025	50/M/W		Screening	23AUG2019 10:59 (-26)	Basophils	0.04	10^9/L			0-0.08	

Sex: M=Male, F=Female;
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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9025	50/M/W		Screening	23AUG2019 10:59 (-26)	Basophils/ Leukocytes	0.7	%			0-1.4	
					Eosinophils	0.17	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	2.8	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	333	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	25.8	pg			25-33.6	
					Ery. Mean Corpuscular Volume	77.7	fL			76.5-97.5	
					Erythrocytes	5.21	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	15.1	%			11.8-15.5	
					Hematocrit	0.405	fraction of 1			0.387-0.507	
					Hemoglobin	135	g/L			128-174	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9025	50/M/W		Screening	23AUG2019 10:59 (-26)	Leukocytes	5.9	10^9/L			3.1-9.7	
					Lymphocytes	1.57	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	26.4	%			13.9-48.3	
					Monocytes	0.40	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	6.7	%			3.3-12.1	
					Neutrophils	3.77	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	63.4	%			39.1-77.2	
					Platelets	227	10^9/L			140-400	
			Check-in	17SEP2019 09:06 (-1)	Basophils	0.05	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.8	%			0-1.4	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9025	50/M/W		Check-in	17SEP2019 09:06 (-1)	Eosinophils	0.29	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	4.2	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	329	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	25.4	pg			25-33.6	
					Ery. Mean Corpuscular Volume	77.1	fL			76.5-97.5	
					Erythrocytes	5.24	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	15.3	%			11.8-15.5	
					Hematocrit	0.404	fraction of 1			0.387-0.507	
					Hemoglobin	133	g/L			128-174	
					Leukocytes	6.8	10^9/L			3.1-9.7	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9025	50/M/W		Check-in	17SEP2019 09:06 (-1)	Lymphocytes	1.63	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	23.9	%			13.9-48.3	
					Monocytes	0.43	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	6.4	%			3.3-12.1	
					Neutrophils	4.41	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	64.8	%			39.1-77.2	
					Platelets	239	10^9/L			140-400	
		TPOXX 600 mg	Day 4	21SEP2019 07:25 (4)	Basophils	0.05	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.6	%			0-1.4	
					Eosinophils	0.18	10^9/L			0-0.35	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9025	50/M/W	TPOXX 600 mg	Day 4	21SEP2019 07:25 (4)	Eosinophils/ Leukocytes	2.3	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	334	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	25.7	pg			25-33.6	
					Ery. Mean Corpuscular Volume	76.9	fL			76.5-97.5	
					Erythrocytes	5.42	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	15.6	%	H NCS		11.8-15.5	
					Hematocrit	0.417	fraction of 1			0.387-0.507	
					Hemoglobin	139	g/L			128-174	
					Leukocytes	8.0	10^9/L			3.1-9.7	
					Lymphocytes	1.63	10^9/L			0.8-2.91	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9025	50/M/W	TPOXX 600 mg	Day 4	21SEP2019 07:25 (4)	Lymphocytes/ Leukocytes	20.2	%			13.9-48.3	
					Monocytes	0.43	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	5.3	%			3.3-12.1	
					Neutrophils	5.76	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	71.6	%			39.1-77.2	
					Platelets	272	10^9/L			140-400	
			Day 8 - 12 Hours Postdose	25SEP2019 08:00 (8)	Basophils	0.05	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.6	%			0-1.4	
					Eosinophils	0.14	10^9/L			0-0.35	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9025	50/M/W	TPOXX 600 mg	Day 8 - 12 Hours Postdose	25SEP2019 08:00 (8)	Eosinophils/ Leukocytes	2.0	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	329	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	25.6	pg			25-33.6	
					Ery. Mean Corpuscular Volume	77.9	fL			76.5-97.5	
					Erythrocytes	5.41	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	15.6	%	H	NCS	11.8-15.5	
					Hematocrit	0.421	fraction of 1			0.387-0.507	
					Hemoglobin	139	g/L			128-174	
					Leukocytes	7.2	10^9/L			3.1-9.7	
					Lymphocytes	1.46	10^9/L			0.8-2.91	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9025	50/M/W	TPOXX 600 mg	Day 8 - 12 Hours Postdose	25SEP2019 08:00 (8)	Lymphocytes/ Leukocytes	20.3	%			13.9-48.3	
					Monocytes	0.39	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	5.4	%			3.3-12.1	
					Neutrophils	5.18	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	71.7	%			39.1-77.2	
					Platelets	247	10^9/L			140-400	
			Day 9	26SEP2019 08:00 (9)	Basophils	0.03	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.5	%			0-1.4	
					Eosinophils	0.12	10^9/L			0-0.35	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9025	50/M/W	TPOXX 600 mg	Day 9	26SEP2019 08:00 (9)	Eosinophils/ Leukocytes	1.8	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	330	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	25.6	pg			25-33.6	
					Ery. Mean Corpuscular Volume	77.5	fL			76.5-97.5	
					Erythrocytes	5.35	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	15.6	%	H NCS		11.8-15.5	
					Hematocrit	0.415	fraction of 1			0.387-0.507	
					Hemoglobin	137	g/L			128-174	
					Leukocytes	6.8	10^9/L			3.1-9.7	
					Lymphocytes	1.35	10^9/L			0.8-2.91	

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Day = The presented date — First dose date + 1
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Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9025	50/M/W	TPOXX 600 mg	Day 9	26SEP2019 08:00 (9)	Lymphocytes/ Leukocytes	19.9	%			13.9-48.3	
					Monocytes	0.45	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	6.6	%			3.3-12.1	
					Neutrophils	4.84	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	71.3	%			39.1-77.2	
					Platelets	246	10^9/L			140-400	
9033	32/M/W		Screening	29AUG2019 09:53 (-6)	Basophils	0.05	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.7	%			0-1.4	
					Eosinophils	0.07	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	0.9	%			0-6.1	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9033	32/M/W		Screening	29AUG2019 09:53 (-6)	Ery. Mean Corpuscular HGB Concentration	345	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	30.3	pg			25-33.6	
					Ery. Mean Corpuscular Volume	87.9	fL			76.5-97.5	
					Erythrocytes	5.06	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	13.7	%			11.8-15.5	
					Hematocrit	0.445	fraction of 1			0.387-0.507	
					Hemoglobin	154	g/L			128-174	
					Leukocytes	7.4	10^9/L			3.1-9.7	
					Lymphocytes	2.45	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	33.0	%			13.9-48.3	
					Monocytes	0.63	10^9/L			0.15-0.75	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
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Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9033	32/M/W		Screening	29AUG2019 09:53 (-6)	Monocytes/ Leukocytes	8.5	%			3.3-12.1	
					Neutrophils	4.23	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	56.9	%			39.1-77.2	
					Platelets	227	10^9/L			140-400	
			Check-in	03SEP2019 09:15 (-1)	Basophils	0.03	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.4	%			0-1.4	
					Eosinophils	0.06	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	0.8	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	339	g/L			320-354	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9033	32/M/W		Check-in	03SEP2019 09:15 (-1)	Ery. Mean Corpuscular Hemoglobin	29.8	pg			25-33.6	
					Ery. Mean Corpuscular Volume	87.8	fL			76.5-97.5	
					Erythrocytes	5.10	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	13.8	%			11.8-15.5	
					Hematocrit	0.448	fraction of 1			0.387-0.507	
					Hemoglobin	152	g/L			128-174	
					Leukocytes	7.7	10^9/L			3.1-9.7	
					Lymphocytes	2.50	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	32.5	%			13.9-48.3	
					Monocytes	0.65	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	8.5	%			3.3-12.1	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9033	32/M/W		Check-in	03SEP2019 09:15 (-1)	Neutrophils	4.44	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	57.8	%			39.1-77.2	
					Platelets	238	10^9/L			140-400	
		TPOXX 600 mg	Day 4	07SEP2019 07:48 (4)	Basophils	0.05	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.6	%			0-1.4	
					Eosinophils	0.08	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	0.9	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	345	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	30.2	pg			25-33.6	

Sex: M=Male, F=Female;
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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9033	32/M/W	TPOXX 600 mg	Day 4	07SEP2019 07:48 (4)	Ery. Mean Corpuscular Volume	87.6	fL			76.5-97.5	
					Erythrocytes	5.09	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	13.9	%			11.8-15.5	
					Hematocrit	0.446	fraction of 1			0.387-0.507	
					Hemoglobin	154	g/L			128-174	
					Leukocytes	8.3	10^9/L			3.1-9.7	
					Lymphocytes	2.68	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	32.2	%			13.9-48.3	
					Monocytes	0.52	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	6.3	%			3.3-12.1	
					Neutrophils	4.99	10^9/L			1.5-6.75	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9033	32/M/W	TPOXX 600 mg	Day 4	07SEP2019 07:48 (4)	Neutrophils/ Leukocytes	60.0	%			39.1-77.2	
					Platelets	245	10^9/L			140-400	
			Day 8 - 12 Hours Postdose	11SEP2019 08:18 (8)	Basophils	0.04	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.6	%			0-1.4	
					Eosinophils	0.07	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	0.9	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	336	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	29.8	pg			25-33.6	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9033	32/M/W	TPOXX 600 mg	Day 8 - 12 Hours Postdose	11SEP2019 08:18 (8)	Ery. Mean Corpuscular Volume	88.7	fL			76.5-97.5	
					Erythrocytes	5.18	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	13.8	%			11.8-15.5	
					Hematocrit	0.459	fraction of 1			0.387-0.507	
					Hemoglobin	154	g/L			128-174	
					Leukocytes	7.5	10^9/L			3.1-9.7	
					Lymphocytes	2.74	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	36.8	%			13.9-48.3	
					Monocytes	0.51	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	6.8	%			3.3-12.1	
					Neutrophils	4.10	10^9/L			1.5-6.75	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9033	32/M/W	TPOXX 600 mg	Day 8 - 12 Hours Postdose	11SEP2019 08:18 (8)	Neutrophils/ Leukocytes	55.0	%			39.1-77.2	
					Platelets	247	10^9/L			140-400	
			Day 9	12SEP2019 08:18 (9)	Basophils	0.04	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.6	%			0-1.4	
					Eosinophils	0.07	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	1.0	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	344	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	30.1	pg			25-33.6	

Sex: M=Male, F=Female;
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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9033	32/M/W	TPOXX 600 mg	Day 9	12SEP2019 08:18 (9)	Ery. Mean Corpuscular Volume	87.4	fL			76.5-97.5	
					Erythrocytes	5.34	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	13.5	%			11.8-15.5	
					Hematocrit	0.467	fraction of 1			0.387-0.507	
					Hemoglobin	161	g/L			128-174	
					Leukocytes	7.2	10^9/L			3.1-9.7	
					Lymphocytes	2.50	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	34.7	%			13.9-48.3	
					Monocytes	0.39	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	5.3	%			3.3-12.1	
					Neutrophils	4.20	10^9/L			1.5-6.75	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9033	32/M/W	TPOXX 600 mg	Day 9	12SEP2019 08:18 (9)	Neutrophils/ Leukocytes	58.3	%			39.1-77.2	
					Platelets	258	10^9/L			140-400	
9043	22/M/BL		Screening	11SEP2019 09:38 (-7)	Basophils	0.02	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.5	%			0-1.4	
					Eosinophils	0.08	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	2.0	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	337	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	28.4	pg			25-33.6	
					Ery. Mean Corpuscular Volume	84.2	fL			76.5-97.5	

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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9043	22/M/BL		Screening	11SEP2019 09:38 (-7)	Erythrocytes	5.18	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	12.3	%			11.8-15.5	
					Hematocrit	0.436	fraction of 1			0.387-0.507	
					Hemoglobin	147	g/L			128-174	
					Leukocytes	3.7	10^9/L			3.1-9.7	
					Lymphocytes	1.04	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	28.1	%			13.9-48.3	
					Monocytes	0.44	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	11.9	%			3.3-12.1	
					Neutrophils	2.14	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	57.5	%			39.1-77.2	

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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9043	22/M/BL		Screening	11SEP2019 09:38 (-7)	Platelets	260	10^9/L			140-400	
			Check-in	17SEP2019 09:06 (-1)	Basophils	0.03	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.7	%			0-1.4	
					Eosinophils	0.10	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	2.7	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	342	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	28.7	pg			25-33.6	
					Ery. Mean Corpuscular Volume	84.0	fL			76.5-97.5	
					Erythrocytes	5.22	10^12/L			4.28-6.03	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9043	22/M/BL		Check-in	17SEP2019 09:06 (-1)	Erythrocytes Distribution Width	12.4	%			11.8-15.5	
					Hematocrit	0.439	fraction of 1			0.387-0.507	
					Hemoglobin	150	g/L			128-174	
					Leukocytes	3.9	10^9/L			3.1-9.7	
					Lymphocytes	1.10	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	28.3	%			13.9-48.3	
					Monocytes	0.54	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	13.9	%	H NCS		3.3-12.1	
					Neutrophils	2.11	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	54.5	%			39.1-77.2	
					Platelets	236	10^9/L			140-400	

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Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9043	22/M/BL	TPOXX 600 mg	Day 4	21SEP2019 07:28 (4)	Basophils	0.02	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.4	%			0-1.4	
					Eosinophils	0.12	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	3.2	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	341	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	28.7	pg			25-33.6	
					Ery. Mean Corpuscular Volume	84.1	fL			76.5-97.5	
					Erythrocytes	5.71	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	12.3	%			11.8-15.5	

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Day = The presented date — First dose date + 1
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Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9043	22/M/BL	TPOXX 600 mg	Day 4	21SEP2019 07:28 (4)	Hematocrit	0.481	fraction of 1			0.387-0.507	
					Hemoglobin	164	g/L			128-174	
					Leukocytes	3.8	10^9/L			3.1-9.7	
					Lymphocytes	1.38	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	36.2	%			13.9-48.3	
					Monocytes	0.53	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	13.9	%	H NCS		3.3-12.1	
					Neutrophils	1.77	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	46.3	%			39.1-77.2	
					Platelets	251	10^9/L			140-400	
			Day 4	23SEP2019 10:02 (6), R	Basophils	0.02	10^9/L			0-0.08	

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Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
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Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9043	22/M/BL	TPOXX 600 mg	Day 4	23SEP2019 10:02 (6), R	Basophils/ Leukocytes	0.4	%			0-1.4	
					Eosinophils	0.10	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	2.4	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	344	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	28.5	pg			25-33.6	
					Ery. Mean Corpuscular Volume	82.8	fL			76.5-97.5	
					Erythrocytes	5.52	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	12.0	%			11.8-15.5	
					Hematocrit	0.457	fraction of 1			0.387-0.507	
					Hemoglobin	157	g/L			128-174	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9043	22/M/BL	TPOXX 600 mg	Day 4	23SEP2019 10:02 (6), R	Leukocytes	4.0	10^9/L			3.1-9.7	
					Lymphocytes	1.16	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	28.6	%			13.9-48.3	
					Monocytes	0.57	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	14.1	%	H NCS		3.3-12.1	
					Neutrophils	2.21	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	54.6	%			39.1-77.2	
					Platelets	260	10^9/L			140-400	
			Day 8 - 12 Hours Postdose	25SEP2019 08:32 (8)	Basophils	0.03	10^9/L			0-0.08	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9043	22/M/BL	TPOXX 600 mg	Day 8 - 12 Hours Postdose	25SEP2019 08:32 (8)	Basophils/ Leukocytes	0.6	%			0-1.4	
					Eosinophils	0.13	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	2.8	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	340	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	28.4	pg			25-33.6	
					Ery. Mean Corpuscular Volume	83.6	fL			76.5-97.5	
					Erythrocytes	5.69	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	12.1	%			11.8-15.5	
					Hematocrit	0.476	fraction of 1			0.387-0.507	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9043	22/M/BL	TPOXX 600 mg	Day 8 - 12 Hours Postdose	25SEP2019 08:32 (8)	Hemoglobin	162	g/L			128-174	
					Leukocytes	4.7	10^9/L			3.1-9.7	
					Lymphocytes	1.37	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	29.5	%			13.9-48.3	
					Monocytes	0.67	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	14.3	%	H NCS		3.3-12.1	
					Neutrophils	2.46	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	52.9	%			39.1-77.2	
					Platelets	242	10^9/L			140-400	
			Day 9	26SEP2019 08:11 (9)	Basophils	0.02	10^9/L			0-0.08	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9043	22/M/BL	TPOXX 600 mg	Day 9	26SEP2019 08:11 (9)	Basophils/ Leukocytes	0.5	%			0-1.4	
					Eosinophils	0.10	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	2.7	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	346	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	28.8	pg			25-33.6	
					Ery. Mean Corpuscular Volume	83.4	fL			76.5-97.5	
					Erythrocytes	5.35	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	12.4	%			11.8-15.5	
					Hematocrit	0.446	fraction of 1			0.387-0.507	
					Hemoglobin	154	g/L			128-174	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9043	22/M/BL	TPOXX 600 mg	Day 9	26SEP2019 08:11 (9)	Leukocytes	3.8	10^9/L			3.1-9.7	
					Lymphocytes	1.16	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	30.3	%			13.9-48.3	
					Monocytes	0.58	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	15.2	%	H NCS		3.3-12.1	
					Neutrophils	1.97	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	51.4	%			39.1-77.2	
					Platelets	234	10^9/L			140-400	
9046	34/M/BL		Screening	13SEP2019 09:12 (-5)	Basophils	0.09	10^9/L	H NCS		0-0.08	
					Basophils/ Leukocytes	2.7	%	H NCS		0-1.4	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9046	34/M/BL		Screening	13SEP2019 09:12 (-5)	Eosinophils	0.15	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	4.3	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	328	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	30.2	pg			25-33.6	
					Ery. Mean Corpuscular Volume	92.1	fL			76.5-97.5	
					Erythrocytes	4.40	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	12.7	%			11.8-15.5	
					Hematocrit	0.405	fraction of 1			0.387-0.507	
					Hemoglobin	133	g/L			128-174	
					Leukocytes	3.3	10^9/L			3.1-9.7	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9046	34/M/BL		Screening	13SEP2019 09:12 (-5)	Lymphocytes	1.14	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	34.1	%			13.9-48.3	
					Monocytes	0.36	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	10.8	%			3.3-12.1	
					Neutrophils	1.60	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	48.1	%			39.1-77.2	
					Platelets	175	10^9/L			140-400	
			Check-in	17SEP2019 09:05 (-1)	Basophils	0.09	10^9/L	H NCS		0-0.08	
					Basophils/ Leukocytes	2.8	%	H NCS		0-1.4	
					Eosinophils	0.10	10^9/L			0-0.35	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9046	34/M/BL		Check-in	17SEP2019 09:05 (-1)	Eosinophils/ Leukocytes	3.1	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	326	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	30.1	pg			25-33.6	
					Ery. Mean Corpuscular Volume	92.5	fL			76.5-97.5	
					Erythrocytes	4.45	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	12.6	%			11.8-15.5	
					Hematocrit	0.412	fraction of 1			0.387-0.507	
					Hemoglobin	134	g/L			128-174	
					Leukocytes	3.2	10^9/L			3.1-9.7	
					Lymphocytes	1.09	10^9/L			0.8-2.91	

Sex: M=Male, F=Female;
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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9046	34/M/BL		Check-in	17SEP2019 09:05 (-1)	Lymphocytes/ Leukocytes	34.3	%			13.9-48.3	
					Monocytes	0.36	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	11.4	%			3.3-12.1	
					Neutrophils	1.54	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	48.3	%			39.1-77.2	
					Platelets	188	10^9/L			140-400	
		TPOXX 600 mg	Day 4	21SEP2019 07:31 (4)	Basophils	0.09	10^9/L	H NCS		0-0.08	
					Basophils/ Leukocytes	2.6	%	H NCS		0-1.4	
					Eosinophils	0.11	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	3.5	%			0-6.1	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9046	34/M/BL	TPOXX 600 mg	Day 4	21SEP2019 07:31 (4)	Ery. Mean Corpuscular HGB Concentration	328	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	30.1	pg			25-33.6	
					Ery. Mean Corpuscular Volume	91.9	fL			76.5-97.5	
					Erythrocytes	4.67	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	12.5	%			11.8-15.5	
					Hematocrit	0.429	fraction of 1			0.387-0.507	
					Hemoglobin	141	g/L			128-174	
					Leukocytes	3.3	10^9/L			3.1-9.7	
					Lymphocytes	1.32	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	39.7	%			13.9-48.3	
					Monocytes	0.45	10^9/L			0.15-0.75	

Sex: M=Male, F=Female;
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Day = The presented date — First dose date + 1
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Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9046	34/M/BL	TPOXX 600 mg	Day 4	21SEP2019 07:31 (4)	Monocytes/ Leukocytes	13.5	%	H NCS		3.3-12.1	
					Neutrophils	1.35	10^9/L	L NCS		1.5-6.75	
					Neutrophils/ Leukocytes	40.8	%			39.1-77.2	
					Platelets	201	10^9/L			140-400	
			Day 8 - 12 Hours Postdose	25SEP2019 08:06 (8)	Basophils	0.08	10^9/L			0-0.08	
					Basophils/ Leukocytes	2.4	%	H NCS		0-1.4	
					Eosinophils	0.13	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	3.9	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	327	g/L			320-354	

Sex: M=Male, F=Female;
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Day = The presented date — First dose date + 1
R=Repeat
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Laboratory Results - Hematology
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Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9046	34/M/BL	TPOXX 600 mg	Day 8 - 12 Hours Postdose	25SEP2019 08:06 (8)	Ery. Mean Corpuscular Hemoglobin	30.3	pg			25-33.6	
					Ery. Mean Corpuscular Volume	92.5	fL			76.5-97.5	
					Erythrocytes	4.69	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	12.4	%			11.8-15.5	
					Hematocrit	0.434	fraction of 1			0.387-0.507	
					Hemoglobin	142	g/L			128-174	
					Leukocytes	3.2	10^9/L			3.1-9.7	
					Lymphocytes	1.12	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	34.6	%			13.9-48.3	
					Monocytes	0.43	10^9/L			0.15-0.75	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9046	34/M/BL	TPOXX 600 mg	Day 8 - 12 Hours Postdose	25SEP2019 08:06 (8)	Monocytes/ Leukocytes	13.3	%	H NCS		3.3-12.1	
					Neutrophils	1.48	10^9/L	L NCS		1.5-6.75	
					Neutrophils/ Leukocytes	45.8	%			39.1-77.2	
					Platelets	195	10^9/L			140-400	
			Day 9	26SEP2019 08:06 (9)	Basophils	0.07	10^9/L			0-0.08	
					Basophils/ Leukocytes	2.2	%	H NCS		0-1.4	
					Eosinophils	0.13	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	4.3	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	325	g/L			320-354	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9046	34/M/BL	TPOXX 600 mg	Day 9	26SEP2019 08:06 (9)	Ery. Mean Corpuscular Hemoglobin	30.0	pg			25-33.6	
					Ery. Mean Corpuscular Volume	92.4	fL			76.5-97.5	
					Erythrocytes	4.67	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	12.5	%			11.8-15.5	
					Hematocrit	0.432	fraction of 1			0.387-0.507	
					Hemoglobin	140	g/L			128-174	
					Leukocytes	3.1	10^9/L			3.1-9.7	
					Lymphocytes	0.84	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	27.4	%			13.9-48.3	
					Monocytes	0.52	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	17.1	%	H NCS		3.3-12.1	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9046	34/M/BL	TPOXX 600 mg	Day 9	26SEP2019 08:06 (9)	Neutrophils	1.50	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	49.1	%			39.1-77.2	
					Platelets	196	10^9/L			140-400	
9051	34/M/BL		Screening	19SEP2019 09:10 (-13)	Basophils	0.04	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.7	%			0-1.4	
					Eosinophils	0.11	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	1.9	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	335	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	30.1	pg			25-33.6	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9051	34/M/BL		Screening	19SEP2019 09:10 (-13)	Ery. Mean Corpuscular Volume	89.8	fL			76.5-97.5	
					Erythrocytes	5.20	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	13.5	%			11.8-15.5	
					Hematocrit	0.467	fraction of 1			0.387-0.507	
					Hemoglobin	157	g/L			128-174	
					Leukocytes	5.8	10^9/L			3.1-9.7	
					Lymphocytes	2.10	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	36.1	%			13.9-48.3	
					Monocytes	0.51	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	8.7	%			3.3-12.1	
					Neutrophils	3.06	10^9/L			1.5-6.75	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9051	34/M/BL		Screening	19SEP2019 09:10 (-13)	Neutrophils/ Leukocytes	52.6	%			39.1-77.2	
					Platelets	195	10^9/L			140-400	
			Check-in	01OCT2019 09:01 (-1)	Basophils	0.03	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.6	%			0-1.4	
					Eosinophils	0.13	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	2.6	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	337	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	30.2	pg			25-33.6	
					Ery. Mean Corpuscular Volume	89.7	fL			76.5-97.5	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9051	34/M/BL		Check-in	01OCT2019 09:01 (-1)	Erythrocytes	4.98	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	13.5	%			11.8-15.5	
					Hematocrit	0.447	fraction of 1			0.387-0.507	
					Hemoglobin	151	g/L			128-174	
					Leukocytes	5.1	10^9/L			3.1-9.7	
					Lymphocytes	1.80	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	35.6	%			13.9-48.3	
					Monocytes	0.40	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	7.9	%			3.3-12.1	
					Neutrophils	2.70	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	53.4	%			39.1-77.2	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9051	34/M/BL		Check-in	01OCT2019 09:01 (-1)	Platelets	206	10^9/L			140-400	
		TPOXX 600 mg	Day 4	05OCT2019 07:40 (4)	Basophils	0.03	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.5	%			0-1.4	
					Eosinophils	0.16	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	2.5	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	336	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	30.1	pg			25-33.6	
					Ery. Mean Corpuscular Volume	89.5	fL			76.5-97.5	
					Erythrocytes	5.39	10^12/L			4.28-6.03	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9051	34/M/BL	TPOXX 600 mg	Day 4	05OCT2019 07:40 (4)	Erythrocytes Distribution Width	13.6	%			11.8-15.5	
					Hematocrit	0.483	fraction of 1			0.387-0.507	
					Hemoglobin	162	g/L			128-174	
					Leukocytes	6.2	10^9/L			3.1-9.7	
					Lymphocytes	2.38	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	38.3	%			13.9-48.3	
					Monocytes	0.59	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	9.5	%			3.3-12.1	
					Neutrophils	3.06	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	49.2	%			39.1-77.2	
					Platelets	248	10^9/L			140-400	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9051	34/M/BL	TPOXX 600 mg	Day 8 - 12 Hours Postdose	09OCT2019 08:15 (8)	Basophils	0.03	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.7	%			0-1.4	
					Eosinophils	0.12	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	2.5	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	336	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	29.9	pg			25-33.6	
					Ery. Mean Corpuscular Volume	88.9	fL			76.5-97.5	
					Erythrocytes	5.27	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	13.3	%			11.8-15.5	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9051	34/M/BL	TPOXX 600 mg	Day 8 - 12 Hours Postdose	09OCT2019 08:15 (8)	Hematocrit	0.468	fraction of 1			0.387-0.507	
					Hemoglobin	157	g/L			128-174	
					Leukocytes	4.9	10^9/L			3.1-9.7	
					Lymphocytes	2.01	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	41.3	%			13.9-48.3	
					Monocytes	0.51	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	10.4	%			3.3-12.1	
					Neutrophils	2.20	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	45.1	%			39.1-77.2	
					Platelets	246	10^9/L			140-400	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9051	34/M/BL	TPOXX 600 mg	Day 9	10OCT2019 08:15 (9)	Basophils	0.03	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.7	%			0-1.4	
					Eosinophils	0.07	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	1.5	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	339	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	30.1	pg			25-33.6	
					Ery. Mean Corpuscular Volume	88.8	fL			76.5-97.5	
					Erythrocytes	5.16	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	13.3	%			11.8-15.5	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9051	34/M/BL	TPOXX 600 mg	Day 9	10OCT2019 08:15 (9)	Hematocrit	0.458	fraction of 1			0.387-0.507	
					Hemoglobin	155	g/L			128-174	
					Leukocytes	4.6	10^9/L			3.1-9.7	
					Lymphocytes	1.63	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	35.5	%			13.9-48.3	
					Monocytes	0.48	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	10.6	%			3.3-12.1	
					Neutrophils	2.38	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	51.8	%			39.1-77.2	
					Platelets	244	10^9/L			140-400	
9052	42/M/BL		Screening	21SEP2019 13:12 (-11)	Basophils	0.02	10^9/L			0-0.08	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9052	42/M/BL		Screening	21SEP2019 13:12 (-11)	Basophils/ Leukocytes	0.4	%			0-1.4	
					Eosinophils	0.04	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	0.8	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	336	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	29.0	pg			25-33.6	
					Ery. Mean Corpuscular Volume	86.2	fL			76.5-97.5	
					Erythrocytes	5.09	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	13.9	%			11.8-15.5	
					Hematocrit	0.439	fraction of 1			0.387-0.507	
					Hemoglobin	148	g/L			128-174	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9052	42/M/BL		Screening	21SEP2019 13:12 (-11)	Leukocytes	5.5	10^9/L			3.1-9.7	
					Lymphocytes	2.10	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	38.4	%			13.9-48.3	
					Monocytes	0.40	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	7.3	%			3.3-12.1	
					Neutrophils	2.90	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	53.0	%			39.1-77.2	
					Platelets	192	10^9/L			140-400	
			Check-in	01OCT2019 09:15 (-1)	Basophils	0.03	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.6	%			0-1.4	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9052	42/M/BL		Check-in	01OCT2019 09:15 (-1)	Eosinophils	0.03	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	0.7	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	335	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	29.0	pg			25-33.6	
					Ery. Mean Corpuscular Volume	86.7	fL			76.5-97.5	
					Erythrocytes	5.15	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	13.9	%			11.8-15.5	
					Hematocrit	0.447	fraction of 1			0.387-0.507	
					Hemoglobin	150	g/L			128-174	
					Leukocytes	4.8	10^9/L			3.1-9.7	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9052	42/M/BL		Check-in	01OCT2019 09:15 (-1)	Lymphocytes	2.27	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	47.0	%			13.9-48.3	
					Monocytes	0.40	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	8.2	%			3.3-12.1	
					Neutrophils	2.10	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	43.6	%			39.1-77.2	
					Platelets	207	10^9/L			140-400	
		TPOXX 600 mg	Day 4	05OCT2019 07:44 (4)	Basophils	0.03	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.6	%			0-1.4	
					Eosinophils	0.05	10^9/L			0-0.35	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9052	42/M/BL	TPOXX 600 mg	Day 4	05OCT2019 07:44 (4)	Eosinophils/ Leukocytes	1.1	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	336	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	29.0	pg			25-33.6	
					Ery. Mean Corpuscular Volume	86.5	fL			76.5-97.5	
					Erythrocytes	5.02	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	13.9	%			11.8-15.5	
					Hematocrit	0.434	fraction of 1			0.387-0.507	
					Hemoglobin	146	g/L			128-174	
					Leukocytes	5.1	10^9/L			3.1-9.7	
					Lymphocytes	2.34	10^9/L			0.8-2.91	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9052	42/M/BL	TPOXX 600 mg	Day 4	05OCT2019 07:44 (4)	Lymphocytes/ Leukocytes	46.2	%			13.9-48.3	
					Monocytes	0.40	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	7.9	%			3.3-12.1	
					Neutrophils	2.24	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	44.4	%			39.1-77.2	
					Platelets	202	10^9/L			140-400	
			Day 8 - 12 Hours Postdose	09OCT2019 08:19 (8)	Basophils	0.06	10^9/L			0-0.08	
					Basophils/ Leukocytes	1.2	%			0-1.4	
					Eosinophils	0.15	10^9/L			0-0.35	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9052	42/M/BL	TPOXX 600 mg	Day 8 - 12 Hours Postdose	09OCT2019 08:19 (8)	Eosinophils/ Leukocytes	2.8	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	340	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	29.2	pg			25-33.6	
					Ery. Mean Corpuscular Volume	85.9	fL			76.5-97.5	
					Erythrocytes	4.91	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	13.7	%			11.8-15.5	
					Hematocrit	0.422	fraction of 1			0.387-0.507	
					Hemoglobin	143	g/L			128-174	
					Leukocytes	5.2	10^9/L			3.1-9.7	
					Lymphocytes	1.81	10^9/L			0.8-2.91	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9052	42/M/BL	TPOXX 600 mg	Day 8 - 12 Hours Postdose	09OCT2019 08:19 (8)	Lymphocytes/ Leukocytes	34.8	%			13.9-48.3	
					Monocytes	0.52	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	10.1	%			3.3-12.1	
					Neutrophils	2.66	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	51.2	%			39.1-77.2	
					Platelets	195	10^9/L			140-400	
			Day 9	10OCT2019 08:19 (9)	Basophils	0.03	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.6	%			0-1.4	
					Eosinophils	0.11	10^9/L			0-0.35	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9052	42/M/BL	TPOXX 600 mg	Day 9	10OCT2019 08:19 (9)	Eosinophils/ Leukocytes	2.6	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	338	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	29.2	pg			25-33.6	
					Ery. Mean Corpuscular Volume	86.3	fL			76.5-97.5	
					Erythrocytes	4.95	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	14.0	%			11.8-15.5	
					Hematocrit	0.427	fraction of 1			0.387-0.507	
					Hemoglobin	145	g/L			128-174	
					Leukocytes	4.2	10^9/L			3.1-9.7	
					Lymphocytes	1.81	10^9/L			0.8-2.91	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9052	42/M/BL	TPOXX 600 mg	Day 9	10OCT2019 08:19 (9)	Lymphocytes/ Leukocytes	43.1	%			13.9-48.3	
					Monocytes	0.39	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	9.2	%			3.3-12.1	
					Neutrophils	1.87	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	44.5	%			39.1-77.2	
					Platelets	200	10^9/L			140-400	
9056	31/F/BL		Screening	24SEP2019 10:06 (-8)	Basophils	0.04	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.7	%			0-1.4	
					Eosinophils	0.20	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	3.1	%			0-6.1	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9056	31/F/BL		Screening	24SEP2019 10:06 (-8)	Ery. Mean Corpuscular HGB Concentration	328	g/L			314-348	
					Ery. Mean Corpuscular Hemoglobin	29.2	pg			22.9-33.9	
					Ery. Mean Corpuscular Volume	88.9	fL			72.2-99.1	
					Erythrocytes	4.40	10^12/L			3.84-5.28	
					Erythrocytes Distribution Width	13.1	%			11.1-17.3	
					Hematocrit	0.391	fraction of 1			0.335-0.444	
					Hemoglobin	129	g/L			108-150	
					Leukocytes	6.4	10^9/L			3.1-9.7	
					Lymphocytes	2.29	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	35.6	%			13.9-48.3	
					Monocytes	0.37	10^9/L			0.15-0.75	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9056	31/F/BL		Screening	24SEP2019 10:06 (-8)	Monocytes/ Leukocytes	5.7	%			3.3-12.1	
					Neutrophils	3.52	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	54.9	%			39.1-77.2	
					Platelets	273	10^9/L			140-400	
			Check-in	01OCT2019 09:26 (-1)	Basophils	0.03	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.6	%			0-1.4	
					Eosinophils	0.10	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	2.3	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	335	g/L			314-348	

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R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9056	31/F/BL		Check-in	01OCT2019 09:26 (-1)	Ery. Mean Corpuscular Hemoglobin	29.5	pg			22.9-33.9	
					Ery. Mean Corpuscular Volume	88.1	fL			72.2-99.1	
					Erythrocytes	4.42	10^12/L			3.84-5.28	
					Erythrocytes Distribution Width	13.0	%			11.1-17.3	
					Hematocrit	0.390	fraction of 1			0.335-0.444	
					Hemoglobin	131	g/L			108-150	
					Leukocytes	4.5	10^9/L			3.1-9.7	
					Lymphocytes	1.74	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	38.4	%			13.9-48.3	
					Monocytes	0.30	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	6.5	%			3.3-12.1	

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Day = The presented date — First dose date + 1
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Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9056	31/F/BL		Check-in	01OCT2019 09:26 (-1)	Neutrophils	2.37	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	52.3	%			39.1-77.2	
					Platelets	294	10^9/L			140-400	
		TPOXX 600 mg	Day 4	05OCT2019 07:25 (4)	Basophils	0.04	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.8	%			0-1.4	
					Eosinophils	0.14	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	3.3	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	334	g/L			314-348	
					Ery. Mean Corpuscular Hemoglobin	29.7	pg			22.9-33.9	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
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Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Laboratory Results - Hematology
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Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9056	31/F/BL	TPOXX 600 mg	Day 4	05OCT2019 07:25 (4)	Ery. Mean Corpuscular Volume	88.9	fL			72.2-99.1	
					Erythrocytes	4.53	10^12/L			3.84-5.28	
					Erythrocytes Distribution Width	13.3	%			11.1-17.3	
					Hematocrit	0.403	fraction of 1			0.335-0.444	
					Hemoglobin	135	g/L			108-150	
					Leukocytes	4.3	10^9/L			3.1-9.7	
					Lymphocytes	1.90	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	44.5	%			13.9-48.3	
					Monocytes	0.27	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	6.4	%			3.3-12.1	
					Neutrophils	1.93	10^9/L			1.5-6.75	

Sex: M=Male, F=Female;
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Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9056	31/F/BL	TPOXX 600 mg	Day 4	05OCT2019 07:25 (4)	Neutrophils/ Leukocytes	45.1	%			39.1-77.2	
					Platelets	304	10^9/L			140-400	
			Day 8 - 12 Hours Postdose	09OCT2019 08:03 (8)	Basophils	0.03	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.6	%			0-1.4	
					Eosinophils	0.21	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	4.0	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	340	g/L			314-348	
					Ery. Mean Corpuscular Hemoglobin	30.1	pg			22.9-33.9	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
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Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9056	31/F/BL	TPOXX 600 mg	Day 8 - 12 Hours Postdose	09OCT2019 08:03 (8)	Ery. Mean Corpuscular Volume	88.4	fL			72.2-99.1	
					Erythrocytes	4.55	10^12/L			3.84-5.28	
					Erythrocytes Distribution Width	13.3	%			11.1-17.3	
					Hematocrit	0.402	fraction of 1			0.335-0.444	
					Hemoglobin	137	g/L			108-150	
					Leukocytes	5.2	10^9/L			3.1-9.7	
					Lymphocytes	2.34	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	44.8	%			13.9-48.3	
					Monocytes	0.38	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	7.3	%			3.3-12.1	
					Neutrophils	2.27	10^9/L			1.5-6.75	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9056	31/F/BL	TPOXX 600 mg	Day 8 - 12 Hours Postdose	09OCT2019 08:03 (8)	Neutrophils/ Leukocytes	43.4	%			39.1-77.2	
					Platelets	319	10^9/L			140-400	
			Day 9	10OCT2019 08:00 (9)	Basophils	0.02	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.4	%			0-1.4	
					Eosinophils	0.16	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	3.6	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	337	g/L			314-348	
					Ery. Mean Corpuscular Hemoglobin	30.0	pg			22.9-33.9	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9056	31/F/BL	TPOXX 600 mg	Day 9	10OCT2019 08:00 (9)	Ery. Mean Corpuscular Volume	89.0	fL			72.2-99.1	
					Erythrocytes	4.30	10^12/L			3.84-5.28	
					Erythrocytes Distribution Width	13.1	%			11.1-17.3	
					Hematocrit	0.382	fraction of 1			0.335-0.444	
					Hemoglobin	129	g/L			108-150	
					Leukocytes	4.4	10^9/L			3.1-9.7	
					Lymphocytes	1.81	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	41.5	%			13.9-48.3	
					Monocytes	0.30	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	6.9	%			3.3-12.1	
					Neutrophils	2.08	10^9/L			1.5-6.75	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9056	31/F/BL	TPOXX 600 mg	Day 9	10OCT2019 08:00 (9)	Neutrophils/ Leukocytes	47.6	%			39.1-77.2	
					Platelets	299	10^9/L			140-400	
9057	29/F/W		Screening	25SEP2019 16:27 (-7)	Basophils	0.04	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.5	%			0-1.4	
					Eosinophils	0.08	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	1.1	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	329	g/L			314-348	
					Ery. Mean Corpuscular Hemoglobin	27.8	pg			22.9-33.9	
					Ery. Mean Corpuscular Volume	84.5	fL			72.2-99.1	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9057	29/F/W		Screening	25SEP2019 16:27 (-7)	Erythrocytes	4.91	10^12/L			3.84-5.28	
					Erythrocytes Distribution Width	13.5	%			11.1-17.3	
					Hematocrit	0.415	fraction of 1			0.335-0.444	
					Hemoglobin	136	g/L			108-150	
					Leukocytes	7.2	10^9/L			3.1-9.7	
					Lymphocytes	1.94	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	26.9	%			13.9-48.3	
					Monocytes	0.50	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	6.9	%			3.3-12.1	
					Neutrophils	4.66	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	64.6	%			39.1-77.2	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9057	29/F/W		Screening	25SEP2019 16:27 (-7)	Platelets	333	10^9/L			140-400	
			Check-in	01OCT2019 09:22 (-1)	Basophils	0.03	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.4	%			0-1.4	
					Eosinophils	0.07	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	1.0	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	336	g/L			314-348	
					Ery. Mean Corpuscular Hemoglobin	28.3	pg			22.9-33.9	
					Ery. Mean Corpuscular Volume	84.1	fL			72.2-99.1	
					Erythrocytes	4.64	10^12/L			3.84-5.28	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9057	29/F/W		Check-in	01OCT2019 09:22 (-1)	Erythrocytes Distribution Width	13.4	%			11.1-17.3	
					Hematocrit	0.390	fraction of 1			0.335-0.444	
					Hemoglobin	131	g/L			108-150	
					Leukocytes	7.3	10^9/L			3.1-9.7	
					Lymphocytes	1.51	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	20.7	%			13.9-48.3	
					Monocytes	0.44	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	6.0	%			3.3-12.1	
					Neutrophils	5.27	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	72.0	%			39.1-77.2	
					Platelets	320	10^9/L			140-400	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9057	29/F/W	TPOXX 600 mg	Day 4	05OCT2019 07:28 (4)	Basophils	0.03	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.4	%			0-1.4	
					Eosinophils	0.09	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	1.3	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	345	g/L			314-348	
					Ery. Mean Corpuscular Hemoglobin	29.0	pg			22.9-33.9	
					Ery. Mean Corpuscular Volume	84.0	fL			72.2-99.1	
					Erythrocytes	4.69	10^12/L			3.84-5.28	
					Erythrocytes Distribution Width	13.1	%			11.1-17.3	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9057	29/F/W	TPOXX 600 mg	Day 4	05OCT2019 07:28 (4)	Hematocrit	0.394	fraction of 1			0.335-0.444	
					Hemoglobin	136	g/L			108-150	
					Leukocytes	7.3	10^9/L			3.1-9.7	
					Lymphocytes	1.85	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	25.3	%			13.9-48.3	
					Monocytes	0.50	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	6.9	%			3.3-12.1	
					Neutrophils	4.84	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	66.2	%			39.1-77.2	
					Platelets	361	10^9/L			140-400	

Sex: M=Male, F=Female;
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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9057	29/F/W	TPOXX 600 mg	Day 8 - 12 Hours Postdose	09OCT2019 08:03 (8)	Basophils	0.03	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.4	%			0-1.4	
					Eosinophils	0.09	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	1.3	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	340	g/L			314-348	
					Ery. Mean Corpuscular Hemoglobin	28.6	pg			22.9-33.9	
					Ery. Mean Corpuscular Volume	84.1	fL			72.2-99.1	
					Erythrocytes	4.72	10^12/L			3.84-5.28	
					Erythrocytes Distribution Width	13.3	%			11.1-17.3	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9057	29/F/W	TPOXX 600 mg	Day 8 - 12 Hours Postdose	09OCT2019 08:03 (8)	Hematocrit	0.396	fraction of 1			0.335-0.444	
					Hemoglobin	135	g/L			108-150	
					Leukocytes	7.1	10^9/L			3.1-9.7	
					Lymphocytes	1.45	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	20.4	%			13.9-48.3	
					Monocytes	0.42	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	5.9	%			3.3-12.1	
					Neutrophils	5.13	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	72.1	%			39.1-77.2	
					Platelets	356	10^9/L			140-400	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9057	29/F/W	TPOXX 600 mg	Day 9	10OCT2019 08:03 (9)	Basophils	0.05	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.8	%			0-1.4	
					Eosinophils	0.09	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	1.4	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	340	g/L			314-348	
					Ery. Mean Corpuscular Hemoglobin	29.0	pg			22.9-33.9	
					Ery. Mean Corpuscular Volume	85.1	fL			72.2-99.1	
					Erythrocytes	4.84	10^12/L			3.84-5.28	
					Erythrocytes Distribution Width	13.2	%			11.1-17.3	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9057	29/F/W	TPOXX 600 mg	Day 9	10OCT2019 08:03 (9)	Hematocrit	0.412	fraction of 1			0.335-0.444	
					Hemoglobin	140	g/L			108-150	
					Leukocytes	6.6	10^9/L			3.1-9.7	
					Lymphocytes	1.51	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	23.0	%			13.9-48.3	
					Monocytes	0.43	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	6.5	%			3.3-12.1	
					Neutrophils	4.50	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	68.4	%			39.1-77.2	
					Platelets	353	10^9/L			140-400	
9058	32/M/W		Screening	26SEP2019 09:26 (-20)	Basophils	0.07	10^9/L			0-0.08	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9058	32/M/W		Screening	26SEP2019 09:26 (-20)	Basophils/ Leukocytes	1.0	%			0-1.4	
					Eosinophils	0.09	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	1.4	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	315	g/L	L NCS		320-354	
					Ery. Mean Corpuscular Hemoglobin	19.2	pg	L NCS		25-33.6	
					Ery. Mean Corpuscular Volume	60.9	fL	L NCS		76.5-97.5	
					Erythrocytes	6.73	10^12/L	H NCS		4.28-6.03	
					Erythrocytes Distribution Width	15.7	%	H NCS		11.8-15.5	
					Hematocrit	0.409	fraction of 1			0.387-0.507	
					Hemoglobin	129	g/L			128-174	

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Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9058	32/M/W		Screening	26SEP2019 09:26 (-20)	Leukocytes	6.7	10^9/L			3.1-9.7	
					Lymphocytes	1.81	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	27.0	%			13.9-48.3	
					Monocytes	0.56	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	8.4	%			3.3-12.1	
					Neutrophils	4.17	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	62.3	%			39.1-77.2	
					Platelets	245	10^9/L			140-400	
			Check-in	15OCT2019 09:07 (-1)	Basophils	0.05	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.9	%			0-1.4	

Sex: M=Male, F=Female;
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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9058	32/M/W		Check-in	15OCT2019 09:07 (-1)	Eosinophils	0.08	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	1.3	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	312	g/L	L NCS		320-354	
					Ery. Mean Corpuscular Hemoglobin	19.0	pg	L NCS		25-33.6	
					Ery. Mean Corpuscular Volume	60.9	fL	L NCS		76.5-97.5	
					Erythrocytes	6.66	10^12/L	H NCS		4.28-6.03	
					Erythrocytes Distribution Width	15.6	%	H NCS		11.8-15.5	
					Hematocrit	0.406	fraction of 1			0.387-0.507	
					Hemoglobin	127	g/L	L NCS		128-174	
					Leukocytes	5.8	10^9/L			3.1-9.7	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9058	32/M/W		Check-in	15OCT2019 09:07 (-1)	Lymphocytes	1.85	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	31.7	%			13.9-48.3	
					Monocytes	0.43	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	7.4	%			3.3-12.1	
					Neutrophils	3.42	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	58.7	%			39.1-77.2	
					Platelets	252	10^9/L			140-400	
		TPOXX 600 mg	Day 4	19OCT2019 07:32 (4)	Basophils	0.08	10^9/L			0-0.08	
					Basophils/ Leukocytes	1.2	%			0-1.4	
					Eosinophils	0.08	10^9/L			0-0.35	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9058	32/M/W	TPOXX 600 mg	Day 4	19OCT2019 07:32 (4)	Eosinophils/ Leukocytes	1.1	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	316	g/L	L NCS		320-354	
					Ery. Mean Corpuscular Hemoglobin	19.4	pg	L NCS		25-33.6	
					Ery. Mean Corpuscular Volume	61.5	fL	L NCS		76.5-97.5	
					Erythrocytes	6.60	10^12/L	H NCS		4.28-6.03	
					Erythrocytes Distribution Width	15.8	%	H NCS		11.8-15.5	
					Hematocrit	0.406	fraction of 1			0.387-0.507	
					Hemoglobin	128	g/L			128-174	
					Leukocytes	7.0	10^9/L			3.1-9.7	
					Lymphocytes	2.14	10^9/L			0.8-2.91	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9058	32/M/W	TPOXX 600 mg	Day 4	19OCT2019 07:32 (4)	Lymphocytes/ Leukocytes	30.7	%			13.9-48.3	
					Monocytes	0.55	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	7.9	%			3.3-12.1	
					Neutrophils	4.12	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	59.1	%			39.1-77.2	
					Platelets	238	10^9/L			140-400	
			Day 8 - 12 Hours Postdose	23OCT2019 08:29 (8)	Basophils	0.05	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.8	%			0-1.4	
					Eosinophils	0.09	10^9/L			0-0.35	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9058	32/M/W	TPOXX 600 mg	Day 8 - 12 Hours Postdose	23OCT2019 08:29 (8)	Eosinophils/ Leukocytes	1.4	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	317	g/L	L NCS		320-354	
					Ery. Mean Corpuscular Hemoglobin	19.2	pg	L NCS		25-33.6	
					Ery. Mean Corpuscular Volume	60.8	fL	L NCS		76.5-97.5	
					Erythrocytes	6.59	10^12/L	H NCS		4.28-6.03	
					Erythrocytes Distribution Width	15.6	%	H NCS		11.8-15.5	
					Hematocrit	0.401	fraction of 1			0.387-0.507	
					Hemoglobin	127	g/L	L NCS		128-174	
					Leukocytes	6.0	10^9/L			3.1-9.7	
					Lymphocytes	1.94	10^9/L			0.8-2.91	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9058	32/M/W	TPOXX 600 mg	Day 8 - 12 Hours Postdose	23OCT2019 08:29 (8)	Lymphocytes/ Leukocytes	32.4	%			13.9-48.3	
					Monocytes	0.46	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	7.6	%			3.3-12.1	
					Neutrophils	3.47	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	57.8	%			39.1-77.2	
					Platelets	236	10^9/L			140-400	
			Day 9	24OCT2019 08:08 (9)	Basophils	0.05	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.8	%			0-1.4	
					Eosinophils	0.08	10^9/L			0-0.35	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9058	32/M/W	TPOXX 600 mg	Day 9	24OCT2019 08:08 (9)	Eosinophils/ Leukocytes	1.4	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	308	g/L	L NCS		320-354	
					Ery. Mean Corpuscular Hemoglobin	18.9	pg	L NCS		25-33.6	
					Ery. Mean Corpuscular Volume	61.4	fL	L NCS		76.5-97.5	
					Erythrocytes	6.82	10^12/L	H NCS		4.28-6.03	
					Erythrocytes Distribution Width	16.0	%	H NCS		11.8-15.5	
					Hematocrit	0.419	fraction of 1			0.387-0.507	
					Hemoglobin	129	g/L			128-174	
					Leukocytes	5.7	10^9/L			3.1-9.7	
					Lymphocytes	1.72	10^9/L			0.8-2.91	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9058	32/M/W	TPOXX 600 mg	Day 9	24OCT2019 08:08 (9)	Lymphocytes/ Leukocytes	30.0	%			13.9-48.3	
					Monocytes	0.47	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	8.2	%			3.3-12.1	
					Neutrophils	3.42	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	59.6	%			39.1-77.2	
					Platelets	258	10^9/L			140-400	
9061	21/F/BL		Screening	26SEP2019 11:06 (-20)	Basophils	0.06	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.9	%			0-1.4	
					Eosinophils	0.18	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	2.8	%			0-6.1	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9061	21/F/BL		Screening	26SEP2019 11:06 (-20)	Ery. Mean Corpuscular HGB Concentration	335	g/L			314-348	
					Ery. Mean Corpuscular Hemoglobin	28.0	pg			22.9-33.9	
					Ery. Mean Corpuscular Volume	83.5	fL			72.2-99.1	
					Erythrocytes	4.46	10^12/L			3.84-5.28	
					Erythrocytes Distribution Width	15.0	%			11.1-17.3	
					Hematocrit	0.372	fraction of 1			0.335-0.444	
					Hemoglobin	125	g/L			108-150	
					Leukocytes	6.4	10^9/L			3.1-9.7	
					Lymphocytes	2.16	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	33.8	%			13.9-48.3	
					Monocytes	0.48	10^9/L			0.15-0.75	

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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9061	21/F/BL		Screening	26SEP2019 11:06 (-20)	Monocytes/ Leukocytes	7.5	%			3.3-12.1	
					Neutrophils	3.51	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	55.0	%			39.1-77.2	
					Platelets	296	10^9/L			140-400	
			Check-in	15OCT2019 09:01 (-1)	Basophils	0.04	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.7	%			0-1.4	
					Eosinophils	0.44	10^9/L	H NCS		0-0.35	
					Eosinophils/ Leukocytes	6.7	%	H NCS		0-6.1	
					Ery. Mean Corpuscular HGB Concentration	327	g/L			314-348	

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Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9061	21/F/BL		Check-in	15OCT2019 09:01 (-1)	Ery. Mean Corpuscular Hemoglobin	27.6	pg			22.9-33.9	
					Ery. Mean Corpuscular Volume	84.4	fL			72.2-99.1	
					Erythrocytes	4.41	10^12/L			3.84-5.28	
					Erythrocytes Distribution Width	14.6	%			11.1-17.3	
					Hematocrit	0.372	fraction of 1			0.335-0.444	
					Hemoglobin	122	g/L			108-150	
					Leukocytes	6.5	10^9/L			3.1-9.7	
					Lymphocytes	2.40	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	37.0	%			13.9-48.3	
					Monocytes	0.52	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	8.0	%			3.3-12.1	

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Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9061	21/F/BL		Check-in	15OCT2019 09:01 (-1)	Neutrophils	3.09	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	47.6	%			39.1-77.2	
					Platelets	296	10^9/L			140-400	
		TPOXX 600 mg	Day 4	19OCT2019 07:35 (4)	Basophils	0.05	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.8	%			0-1.4	
					Eosinophils	0.25	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	3.9	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	328	g/L			314-348	
					Ery. Mean Corpuscular Hemoglobin	27.4	pg			22.9-33.9	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Laboratory Results - Hematology
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Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9061	21/F/BL	TPOXX 600 mg	Day 4	19OCT2019 07:35 (4)	Ery. Mean Corpuscular Volume	83.5	fL			72.2-99.1	
					Erythrocytes	4.57	10^12/L			3.84-5.28	
					Erythrocytes Distribution Width	14.6	%			11.1-17.3	
					Hematocrit	0.381	fraction of 1			0.335-0.444	
					Hemoglobin	125	g/L			108-150	
					Leukocytes	6.4	10^9/L			3.1-9.7	
					Lymphocytes	2.44	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	38.2	%			13.9-48.3	
					Monocytes	0.43	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	6.8	%			3.3-12.1	
					Neutrophils	3.21	10^9/L			1.5-6.75	

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Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9061	21/F/BL	TPOXX 600 mg	Day 4	19OCT2019 07:35 (4)	Neutrophils/ Leukocytes	50.3	%			39.1-77.2	
					Platelets	318	10^9/L			140-400	
			Day 8 - 12 Hours Postdose	23OCT2019 08:06 (8)	Basophils	0.06	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.9	%			0-1.4	
					Eosinophils	0.21	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	3.2	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	333	g/L			314-348	
					Ery. Mean Corpuscular Hemoglobin	27.8	pg			22.9-33.9	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9061	21/F/BL	TPOXX 600 mg	Day 8 - 12 Hours Postdose	23OCT2019 08:06 (8)	Ery. Mean Corpuscular Volume	83.5	fL			72.2-99.1	
					Erythrocytes	4.45	10^12/L			3.84-5.28	
					Erythrocytes Distribution Width	14.2	%			11.1-17.3	
					Hematocrit	0.372	fraction of 1			0.335-0.444	
					Hemoglobin	124	g/L			108-150	
					Leukocytes	6.6	10^9/L			3.1-9.7	
					Lymphocytes	2.12	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	32.2	%			13.9-48.3	
					Monocytes	0.56	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	8.4	%			3.3-12.1	
					Neutrophils	3.65	10^9/L			1.5-6.75	

Sex: M=Male, F=Female;
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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9061	21/F/BL	TPOXX 600 mg	Day 8 - 12 Hours Postdose	23OCT2019 08:06 (8)	Neutrophils/ Leukocytes	55.3	%			39.1-77.2	
					Platelets	305	10^9/L			140-400	
			Day 9	24OCT2019 08:03 (9)	Basophils	0.04	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.6	%			0-1.4	
					Eosinophils	0.18	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	3.0	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	325	g/L			314-348	
					Ery. Mean Corpuscular Hemoglobin	27.5	pg			22.9-33.9	

Sex: M=Male, F=Female;
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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9061	21/F/BL	TPOXX 600 mg	Day 9	24OCT2019 08:03 (9)	Ery. Mean Corpuscular Volume	84.6	fL			72.2-99.1	
					Erythrocytes	4.64	10^12/L			3.84-5.28	
					Erythrocytes Distribution Width	14.6	%			11.1-17.3	
					Hematocrit	0.393	fraction of 1			0.335-0.444	
					Hemoglobin	128	g/L			108-150	
					Leukocytes	6.1	10^9/L			3.1-9.7	
					Lymphocytes	2.05	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	33.6	%			13.9-48.3	
					Monocytes	0.55	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	8.9	%			3.3-12.1	
					Neutrophils	3.29	10^9/L			1.5-6.75	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9061	21/F/BL	TPOXX 600 mg	Day 9	24OCT2019 08:03 (9)	Neutrophils/ Leukocytes	53.8	%			39.1-77.2	
					Platelets	324	10^9/L			140-400	
9062	33/M/BL		Screening	30SEP2019 10:25 (-2)	Basophils	0.02	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.4	%			0-1.4	
					Eosinophils	0.07	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	1.3	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	332	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	28.6	pg			25-33.6	
					Ery. Mean Corpuscular Volume	86.2	fL			76.5-97.5	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9062	33/M/BL		Screening	30SEP2019 10:25 (-2)	Erythrocytes	4.98	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	14.4	%			11.8-15.5	
					Hematocrit	0.430	fraction of 1			0.387-0.507	
					Hemoglobin	143	g/L			128-174	
					Leukocytes	5.5	10^9/L			3.1-9.7	
					Lymphocytes	1.50	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	27.1	%			13.9-48.3	
					Monocytes	0.58	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	10.6	%			3.3-12.1	
					Neutrophils	3.35	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	60.7	%			39.1-77.2	

Sex: M=Male, F=Female;
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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9062	33/M/BL		Screening	30SEP2019 10:25 (-2)	Platelets	211	10^9/L			140-400	
			Check-in	01OCT2019 09:29 (-1)	Basophils	0.02	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.4	%			0-1.4	
					Eosinophils	0.05	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	0.8	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	330	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	28.4	pg			25-33.6	
					Ery. Mean Corpuscular Volume	86.0	fL			76.5-97.5	
					Erythrocytes	4.83	10^12/L			4.28-6.03	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9062	33/M/BL		Check-in	01OCT2019 09:29 (-1)	Erythrocytes Distribution Width	14.1	%			11.8-15.5	
					Hematocrit	0.416	fraction of 1			0.387-0.507	
					Hemoglobin	137	g/L			128-174	
					Leukocytes	5.9	10^9/L			3.1-9.7	
					Lymphocytes	1.60	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	27.3	%			13.9-48.3	
					Monocytes	0.63	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	10.8	%			3.3-12.1	
					Neutrophils	3.56	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	60.8	%			39.1-77.2	
					Platelets	230	10^9/L			140-400	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9062	33/M/BL	TPOXX 600 mg	Day 4	05OCT2019 07:31 (4)	Basophils	0.03	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.5	%			0-1.4	
					Eosinophils	0.07	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	1.3	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	333	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	28.8	pg			25-33.6	
					Ery. Mean Corpuscular Volume	86.3	fL			76.5-97.5	
					Erythrocytes	5.09	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	14.1	%			11.8-15.5	

Sex: M=Male, F=Female;
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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9062	33/M/BL	TPOXX 600 mg	Day 4	05OCT2019 07:31 (4)	Hematocrit	0.439	fraction of 1			0.387-0.507	
					Hemoglobin	146	g/L			128-174	
					Leukocytes	5.8	10^9/L			3.1-9.7	
					Lymphocytes	1.61	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	27.7	%			13.9-48.3	
					Monocytes	0.56	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	9.6	%			3.3-12.1	
					Neutrophils	3.55	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	61.0	%			39.1-77.2	
					Platelets	244	10^9/L			140-400	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9062	33/M/BL	TPOXX 600 mg	Day 8 - 12 Hours Postdose	09OCT2019 08:06 (8)	Basophils	0.04	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.7	%			0-1.4	
					Eosinophils	0.07	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	1.2	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	338	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	29.1	pg			25-33.6	
					Ery. Mean Corpuscular Volume	86.1	fL			76.5-97.5	
					Erythrocytes	5.07	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	14.0	%			11.8-15.5	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9062	33/M/BL	TPOXX 600 mg	Day 8 - 12 Hours Postdose	09OCT2019 08:06 (8)	Hematocrit	0.437	fraction of 1			0.387-0.507	
					Hemoglobin	148	g/L			128-174	
					Leukocytes	6.3	10^9/L			3.1-9.7	
					Lymphocytes	2.17	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	34.6	%			13.9-48.3	
					Monocytes	0.59	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	9.4	%			3.3-12.1	
					Neutrophils	3.41	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	54.2	%			39.1-77.2	
					Platelets	240	10^9/L			140-400	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9062	33/M/BL	TPOXX 600 mg	Day 9	10OCT2019 08:06 (9)	Basophils	0.02	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.4	%			0-1.4	
					Eosinophils	0.06	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	1.1	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	337	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	29.0	pg			25-33.6	
					Ery. Mean Corpuscular Volume	86.0	fL			76.5-97.5	
					Erythrocytes	4.99	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	13.8	%			11.8-15.5	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9062	33/M/BL	TPOXX 600 mg	Day 9	10OCT2019 08:06 (9)	Hematocrit	0.430	fraction of 1			0.387-0.507	
					Hemoglobin	145	g/L			128-174	
					Leukocytes	5.4	10^9/L			3.1-9.7	
					Lymphocytes	1.50	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	27.7	%			13.9-48.3	
					Monocytes	0.54	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	10.0	%			3.3-12.1	
					Neutrophils	3.30	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	61.0	%			39.1-77.2	
					Platelets	236	10^9/L			140-400	
9063	35/M/W		Screening	30SEP2019 09:38 (-2)	Basophils	0.03	10^9/L			0-0.08	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9063	35/M/W		Screening	30SEP2019 09:38 (-2)	Basophils/ Leukocytes	0.5	%			0-1.4	
					Eosinophils	0.22	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	3.0	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	343	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	30.6	pg			25-33.6	
					Ery. Mean Corpuscular Volume	89.1	fL			76.5-97.5	
					Erythrocytes	5.00	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	12.8	%			11.8-15.5	
					Hematocrit	0.445	fraction of 1			0.387-0.507	
					Hemoglobin	153	g/L			128-174	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9063	35/M/W		Screening	30SEP2019 09:38 (-2)	Leukocytes	7.3	10^9/L			3.1-9.7	
					Lymphocytes	1.88	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	25.8	%			13.9-48.3	
					Monocytes	0.54	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	7.4	%			3.3-12.1	
					Neutrophils	4.63	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	63.4	%			39.1-77.2	
					Platelets	315	10^9/L			140-400	
			Check-in	01OCT2019 08:48 (-1)	Basophils	0.02	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.3	%			0-1.4	

Sex: M=Male, F=Female;
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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9063	35/M/W		Check-in	01OCT2019 08:48 (-1)	Eosinophils	0.27	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	3.5	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	336	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	30.0	pg			25-33.6	
					Ery. Mean Corpuscular Volume	89.5	fL			76.5-97.5	
					Erythrocytes	5.03	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	12.9	%			11.8-15.5	
					Hematocrit	0.450	fraction of 1			0.387-0.507	
					Hemoglobin	151	g/L			128-174	
					Leukocytes	7.9	10^9/L			3.1-9.7	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9063	35/M/W		Check-in	01OCT2019 08:48 (-1)	Lymphocytes	2.25	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	28.6	%			13.9-48.3	
					Monocytes	0.62	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	7.9	%			3.3-12.1	
					Neutrophils	4.71	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	59.8	%			39.1-77.2	
					Platelets	307	10^9/L			140-400	
		TPOXX 600 mg	Day 4	05OCT2019 07:34 (4)	Basophils	0.04	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.5	%			0-1.4	
					Eosinophils	0.20	10^9/L			0-0.35	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9063	35/M/W	TPOXX 600 mg	Day 4	05OCT2019 07:34 (4)	Eosinophils/ Leukocytes	3.0	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	338	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	30.2	pg			25-33.6	
					Ery. Mean Corpuscular Volume	89.2	fL			76.5-97.5	
					Erythrocytes	5.07	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	12.8	%			11.8-15.5	
					Hematocrit	0.452	fraction of 1			0.387-0.507	
					Hemoglobin	153	g/L			128-174	
					Leukocytes	6.7	10^9/L			3.1-9.7	
					Lymphocytes	2.13	10^9/L			0.8-2.91	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9063	35/M/W	TPOXX 600 mg	Day 4	05OCT2019 07:34 (4)	Lymphocytes/ Leukocytes	31.7	%			13.9-48.3	
					Monocytes	0.57	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	8.5	%			3.3-12.1	
					Neutrophils	3.78	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	56.3	%			39.1-77.2	
					Platelets	332	10^9/L			140-400	
			Day 8 - 12 Hours Postdose	09OCT2019 08:09 (8)	Basophils	0.04	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.6	%			0-1.4	
					Eosinophils	0.17	10^9/L			0-0.35	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9063	35/M/W	TPOXX 600 mg	Day 8 - 12 Hours Postdose	09OCT2019 08:09 (8)	Eosinophils/ Leukocytes	2.3	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	336	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	29.9	pg			25-33.6	
					Ery. Mean Corpuscular Volume	89.1	fL			76.5-97.5	
					Erythrocytes	5.26	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	12.9	%			11.8-15.5	
					Hematocrit	0.469	fraction of 1			0.387-0.507	
					Hemoglobin	157	g/L			128-174	
					Leukocytes	7.3	10^9/L			3.1-9.7	
					Lymphocytes	2.43	10^9/L			0.8-2.91	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9063	35/M/W	TPOXX 600 mg	Day 8 - 12 Hours Postdose	09OCT2019 08:09 (8)	Lymphocytes/ Leukocytes	33.1	%			13.9-48.3	
					Monocytes	0.56	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	7.7	%			3.3-12.1	
					Neutrophils	4.13	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	56.4	%			39.1-77.2	
					Platelets	357	10^9/L			140-400	
			Day 9	10OCT2019 08:09 (9)	Basophils	0.03	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.4	%			0-1.4	
					Eosinophils	0.14	10^9/L			0-0.35	

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Day = The presented date — First dose date + 1
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Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9063	35/M/W	TPOXX 600 mg	Day 9	10OCT2019 08:09 (9)	Eosinophils/ Leukocytes	1.9	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	342	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	30.6	pg			25-33.6	
					Ery. Mean Corpuscular Volume	89.4	fL			76.5-97.5	
					Erythrocytes	5.22	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	12.7	%			11.8-15.5	
					Hematocrit	0.466	fraction of 1			0.387-0.507	
					Hemoglobin	160	g/L			128-174	
					Leukocytes	7.4	10^9/L			3.1-9.7	
					Lymphocytes	1.95	10^9/L			0.8-2.91	

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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9063	35/M/W	TPOXX 600 mg	Day 9	10OCT2019 08:09 (9)	Lymphocytes/ Leukocytes	26.3	%			13.9-48.3	
					Monocytes	0.56	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	7.5	%			3.3-12.1	
					Neutrophils	4.75	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	63.9	%			39.1-77.2	
					Platelets	347	10^9/L			140-400	
9069	41/F/BL		Screening	30SEP2019 11:19 (-16)	Basophils	0.06	10^9/L			0-0.08	
					Basophils/ Leukocytes	1.0	%			0-1.4	
					Eosinophils	0.23	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	3.5	%			0-6.1	

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Day = The presented date — First dose date + 1
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Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9069	41/F/BL		Screening	30SEP2019 11:19 (-16)	Ery. Mean Corpuscular HGB Concentration	319	g/L			314-348	
					Ery. Mean Corpuscular Hemoglobin	24.8	pg			22.9-33.9	
					Ery. Mean Corpuscular Volume	77.7	fL			72.2-99.1	
					Erythrocytes	5.05	10^12/L			3.84-5.28	
					Erythrocytes Distribution Width	15.7	%			11.1-17.3	
					Hematocrit	0.392	fraction of 1			0.335-0.444	
					Hemoglobin	125	g/L			108-150	
					Leukocytes	6.5	10^9/L			3.1-9.7	
					Lymphocytes	1.93	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	29.7	%			13.9-48.3	
					Monocytes	0.50	10^9/L			0.15-0.75	

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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9069	41/F/BL		Screening	30SEP2019 11:19 (-16)	Monocytes/ Leukocytes	7.6	%			3.3-12.1	
					Neutrophils	3.78	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	58.2	%			39.1-77.2	
					Platelets	243	10^9/L			140-400	
			Check-in	15OCT2019 12:32 (-1)	Basophils	0.05	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.7	%			0-1.4	
					Eosinophils	0.20	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	3.0	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	318	g/L			314-348	

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Laboratory Results - Hematology
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Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9069	41/F/BL		Check-in	15OCT2019 12:32 (-1)	Ery. Mean Corpuscular Hemoglobin	25.1	pg			22.9-33.9	
					Ery. Mean Corpuscular Volume	78.8	fL			72.2-99.1	
					Erythrocytes	4.73	10^12/L			3.84-5.28	
					Erythrocytes Distribution Width	15.3	%			11.1-17.3	
					Hematocrit	0.373	fraction of 1			0.335-0.444	
					Hemoglobin	119	g/L			108-150	
					Leukocytes	6.6	10^9/L			3.1-9.7	
					Lymphocytes	1.79	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	26.9	%			13.9-48.3	
					Monocytes	0.51	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	7.7	%			3.3-12.1	

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Day = The presented date — First dose date + 1
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Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9069	41/F/BL		Check-in	15OCT2019 12:32 (-1)	Neutrophils	4.11	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	61.8	%			39.1-77.2	
					Platelets	250	10^9/L			140-400	
		TPOXX 600 mg	Day 4	19OCT2019 07:35 (4)	Basophils	0.04	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.5	%			0-1.4	
					Eosinophils	0.21	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	2.8	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	318	g/L			314-348	
					Ery. Mean Corpuscular Hemoglobin	24.7	pg			22.9-33.9	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
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Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9069	41/F/BL	TPOXX 600 mg	Day 4	19OCT2019 07:35 (4)	Ery. Mean Corpuscular Volume	77.7	fL			72.2-99.1	
					Erythrocytes	4.75	10^12/L			3.84-5.28	
					Erythrocytes Distribution Width	15.3	%			11.1-17.3	
					Hematocrit	0.369	fraction of 1			0.335-0.444	
					Hemoglobin	117	g/L			108-150	
					Leukocytes	7.5	10^9/L			3.1-9.7	
					Lymphocytes	1.92	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	25.8	%			13.9-48.3	
					Monocytes	0.61	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	8.1	%			3.3-12.1	
					Neutrophils	4.68	10^9/L			1.5-6.75	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9069	41/F/BL	TPOXX 600 mg	Day 4	19OCT2019 07:35 (4)	Neutrophils/ Leukocytes	62.8	%			39.1-77.2	
					Platelets	245	10^9/L			140-400	
			Day 8 - 12 Hours Postdose	23OCT2019 08:17 (8)	Basophils	0.05	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.8	%			0-1.4	
					Eosinophils	0.20	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	2.8	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	321	g/L			314-348	
					Ery. Mean Corpuscular Hemoglobin	25.2	pg			22.9-33.9	

Sex: M=Male, F=Female;
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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9069	41/F/BL	TPOXX 600 mg	Day 8 - 12 Hours Postdose	23OCT2019 08:17 (8)	Ery. Mean Corpuscular Volume	78.4	fL			72.2-99.1	
					Erythrocytes	4.72	10^12/L			3.84-5.28	
					Erythrocytes Distribution Width	15.3	%			11.1-17.3	
					Hematocrit	0.370	fraction of 1			0.335-0.444	
					Hemoglobin	119	g/L			108-150	
					Leukocytes	6.9	10^9/L			3.1-9.7	
					Lymphocytes	2.12	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	30.5	%			13.9-48.3	
					Monocytes	0.62	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	9.0	%			3.3-12.1	
					Neutrophils	3.95	10^9/L			1.5-6.75	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9069	41/F/BL	TPOXX 600 mg	Day 8 - 12 Hours Postdose	23OCT2019 08:17 (8)	Neutrophils/ Leukocytes	56.9	%			39.1-77.2	
					Platelets	248	10^9/L			140-400	
			Day 9	24OCT2019 08:06 (9)	Basophils	0.05	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.6	%			0-1.4	
					Eosinophils	0.19	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	2.6	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	317	g/L			314-348	
					Ery. Mean Corpuscular Hemoglobin	24.6	pg			22.9-33.9	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
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Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9069	41/F/BL	TPOXX 600 mg	Day 9	24OCT2019 08:06 (9)	Ery. Mean Corpuscular Volume	77.5	fL			72.2-99.1	
					Erythrocytes	4.72	10^12/L			3.84-5.28	
					Erythrocytes Distribution Width	15.2	%			11.1-17.3	
					Hematocrit	0.365	fraction of 1			0.335-0.444	
					Hemoglobin	116	g/L			108-150	
					Leukocytes	7.4	10^9/L			3.1-9.7	
					Lymphocytes	1.80	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	24.2	%			13.9-48.3	
					Monocytes	0.62	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	8.3	%			3.3-12.1	
					Neutrophils	4.78	10^9/L			1.5-6.75	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9069	41/F/BL	TPOXX 600 mg	Day 9	24OCT2019 08:06 (9)	Neutrophils/ Leukocytes	64.3	%			39.1-77.2	
					Platelets	239	10^9/L			140-400	
9073	40/M/BL		Screening	04OCT2019 13:56 (-12)	Basophils	0.03	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.5	%			0-1.4	
					Eosinophils	0.17	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	2.3	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	334	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	29.2	pg			25-33.6	
					Ery. Mean Corpuscular Volume	87.5	fL			76.5-97.5	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9073	40/M/BL		Screening	04OCT2019 13:56 (-12)	Erythrocytes	4.80	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	13.0	%			11.8-15.5	
					Hematocrit	0.420	fraction of 1			0.387-0.507	
					Hemoglobin	140	g/L			128-174	
					Leukocytes	7.4	10^9/L			3.1-9.7	
					Lymphocytes	2.15	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	28.9	%			13.9-48.3	
					Monocytes	0.60	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	8.1	%			3.3-12.1	
					Neutrophils	4.47	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	60.3	%			39.1-77.2	

Sex: M=Male, F=Female;
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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9073	40/M/BL		Screening	04OCT2019 13:56 (-12)	Platelets	242	10^9/L			140-400	
			Check-in	15OCT2019 09:18 (-1)	Basophils	0.05	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.7	%			0-1.4	
					Eosinophils	0.16	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	2.3	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	332	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	28.9	pg			25-33.6	
					Ery. Mean Corpuscular Volume	87.2	fL			76.5-97.5	
					Erythrocytes	4.64	10^12/L			4.28-6.03	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Laboratory Results - Hematology
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Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9073	40/M/BL		Check-in	15OCT2019 09:18 (-1)	Erythrocytes Distribution Width	13.5	%			11.8-15.5	
					Hematocrit	0.405	fraction of 1			0.387-0.507	
					Hemoglobin	134	g/L			128-174	
					Leukocytes	7.2	10^9/L			3.1-9.7	
					Lymphocytes	2.50	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	34.6	%			13.9-48.3	
					Monocytes	0.63	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	8.6	%			3.3-12.1	
					Neutrophils	3.91	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	53.9	%			39.1-77.2	
					Platelets	223	10^9/L			140-400	

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Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9073	40/M/BL	TPOXX 600 mg	Day 4	19OCT2019 07:41 (4)	Basophils	0.05	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.8	%			0-1.4	
					Eosinophils	0.16	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	2.4	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	332	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	28.6	pg			25-33.6	
					Ery. Mean Corpuscular Volume	86.3	fL			76.5-97.5	
					Erythrocytes	4.83	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	13.1	%			11.8-15.5	

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Day = The presented date — First dose date + 1
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Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9073	40/M/BL	TPOXX 600 mg	Day 4	19OCT2019 07:41 (4)	Hematocrit	0.417	fraction of 1			0.387-0.507	
					Hemoglobin	138	g/L			128-174	
					Leukocytes	6.9	10^9/L			3.1-9.7	
					Lymphocytes	2.67	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	38.8	%			13.9-48.3	
					Monocytes	0.47	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	6.9	%			3.3-12.1	
					Neutrophils	3.52	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	51.2	%			39.1-77.2	
					Platelets	225	10^9/L			140-400	

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Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9073	40/M/BL	TPOXX 600 mg	Day 8 - 12 Hours Postdose	23OCT2019 08:16 (8)	Basophils	0.05	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.6	%			0-1.4	
					Eosinophils	0.19	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	2.7	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	331	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	28.8	pg			25-33.6	
					Ery. Mean Corpuscular Volume	87.2	fL			76.5-97.5	
					Erythrocytes	5.00	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	13.3	%			11.8-15.5	

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Day = The presented date — First dose date + 1
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Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Laboratory Results - Hematology
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Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9073	40/M/BL	TPOXX 600 mg	Day 8 - 12 Hours Postdose	23OCT2019 08:16 (8)	Hematocrit	0.436	fraction of 1			0.387-0.507	
					Hemoglobin	144	g/L			128-174	
					Leukocytes	7.1	10^9/L			3.1-9.7	
					Lymphocytes	2.89	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	40.7	%			13.9-48.3	
					Monocytes	0.49	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	6.9	%			3.3-12.1	
					Neutrophils	3.49	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	49.2	%			39.1-77.2	
					Platelets	246	10^9/L			140-400	

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Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9073	40/M/BL	TPOXX 600 mg	Day 9	24OCT2019 08:16 (9)	Basophils	0.04	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.6	%			0-1.4	
					Eosinophils	0.16	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	2.4	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	330	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	28.7	pg			25-33.6	
					Ery. Mean Corpuscular Volume	87.1	fL			76.5-97.5	
					Erythrocytes	4.88	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	13.2	%			11.8-15.5	

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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9073	40/M/BL	TPOXX 600 mg	Day 9	24OCT2019 08:16 (9)	Hematocrit	0.425	fraction of 1			0.387-0.507	
					Hemoglobin	140	g/L			128-174	
					Leukocytes	6.9	10^9/L			3.1-9.7	
					Lymphocytes	2.70	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	38.9	%			13.9-48.3	
					Monocytes	0.53	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	7.7	%			3.3-12.1	
					Neutrophils	3.49	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	50.4	%			39.1-77.2	
					Platelets	233	10^9/L			140-400	
9077	37/F/W		Screening	05OCT2019 13:15 (-11)	Basophils	0.04	10^9/L			0-0.08	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9077	37/F/W		Screening	05OCT2019 13:15 (-11)	Basophils/ Leukocytes	0.8	%			0-1.4	
					Eosinophils	0.18	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	3.4	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	335	g/L			314-348	
					Ery. Mean Corpuscular Hemoglobin	29.3	pg			22.9-33.9	
					Ery. Mean Corpuscular Volume	87.4	fL			72.2-99.1	
					Erythrocytes	4.40	10^12/L			3.84-5.28	
					Erythrocytes Distribution Width	13.0	%			11.1-17.3	
					Hematocrit	0.385	fraction of 1			0.335-0.444	
					Hemoglobin	129	g/L			108-150	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9077	37/F/W		Screening	05OCT2019 13:15 (-11)	Leukocytes	5.3	10^9/L			3.1-9.7	
					Lymphocytes	1.62	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	30.6	%			13.9-48.3	
					Monocytes	0.39	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	7.4	%			3.3-12.1	
					Neutrophils	3.06	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	57.8	%			39.1-77.2	
					Platelets	313	10^9/L			140-400	
			Check-in	15OCT2019 09:28 (-1)	Basophils	0.04	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.6	%			0-1.4	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9077	37/F/W		Check-in	15OCT2019 09:28 (-1)	Eosinophils	0.10	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	1.7	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	338	g/L			314-348	
					Ery. Mean Corpuscular Hemoglobin	29.0	pg			22.9-33.9	
					Ery. Mean Corpuscular Volume	85.6	fL			72.2-99.1	
					Erythrocytes	4.51	10^12/L			3.84-5.28	
					Erythrocytes Distribution Width	13.0	%			11.1-17.3	
					Hematocrit	0.386	fraction of 1			0.335-0.444	
					Hemoglobin	131	g/L			108-150	
					Leukocytes	5.9	10^9/L			3.1-9.7	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9077	37/F/W		Check-in	15OCT2019 09:28 (-1)	Lymphocytes	1.66	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	27.9	%			13.9-48.3	
					Monocytes	0.51	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	8.6	%			3.3-12.1	
					Neutrophils	3.64	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	61.2	%			39.1-77.2	
					Platelets	330	10^9/L			140-400	
		TPOXX 600 mg	Day 4	19OCT2019 07:37 (4)	Basophils	0.04	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.6	%			0-1.4	
					Eosinophils	0.11	10^9/L			0-0.35	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9077	37/F/W	TPOXX 600 mg	Day 4	19OCT2019 07:37 (4)	Eosinophils/ Leukocytes	1.8	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	337	g/L			314-348	
					Ery. Mean Corpuscular Hemoglobin	29.0	pg			22.9-33.9	
					Ery. Mean Corpuscular Volume	86.0	fL			72.2-99.1	
					Erythrocytes	4.64	10^12/L			3.84-5.28	
					Erythrocytes Distribution Width	13.0	%			11.1-17.3	
					Hematocrit	0.399	fraction of 1			0.335-0.444	
					Hemoglobin	134	g/L			108-150	
					Leukocytes	6.0	10^9/L			3.1-9.7	
					Lymphocytes	1.99	10^9/L			0.8-2.91	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9077	37/F/W	TPOXX 600 mg	Day 4	19OCT2019 07:37 (4)	Lymphocytes/ Leukocytes	32.9	%			13.9-48.3	
					Monocytes	0.50	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	8.3	%			3.3-12.1	
					Neutrophils	3.40	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	56.4	%			39.1-77.2	
					Platelets	331	10^9/L			140-400	
			Day 8 - 12 Hours Postdose	23OCT2019 08:12 (8)	Basophils	0.03	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.6	%			0-1.4	
					Eosinophils	0.10	10^9/L			0-0.35	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9077	37/F/W	TPOXX 600 mg	Day 8 - 12 Hours Postdose	23OCT2019 08:12 (8)	Eosinophils/ Leukocytes	1.9	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	339	g/L			314-348	
					Ery. Mean Corpuscular Hemoglobin	29.5	pg			22.9-33.9	
					Ery. Mean Corpuscular Volume	86.9	fL			72.2-99.1	
					Erythrocytes	4.45	10^12/L			3.84-5.28	
					Erythrocytes Distribution Width	13.0	%			11.1-17.3	
					Hematocrit	0.387	fraction of 1			0.335-0.444	
					Hemoglobin	131	g/L			108-150	
					Leukocytes	5.2	10^9/L			3.1-9.7	
					Lymphocytes	1.55	10^9/L			0.8-2.91	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9077	37/F/W	TPOXX 600 mg	Day 8 - 12 Hours Postdose	23OCT2019 08:12 (8)	Lymphocytes/ Leukocytes	30.0	%			13.9-48.3	
					Monocytes	0.39	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	7.6	%			3.3-12.1	
					Neutrophils	3.11	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	60.0	%			39.1-77.2	
					Platelets	314	10^9/L			140-400	
			Day 9	24OCT2019 08:12 (9)	Basophils	0.03	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.7	%			0-1.4	
					Eosinophils	0.11	10^9/L			0-0.35	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9077	37/F/W	TPOXX 600 mg	Day 9	24OCT2019 08:12 (9)	Eosinophils/ Leukocytes	2.2	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	330	g/L			314-348	
					Ery. Mean Corpuscular Hemoglobin	28.5	pg			22.9-33.9	
					Ery. Mean Corpuscular Volume	86.3	fL			72.2-99.1	
					Erythrocytes	4.54	10^12/L			3.84-5.28	
					Erythrocytes Distribution Width	13.0	%			11.1-17.3	
					Hematocrit	0.392	fraction of 1			0.335-0.444	
					Hemoglobin	129	g/L			108-150	
					Leukocytes	5.1	10^9/L			3.1-9.7	
					Lymphocytes	1.52	10^9/L			0.8-2.91	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9077	37/F/W	TPOXX 600 mg	Day 9	24OCT2019 08:12 (9)	Lymphocytes/ Leukocytes	29.8	%			13.9-48.3	
					Monocytes	0.37	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	7.2	%			3.3-12.1	
					Neutrophils	3.06	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	60.1	%			39.1-77.2	
					Platelets	330	10^9/L			140-400	
9080	41/F/BL		Screening	08OCT2019 11:46 (-8)	Basophils	0.04	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.6	%			0-1.4	
					Eosinophils	0.18	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	2.9	%			0-6.1	

Sex: M=Male, F=Female;
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Day = The presented date — First dose date + 1
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Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9080	41/F/BL		Screening	08OCT2019 11:46 (-8)	Ery. Mean Corpuscular HGB Concentration	341	g/L			314-348	
					Ery. Mean Corpuscular Hemoglobin	32.3	pg			22.9-33.9	
					Ery. Mean Corpuscular Volume	94.8	fL			72.2-99.1	
					Erythrocytes	4.40	10^12/L			3.84-5.28	
					Erythrocytes Distribution Width	13.8	%			11.1-17.3	
					Hematocrit	0.417	fraction of 1			0.335-0.444	
					Hemoglobin	142	g/L			108-150	
					Leukocytes	6.4	10^9/L			3.1-9.7	
					Lymphocytes	2.48	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	38.8	%			13.9-48.3	
					Monocytes	0.46	10^9/L			0.15-0.75	

Sex: M=Male, F=Female;
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Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9080	41/F/BL		Screening	08OCT2019 11:46 (-8)	Monocytes/ Leukocytes	7.1	%			3.3-12.1	
					Neutrophils	3.24	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	50.7	%			39.1-77.2	
					Platelets	305	10^9/L			140-400	
			Check-in	15OCT2019 09:30 (-1)	Basophils	0.04	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.6	%			0-1.4	
					Eosinophils	0.20	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	2.6	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	340	g/L			314-348	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9080	41/F/BL		Check-in	15OCT2019 09:30 (-1)	Ery. Mean Corpuscular Hemoglobin	32.1	pg			22.9-33.9	
					Ery. Mean Corpuscular Volume	94.6	fL			72.2-99.1	
					Erythrocytes	4.13	10^12/L			3.84-5.28	
					Erythrocytes Distribution Width	13.4	%			11.1-17.3	
					Hematocrit	0.391	fraction of 1			0.335-0.444	
					Hemoglobin	133	g/L			108-150	
					Leukocytes	7.7	10^9/L			3.1-9.7	
					Lymphocytes	2.72	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	35.4	%			13.9-48.3	
					Monocytes	0.64	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	8.4	%			3.3-12.1	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
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Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9080	41/F/BL		Check-in	15OCT2019 09:30 (-1)	Neutrophils	4.07	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	53.1	%			39.1-77.2	
					Platelets	283	10^9/L			140-400	
		TPOXX 600 mg	Day 4	19OCT2019 07:46 (4)	Basophils	0.03	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.4	%			0-1.4	
					Eosinophils	0.34	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	4.2	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	335	g/L			314-348	
					Ery. Mean Corpuscular Hemoglobin	31.7	pg			22.9-33.9	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9080	41/F/BL	TPOXX 600 mg	Day 4	19OCT2019 07:46 (4)	Ery. Mean Corpuscular Volume	94.6	fL			72.2-99.1	
					Erythrocytes	4.75	10^12/L			3.84-5.28	
					Erythrocytes Distribution Width	13.8	%			11.1-17.3	
					Hematocrit	0.449	fraction of 1	H NCS		0.335-0.444	
					Hemoglobin	150	g/L			108-150	
					Leukocytes	8.1	10^9/L			3.1-9.7	
					Lymphocytes	3.24	10^9/L	H NCS		0.8-2.91	
					Lymphocytes/ Leukocytes	40.0	%			13.9-48.3	
					Monocytes	0.50	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	6.2	%			3.3-12.1	
					Neutrophils	3.99	10^9/L			1.5-6.75	

Sex: M=Male, F=Female;
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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9080	41/F/BL	TPOXX 600 mg	Day 4	19OCT2019 07:46 (4)	Neutrophils/ Leukocytes	49.2	%			39.1-77.2	
					Platelets	313	10^9/L			140-400	
			Day 8 - 12 Hours Postdose	23OCT2019 08:21 (8)	Basophils	0.04	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.6	%			0-1.4	
					Eosinophils	0.20	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	2.8	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	341	g/L			314-348	
					Ery. Mean Corpuscular Hemoglobin	32.3	pg			22.9-33.9	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9080	41/F/BL	TPOXX 600 mg	Day 8 - 12 Hours Postdose	23OCT2019 08:21 (8)	Ery. Mean Corpuscular Volume	94.5	fL			72.2-99.1	
					Erythrocytes	4.42	10^12/L			3.84-5.28	
					Erythrocytes Distribution Width	13.3	%			11.1-17.3	
					Hematocrit	0.418	fraction of 1			0.335-0.444	
					Hemoglobin	143	g/L			108-150	
					Leukocytes	7.4	10^9/L			3.1-9.7	
					Lymphocytes	2.78	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	37.7	%			13.9-48.3	
					Monocytes	0.57	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	7.7	%			3.3-12.1	
					Neutrophils	3.78	10^9/L			1.5-6.75	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9080	41/F/BL	TPOXX 600 mg	Day 8 - 12 Hours Postdose	23OCT2019 08:21 (8)	Neutrophils/ Leukocytes	51.3	%			39.1-77.2	
					Platelets	303	10^9/L			140-400	
			Day 9	24OCT2019 08:21 (9)	Basophils	0.04	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.6	%			0-1.4	
					Eosinophils	0.16	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	2.3	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	344	g/L			314-348	
					Ery. Mean Corpuscular Hemoglobin	32.3	pg			22.9-33.9	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9080	41/F/BL	TPOXX 600 mg	Day 9	24OCT2019 08:21 (9)	Ery. Mean Corpuscular Volume	93.9	fL			72.2-99.1	
					Erythrocytes	4.11	10^12/L			3.84-5.28	
					Erythrocytes Distribution Width	13.2	%			11.1-17.3	
					Hematocrit	0.386	fraction of 1			0.335-0.444	
					Hemoglobin	133	g/L			108-150	
					Leukocytes	6.9	10^9/L			3.1-9.7	
					Lymphocytes	2.55	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	37.1	%			13.9-48.3	
					Monocytes	0.62	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	9.1	%			3.3-12.1	
					Neutrophils	3.51	10^9/L			1.5-6.75	

Sex: M=Male, F=Female;
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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9080	41/F/BL	TPOXX 600 mg	Day 9	24OCT2019 08:21 (9)	Neutrophils/ Leukocytes	51.0	%			39.1-77.2	
					Platelets	283	10^9/L			140-400	
9081	49/M/BL		Screening	10OCT2019 12:25 (-20)	Basophils	0.04	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.6	%			0-1.4	
					Eosinophils	0.19	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	2.8	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	333	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	29.6	pg			25-33.6	
					Ery. Mean Corpuscular Volume	88.9	fL			76.5-97.5	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9081	49/M/BL		Screening	10OCT2019 12:25 (-20)	Erythrocytes	5.05	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	14.1	%			11.8-15.5	
					Hematocrit	0.449	fraction of 1			0.387-0.507	
					Hemoglobin	150	g/L			128-174	
					Leukocytes	6.6	10^9/L			3.1-9.7	
					Lymphocytes	2.06	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	31.3	%			13.9-48.3	
					Monocytes	0.69	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	10.5	%			3.3-12.1	
					Neutrophils	3.60	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	54.7	%			39.1-77.2	

Sex: M=Male, F=Female;
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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9081	49/M/BL		Screening	10OCT2019 12:25 (-20)	Platelets	286	10^9/L			140-400	
			Check-in	29OCT2019 10:08 (-1)	Basophils	0.04	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.6	%			0-1.4	
					Eosinophils	0.17	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	2.8	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	325	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	29.1	pg			25-33.6	
					Ery. Mean Corpuscular Volume	89.3	fL			76.5-97.5	
					Erythrocytes	5.02	10^12/L			4.28-6.03	

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Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9081	49/M/BL		Check-in	29OCT2019 10:08 (-1)	Erythrocytes Distribution Width	14.2	%			11.8-15.5	
					Hematocrit	0.448	fraction of 1			0.387-0.507	
					Hemoglobin	146	g/L			128-174	
					Leukocytes	6.2	10^9/L			3.1-9.7	
					Lymphocytes	2.01	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	32.4	%			13.9-48.3	
					Monocytes	0.73	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	11.7	%			3.3-12.1	
					Neutrophils	3.25	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	52.5	%			39.1-77.2	
					Platelets	294	10^9/L			140-400	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9081	49/M/BL	TPOXX 600 mg	Day 4	02NOV2019 07:27 (4)	Basophils	0.07	10^9/L			0-0.08	
					Basophils/ Leukocytes	1.0	%			0-1.4	
					Eosinophils	0.19	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	2.9	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	333	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	29.7	pg			25-33.6	
					Ery. Mean Corpuscular Volume	89.2	fL			76.5-97.5	
					Erythrocytes	4.87	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	13.9	%			11.8-15.5	

Sex: M=Male, F=Female;
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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9081	49/M/BL	TPOXX 600 mg	Day 4	02NOV2019 07:27 (4)	Hematocrit	0.434	fraction of 1			0.387-0.507	
					Hemoglobin	145	g/L			128-174	
					Leukocytes	6.6	10^9/L			3.1-9.7	
					Lymphocytes	2.34	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	35.3	%			13.9-48.3	
					Monocytes	0.65	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	9.8	%			3.3-12.1	
					Neutrophils	3.39	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	51.1	%			39.1-77.2	
					Platelets	284	10^9/L			140-400	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9081	49/M/BL	TPOXX 600 mg	Day 8 - 12 Hours Postdose	06NOV2019 07:00 (8)	Basophils	0.04	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.7	%			0-1.4	
					Eosinophils	0.17	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	2.9	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	330	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	29.6	pg			25-33.6	
					Ery. Mean Corpuscular Volume	89.7	fL			76.5-97.5	
					Erythrocytes	4.90	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	13.9	%			11.8-15.5	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9081	49/M/BL	TPOXX 600 mg	Day 8 - 12 Hours Postdose	06NOV2019 07:00 (8)	Hematocrit	0.440	fraction of 1			0.387-0.507	
					Hemoglobin	145	g/L			128-174	
					Leukocytes	6.0	10^9/L			3.1-9.7	
					Lymphocytes	1.90	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	31.7	%			13.9-48.3	
					Monocytes	0.64	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	10.7	%			3.3-12.1	
					Neutrophils	3.24	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	54.0	%			39.1-77.2	
					Platelets	304	10^9/L			140-400	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9081	49/M/BL	TPOXX 600 mg	Day 9	07NOV2019 07:00 (9)	Basophils	0.03	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.6	%			0-1.4	
					Eosinophils	0.17	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	2.9	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	333	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	29.8	pg			25-33.6	
					Ery. Mean Corpuscular Volume	89.3	fL			76.5-97.5	
					Erythrocytes	4.88	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	14.2	%			11.8-15.5	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9081	49/M/BL	TPOXX 600 mg	Day 9	07NOV2019 07:00 (9)	Hematocrit	0.436	fraction of 1			0.387-0.507	
					Hemoglobin	145	g/L			128-174	
					Leukocytes	5.8	10^9/L			3.1-9.7	
					Lymphocytes	1.89	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	32.3	%			13.9-48.3	
					Monocytes	0.60	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	10.3	%			3.3-12.1	
					Neutrophils	3.15	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	53.9	%			39.1-77.2	
					Platelets	308	10^9/L			140-400	
9086	36/M/BL		Screening	11OCT2019 10:03 (-5)	Basophils	0.01	10^9/L			0-0.08	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9086	36/M/BL		Screening	11OCT2019 10:03 (-5)	Basophils/ Leukocytes	0.2	%			0-1.4	
					Eosinophils	0.03	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	0.6	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	325	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	27.8	pg			25-33.6	
					Ery. Mean Corpuscular Volume	85.4	fL			76.5-97.5	
					Erythrocytes	5.25	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	15.5	%			11.8-15.5	
					Hematocrit	0.449	fraction of 1			0.387-0.507	
					Hemoglobin	146	g/L			128-174	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9086	36/M/BL		Screening	11OCT2019 10:03 (-5)	Leukocytes	4.9	10^9/L			3.1-9.7	
					Lymphocytes	1.77	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	35.9	%			13.9-48.3	
					Monocytes	0.41	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	8.4	%			3.3-12.1	
					Neutrophils	2.71	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	54.9	%			39.1-77.2	
					Platelets	219	10^9/L			140-400	
			Check-in	15OCT2019 09:28 (-1)	Basophils	0.01	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.3	%			0-1.4	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9086	36/M/BL		Check-in	15OCT2019 09:28 (-1)	Eosinophils	0.03	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	0.6	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	335	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	27.9	pg			25-33.6	
					Ery. Mean Corpuscular Volume	83.4	fL			76.5-97.5	
					Erythrocytes	5.08	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	15.6	%	H NCS		11.8-15.5	
					Hematocrit	0.424	fraction of 1			0.387-0.507	
					Hemoglobin	142	g/L			128-174	
					Leukocytes	4.1	10^9/L			3.1-9.7	

Sex: M=Male, F=Female;
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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9086	36/M/BL		Check-in	15OCT2019 09:28 (-1)	Lymphocytes	1.71	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	41.4	%			13.9-48.3	
					Monocytes	0.34	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	8.3	%			3.3-12.1	
					Neutrophils	2.04	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	49.3	%			39.1-77.2	
					Platelets	214	10^9/L			140-400	
		TPOXX 600 mg	Day 4	19OCT2019 07:40 (4)	Basophils	0.02	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.5	%			0-1.4	
					Eosinophils	0.03	10^9/L			0-0.35	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9086	36/M/BL	TPOXX 600 mg	Day 4	19OCT2019 07:40 (4)	Eosinophils/ Leukocytes	0.7	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	333	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	28.0	pg			25-33.6	
					Ery. Mean Corpuscular Volume	84.2	fL			76.5-97.5	
					Erythrocytes	5.35	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	15.3	%			11.8-15.5	
					Hematocrit	0.450	fraction of 1			0.387-0.507	
					Hemoglobin	150	g/L			128-174	
					Leukocytes	4.4	10^9/L			3.1-9.7	
					Lymphocytes	2.04	10^9/L			0.8-2.91	

Sex: M=Male, F=Female;
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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9086	36/M/BL	TPOXX 600 mg	Day 4	19OCT2019 07:40 (4)	Lymphocytes/ Leukocytes	46.0	%			13.9-48.3	
					Monocytes	0.41	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	9.2	%			3.3-12.1	
					Neutrophils	1.94	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	43.7	%			39.1-77.2	
					Platelets	224	10^9/L			140-400	
			Day 8 - 12 Hours Postdose	23OCT2019 08:15 (8)	Basophils	0.02	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.5	%			0-1.4	
					Eosinophils	0.04	10^9/L			0-0.35	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9086	36/M/BL	TPOXX 600 mg	Day 8 - 12 Hours Postdose	23OCT2019 08:15 (8)	Eosinophils/ Leukocytes	0.8	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	332	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	28.2	pg			25-33.6	
					Ery. Mean Corpuscular Volume	85.1	fL			76.5-97.5	
					Erythrocytes	5.38	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	15.2	%			11.8-15.5	
					Hematocrit	0.458	fraction of 1			0.387-0.507	
					Hemoglobin	152	g/L			128-174	
					Leukocytes	4.7	10^9/L			3.1-9.7	
					Lymphocytes	2.07	10^9/L			0.8-2.91	

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R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9086	36/M/BL	TPOXX 600 mg	Day 8 - 12 Hours Postdose	23OCT2019 08:15 (8)	Lymphocytes/ Leukocytes	43.6	%			13.9-48.3	
					Monocytes	0.38	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	7.9	%			3.3-12.1	
					Neutrophils	2.24	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	47.3	%			39.1-77.2	
					Platelets	218	10^9/L			140-400	
			Day 9	24OCT2019 08:15 (9)	Basophils	0.01	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.3	%			0-1.4	
					Eosinophils	0.04	10^9/L			0-0.35	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9086	36/M/BL	TPOXX 600 mg	Day 9	24OCT2019 08:15 (9)	Eosinophils/ Leukocytes	1.0	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	329	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	27.7	pg			25-33.6	
					Ery. Mean Corpuscular Volume	84.0	fL			76.5-97.5	
					Erythrocytes	5.42	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	15.2	%			11.8-15.5	
					Hematocrit	0.455	fraction of 1			0.387-0.507	
					Hemoglobin	150	g/L			128-174	
					Leukocytes	4.4	10^9/L			3.1-9.7	
					Lymphocytes	1.85	10^9/L			0.8-2.91	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9086	36/M/BL	TPOXX 600 mg	Day 9	24OCT2019 08:15 (9)	Lymphocytes/ Leukocytes	42.0	%			13.9-48.3	
					Monocytes	0.36	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	8.1	%			3.3-12.1	
					Neutrophils	2.14	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	48.6	%			39.1-77.2	
					Platelets	220	10^9/L			140-400	
9087	34/F/BL		Screening	11OCT2019 09:47 (-5)	Basophils	0.03	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.4	%			0-1.4	
					Eosinophils	0.10	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	1.1	%			0-6.1	

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Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9087	34/F/BL		Screening	11OCT2019 09:47 (-5)	Ery. Mean Corpuscular HGB Concentration	308	g/L	L NCS		314-348	
					Ery. Mean Corpuscular Hemoglobin	21.8	pg	L NCS		22.9-33.9	
					Ery. Mean Corpuscular Volume	70.9	fL	L NCS		72.2-99.1	
					Erythrocytes	4.76	10^12/L			3.84-5.28	
					Erythrocytes Distribution Width	19.2	%	H NCS		11.1-17.3	
					Hematocrit	0.337	fraction of 1			0.335-0.444	
					Hemoglobin	104	g/L	L NCS	G1	108-150	
					Leukocytes	9.1	10^9/L			3.1-9.7	
					Lymphocytes	2.10	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	23.1	%			13.9-48.3	
					Monocytes	0.78	10^9/L	H NCS		0.15-0.75	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9087	34/F/BL		Screening	11OCT2019 09:47 (-5)	Monocytes/ Leukocytes	8.6	%			3.3-12.1	
					Neutrophils	6.08	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	66.9	%			39.1-77.2	
					Platelets	367	10^9/L			140-400	
			Check-in	15OCT2019 09:17 (-1)	Basophils	0.04	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.4	%			0-1.4	
					Eosinophils	0.23	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	2.4	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	309	g/L	L NCS		314-348	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9087	34/F/BL		Check-in	15OCT2019 09:17 (-1)	Ery. Mean Corpuscular Hemoglobin	21.5	pg	L NCS		22.9-33.9	
					Ery. Mean Corpuscular Volume	69.8	fL	L NCS		72.2-99.1	
					Erythrocytes	4.82	10^12/L			3.84-5.28	
					Erythrocytes Distribution Width	19.0	%	H NCS		11.1-17.3	
					Hematocrit	0.336	fraction of 1			0.335-0.444	
					Hemoglobin	104	g/L	L NCS	G1	108-150	
					Leukocytes	9.6	10^9/L			3.1-9.7	
					Lymphocytes	2.70	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	28.1	%			13.9-48.3	
					Monocytes	0.82	10^9/L	H NCS		0.15-0.75	
					Monocytes/ Leukocytes	8.6	%			3.3-12.1	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9087	34/F/BL		Check-in	15OCT2019 09:17 (-1)	Neutrophils	5.82	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	60.6	%			39.1-77.2	
					Platelets	399	10^9/L			140-400	
		TPOXX 600 mg	Day 4	19OCT2019 07:43 (4)	Basophils	0.04	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.4	%			0-1.4	
					Eosinophils	0.21	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	2.0	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	307	g/L	L NCS		314-348	
					Ery. Mean Corpuscular Hemoglobin	21.5	pg	L NCS		22.9-33.9	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9087	34/F/BL	TPOXX 600 mg	Day 4	19OCT2019 07:43 (4)	Ery. Mean Corpuscular Volume	70.1	fL	L NCS		72.2-99.1	
					Erythrocytes	4.76	10^12/L			3.84-5.28	
					Erythrocytes Distribution Width	18.6	%	H NCS		11.1-17.3	
					Hematocrit	0.334	fraction of 1	L NCS		0.335-0.444	
					Hemoglobin	102	g/L	L NCS	G1	108-150	
					Leukocytes	10.4	10^9/L	H NCS		3.1-9.7	
					Lymphocytes	2.43	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	23.3	%			13.9-48.3	
					Monocytes	0.83	10^9/L	H NCS		0.15-0.75	
					Monocytes/ Leukocytes	8.0	%			3.3-12.1	
					Neutrophils	6.91	10^9/L	H NCS		1.5-6.75	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9087	34/F/BL	TPOXX 600 mg	Day 4	19OCT2019 07:43 (4)	Neutrophils/ Leukocytes	66.3	%			39.1-77.2	
					Platelets	407	10^9/L	H NCS		140-400	
			Day 4	20OCT2019 07:04 (5), R	Basophils	0.06	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.5	%			0-1.4	
					Eosinophils	0.20	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	1.9	%			0-6.1	
					Leukocytes	10.7	10^9/L	H NCS		3.1-9.7	
					Lymphocytes	2.75	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	25.8	%			13.9-48.3	
					Monocytes	0.96	10^9/L	H NCS		0.15-0.75	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9087	34/F/BL	TPOXX 600 mg	Day 4	20OCT2019 07:04 (5), R	Monocytes/ Leukocytes	8.9	%			3.3-12.1	
					Neutrophils	6.72	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	62.9	%			39.1-77.2	
			Day 8 - 12 Hours Postdose	23OCT2019 08:18 (8)	Basophils	0.04	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.4	%			0-1.4	
					Eosinophils	0.19	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	2.1	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	311	g/L	L NCS		314-348	

Sex: M=Male, F=Female;
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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9087	34/F/BL	TPOXX 600 mg	Day 8 - 12 Hours Postdose	23OCT2019 08:18 (8)	Ery. Mean Corpuscular Hemoglobin	21.8	pg	L NCS		22.9-33.9	
					Ery. Mean Corpuscular Volume	70.1	fL	L NCS		72.2-99.1	
					Erythrocytes	4.88	10^12/L			3.84-5.28	
					Erythrocytes Distribution Width	18.0	%	H NCS		11.1-17.3	
					Hematocrit	0.342	fraction of 1			0.335-0.444	
					Hemoglobin	107	g/L	L NCS		108-150	
					Leukocytes	9.1	10^9/L			3.1-9.7	
					Lymphocytes	2.69	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	29.7	%			13.9-48.3	
					Monocytes	0.75	10^9/L			0.15-0.75	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9087	34/F/BL	TPOXX 600 mg	Day 8 - 12 Hours Postdose	23OCT2019 08:18 (8)	Monocytes/ Leukocytes	8.2	%			3.3-12.1	
					Neutrophils	5.40	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	59.6	%			39.1-77.2	
					Platelets	437	10^9/L	H NCS		140-400	
			Day 9	24OCT2019 08:18 (9)	Basophils	0.04	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.5	%			0-1.4	
					Eosinophils	0.16	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	1.8	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	310	g/L	L NCS		314-348	

Sex: M=Male, F=Female;
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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9087	34/F/BL	TPOXX 600 mg	Day 9	24OCT2019 08:18 (9)	Ery. Mean Corpuscular Hemoglobin	21.7	pg	L NCS		22.9-33.9	
					Ery. Mean Corpuscular Volume	69.9	fL	L NCS		72.2-99.1	
					Erythrocytes	4.78	10^12/L			3.84-5.28	
					Erythrocytes Distribution Width	17.8	%	H NCS		11.1-17.3	
					Hematocrit	0.334	fraction of 1	L NCS		0.335-0.444	
					Hemoglobin	104	g/L	L NCS	G1	108-150	
					Leukocytes	9.0	10^9/L			3.1-9.7	
					Lymphocytes	2.42	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	26.9	%			13.9-48.3	
					Monocytes	0.84	10^9/L	H NCS		0.15-0.75	
					Monocytes/ Leukocytes	9.3	%			3.3-12.1	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9087	34/F/BL	TPOXX 600 mg	Day 9	24OCT2019 08:18 (9)	Neutrophils	5.55	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	61.6	%			39.1-77.2	
					Platelets	420	10^9/L	H NCS		140-400	
9089	29/M/BL		Screening	14OCT2019 09:26 (-2)	Basophils	0.06	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.8	%			0-1.4	
					Eosinophils	0.35	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	4.6	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	335	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	27.6	pg			25-33.6	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9089	29/M/BL		Screening	14OCT2019 09:26 (-2)	Ery. Mean Corpuscular Volume	82.2	fL			76.5-97.5	
					Erythrocytes	5.17	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	14.5	%			11.8-15.5	
					Hematocrit	0.425	fraction of 1			0.387-0.507	
					Hemoglobin	142	g/L			128-174	
					Leukocytes	7.6	10^9/L			3.1-9.7	
					Lymphocytes	2.22	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	29.0	%			13.9-48.3	
					Monocytes	0.66	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	8.6	%			3.3-12.1	
					Neutrophils	4.35	10^9/L			1.5-6.75	

Sex: M=Male, F=Female;
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Day = The presented date — First dose date + 1
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Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9089	29/M/BL		Screening	14OCT2019 09:26 (-2)	Neutrophils/ Leukocytes	57.0	%			39.1-77.2	
					Platelets	184	10^9/L			140-400	
			Check-in	15OCT2019 08:52 (-1)	Basophils	0.04	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.5	%			0-1.4	
					Eosinophils	0.27	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	3.7	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	330	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	26.9	pg			25-33.6	
					Ery. Mean Corpuscular Volume	81.7	fL			76.5-97.5	

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Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9089	29/M/BL		Check-in	15OCT2019 08:52 (-1)	Erythrocytes	5.14	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	14.1	%			11.8-15.5	
					Hematocrit	0.419	fraction of 1			0.387-0.507	
					Hemoglobin	138	g/L			128-174	
					Leukocytes	7.2	10^9/L			3.1-9.7	
					Lymphocytes	2.16	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	29.9	%			13.9-48.3	
					Monocytes	0.57	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	7.9	%			3.3-12.1	
					Neutrophils	4.19	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	57.9	%			39.1-77.2	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
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Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9089	29/M/BL		Check-in	15OCT2019 08:52 (-1)	Platelets	184	10^9/L			140-400	
		TPOXX 600 mg	Day 4	19OCT2019 07:49 (4)	Basophils	0.05	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.6	%			0-1.4	
					Eosinophils	0.28	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	3.3	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	331	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	27.3	pg			25-33.6	
					Ery. Mean Corpuscular Volume	82.4	fL			76.5-97.5	
					Erythrocytes	5.32	10^12/L			4.28-6.03	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9089	29/M/BL	TPOXX 600 mg	Day 4	19OCT2019 07:49 (4)	Erythrocytes Distribution Width	14.7	%			11.8-15.5	
					Hematocrit	0.438	fraction of 1			0.387-0.507	
					Hemoglobin	145	g/L			128-174	
					Leukocytes	8.5	10^9/L			3.1-9.7	
					Lymphocytes	2.83	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	33.1	%			13.9-48.3	
					Monocytes	0.69	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	8.1	%			3.3-12.1	
					Neutrophils	4.69	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	54.9	%			39.1-77.2	
					Platelets	212	10^9/L			140-400	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9089	29/M/BL	TPOXX 600 mg	Day 8 - 12 Hours Postdose	23OCT2019 08:24 (8)	Basophils	0.04	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.5	%			0-1.4	
					Eosinophils	0.26	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	3.4	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	335	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	27.8	pg			25-33.6	
					Ery. Mean Corpuscular Volume	82.9	fL			76.5-97.5	
					Erythrocytes	5.22	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	14.1	%			11.8-15.5	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9089	29/M/BL	TPOXX 600 mg	Day 8 - 12 Hours Postdose	23OCT2019 08:24 (8)	Hematocrit	0.433	fraction of 1			0.387-0.507	
					Hemoglobin	145	g/L			128-174	
					Leukocytes	7.6	10^9/L			3.1-9.7	
					Lymphocytes	2.46	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	32.4	%			13.9-48.3	
					Monocytes	0.62	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	8.2	%			3.3-12.1	
					Neutrophils	4.21	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	55.5	%			39.1-77.2	
					Platelets	201	10^9/L			140-400	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9089	29/M/BL	TPOXX 600 mg	Day 9	24OCT2019 08:24 (9)	Basophils	0.04	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.5	%			0-1.4	
					Eosinophils	0.27	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	3.8	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	331	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	27.3	pg			25-33.6	
					Ery. Mean Corpuscular Volume	82.4	fL			76.5-97.5	
					Erythrocytes	5.23	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	14.3	%			11.8-15.5	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9089	29/M/BL	TPOXX 600 mg	Day 9	24OCT2019 08:24 (9)	Hematocrit	0.431	fraction of 1			0.387-0.507	
					Hemoglobin	143	g/L			128-174	
					Leukocytes	7.2	10^9/L			3.1-9.7	
					Lymphocytes	2.45	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	34.1	%			13.9-48.3	
					Monocytes	0.60	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	8.3	%			3.3-12.1	
					Neutrophils	3.83	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	53.3	%			39.1-77.2	
					Platelets	204	10^9/L			140-400	
9092	24/M/W		Screening	14OCT2019 09:33 (-2)	Basophils	0.02	10^9/L			0-0.08	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9092	24/M/W		Screening	14OCT2019 09:33 (-2)	Basophils/ Leukocytes	0.2	%			0-1.4	
					Eosinophils	0.18	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	2.2	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	337	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	29.6	pg			25-33.6	
					Ery. Mean Corpuscular Volume	87.9	fL			76.5-97.5	
					Erythrocytes	4.98	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	14.6	%			11.8-15.5	
					Hematocrit	0.438	fraction of 1			0.387-0.507	
					Hemoglobin	148	g/L			128-174	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9092	24/M/W		Screening	14OCT2019 09:33 (-2)	Leukocytes	8.4	10^9/L			3.1-9.7	
					Lymphocytes	1.73	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	20.7	%			13.9-48.3	
					Monocytes	0.62	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	7.5	%			3.3-12.1	
					Neutrophils	5.80	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	69.5	%			39.1-77.2	
					Platelets	245	10^9/L			140-400	
			Check-in	15OCT2019 09:13 (-1)	Basophils	0.01	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.2	%			0-1.4	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9092	24/M/W		Check-in	15OCT2019 09:13 (-1)	Eosinophils	0.26	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	3.1	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	336	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	29.4	pg			25-33.6	
					Ery. Mean Corpuscular Volume	87.5	fL			76.5-97.5	
					Erythrocytes	4.80	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	14.3	%			11.8-15.5	
					Hematocrit	0.420	fraction of 1			0.387-0.507	
					Hemoglobin	141	g/L			128-174	
					Leukocytes	8.5	10^9/L			3.1-9.7	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9092	24/M/W		Check-in	15OCT2019 09:13 (-1)	Lymphocytes	2.07	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	24.4	%			13.9-48.3	
					Monocytes	0.69	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	8.1	%			3.3-12.1	
					Neutrophils	5.43	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	64.2	%			39.1-77.2	
					Platelets	239	10^9/L			140-400	
		TPOXX 600 mg	Day 4	19OCT2019 07:52 (4)	Basophils	0.02	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.3	%			0-1.4	
					Eosinophils	0.12	10^9/L			0-0.35	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9092	24/M/W	TPOXX 600 mg	Day 4	19OCT2019 07:52 (4)	Eosinophils/ Leukocytes	1.8	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	339	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	29.3	pg			25-33.6	
					Ery. Mean Corpuscular Volume	86.3	fL			76.5-97.5	
					Erythrocytes	4.89	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	14.7	%			11.8-15.5	
					Hematocrit	0.422	fraction of 1			0.387-0.507	
					Hemoglobin	143	g/L			128-174	
					Leukocytes	6.8	10^9/L			3.1-9.7	
					Lymphocytes	1.78	10^9/L			0.8-2.91	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9092	24/M/W	TPOXX 600 mg	Day 4	19OCT2019 07:52 (4)	Lymphocytes/ Leukocytes	26.3	%			13.9-48.3	
					Monocytes	0.45	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	6.7	%			3.3-12.1	
					Neutrophils	4.39	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	64.9	%			39.1-77.2	
					Platelets	233	10^9/L			140-400	
			Day 8 - 12 Hours Postdose	23OCT2019 08:27 (8)	Basophils	0.02	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.3	%			0-1.4	
					Eosinophils	0.14	10^9/L			0-0.35	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9092	24/M/W	TPOXX 600 mg	Day 8 - 12 Hours Postdose	23OCT2019 08:27 (8)	Eosinophils/ Leukocytes	1.9	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	344	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	30.0	pg			25-33.6	
					Ery. Mean Corpuscular Volume	87.2	fL			76.5-97.5	
					Erythrocytes	5.03	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	14.2	%			11.8-15.5	
					Hematocrit	0.438	fraction of 1			0.387-0.507	
					Hemoglobin	151	g/L			128-174	
					Leukocytes	7.3	10^9/L			3.1-9.7	
					Lymphocytes	1.80	10^9/L			0.8-2.91	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9092	24/M/W	TPOXX 600 mg	Day 8 - 12 Hours Postdose	23OCT2019 08:27 (8)	Lymphocytes/ Leukocytes	24.7	%			13.9-48.3	
					Monocytes	0.46	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	6.3	%			3.3-12.1	
					Neutrophils	4.87	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	66.9	%			39.1-77.2	
					Platelets	247	10^9/L			140-400	
			Day 9	24OCT2019 08:27 (9)	Basophils	0.02	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.3	%			0-1.4	
					Eosinophils	0.11	10^9/L			0-0.35	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9092	24/M/W	TPOXX 600 mg	Day 9	24OCT2019 08:27 (9)	Eosinophils/ Leukocytes	1.7	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	342	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	29.4	pg			25-33.6	
					Ery. Mean Corpuscular Volume	85.8	fL			76.5-97.5	
					Erythrocytes	5.02	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	14.5	%			11.8-15.5	
					Hematocrit	0.431	fraction of 1			0.387-0.507	
					Hemoglobin	148	g/L			128-174	
					Leukocytes	6.9	10^9/L			3.1-9.7	
					Lymphocytes	1.88	10^9/L			0.8-2.91	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9092	24/M/W	TPOXX 600 mg	Day 9	24OCT2019 08:27 (9)	Lymphocytes/ Leukocytes	27.5	%			13.9-48.3	
					Monocytes	0.39	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	5.7	%			3.3-12.1	
					Neutrophils	4.45	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	64.9	%			39.1-77.2	
					Platelets	256	10^9/L			140-400	
9095	42/M/W		Screening	17OCT2019 13:31 (-13)	Basophils	0.11	10^9/L	H NCS		0-0.08	
					Basophils/ Leukocytes	1.2	%			0-1.4	
					Eosinophils	0.14	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	1.5	%			0-6.1	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9095	42/M/W		Screening	17OCT2019 13:31 (-13)	Ery. Mean Corpuscular HGB Concentration	343	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	31.6	pg			25-33.6	
					Ery. Mean Corpuscular Volume	92.0	fL			76.5-97.5	
					Erythrocytes	4.94	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	12.8	%			11.8-15.5	
					Hematocrit	0.455	fraction of 1			0.387-0.507	
					Hemoglobin	156	g/L			128-174	
					Leukocytes	9.1	10^9/L			3.1-9.7	
					Lymphocytes	1.18	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	13.0	%	L NCS		13.9-48.3	
					Monocytes	0.26	10^9/L			0.15-0.75	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9095	42/M/W		Screening	17OCT2019 13:31 (-13)	Monocytes/ Leukocytes	2.9	%	L NCS		3.3-12.1	
					Neutrophils	7.40	10^9/L	H NCS		1.5-6.75	
					Neutrophils/ Leukocytes	81.4	%	H NCS		39.1-77.2	
					Platelets	253	10^9/L			140-400	
			Screening	23OCT2019 14:43 (-7), R	Basophils	0.03	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.4	%			0-1.4	
					Eosinophils	0.28	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	3.3	%			0-6.1	
					Leukocytes	8.3	10^9/L			3.1-9.7	
					Lymphocytes	1.87	10^9/L			0.8-2.91	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9095	42/M/W		Screening	23OCT2019 14:43 (-7), R	Lymphocytes/ Leukocytes	22.4	%			13.9-48.3	
					Monocytes	0.60	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	7.2	%			3.3-12.1	
					Neutrophils	5.56	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	66.7	%			39.1-77.2	
			Check-in	29OCT2019 08:52 (-1)	Basophils	0.06	10^9/L			0-0.08	
					Basophils/ Leukocytes	1.0	%			0-1.4	
					Eosinophils	0.25	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	3.8	%			0-6.1	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9095	42/M/W		Check-in	29OCT2019 08:52 (-1)	Ery. Mean Corpuscular HGB Concentration	340	g/L			320-354	
					Ery. Mean Corpuscular Hemoglobin	31.6	pg			25-33.6	
					Ery. Mean Corpuscular Volume	93.0	fL			76.5-97.5	
					Erythrocytes	4.83	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	12.7	%			11.8-15.5	
					Hematocrit	0.449	fraction of 1			0.387-0.507	
					Hemoglobin	153	g/L			128-174	
					Leukocytes	6.5	10^9/L			3.1-9.7	
					Lymphocytes	1.63	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	25.2	%			13.9-48.3	
					Monocytes	0.39	10^9/L			0.15-0.75	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9095	42/M/W		Check-in	29OCT2019 08:52 (-1)	Monocytes/ Leukocytes	6.1	%			3.3-12.1	
					Neutrophils	4.12	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	63.9	%			39.1-77.2	
					Platelets	242	10^9/L			140-400	
		TPOXX 600 mg	Day 4	02NOV2019 07:31 (4)	Basophils	0.05	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.7	%			0-1.4	
					Eosinophils	0.24	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	3.0	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	336	g/L			320-354	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9095	42/M/W	TPOXX 600 mg	Day 4	02NOV2019 07:31 (4)	Ery. Mean Corpuscular Hemoglobin	31.3	pg			25-33.6	
					Ery. Mean Corpuscular Volume	93.2	fL			76.5-97.5	
					Erythrocytes	5.00	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	12.8	%			11.8-15.5	
					Hematocrit	0.466	fraction of 1			0.387-0.507	
					Hemoglobin	157	g/L			128-174	
					Leukocytes	8.1	10^9/L			3.1-9.7	
					Lymphocytes	2.32	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	28.6	%			13.9-48.3	
					Monocytes	0.46	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	5.7	%			3.3-12.1	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9095	42/M/W	TPOXX 600 mg	Day 4	02NOV2019 07:31 (4)	Neutrophils	5.03	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	62.1	%			39.1-77.2	
					Platelets	265	10^9/L			140-400	
			Day 8 - 12 Hours Postdose	06NOV2019 07:06 (8)	Basophils	0.07	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.9	%			0-1.4	
					Eosinophils	0.24	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	2.9	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	343	g/L			320-354	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9095	42/M/W	TPOXX 600 mg	Day 8 - 12 Hours Postdose	06NOV2019 07:06 (8)	Ery. Mean Corpuscular Hemoglobin	31.7	pg			25-33.6	
					Ery. Mean Corpuscular Volume	92.6	fL			76.5-97.5	
					Erythrocytes	4.88	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	13.1	%			11.8-15.5	
					Hematocrit	0.452	fraction of 1			0.387-0.507	
					Hemoglobin	155	g/L			128-174	
					Leukocytes	8.4	10^9/L			3.1-9.7	
					Lymphocytes	2.22	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	26.5	%			13.9-48.3	
					Monocytes	0.42	10^9/L			0.15-0.75	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9095	42/M/W	TPOXX 600 mg	Day 8 - 12 Hours Postdose	06NOV2019 07:06 (8)	Monocytes/ Leukocytes	5.0	%			3.3-12.1	
					Neutrophils	5.44	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	64.8	%			39.1-77.2	
					Platelets	283	10^9/L			140-400	
			Day 9	07NOV2019 07:06 (9)	Basophils	0.06	10^9/L			0-0.08	
					Basophils/ Leukocytes	0.8	%			0-1.4	
					Eosinophils	0.21	10^9/L			0-0.35	
					Eosinophils/ Leukocytes	2.9	%			0-6.1	
					Ery. Mean Corpuscular HGB Concentration	341	g/L			320-354	

Sex: M=Male, F=Female;
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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9095	42/M/W	TPOXX 600 mg	Day 9	07NOV2019 07:06 (9)	Ery. Mean Corpuscular Hemoglobin	31.7	pg			25-33.6	
					Ery. Mean Corpuscular Volume	93.0	fL			76.5-97.5	
					Erythrocytes	4.88	10^12/L			4.28-6.03	
					Erythrocytes Distribution Width	12.7	%			11.8-15.5	
					Hematocrit	0.454	fraction of 1			0.387-0.507	
					Hemoglobin	155	g/L			128-174	
					Leukocytes	7.5	10^9/L			3.1-9.7	
					Lymphocytes	2.01	10^9/L			0.8-2.91	
					Lymphocytes/ Leukocytes	26.9	%			13.9-48.3	
					Monocytes	0.40	10^9/L			0.15-0.75	
					Monocytes/ Leukocytes	5.3	%			3.3-12.1	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.1
Laboratory Results - Hematology
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9095	42/M/W	TPOXX 600 mg	Day 9	07NOV2019 07:06 (9)	Neutrophils	4.79	10^9/L			1.5-6.75	
					Neutrophils/ Leukocytes	64.2	%			39.1-77.2	
					Platelets	273	10^9/L			140-400	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9001	41/M/BL		Screening	19JUL2019 12:06 (-26)	Alanine Aminotransferase	34	IU/L			7-56	
					Albumin	44	g/L			37-55	
					Alkaline Phosphatase	42	IU/L			20-116	
					Anion Gap	10	mmol/L			6-17	
					Aspartate Aminotransferase	24	IU/L			10-40	
					Bilirubin	20.7	umol/L			3.2-28.9	
					Blood Urea Nitrogen	3.50	mmol/L			1.79-9.28	
					Calcium	2.35	mmol/L			2.13-2.58	
					Carbon Dioxide	31	mmol/L			22-34	
					Chloride	103	mmol/L			96-108	
					Cholesterol	3.81	mmol/L			2.2-6.22	
					Creatinine	86.6	umol/L			56.6-114.9	
					Creatinine Clearance	179.6	mL/min			90-N/A	
					Gamma Glutamyl Transferase	27	IU/L			5-85	
					Globulin	33	g/L			19-39	
					Glucose	4.77	mmol/L			3-6.44	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9001	41/M/BL		Screening	19JUL2019 12:06 (-26)	HDL Cholesterol	0.91	mmol/L			0.65-2.46	
					LDL Cholesterol	1.92	mmol/L			0.96-4.22	
					Lactate Dehydrogenase	168	IU/L			82-216	
					Phosphate	1.07	mmol/L			0.68-1.52	
					Potassium	3.9	mmol/L			3.5-5	
					Protein	77	g/L			57-88	
					Sodium	140	mmol/L			132-145	
					Triglycerides	2.17	mmol/L		G1	0-4.52	
					Urate	351	umol/L			173-494	
			Check-in	13AUG2019 09:44 (-1)	Alanine Aminotransferase	29	IU/L			7-56	
					Albumin	44	g/L			37-55	
					Alkaline Phosphatase	37	IU/L			20-116	
					Anion Gap	10	mmol/L			6-17	
					Aspartate Aminotransferase	21	IU/L			10-40	
					Bilirubin	21.2	umol/L			3.2-28.9	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9001	41/M/BL		Check-in	13AUG2019 09:44 (-1)	Blood Urea Nitrogen	4.64	mmol/L			1.79-9.28	
					Calcium	2.40	mmol/L			2.13-2.58	
					Carbon Dioxide	31	mmol/L			22-34	
					Chloride	103	mmol/L			96-108	
					Creatinine	92.8	umol/L			56.6-114.9	
					Gamma Glutamyl Transferase	33	IU/L			5-85	
					Globulin	35	g/L			19-39	
					Glucose	5.05	mmol/L			3-6.44	
					Lactate Dehydrogenase	150	IU/L			82-216	
					Phosphate	1.07	mmol/L			0.68-1.52	
					Potassium	4.0	mmol/L			3.5-5	
					Protein	79	g/L			57-88	
					Sodium	140	mmol/L			132-145	
					Urate	333	umol/L			173-494	
		TPOXX 600 mg	Day 4	17AUG2019 08:54 (4)	Alanine Aminotransferase	27	IU/L			7-56	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9001	41/M/BL	TPOXX 600 mg	Day 4	17AUG2019 08:54 (4)	Albumin	47	g/L			37-55	
					Alkaline Phosphatase	37	IU/L			20-116	
					Anion Gap	11	mmol/L			6-17	
					Aspartate Aminotransferase	21	IU/L			10-40	
					Bilirubin	23.6	umol/L			3.2-28.9	
					Blood Urea Nitrogen	5.32	mmol/L			1.79-9.28	
					Calcium	2.45	mmol/L			2.13-2.58	
					Carbon Dioxide	30	mmol/L			22-34	
					Chloride	104	mmol/L			96-108	
					Creatinine	94.6	umol/L			56.6-114.9	
					Gamma Glutamyl Transferase	32	IU/L			5-85	
					Globulin	36	g/L			19-39	
					Glucose	4.83	mmol/L			3-6.44	
					Lactate Dehydrogenase	150	IU/L			82-216	
					Phosphate	1.07	mmol/L			0.68-1.52	
					Potassium	3.9	mmol/L			3.5-5	

Sex: M=Male, F=Female;
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Day = The presented date — First dose date + 1
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Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9001	41/M/BL	TPOXX 600 mg	Day 4	17AUG2019 08:54 (4)	Protein	83	g/L			57-88	
					Sodium	141	mmol/L			132-145	
					Urate	345	umol/L			173-494	
			Day 8 - 12 Hours Postdose	21AUG2019 09:25 (8)	Alanine Aminotransferase	26	IU/L			7-56	
					Albumin	46	g/L			37-55	
					Alkaline Phosphatase	42	IU/L			20-116	
					Anion Gap	11	mmol/L			6-17	
					Aspartate Aminotransferase	18	IU/L			10-40	
					Bilirubin	20.5	umol/L			3.2-28.9	
					Blood Urea Nitrogen	4.68	mmol/L			1.79-9.28	
					Calcium	2.45	mmol/L			2.13-2.58	
					Carbon Dioxide	31	mmol/L			22-34	
					Chloride	103	mmol/L			96-108	
					Creatinine	92.8	umol/L			56.6-114.9	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9001	41/M/BL	TPOXX 600 mg	Day 8 - 12 Hours Postdose	21AUG2019 09:25 (8)	Gamma Glutamyl Transferase	32	IU/L			5-85	
					Globulin	33	g/L			19-39	
					Glucose	4.83	mmol/L			3-6.44	
					Lactate Dehydrogenase	135	IU/L			82-216	
					Phosphate	1.29	mmol/L			0.68-1.52	
					Potassium	3.8	mmol/L			3.5-5	
					Protein	79	g/L			57-88	
					Sodium	141	mmol/L			132-145	
					Urate	321	umol/L			173-494	
			Day 9	22AUG2019 09:25 (9)	Alanine Aminotransferase	28	IU/L			7-56	
					Albumin	47	g/L			37-55	
					Alkaline Phosphatase	43	IU/L			20-116	
					Anion Gap	11	mmol/L			6-17	
					Aspartate Aminotransferase	20	IU/L			10-40	

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Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9001	41/M/BL	TPOXX 600 mg	Day 9	22AUG2019 09:25 (9)	Bilirubin	16.1	umol/L			3.2-28.9	
					Blood Urea Nitrogen	4.50	mmol/L			1.79-9.28	
					Calcium	2.43	mmol/L			2.13-2.58	
					Carbon Dioxide	31	mmol/L			22-34	
					Chloride	101	mmol/L			96-108	
					Creatinine	95.5	umol/L			56.6-114.9	
					Gamma Glutamyl Transferase	33	IU/L			5-85	
					Globulin	36	g/L			19-39	
					Glucose	4.77	mmol/L			3-6.44	
					Lactate Dehydrogenase	160	IU/L			82-216	
					Phosphate	1.10	mmol/L			0.68-1.52	
					Potassium	4.1	mmol/L			3.5-5	
					Protein	83	g/L			57-88	
					Sodium	139	mmol/L			132-145	
					Urate	321	umol/L			173-494	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9002	48/M/W		Screening	19JUL2019 12:02 (-26)	Alanine Aminotransferase	23	IU/L			7-56	
					Albumin	43	g/L			37-55	
					Alkaline Phosphatase	66	IU/L			20-116	
					Anion Gap	8	mmol/L			6-17	
					Aspartate Aminotransferase	17	IU/L			10-40	
					Bilirubin	6.0	umol/L			3.2-28.9	
					Blood Urea Nitrogen	3.96	mmol/L			1.79-9.28	
					Calcium	2.28	mmol/L			2.13-2.58	
					Carbon Dioxide	29	mmol/L			22-34	
					Chloride	102	mmol/L			96-108	
					Cholesterol	4.95	mmol/L			2.2-6.22	
					Creatinine	68.1	umol/L			56.6-114.9	
					Creatinine Clearance	265.5	mL/min			90-N/A	
					Gamma Glutamyl Transferase	42	IU/L			5-85	
					Globulin	30	g/L			19-39	
					Glucose	5.49	mmol/L			3-6.44	

Sex: M=Male, F=Female;
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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9002	48/M/W		Screening	19JUL2019 12:02 (-26)	HDL Cholesterol	1.24	mmol/L			0.65-2.46	
					LDL Cholesterol	2.67	mmol/L			0.96-4.22	
					Lactate Dehydrogenase	200	IU/L			82-216	
					Phosphate	1.03	mmol/L			0.68-1.52	
					Potassium	4.2	mmol/L			3.5-5	
					Protein	73	g/L			57-88	
					Sodium	135	mmol/L			132-145	
					Triglycerides	2.28	mmol/L		G1	0-4.52	
					Urate	363	umol/L			173-494	
			Check-in	13AUG2019 10:01 (-1)	Alanine Aminotransferase	23	IU/L			7-56	
					Albumin	43	g/L			37-55	
					Alkaline Phosphatase	67	IU/L			20-116	
					Anion Gap	12	mmol/L			6-17	
					Aspartate Aminotransferase	18	IU/L			10-40	
					Bilirubin	5.3	umol/L			3.2-28.9	

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Day = The presented date — First dose date + 1
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Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9002	48/M/W		Check-in	13AUG2019 10:01 (-1)	Blood Urea Nitrogen	5.93	mmol/L			1.79-9.28	
					Calcium	2.25	mmol/L			2.13-2.58	
					Carbon Dioxide	28	mmol/L			22-34	
					Chloride	102	mmol/L			96-108	
					Creatinine	80.4	umol/L			56.6-114.9	
					Gamma Glutamyl Transferase	38	IU/L			5-85	
					Globulin	31	g/L			19-39	
					Glucose	5.61	mmol/L			3-6.44	
					Lactate Dehydrogenase	223	IU/L	H NCS		82-216	
					Phosphate	0.94	mmol/L			0.68-1.52	
					Potassium	4.6	mmol/L			3.5-5	
					Protein	74	g/L			57-88	
					Sodium	137	mmol/L			132-145	
					Urate	416	umol/L			173-494	
		TPOXX 600 mg	Day 4	17AUG2019 08:49 (4)	Alanine Aminotransferase	26	IU/L			7-56	

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Day = The presented date — First dose date + 1
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Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9002	48/M/W	TPOXX 600 mg	Day 4	17AUG2019 08:49 (4)	Albumin	44	g/L			37-55	
					Alkaline Phosphatase	63	IU/L			20-116	
					Anion Gap	12	mmol/L			6-17	
					Aspartate Aminotransferase	16	IU/L			10-40	
					Bilirubin	8.9	umol/L			3.2-28.9	
					Blood Urea Nitrogen	4.11	mmol/L			1.79-9.28	
					Calcium	2.35	mmol/L			2.13-2.58	
					Carbon Dioxide	29	mmol/L			22-34	
					Chloride	102	mmol/L			96-108	
					Creatinine	77.8	umol/L			56.6-114.9	
					Gamma Glutamyl Transferase	36	IU/L			5-85	
					Globulin	32	g/L			19-39	
					Glucose	6.11	mmol/L		G1	3-6.44	
					Lactate Dehydrogenase	223	IU/L	H NCS		82-216	
					Phosphate	1.10	mmol/L			0.68-1.52	
					Potassium	4.5	mmol/L			3.5-5	

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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9002	48/M/W	TPOXX 600 mg	Day 4	17AUG2019 08:49 (4)	Protein	76	g/L			57-88	
					Sodium	138	mmol/L			132-145	
					Urate	446	umol/L			173-494	
			Day 8 - 12 Hours Postdose	21AUG2019 09:24 (8)	Alanine Aminotransferase	32	IU/L			7-56	
					Albumin	45	g/L			37-55	
					Alkaline Phosphatase	74	IU/L			20-116	
					Anion Gap	10	mmol/L			6-17	
					Aspartate Aminotransferase	19	IU/L			10-40	
					Bilirubin	10.8	umol/L			3.2-28.9	
					Blood Urea Nitrogen	4.36	mmol/L			1.79-9.28	
					Calcium	2.35	mmol/L			2.13-2.58	
					Carbon Dioxide	30	mmol/L			22-34	
					Chloride	100	mmol/L			96-108	
					Creatinine	75.1	umol/L			56.6-114.9	

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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9002	48/M/W	TPOXX 600 mg	Day 8 - 12 Hours Postdose	21AUG2019 09:24 (8)	Gamma Glutamyl Transferase	34	IU/L			5-85	
					Globulin	29	g/L			19-39	
					Glucose	5.94	mmol/L			3-6.44	
					Lactate Dehydrogenase	216	IU/L			82-216	
					Phosphate	1.16	mmol/L			0.68-1.52	
					Potassium	4.6	mmol/L			3.5-5	
					Protein	74	g/L			57-88	
					Sodium	135	mmol/L			132-145	
					Urate	446	umol/L			173-494	
			Day 9	22AUG2019 09:27 (9)	Alanine Aminotransferase	31	IU/L			7-56	
					Albumin	44	g/L			37-55	
					Alkaline Phosphatase	72	IU/L			20-116	
					Anion Gap	9	mmol/L			6-17	
					Aspartate Aminotransferase	17	IU/L			10-40	

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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9002	48/M/W	TPOXX 600 mg	Day 9	22AUG2019 09:27 (9)	Bilirubin	8.0	umol/L			3.2-28.9	
					Blood Urea Nitrogen	4.14	mmol/L			1.79-9.28	
					Calcium	2.28	mmol/L			2.13-2.58	
					Carbon Dioxide	30	mmol/L			22-34	
					Chloride	100	mmol/L			96-108	
					Creatinine	74.3	umol/L			56.6-114.9	
					Gamma Glutamyl Transferase	33	IU/L			5-85	
					Globulin	32	g/L			19-39	
					Glucose	6.05	mmol/L			3-6.44	
					Lactate Dehydrogenase	202	IU/L			82-216	
					Phosphate	0.90	mmol/L			0.68-1.52	
					Potassium	4.5	mmol/L			3.5-5	
					Protein	76	g/L			57-88	
					Sodium	134	mmol/L		G1	132-145	
					Urate	434	umol/L			173-494	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9005	40/M/W		Screening	23JUL2019 10:05 (-22)	Alanine Aminotransferase	44	IU/L			7-56	
					Albumin	40	g/L			37-55	
					Alkaline Phosphatase	64	IU/L			20-116	
					Anion Gap	10	mmol/L			6-17	
					Aspartate Aminotransferase	36	IU/L			10-40	
					Bilirubin	10.1	umol/L			3.2-28.9	
					Blood Urea Nitrogen	3.86	mmol/L			1.79-9.28	
					Calcium	2.20	mmol/L			2.13-2.58	
					Carbon Dioxide	28	mmol/L			22-34	
					Chloride	107	mmol/L			96-108	
					Cholesterol	4.51	mmol/L			2.2-6.22	
					Creatinine	76.0	umol/L			56.6-114.9	
					Creatinine Clearance	227.7	mL/min			90-N/A	
					Gamma Glutamyl Transferase	16	IU/L			5-85	
					Globulin	19	g/L			19-39	
					Glucose	6.44	mmol/L		G1	3-6.44	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9005	40/M/W		Screening	23JUL2019 10:05 (-22)	HDL Cholesterol	0.88	mmol/L			0.65-2.46	
					LDL Cholesterol	2.95	mmol/L			0.96-4.22	
					Lactate Dehydrogenase	173	IU/L			82-216	
					Phosphate	1.07	mmol/L			0.68-1.52	
					Potassium	4.5	mmol/L			3.5-5	
					Protein	59	g/L			57-88	
					Sodium	140	mmol/L			132-145	
					Triglycerides	1.47	mmol/L			0-4.52	
					Urate	458	umol/L		G1	173-494	
			Check-in	13AUG2019 09:35 (-1)	Alanine Aminotransferase	36	IU/L			7-56	
					Albumin	39	g/L			37-55	
					Alkaline Phosphatase	75	IU/L			20-116	
					Anion Gap	10	mmol/L			6-17	
					Aspartate Aminotransferase	33	IU/L			10-40	
					Bilirubin	7.2	umol/L			3.2-28.9	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9005	40/M/W		Check-in	13AUG2019 09:35 (-1)	Blood Urea Nitrogen	3.21	mmol/L			1.79-9.28	
					Calcium	2.10	mmol/L	L NCS		2.13-2.58	
					Carbon Dioxide	27	mmol/L			22-34	
					Chloride	105	mmol/L			96-108	
					Creatinine	69.0	umol/L			56.6-114.9	
					Gamma Glutamyl Transferase	17	IU/L			5-85	
					Globulin	19	g/L			19-39	
					Glucose	6.33	mmol/L		G1	3-6.44	
					Lactate Dehydrogenase	160	IU/L			82-216	
					Phosphate	0.97	mmol/L			0.68-1.52	
					Potassium	4.3	mmol/L			3.5-5	
					Protein	58	g/L			57-88	
					Sodium	138	mmol/L			132-145	
					Urate	440	umol/L			173-494	
		TPOXX 600 mg	Day 4	17AUG2019 08:27 (4)	Alanine Aminotransferase	54	IU/L			7-56	

Sex: M=Male, F=Female;
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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9005	40/M/W	TPOXX 600 mg	Day 4	17AUG2019 08:27 (4)	Albumin	42	g/L			37-55	
					Alkaline Phosphatase	73	IU/L			20-116	
					Anion Gap	9	mmol/L			6-17	
					Aspartate Aminotransferase	37	IU/L			10-40	
					Bilirubin	12.0	umol/L			3.2-28.9	
					Blood Urea Nitrogen	4.28	mmol/L			1.79-9.28	
					Calcium	2.28	mmol/L			2.13-2.58	
					Carbon Dioxide	29	mmol/L			22-34	
					Chloride	105	mmol/L			96-108	
					Creatinine	77.8	umol/L			56.6-114.9	
					Gamma Glutamyl Transferase	20	IU/L			5-85	
					Globulin	21	g/L			19-39	
					Glucose	6.11	mmol/L		G1	3-6.44	
					Lactate Dehydrogenase	143	IU/L			82-216	
					Phosphate	0.94	mmol/L			0.68-1.52	
					Potassium	4.4	mmol/L			3.5-5	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9005	40/M/W	TPOXX 600 mg	Day 4	17AUG2019 08:27 (4)	Protein	63	g/L			57-88	
					Sodium	139	mmol/L			132-145	
					Urate	464	umol/L		G1	173-494	
			Day 8 - 12 Hours Postdose	21AUG2019 09:02 (8)	Alanine Aminotransferase	45	IU/L			7-56	
					Albumin	41	g/L			37-55	
					Alkaline Phosphatase	83	IU/L			20-116	
					Anion Gap	10	mmol/L			6-17	
					Aspartate Aminotransferase	27	IU/L			10-40	
					Bilirubin	11.6	umol/L			3.2-28.9	
					Blood Urea Nitrogen	3.93	mmol/L			1.79-9.28	
					Calcium	2.23	mmol/L			2.13-2.58	
					Carbon Dioxide	27	mmol/L			22-34	
					Chloride	107	mmol/L			96-108	
					Creatinine	73.4	umol/L			56.6-114.9	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9005	40/M/W	TPOXX 600 mg	Day 8 - 12 Hours Postdose	21AUG2019 09:02 (8)	Gamma Glutamyl Transferase	20	IU/L			5-85	
					Globulin	18	g/L	L NCS		19-39	
					Glucose	5.77	mmol/L			3-6.44	
					Lactate Dehydrogenase	130	IU/L			82-216	
					Phosphate	1.03	mmol/L			0.68-1.52	
					Potassium	4.2	mmol/L			3.5-5	
					Protein	59	g/L			57-88	
					Sodium	140	mmol/L			132-145	
					Urate	458	umol/L		G1	173-494	
			Day 9	22AUG2019 09:02 (9)	Alanine Aminotransferase	44	IU/L			7-56	
					Albumin	41	g/L			37-55	
					Alkaline Phosphatase	81	IU/L			20-116	
					Anion Gap	10	mmol/L			6-17	
					Aspartate Aminotransferase	28	IU/L			10-40	

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Day = The presented date — First dose date + 1
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Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9005	40/M/W	TPOXX 600 mg	Day 9	22AUG2019 09:02 (9)	Bilirubin	10.4	umol/L			3.2-28.9	
					Blood Urea Nitrogen	4.00	mmol/L			1.79-9.28	
					Calcium	2.18	mmol/L			2.13-2.58	
					Carbon Dioxide	27	mmol/L			22-34	
					Chloride	104	mmol/L			96-108	
					Creatinine	72.5	umol/L			56.6-114.9	
					Gamma Glutamyl Transferase	20	IU/L			5-85	
					Globulin	19	g/L			19-39	
					Glucose	5.33	mmol/L			3-6.44	
					Lactate Dehydrogenase	141	IU/L			82-216	
					Phosphate	0.94	mmol/L			0.68-1.52	
					Potassium	4.1	mmol/L			3.5-5	
					Protein	60	g/L			57-88	
					Sodium	137	mmol/L			132-145	
					Urate	446	umol/L			173-494	

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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9009	21/F/BL		Screening	31JUL2019 10:20 (-14)	Alanine Aminotransferase	18	IU/L			4-45	
					Albumin	40	g/L			38-49	
					Alkaline Phosphatase	88	IU/L			20-116	
					Anion Gap	8	mmol/L			6-17	
					Aspartate Aminotransferase	14	IU/L			10-40	
					Bilirubin	14.0	umol/L			3.2-21.7	
					Blood Urea Nitrogen	4.14	mmol/L			1.79-9.28	
					Calcium	2.30	mmol/L			2.13-2.58	
					Carbon Dioxide	27	mmol/L			22-34	
					Chloride	103	mmol/L			96-108	
					Cholesterol	5.26	mmol/L		G1	2.2-6.22	
					Creatinine	68.1	umol/L			39.8-93.7	
					Creatinine Clearance	251.8	mL/min			90-N/A	
					Gamma Glutamyl Transferase	38	IU/L			5-85	
					Globulin	31	g/L			19-39	
					Glucose	4.33	mmol/L			3-6.44	

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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9009	21/F/BL		Screening	31JUL2019 10:20 (-14)	HDL Cholesterol	1.45	mmol/L			0.88-2.36	
					LDL Cholesterol	3.50	mmol/L		G1	0.96-4.22	
					Lactate Dehydrogenase	162	IU/L			82-216	
					Phosphate	1.10	mmol/L			0.68-1.52	
					Potassium	3.9	mmol/L			3.5-5	
					Protein	71	g/L			57-88	
					Sodium	134	mmol/L		G1	132-145	
					Triglycerides	0.70	mmol/L			0-4.52	
					Urate	416	umol/L	H NCS		119-345	
			Check-in	13AUG2019 09:32 (-1)	Alanine Aminotransferase	14	IU/L			4-45	
					Albumin	40	g/L			38-49	
					Alkaline Phosphatase	101	IU/L			20-116	
					Anion Gap	11	mmol/L			6-17	
					Aspartate Aminotransferase	12	IU/L			10-40	
					Bilirubin	7.7	umol/L			3.2-21.7	

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Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9009	21/F/BL		Check-in	13AUG2019 09:32 (-1)	Blood Urea Nitrogen	2.78	mmol/L			1.79-9.28	
					Calcium	2.38	mmol/L			2.13-2.58	
					Carbon Dioxide	26	mmol/L			22-34	
					Chloride	104	mmol/L			96-108	
					Creatinine	69.0	umol/L			39.8-93.7	
					Gamma Glutamyl Transferase	33	IU/L			5-85	
					Globulin	31	g/L			19-39	
					Glucose	5.38	mmol/L			3-6.44	
					Lactate Dehydrogenase	161	IU/L			82-216	
					Phosphate	1.10	mmol/L			0.68-1.52	
					Potassium	4.3	mmol/L			3.5-5	
					Protein	71	g/L			57-88	
					Sodium	137	mmol/L			132-145	
					Urate	345	umol/L			119-345	
		TPOXX 600 mg	Day 4	17AUG2019 08:31 (4)	Alanine Aminotransferase	15	IU/L			4-45	

Sex: M=Male, F=Female;
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9009	21/F/BL	TPOXX 600 mg	Day 4	17AUG2019 08:31 (4)	Albumin	37	g/L	L NCS	G1	38-49	
					Alkaline Phosphatase	92	IU/L			20-116	
					Anion Gap	9	mmol/L			6-17	
					Aspartate Aminotransferase	12	IU/L			10-40	
					Bilirubin	10.8	umol/L			3.2-21.7	
					Blood Urea Nitrogen	4.18	mmol/L			1.79-9.28	
					Calcium	2.28	mmol/L			2.13-2.58	
					Carbon Dioxide	26	mmol/L			22-34	
					Chloride	105	mmol/L			96-108	
					Creatinine	68.1	umol/L			39.8-93.7	
					Gamma Glutamyl Transferase	31	IU/L			5-85	
					Globulin	29	g/L			19-39	
					Glucose	4.72	mmol/L			3-6.44	
					Lactate Dehydrogenase	150	IU/L			82-216	
					Phosphate	1.36	mmol/L			0.68-1.52	
					Potassium	4.1	mmol/L			3.5-5	

Sex: M=Male, F=Female;
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9009	21/F/BL	TPOXX 600 mg	Day 4	17AUG2019 08:31 (4)	Protein	66	g/L			57-88	
					Sodium	136	mmol/L			132-145	
					Urate	404	umol/L	H NCS		119-345	
			Day 8 - 12 Hours Postdose	21AUG2019 09:06 (8)	Alanine Aminotransferase	17	IU/L			4-45	
					Albumin	37	g/L	L NCS	G1	38-49	
					Alkaline Phosphatase	98	IU/L			20-116	
					Anion Gap	9	mmol/L			6-17	
					Aspartate Aminotransferase	12	IU/L			10-40	
					Bilirubin	9.9	umol/L			3.2-21.7	
					Blood Urea Nitrogen	3.93	mmol/L			1.79-9.28	
					Calcium	2.30	mmol/L			2.13-2.58	
					Carbon Dioxide	28	mmol/L			22-34	
					Chloride	105	mmol/L			96-108	
					Creatinine	69.0	umol/L			39.8-93.7	

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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9009	21/F/BL	TPOXX 600 mg	Day 8 - 12 Hours Postdose	21AUG2019 09:06 (8)	Gamma Glutamyl Transferase	32	IU/L			5-85	
					Globulin	26	g/L			19-39	
					Glucose	4.44	mmol/L			3-6.44	
					Lactate Dehydrogenase	153	IU/L			82-216	
					Phosphate	1.42	mmol/L			0.68-1.52	
					Potassium	4.2	mmol/L			3.5-5	
					Protein	63	g/L			57-88	
					Sodium	138	mmol/L			132-145	
					Urate	381	umol/L	H NCS		119-345	
			Day 9	22AUG2019 09:07 (9)	Alanine Aminotransferase	19	IU/L			4-45	
					Albumin	38	g/L			38-49	
					Alkaline Phosphatase	103	IU/L			20-116	
					Anion Gap	9	mmol/L			6-17	
					Aspartate Aminotransferase	13	IU/L			10-40	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
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Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9009	21/F/BL	TPOXX 600 mg	Day 9	22AUG2019 09:07 (9)	Bilirubin	9.9	umol/L			3.2-21.7	
					Blood Urea Nitrogen	4.32	mmol/L			1.79-9.28	
					Calcium	2.25	mmol/L			2.13-2.58	
					Carbon Dioxide	27	mmol/L			22-34	
					Chloride	103	mmol/L			96-108	
					Creatinine	65.4	umol/L			39.8-93.7	
					Gamma Glutamyl Transferase	33	IU/L			5-85	
					Globulin	29	g/L			19-39	
					Glucose	4.61	mmol/L			3-6.44	
					Lactate Dehydrogenase	163	IU/L			82-216	
					Phosphate	1.07	mmol/L			0.68-1.52	
					Potassium	4.0	mmol/L			3.5-5	
					Protein	67	g/L			57-88	
					Sodium	135	mmol/L			132-145	
					Urate	381	umol/L	H NCS		119-345	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9012	34/M/BL		Screening	06AUG2019 10:31 (-8)	Alanine Aminotransferase	48	IU/L			7-56	
					Albumin	45	g/L			37-55	
					Alkaline Phosphatase	46	IU/L			20-116	
					Anion Gap	10	mmol/L			6-17	
					Aspartate Aminotransferase	23	IU/L			10-40	
					Bilirubin	10.9	umol/L			3.2-28.9	
					Blood Urea Nitrogen	4.57	mmol/L			1.79-9.28	
					Calcium	2.28	mmol/L			2.13-2.58	
					Carbon Dioxide	31	mmol/L			22-34	
					Chloride	103	mmol/L			96-108	
					Cholesterol	3.57	mmol/L			2.2-6.22	
					Creatinine	102.5	umol/L			56.6-114.9	
					Creatinine Clearance	166.3	mL/min			90-N/A	
					Gamma Glutamyl Transferase	24	IU/L			5-85	
					Globulin	29	g/L			19-39	
					Glucose	5.05	mmol/L			3-6.44	

Sex: M=Male, F=Female;
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Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9012	34/M/BL		Screening	06AUG2019 10:31 (-8)	HDL Cholesterol	0.85	mmol/L			0.65-2.46	
					LDL Cholesterol	1.89	mmol/L			0.96-4.22	
					Lactate Dehydrogenase	200	IU/L			82-216	
					Phosphate	1.07	mmol/L			0.68-1.52	
					Potassium	3.8	mmol/L			3.5-5	
					Protein	74	g/L			57-88	
					Sodium	140	mmol/L			132-145	
					Triglycerides	1.83	mmol/L		G1	0-4.52	
					Urate	399	umol/L			173-494	
			Check-in	13AUG2019 09:53 (-1)	Alanine Aminotransferase	38	IU/L			7-56	
					Albumin	46	g/L			37-55	
					Alkaline Phosphatase	52	IU/L			20-116	
					Anion Gap	9	mmol/L			6-17	
					Aspartate Aminotransferase	21	IU/L			10-40	
					Bilirubin	9.4	umol/L			3.2-28.9	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9012	34/M/BL		Check-in	13AUG2019 09:53 (-1)	Blood Urea Nitrogen	5.32	mmol/L			1.79-9.28	
					Calcium	2.38	mmol/L			2.13-2.58	
					Carbon Dioxide	29	mmol/L			22-34	
					Chloride	104	mmol/L			96-108	
					Creatinine	106.1	umol/L			56.6-114.9	
					Gamma Glutamyl Transferase	22	IU/L			5-85	
					Globulin	29	g/L			19-39	
					Glucose	5.55	mmol/L			3-6.44	
					Lactate Dehydrogenase	187	IU/L			82-216	
					Phosphate	1.10	mmol/L			0.68-1.52	
					Potassium	3.9	mmol/L			3.5-5	
					Protein	75	g/L			57-88	
					Sodium	138	mmol/L			132-145	
					Urate	404	umol/L			173-494	
		TPOXX 600 mg	Day 4	17AUG2019 08:35 (4)	Alanine Aminotransferase	33	IU/L			7-56	

Sex: M=Male, F=Female;
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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9012	34/M/BL	TPOXX 600 mg	Day 4	17AUG2019 08:35 (4)	Albumin	47	g/L			37-55	
					Alkaline Phosphatase	43	IU/L			20-116	
					Anion Gap	9	mmol/L			6-17	
					Aspartate Aminotransferase	19	IU/L			10-40	
					Bilirubin	11.1	umol/L			3.2-28.9	
					Blood Urea Nitrogen	4.14	mmol/L			1.79-9.28	
					Calcium	2.40	mmol/L			2.13-2.58	
					Carbon Dioxide	30	mmol/L			22-34	
					Chloride	105	mmol/L			96-108	
					Creatinine	102.5	umol/L			56.6-114.9	
					Gamma Glutamyl Transferase	23	IU/L			5-85	
					Globulin	30	g/L			19-39	
					Glucose	5.22	mmol/L			3-6.44	
					Lactate Dehydrogenase	183	IU/L			82-216	
					Phosphate	1.03	mmol/L			0.68-1.52	
					Potassium	4.4	mmol/L			3.5-5	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9012	34/M/BL	TPOXX 600 mg	Day 4	17AUG2019 08:35 (4)	Protein	77	g/L			57-88	
					Sodium	140	mmol/L			132-145	
					Urate	410	umol/L			173-494	
			Day 8 - 12 Hours Postdose	21AUG2019 09:10 (8)	Alanine Aminotransferase	44	IU/L			7-56	
					Albumin	45	g/L			37-55	
					Alkaline Phosphatase	47	IU/L			20-116	
					Anion Gap	8	mmol/L			6-17	
					Aspartate Aminotransferase	22	IU/L			10-40	
					Bilirubin	12.5	umol/L			3.2-28.9	
					Blood Urea Nitrogen	4.43	mmol/L			1.79-9.28	
					Calcium	2.40	mmol/L			2.13-2.58	
					Carbon Dioxide	31	mmol/L			22-34	
					Chloride	105	mmol/L			96-108	
					Creatinine	105.2	umol/L			56.6-114.9	

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Day = The presented date — First dose date + 1
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Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9012	34/M/BL	TPOXX 600 mg	Day 8 - 12 Hours Postdose	21AUG2019 09:10 (8)	Gamma Glutamyl Transferase	23	IU/L			5-85	
					Globulin	27	g/L			19-39	
					Glucose	4.83	mmol/L			3-6.44	
					Lactate Dehydrogenase	166	IU/L			82-216	
					Phosphate	1.26	mmol/L			0.68-1.52	
					Potassium	4.1	mmol/L			3.5-5	
					Protein	72	g/L			57-88	
					Sodium	140	mmol/L			132-145	
					Urate	399	umol/L			173-494	
			Day 9	22AUG2019 09:13 (9)	Alanine Aminotransferase	56	IU/L			7-56	
					Albumin	47	g/L			37-55	
					Alkaline Phosphatase	50	IU/L			20-116	
					Anion Gap	9	mmol/L			6-17	
					Aspartate Aminotransferase	24	IU/L			10-40	

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Day = The presented date — First dose date + 1
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9012	34/M/BL	TPOXX 600 mg	Day 9	22AUG2019 09:13 (9)	Bilirubin	9.7	umol/L			3.2-28.9	
					Blood Urea Nitrogen	4.32	mmol/L			1.79-9.28	
					Calcium	2.35	mmol/L			2.13-2.58	
					Carbon Dioxide	30	mmol/L			22-34	
					Chloride	103	mmol/L			96-108	
					Creatinine	106.1	umol/L			56.6-114.9	
					Gamma Glutamyl Transferase	25	IU/L			5-85	
					Globulin	30	g/L			19-39	
					Glucose	4.94	mmol/L			3-6.44	
					Lactate Dehydrogenase	182	IU/L			82-216	
					Phosphate	1.00	mmol/L			0.68-1.52	
					Potassium	4.1	mmol/L			3.5-5	
					Protein	77	g/L			57-88	
					Sodium	138	mmol/L			132-145	
					Urate	387	umol/L			173-494	

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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9015	29/M/BL		Screening	12AUG2019 11:07 (-2)	Alanine Aminotransferase	16	IU/L			7-56	
					Albumin	39	g/L			37-55	
					Alkaline Phosphatase	74	IU/L			20-116	
					Anion Gap	8	mmol/L			6-17	
					Aspartate Aminotransferase	18	IU/L			10-40	
					Bilirubin	6.7	umol/L			3.2-28.9	
					Blood Urea Nitrogen	3.39	mmol/L			1.79-9.28	
					Calcium	2.23	mmol/L			2.13-2.58	
					Carbon Dioxide	31	mmol/L			22-34	
					Chloride	102	mmol/L			96-108	
					Cholesterol	4.58	mmol/L			2.2-6.22	
					Creatinine	101.7	umol/L			56.6-114.9	
					Creatinine Clearance	162.2	mL/min			90-N/A	
					Gamma Glutamyl Transferase	27	IU/L			5-85	
					Globulin	22	g/L			19-39	
					Glucose	5.61	mmol/L			3-6.44	

Sex: M=Male, F=Female;
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9015	29/M/BL		Screening	12AUG2019 11:07 (-2)	HDL Cholesterol	0.73	mmol/L			0.65-2.46	
					LDL Cholesterol	2.54	mmol/L			0.96-4.22	
					Lactate Dehydrogenase	167	IU/L			82-216	
					Phosphate	0.84	mmol/L			0.68-1.52	
					Potassium	4.1	mmol/L			3.5-5	
					Protein	61	g/L			57-88	
					Sodium	137	mmol/L			132-145	
					Triglycerides	2.90	mmol/L		G1	0-4.52	
					Urate	422	umol/L			173-494	
			Check-in	13AUG2019 09:39 (-1)	Alanine Aminotransferase	16	IU/L			7-56	
					Albumin	38	g/L			37-55	
					Alkaline Phosphatase	74	IU/L			20-116	
					Anion Gap	9	mmol/L			6-17	
					Aspartate Aminotransferase	17	IU/L			10-40	
					Bilirubin	4.3	umol/L			3.2-28.9	

Sex: M=Male, F=Female;
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9015	29/M/BL		Check-in	13AUG2019 09:39 (-1)	Blood Urea Nitrogen	3.07	mmol/L			1.79-9.28	
					Calcium	2.23	mmol/L			2.13-2.58	
					Carbon Dioxide	31	mmol/L			22-34	
					Chloride	103	mmol/L			96-108	
					Creatinine	108.7	umol/L			56.6-114.9	
					Gamma Glutamyl Transferase	26	IU/L			5-85	
					Globulin	21	g/L			19-39	
					Glucose	5.88	mmol/L			3-6.44	
					Lactate Dehydrogenase	158	IU/L			82-216	
					Phosphate	1.03	mmol/L			0.68-1.52	
					Potassium	4.3	mmol/L			3.5-5	
					Protein	59	g/L			57-88	
					Sodium	139	mmol/L			132-145	
					Urate	387	umol/L			173-494	
		TPOXX 600 mg	Day 4	17AUG2019 08:33 (4)	Alanine Aminotransferase	20	IU/L			7-56	

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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9015	29/M/BL	TPOXX 600 mg	Day 4	17AUG2019 08:33 (4)	Albumin	39	g/L			37-55	
					Alkaline Phosphatase	61	IU/L			20-116	
					Anion Gap	6	mmol/L			6-17	
					Aspartate Aminotransferase	19	IU/L			10-40	
					Bilirubin	9.4	umol/L			3.2-28.9	
					Blood Urea Nitrogen	4.36	mmol/L			1.79-9.28	
					Calcium	2.28	mmol/L			2.13-2.58	
					Carbon Dioxide	32	mmol/L			22-34	
					Chloride	103	mmol/L			96-108	
					Creatinine	106.1	umol/L			56.6-114.9	
					Gamma Glutamyl Transferase	28	IU/L			5-85	
					Globulin	21	g/L			19-39	
					Glucose	4.94	mmol/L			3-6.44	
					Lactate Dehydrogenase	148	IU/L			82-216	
					Phosphate	1.36	mmol/L			0.68-1.52	
					Potassium	4.2	mmol/L			3.5-5	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9015	29/M/BL	TPOXX 600 mg	Day 4	17AUG2019 08:33 (4)	Protein	60	g/L			57-88	
					Sodium	137	mmol/L			132-145	
					Urate	399	umol/L			173-494	
			Day 8 - 12 Hours Postdose	21AUG2019 09:08 (8)	Alanine Aminotransferase	23	IU/L			7-56	
					Albumin	42	g/L			37-55	
					Alkaline Phosphatase	71	IU/L			20-116	
					Anion Gap	7	mmol/L			6-17	
					Aspartate Aminotransferase	19	IU/L			10-40	
					Bilirubin	9.4	umol/L			3.2-28.9	
					Blood Urea Nitrogen	5.14	mmol/L			1.79-9.28	
					Calcium	2.40	mmol/L			2.13-2.58	
					Carbon Dioxide	32	mmol/L			22-34	
					Chloride	103	mmol/L			96-108	
					Creatinine	113.2	umol/L			56.6-114.9	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9015	29/M/BL	TPOXX 600 mg	Day 8 - 12 Hours Postdose	21AUG2019 09:08 (8)	Gamma Glutamyl Transferase	30	IU/L			5-85	
					Globulin	21	g/L			19-39	
					Glucose	4.66	mmol/L			3-6.44	
					Lactate Dehydrogenase	148	IU/L			82-216	
					Phosphate	1.26	mmol/L			0.68-1.52	
					Potassium	4.4	mmol/L			3.5-5	
					Protein	63	g/L			57-88	
					Sodium	138	mmol/L			132-145	
					Urate	410	umol/L			173-494	
			Day 9	22AUG2019 09:10 (9)	Alanine Aminotransferase	23	IU/L			7-56	
					Albumin	43	g/L			37-55	
					Alkaline Phosphatase	73	IU/L			20-116	
					Anion Gap	8	mmol/L			6-17	
					Aspartate Aminotransferase	20	IU/L			10-40	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9015	29/M/BL	TPOXX 600 mg	Day 9	22AUG2019 09:10 (9)	Bilirubin	9.1	umol/L			3.2-28.9	
					Blood Urea Nitrogen	5.25	mmol/L			1.79-9.28	
					Calcium	2.40	mmol/L			2.13-2.58	
					Carbon Dioxide	31	mmol/L			22-34	
					Chloride	103	mmol/L			96-108	
					Creatinine	111.4	umol/L			56.6-114.9	
					Gamma Glutamyl Transferase	31	IU/L			5-85	
					Globulin	23	g/L			19-39	
					Glucose	4.61	mmol/L			3-6.44	
					Lactate Dehydrogenase	155	IU/L			82-216	
					Phosphate	1.20	mmol/L			0.68-1.52	
					Potassium	4.4	mmol/L			3.5-5	
					Protein	66	g/L			57-88	
					Sodium	138	mmol/L			132-145	
					Urate	410	umol/L			173-494	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
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Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9016	48/F/W		Screening	12AUG2019 11:08 (-23)	Alanine Aminotransferase	12	IU/L			4-45	
					Albumin	41	g/L			38-49	
					Alkaline Phosphatase	72	IU/L			20-116	
					Anion Gap	11	mmol/L			6-17	
					Aspartate Aminotransferase	15	IU/L			10-40	
					Bilirubin	8.0	umol/L			3.2-21.7	
					Blood Urea Nitrogen	4.75	mmol/L			1.79-9.28	
					Calcium	2.30	mmol/L			2.13-2.58	
					Carbon Dioxide	30	mmol/L			22-34	
					Chloride	103	mmol/L			96-108	
					Cholesterol	6.84	mmol/L	H NCS	G2	2.2-6.22	
					Creatinine	75.1	umol/L			39.8-93.7	
					Creatinine Clearance	182.7	mL/min			90-N/A	
					Gamma Glutamyl Transferase	13	IU/L			5-85	
					Globulin	32	g/L			19-39	
					Glucose	4.16	mmol/L			3-6.44	

Sex: M=Male, F=Female;
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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9016	48/F/W		Screening	12AUG2019 11:08 (-23)	HDL Cholesterol	1.81	mmol/L			0.88-2.36	
					LDL Cholesterol	4.45	mmol/L	H NCS	G2	0.96-4.22	
					Lactate Dehydrogenase	114	IU/L			82-216	
					Phosphate	1.10	mmol/L			0.68-1.52	
					Potassium	4.2	mmol/L			3.5-5	
					Protein	73	g/L			57-88	
					Sodium	140	mmol/L			132-145	
					Triglycerides	1.24	mmol/L			0-4.52	
					Urate	309	umol/L			119-345	
			Check-in	03SEP2019 09:04 (-1)	Alanine Aminotransferase	11	IU/L			4-45	
					Albumin	38	g/L			38-49	
					Alkaline Phosphatase	66	IU/L			20-116	
					Anion Gap	9	mmol/L			6-17	
					Aspartate Aminotransferase	12	IU/L			10-40	
					Bilirubin	9.2	umol/L			3.2-21.7	

Sex: M=Male, F=Female;
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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9016	48/F/W		Check-in	03SEP2019 09:04 (-1)	Blood Urea Nitrogen	5.07	mmol/L			1.79-9.28	
					Calcium	2.13	mmol/L			2.13-2.58	
					Carbon Dioxide	27	mmol/L			22-34	
					Chloride	104	mmol/L			96-108	
					Creatinine	70.7	umol/L			39.8-93.7	
					Gamma Glutamyl Transferase	13	IU/L			5-85	
					Globulin	27	g/L			19-39	
					Glucose	5.05	mmol/L			3-6.44	
					Lactate Dehydrogenase	107	IU/L			82-216	
					Phosphate	0.90	mmol/L			0.68-1.52	
					Potassium	4.1	mmol/L			3.5-5	
					Protein	65	g/L			57-88	
					Sodium	136	mmol/L			132-145	
					Urate	309	umol/L			119-345	
		TPOXX 600 mg	Day 4	07SEP2019 07:25 (4)	Alanine Aminotransferase	13	IU/L			4-45	

Sex: M=Male, F=Female;
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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9016	48/F/W	TPOXX 600 mg	Day 4	07SEP2019 07:25 (4)	Albumin	38	g/L			38-49	
					Alkaline Phosphatase	58	IU/L			20-116	
					Anion Gap	7	mmol/L			6-17	
					Aspartate Aminotransferase	15	IU/L			10-40	
					Bilirubin	9.7	umol/L			3.2-21.7	
					Blood Urea Nitrogen	6.18	mmol/L			1.79-9.28	
					Calcium	2.15	mmol/L			2.13-2.58	
					Carbon Dioxide	29	mmol/L			22-34	
					Chloride	105	mmol/L			96-108	
					Creatinine	73.4	umol/L			39.8-93.7	
					Gamma Glutamyl Transferase	12	IU/L			5-85	
					Globulin	29	g/L			19-39	
					Glucose	5.05	mmol/L			3-6.44	
					Lactate Dehydrogenase	121	IU/L			82-216	
					Phosphate	1.16	mmol/L			0.68-1.52	
					Potassium	4.1	mmol/L			3.5-5	

Sex: M=Male, F=Female;
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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9016	48/F/W	TPOXX 600 mg	Day 4	07SEP2019 07:25 (4)	Protein	67	g/L			57-88	
					Sodium	137	mmol/L			132-145	
					Urate	339	umol/L			119-345	
			Day 8 - 12 Hours Postdose	11SEP2019 08:00 (8)	Alanine Aminotransferase	15	IU/L			4-45	
					Albumin	40	g/L			38-49	
					Alkaline Phosphatase	64	IU/L			20-116	
					Anion Gap	11	mmol/L			6-17	
					Aspartate Aminotransferase	16	IU/L			10-40	
					Bilirubin	9.7	umol/L			3.2-21.7	
					Blood Urea Nitrogen	4.86	mmol/L			1.79-9.28	
					Calcium	2.33	mmol/L			2.13-2.58	
					Carbon Dioxide	29	mmol/L			22-34	
					Chloride	104	mmol/L			96-108	
					Creatinine	75.1	umol/L			39.8-93.7	

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Day = The presented date — First dose date + 1
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9016	48/F/W	TPOXX 600 mg	Day 8 - 12 Hours Postdose	11SEP2019 08:00 (8)	Gamma Glutamyl Transferase	13	IU/L			5-85	
					Globulin	30	g/L			19-39	
					Glucose	5.16	mmol/L			3-6.44	
					Lactate Dehydrogenase	127	IU/L			82-216	
					Phosphate	1.13	mmol/L			0.68-1.52	
					Potassium	4.2	mmol/L			3.5-5	
					Protein	70	g/L			57-88	
					Sodium	140	mmol/L			132-145	
					Urate	315	umol/L			119-345	
			Day 9	12SEP2019 08:05 (9)	Alanine Aminotransferase	15	IU/L			4-45	
					Albumin	41	g/L			38-49	
					Alkaline Phosphatase	64	IU/L			20-116	
					Anion Gap	10	mmol/L			6-17	
					Aspartate Aminotransferase	15	IU/L			10-40	

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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9016	48/F/W	TPOXX 600 mg	Day 9	12SEP2019 08:05 (9)	Bilirubin	9.1	umol/L			3.2-21.7	
					Blood Urea Nitrogen	5.39	mmol/L			1.79-9.28	
					Calcium	2.28	mmol/L			2.13-2.58	
					Carbon Dioxide	30	mmol/L			22-34	
					Chloride	102	mmol/L			96-108	
					Creatinine	76.0	umol/L			39.8-93.7	
					Gamma Glutamyl Transferase	14	IU/L			5-85	
					Globulin	29	g/L			19-39	
					Glucose	5.16	mmol/L			3-6.44	
					Lactate Dehydrogenase	129	IU/L			82-216	
					Phosphate	1.03	mmol/L			0.68-1.52	
					Potassium	4.2	mmol/L			3.5-5	
					Protein	70	g/L			57-88	
					Sodium	138	mmol/L			132-145	
					Urate	315	umol/L			119-345	

Sex: M=Male, F=Female;
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9019	41/M/BL		Screening	15AUG2019 17:21 (-20)	Alanine Aminotransferase	25	IU/L			7-56	
					Albumin	44	g/L			37-55	
					Alkaline Phosphatase	40	IU/L			20-116	
					Anion Gap	12	mmol/L			6-17	
					Aspartate Aminotransferase	26	IU/L			10-40	
					Bilirubin	11.1	umol/L			3.2-28.9	
					Blood Urea Nitrogen	3.57	mmol/L			1.79-9.28	
					Calcium	2.35	mmol/L			2.13-2.58	
					Carbon Dioxide	31	mmol/L			22-34	
					Chloride	100	mmol/L			96-108	
					Cholesterol	5.18	mmol/L		G1	2.2-6.22	
					Creatinine	90.2	umol/L			56.6-114.9	
					Creatinine Clearance	182.0	mL/min			90-N/A	
					Gamma Glutamyl Transferase	32	IU/L			5-85	
					Globulin	20	g/L			19-39	
					Glucose	5.49	mmol/L			3-6.44	

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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9019	41/M/BL		Screening	15AUG2019 17:21 (-20)	HDL Cholesterol	0.93	mmol/L			0.65-2.46	
					LDL Cholesterol	3.55	mmol/L		G1	0.96-4.22	
					Lactate Dehydrogenase	151	IU/L			82-216	
					Phosphate	1.26	mmol/L			0.68-1.52	
					Potassium	4.3	mmol/L			3.5-5	
					Protein	64	g/L			57-88	
					Sodium	139	mmol/L			132-145	
					Triglycerides	1.53	mmol/L			0-4.52	
					Urate	512	umol/L	H NCS	G1	173-494	
			Check-in	03SEP2019 11:40 (-1)	Alanine Aminotransferase	23	IU/L			7-56	
					Albumin	47	g/L			37-55	
					Alkaline Phosphatase	42	IU/L			20-116	
					Anion Gap	14	mmol/L			6-17	
					Aspartate Aminotransferase	23	IU/L			10-40	
					Bilirubin	10.8	umol/L			3.2-28.9	

Sex: M=Male, F=Female;
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9019	41/M/BL		Check-in	03SEP2019 11:40 (-1)	Blood Urea Nitrogen	5.68	mmol/L			1.79-9.28	
					Calcium	2.40	mmol/L			2.13-2.58	
					Carbon Dioxide	29	mmol/L			22-34	
					Chloride	102	mmol/L			96-108	
					Creatinine	99.9	umol/L			56.6-114.9	
					Gamma Glutamyl Transferase	34	IU/L			5-85	
					Globulin	20	g/L			19-39	
					Glucose	5.44	mmol/L			3-6.44	
					Lactate Dehydrogenase	177	IU/L			82-216	
					Phosphate	1.13	mmol/L			0.68-1.52	
					Potassium	4.6	mmol/L			3.5-5	
					Protein	67	g/L			57-88	
					Sodium	140	mmol/L			132-145	
					Urate	506	umol/L	H NCS	G1	173-494	
		TPOXX 600 mg	Day 4	07SEP2019 07:32 (4)	Alanine Aminotransferase	25	IU/L			7-56	

Sex: M=Male, F=Female;
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Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9019	41/M/BL	TPOXX 600 mg	Day 4	07SEP2019 07:32 (4)	Albumin	43	g/L			37-55	
					Alkaline Phosphatase	41	IU/L			20-116	
					Anion Gap	8	mmol/L			6-17	
					Aspartate Aminotransferase	26	IU/L			10-40	
					Bilirubin	10.8	umol/L			3.2-28.9	
					Blood Urea Nitrogen	3.50	mmol/L			1.79-9.28	
					Calcium	2.35	mmol/L			2.13-2.58	
					Carbon Dioxide	31	mmol/L			22-34	
					Chloride	104	mmol/L			96-108	
					Creatinine	91.1	umol/L			56.6-114.9	
					Gamma Glutamyl Transferase	34	IU/L			5-85	
					Globulin	22	g/L			19-39	
					Glucose	5.55	mmol/L			3-6.44	
					Lactate Dehydrogenase	147	IU/L			82-216	
					Phosphate	1.42	mmol/L			0.68-1.52	
					Potassium	4.2	mmol/L			3.5-5	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9019	41/M/BL	TPOXX 600 mg	Day 4	07SEP2019 07:32 (4)	Protein	65	g/L			57-88	
					Sodium	139	mmol/L			132-145	
					Urate	458	umol/L		G1	173-494	
			Day 8 - 12 Hours Postdose	11SEP2019 08:03 (8)	Alanine Aminotransferase	27	IU/L			7-56	
					Albumin	46	g/L			37-55	
					Alkaline Phosphatase	47	IU/L			20-116	
					Anion Gap	11	mmol/L			6-17	
					Aspartate Aminotransferase	25	IU/L			10-40	
					Bilirubin	10.8	umol/L			3.2-28.9	
					Blood Urea Nitrogen	3.39	mmol/L			1.79-9.28	
					Calcium	2.38	mmol/L			2.13-2.58	
					Carbon Dioxide	32	mmol/L			22-34	
					Chloride	102	mmol/L			96-108	
					Creatinine	93.7	umol/L			56.6-114.9	

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Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9019	41/M/BL	TPOXX 600 mg	Day 8 - 12 Hours Postdose	11SEP2019 08:03 (8)	Gamma Glutamyl Transferase	36	IU/L			5-85	
					Globulin	22	g/L			19-39	
					Glucose	5.49	mmol/L			3-6.44	
					Lactate Dehydrogenase	150	IU/L			82-216	
					Phosphate	1.32	mmol/L			0.68-1.52	
					Potassium	4.4	mmol/L			3.5-5	
					Protein	68	g/L			57-88	
					Sodium	141	mmol/L			132-145	
					Urate	446	umol/L			173-494	
			Day 9	12SEP2019 08:08 (9)	Alanine Aminotransferase	27	IU/L			7-56	
					Albumin	46	g/L			37-55	
					Alkaline Phosphatase	49	IU/L			20-116	
					Anion Gap	12	mmol/L			6-17	
					Aspartate Aminotransferase	27	IU/L			10-40	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9019	41/M/BL	TPOXX 600 mg	Day 9	12SEP2019 08:08 (9)	Bilirubin	9.9	umol/L			3.2-28.9	
					Blood Urea Nitrogen	3.86	mmol/L			1.79-9.28	
					Calcium	2.40	mmol/L			2.13-2.58	
					Carbon Dioxide	31	mmol/L			22-34	
					Chloride	101	mmol/L			96-108	
					Creatinine	93.7	umol/L			56.6-114.9	
					Gamma Glutamyl Transferase	37	IU/L			5-85	
					Globulin	22	g/L			19-39	
					Glucose	5.55	mmol/L			3-6.44	
					Lactate Dehydrogenase	150	IU/L			82-216	
					Phosphate	1.20	mmol/L			0.68-1.52	
					Potassium	4.5	mmol/L			3.5-5	
					Protein	68	g/L			57-88	
					Sodium	139	mmol/L			132-145	
					Urate	452	umol/L		G1	173-494	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9020	47/F/BL		Screening	21AUG2019 10:37 (-14)	Alanine Aminotransferase	16	IU/L			4-45	
					Albumin	38	g/L			38-49	
					Alkaline Phosphatase	76	IU/L			20-116	
					Anion Gap	11	mmol/L			6-17	
					Aspartate Aminotransferase	20	IU/L			10-40	
					Bilirubin	7.5	umol/L			3.2-21.7	
					Blood Urea Nitrogen	3.36	mmol/L			1.79-9.28	
					Calcium	2.23	mmol/L			2.13-2.58	
					Carbon Dioxide	29	mmol/L			22-34	
					Chloride	101	mmol/L			96-108	
					Cholesterol	4.30	mmol/L			2.2-6.22	
					Creatinine	61.9	umol/L			39.8-93.7	
					Creatinine Clearance	216.4	mL/min			90-N/A	
					Gamma Glutamyl Transferase	14	IU/L			5-85	
					Globulin	31	g/L			19-39	
					Glucose	5.16	mmol/L			3-6.44	

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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9020	47/F/BL		Screening	21AUG2019 10:37 (-14)	HDL Cholesterol	1.24	mmol/L			0.88-2.36	
					LDL Cholesterol	2.59	mmol/L			0.96-4.22	
					Lactate Dehydrogenase	109	IU/L			82-216	
					Phosphate	1.03	mmol/L			0.68-1.52	
					Potassium	3.6	mmol/L			3.5-5	
					Protein	69	g/L			57-88	
					Sodium	137	mmol/L			132-145	
					Triglycerides	1.02	mmol/L			0-4.52	
					Urate	327	umol/L			119-345	
			Check-in	03SEP2019 08:56 (-1)	Alanine Aminotransferase	11	IU/L			4-45	
					Albumin	39	g/L			38-49	
					Alkaline Phosphatase	69	IU/L			20-116	
					Anion Gap	11	mmol/L			6-17	
					Aspartate Aminotransferase	19	IU/L			10-40	
					Bilirubin	6.5	umol/L			3.2-21.7	

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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9020	47/F/BL		Check-in	03SEP2019 08:56 (-1)	Blood Urea Nitrogen	5.75	mmol/L			1.79-9.28	
					Calcium	2.25	mmol/L			2.13-2.58	
					Carbon Dioxide	28	mmol/L			22-34	
					Chloride	100	mmol/L			96-108	
					Creatinine	66.3	umol/L			39.8-93.7	
					Gamma Glutamyl Transferase	13	IU/L			5-85	
					Globulin	33	g/L			19-39	
					Glucose	4.77	mmol/L			3-6.44	
					Lactate Dehydrogenase	127	IU/L			82-216	
					Phosphate	1.07	mmol/L			0.68-1.52	
					Potassium	3.7	mmol/L			3.5-5	
					Protein	72	g/L			57-88	
					Sodium	135	mmol/L			132-145	
					Urate	357	umol/L	H NCS		119-345	
		TPOXX 600 mg	Day 4	07SEP2019 07:31 (4)	Alanine Aminotransferase	12	IU/L			4-45	

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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9020	47/F/BL	TPOXX 600 mg	Day 4	07SEP2019 07:31 (4)	Albumin	37	g/L	L NCS	G1	38-49	
					Alkaline Phosphatase	61	IU/L			20-116	
					Anion Gap	9	mmol/L			6-17	
					Aspartate Aminotransferase	20	IU/L			10-40	
					Bilirubin	7.5	umol/L			3.2-21.7	
					Blood Urea Nitrogen	4.86	mmol/L			1.79-9.28	
					Calcium	2.23	mmol/L			2.13-2.58	
					Carbon Dioxide	28	mmol/L			22-34	
					Chloride	106	mmol/L			96-108	
					Creatinine	68.1	umol/L			39.8-93.7	
					Gamma Glutamyl Transferase	13	IU/L			5-85	
					Globulin	33	g/L			19-39	
					Glucose	5.83	mmol/L			3-6.44	
					Lactate Dehydrogenase	108	IU/L			82-216	
					Phosphate	1.10	mmol/L			0.68-1.52	
					Potassium	4.2	mmol/L			3.5-5	

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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9020	47/F/BL	TPOXX 600 mg	Day 4	07SEP2019 07:31 (4)	Protein	70	g/L			57-88	
					Sodium	139	mmol/L			132-145	
					Urate	393	umol/L	H NCS		119-345	
			Day 8 - 12 Hours Postdose	11SEP2019 08:06 (8)	Alanine Aminotransferase	14	IU/L			4-45	
					Albumin	38	g/L			38-49	
					Alkaline Phosphatase	69	IU/L			20-116	
					Anion Gap	11	mmol/L			6-17	
					Aspartate Aminotransferase	21	IU/L			10-40	
					Bilirubin	7.4	umol/L			3.2-21.7	
					Blood Urea Nitrogen	4.21	mmol/L			1.79-9.28	
					Calcium	2.28	mmol/L			2.13-2.58	
					Carbon Dioxide	29	mmol/L			22-34	
					Chloride	103	mmol/L			96-108	
					Creatinine	66.3	umol/L			39.8-93.7	

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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9020	47/F/BL	TPOXX 600 mg	Day 8 - 12 Hours Postdose	11SEP2019 08:06 (8)	Gamma Glutamyl Transferase	14	IU/L			5-85	
					Globulin	33	g/L			19-39	
					Glucose	5.38	mmol/L			3-6.44	
					Lactate Dehydrogenase	111	IU/L			82-216	
					Phosphate	1.13	mmol/L			0.68-1.52	
					Potassium	3.7	mmol/L			3.5-5	
					Protein	71	g/L			57-88	
					Sodium	139	mmol/L			132-145	
					Urate	375	umol/L	H NCS		119-345	
			Day 9	12SEP2019 08:13 (9)	Alanine Aminotransferase	13	IU/L			4-45	
					Albumin	40	g/L			38-49	
					Alkaline Phosphatase	72	IU/L			20-116	
					Anion Gap	11	mmol/L			6-17	
					Aspartate Aminotransferase	22	IU/L			10-40	

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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9020	47/F/BL	TPOXX 600 mg	Day 9	12SEP2019 08:13 (9)	Bilirubin	7.0	umol/L			3.2-21.7	
					Blood Urea Nitrogen	4.07	mmol/L			1.79-9.28	
					Calcium	2.23	mmol/L			2.13-2.58	
					Carbon Dioxide	28	mmol/L			22-34	
					Chloride	101	mmol/L			96-108	
					Creatinine	64.5	umol/L			39.8-93.7	
					Gamma Glutamyl Transferase	15	IU/L			5-85	
					Globulin	32	g/L			19-39	
					Glucose	5.22	mmol/L			3-6.44	
					Lactate Dehydrogenase	115	IU/L			82-216	
					Phosphate	0.97	mmol/L			0.68-1.52	
					Potassium	3.5	mmol/L			3.5-5	
					Protein	72	g/L			57-88	
					Sodium	136	mmol/L			132-145	
					Urate	351	umol/L	H NCS		119-345	

Sex: M=Male, F=Female;
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9021	39/F/BL		Screening	21AUG2019 10:44 (-14)	Alanine Aminotransferase	18	IU/L			4-45	
					Albumin	44	g/L			38-49	
					Alkaline Phosphatase	91	IU/L			20-116	
					Anion Gap	11	mmol/L			6-17	
					Aspartate Aminotransferase	16	IU/L			10-40	
					Bilirubin	4.8	umol/L			3.2-21.7	
					Blood Urea Nitrogen	3.43	mmol/L			1.79-9.28	
					Calcium	2.35	mmol/L			2.13-2.58	
					Carbon Dioxide	27	mmol/L			22-34	
					Chloride	101	mmol/L			96-108	
					Cholesterol	5.72	mmol/L		G1	2.2-6.22	
					Creatinine	63.6	umol/L			39.8-93.7	
					Creatinine Clearance	203.7	mL/min			90-N/A	
					Gamma Glutamyl Transferase	31	IU/L			5-85	
					Globulin	30	g/L			19-39	
					Glucose	5.72	mmol/L			3-6.44	

Sex: M=Male, F=Female;
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Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9021	39/F/BL		Screening	21AUG2019 10:44 (-14)	HDL Cholesterol	1.09	mmol/L			0.88-2.36	
					LDL Cholesterol	4.14	mmol/L		G2	0.96-4.22	
					Lactate Dehydrogenase	179	IU/L			82-216	
					Phosphate	1.23	mmol/L			0.68-1.52	
					Potassium	4.0	mmol/L			3.5-5	
					Protein	74	g/L			57-88	
					Sodium	135	mmol/L			132-145	
					Triglycerides	1.08	mmol/L			0-4.52	
					Urate	387	umol/L	H NCS		119-345	
			Check-in	03SEP2019 09:00 (-1)	Alanine Aminotransferase	21	IU/L			4-45	
					Albumin	47	g/L			38-49	
					Alkaline Phosphatase	86	IU/L			20-116	
					Anion Gap	15	mmol/L			6-17	
					Aspartate Aminotransferase	19	IU/L			10-40	
					Bilirubin	3.2	umol/L			3.2-21.7	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9021	39/F/BL		Check-in	03SEP2019 09:00 (-1)	Blood Urea Nitrogen	3.71	mmol/L			1.79-9.28	
					Calcium	2.45	mmol/L			2.13-2.58	
					Carbon Dioxide	27	mmol/L			22-34	
					Chloride	101	mmol/L			96-108	
					Creatinine	65.4	umol/L			39.8-93.7	
					Gamma Glutamyl Transferase	30	IU/L			5-85	
					Globulin	29	g/L			19-39	
					Glucose	6.11	mmol/L		G1	3-6.44	
					Lactate Dehydrogenase	176	IU/L			82-216	
					Phosphate	1.23	mmol/L			0.68-1.52	
					Potassium	4.0	mmol/L			3.5-5	
					Protein	76	g/L			57-88	
					Sodium	139	mmol/L			132-145	
					Urate	458	umol/L	H NCS	G1	119-345	
		TPOXX 600 mg	Day 4	07SEP2019 07:34 (4)	Alanine Aminotransferase	25	IU/L			4-45	

Sex: M=Male, F=Female;
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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9021	39/F/BL	TPOXX 600 mg	Day 4	07SEP2019 07:34 (4)	Albumin	46	g/L			38-49	
					Alkaline Phosphatase	73	IU/L			20-116	
					Anion Gap	9	mmol/L			6-17	
					Aspartate Aminotransferase	21	IU/L			10-40	
					Bilirubin	6.5	umol/L			3.2-21.7	
					Blood Urea Nitrogen	3.75	mmol/L			1.79-9.28	
					Calcium	2.43	mmol/L			2.13-2.58	
					Carbon Dioxide	30	mmol/L			22-34	
					Chloride	103	mmol/L			96-108	
					Creatinine	69.8	umol/L			39.8-93.7	
					Gamma Glutamyl Transferase	28	IU/L			5-85	
					Globulin	31	g/L			19-39	
					Glucose	5.33	mmol/L			3-6.44	
					Lactate Dehydrogenase	170	IU/L			82-216	
					Phosphate	1.39	mmol/L			0.68-1.52	
					Potassium	4.0	mmol/L			3.5-5	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9021	39/F/BL	TPOXX 600 mg	Day 4	07SEP2019 07:34 (4)	Protein	77	g/L			57-88	
					Sodium	138	mmol/L			132-145	
					Urate	482	umol/L	H NCS	G1	119-345	
			Day 8 - 12 Hours Postdose	11SEP2019 08:09 (8)	Alanine Aminotransferase	21	IU/L			4-45	
					Albumin	44	g/L			38-49	
					Alkaline Phosphatase	72	IU/L			20-116	
					Anion Gap	11	mmol/L			6-17	
					Aspartate Aminotransferase	16	IU/L			10-40	
					Bilirubin	6.2	umol/L			3.2-21.7	
					Blood Urea Nitrogen	3.03	mmol/L			1.79-9.28	
					Calcium	2.43	mmol/L			2.13-2.58	
					Carbon Dioxide	29	mmol/L			22-34	
					Chloride	101	mmol/L			96-108	
					Creatinine	66.3	umol/L			39.8-93.7	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9021	39/F/BL	TPOXX 600 mg	Day 8 - 12 Hours Postdose	11SEP2019 08:09 (8)	Gamma Glutamyl Transferase	27	IU/L			5-85	
					Globulin	29	g/L			19-39	
					Glucose	4.88	mmol/L			3-6.44	
					Lactate Dehydrogenase	150	IU/L			82-216	
					Phosphate	1.26	mmol/L			0.68-1.52	
					Potassium	4.1	mmol/L			3.5-5	
					Protein	73	g/L			57-88	
					Sodium	137	mmol/L			132-145	
					Urate	464	umol/L	H NCS	G1	119-345	
			Day 9	12SEP2019 08:09 (9)	Alanine Aminotransferase	21	IU/L			4-45	
					Albumin	47	g/L			38-49	
					Alkaline Phosphatase	77	IU/L			20-116	
					Anion Gap	10	mmol/L			6-17	
					Aspartate Aminotransferase	17	IU/L			10-40	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9021	39/F/BL	TPOXX 600 mg	Day 9	12SEP2019 08:09 (9)	Bilirubin	5.3	umol/L			3.2-21.7	
					Blood Urea Nitrogen	3.25	mmol/L			1.79-9.28	
					Calcium	2.43	mmol/L			2.13-2.58	
					Carbon Dioxide	30	mmol/L			22-34	
					Chloride	101	mmol/L			96-108	
					Creatinine	75.1	umol/L			39.8-93.7	
					Gamma Glutamyl Transferase	28	IU/L			5-85	
					Globulin	30	g/L			19-39	
					Glucose	5.27	mmol/L			3-6.44	
					Lactate Dehydrogenase	167	IU/L			82-216	
					Phosphate	1.03	mmol/L			0.68-1.52	
					Potassium	4.2	mmol/L			3.5-5	
					Protein	77	g/L			57-88	
					Sodium	137	mmol/L			132-145	
					Urate	452	umol/L	H NCS	G1	119-345	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9022	31/M/W		Screening	21AUG2019 11:05 (-14)	Alanine Aminotransferase	40	IU/L			7-56	
					Albumin	41	g/L			37-55	
					Alkaline Phosphatase	60	IU/L			20-116	
					Anion Gap	9	mmol/L			6-17	
					Aspartate Aminotransferase	18	IU/L			10-40	
					Bilirubin	14.4	umol/L			3.2-28.9	
					Blood Urea Nitrogen	3.64	mmol/L			1.79-9.28	
					Calcium	2.23	mmol/L			2.13-2.58	
					Carbon Dioxide	29	mmol/L			22-34	
					Chloride	103	mmol/L			96-108	
					Cholesterol	4.66	mmol/L			2.2-6.22	
					Creatinine	83.1	umol/L			56.6-114.9	
					Creatinine Clearance	275.4	mL/min			90-N/A	
					Gamma Glutamyl Transferase	32	IU/L			5-85	
					Globulin	26	g/L			19-39	
					Glucose	5.16	mmol/L			3-6.44	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9022	31/M/W		Screening	21AUG2019 11:05 (-14)	HDL Cholesterol	0.93	mmol/L			0.65-2.46	
					LDL Cholesterol	2.62	mmol/L			0.96-4.22	
					Lactate Dehydrogenase	189	IU/L			82-216	
					Phosphate	1.23	mmol/L			0.68-1.52	
					Potassium	4.3	mmol/L			3.5-5	
					Protein	67	g/L			57-88	
					Sodium	137	mmol/L			132-145	
					Triglycerides	2.45	mmol/L		G1	0-4.52	
					Urate	494	umol/L		G1	173-494	
			Check-in	03SEP2019 09:54 (-1)	Alanine Aminotransferase	45	IU/L			7-56	
					Albumin	41	g/L			37-55	
					Alkaline Phosphatase	54	IU/L			20-116	
					Anion Gap	10	mmol/L			6-17	
					Aspartate Aminotransferase	26	IU/L			10-40	
					Bilirubin	14.5	umol/L			3.2-28.9	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9022	31/M/W		Check-in	03SEP2019 09:54 (-1)	Blood Urea Nitrogen	4.28	mmol/L			1.79-9.28	
					Calcium	2.20	mmol/L			2.13-2.58	
					Carbon Dioxide	29	mmol/L			22-34	
					Chloride	102	mmol/L			96-108	
					Creatinine	82.2	umol/L			56.6-114.9	
					Gamma Glutamyl Transferase	33	IU/L			5-85	
					Globulin	27	g/L			19-39	
					Glucose	5.77	mmol/L			3-6.44	
					Lactate Dehydrogenase	215	IU/L			82-216	
					Phosphate	1.23	mmol/L			0.68-1.52	
					Potassium	3.9	mmol/L			3.5-5	
					Protein	68	g/L			57-88	
					Sodium	137	mmol/L			132-145	
					Urate	464	umol/L		G1	173-494	
		TPOXX 600 mg	Day 4	07SEP2019 07:44 (4)	Alanine Aminotransferase	61	IU/L	H NCS		7-56	

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Day = The presented date — First dose date + 1
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Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9022	31/M/W	TPOXX 600 mg	Day 4	07SEP2019 07:44 (4)	Albumin	44	g/L			37-55	
					Alkaline Phosphatase	57	IU/L			20-116	
					Anion Gap	7	mmol/L			6-17	
					Aspartate Aminotransferase	31	IU/L			10-40	
					Bilirubin	20.5	umol/L			3.2-28.9	
					Blood Urea Nitrogen	3.78	mmol/L			1.79-9.28	
					Calcium	2.33	mmol/L			2.13-2.58	
					Carbon Dioxide	32	mmol/L			22-34	
					Chloride	101	mmol/L			96-108	
					Creatinine	82.2	umol/L			56.6-114.9	
					Gamma Glutamyl Transferase	36	IU/L			5-85	
					Globulin	31	g/L			19-39	
					Glucose	5.22	mmol/L			3-6.44	
					Lactate Dehydrogenase	203	IU/L			82-216	
					Phosphate	1.42	mmol/L			0.68-1.52	
					Potassium	4.1	mmol/L			3.5-5	

Sex: M=Male, F=Female;
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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9022	31/M/W	TPOXX 600 mg	Day 4	07SEP2019 07:44 (4)	Protein	75	g/L			57-88	
					Sodium	136	mmol/L			132-145	
					Urate	589	umol/L	H NCS	G1	173-494	
			Day 4	08SEP2019 07:42 (5), R	Alanine Aminotransferase	58	IU/L	H NCS		7-56	
					Aspartate Aminotransferase	27	IU/L			10-40	
					Bilirubin	19.3	umol/L			3.2-28.9	
			Day 4	09SEP2019 08:07 (6), R	Alanine Aminotransferase	58	IU/L	H NCS		7-56	
					Aspartate Aminotransferase	28	IU/L			10-40	
			Day 8 - 12 Hours Postdose	11SEP2019 08:12 (8)	Alanine Aminotransferase	55	IU/L			7-56	

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Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9022	31/M/W	TPOXX 600 mg	Day 8 - 12 Hours Postdose	11SEP2019 08:12 (8)	Albumin	43	g/L			37-55	
					Alkaline Phosphatase	59	IU/L			20-116	
					Anion Gap	10	mmol/L			6-17	
					Aspartate Aminotransferase	26	IU/L			10-40	
					Bilirubin	19.2	umol/L			3.2-28.9	
					Blood Urea Nitrogen	3.43	mmol/L			1.79-9.28	
					Calcium	2.30	mmol/L			2.13-2.58	
					Carbon Dioxide	31	mmol/L			22-34	
					Chloride	101	mmol/L			96-108	
					Creatinine	82.2	umol/L			56.6-114.9	
					Gamma Glutamyl Transferase	35	IU/L			5-85	
					Globulin	29	g/L			19-39	
					Glucose	4.94	mmol/L			3-6.44	
					Lactate Dehydrogenase	192	IU/L			82-216	
					Phosphate	1.52	mmol/L			0.68-1.52	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9022	31/M/W	TPOXX 600 mg	Day 8 - 12 Hours Postdose	11SEP2019 08:12 (8)	Potassium	4.2	mmol/L			3.5-5	
					Protein	72	g/L			57-88	
					Sodium	138	mmol/L			132-145	
					Urate	571	umol/L	H NCS	G1	173-494	
			Day 9	12SEP2019 08:12 (9)	Alanine Aminotransferase	53	IU/L			7-56	
					Albumin	43	g/L			37-55	
					Alkaline Phosphatase	58	IU/L			20-116	
					Anion Gap	9	mmol/L			6-17	
					Aspartate Aminotransferase	25	IU/L			10-40	
					Bilirubin	17.1	umol/L			3.2-28.9	
					Blood Urea Nitrogen	3.71	mmol/L			1.79-9.28	
					Calcium	2.25	mmol/L			2.13-2.58	
					Carbon Dioxide	31	mmol/L			22-34	
					Chloride	101	mmol/L			96-108	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9022	31/M/W	TPOXX 600 mg	Day 9	12SEP2019 08:12 (9)	Creatinine	84.0	umol/L			56.6-114.9	
					Gamma Glutamyl Transferase	35	IU/L			5-85	
					Globulin	29	g/L			19-39	
					Glucose	5.27	mmol/L			3-6.44	
					Lactate Dehydrogenase	186	IU/L			82-216	
					Phosphate	1.23	mmol/L			0.68-1.52	
					Potassium	4.0	mmol/L			3.5-5	
					Protein	72	g/L			57-88	
					Sodium	137	mmol/L			132-145	
					Urate	577	umol/L	H NCS	G1	173-494	
9024	20/M/BL		Screening	23AUG2019 10:48 (-12)	Alanine Aminotransferase	26	IU/L			7-56	
					Albumin	45	g/L			37-55	
					Alkaline Phosphatase	114	IU/L			20-116	
					Anion Gap	10	mmol/L			6-17	

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R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9024	20/M/BL		Screening	23AUG2019 10:48 (-12)	Aspartate Aminotransferase	17	IU/L			10-40	
					Bilirubin	8.0	umol/L			3.2-28.9	
					Blood Urea Nitrogen	5.57	mmol/L			1.79-9.28	
					Calcium	2.40	mmol/L			2.13-2.58	
					Carbon Dioxide	27	mmol/L			22-34	
					Chloride	106	mmol/L			96-108	
					Cholesterol	4.01	mmol/L			2.2-6.22	
					Creatinine	79.6	umol/L			56.6-114.9	
					Creatinine Clearance	248.1	mL/min			90-N/A	
					Gamma Glutamyl Transferase	60	IU/L			5-85	
					Globulin	27	g/L			19-39	
					Glucose	4.88	mmol/L			3-6.44	
					HDL Cholesterol	1.17	mmol/L			0.65-2.46	
					LDL Cholesterol	2.67	mmol/L			0.96-4.22	
					Lactate Dehydrogenase	171	IU/L			82-216	
					Phosphate	1.16	mmol/L			0.68-1.52	
					Potassium	4.5	mmol/L			3.5-5	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9024	20/M/BL		Screening	23AUG2019 10:48 (-12)	Protein	72	g/L			57-88	
					Sodium	138	mmol/L			132-145	
					Triglycerides	0.41	mmol/L			0-4.52	
					Urate	333	umol/L			173-494	
			Check-in	03SEP2019 09:18 (-1)	Alanine Aminotransferase	20	IU/L			7-56	
					Albumin	44	g/L			37-55	
					Alkaline Phosphatase	106	IU/L			20-116	
					Anion Gap	10	mmol/L			6-17	
					Aspartate Aminotransferase	16	IU/L			10-40	
					Bilirubin	9.2	umol/L			3.2-28.9	
					Blood Urea Nitrogen	3.50	mmol/L			1.79-9.28	
					Calcium	2.33	mmol/L			2.13-2.58	
					Carbon Dioxide	29	mmol/L			22-34	
					Chloride	104	mmol/L			96-108	
					Creatinine	80.4	umol/L			56.6-114.9	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9024	20/M/BL		Check-in	03SEP2019 09:18 (-1)	Gamma Glutamyl Transferase	43	IU/L			5-85	
					Globulin	24	g/L			19-39	
					Glucose	5.05	mmol/L			3-6.44	
					Lactate Dehydrogenase	163	IU/L			82-216	
					Phosphate	1.16	mmol/L			0.68-1.52	
					Potassium	4.1	mmol/L			3.5-5	
					Protein	68	g/L			57-88	
					Sodium	139	mmol/L			132-145	
					Urate	357	umol/L			173-494	
		TPOXX 600 mg	Day 4	07SEP2019 07:40 (4)	Alanine Aminotransferase	42	IU/L			7-56	
					Albumin	49	g/L			37-55	
					Alkaline Phosphatase	121	IU/L	H NCS		20-116	
					Anion Gap	8	mmol/L			6-17	
					Aspartate Aminotransferase	29	IU/L			10-40	
					Bilirubin	11.8	umol/L			3.2-28.9	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9024	20/M/BL	TPOXX 600 mg	Day 4	07SEP2019 07:40 (4)	Blood Urea Nitrogen	3.14	mmol/L			1.79-9.28	
					Calcium	2.53	mmol/L			2.13-2.58	
					Carbon Dioxide	30	mmol/L			22-34	
					Chloride	104	mmol/L			96-108	
					Creatinine	83.1	umol/L			56.6-114.9	
					Gamma Glutamyl Transferase	56	IU/L			5-85	
					Globulin	29	g/L			19-39	
					Glucose	4.88	mmol/L			3-6.44	
					Lactate Dehydrogenase	172	IU/L			82-216	
					Phosphate	1.26	mmol/L			0.68-1.52	
					Potassium	4.3	mmol/L			3.5-5	
					Protein	78	g/L			57-88	
					Sodium	138	mmol/L			132-145	
					Urate	339	umol/L			173-494	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9024	20/M/BL	TPOXX 600 mg	Day 8 - 12 Hours Postdose	11SEP2019 08:15 (8)	Alanine Aminotransferase	56	IU/L			7-56	
					Albumin	46	g/L			37-55	
					Alkaline Phosphatase	124	IU/L	H NCS		20-116	
					Anion Gap	10	mmol/L			6-17	
					Aspartate Aminotransferase	29	IU/L			10-40	
					Bilirubin	13.0	umol/L			3.2-28.9	
					Blood Urea Nitrogen	3.00	mmol/L			1.79-9.28	
					Calcium	2.48	mmol/L			2.13-2.58	
					Carbon Dioxide	30	mmol/L			22-34	
					Chloride	102	mmol/L			96-108	
					Creatinine	87.5	umol/L			56.6-114.9	
					Gamma Glutamyl Transferase	64	IU/L			5-85	
					Globulin	26	g/L			19-39	
					Glucose	4.88	mmol/L			3-6.44	
					Lactate Dehydrogenase	139	IU/L			82-216	

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Day = The presented date — First dose date + 1
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Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9024	20/M/BL	TPOXX 600 mg	Day 8 - 12 Hours Postdose	11SEP2019 08:15 (8)	Phosphate	1.16	mmol/L			0.68-1.52	
					Potassium	4.2	mmol/L			3.5-5	
					Protein	72	g/L			57-88	
					Sodium	138	mmol/L			132-145	
					Urate	339	umol/L			173-494	
			Day 9	12SEP2019 08:15 (9)	Alanine Aminotransferase	54	IU/L			7-56	
					Albumin	47	g/L			37-55	
					Alkaline Phosphatase	127	IU/L	H NCS		20-116	
					Anion Gap	9	mmol/L			6-17	
					Aspartate Aminotransferase	25	IU/L			10-40	
					Bilirubin	12.0	umol/L			3.2-28.9	
					Blood Urea Nitrogen	3.43	mmol/L			1.79-9.28	
					Calcium	2.43	mmol/L			2.13-2.58	
					Carbon Dioxide	30	mmol/L			22-34	

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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9024	20/M/BL	TPOXX 600 mg	Day 9	12SEP2019 08:15 (9)	Chloride	104	mmol/L			96-108	
					Creatinine	87.5	umol/L			56.6-114.9	
					Gamma Glutamyl Transferase	66	IU/L			5-85	
					Globulin	27	g/L			19-39	
					Glucose	5.11	mmol/L			3-6.44	
					Lactate Dehydrogenase	137	IU/L			82-216	
					Phosphate	1.07	mmol/L			0.68-1.52	
					Potassium	4.1	mmol/L			3.5-5	
					Protein	74	g/L			57-88	
					Sodium	139	mmol/L			132-145	
					Urate	339	umol/L			173-494	
9025	50/M/W		Screening	23AUG2019 10:59 (-26)	Alanine Aminotransferase	21	IU/L			7-56	
					Albumin	44	g/L			37-55	
					Alkaline Phosphatase	57	IU/L			20-116	
					Anion Gap	7	mmol/L			6-17	

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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9025	50/M/W		Screening	23AUG2019 10:59 (-26)	Aspartate Aminotransferase	16	IU/L			10-40	
					Bilirubin	6.0	umol/L			3.2-28.9	
					Blood Urea Nitrogen	5.82	mmol/L			1.79-9.28	
					Calcium	2.33	mmol/L			2.13-2.58	
					Carbon Dioxide	32	mmol/L			22-34	
					Chloride	103	mmol/L			96-108	
					Cholesterol	4.12	mmol/L			2.2-6.22	
					Creatinine	76.9	umol/L			56.6-114.9	
					Creatinine Clearance	176.7	mL/min			90-N/A	
					Gamma Glutamyl Transferase	20	IU/L			5-85	
					Globulin	31	g/L			19-39	
					Glucose	5.38	mmol/L			3-6.44	
					HDL Cholesterol	0.75	mmol/L			0.65-2.46	
					LDL Cholesterol	2.72	mmol/L			0.96-4.22	
					Lactate Dehydrogenase	132	IU/L			82-216	
					Phosphate	1.20	mmol/L			0.68-1.52	
					Potassium	4.3	mmol/L			3.5-5	

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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9025	50/M/W		Screening	23AUG2019 10:59 (-26)	Protein	75	g/L			57-88	
					Sodium	138	mmol/L			132-145	
					Triglycerides	1.41	mmol/L			0-4.52	
					Urate	286	umol/L			173-494	
			Check-in	17SEP2019 09:06 (-1)	Alanine Aminotransferase	19	IU/L			7-56	
					Albumin	42	g/L			37-55	
					Alkaline Phosphatase	56	IU/L			20-116	
					Anion Gap	8	mmol/L			6-17	
					Aspartate Aminotransferase	16	IU/L			10-40	
					Bilirubin	5.8	umol/L			3.2-28.9	
					Blood Urea Nitrogen	4.53	mmol/L			1.79-9.28	
					Calcium	2.23	mmol/L			2.13-2.58	
					Carbon Dioxide	29	mmol/L			22-34	
					Chloride	105	mmol/L			96-108	
					Creatinine	77.8	umol/L			56.6-114.9	

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Day = The presented date — First dose date + 1
R=Repeat
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9025	50/M/W		Check-in	17SEP2019 09:06 (-1)	Gamma Glutamyl Transferase	20	IU/L			5-85	
					Globulin	28	g/L			19-39	
					Glucose	5.83	mmol/L			3-6.44	
					Lactate Dehydrogenase	137	IU/L			82-216	
					Phosphate	1.20	mmol/L			0.68-1.52	
					Potassium	4.1	mmol/L			3.5-5	
					Protein	70	g/L			57-88	
					Sodium	138	mmol/L			132-145	
					Urate	274	umol/L			173-494	
		TPOXX 600 mg	Day 4	21SEP2019 07:25 (4)	Alanine Aminotransferase	21	IU/L			7-56	
					Albumin	45	g/L			37-55	
					Alkaline Phosphatase	56	IU/L			20-116	
					Anion Gap	11	mmol/L			6-17	
					Aspartate Aminotransferase	18	IU/L			10-40	
					Bilirubin	9.9	umol/L			3.2-28.9	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9025	50/M/W	TPOXX 600 mg	Day 4	21SEP2019 07:25 (4)	Blood Urea Nitrogen	4.53	mmol/L			1.79-9.28	
					Calcium	2.33	mmol/L			2.13-2.58	
					Carbon Dioxide	27	mmol/L			22-34	
					Chloride	103	mmol/L			96-108	
					Creatinine	85.7	umol/L			56.6-114.9	
					Gamma Glutamyl Transferase	23	IU/L			5-85	
					Globulin	31	g/L			19-39	
					Glucose	5.94	mmol/L			3-6.44	
					Lactate Dehydrogenase	121	IU/L			82-216	
					Phosphate	1.20	mmol/L			0.68-1.52	
					Potassium	4.4	mmol/L			3.5-5	
					Protein	76	g/L			57-88	
					Sodium	137	mmol/L			132-145	
					Urate	327	umol/L			173-494	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9025	50/M/W	TPOXX 600 mg	Day 8 - 12 Hours Postdose	25SEP2019 08:00 (8)	Alanine Aminotransferase	23	IU/L			7-56	
					Albumin	45	g/L			37-55	
					Alkaline Phosphatase	54	IU/L			20-116	
					Anion Gap	13	mmol/L			6-17	
					Aspartate Aminotransferase	16	IU/L			10-40	
					Bilirubin	11.3	umol/L			3.2-28.9	
					Blood Urea Nitrogen	4.43	mmol/L			1.79-9.28	
					Calcium	2.38	mmol/L			2.13-2.58	
					Carbon Dioxide	28	mmol/L			22-34	
					Chloride	102	mmol/L			96-108	
					Creatinine	84.0	umol/L			56.6-114.9	
					Gamma Glutamyl Transferase	25	IU/L			5-85	
					Globulin	30	g/L			19-39	
					Glucose	5.66	mmol/L			3-6.44	
					Lactate Dehydrogenase	113	IU/L			82-216	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9025	50/M/W	TPOXX 600 mg	Day 8 - 12 Hours Postdose	25SEP2019 08:00 (8)	Phosphate	1.20	mmol/L			0.68-1.52	
					Potassium	4.5	mmol/L			3.5-5	
					Protein	75	g/L			57-88	
					Sodium	138	mmol/L			132-145	
					Urate	321	umol/L			173-494	
			Day 9	26SEP2019 08:00 (9)	Alanine Aminotransferase	24	IU/L			7-56	
					Albumin	44	g/L			37-55	
					Alkaline Phosphatase	59	IU/L			20-116	
					Anion Gap	12	mmol/L			6-17	
					Aspartate Aminotransferase	18	IU/L			10-40	
					Bilirubin	8.0	umol/L			3.2-28.9	
					Blood Urea Nitrogen	4.71	mmol/L			1.79-9.28	
					Calcium	2.30	mmol/L			2.13-2.58	
					Carbon Dioxide	29	mmol/L			22-34	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9025	50/M/W	TPOXX 600 mg	Day 9	26SEP2019 08:00 (9)	Chloride	102	mmol/L			96-108	
					Creatinine	82.2	umol/L			56.6-114.9	
					Gamma Glutamyl Transferase	25	IU/L			5-85	
					Globulin	29	g/L			19-39	
					Glucose	5.61	mmol/L			3-6.44	
					Lactate Dehydrogenase	119	IU/L			82-216	
					Phosphate	1.16	mmol/L			0.68-1.52	
					Potassium	4.5	mmol/L			3.5-5	
					Protein	73	g/L			57-88	
					Sodium	138	mmol/L			132-145	
					Urate	321	umol/L			173-494	
9033	32/M/W		Screening	29AUG2019 09:53 (-6)	Alanine Aminotransferase	26	IU/L			7-56	
					Albumin	45	g/L			37-55	
					Alkaline Phosphatase	66	IU/L			20-116	
					Anion Gap	13	mmol/L			6-17	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9033	32/M/W		Screening	29AUG2019 09:53 (-6)	Aspartate Aminotransferase	18	IU/L			10-40	
					Bilirubin	6.0	umol/L			3.2-28.9	
					Blood Urea Nitrogen	6.32	mmol/L			1.79-9.28	
					Calcium	2.33	mmol/L			2.13-2.58	
					Carbon Dioxide	29	mmol/L			22-34	
					Chloride	100	mmol/L			96-108	
					Cholesterol	4.43	mmol/L			2.2-6.22	
					Creatinine	61.0	umol/L			56.6-114.9	
					Creatinine Clearance	319.6	mL/min			90-N/A	
					Gamma Glutamyl Transferase	28	IU/L			5-85	
					Globulin	28	g/L			19-39	
					Glucose	5.38	mmol/L			3-6.44	
					HDL Cholesterol	0.91	mmol/L			0.65-2.46	
					LDL Cholesterol	2.05	mmol/L			0.96-4.22	
					Lactate Dehydrogenase	201	IU/L			82-216	
					Phosphate	1.42	mmol/L			0.68-1.52	
					Potassium	4.6	mmol/L			3.5-5	

Sex: M=Male, F=Female;
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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9033	32/M/W		Screening	29AUG2019 09:53 (-6)	Protein	73	g/L			57-88	
					Sodium	137	mmol/L			132-145	
					Triglycerides	3.23	mmol/L			0-4.52	
					Urate	488	umol/L		G1	173-494	
			Check-in	03SEP2019 09:15 (-1)	Alanine Aminotransferase	20	IU/L			7-56	
					Albumin	45	g/L			37-55	
					Alkaline Phosphatase	64	IU/L			20-116	
					Anion Gap	10	mmol/L			6-17	
					Aspartate Aminotransferase	14	IU/L			10-40	
					Bilirubin	6.8	umol/L			3.2-28.9	
					Blood Urea Nitrogen	6.46	mmol/L			1.79-9.28	
					Calcium	2.30	mmol/L			2.13-2.58	
					Carbon Dioxide	30	mmol/L			22-34	
					Chloride	101	mmol/L			96-108	
					Creatinine	61.0	umol/L			56.6-114.9	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9033	32/M/W		Check-in	03SEP2019 09:15 (-1)	Gamma Glutamyl Transferase	30	IU/L			5-85	
					Globulin	26	g/L			19-39	
					Glucose	6.05	mmol/L			3-6.44	
					Lactate Dehydrogenase	162	IU/L			82-216	
					Phosphate	0.97	mmol/L			0.68-1.52	
					Potassium	4.2	mmol/L			3.5-5	
					Protein	71	g/L			57-88	
					Sodium	137	mmol/L			132-145	
					Urate	500	umol/L	H NCS	G1	173-494	
		TPOXX 600 mg	Day 4	07SEP2019 07:48 (4)	Alanine Aminotransferase	20	IU/L			7-56	
					Albumin	45	g/L			37-55	
					Alkaline Phosphatase	55	IU/L			20-116	
					Anion Gap	8	mmol/L			6-17	
					Aspartate Aminotransferase	16	IU/L			10-40	
					Bilirubin	12.0	umol/L			3.2-28.9	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9033	32/M/W	TPOXX 600 mg	Day 4	07SEP2019 07:48 (4)	Blood Urea Nitrogen	5.11	mmol/L			1.79-9.28	
					Calcium	2.25	mmol/L			2.13-2.58	
					Carbon Dioxide	29	mmol/L			22-34	
					Chloride	105	mmol/L			96-108	
					Creatinine	64.5	umol/L			56.6-114.9	
					Gamma Glutamyl Transferase	29	IU/L			5-85	
					Globulin	28	g/L			19-39	
					Glucose	5.77	mmol/L			3-6.44	
					Lactate Dehydrogenase	158	IU/L			82-216	
					Phosphate	1.39	mmol/L			0.68-1.52	
					Potassium	4.1	mmol/L			3.5-5	
					Protein	73	g/L			57-88	
					Sodium	138	mmol/L			132-145	
					Urate	518	umol/L	H NCS	G1	173-494	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9033	32/M/W	TPOXX 600 mg	Day 8 - 12 Hours Postdose	11SEP2019 08:18 (8)	Alanine Aminotransferase	21	IU/L			7-56	
					Albumin	47	g/L			37-55	
					Alkaline Phosphatase	59	IU/L			20-116	
					Anion Gap	12	mmol/L			6-17	
					Aspartate Aminotransferase	16	IU/L			10-40	
					Bilirubin	14.5	umol/L			3.2-28.9	
					Blood Urea Nitrogen	4.25	mmol/L			1.79-9.28	
					Calcium	2.40	mmol/L			2.13-2.58	
					Carbon Dioxide	30	mmol/L			22-34	
					Chloride	102	mmol/L			96-108	
					Creatinine	69.8	umol/L			56.6-114.9	
					Gamma Glutamyl Transferase	34	IU/L			5-85	
					Globulin	26	g/L			19-39	
					Glucose	5.49	mmol/L			3-6.44	
					Lactate Dehydrogenase	156	IU/L			82-216	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9033	32/M/W	TPOXX 600 mg	Day 8 - 12 Hours Postdose	11SEP2019 08:18 (8)	Phosphate	1.49	mmol/L			0.68-1.52	
					Potassium	4.2	mmol/L			3.5-5	
					Protein	73	g/L			57-88	
					Sodium	140	mmol/L			132-145	
					Urate	494	umol/L		G1	173-494	
			Day 9	12SEP2019 08:18 (9)	Alanine Aminotransferase	23	IU/L			7-56	
					Albumin	50	g/L			37-55	
					Alkaline Phosphatase	63	IU/L			20-116	
					Anion Gap	11	mmol/L			6-17	
					Aspartate Aminotransferase	16	IU/L			10-40	
					Bilirubin	13.5	umol/L			3.2-28.9	
					Blood Urea Nitrogen	4.89	mmol/L			1.79-9.28	
					Calcium	2.35	mmol/L			2.13-2.58	
					Carbon Dioxide	30	mmol/L			22-34	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9033	32/M/W	TPOXX 600 mg	Day 9	12SEP2019 08:18 (9)	Chloride	101	mmol/L			96-108	
					Creatinine	71.6	umol/L			56.6-114.9	
					Gamma Glutamyl Transferase	35	IU/L			5-85	
					Globulin	30	g/L			19-39	
					Glucose	5.55	mmol/L			3-6.44	
					Lactate Dehydrogenase	162	IU/L			82-216	
					Phosphate	1.29	mmol/L			0.68-1.52	
					Potassium	3.8	mmol/L			3.5-5	
					Protein	80	g/L			57-88	
					Sodium	138	mmol/L			132-145	
					Urate	488	umol/L		G1	173-494	
9043	22/M/BL		Screening	11SEP2019 09:38 (-7)	Alanine Aminotransferase	25	IU/L			7-56	
					Albumin	46	g/L			37-55	
					Alkaline Phosphatase	36	IU/L			20-116	
					Anion Gap	11	mmol/L			6-17	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9043	22/M/BL		Screening	11SEP2019 09:38 (-7)	Aspartate Aminotransferase	20	IU/L			10-40	
					Bilirubin	11.8	umol/L			3.2-28.9	
					Blood Urea Nitrogen	2.96	mmol/L			1.79-9.28	
					Calcium	2.43	mmol/L			2.13-2.58	
					Carbon Dioxide	27	mmol/L			22-34	
					Chloride	103	mmol/L			96-108	
					Cholesterol	3.89	mmol/L			2.2-6.22	
					Creatinine	94.6	umol/L			56.6-114.9	
					Creatinine Clearance	243.5	mL/min			90-N/A	
					Gamma Glutamyl Transferase	30	IU/L			5-85	
					Globulin	27	g/L			19-39	
					Glucose	5.55	mmol/L			3-6.44	
					HDL Cholesterol	1.30	mmol/L			0.65-2.46	
					LDL Cholesterol	2.20	mmol/L			0.96-4.22	
					Lactate Dehydrogenase	154	IU/L			82-216	
					Phosphate	0.90	mmol/L			0.68-1.52	
					Potassium	4.1	mmol/L			3.5-5	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9043	22/M/BL		Screening	11SEP2019 09:38 (-7)	Protein	73	g/L			57-88	
					Sodium	137	mmol/L			132-145	
					Triglycerides	0.82	mmol/L			0-4.52	
					Urate	452	umol/L		G1	173-494	
			Check-in	17SEP2019 09:06 (-1)	Alanine Aminotransferase	21	IU/L			7-56	
					Albumin	47	g/L			37-55	
					Alkaline Phosphatase	39	IU/L			20-116	
					Anion Gap	11	mmol/L			6-17	
					Aspartate Aminotransferase	20	IU/L			10-40	
					Bilirubin	9.9	umol/L			3.2-28.9	
					Blood Urea Nitrogen	4.61	mmol/L			1.79-9.28	
					Calcium	2.48	mmol/L			2.13-2.58	
					Carbon Dioxide	28	mmol/L			22-34	
					Chloride	103	mmol/L			96-108	
					Creatinine	99.9	umol/L			56.6-114.9	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9043	22/M/BL		Check-in	17SEP2019 09:06 (-1)	Gamma Glutamyl Transferase	27	IU/L			5-85	
					Globulin	27	g/L			19-39	
					Glucose	5.55	mmol/L			3-6.44	
					Lactate Dehydrogenase	171	IU/L			82-216	
					Phosphate	1.07	mmol/L			0.68-1.52	
					Potassium	4.1	mmol/L			3.5-5	
					Protein	74	g/L			57-88	
					Sodium	138	mmol/L			132-145	
					Urate	535	umol/L	H NCS	G1	173-494	
		TPOXX 600 mg	Day 4	21SEP2019 07:28 (4)	Alanine Aminotransferase	25	IU/L			7-56	
					Albumin	48	g/L			37-55	
					Alkaline Phosphatase	42	IU/L			20-116	
					Anion Gap	9	mmol/L			6-17	
					Aspartate Aminotransferase	19	IU/L			10-40	
					Bilirubin	12.3	umol/L			3.2-28.9	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9043	22/M/BL	TPOXX 600 mg	Day 4	21SEP2019 07:28 (4)	Blood Urea Nitrogen	3.28	mmol/L			1.79-9.28	
					Calcium	2.58	mmol/L			2.13-2.58	
					Carbon Dioxide	32	mmol/L			22-34	
					Chloride	100	mmol/L			96-108	
					Creatinine	93.7	umol/L			56.6-114.9	
					Gamma Glutamyl Transferase	27	IU/L			5-85	
					Globulin	29	g/L			19-39	
					Glucose	5.66	mmol/L			3-6.44	
					Lactate Dehydrogenase	147	IU/L			82-216	
					Phosphate	1.10	mmol/L			0.68-1.52	
					Potassium	4.2	mmol/L			3.5-5	
					Protein	77	g/L			57-88	
					Sodium	137	mmol/L			132-145	
					Urate	470	umol/L		G1	173-494	

Sex: M=Male, F=Female;
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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9043	22/M/BL	TPOXX 600 mg	Day 8 - 12 Hours Postdose	25SEP2019 08:32 (8)	Alanine Aminotransferase	31	IU/L			7-56	
					Albumin	47	g/L			37-55	
					Alkaline Phosphatase	37	IU/L			20-116	
					Anion Gap	11	mmol/L			6-17	
					Aspartate Aminotransferase	21	IU/L			10-40	
					Bilirubin	12.5	umol/L			3.2-28.9	
					Blood Urea Nitrogen	3.28	mmol/L			1.79-9.28	
					Calcium	2.58	mmol/L			2.13-2.58	
					Carbon Dioxide	30	mmol/L			22-34	
					Chloride	100	mmol/L			96-108	
					Creatinine	87.5	umol/L			56.6-114.9	
					Gamma Glutamyl Transferase	28	IU/L			5-85	
					Globulin	27	g/L			19-39	
					Glucose	5.49	mmol/L			3-6.44	
					Lactate Dehydrogenase	147	IU/L			82-216	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9043	22/M/BL	TPOXX 600 mg	Day 8 - 12 Hours Postdose	25SEP2019 08:32 (8)	Phosphate	1.13	mmol/L			0.68-1.52	
					Potassium	4.3	mmol/L			3.5-5	
					Protein	74	g/L			57-88	
					Sodium	137	mmol/L			132-145	
					Urate	428	umol/L			173-494	
			Day 9	26SEP2019 08:11 (9)	Alanine Aminotransferase	30	IU/L			7-56	
					Albumin	45	g/L			37-55	
					Alkaline Phosphatase	40	IU/L			20-116	
					Anion Gap	12	mmol/L			6-17	
					Aspartate Aminotransferase	19	IU/L			10-40	
					Bilirubin	10.4	umol/L			3.2-28.9	
					Blood Urea Nitrogen	3.78	mmol/L			1.79-9.28	
					Calcium	2.45	mmol/L			2.13-2.58	
					Carbon Dioxide	29	mmol/L			22-34	

Sex: M=Male, F=Female;
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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9043	22/M/BL	TPOXX 600 mg	Day 9	26SEP2019 08:11 (9)	Chloride	98	mmol/L			96-108	
					Creatinine	87.5	umol/L			56.6-114.9	
					Gamma Glutamyl Transferase	26	IU/L			5-85	
					Globulin	26	g/L			19-39	
					Glucose	5.33	mmol/L			3-6.44	
					Lactate Dehydrogenase	143	IU/L			82-216	
					Phosphate	0.94	mmol/L			0.68-1.52	
					Potassium	4.1	mmol/L			3.5-5	
					Protein	71	g/L			57-88	
					Sodium	135	mmol/L			132-145	
					Urate	434	umol/L			173-494	
9046	34/M/BL		Screening	13SEP2019 09:12 (-5)	Alanine Aminotransferase	12	IU/L			7-56	
					Albumin	42	g/L			37-55	
					Alkaline Phosphatase	43	IU/L			20-116	
					Anion Gap	8	mmol/L			6-17	

Sex: M=Male, F=Female;
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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9046	34/M/BL		Screening	13SEP2019 09:12 (-5)	Aspartate Aminotransferase	13	IU/L			10-40	
					Bilirubin	9.1	umol/L			3.2-28.9	
					Blood Urea Nitrogen	5.07	mmol/L			1.79-9.28	
					Calcium	2.23	mmol/L			2.13-2.58	
					Carbon Dioxide	30	mmol/L			22-34	
					Chloride	106	mmol/L			96-108	
					Cholesterol	3.86	mmol/L			2.2-6.22	
					Creatinine	97.2	umol/L			56.6-114.9	
					Creatinine Clearance	163.3	mL/min			90-N/A	
					Gamma Glutamyl Transferase	16	IU/L			5-85	
					Globulin	22	g/L			19-39	
					Glucose	5.33	mmol/L			3-6.44	
					HDL Cholesterol	1.11	mmol/L			0.65-2.46	
					LDL Cholesterol	2.54	mmol/L			0.96-4.22	
					Lactate Dehydrogenase	141	IU/L			82-216	
					Phosphate	1.20	mmol/L			0.68-1.52	
					Potassium	3.9	mmol/L			3.5-5	

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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9046	34/M/BL		Screening	13SEP2019 09:12 (-5)	Protein	64	g/L			57-88	
					Sodium	140	mmol/L			132-145	
					Triglycerides	0.45	mmol/L			0-4.52	
					Urate	369	umol/L			173-494	
			Check-in	17SEP2019 09:05 (-1)	Alanine Aminotransferase	12	IU/L			7-56	
					Albumin	43	g/L			37-55	
					Alkaline Phosphatase	41	IU/L			20-116	
					Anion Gap	8	mmol/L			6-17	
					Aspartate Aminotransferase	14	IU/L			10-40	
					Bilirubin	11.8	umol/L			3.2-28.9	
					Blood Urea Nitrogen	3.96	mmol/L			1.79-9.28	
					Calcium	2.35	mmol/L			2.13-2.58	
					Carbon Dioxide	31	mmol/L			22-34	
					Chloride	104	mmol/L			96-108	
					Creatinine	98.1	umol/L			56.6-114.9	

Sex: M=Male, F=Female;
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Day = The presented date — First dose date + 1
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Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9046	34/M/BL		Check-in	17SEP2019 09:05 (-1)	Gamma Glutamyl Transferase	17	IU/L			5-85	
					Globulin	24	g/L			19-39	
					Glucose	5.16	mmol/L			3-6.44	
					Lactate Dehydrogenase	140	IU/L			82-216	
					Phosphate	0.97	mmol/L			0.68-1.52	
					Potassium	3.8	mmol/L			3.5-5	
					Protein	67	g/L			57-88	
					Sodium	139	mmol/L			132-145	
					Urate	315	umol/L			173-494	
		TPOXX 600 mg	Day 4	21SEP2019 07:31 (4)	Alanine Aminotransferase	12	IU/L			7-56	
					Albumin	43	g/L			37-55	
					Alkaline Phosphatase	36	IU/L			20-116	
					Anion Gap	8	mmol/L			6-17	
					Aspartate Aminotransferase	14	IU/L			10-40	
					Bilirubin	12.7	umol/L			3.2-28.9	

Sex: M=Male, F=Female;
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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9046	34/M/BL	TPOXX 600 mg	Day 4	21SEP2019 07:31 (4)	Blood Urea Nitrogen	3.82	mmol/L			1.79-9.28	
					Calcium	2.38	mmol/L			2.13-2.58	
					Carbon Dioxide	31	mmol/L			22-34	
					Chloride	104	mmol/L			96-108	
					Creatinine	98.1	umol/L			56.6-114.9	
					Gamma Glutamyl Transferase	17	IU/L			5-85	
					Globulin	25	g/L			19-39	
					Glucose	5.00	mmol/L			3-6.44	
					Lactate Dehydrogenase	125	IU/L			82-216	
					Phosphate	1.20	mmol/L			0.68-1.52	
					Potassium	4.3	mmol/L			3.5-5	
					Protein	68	g/L			57-88	
					Sodium	139	mmol/L			132-145	
					Urate	357	umol/L			173-494	

Sex: M=Male, F=Female;
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Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9046	34/M/BL	TPOXX 600 mg	Day 8 - 12 Hours Postdose	25SEP2019 08:06 (8)	Alanine Aminotransferase	13	IU/L			7-56	
					Albumin	46	g/L			37-55	
					Alkaline Phosphatase	34	IU/L			20-116	
					Anion Gap	8	mmol/L			6-17	
					Aspartate Aminotransferase	14	IU/L			10-40	
					Bilirubin	12.1	umol/L			3.2-28.9	
					Blood Urea Nitrogen	3.93	mmol/L			1.79-9.28	
					Calcium	2.48	mmol/L			2.13-2.58	
					Carbon Dioxide	32	mmol/L			22-34	
					Chloride	103	mmol/L			96-108	
					Creatinine	98.1	umol/L			56.6-114.9	
					Gamma Glutamyl Transferase	18	IU/L			5-85	
					Globulin	24	g/L			19-39	
					Glucose	4.94	mmol/L			3-6.44	
					Lactate Dehydrogenase	124	IU/L			82-216	

Sex: M=Male, F=Female;
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Day = The presented date — First dose date + 1
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Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9046	34/M/BL	TPOXX 600 mg	Day 8 - 12 Hours Postdose	25SEP2019 08:06 (8)	Phosphate	1.23	mmol/L			0.68-1.52	
					Potassium	4.3	mmol/L			3.5-5	
					Protein	70	g/L			57-88	
					Sodium	139	mmol/L			132-145	
					Urate	357	umol/L			173-494	
			Day 9	26SEP2019 08:06 (9)	Alanine Aminotransferase	11	IU/L			7-56	
					Albumin	45	g/L			37-55	
					Alkaline Phosphatase	39	IU/L			20-116	
					Anion Gap	9	mmol/L			6-17	
					Aspartate Aminotransferase	13	IU/L			10-40	
					Bilirubin	11.3	umol/L			3.2-28.9	
					Blood Urea Nitrogen	3.96	mmol/L			1.79-9.28	
					Calcium	2.43	mmol/L			2.13-2.58	
					Carbon Dioxide	32	mmol/L			22-34	

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Day = The presented date — First dose date + 1
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Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9046	34/M/BL	TPOXX 600 mg	Day 9	26SEP2019 08:06 (9)	Chloride	103	mmol/L			96-108	
					Creatinine	94.6	umol/L			56.6-114.9	
					Gamma Glutamyl Transferase	17	IU/L			5-85	
					Globulin	25	g/L			19-39	
					Glucose	5.00	mmol/L			3-6.44	
					Lactate Dehydrogenase	128	IU/L			82-216	
					Phosphate	1.16	mmol/L			0.68-1.52	
					Potassium	4.3	mmol/L			3.5-5	
					Protein	70	g/L			57-88	
					Sodium	140	mmol/L			132-145	
					Urate	363	umol/L			173-494	
9051	34/M/BL		Screening	19SEP2019 09:10 (-13)	Alanine Aminotransferase	31	IU/L			7-56	
					Albumin	44	g/L			37-55	
					Alkaline Phosphatase	33	IU/L			20-116	
					Anion Gap	10	mmol/L			6-17	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
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Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9051	34/M/BL		Screening	19SEP2019 09:10 (-13)	Aspartate Aminotransferase	17	IU/L			10-40	
					Bilirubin	6.2	umol/L			3.2-28.9	
					Blood Urea Nitrogen	4.78	mmol/L			1.79-9.28	
					Calcium	2.25	mmol/L			2.13-2.58	
					Carbon Dioxide	31	mmol/L			22-34	
					Chloride	104	mmol/L			96-108	
					Cholesterol	6.58	mmol/L	H NCS	G2	2.2-6.22	
					Creatinine	91.1	umol/L			56.6-114.9	
					Creatinine Clearance	184.4	mL/min			90-N/A	
					Gamma Glutamyl Transferase	54	IU/L			5-85	
					Globulin	19	g/L			19-39	
					Glucose	5.77	mmol/L			3-6.44	
					HDL Cholesterol	1.45	mmol/L			0.65-2.46	
					LDL Cholesterol	4.27	mmol/L	H NCS	G2	0.96-4.22	
					Lactate Dehydrogenase	215	IU/L			82-216	
					Phosphate	0.87	mmol/L			0.68-1.52	
					Potassium	4.2	mmol/L			3.5-5	

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R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9051	34/M/BL		Screening	19SEP2019 09:10 (-13)	Protein	63	g/L			57-88	
					Sodium	141	mmol/L			132-145	
					Triglycerides	1.84	mmol/L		G1	0-4.52	
					Urate	363	umol/L			173-494	
			Check-in	01OCT2019 09:01 (-1)	Alanine Aminotransferase	37	IU/L			7-56	
					Albumin	42	g/L			37-55	
					Alkaline Phosphatase	38	IU/L			20-116	
					Anion Gap	10	mmol/L			6-17	
					Aspartate Aminotransferase	21	IU/L			10-40	
					Bilirubin	9.1	umol/L			3.2-28.9	
					Blood Urea Nitrogen	3.89	mmol/L			1.79-9.28	
					Calcium	2.18	mmol/L			2.13-2.58	
					Carbon Dioxide	30	mmol/L			22-34	
					Chloride	103	mmol/L			96-108	
					Creatinine	88.4	umol/L			56.6-114.9	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9051	34/M/BL		Check-in	01OCT2019 09:01 (-1)	Gamma Glutamyl Transferase	64	IU/L			5-85	
					Globulin	20	g/L			19-39	
					Glucose	5.55	mmol/L			3-6.44	
					Lactate Dehydrogenase	209	IU/L			82-216	
					Phosphate	1.07	mmol/L			0.68-1.52	
					Potassium	3.9	mmol/L			3.5-5	
					Protein	62	g/L			57-88	
					Sodium	139	mmol/L			132-145	
					Urate	393	umol/L			173-494	
		TPOXX 600 mg	Day 4	05OCT2019 07:40 (4)	Alanine Aminotransferase	40	IU/L			7-56	
					Albumin	49	g/L			37-55	
					Alkaline Phosphatase	40	IU/L			20-116	
					Anion Gap	13	mmol/L			6-17	
					Aspartate Aminotransferase	20	IU/L			10-40	
					Bilirubin	9.6	umol/L			3.2-28.9	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9051	34/M/BL	TPOXX 600 mg	Day 4	05OCT2019 07:40 (4)	Blood Urea Nitrogen	4.21	mmol/L			1.79-9.28	
					Calcium	2.35	mmol/L			2.13-2.58	
					Carbon Dioxide	29	mmol/L			22-34	
					Chloride	101	mmol/L			96-108	
					Creatinine	91.9	umol/L			56.6-114.9	
					Gamma Glutamyl Transferase	69	IU/L			5-85	
					Globulin	25	g/L			19-39	
					Glucose	5.38	mmol/L			3-6.44	
					Lactate Dehydrogenase	215	IU/L			82-216	
					Phosphate	1.32	mmol/L			0.68-1.52	
					Potassium	4.0	mmol/L			3.5-5	
					Protein	74	g/L			57-88	
					Sodium	139	mmol/L			132-145	
					Urate	387	umol/L			173-494	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9051	34/M/BL	TPOXX 600 mg	Day 8 - 12 Hours Postdose	09OCT2019 08:15 (8)	Alanine Aminotransferase	40	IU/L			7-56	
					Albumin	46	g/L			37-55	
					Alkaline Phosphatase	44	IU/L			20-116	
					Anion Gap	12	mmol/L			6-17	
					Aspartate Aminotransferase	22	IU/L			10-40	
					Bilirubin	10.6	umol/L			3.2-28.9	
					Blood Urea Nitrogen	3.71	mmol/L			1.79-9.28	
					Calcium	2.33	mmol/L			2.13-2.58	
					Carbon Dioxide	29	mmol/L			22-34	
					Chloride	102	mmol/L			96-108	
					Creatinine	94.6	umol/L			56.6-114.9	
					Gamma Glutamyl Transferase	65	IU/L			5-85	
					Globulin	25	g/L			19-39	
					Glucose	5.05	mmol/L			3-6.44	
					Lactate Dehydrogenase	222	IU/L	H NCS		82-216	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9051	34/M/BL	TPOXX 600 mg	Day 8 - 12 Hours Postdose	09OCT2019 08:15 (8)	Phosphate	1.20	mmol/L			0.68-1.52	
					Potassium	4.2	mmol/L			3.5-5	
					Protein	71	g/L			57-88	
					Sodium	139	mmol/L			132-145	
					Urate	375	umol/L			173-494	
			Day 9	10OCT2019 08:15 (9)	Alanine Aminotransferase	42	IU/L			7-56	
					Albumin	47	g/L			37-55	
					Alkaline Phosphatase	44	IU/L			20-116	
					Anion Gap	13	mmol/L			6-17	
					Aspartate Aminotransferase	22	IU/L			10-40	
					Bilirubin	8.9	umol/L			3.2-28.9	
					Blood Urea Nitrogen	4.43	mmol/L			1.79-9.28	
					Calcium	2.30	mmol/L			2.13-2.58	
					Carbon Dioxide	28	mmol/L			22-34	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9051	34/M/BL	TPOXX 600 mg	Day 9	10OCT2019 08:15 (9)	Chloride	103	mmol/L			96-108	
					Creatinine	94.6	umol/L			56.6-114.9	
					Gamma Glutamyl Transferase	64	IU/L			5-85	
					Globulin	25	g/L			19-39	
					Glucose	5.55	mmol/L			3-6.44	
					Lactate Dehydrogenase	223	IU/L	H NCS		82-216	
					Phosphate	1.10	mmol/L			0.68-1.52	
					Potassium	4.0	mmol/L			3.5-5	
					Protein	72	g/L			57-88	
					Sodium	140	mmol/L			132-145	
					Urate	387	umol/L			173-494	
9052	42/M/BL		Screening	21SEP2019 13:12 (-11)	Alanine Aminotransferase	12	IU/L			7-56	
					Albumin	45	g/L			37-55	
					Alkaline Phosphatase	49	IU/L			20-116	
					Anion Gap	10	mmol/L			6-17	

Sex: M=Male, F=Female;
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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9052	42/M/BL		Screening	21SEP2019 13:12 (-11)	Aspartate Aminotransferase	17	IU/L			10-40	
					Bilirubin	7.7	umol/L			3.2-28.9	
					Blood Urea Nitrogen	4.25	mmol/L			1.79-9.28	
					Calcium	2.38	mmol/L			2.13-2.58	
					Carbon Dioxide	31	mmol/L			22-34	
					Chloride	103	mmol/L			96-108	
					Cholesterol	4.38	mmol/L			2.2-6.22	
					Creatinine	110.5	umol/L			56.6-114.9	
					Creatinine Clearance	131.8	mL/min			90-N/A	
					Gamma Glutamyl Transferase	13	IU/L			5-85	
					Globulin	32	g/L			19-39	
					Glucose	4.77	mmol/L			3-6.44	
					HDL Cholesterol	1.32	mmol/L			0.65-2.46	
					LDL Cholesterol	2.64	mmol/L			0.96-4.22	
					Lactate Dehydrogenase	179	IU/L			82-216	
					Phosphate	1.03	mmol/L			0.68-1.52	
					Potassium	3.8	mmol/L			3.5-5	

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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9052	42/M/BL		Screening	21SEP2019 13:12 (-11)	Protein	77	g/L			57-88	
					Sodium	140	mmol/L			132-145	
					Triglycerides	0.93	mmol/L			0-4.52	
					Urate	327	umol/L			173-494	
			Check-in	01OCT2019 09:15 (-1)	Alanine Aminotransferase	19	IU/L			7-56	
					Albumin	45	g/L			37-55	
					Alkaline Phosphatase	49	IU/L			20-116	
					Anion Gap	12	mmol/L			6-17	
					Aspartate Aminotransferase	19	IU/L			10-40	
					Bilirubin	8.0	umol/L			3.2-28.9	
					Blood Urea Nitrogen	5.18	mmol/L			1.79-9.28	
					Calcium	2.33	mmol/L			2.13-2.58	
					Carbon Dioxide	30	mmol/L			22-34	
					Chloride	102	mmol/L			96-108	
					Creatinine	109.6	umol/L			56.6-114.9	

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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9052	42/M/BL		Check-in	01OCT2019 09:15 (-1)	Gamma Glutamyl Transferase	14	IU/L			5-85	
					Globulin	32	g/L			19-39	
					Glucose	5.66	mmol/L			3-6.44	
					Lactate Dehydrogenase	184	IU/L			82-216	
					Phosphate	0.78	mmol/L			0.68-1.52	
					Potassium	3.8	mmol/L			3.5-5	
					Protein	77	g/L			57-88	
					Sodium	140	mmol/L			132-145	
					Urate	309	umol/L			173-494	
		TPOXX 600 mg	Day 4	05OCT2019 07:44 (4)	Alanine Aminotransferase	16	IU/L			7-56	
					Albumin	45	g/L			37-55	
					Alkaline Phosphatase	46	IU/L			20-116	
					Anion Gap	11	mmol/L			6-17	
					Aspartate Aminotransferase	16	IU/L			10-40	
					Bilirubin	8.2	umol/L			3.2-28.9	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
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Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9052	42/M/BL	TPOXX 600 mg	Day 4	05OCT2019 07:44 (4)	Blood Urea Nitrogen	4.57	mmol/L			1.79-9.28	
					Calcium	2.38	mmol/L			2.13-2.58	
					Carbon Dioxide	30	mmol/L			22-34	
					Chloride	102	mmol/L			96-108	
					Creatinine	108.7	umol/L			56.6-114.9	
					Gamma Glutamyl Transferase	13	IU/L			5-85	
					Globulin	34	g/L			19-39	
					Glucose	5.38	mmol/L			3-6.44	
					Lactate Dehydrogenase	171	IU/L			82-216	
					Phosphate	1.07	mmol/L			0.68-1.52	
					Potassium	3.6	mmol/L			3.5-5	
					Protein	79	g/L			57-88	
					Sodium	139	mmol/L			132-145	
					Urate	327	umol/L			173-494	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9052	42/M/BL	TPOXX 600 mg	Day 8 - 12 Hours Postdose	09OCT2019 08:19 (8)	Alanine Aminotransferase	16	IU/L			7-56	
					Albumin	44	g/L			37-55	
					Alkaline Phosphatase	53	IU/L			20-116	
					Anion Gap	12	mmol/L			6-17	
					Aspartate Aminotransferase	18	IU/L			10-40	
					Bilirubin	9.2	umol/L			3.2-28.9	
					Blood Urea Nitrogen	4.78	mmol/L			1.79-9.28	
					Calcium	2.35	mmol/L			2.13-2.58	
					Carbon Dioxide	29	mmol/L			22-34	
					Chloride	103	mmol/L			96-108	
					Creatinine	118.5	umol/L	H NCS		56.6-114.9	
					Gamma Glutamyl Transferase	14	IU/L			5-85	
					Globulin	34	g/L			19-39	
					Glucose	5.22	mmol/L			3-6.44	
					Lactate Dehydrogenase	176	IU/L			82-216	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
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Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9052	42/M/BL	TPOXX 600 mg	Day 8 - 12 Hours Postdose	09OCT2019 08:19 (8)	Phosphate	1.07	mmol/L			0.68-1.52	
					Potassium	3.8	mmol/L			3.5-5	
					Protein	78	g/L			57-88	
					Sodium	140	mmol/L			132-145	
					Urate	339	umol/L			173-494	
			Day 9	10OCT2019 08:19 (9)	Alanine Aminotransferase	17	IU/L			7-56	
					Albumin	43	g/L			37-55	
					Alkaline Phosphatase	53	IU/L			20-116	
					Anion Gap	11	mmol/L			6-17	
					Aspartate Aminotransferase	18	IU/L			10-40	
					Bilirubin	7.9	umol/L			3.2-28.9	
					Blood Urea Nitrogen	4.93	mmol/L			1.79-9.28	
					Calcium	2.30	mmol/L			2.13-2.58	
					Carbon Dioxide	30	mmol/L			22-34	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
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Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9052	42/M/BL	TPOXX 600 mg	Day 9	10OCT2019 08:19 (9)	Chloride	103	mmol/L			96-108	
					Creatinine	114.9	umol/L			56.6-114.9	
					Gamma Glutamyl Transferase	15	IU/L			5-85	
					Globulin	36	g/L			19-39	
					Glucose	5.16	mmol/L			3-6.44	
					Lactate Dehydrogenase	166	IU/L			82-216	
					Phosphate	0.97	mmol/L			0.68-1.52	
					Potassium	3.8	mmol/L			3.5-5	
					Protein	79	g/L			57-88	
					Sodium	140	mmol/L			132-145	
					Urate	351	umol/L			173-494	
9056	31/F/BL		Screening	24SEP2019 10:06 (-8)	Alanine Aminotransferase	14	IU/L			4-45	
					Albumin	44	g/L			38-49	
					Alkaline Phosphatase	49	IU/L			20-116	
					Anion Gap	12	mmol/L			6-17	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9056	31/F/BL		Screening	24SEP2019 10:06 (-8)	Aspartate Aminotransferase	13	IU/L			10-40	
					Bilirubin	4.6	umol/L			3.2-21.7	
					Blood Urea Nitrogen	4.21	mmol/L			1.79-9.28	
					Calcium	2.30	mmol/L			2.13-2.58	
					Carbon Dioxide	29	mmol/L			22-34	
					Chloride	104	mmol/L			96-108	
					Cholesterol	4.66	mmol/L			2.2-6.22	
					Creatinine	57.5	umol/L			39.8-93.7	
					Creatinine Clearance	241.5	mL/min			90-N/A	
					Gamma Glutamyl Transferase	21	IU/L			5-85	
					Globulin	26	g/L			19-39	
					Glucose	5.05	mmol/L			3-6.44	
					HDL Cholesterol	1.11	mmol/L			0.88-2.36	
					LDL Cholesterol	3.00	mmol/L			0.96-4.22	
					Lactate Dehydrogenase	125	IU/L			82-216	
					Phosphate	0.90	mmol/L			0.68-1.52	
					Potassium	4.6	mmol/L			3.5-5	

Sex: M=Male, F=Female;
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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9056	31/F/BL		Screening	24SEP2019 10:06 (-8)	Protein	70	g/L			57-88	
					Sodium	140	mmol/L			132-145	
					Triglycerides	1.18	mmol/L			0-4.52	
					Urate	422	umol/L	H NCS		119-345	
			Check-in	01OCT2019 09:26 (-1)	Alanine Aminotransferase	15	IU/L			4-45	
					Albumin	43	g/L			38-49	
					Alkaline Phosphatase	51	IU/L			20-116	
					Anion Gap	10	mmol/L			6-17	
					Aspartate Aminotransferase	14	IU/L			10-40	
					Bilirubin	6.2	umol/L			3.2-21.7	
					Blood Urea Nitrogen	4.21	mmol/L			1.79-9.28	
					Calcium	2.38	mmol/L			2.13-2.58	
					Carbon Dioxide	31	mmol/L			22-34	
					Chloride	101	mmol/L			96-108	
					Creatinine	69.8	umol/L			39.8-93.7	

Sex: M=Male, F=Female;
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9056	31/F/BL		Check-in	01OCT2019 09:26 (-1)	Gamma Glutamyl Transferase	22	IU/L			5-85	
					Globulin	28	g/L			19-39	
					Glucose	4.77	mmol/L			3-6.44	
					Lactate Dehydrogenase	120	IU/L			82-216	
					Phosphate	1.10	mmol/L			0.68-1.52	
					Potassium	4.2	mmol/L			3.5-5	
					Protein	71	g/L			57-88	
					Sodium	138	mmol/L			132-145	
					Urate	434	umol/L	H NCS		119-345	
		TPOXX 600 mg	Day 4	05OCT2019 07:25 (4)	Alanine Aminotransferase	14	IU/L			4-45	
					Albumin	45	g/L			38-49	
					Alkaline Phosphatase	47	IU/L			20-116	
					Anion Gap	13	mmol/L			6-17	
					Aspartate Aminotransferase	12	IU/L			10-40	
					Bilirubin	7.7	umol/L			3.2-21.7	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9056	31/F/BL	TPOXX 600 mg	Day 4	05OCT2019 07:25 (4)	Blood Urea Nitrogen	4.07	mmol/L			1.79-9.28	
					Calcium	2.38	mmol/L			2.13-2.58	
					Carbon Dioxide	28	mmol/L			22-34	
					Chloride	102	mmol/L			96-108	
					Creatinine	73.4	umol/L			39.8-93.7	
					Gamma Glutamyl Transferase	22	IU/L			5-85	
					Globulin	29	g/L			19-39	
					Glucose	5.33	mmol/L			3-6.44	
					Lactate Dehydrogenase	108	IU/L			82-216	
					Phosphate	1.00	mmol/L			0.68-1.52	
					Potassium	4.2	mmol/L			3.5-5	
					Protein	74	g/L			57-88	
					Sodium	139	mmol/L			132-145	
					Urate	446	umol/L	H NCS		119-345	

Sex: M=Male, F=Female;
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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9056	31/F/BL	TPOXX 600 mg	Day 8 - 12 Hours Postdose	09OCT2019 08:03 (8)	Alanine Aminotransferase	17	IU/L			4-45	
					Albumin	46	g/L			38-49	
					Alkaline Phosphatase	56	IU/L			20-116	
					Anion Gap	12	mmol/L			6-17	
					Aspartate Aminotransferase	15	IU/L			10-40	
					Bilirubin	8.4	umol/L			3.2-21.7	
					Blood Urea Nitrogen	4.07	mmol/L			1.79-9.28	
					Calcium	2.50	mmol/L			2.13-2.58	
					Carbon Dioxide	30	mmol/L			22-34	
					Chloride	101	mmol/L			96-108	
					Creatinine	76.9	umol/L			39.8-93.7	
					Gamma Glutamyl Transferase	24	IU/L			5-85	
					Globulin	31	g/L			19-39	
					Glucose	4.94	mmol/L			3-6.44	
					Lactate Dehydrogenase	111	IU/L			82-216	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9056	31/F/BL	TPOXX 600 mg	Day 8 - 12 Hours Postdose	09OCT2019 08:03 (8)	Phosphate	1.16	mmol/L			0.68-1.52	
					Potassium	4.6	mmol/L			3.5-5	
					Protein	77	g/L			57-88	
					Sodium	138	mmol/L			132-145	
					Urate	446	umol/L	H NCS		119-345	
			Day 9	10OCT2019 08:00 (9)	Alanine Aminotransferase	15	IU/L			4-45	
					Albumin	43	g/L			38-49	
					Alkaline Phosphatase	52	IU/L			20-116	
					Anion Gap	11	mmol/L			6-17	
					Aspartate Aminotransferase	14	IU/L			10-40	
					Bilirubin	6.5	umol/L			3.2-21.7	
					Blood Urea Nitrogen	4.57	mmol/L			1.79-9.28	
					Calcium	2.28	mmol/L			2.13-2.58	
					Carbon Dioxide	29	mmol/L			22-34	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9056	31/F/BL	TPOXX 600 mg	Day 9	10OCT2019 08:00 (9)	Chloride	103	mmol/L			96-108	
					Creatinine	76.0	umol/L			39.8-93.7	
					Gamma Glutamyl Transferase	23	IU/L			5-85	
					Globulin	29	g/L			19-39	
					Glucose	4.72	mmol/L			3-6.44	
					Lactate Dehydrogenase	103	IU/L			82-216	
					Phosphate	1.00	mmol/L			0.68-1.52	
					Potassium	4.1	mmol/L			3.5-5	
					Protein	72	g/L			57-88	
					Sodium	139	mmol/L			132-145	
					Urate	446	umol/L	H NCS		119-345	
9057	29/F/W		Screening	25SEP2019 16:27 (-7)	Alanine Aminotransferase	25	IU/L			4-45	
					Albumin	41	g/L			38-49	
					Alkaline Phosphatase	70	IU/L			20-116	
					Anion Gap	11	mmol/L			6-17	

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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9057	29/F/W		Screening	25SEP2019 16:27 (-7)	Aspartate Aminotransferase	22	IU/L			10-40	
					Bilirubin	6.3	umol/L			3.2-21.7	
					Blood Urea Nitrogen	3.64	mmol/L			1.79-9.28	
					Calcium	2.33	mmol/L			2.13-2.58	
					Carbon Dioxide	29	mmol/L			22-34	
					Chloride	102	mmol/L			96-108	
					Cholesterol	6.53	mmol/L	H NCS	G2	2.2-6.22	
					Creatinine	45.1	umol/L			39.8-93.7	
					Creatinine Clearance	328.9	mL/min			90-N/A	
					Gamma Glutamyl Transferase	26	IU/L			5-85	
					Globulin	31	g/L			19-39	
					Glucose	4.55	mmol/L			3-6.44	
					HDL Cholesterol	0.93	mmol/L			0.88-2.36	
					LDL Cholesterol	3.68	mmol/L		G1	0.96-4.22	
					Lactate Dehydrogenase	115	IU/L			82-216	
					Phosphate	1.13	mmol/L			0.68-1.52	
					Potassium	4.0	mmol/L			3.5-5	

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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9057	29/F/W		Screening	25SEP2019 16:27 (-7)	Protein	72	g/L			57-88	
					Sodium	138	mmol/L			132-145	
					Triglycerides	4.19	mmol/L		G2	0-4.52	
					Urate	327	umol/L			119-345	
			Check-in	01OCT2019 09:22 (-1)	Alanine Aminotransferase	20	IU/L			4-45	
					Albumin	40	g/L			38-49	
					Alkaline Phosphatase	70	IU/L			20-116	
					Anion Gap	11	mmol/L			6-17	
					Aspartate Aminotransferase	15	IU/L			10-40	
					Bilirubin	6.2	umol/L			3.2-21.7	
					Blood Urea Nitrogen	2.93	mmol/L			1.79-9.28	
					Calcium	2.23	mmol/L			2.13-2.58	
					Carbon Dioxide	28	mmol/L			22-34	
					Chloride	102	mmol/L			96-108	
					Creatinine	46.0	umol/L			39.8-93.7	

Sex: M=Male, F=Female;
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Day = The presented date — First dose date + 1
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9057	29/F/W		Check-in	01OCT2019 09:22 (-1)	Gamma Glutamyl Transferase	25	IU/L			5-85	
					Globulin	30	g/L			19-39	
					Glucose	5.22	mmol/L			3-6.44	
					Lactate Dehydrogenase	114	IU/L			82-216	
					Phosphate	0.97	mmol/L			0.68-1.52	
					Potassium	4.0	mmol/L			3.5-5	
					Protein	70	g/L			57-88	
					Sodium	137	mmol/L			132-145	
					Urate	321	umol/L			119-345	
		TPOXX 600 mg	Day 4	05OCT2019 07:28 (4)	Alanine Aminotransferase	21	IU/L			4-45	
					Albumin	43	g/L			38-49	
					Alkaline Phosphatase	67	IU/L			20-116	
					Anion Gap	15	mmol/L			6-17	
					Aspartate Aminotransferase	17	IU/L			10-40	
					Bilirubin	6.3	umol/L			3.2-21.7	

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Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9057	29/F/W	TPOXX 600 mg	Day 4	05OCT2019 07:28 (4)	Blood Urea Nitrogen	3.93	mmol/L			1.79-9.28	
					Calcium	2.33	mmol/L			2.13-2.58	
					Carbon Dioxide	24	mmol/L			22-34	
					Chloride	103	mmol/L			96-108	
					Creatinine	47.7	umol/L			39.8-93.7	
					Gamma Glutamyl Transferase	25	IU/L			5-85	
					Globulin	32	g/L			19-39	
					Glucose	5.66	mmol/L			3-6.44	
					Lactate Dehydrogenase	103	IU/L			82-216	
					Phosphate	1.36	mmol/L			0.68-1.52	
					Potassium	4.1	mmol/L			3.5-5	
					Protein	75	g/L			57-88	
					Sodium	138	mmol/L			132-145	
					Urate	363	umol/L	H NCS		119-345	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9057	29/F/W	TPOXX 600 mg	Day 8 - 12 Hours Postdose	09OCT2019 08:03 (8)	Alanine Aminotransferase	21	IU/L			4-45	
					Albumin	41	g/L			38-49	
					Alkaline Phosphatase	71	IU/L			20-116	
					Anion Gap	13	mmol/L			6-17	
					Aspartate Aminotransferase	17	IU/L			10-40	
					Bilirubin	6.8	umol/L			3.2-21.7	
					Blood Urea Nitrogen	3.28	mmol/L			1.79-9.28	
					Calcium	2.38	mmol/L			2.13-2.58	
					Carbon Dioxide	27	mmol/L			22-34	
					Chloride	102	mmol/L			96-108	
					Creatinine	49.5	umol/L			39.8-93.7	
					Gamma Glutamyl Transferase	26	IU/L			5-85	
					Globulin	32	g/L			19-39	
					Glucose	5.27	mmol/L			3-6.44	
					Lactate Dehydrogenase	96	IU/L			82-216	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9057	29/F/W	TPOXX 600 mg	Day 8 - 12 Hours Postdose	09OCT2019 08:03 (8)	Phosphate	1.29	mmol/L			0.68-1.52	
					Potassium	4.1	mmol/L			3.5-5	
					Protein	73	g/L			57-88	
					Sodium	138	mmol/L			132-145	
					Urate	345	umol/L			119-345	
			Day 9	10OCT2019 08:03 (9)	Alanine Aminotransferase	22	IU/L			4-45	
					Albumin	44	g/L			38-49	
					Alkaline Phosphatase	78	IU/L			20-116	
					Anion Gap	14	mmol/L			6-17	
					Aspartate Aminotransferase	17	IU/L			10-40	
					Bilirubin	5.6	umol/L			3.2-21.7	
					Blood Urea Nitrogen	4.00	mmol/L			1.79-9.28	
					Calcium	2.38	mmol/L			2.13-2.58	
					Carbon Dioxide	27	mmol/L			22-34	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9057	29/F/W	TPOXX 600 mg	Day 9	10OCT2019 08:03 (9)	Chloride	102	mmol/L			96-108	
					Creatinine	52.2	umol/L			39.8-93.7	
					Gamma Glutamyl Transferase	29	IU/L			5-85	
					Globulin	34	g/L			19-39	
					Glucose	5.00	mmol/L			3-6.44	
					Lactate Dehydrogenase	99	IU/L			82-216	
					Phosphate	1.16	mmol/L			0.68-1.52	
					Potassium	4.0	mmol/L			3.5-5	
					Protein	78	g/L			57-88	
					Sodium	139	mmol/L			132-145	
					Urate	351	umol/L	H NCS		119-345	
9058	32/M/W		Screening	26SEP2019 09:26 (-20)	Alanine Aminotransferase	39	IU/L			7-56	
					Albumin	46	g/L			37-55	
					Alkaline Phosphatase	72	IU/L			20-116	
					Anion Gap	12	mmol/L			6-17	

Sex: M=Male, F=Female;
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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9058	32/M/W		Screening	26SEP2019 09:26 (-20)	Aspartate Aminotransferase	20	IU/L			10-40	
					Bilirubin	5.3	umol/L			3.2-28.9	
					Blood Urea Nitrogen	5.57	mmol/L			1.79-9.28	
					Calcium	2.28	mmol/L			2.13-2.58	
					Carbon Dioxide	30	mmol/L			22-34	
					Chloride	102	mmol/L			96-108	
					Cholesterol	6.66	mmol/L	H NCS	G2	2.2-6.22	
					Creatinine	84.0	umol/L			56.6-114.9	
					Creatinine Clearance	192.6	mL/min			90-N/A	
					Gamma Glutamyl Transferase	23	IU/L			5-85	
					Globulin	28	g/L			19-39	
					Glucose	5.72	mmol/L			3-6.44	
					HDL Cholesterol	1.45	mmol/L			0.65-2.46	
					LDL Cholesterol	4.77	mmol/L	H NCS	G2	0.96-4.22	
					Lactate Dehydrogenase	85	IU/L			82-216	
					Phosphate	1.23	mmol/L			0.68-1.52	
					Potassium	4.0	mmol/L			3.5-5	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9058	32/M/W		Screening	26SEP2019 09:26 (-20)	Protein	74	g/L			57-88	
					Sodium	140	mmol/L			132-145	
					Triglycerides	0.95	mmol/L			0-4.52	
					Urate	345	umol/L			173-494	
			Check-in	15OCT2019 09:07 (-1)	Alanine Aminotransferase	34	IU/L			7-56	
					Albumin	45	g/L			37-55	
					Alkaline Phosphatase	56	IU/L			20-116	
					Anion Gap	11	mmol/L			6-17	
					Aspartate Aminotransferase	20	IU/L			10-40	
					Bilirubin	6.8	umol/L			3.2-28.9	
					Blood Urea Nitrogen	5.11	mmol/L			1.79-9.28	
					Calcium	2.28	mmol/L			2.13-2.58	
					Carbon Dioxide	29	mmol/L			22-34	
					Chloride	103	mmol/L			96-108	
					Creatinine	75.1	umol/L			56.6-114.9	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9058	32/M/W		Check-in	15OCT2019 09:07 (-1)	Gamma Glutamyl Transferase	23	IU/L			5-85	
					Globulin	28	g/L			19-39	
					Glucose	5.27	mmol/L			3-6.44	
					Lactate Dehydrogenase	82	IU/L			82-216	
					Phosphate	1.29	mmol/L			0.68-1.52	
					Potassium	4.1	mmol/L			3.5-5	
					Protein	73	g/L			57-88	
					Sodium	139	mmol/L			132-145	
					Urate	345	umol/L			173-494	
		TPOXX 600 mg	Day 4	19OCT2019 07:32 (4)	Alanine Aminotransferase	33	IU/L			7-56	
					Albumin	46	g/L			37-55	
					Alkaline Phosphatase	53	IU/L			20-116	
					Anion Gap	11	mmol/L			6-17	
					Aspartate Aminotransferase	19	IU/L			10-40	
					Bilirubin	10.6	umol/L			3.2-28.9	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9058	32/M/W	TPOXX 600 mg	Day 4	19OCT2019 07:32 (4)	Blood Urea Nitrogen	5.39	mmol/L			1.79-9.28	
					Calcium	2.38	mmol/L			2.13-2.58	
					Carbon Dioxide	31	mmol/L			22-34	
					Chloride	102	mmol/L			96-108	
					Creatinine	76.9	umol/L			56.6-114.9	
					Gamma Glutamyl Transferase	24	IU/L			5-85	
					Globulin	29	g/L			19-39	
					Glucose	4.77	mmol/L			3-6.44	
					Lactate Dehydrogenase	82	IU/L			82-216	
					Phosphate	1.42	mmol/L			0.68-1.52	
					Potassium	4.2	mmol/L			3.5-5	
					Protein	75	g/L			57-88	
					Sodium	140	mmol/L			132-145	
					Urate	351	umol/L			173-494	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9058	32/M/W	TPOXX 600 mg	Day 8 - 12 Hours Postdose	23OCT2019 08:29 (8)	Alanine Aminotransferase	32	IU/L			7-56	
					Albumin	45	g/L			37-55	
					Alkaline Phosphatase	61	IU/L			20-116	
					Anion Gap	11	mmol/L			6-17	
					Aspartate Aminotransferase	18	IU/L			10-40	
					Bilirubin	9.9	umol/L			3.2-28.9	
					Blood Urea Nitrogen	5.39	mmol/L			1.79-9.28	
					Calcium	2.38	mmol/L			2.13-2.58	
					Carbon Dioxide	31	mmol/L			22-34	
					Chloride	101	mmol/L			96-108	
					Creatinine	77.8	umol/L			56.6-114.9	
					Gamma Glutamyl Transferase	25	IU/L			5-85	
					Globulin	30	g/L			19-39	
					Glucose	4.83	mmol/L			3-6.44	
					Lactate Dehydrogenase	75	IU/L	L NCS		82-216	

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Day = The presented date — First dose date + 1
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Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9058	32/M/W	TPOXX 600 mg	Day 8 - 12 Hours Postdose	23OCT2019 08:29 (8)	Phosphate	1.32	mmol/L			0.68-1.52	
					Potassium	3.9	mmol/L			3.5-5	
					Protein	75	g/L			57-88	
					Sodium	139	mmol/L			132-145	
					Urate	351	umol/L			173-494	
			Day 9	24OCT2019 08:08 (9)	Alanine Aminotransferase	33	IU/L			7-56	
					Albumin	48	g/L			37-55	
					Alkaline Phosphatase	63	IU/L			20-116	
					Anion Gap	11	mmol/L			6-17	
					Aspartate Aminotransferase	18	IU/L			10-40	
					Bilirubin	8.0	umol/L			3.2-28.9	
					Blood Urea Nitrogen	6.46	mmol/L			1.79-9.28	
					Calcium	2.43	mmol/L			2.13-2.58	
					Carbon Dioxide	30	mmol/L			22-34	

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Day = The presented date — First dose date + 1
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9058	32/M/W	TPOXX 600 mg	Day 9	24OCT2019 08:08 (9)	Chloride	104	mmol/L			96-108	
					Creatinine	86.6	umol/L			56.6-114.9	
					Gamma Glutamyl Transferase	25	IU/L			5-85	
					Globulin	29	g/L			19-39	
					Glucose	5.16	mmol/L			3-6.44	
					Lactate Dehydrogenase	85	IU/L			82-216	
					Phosphate	1.23	mmol/L			0.68-1.52	
					Potassium	4.5	mmol/L			3.5-5	
					Protein	77	g/L			57-88	
					Sodium	140	mmol/L			132-145	
					Urate	363	umol/L			173-494	
9061	21/F/BL		Screening	26SEP2019 11:06 (-20)	Alanine Aminotransferase	13	IU/L			4-45	
					Albumin	42	g/L			38-49	
					Alkaline Phosphatase	66	IU/L			20-116	
					Anion Gap	13	mmol/L			6-17	

Sex: M=Male, F=Female;
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9061	21/F/BL		Screening	26SEP2019 11:06 (-20)	Aspartate Aminotransferase	12	IU/L			10-40	
					Bilirubin	3.1	umol/L	L NCS		3.2-21.7	
					Blood Urea Nitrogen	5.00	mmol/L			1.79-9.28	
					Calcium	2.30	mmol/L			2.13-2.58	
					Carbon Dioxide	27	mmol/L			22-34	
					Chloride	105	mmol/L			96-108	
					Cholesterol	3.24	mmol/L			2.2-6.22	
					Creatinine	55.7	umol/L			39.8-93.7	
					Creatinine Clearance	278.7	mL/min			90-N/A	
					Gamma Glutamyl Transferase	14	IU/L			5-85	
					Globulin	27	g/L			19-39	
					Glucose	4.88	mmol/L			3-6.44	
					HDL Cholesterol	0.88	mmol/L			0.88-2.36	
					LDL Cholesterol	1.94	mmol/L			0.96-4.22	
					Lactate Dehydrogenase	147	IU/L			82-216	
					Phosphate	1.39	mmol/L			0.68-1.52	
					Potassium	3.8	mmol/L			3.5-5	

Sex: M=Male, F=Female;
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9061	21/F/BL		Screening	26SEP2019 11:06 (-20)	Protein	69	g/L			57-88	
					Sodium	141	mmol/L			132-145	
					Triglycerides	0.93	mmol/L			0-4.52	
					Urate	309	umol/L			119-345	
			Check-in	15OCT2019 09:01 (-1)	Alanine Aminotransferase	14	IU/L			4-45	
					Albumin	41	g/L			38-49	
					Alkaline Phosphatase	60	IU/L			20-116	
					Anion Gap	10	mmol/L			6-17	
					Aspartate Aminotransferase	15	IU/L			10-40	
					Bilirubin	4.1	umol/L			3.2-21.7	
					Blood Urea Nitrogen	4.11	mmol/L			1.79-9.28	
					Calcium	2.25	mmol/L			2.13-2.58	
					Carbon Dioxide	29	mmol/L			22-34	
					Chloride	104	mmol/L			96-108	
					Creatinine	60.1	umol/L			39.8-93.7	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9061	21/F/BL		Check-in	15OCT2019 09:01 (-1)	Gamma Glutamyl Transferase	17	IU/L			5-85	
					Globulin	28	g/L			19-39	
					Glucose	4.66	mmol/L			3-6.44	
					Lactate Dehydrogenase	167	IU/L			82-216	
					Phosphate	1.29	mmol/L			0.68-1.52	
					Potassium	3.8	mmol/L			3.5-5	
					Protein	69	g/L			57-88	
					Sodium	139	mmol/L			132-145	
					Urate	321	umol/L			119-345	
		TPOXX 600 mg	Day 4	19OCT2019 07:35 (4)	Alanine Aminotransferase	12	IU/L			4-45	
					Albumin	41	g/L			38-49	
					Alkaline Phosphatase	54	IU/L			20-116	
					Anion Gap	14	mmol/L			6-17	
					Aspartate Aminotransferase	14	IU/L			10-40	
					Bilirubin	6.2	umol/L			3.2-21.7	

Sex: M=Male, F=Female;
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Day = The presented date — First dose date + 1
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Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9061	21/F/BL	TPOXX 600 mg	Day 4	19OCT2019 07:35 (4)	Blood Urea Nitrogen	3.96	mmol/L			1.79-9.28	
					Calcium	2.35	mmol/L			2.13-2.58	
					Carbon Dioxide	29	mmol/L			22-34	
					Chloride	101	mmol/L			96-108	
					Creatinine	60.1	umol/L			39.8-93.7	
					Gamma Glutamyl Transferase	18	IU/L			5-85	
					Globulin	30	g/L			19-39	
					Glucose	4.61	mmol/L			3-6.44	
					Lactate Dehydrogenase	146	IU/L			82-216	
					Phosphate	1.52	mmol/L			0.68-1.52	
					Potassium	3.6	mmol/L			3.5-5	
					Protein	71	g/L			57-88	
					Sodium	140	mmol/L			132-145	
					Urate	351	umol/L	H NCS		119-345	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9061	21/F/BL	TPOXX 600 mg	Day 8 - 12 Hours Postdose	23OCT2019 08:06 (8)	Alanine Aminotransferase	13	IU/L			4-45	
					Albumin	40	g/L			38-49	
					Alkaline Phosphatase	61	IU/L			20-116	
					Anion Gap	13	mmol/L			6-17	
					Aspartate Aminotransferase	13	IU/L			10-40	
					Bilirubin	6.7	umol/L			3.2-21.7	
					Blood Urea Nitrogen	3.71	mmol/L			1.79-9.28	
					Calcium	2.35	mmol/L			2.13-2.58	
					Carbon Dioxide	28	mmol/L			22-34	
					Chloride	101	mmol/L			96-108	
					Creatinine	61.9	umol/L			39.8-93.7	
					Gamma Glutamyl Transferase	17	IU/L			5-85	
					Globulin	29	g/L			19-39	
					Glucose	4.66	mmol/L			3-6.44	
					Lactate Dehydrogenase	135	IU/L			82-216	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9061	21/F/BL	TPOXX 600 mg	Day 8 - 12 Hours Postdose	23OCT2019 08:06 (8)	Phosphate	1.42	mmol/L			0.68-1.52	
					Potassium	3.9	mmol/L			3.5-5	
					Protein	69	g/L			57-88	
					Sodium	138	mmol/L			132-145	
					Urate	315	umol/L			119-345	
			Day 9	24OCT2019 08:03 (9)	Alanine Aminotransferase	14	IU/L			4-45	
					Albumin	45	g/L			38-49	
					Alkaline Phosphatase	64	IU/L			20-116	
					Anion Gap	11	mmol/L			6-17	
					Aspartate Aminotransferase	14	IU/L			10-40	
					Bilirubin	6.8	umol/L			3.2-21.7	
					Blood Urea Nitrogen	4.93	mmol/L			1.79-9.28	
					Calcium	2.40	mmol/L			2.13-2.58	
					Carbon Dioxide	29	mmol/L			22-34	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9061	21/F/BL	TPOXX 600 mg	Day 9	24OCT2019 08:03 (9)	Chloride	103	mmol/L			96-108	
					Creatinine	68.1	umol/L			39.8-93.7	
					Gamma Glutamyl Transferase	18	IU/L			5-85	
					Globulin	30	g/L			19-39	
					Glucose	4.61	mmol/L			3-6.44	
					Lactate Dehydrogenase	157	IU/L			82-216	
					Phosphate	1.29	mmol/L			0.68-1.52	
					Potassium	3.7	mmol/L			3.5-5	
					Protein	75	g/L			57-88	
					Sodium	139	mmol/L			132-145	
					Urate	333	umol/L			119-345	
9062	33/M/BL		Screening	30SEP2019 10:25 (-2)	Alanine Aminotransferase	39	IU/L			7-56	
					Albumin	43	g/L			37-55	
					Alkaline Phosphatase	78	IU/L			20-116	
					Anion Gap	13	mmol/L			6-17	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9062	33/M/BL		Screening	30SEP2019 10:25 (-2)	Aspartate Aminotransferase	21	IU/L			10-40	
					Bilirubin	6.3	umol/L			3.2-28.9	
					Blood Urea Nitrogen	5.39	mmol/L			1.79-9.28	
					Calcium	2.28	mmol/L			2.13-2.58	
					Carbon Dioxide	29	mmol/L			22-34	
					Chloride	100	mmol/L			96-108	
					Cholesterol	3.44	mmol/L			2.2-6.22	
					Creatinine	84.9	umol/L			56.6-114.9	
					Creatinine Clearance	207.4	mL/min			90-N/A	
					Gamma Glutamyl Transferase	58	IU/L			5-85	
					Globulin	27	g/L			19-39	
					Glucose	5.11	mmol/L			3-6.44	
					HDL Cholesterol	0.93	mmol/L			0.65-2.46	
					LDL Cholesterol	1.79	mmol/L			0.96-4.22	
					Lactate Dehydrogenase	175	IU/L			82-216	
					Phosphate	1.16	mmol/L			0.68-1.52	
					Potassium	4.4	mmol/L			3.5-5	

Sex: M=Male, F=Female;
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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9062	33/M/BL		Screening	30SEP2019 10:25 (-2)	Protein	70	g/L			57-88	
					Sodium	138	mmol/L			132-145	
					Triglycerides	1.60	mmol/L			0-4.52	
					Urate	404	umol/L			173-494	
			Check-in	01OCT2019 09:29 (-1)	Alanine Aminotransferase	37	IU/L			7-56	
					Albumin	43	g/L			37-55	
					Alkaline Phosphatase	76	IU/L			20-116	
					Anion Gap	11	mmol/L			6-17	
					Aspartate Aminotransferase	19	IU/L			10-40	
					Bilirubin	5.6	umol/L			3.2-28.9	
					Blood Urea Nitrogen	5.60	mmol/L			1.79-9.28	
					Calcium	2.33	mmol/L			2.13-2.58	
					Carbon Dioxide	31	mmol/L			22-34	
					Chloride	100	mmol/L			96-108	
					Creatinine	88.4	umol/L			56.6-114.9	

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Day = The presented date — First dose date + 1
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Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9062	33/M/BL		Check-in	01OCT2019 09:29 (-1)	Gamma Glutamyl Transferase	57	IU/L			5-85	
					Globulin	27	g/L			19-39	
					Glucose	5.49	mmol/L			3-6.44	
					Lactate Dehydrogenase	159	IU/L			82-216	
					Phosphate	1.13	mmol/L			0.68-1.52	
					Potassium	4.6	mmol/L			3.5-5	
					Protein	70	g/L			57-88	
					Sodium	137	mmol/L			132-145	
					Urate	399	umol/L			173-494	
		TPOXX 600 mg	Day 4	05OCT2019 07:31 (4)	Alanine Aminotransferase	31	IU/L			7-56	
					Albumin	44	g/L			37-55	
					Alkaline Phosphatase	77	IU/L			20-116	
					Anion Gap	9	mmol/L			6-17	
					Aspartate Aminotransferase	14	IU/L			10-40	
					Bilirubin	5.5	umol/L			3.2-28.9	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9062	33/M/BL	TPOXX 600 mg	Day 4	05OCT2019 07:31 (4)	Blood Urea Nitrogen	4.21	mmol/L			1.79-9.28	
					Calcium	2.35	mmol/L			2.13-2.58	
					Carbon Dioxide	32	mmol/L			22-34	
					Chloride	102	mmol/L			96-108	
					Creatinine	99.0	umol/L			56.6-114.9	
					Gamma Glutamyl Transferase	48	IU/L			5-85	
					Globulin	28	g/L			19-39	
					Glucose	5.38	mmol/L			3-6.44	
					Lactate Dehydrogenase	126	IU/L			82-216	
					Phosphate	1.16	mmol/L			0.68-1.52	
					Potassium	4.2	mmol/L			3.5-5	
					Protein	72	g/L			57-88	
					Sodium	139	mmol/L			132-145	
					Urate	404	umol/L			173-494	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
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Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9062	33/M/BL	TPOXX 600 mg	Day 8 - 12 Hours Postdose	09OCT2019 08:06 (8)	Alanine Aminotransferase	31	IU/L			7-56	
					Albumin	44	g/L			37-55	
					Alkaline Phosphatase	89	IU/L			20-116	
					Anion Gap	10	mmol/L			6-17	
					Aspartate Aminotransferase	16	IU/L			10-40	
					Bilirubin	6.8	umol/L			3.2-28.9	
					Blood Urea Nitrogen	4.36	mmol/L			1.79-9.28	
					Calcium	2.43	mmol/L			2.13-2.58	
					Carbon Dioxide	31	mmol/L			22-34	
					Chloride	102	mmol/L			96-108	
					Creatinine	109.6	umol/L			56.6-114.9	
					Gamma Glutamyl Transferase	43	IU/L			5-85	
					Globulin	29	g/L			19-39	
					Glucose	5.11	mmol/L			3-6.44	
					Lactate Dehydrogenase	131	IU/L			82-216	

Sex: M=Male, F=Female;
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Day = The presented date — First dose date + 1
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9062	33/M/BL	TPOXX 600 mg	Day 8 - 12 Hours Postdose	09OCT2019 08:06 (8)	Phosphate	1.45	mmol/L			0.68-1.52	
					Potassium	4.3	mmol/L			3.5-5	
					Protein	73	g/L			57-88	
					Sodium	139	mmol/L			132-145	
					Urate	399	umol/L			173-494	
			Day 9	10OCT2019 08:06 (9)	Alanine Aminotransferase	32	IU/L			7-56	
					Albumin	44	g/L			37-55	
					Alkaline Phosphatase	90	IU/L			20-116	
					Anion Gap	11	mmol/L			6-17	
					Aspartate Aminotransferase	17	IU/L			10-40	
					Bilirubin	5.8	umol/L			3.2-28.9	
					Blood Urea Nitrogen	4.46	mmol/L			1.79-9.28	
					Calcium	2.35	mmol/L			2.13-2.58	
					Carbon Dioxide	32	mmol/L			22-34	

Sex: M=Male, F=Female;
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Day = The presented date — First dose date + 1
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9062	33/M/BL	TPOXX 600 mg	Day 9	10OCT2019 08:06 (9)	Chloride	101	mmol/L			96-108	
					Creatinine	99.0	umol/L			56.6-114.9	
					Gamma Glutamyl Transferase	44	IU/L			5-85	
					Globulin	30	g/L			19-39	
					Glucose	4.83	mmol/L			3-6.44	
					Lactate Dehydrogenase	129	IU/L			82-216	
					Phosphate	1.10	mmol/L			0.68-1.52	
					Potassium	4.5	mmol/L			3.5-5	
					Protein	74	g/L			57-88	
					Sodium	139	mmol/L			132-145	
					Urate	404	umol/L			173-494	
9063	35/M/W		Screening	30SEP2019 09:38 (-2)	Alanine Aminotransferase	21	IU/L			7-56	
					Albumin	45	g/L			37-55	
					Alkaline Phosphatase	53	IU/L			20-116	
					Anion Gap	14	mmol/L			6-17	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9063	35/M/W		Screening	30SEP2019 09:38 (-2)	Aspartate Aminotransferase	15	IU/L			10-40	
					Bilirubin	6.2	umol/L			3.2-28.9	
					Blood Urea Nitrogen	3.57	mmol/L			1.79-9.28	
					Calcium	2.33	mmol/L			2.13-2.58	
					Carbon Dioxide	29	mmol/L			22-34	
					Chloride	102	mmol/L			96-108	
					Cholesterol	4.82	mmol/L			2.2-6.22	
					Creatinine	63.6	umol/L			56.6-114.9	
					Creatinine Clearance	253.2	mL/min			90-N/A	
					Gamma Glutamyl Transferase	25	IU/L			5-85	
					Globulin	30	g/L			19-39	
					Glucose	4.55	mmol/L			3-6.44	
					HDL Cholesterol	1.14	mmol/L			0.65-2.46	
					LDL Cholesterol	2.43	mmol/L			0.96-4.22	
					Lactate Dehydrogenase	135	IU/L			82-216	
					Phosphate	1.32	mmol/L			0.68-1.52	
					Potassium	4.5	mmol/L			3.5-5	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9063	35/M/W		Screening	30SEP2019 09:38 (-2)	Protein	75	g/L			57-88	
					Sodium	140	mmol/L			132-145	
					Triglycerides	2.71	mmol/L		G1	0-4.52	
					Urate	268	umol/L			173-494	
			Check-in	01OCT2019 08:48 (-1)	Alanine Aminotransferase	23	IU/L			7-56	
					Albumin	45	g/L			37-55	
					Alkaline Phosphatase	51	IU/L			20-116	
					Anion Gap	12	mmol/L			6-17	
					Aspartate Aminotransferase	19	IU/L			10-40	
					Bilirubin	9.1	umol/L			3.2-28.9	
					Blood Urea Nitrogen	4.43	mmol/L			1.79-9.28	
					Calcium	2.25	mmol/L			2.13-2.58	
					Carbon Dioxide	31	mmol/L			22-34	
					Chloride	101	mmol/L			96-108	
					Creatinine	70.7	umol/L			56.6-114.9	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9063	35/M/W		Check-in	01OCT2019 08:48 (-1)	Gamma Glutamyl Transferase	25	IU/L			5-85	
					Globulin	28	g/L			19-39	
					Glucose	4.38	mmol/L			3-6.44	
					Lactate Dehydrogenase	143	IU/L			82-216	
					Phosphate	1.26	mmol/L			0.68-1.52	
					Potassium	4.6	mmol/L			3.5-5	
					Protein	73	g/L			57-88	
					Sodium	139	mmol/L			132-145	
					Urate	333	umol/L			173-494	
		TPOXX 600 mg	Day 4	05OCT2019 07:34 (4)	Alanine Aminotransferase	19	IU/L			7-56	
					Albumin	47	g/L			37-55	
					Alkaline Phosphatase	46	IU/L			20-116	
					Anion Gap	12	mmol/L			6-17	
					Aspartate Aminotransferase	13	IU/L			10-40	
					Bilirubin	11.3	umol/L			3.2-28.9	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9063	35/M/W	TPOXX 600 mg	Day 4	05OCT2019 07:34 (4)	Blood Urea Nitrogen	4.75	mmol/L			1.79-9.28	
					Calcium	2.33	mmol/L			2.13-2.58	
					Carbon Dioxide	30	mmol/L			22-34	
					Chloride	100	mmol/L			96-108	
					Creatinine	76.0	umol/L			56.6-114.9	
					Gamma Glutamyl Transferase	24	IU/L			5-85	
					Globulin	29	g/L			19-39	
					Glucose	4.77	mmol/L			3-6.44	
					Lactate Dehydrogenase	103	IU/L			82-216	
					Phosphate	1.45	mmol/L			0.68-1.52	
					Potassium	4.0	mmol/L			3.5-5	
					Protein	76	g/L			57-88	
					Sodium	138	mmol/L			132-145	
					Urate	416	umol/L			173-494	

Sex: M=Male, F=Female;
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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9063	35/M/W	TPOXX 600 mg	Day 8 - 12 Hours Postdose	09OCT2019 08:09 (8)	Alanine Aminotransferase	14	IU/L			7-56	
					Albumin	48	g/L			37-55	
					Alkaline Phosphatase	54	IU/L			20-116	
					Anion Gap	11	mmol/L			6-17	
					Aspartate Aminotransferase	12	IU/L			10-40	
					Bilirubin	11.1	umol/L			3.2-28.9	
					Blood Urea Nitrogen	4.57	mmol/L			1.79-9.28	
					Calcium	2.45	mmol/L			2.13-2.58	
					Carbon Dioxide	30	mmol/L			22-34	
					Chloride	99	mmol/L			96-108	
					Creatinine	86.6	umol/L			56.6-114.9	
					Gamma Glutamyl Transferase	24	IU/L			5-85	
					Globulin	31	g/L			19-39	
					Glucose	4.66	mmol/L			3-6.44	
					Lactate Dehydrogenase	109	IU/L			82-216	

Sex: M=Male, F=Female;
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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9063	35/M/W	TPOXX 600 mg	Day 8 - 12 Hours Postdose	09OCT2019 08:09 (8)	Phosphate	1.45	mmol/L			0.68-1.52	
					Potassium	4.0	mmol/L			3.5-5	
					Protein	79	g/L			57-88	
					Sodium	136	mmol/L			132-145	
					Urate	399	umol/L			173-494	
			Day 9	10OCT2019 08:09 (9)	Alanine Aminotransferase	13	IU/L			7-56	
					Albumin	50	g/L			37-55	
					Alkaline Phosphatase	56	IU/L			20-116	
					Anion Gap	11	mmol/L			6-17	
					Aspartate Aminotransferase	13	IU/L			10-40	
					Bilirubin	10.6	umol/L			3.2-28.9	
					Blood Urea Nitrogen	4.71	mmol/L			1.79-9.28	
					Calcium	2.43	mmol/L			2.13-2.58	
					Carbon Dioxide	30	mmol/L			22-34	

Sex: M=Male, F=Female;
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Day = The presented date — First dose date + 1
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Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9063	35/M/W	TPOXX 600 mg	Day 9	10OCT2019 08:09 (9)	Chloride	100	mmol/L			96-108	
					Creatinine	84.0	umol/L			56.6-114.9	
					Gamma Glutamyl Transferase	25	IU/L			5-85	
					Globulin	33	g/L			19-39	
					Glucose	4.77	mmol/L			3-6.44	
					Lactate Dehydrogenase	122	IU/L			82-216	
					Phosphate	1.36	mmol/L			0.68-1.52	
					Potassium	4.3	mmol/L			3.5-5	
					Protein	83	g/L			57-88	
					Sodium	137	mmol/L			132-145	
					Urate	399	umol/L			173-494	
9069	41/F/BL		Screening	30SEP2019 11:19 (-16)	Alanine Aminotransferase	15	IU/L			4-45	
					Albumin	42	g/L			38-49	
					Alkaline Phosphatase	113	IU/L			20-116	
					Anion Gap	10	mmol/L			6-17	

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Day = The presented date — First dose date + 1
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9069	41/F/BL		Screening	30SEP2019 11:19 (-16)	Aspartate Aminotransferase	16	IU/L			10-40	
					Bilirubin	7.4	umol/L			3.2-21.7	
					Blood Urea Nitrogen	3.68	mmol/L			1.79-9.28	
					Calcium	2.23	mmol/L			2.13-2.58	
					Carbon Dioxide	32	mmol/L			22-34	
					Chloride	101	mmol/L			96-108	
					Cholesterol	4.79	mmol/L			2.2-6.22	
					Creatinine	59.2	umol/L			39.8-93.7	
					Creatinine Clearance	263.4	mL/min			90-N/A	
					Gamma Glutamyl Transferase	18	IU/L			5-85	
					Globulin	31	g/L			19-39	
					Glucose	4.72	mmol/L			3-6.44	
					HDL Cholesterol	0.88	mmol/L			0.88-2.36	
					LDL Cholesterol	3.32	mmol/L			0.96-4.22	
					Lactate Dehydrogenase	237	IU/L	H NCS		82-216	
					Phosphate	1.10	mmol/L			0.68-1.52	
					Potassium	4.1	mmol/L			3.5-5	

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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9069	41/F/BL		Screening	30SEP2019 11:19 (-16)	Protein	73	g/L			57-88	
					Sodium	139	mmol/L			132-145	
					Triglycerides	1.29	mmol/L			0-4.52	
					Urate	303	umol/L			119-345	
			Check-in	15OCT2019 12:32 (-1)	Alanine Aminotransferase	15	IU/L			4-45	
					Albumin	40	g/L			38-49	
					Alkaline Phosphatase	108	IU/L			20-116	
					Anion Gap	11	mmol/L			6-17	
					Aspartate Aminotransferase	16	IU/L			10-40	
					Bilirubin	6.7	umol/L			3.2-21.7	
					Blood Urea Nitrogen	3.46	mmol/L			1.79-9.28	
					Calcium	2.28	mmol/L			2.13-2.58	
					Carbon Dioxide	31	mmol/L			22-34	
					Chloride	101	mmol/L			96-108	
					Creatinine	67.2	umol/L			39.8-93.7	

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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9069	41/F/BL		Check-in	15OCT2019 12:32 (-1)	Gamma Glutamyl Transferase	17	IU/L			5-85	
					Globulin	29	g/L			19-39	
					Glucose	5.16	mmol/L			3-6.44	
					Lactate Dehydrogenase	233	IU/L	H NCS		82-216	
					Phosphate	1.20	mmol/L			0.68-1.52	
					Potassium	3.9	mmol/L			3.5-5	
					Protein	69	g/L			57-88	
					Sodium	139	mmol/L			132-145	
					Urate	315	umol/L			119-345	
		TPOXX 600 mg	Day 4	19OCT2019 07:35 (4)	Alanine Aminotransferase	15	IU/L			4-45	
					Albumin	40	g/L			38-49	
					Alkaline Phosphatase	94	IU/L			20-116	
					Anion Gap	11	mmol/L			6-17	
					Aspartate Aminotransferase	16	IU/L			10-40	
					Bilirubin	5.6	umol/L			3.2-21.7	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9069	41/F/BL	TPOXX 600 mg	Day 4	19OCT2019 07:35 (4)	Blood Urea Nitrogen	3.18	mmol/L			1.79-9.28	
					Calcium	2.28	mmol/L			2.13-2.58	
					Carbon Dioxide	30	mmol/L			22-34	
					Chloride	103	mmol/L			96-108	
					Creatinine	60.1	umol/L			39.8-93.7	
					Gamma Glutamyl Transferase	17	IU/L			5-85	
					Globulin	30	g/L			19-39	
					Glucose	5.05	mmol/L			3-6.44	
					Lactate Dehydrogenase	226	IU/L	H NCS		82-216	
					Phosphate	1.39	mmol/L			0.68-1.52	
					Potassium	4.2	mmol/L			3.5-5	
					Protein	70	g/L			57-88	
					Sodium	140	mmol/L			132-145	
					Urate	309	umol/L			119-345	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9069	41/F/BL	TPOXX 600 mg	Day 8 - 12 Hours Postdose	23OCT2019 08:17 (8)	Alanine Aminotransferase	14	IU/L			4-45	
					Albumin	41	g/L			38-49	
					Alkaline Phosphatase	102	IU/L			20-116	
					Anion Gap	9	mmol/L			6-17	
					Aspartate Aminotransferase	15	IU/L			10-40	
					Bilirubin	6.2	umol/L			3.2-21.7	
					Blood Urea Nitrogen	3.61	mmol/L			1.79-9.28	
					Calcium	2.33	mmol/L			2.13-2.58	
					Carbon Dioxide	29	mmol/L			22-34	
					Chloride	101	mmol/L			96-108	
					Creatinine	62.8	umol/L			39.8-93.7	
					Gamma Glutamyl Transferase	18	IU/L			5-85	
					Globulin	31	g/L			19-39	
					Glucose	4.66	mmol/L			3-6.44	
					Lactate Dehydrogenase	205	IU/L			82-216	

Sex: M=Male, F=Female;
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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9069	41/F/BL	TPOXX 600 mg	Day 8 - 12 Hours Postdose	23OCT2019 08:17 (8)	Phosphate	1.29	mmol/L			0.68-1.52	
					Potassium	4.0	mmol/L			3.5-5	
					Protein	72	g/L			57-88	
					Sodium	135	mmol/L			132-145	
					Urate	303	umol/L			119-345	
			Day 9	24OCT2019 08:06 (9)	Alanine Aminotransferase	13	IU/L			4-45	
					Albumin	40	g/L			38-49	
					Alkaline Phosphatase	92	IU/L			20-116	
					Anion Gap	9	mmol/L			6-17	
					Aspartate Aminotransferase	15	IU/L			10-40	
					Bilirubin	5.1	umol/L			3.2-21.7	
					Blood Urea Nitrogen	4.21	mmol/L			1.79-9.28	
					Calcium	2.20	mmol/L			2.13-2.58	
					Carbon Dioxide	27	mmol/L			22-34	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9069	41/F/BL	TPOXX 600 mg	Day 9	24OCT2019 08:06 (9)	Chloride	104	mmol/L			96-108	
					Creatinine	65.4	umol/L			39.8-93.7	
					Gamma Glutamyl Transferase	17	IU/L			5-85	
					Globulin	29	g/L			19-39	
					Glucose	5.11	mmol/L			3-6.44	
					Lactate Dehydrogenase	204	IU/L			82-216	
					Phosphate	1.16	mmol/L			0.68-1.52	
					Potassium	4.0	mmol/L			3.5-5	
					Protein	69	g/L			57-88	
					Sodium	136	mmol/L			132-145	
					Urate	303	umol/L			119-345	
9073	40/M/BL		Screening	04OCT2019 13:56 (-12)	Alanine Aminotransferase	22	IU/L			7-56	
					Albumin	40	g/L			37-55	
					Alkaline Phosphatase	31	IU/L			20-116	
					Anion Gap	14	mmol/L			6-17	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9073	40/M/BL		Screening	04OCT2019 13:56 (-12)	Aspartate Aminotransferase	12	IU/L			10-40	
					Bilirubin	5.0	umol/L			3.2-28.9	
					Blood Urea Nitrogen	4.61	mmol/L			1.79-9.28	
					Calcium	2.28	mmol/L			2.13-2.58	
					Carbon Dioxide	26	mmol/L			22-34	
					Chloride	105	mmol/L			96-108	
					Cholesterol	4.04	mmol/L			2.2-6.22	
					Creatinine	87.5	umol/L			56.6-114.9	
					Creatinine Clearance	221.7	mL/min			90-N/A	
					Gamma Glutamyl Transferase	20	IU/L			5-85	
					Globulin	30	g/L			19-39	
					Glucose	6.38	mmol/L		G1	3-6.44	
					HDL Cholesterol	1.01	mmol/L			0.65-2.46	
					LDL Cholesterol	2.38	mmol/L			0.96-4.22	
					Lactate Dehydrogenase	143	IU/L			82-216	
					Phosphate	1.55	mmol/L	H NCS		0.68-1.52	
					Potassium	4.1	mmol/L			3.5-5	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9073	40/M/BL		Screening	04OCT2019 13:56 (-12)	Protein	70	g/L			57-88	
					Sodium	141	mmol/L			132-145	
					Triglycerides	1.42	mmol/L			0-4.52	
					Urate	381	umol/L			173-494	
			Check-in	15OCT2019 09:18 (-1)	Alanine Aminotransferase	21	IU/L			7-56	
					Albumin	38	g/L			37-55	
					Alkaline Phosphatase	30	IU/L			20-116	
					Anion Gap	13	mmol/L			6-17	
					Aspartate Aminotransferase	12	IU/L			10-40	
					Bilirubin	7.2	umol/L			3.2-28.9	
					Blood Urea Nitrogen	4.36	mmol/L			1.79-9.28	
					Calcium	2.15	mmol/L			2.13-2.58	
					Carbon Dioxide	28	mmol/L			22-34	
					Chloride	103	mmol/L			96-108	
					Creatinine	86.6	umol/L			56.6-114.9	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9073	40/M/BL		Check-in	15OCT2019 09:18 (-1)	Gamma Glutamyl Transferase	24	IU/L			5-85	
					Globulin	26	g/L			19-39	
					Glucose	5.94	mmol/L			3-6.44	
					Lactate Dehydrogenase	148	IU/L			82-216	
					Phosphate	1.71	mmol/L	H NCS		0.68-1.52	
					Potassium	3.8	mmol/L			3.5-5	
					Protein	64	g/L			57-88	
					Sodium	140	mmol/L			132-145	
					Urate	369	umol/L			173-494	
		TPOXX 600 mg	Day 4	19OCT2019 07:41 (4)	Alanine Aminotransferase	23	IU/L			7-56	
					Albumin	38	g/L			37-55	
					Alkaline Phosphatase	29	IU/L			20-116	
					Anion Gap	12	mmol/L			6-17	
					Aspartate Aminotransferase	15	IU/L			10-40	
					Bilirubin	8.7	umol/L			3.2-28.9	

Sex: M=Male, F=Female;
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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9073	40/M/BL	TPOXX 600 mg	Day 4	19OCT2019 07:41 (4)	Blood Urea Nitrogen	3.82	mmol/L			1.79-9.28	
					Calcium	2.25	mmol/L			2.13-2.58	
					Carbon Dioxide	29	mmol/L			22-34	
					Chloride	105	mmol/L			96-108	
					Creatinine	84.0	umol/L			56.6-114.9	
					Gamma Glutamyl Transferase	23	IU/L			5-85	
					Globulin	28	g/L			19-39	
					Glucose	4.88	mmol/L			3-6.44	
					Lactate Dehydrogenase	133	IU/L			82-216	
					Phosphate	1.65	mmol/L	H NCS		0.68-1.52	
					Potassium	3.8	mmol/L			3.5-5	
					Protein	66	g/L			57-88	
					Sodium	142	mmol/L			132-145	
					Urate	452	umol/L		G1	173-494	

Sex: M=Male, F=Female;
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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9073	40/M/BL	TPOXX 600 mg	Day 8 - 12 Hours Postdose	23OCT2019 08:16 (8)	Alanine Aminotransferase	22	IU/L			7-56	
					Albumin	41	g/L			37-55	
					Alkaline Phosphatase	33	IU/L			20-116	
					Anion Gap	12	mmol/L			6-17	
					Aspartate Aminotransferase	13	IU/L			10-40	
					Bilirubin	7.2	umol/L			3.2-28.9	
					Blood Urea Nitrogen	4.36	mmol/L			1.79-9.28	
					Calcium	2.33	mmol/L			2.13-2.58	
					Carbon Dioxide	29	mmol/L			22-34	
					Chloride	104	mmol/L			96-108	
					Creatinine	93.7	umol/L			56.6-114.9	
					Gamma Glutamyl Transferase	24	IU/L			5-85	
					Globulin	29	g/L			19-39	
					Glucose	4.55	mmol/L			3-6.44	
					Lactate Dehydrogenase	131	IU/L			82-216	

Sex: M=Male, F=Female;
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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9073	40/M/BL	TPOXX 600 mg	Day 8 - 12 Hours Postdose	23OCT2019 08:16 (8)	Phosphate	1.81	mmol/L	H NCS		0.68-1.52	
					Potassium	4.0	mmol/L			3.5-5	
					Protein	70	g/L			57-88	
					Sodium	141	mmol/L			132-145	
					Urate	440	umol/L			173-494	
			Day 9	24OCT2019 08:16 (9)	Alanine Aminotransferase	22	IU/L			7-56	
					Albumin	41	g/L			37-55	
					Alkaline Phosphatase	30	IU/L			20-116	
					Anion Gap	9	mmol/L			6-17	
					Aspartate Aminotransferase	13	IU/L			10-40	
					Bilirubin	7.2	umol/L			3.2-28.9	
					Blood Urea Nitrogen	4.25	mmol/L			1.79-9.28	
					Calcium	2.25	mmol/L			2.13-2.58	
					Carbon Dioxide	29	mmol/L			22-34	

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Day = The presented date — First dose date + 1
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Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9073	40/M/BL	TPOXX 600 mg	Day 9	24OCT2019 08:16 (9)	Chloride	102	mmol/L			96-108	
					Creatinine	96.4	umol/L			56.6-114.9	
					Gamma Glutamyl Transferase	22	IU/L			5-85	
					Globulin	27	g/L			19-39	
					Glucose	4.83	mmol/L			3-6.44	
					Lactate Dehydrogenase	140	IU/L			82-216	
					Phosphate	1.42	mmol/L			0.68-1.52	
					Potassium	3.9	mmol/L			3.5-5	
					Protein	68	g/L			57-88	
					Sodium	136	mmol/L			132-145	
					Urate	428	umol/L			173-494	
9077	37/F/W		Screening	05OCT2019 13:15 (-11)	Alanine Aminotransferase	39	IU/L			4-45	
					Albumin	43	g/L			38-49	
					Alkaline Phosphatase	83	IU/L			20-116	
					Anion Gap	13	mmol/L			6-17	

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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9077	37/F/W		Screening	05OCT2019 13:15 (-11)	Aspartate Aminotransferase	25	IU/L			10-40	
					Bilirubin	4.4	umol/L			3.2-21.7	
					Blood Urea Nitrogen	3.00	mmol/L			1.79-9.28	
					Calcium	2.43	mmol/L			2.13-2.58	
					Carbon Dioxide	27	mmol/L			22-34	
					Chloride	98	mmol/L			96-108	
					Cholesterol	4.58	mmol/L			2.2-6.22	
					Creatinine	54.8	umol/L			39.8-93.7	
					Creatinine Clearance	249.1	mL/min			90-N/A	
					Gamma Glutamyl Transferase	19	IU/L			5-85	
					Globulin	28	g/L			19-39	
					Glucose	4.94	mmol/L			3-6.44	
					HDL Cholesterol	1.37	mmol/L			0.88-2.36	
					LDL Cholesterol	2.90	mmol/L			0.96-4.22	
					Lactate Dehydrogenase	149	IU/L			82-216	
					Phosphate	1.03	mmol/L			0.68-1.52	
					Potassium	4.2	mmol/L			3.5-5	

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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9077	37/F/W		Screening	05OCT2019 13:15 (-11)	Protein	71	g/L			57-88	
					Sodium	134	mmol/L		G1	132-145	
					Triglycerides	0.69	mmol/L			0-4.52	
					Urate	286	umol/L			119-345	
			Check-in	15OCT2019 09:28 (-1)	Alanine Aminotransferase	18	IU/L			4-45	
					Albumin	42	g/L			38-49	
					Alkaline Phosphatase	83	IU/L			20-116	
					Anion Gap	11	mmol/L			6-17	
					Aspartate Aminotransferase	13	IU/L			10-40	
					Bilirubin	6.3	umol/L			3.2-21.7	
					Blood Urea Nitrogen	3.78	mmol/L			1.79-9.28	
					Calcium	2.38	mmol/L			2.13-2.58	
					Carbon Dioxide	28	mmol/L			22-34	
					Chloride	100	mmol/L			96-108	
					Creatinine	58.3	umol/L			39.8-93.7	

Sex: M=Male, F=Female;
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9077	37/F/W		Check-in	15OCT2019 09:28 (-1)	Gamma Glutamyl Transferase	14	IU/L			5-85	
					Globulin	27	g/L			19-39	
					Glucose	4.61	mmol/L			3-6.44	
					Lactate Dehydrogenase	136	IU/L			82-216	
					Phosphate	1.03	mmol/L			0.68-1.52	
					Potassium	4.2	mmol/L			3.5-5	
					Protein	69	g/L			57-88	
					Sodium	135	mmol/L			132-145	
					Urate	280	umol/L			119-345	
		TPOXX 600 mg	Day 4	19OCT2019 07:37 (4)	Alanine Aminotransferase	11	IU/L			4-45	
					Albumin	44	g/L			38-49	
					Alkaline Phosphatase	79	IU/L			20-116	
					Anion Gap	12	mmol/L			6-17	
					Aspartate Aminotransferase	11	IU/L			10-40	
					Bilirubin	9.1	umol/L			3.2-21.7	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9077	37/F/W	TPOXX 600 mg	Day 4	19OCT2019 07:37 (4)	Blood Urea Nitrogen	4.43	mmol/L			1.79-9.28	
					Calcium	2.53	mmol/L			2.13-2.58	
					Carbon Dioxide	28	mmol/L			22-34	
					Chloride	104	mmol/L			96-108	
					Creatinine	61.0	umol/L			39.8-93.7	
					Gamma Glutamyl Transferase	14	IU/L			5-85	
					Globulin	28	g/L			19-39	
					Glucose	4.77	mmol/L			3-6.44	
					Lactate Dehydrogenase	126	IU/L			82-216	
					Phosphate	1.07	mmol/L			0.68-1.52	
					Potassium	4.3	mmol/L			3.5-5	
					Protein	72	g/L			57-88	
					Sodium	140	mmol/L			132-145	
					Urate	309	umol/L			119-345	

Sex: M=Male, F=Female;
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Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9077	37/F/W	TPOXX 600 mg	Day 8 - 12 Hours Postdose	23OCT2019 08:12 (8)	Alanine Aminotransferase	10	IU/L			4-45	
					Albumin	42	g/L			38-49	
					Alkaline Phosphatase	86	IU/L			20-116	
					Anion Gap	6	mmol/L			6-17	
					Aspartate Aminotransferase	11	IU/L			10-40	
					Bilirubin	7.4	umol/L			3.2-21.7	
					Blood Urea Nitrogen	4.39	mmol/L			1.79-9.28	
					Calcium	2.48	mmol/L			2.13-2.58	
					Carbon Dioxide	29	mmol/L			22-34	
					Chloride	105	mmol/L			96-108	
					Creatinine	58.3	umol/L			39.8-93.7	
					Gamma Glutamyl Transferase	13	IU/L			5-85	
					Globulin	28	g/L			19-39	
					Glucose	4.61	mmol/L			3-6.44	
					Lactate Dehydrogenase	116	IU/L			82-216	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
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Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9077	37/F/W	TPOXX 600 mg	Day 8 - 12 Hours Postdose	23OCT2019 08:12 (8)	Phosphate	1.13	mmol/L			0.68-1.52	
					Potassium	4.2	mmol/L			3.5-5	
					Protein	70	g/L			57-88	
					Sodium	136	mmol/L			132-145	
					Urate	280	umol/L			119-345	
			Day 9	24OCT2019 08:12 (9)	Alanine Aminotransferase	11	IU/L			4-45	
					Albumin	44	g/L			38-49	
					Alkaline Phosphatase	86	IU/L			20-116	
					Anion Gap	9	mmol/L			6-17	
					Aspartate Aminotransferase	12	IU/L			10-40	
					Bilirubin	6.5	umol/L			3.2-21.7	
					Blood Urea Nitrogen	4.11	mmol/L			1.79-9.28	
					Calcium	2.50	mmol/L			2.13-2.58	
					Carbon Dioxide	28	mmol/L			22-34	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9077	37/F/W	TPOXX 600 mg	Day 9	24OCT2019 08:12 (9)	Chloride	105	mmol/L			96-108	
					Creatinine	59.2	umol/L			39.8-93.7	
					Gamma Glutamyl Transferase	12	IU/L			5-85	
					Globulin	25	g/L			19-39	
					Glucose	4.83	mmol/L			3-6.44	
					Lactate Dehydrogenase	127	IU/L			82-216	
					Phosphate	0.90	mmol/L			0.68-1.52	
					Potassium	4.1	mmol/L			3.5-5	
					Protein	69	g/L			57-88	
					Sodium	138	mmol/L			132-145	
					Urate	286	umol/L			119-345	
9080	41/F/BL		Screening	08OCT2019 11:46 (-8)	Alanine Aminotransferase	18	IU/L			4-45	
					Albumin	44	g/L			38-49	
					Alkaline Phosphatase	56	IU/L			20-116	
					Anion Gap	10	mmol/L			6-17	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9080	41/F/BL		Screening	08OCT2019 11:46 (-8)	Aspartate Aminotransferase	15	IU/L			10-40	
					Bilirubin	8.4	umol/L			3.2-21.7	
					Blood Urea Nitrogen	4.46	mmol/L			1.79-9.28	
					Calcium	2.38	mmol/L			2.13-2.58	
					Carbon Dioxide	32	mmol/L			22-34	
					Chloride	101	mmol/L			96-108	
					Cholesterol	4.95	mmol/L			2.2-6.22	
					Creatinine	76.9	umol/L			39.8-93.7	
					Creatinine Clearance	162.6	mL/min			90-N/A	
					Gamma Glutamyl Transferase	15	IU/L			5-85	
					Globulin	31	g/L			19-39	
					Glucose	5.49	mmol/L			3-6.44	
					HDL Cholesterol	1.50	mmol/L			0.88-2.36	
					LDL Cholesterol	3.16	mmol/L			0.96-4.22	
					Lactate Dehydrogenase	184	IU/L			82-216	
					Phosphate	1.03	mmol/L			0.68-1.52	
					Potassium	4.0	mmol/L			3.5-5	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9080	41/F/BL		Screening	08OCT2019 11:46 (-8)	Protein	75	g/L			57-88	
					Sodium	139	mmol/L			132-145	
					Triglycerides	0.64	mmol/L			0-4.52	
					Urate	393	umol/L	H NCS		119-345	
			Check-in	15OCT2019 09:30 (-1)	Alanine Aminotransferase	15	IU/L			4-45	
					Albumin	41	g/L			38-49	
					Alkaline Phosphatase	60	IU/L			20-116	
					Anion Gap	11	mmol/L			6-17	
					Aspartate Aminotransferase	12	IU/L			10-40	
					Bilirubin	7.4	umol/L			3.2-21.7	
					Blood Urea Nitrogen	5.75	mmol/L			1.79-9.28	
					Calcium	2.33	mmol/L			2.13-2.58	
					Carbon Dioxide	31	mmol/L			22-34	
					Chloride	102	mmol/L			96-108	
					Creatinine	85.7	umol/L			39.8-93.7	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9080	41/F/BL		Check-in	15OCT2019 09:30 (-1)	Gamma Glutamyl Transferase	14	IU/L			5-85	
					Globulin	27	g/L			19-39	
					Glucose	5.61	mmol/L			3-6.44	
					Lactate Dehydrogenase	173	IU/L			82-216	
					Phosphate	0.97	mmol/L			0.68-1.52	
					Potassium	4.6	mmol/L			3.5-5	
					Protein	68	g/L			57-88	
					Sodium	139	mmol/L			132-145	
					Urate	404	umol/L	H NCS		119-345	
		TPOXX 600 mg	Day 4	19OCT2019 07:46 (4)	Alanine Aminotransferase	17	IU/L			4-45	
					Albumin	44	g/L			38-49	
					Alkaline Phosphatase	59	IU/L			20-116	
					Anion Gap	12	mmol/L			6-17	
					Aspartate Aminotransferase	13	IU/L			10-40	
					Bilirubin	10.1	umol/L			3.2-21.7	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9080	41/F/BL	TPOXX 600 mg	Day 4	19OCT2019 07:46 (4)	Blood Urea Nitrogen	4.46	mmol/L			1.79-9.28	
					Calcium	2.35	mmol/L			2.13-2.58	
					Carbon Dioxide	27	mmol/L			22-34	
					Chloride	103	mmol/L			96-108	
					Creatinine	73.4	umol/L			39.8-93.7	
					Gamma Glutamyl Transferase	17	IU/L			5-85	
					Globulin	32	g/L			19-39	
					Glucose	4.94	mmol/L			3-6.44	
					Lactate Dehydrogenase	172	IU/L			82-216	
					Phosphate	1.07	mmol/L			0.68-1.52	
					Potassium	4.1	mmol/L			3.5-5	
					Protein	76	g/L			57-88	
					Sodium	138	mmol/L			132-145	
					Urate	351	umol/L	H NCS		119-345	

Sex: M=Male, F=Female;
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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9080	41/F/BL	TPOXX 600 mg	Day 8 - 12 Hours Postdose	23OCT2019 08:21 (8)	Alanine Aminotransferase	22	IU/L			4-45	
					Albumin	44	g/L			38-49	
					Alkaline Phosphatase	68	IU/L			20-116	
					Anion Gap	12	mmol/L			6-17	
					Aspartate Aminotransferase	14	IU/L			10-40	
					Bilirubin	10.3	umol/L			3.2-21.7	
					Blood Urea Nitrogen	4.25	mmol/L			1.79-9.28	
					Calcium	2.35	mmol/L			2.13-2.58	
					Carbon Dioxide	28	mmol/L			22-34	
					Chloride	102	mmol/L			96-108	
					Creatinine	77.8	umol/L			39.8-93.7	
					Gamma Glutamyl Transferase	18	IU/L			5-85	
					Globulin	31	g/L			19-39	
					Glucose	5.05	mmol/L			3-6.44	
					Lactate Dehydrogenase	177	IU/L			82-216	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9080	41/F/BL	TPOXX 600 mg	Day 8 - 12 Hours Postdose	23OCT2019 08:21 (8)	Phosphate	1.13	mmol/L			0.68-1.52	
					Potassium	4.1	mmol/L			3.5-5	
					Protein	75	g/L			57-88	
					Sodium	138	mmol/L			132-145	
					Urate	327	umol/L			119-345	
			Day 9	24OCT2019 08:21 (9)	Alanine Aminotransferase	22	IU/L			4-45	
					Albumin	43	g/L			38-49	
					Alkaline Phosphatase	60	IU/L			20-116	
					Anion Gap	9	mmol/L			6-17	
					Aspartate Aminotransferase	15	IU/L			10-40	
					Bilirubin	9.4	umol/L			3.2-21.7	
					Blood Urea Nitrogen	4.32	mmol/L			1.79-9.28	
					Calcium	2.20	mmol/L			2.13-2.58	
					Carbon Dioxide	27	mmol/L			22-34	

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Day = The presented date — First dose date + 1
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Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9080	41/F/BL	TPOXX 600 mg	Day 9	24OCT2019 08:21 (9)	Chloride	101	mmol/L			96-108	
					Creatinine	78.7	umol/L			39.8-93.7	
					Gamma Glutamyl Transferase	15	IU/L			5-85	
					Globulin	27	g/L			19-39	
					Glucose	5.33	mmol/L			3-6.44	
					Lactate Dehydrogenase	176	IU/L			82-216	
					Phosphate	0.84	mmol/L			0.68-1.52	
					Potassium	3.8	mmol/L			3.5-5	
					Protein	70	g/L			57-88	
					Sodium	133	mmol/L		G1	132-145	
					Urate	333	umol/L			119-345	
9081	49/M/BL		Screening	10OCT2019 12:25 (-20)	Alanine Aminotransferase	31	IU/L			7-56	
					Albumin	43	g/L			37-55	
					Alkaline Phosphatase	94	IU/L			20-116	
					Anion Gap	10	mmol/L			6-17	

Sex: M=Male, F=Female;
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Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9081	49/M/BL		Screening	10OCT2019 12:25 (-20)	Aspartate Aminotransferase	23	IU/L			10-40	
					Bilirubin	7.2	umol/L			3.2-28.9	
					Blood Urea Nitrogen	4.07	mmol/L			1.79-9.28	
					Calcium	2.45	mmol/L			2.13-2.58	
					Carbon Dioxide	32	mmol/L			22-34	
					Chloride	102	mmol/L			96-108	
					Cholesterol	4.82	mmol/L			2.2-6.22	
					Creatinine	90.2	umol/L			56.6-114.9	
					Creatinine Clearance	271.4	mL/min			90-N/A	
					Gamma Glutamyl Transferase	29	IU/L			5-85	
					Globulin	34	g/L			19-39	
					Glucose	5.00	mmol/L			3-6.44	
					HDL Cholesterol	1.27	mmol/L			0.65-2.46	
					LDL Cholesterol	3.08	mmol/L			0.96-4.22	
					Lactate Dehydrogenase	209	IU/L			82-216	
					Phosphate	1.20	mmol/L			0.68-1.52	
					Potassium	4.4	mmol/L			3.5-5	

Sex: M=Male, F=Female;
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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9081	49/M/BL		Screening	10OCT2019 12:25 (-20)	Protein	77	g/L			57-88	
					Sodium	140	mmol/L			132-145	
					Triglycerides	1.02	mmol/L			0-4.52	
					Urate	416	umol/L			173-494	
			Check-in	29OCT2019 10:08 (-1)	Alanine Aminotransferase	27	IU/L			7-56	
					Albumin	45	g/L			37-55	
					Alkaline Phosphatase	88	IU/L			20-116	
					Anion Gap	10	mmol/L			6-17	
					Aspartate Aminotransferase	18	IU/L			10-40	
					Bilirubin	8.7	umol/L			3.2-28.9	
					Blood Urea Nitrogen	4.46	mmol/L			1.79-9.28	
					Calcium	2.53	mmol/L			2.13-2.58	
					Carbon Dioxide	28	mmol/L			22-34	
					Chloride	102	mmol/L			96-108	
					Creatinine	96.4	umol/L			56.6-114.9	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9081	49/M/BL		Check-in	29OCT2019 10:08 (-1)	Gamma Glutamyl Transferase	29	IU/L			5-85	
					Globulin	31	g/L			19-39	
					Glucose	5.49	mmol/L			3-6.44	
					Lactate Dehydrogenase	190	IU/L			82-216	
					Phosphate	1.07	mmol/L			0.68-1.52	
					Potassium	4.3	mmol/L			3.5-5	
					Protein	76	g/L			57-88	
					Sodium	136	mmol/L			132-145	
					Urate	434	umol/L			173-494	
		TPOXX 600 mg	Day 4	02NOV2019 07:27 (4)	Alanine Aminotransferase	28	IU/L			7-56	
					Albumin	43	g/L			37-55	
					Alkaline Phosphatase	86	IU/L			20-116	
					Anion Gap	12	mmol/L			6-17	
					Aspartate Aminotransferase	20	IU/L			10-40	
					Bilirubin	10.3	umol/L			3.2-28.9	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9081	49/M/BL	TPOXX 600 mg	Day 4	02NOV2019 07:27 (4)	Blood Urea Nitrogen	4.71	mmol/L			1.79-9.28	
					Calcium	2.43	mmol/L			2.13-2.58	
					Carbon Dioxide	28	mmol/L			22-34	
					Chloride	103	mmol/L			96-108	
					Creatinine	98.1	umol/L			56.6-114.9	
					Gamma Glutamyl Transferase	27	IU/L			5-85	
					Globulin	30	g/L			19-39	
					Glucose	5.22	mmol/L			3-6.44	
					Lactate Dehydrogenase	178	IU/L			82-216	
					Phosphate	1.29	mmol/L			0.68-1.52	
					Potassium	4.3	mmol/L			3.5-5	
					Protein	73	g/L			57-88	
					Sodium	139	mmol/L			132-145	
					Urate	446	umol/L			173-494	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9081	49/M/BL	TPOXX 600 mg	Day 8 - 12 Hours Postdose	06NOV2019 07:00 (8)	Alanine Aminotransferase	29	IU/L			7-56	
					Albumin	44	g/L			37-55	
					Alkaline Phosphatase	86	IU/L			20-116	
					Anion Gap	11	mmol/L			6-17	
					Aspartate Aminotransferase	21	IU/L			10-40	
					Bilirubin	8.4	umol/L			3.2-28.9	
					Blood Urea Nitrogen	4.25	mmol/L			1.79-9.28	
					Calcium	2.45	mmol/L			2.13-2.58	
					Carbon Dioxide	28	mmol/L			22-34	
					Chloride	103	mmol/L			96-108	
					Creatinine	97.2	umol/L			56.6-114.9	
					Gamma Glutamyl Transferase	27	IU/L			5-85	
					Globulin	29	g/L			19-39	
					Glucose	5.11	mmol/L			3-6.44	
					Lactate Dehydrogenase	169	IU/L			82-216	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9081	49/M/BL	TPOXX 600 mg	Day 8 - 12 Hours Postdose	06NOV2019 07:00 (8)	Phosphate	1.23	mmol/L			0.68-1.52	
					Potassium	4.1	mmol/L			3.5-5	
					Protein	73	g/L			57-88	
					Sodium	138	mmol/L			132-145	
					Urate	428	umol/L			173-494	
			Day 9	07NOV2019 07:00 (9)	Alanine Aminotransferase	29	IU/L			7-56	
					Albumin	43	g/L			37-55	
					Alkaline Phosphatase	86	IU/L			20-116	
					Anion Gap	12	mmol/L			6-17	
					Aspartate Aminotransferase	22	IU/L			10-40	
					Bilirubin	8.0	umol/L			3.2-28.9	
					Blood Urea Nitrogen	4.11	mmol/L			1.79-9.28	
					Calcium	2.43	mmol/L			2.13-2.58	
					Carbon Dioxide	26	mmol/L			22-34	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9081	49/M/BL	TPOXX 600 mg	Day 9	07NOV2019 07:00 (9)	Chloride	102	mmol/L			96-108	
					Creatinine	95.5	umol/L			56.6-114.9	
					Gamma Glutamyl Transferase	26	IU/L			5-85	
					Globulin	32	g/L			19-39	
					Glucose	5.44	mmol/L			3-6.44	
					Lactate Dehydrogenase	173	IU/L			82-216	
					Phosphate	1.10	mmol/L			0.68-1.52	
					Potassium	4.1	mmol/L			3.5-5	
					Protein	75	g/L			57-88	
					Sodium	136	mmol/L			132-145	
					Urate	428	umol/L			173-494	
9086	36/M/BL		Screening	11OCT2019 10:03 (-5)	Alanine Aminotransferase	11	IU/L			7-56	
					Albumin	44	g/L			37-55	
					Alkaline Phosphatase	72	IU/L			20-116	
					Anion Gap	11	mmol/L			6-17	

Sex: M=Male, F=Female;
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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9086	36/M/BL		Screening	11OCT2019 10:03 (-5)	Aspartate Aminotransferase	11	IU/L			10-40	
					Bilirubin	6.5	umol/L			3.2-28.9	
					Blood Urea Nitrogen	4.78	mmol/L			1.79-9.28	
					Calcium	2.50	mmol/L			2.13-2.58	
					Carbon Dioxide	32	mmol/L			22-34	
					Chloride	103	mmol/L			96-108	
					Cholesterol	6.06	mmol/L		G1	2.2-6.22	
					Creatinine	98.1	umol/L			56.6-114.9	
					Creatinine Clearance	183.5	mL/min			90-N/A	
					Gamma Glutamyl Transferase	32	IU/L			5-85	
					Globulin	35	g/L			19-39	
					Glucose	5.44	mmol/L			3-6.44	
					HDL Cholesterol	0.88	mmol/L			0.65-2.46	
					LDL Cholesterol	4.53	mmol/L	H NCS	G2	0.96-4.22	
					Lactate Dehydrogenase	125	IU/L			82-216	
					Phosphate	1.20	mmol/L			0.68-1.52	
					Potassium	4.1	mmol/L			3.5-5	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9086	36/M/BL		Screening	11OCT2019 10:03 (-5)	Protein	79	g/L			57-88	
					Sodium	142	mmol/L			132-145	
					Triglycerides	1.44	mmol/L			0-4.52	
					Urate	529	umol/L	H NCS	G1	173-494	
			Check-in	15OCT2019 09:28 (-1)	Alanine Aminotransferase	11	IU/L			7-56	
					Albumin	43	g/L			37-55	
					Alkaline Phosphatase	63	IU/L			20-116	
					Anion Gap	11	mmol/L			6-17	
					Aspartate Aminotransferase	11	IU/L			10-40	
					Bilirubin	5.6	umol/L			3.2-28.9	
					Blood Urea Nitrogen	5.14	mmol/L			1.79-9.28	
					Calcium	2.38	mmol/L			2.13-2.58	
					Carbon Dioxide	30	mmol/L			22-34	
					Chloride	105	mmol/L			96-108	
					Creatinine	104.3	umol/L			56.6-114.9	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9086	36/M/BL		Check-in	15OCT2019 09:28 (-1)	Gamma Glutamyl Transferase	29	IU/L			5-85	
					Globulin	31	g/L			19-39	
					Glucose	5.22	mmol/L			3-6.44	
					Lactate Dehydrogenase	126	IU/L			82-216	
					Phosphate	1.16	mmol/L			0.68-1.52	
					Potassium	3.8	mmol/L			3.5-5	
					Protein	74	g/L			57-88	
					Sodium	142	mmol/L			132-145	
					Urate	523	umol/L	H NCS	G1	173-494	
		TPOXX 600 mg	Day 4	19OCT2019 07:40 (4)	Alanine Aminotransferase	10	IU/L			7-56	
					Albumin	44	g/L			37-55	
					Alkaline Phosphatase	66	IU/L			20-116	
					Anion Gap	12	mmol/L			6-17	
					Aspartate Aminotransferase	11	IU/L			10-40	
					Bilirubin	6.2	umol/L			3.2-28.9	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9086	36/M/BL	TPOXX 600 mg	Day 4	19OCT2019 07:40 (4)	Blood Urea Nitrogen	3.89	mmol/L			1.79-9.28	
					Calcium	2.53	mmol/L			2.13-2.58	
					Carbon Dioxide	33	mmol/L			22-34	
					Chloride	103	mmol/L			96-108	
					Creatinine	101.7	umol/L			56.6-114.9	
					Gamma Glutamyl Transferase	29	IU/L			5-85	
					Globulin	34	g/L			19-39	
					Glucose	5.16	mmol/L			3-6.44	
					Lactate Dehydrogenase	117	IU/L			82-216	
					Phosphate	1.20	mmol/L			0.68-1.52	
					Potassium	4.1	mmol/L			3.5-5	
					Protein	78	g/L			57-88	
					Sodium	144	mmol/L			132-145	
					Urate	518	umol/L	H NCS	G1	173-494	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9086	36/M/BL	TPOXX 600 mg	Day 8 - 12 Hours Postdose	23OCT2019 08:15 (8)	Alanine Aminotransferase	12	IU/L			7-56	
					Albumin	44	g/L			37-55	
					Alkaline Phosphatase	76	IU/L			20-116	
					Anion Gap	11	mmol/L			6-17	
					Aspartate Aminotransferase	12	IU/L			10-40	
					Bilirubin	6.0	umol/L			3.2-28.9	
					Blood Urea Nitrogen	3.82	mmol/L			1.79-9.28	
					Calcium	2.53	mmol/L			2.13-2.58	
					Carbon Dioxide	33	mmol/L			22-34	
					Chloride	102	mmol/L			96-108	
					Creatinine	101.7	umol/L			56.6-114.9	
					Gamma Glutamyl Transferase	29	IU/L			5-85	
					Globulin	35	g/L			19-39	
					Glucose	4.66	mmol/L			3-6.44	
					Lactate Dehydrogenase	117	IU/L			82-216	

Sex: M=Male, F=Female;
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Day = The presented date — First dose date + 1
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9086	36/M/BL	TPOXX 600 mg	Day 8 - 12 Hours Postdose	23OCT2019 08:15 (8)	Phosphate	1.32	mmol/L			0.68-1.52	
					Potassium	3.9	mmol/L			3.5-5	
					Protein	79	g/L			57-88	
					Sodium	142	mmol/L			132-145	
					Urate	488	umol/L		G1	173-494	
			Day 9	24OCT2019 08:15 (9)	Alanine Aminotransferase	13	IU/L			7-56	
					Albumin	44	g/L			37-55	
					Alkaline Phosphatase	73	IU/L			20-116	
					Anion Gap	9	mmol/L			6-17	
					Aspartate Aminotransferase	11	IU/L			10-40	
					Bilirubin	5.5	umol/L			3.2-28.9	
					Blood Urea Nitrogen	4.18	mmol/L			1.79-9.28	
					Calcium	2.45	mmol/L			2.13-2.58	
					Carbon Dioxide	32	mmol/L			22-34	

Sex: M=Male, F=Female;
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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9086	36/M/BL	TPOXX 600 mg	Day 9	24OCT2019 08:15 (9)	Chloride	101	mmol/L			96-108	
					Creatinine	107.9	umol/L			56.6-114.9	
					Gamma Glutamyl Transferase	28	IU/L			5-85	
					Globulin	34	g/L			19-39	
					Glucose	5.11	mmol/L			3-6.44	
					Lactate Dehydrogenase	123	IU/L			82-216	
					Phosphate	1.13	mmol/L			0.68-1.52	
					Potassium	3.9	mmol/L			3.5-5	
					Protein	78	g/L			57-88	
					Sodium	138	mmol/L			132-145	
					Urate	482	umol/L		G1	173-494	
9087	34/F/BL		Screening	11OCT2019 09:47 (-5)	Alanine Aminotransferase	13	IU/L			4-45	
					Albumin	39	g/L			38-49	
					Alkaline Phosphatase	85	IU/L			20-116	
					Anion Gap	11	mmol/L			6-17	

Sex: M=Male, F=Female;
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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9087	34/F/BL		Screening	11OCT2019 09:47 (-5)	Aspartate Aminotransferase	15	IU/L			10-40	
					Bilirubin	4.8	umol/L			3.2-21.7	
					Blood Urea Nitrogen	2.57	mmol/L			1.79-9.28	
					Calcium	2.23	mmol/L			2.13-2.58	
					Carbon Dioxide	27	mmol/L			22-34	
					Chloride	101	mmol/L			96-108	
					Cholesterol	4.17	mmol/L			2.2-6.22	
					Creatinine	61.0	umol/L			39.8-93.7	
					Creatinine Clearance	224.9	mL/min			90-N/A	
					Gamma Glutamyl Transferase	28	IU/L			5-85	
					Globulin	34	g/L			19-39	
					Glucose	5.22	mmol/L			3-6.44	
					HDL Cholesterol	1.35	mmol/L			0.88-2.36	
					LDL Cholesterol	2.54	mmol/L			0.96-4.22	
					Lactate Dehydrogenase	173	IU/L			82-216	
					Phosphate	1.26	mmol/L			0.68-1.52	
					Potassium	4.2	mmol/L			3.5-5	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9087	34/F/BL		Screening	11OCT2019 09:47 (-5)	Protein	73	g/L			57-88	
					Sodium	135	mmol/L			132-145	
					Triglycerides	0.61	mmol/L			0-4.52	
					Urate	410	umol/L	H NCS		119-345	
			Check-in	15OCT2019 09:17 (-1)	Alanine Aminotransferase	16	IU/L			4-45	
					Albumin	42	g/L			38-49	
					Alkaline Phosphatase	81	IU/L			20-116	
					Anion Gap	11	mmol/L			6-17	
					Aspartate Aminotransferase	24	IU/L			10-40	
					Bilirubin	5.1	umol/L			3.2-21.7	
					Blood Urea Nitrogen	2.25	mmol/L			1.79-9.28	
					Calcium	2.28	mmol/L			2.13-2.58	
					Carbon Dioxide	28	mmol/L			22-34	
					Chloride	101	mmol/L			96-108	
					Creatinine	61.9	umol/L			39.8-93.7	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9087	34/F/BL		Check-in	15OCT2019 09:17 (-1)	Gamma Glutamyl Transferase	30	IU/L			5-85	
					Globulin	33	g/L			19-39	
					Glucose	5.38	mmol/L			3-6.44	
					Lactate Dehydrogenase	178	IU/L			82-216	
					Phosphate	1.36	mmol/L			0.68-1.52	
					Potassium	4.1	mmol/L			3.5-5	
					Protein	75	g/L			57-88	
					Sodium	136	mmol/L			132-145	
					Urate	416	umol/L	H NCS		119-345	
		TPOXX 600 mg	Day 4	19OCT2019 07:43 (4)	Alanine Aminotransferase	13	IU/L			4-45	
					Albumin	39	g/L			38-49	
					Alkaline Phosphatase	65	IU/L			20-116	
					Anion Gap	12	mmol/L			6-17	
					Aspartate Aminotransferase	16	IU/L			10-40	
					Bilirubin	6.5	umol/L			3.2-21.7	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9087	34/F/BL	TPOXX 600 mg	Day 4	19OCT2019 07:43 (4)	Blood Urea Nitrogen	2.82	mmol/L			1.79-9.28	
					Calcium	2.35	mmol/L			2.13-2.58	
					Carbon Dioxide	28	mmol/L			22-34	
					Chloride	102	mmol/L			96-108	
					Creatinine	57.5	umol/L			39.8-93.7	
					Gamma Glutamyl Transferase	31	IU/L			5-85	
					Globulin	33	g/L			19-39	
					Glucose	5.44	mmol/L			3-6.44	
					Lactate Dehydrogenase	139	IU/L			82-216	
					Phosphate	1.32	mmol/L			0.68-1.52	
					Potassium	4.0	mmol/L			3.5-5	
					Protein	72	g/L			57-88	
					Sodium	138	mmol/L			132-145	
					Urate	345	umol/L			119-345	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9087	34/F/BL	TPOXX 600 mg	Day 8 - 12 Hours Postdose	23OCT2019 08:18 (8)	Alanine Aminotransferase	25	IU/L			4-45	
					Albumin	42	g/L			38-49	
					Alkaline Phosphatase	81	IU/L			20-116	
					Anion Gap	11	mmol/L			6-17	
					Aspartate Aminotransferase	21	IU/L			10-40	
					Bilirubin	6.3	umol/L			3.2-21.7	
					Blood Urea Nitrogen	3.25	mmol/L			1.79-9.28	
					Calcium	2.48	mmol/L			2.13-2.58	
					Carbon Dioxide	30	mmol/L			22-34	
					Chloride	101	mmol/L			96-108	
					Creatinine	60.1	umol/L			39.8-93.7	
					Gamma Glutamyl Transferase	46	IU/L			5-85	
					Globulin	35	g/L			19-39	
					Glucose	5.33	mmol/L			3-6.44	
					Lactate Dehydrogenase	138	IU/L			82-216	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9087	34/F/BL	TPOXX 600 mg	Day 8 - 12 Hours Postdose	23OCT2019 08:18 (8)	Phosphate	1.49	mmol/L			0.68-1.52	
					Potassium	4.6	mmol/L			3.5-5	
					Protein	77	g/L			57-88	
					Sodium	137	mmol/L			132-145	
					Urate	321	umol/L			119-345	
			Day 9	24OCT2019 08:18 (9)	Alanine Aminotransferase	27	IU/L			4-45	
					Albumin	43	g/L			38-49	
					Alkaline Phosphatase	79	IU/L			20-116	
					Anion Gap	9	mmol/L			6-17	
					Aspartate Aminotransferase	23	IU/L			10-40	
					Bilirubin	6.3	umol/L			3.2-21.7	
					Blood Urea Nitrogen	3.32	mmol/L			1.79-9.28	
					Calcium	2.40	mmol/L			2.13-2.58	
					Carbon Dioxide	28	mmol/L			22-34	

Sex: M=Male, F=Female;
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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9087	34/F/BL	TPOXX 600 mg	Day 9	24OCT2019 08:18 (9)	Chloride	101	mmol/L			96-108	
					Creatinine	61.9	umol/L			39.8-93.7	
					Gamma Glutamyl Transferase	46	IU/L			5-85	
					Globulin	33	g/L			19-39	
					Glucose	5.27	mmol/L			3-6.44	
					Lactate Dehydrogenase	145	IU/L			82-216	
					Phosphate	1.20	mmol/L			0.68-1.52	
					Potassium	4.3	mmol/L			3.5-5	
					Protein	76	g/L			57-88	
					Sodium	134	mmol/L		G1	132-145	
					Urate	321	umol/L			119-345	
9089	29/M/BL		Screening	14OCT2019 09:26 (-2)	Alanine Aminotransferase	28	IU/L			7-56	
					Albumin	44	g/L			37-55	
					Alkaline Phosphatase	47	IU/L			20-116	
					Anion Gap	10	mmol/L			6-17	

Sex: M=Male, F=Female;
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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9089	29/M/BL		Screening	14OCT2019 09:26 (-2)	Aspartate Aminotransferase	21	IU/L			10-40	
					Bilirubin	7.4	umol/L			3.2-28.9	
					Blood Urea Nitrogen	4.46	mmol/L			1.79-9.28	
					Calcium	2.38	mmol/L			2.13-2.58	
					Carbon Dioxide	33	mmol/L			22-34	
					Chloride	101	mmol/L			96-108	
					Cholesterol	5.57	mmol/L		G1	2.2-6.22	
					Creatinine	85.7	umol/L			56.6-114.9	
					Creatinine Clearance	195.5	mL/min			90-N/A	
					Gamma Glutamyl Transferase	27	IU/L			5-85	
					Globulin	26	g/L			19-39	
					Glucose	5.11	mmol/L			3-6.44	
					HDL Cholesterol	0.88	mmol/L			0.65-2.46	
					LDL Cholesterol	3.08	mmol/L			0.96-4.22	
					Lactate Dehydrogenase	150	IU/L			82-216	
					Phosphate	1.32	mmol/L			0.68-1.52	
					Potassium	4.3	mmol/L			3.5-5	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9089	29/M/BL		Screening	14OCT2019 09:26 (-2)	Protein	70	g/L			57-88	
					Sodium	140	mmol/L			132-145	
					Triglycerides	3.48	mmol/L		G2	0-4.52	
					Urate	375	umol/L			173-494	
			Check-in	15OCT2019 08:52 (-1)	Alanine Aminotransferase	27	IU/L			7-56	
					Albumin	43	g/L			37-55	
					Alkaline Phosphatase	47	IU/L			20-116	
					Anion Gap	10	mmol/L			6-17	
					Aspartate Aminotransferase	19	IU/L			10-40	
					Bilirubin	8.0	umol/L			3.2-28.9	
					Blood Urea Nitrogen	4.57	mmol/L			1.79-9.28	
					Calcium	2.35	mmol/L			2.13-2.58	
					Carbon Dioxide	31	mmol/L			22-34	
					Chloride	102	mmol/L			96-108	
					Creatinine	81.3	umol/L			56.6-114.9	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9089	29/M/BL		Check-in	15OCT2019 08:52 (-1)	Gamma Glutamyl Transferase	27	IU/L			5-85	
					Globulin	26	g/L			19-39	
					Glucose	5.16	mmol/L			3-6.44	
					Lactate Dehydrogenase	136	IU/L			82-216	
					Phosphate	1.23	mmol/L			0.68-1.52	
					Potassium	4.1	mmol/L			3.5-5	
					Protein	69	g/L			57-88	
					Sodium	139	mmol/L			132-145	
					Urate	381	umol/L			173-494	
		TPOXX 600 mg	Day 4	19OCT2019 07:49 (4)	Alanine Aminotransferase	26	IU/L			7-56	
					Albumin	45	g/L			37-55	
					Alkaline Phosphatase	47	IU/L			20-116	
					Anion Gap	10	mmol/L			6-17	
					Aspartate Aminotransferase	20	IU/L			10-40	
					Bilirubin	10.9	umol/L			3.2-28.9	

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Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9089	29/M/BL	TPOXX 600 mg	Day 4	19OCT2019 07:49 (4)	Blood Urea Nitrogen	4.18	mmol/L			1.79-9.28	
					Calcium	2.43	mmol/L			2.13-2.58	
					Carbon Dioxide	33	mmol/L			22-34	
					Chloride	101	mmol/L			96-108	
					Creatinine	90.2	umol/L			56.6-114.9	
					Gamma Glutamyl Transferase	27	IU/L			5-85	
					Globulin	29	g/L			19-39	
					Glucose	5.27	mmol/L			3-6.44	
					Lactate Dehydrogenase	132	IU/L			82-216	
					Phosphate	1.20	mmol/L			0.68-1.52	
					Potassium	4.1	mmol/L			3.5-5	
					Protein	74	g/L			57-88	
					Sodium	140	mmol/L			132-145	
					Urate	410	umol/L			173-494	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
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Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9089	29/M/BL	TPOXX 600 mg	Day 8 - 12 Hours Postdose	23OCT2019 08:24 (8)	Alanine Aminotransferase	25	IU/L			7-56	
					Albumin	44	g/L			37-55	
					Alkaline Phosphatase	51	IU/L			20-116	
					Anion Gap	9	mmol/L			6-17	
					Aspartate Aminotransferase	18	IU/L			10-40	
					Bilirubin	10.4	umol/L			3.2-28.9	
					Blood Urea Nitrogen	4.50	mmol/L			1.79-9.28	
					Calcium	2.40	mmol/L			2.13-2.58	
					Carbon Dioxide	32	mmol/L			22-34	
					Chloride	100	mmol/L			96-108	
					Creatinine	91.1	umol/L			56.6-114.9	
					Gamma Glutamyl Transferase	26	IU/L			5-85	
					Globulin	29	g/L			19-39	
					Glucose	5.00	mmol/L			3-6.44	
					Lactate Dehydrogenase	121	IU/L			82-216	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
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Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9089	29/M/BL	TPOXX 600 mg	Day 8 - 12 Hours Postdose	23OCT2019 08:24 (8)	Phosphate	1.36	mmol/L			0.68-1.52	
					Potassium	4.0	mmol/L			3.5-5	
					Protein	73	g/L			57-88	
					Sodium	137	mmol/L			132-145	
					Urate	393	umol/L			173-494	
			Day 9	24OCT2019 08:24 (9)	Alanine Aminotransferase	25	IU/L			7-56	
					Albumin	46	g/L			37-55	
					Alkaline Phosphatase	49	IU/L			20-116	
					Anion Gap	10	mmol/L			6-17	
					Aspartate Aminotransferase	19	IU/L			10-40	
					Bilirubin	9.6	umol/L			3.2-28.9	
					Blood Urea Nitrogen	4.89	mmol/L			1.79-9.28	
					Calcium	2.38	mmol/L			2.13-2.58	
					Carbon Dioxide	32	mmol/L			22-34	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9089	29/M/BL	TPOXX 600 mg	Day 9	24OCT2019 08:24 (9)	Chloride	99	mmol/L			96-108	
					Creatinine	93.7	umol/L			56.6-114.9	
					Gamma Glutamyl Transferase	25	IU/L			5-85	
					Globulin	27	g/L			19-39	
					Glucose	5.11	mmol/L			3-6.44	
					Lactate Dehydrogenase	133	IU/L			82-216	
					Phosphate	1.20	mmol/L			0.68-1.52	
					Potassium	4.0	mmol/L			3.5-5	
					Protein	73	g/L			57-88	
					Sodium	137	mmol/L			132-145	
					Urate	393	umol/L			173-494	
9092	24/M/W		Screening	14OCT2019 09:33 (-2)	Alanine Aminotransferase	18	IU/L			7-56	
					Albumin	38	g/L			37-55	
					Alkaline Phosphatase	90	IU/L			20-116	
					Anion Gap	9	mmol/L			6-17	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9092	24/M/W		Screening	14OCT2019 09:33 (-2)	Aspartate Aminotransferase	19	IU/L			10-40	
					Bilirubin	8.7	umol/L			3.2-28.9	
					Blood Urea Nitrogen	2.32	mmol/L			1.79-9.28	
					Calcium	2.28	mmol/L			2.13-2.58	
					Carbon Dioxide	31	mmol/L			22-34	
					Chloride	103	mmol/L			96-108	
					Cholesterol	4.66	mmol/L			2.2-6.22	
					Creatinine	70.7	umol/L			56.6-114.9	
					Creatinine Clearance	338.3	mL/min			90-N/A	
					Gamma Glutamyl Transferase	62	IU/L			5-85	
					Globulin	24	g/L			19-39	
					Glucose	5.27	mmol/L			3-6.44	
					HDL Cholesterol	1.45	mmol/L			0.65-2.46	
					LDL Cholesterol	2.67	mmol/L			0.96-4.22	
					Lactate Dehydrogenase	165	IU/L			82-216	
					Phosphate	0.94	mmol/L			0.68-1.52	
					Potassium	3.9	mmol/L			3.5-5	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9092	24/M/W		Screening	14OCT2019 09:33 (-2)	Protein	62	g/L			57-88	
					Sodium	139	mmol/L			132-145	
					Triglycerides	1.21	mmol/L			0-4.52	
					Urate	404	umol/L			173-494	
			Check-in	15OCT2019 09:13 (-1)	Alanine Aminotransferase	17	IU/L			7-56	
					Albumin	37	g/L			37-55	
					Alkaline Phosphatase	99	IU/L			20-116	
					Anion Gap	9	mmol/L			6-17	
					Aspartate Aminotransferase	18	IU/L			10-40	
					Bilirubin	6.3	umol/L			3.2-28.9	
					Blood Urea Nitrogen	2.71	mmol/L			1.79-9.28	
					Calcium	2.23	mmol/L			2.13-2.58	
					Carbon Dioxide	29	mmol/L			22-34	
					Chloride	104	mmol/L			96-108	
					Creatinine	71.6	umol/L			56.6-114.9	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9092	24/M/W		Check-in	15OCT2019 09:13 (-1)	Gamma Glutamyl Transferase	59	IU/L			5-85	
					Globulin	22	g/L			19-39	
					Glucose	5.61	mmol/L			3-6.44	
					Lactate Dehydrogenase	158	IU/L			82-216	
					Phosphate	1.16	mmol/L			0.68-1.52	
					Potassium	4.0	mmol/L			3.5-5	
					Protein	59	g/L			57-88	
					Sodium	138	mmol/L			132-145	
					Urate	381	umol/L			173-494	
		TPOXX 600 mg	Day 4	19OCT2019 07:52 (4)	Alanine Aminotransferase	18	IU/L			7-56	
					Albumin	39	g/L			37-55	
					Alkaline Phosphatase	79	IU/L			20-116	
					Anion Gap	12	mmol/L			6-17	
					Aspartate Aminotransferase	21	IU/L			10-40	
					Bilirubin	12.7	umol/L			3.2-28.9	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9092	24/M/W	TPOXX 600 mg	Day 4	19OCT2019 07:52 (4)	Blood Urea Nitrogen	3.57	mmol/L			1.79-9.28	
					Calcium	2.30	mmol/L			2.13-2.58	
					Carbon Dioxide	28	mmol/L			22-34	
					Chloride	103	mmol/L			96-108	
					Creatinine	67.2	umol/L			56.6-114.9	
					Gamma Glutamyl Transferase	52	IU/L			5-85	
					Globulin	25	g/L			19-39	
					Glucose	5.38	mmol/L			3-6.44	
					Lactate Dehydrogenase	150	IU/L			82-216	
					Phosphate	1.26	mmol/L			0.68-1.52	
					Potassium	4.1	mmol/L			3.5-5	
					Protein	64	g/L			57-88	
					Sodium	139	mmol/L			132-145	
					Urate	476	umol/L		G1	173-494	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9092	24/M/W	TPOXX 600 mg	Day 8 - 12 Hours Postdose	23OCT2019 08:27 (8)	Alanine Aminotransferase	18	IU/L			7-56	
					Albumin	42	g/L			37-55	
					Alkaline Phosphatase	97	IU/L			20-116	
					Anion Gap	10	mmol/L			6-17	
					Aspartate Aminotransferase	19	IU/L			10-40	
					Bilirubin	12.0	umol/L			3.2-28.9	
					Blood Urea Nitrogen	3.18	mmol/L			1.79-9.28	
					Calcium	2.40	mmol/L			2.13-2.58	
					Carbon Dioxide	30	mmol/L			22-34	
					Chloride	102	mmol/L			96-108	
					Creatinine	68.1	umol/L			56.6-114.9	
					Gamma Glutamyl Transferase	51	IU/L			5-85	
					Globulin	28	g/L			19-39	
					Glucose	5.16	mmol/L			3-6.44	
					Lactate Dehydrogenase	153	IU/L			82-216	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9092	24/M/W	TPOXX 600 mg	Day 8 - 12 Hours Postdose	23OCT2019 08:27 (8)	Phosphate	1.36	mmol/L			0.68-1.52	
					Potassium	4.1	mmol/L			3.5-5	
					Protein	70	g/L			57-88	
					Sodium	138	mmol/L			132-145	
					Urate	434	umol/L			173-494	
			Day 9	24OCT2019 08:27 (9)	Alanine Aminotransferase	20	IU/L			7-56	
					Albumin	44	g/L			37-55	
					Alkaline Phosphatase	95	IU/L			20-116	
					Anion Gap	10	mmol/L			6-17	
					Aspartate Aminotransferase	21	IU/L			10-40	
					Bilirubin	12.5	umol/L			3.2-28.9	
					Blood Urea Nitrogen	3.11	mmol/L			1.79-9.28	
					Calcium	2.35	mmol/L			2.13-2.58	
					Carbon Dioxide	28	mmol/L			22-34	

Sex: M=Male, F=Female;
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Day = The presented date — First dose date + 1
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Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9092	24/M/W	TPOXX 600 mg	Day 9	24OCT2019 08:27 (9)	Chloride	101	mmol/L			96-108	
					Creatinine	69.8	umol/L			56.6-114.9	
					Gamma Glutamyl Transferase	49	IU/L			5-85	
					Globulin	26	g/L			19-39	
					Glucose	5.44	mmol/L			3-6.44	
					Lactate Dehydrogenase	170	IU/L			82-216	
					Phosphate	1.13	mmol/L			0.68-1.52	
					Potassium	3.8	mmol/L			3.5-5	
					Protein	70	g/L			57-88	
					Sodium	135	mmol/L			132-145	
					Urate	434	umol/L			173-494	
9095	42/M/W		Screening	17OCT2019 13:31 (-13)	Alanine Aminotransferase	16	IU/L			7-56	
					Albumin	45	g/L			37-55	
					Alkaline Phosphatase	76	IU/L			20-116	
					Anion Gap	13	mmol/L			6-17	

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Day = The presented date — First dose date + 1
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Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9095	42/M/W		Screening	17OCT2019 13:31 (-13)	Aspartate Aminotransferase	14	IU/L			10-40	
					Bilirubin	12.8	umol/L			3.2-28.9	
					Blood Urea Nitrogen	5.14	mmol/L			1.79-9.28	
					Calcium	2.43	mmol/L			2.13-2.58	
					Carbon Dioxide	31	mmol/L			22-34	
					Chloride	101	mmol/L			96-108	
					Cholesterol	6.06	mmol/L		G1	2.2-6.22	
					Creatinine	73.4	umol/L			56.6-114.9	
					Creatinine Clearance	246.0	mL/min			90-N/A	
					Gamma Glutamyl Transferase	15	IU/L			5-85	
					Globulin	29	g/L			19-39	
					Glucose	6.38	mmol/L		G1	3-6.44	
					HDL Cholesterol	1.32	mmol/L			0.65-2.46	
					LDL Cholesterol	4.22	mmol/L		G2	0.96-4.22	
					Lactate Dehydrogenase	151	IU/L			82-216	
					Phosphate	0.97	mmol/L			0.68-1.52	
					Potassium	4.7	mmol/L			3.5-5	

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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9095	42/M/W		Screening	17OCT2019 13:31 (-13)	Protein	74	g/L			57-88	
					Sodium	140	mmol/L			132-145	
					Triglycerides	1.13	mmol/L			0-4.52	
					Urate	393	umol/L			173-494	
			Check-in	29OCT2019 08:52 (-1)	Alanine Aminotransferase	16	IU/L			7-56	
					Albumin	44	g/L			37-55	
					Alkaline Phosphatase	66	IU/L			20-116	
					Anion Gap	9	mmol/L			6-17	
					Aspartate Aminotransferase	13	IU/L			10-40	
					Bilirubin	11.6	umol/L			3.2-28.9	
					Blood Urea Nitrogen	5.68	mmol/L			1.79-9.28	
					Calcium	2.35	mmol/L			2.13-2.58	
					Carbon Dioxide	31	mmol/L			22-34	
					Chloride	104	mmol/L			96-108	
					Creatinine	79.6	umol/L			56.6-114.9	

Sex: M=Male, F=Female;
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9095	42/M/W		Check-in	29OCT2019 08:52 (-1)	Gamma Glutamyl Transferase	13	IU/L			5-85	
					Globulin	25	g/L			19-39	
					Glucose	5.88	mmol/L			3-6.44	
					Lactate Dehydrogenase	142	IU/L			82-216	
					Phosphate	1.00	mmol/L			0.68-1.52	
					Potassium	4.3	mmol/L			3.5-5	
					Protein	69	g/L			57-88	
					Sodium	140	mmol/L			132-145	
					Urate	387	umol/L			173-494	
		TPOXX 600 mg	Day 4	02NOV2019 07:31 (4)	Alanine Aminotransferase	20	IU/L			7-56	
					Albumin	44	g/L			37-55	
					Alkaline Phosphatase	71	IU/L			20-116	
					Anion Gap	11	mmol/L			6-17	
					Aspartate Aminotransferase	17	IU/L			10-40	
					Bilirubin	13.3	umol/L			3.2-28.9	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
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Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9095	42/M/W	TPOXX 600 mg	Day 4	02NOV2019 07:31 (4)	Blood Urea Nitrogen	5.36	mmol/L			1.79-9.28	
					Calcium	2.35	mmol/L			2.13-2.58	
					Carbon Dioxide	32	mmol/L			22-34	
					Chloride	102	mmol/L			96-108	
					Creatinine	76.9	umol/L			56.6-114.9	
					Gamma Glutamyl Transferase	14	IU/L			5-85	
					Globulin	26	g/L			19-39	
					Glucose	5.83	mmol/L			3-6.44	
					Lactate Dehydrogenase	129	IU/L			82-216	
					Phosphate	1.10	mmol/L			0.68-1.52	
					Potassium	4.8	mmol/L			3.5-5	
					Protein	70	g/L			57-88	
					Sodium	140	mmol/L			132-145	
					Urate	404	umol/L			173-494	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9095	42/M/W	TPOXX 600 mg	Day 8 - 12 Hours Postdose	06NOV2019 07:06 (8)	Alanine Aminotransferase	27	IU/L			7-56	
					Albumin	44	g/L			37-55	
					Alkaline Phosphatase	71	IU/L			20-116	
					Anion Gap	12	mmol/L			6-17	
					Aspartate Aminotransferase	17	IU/L			10-40	
					Bilirubin	13.5	umol/L			3.2-28.9	
					Blood Urea Nitrogen	5.32	mmol/L			1.79-9.28	
					Calcium	2.40	mmol/L			2.13-2.58	
					Carbon Dioxide	32	mmol/L			22-34	
					Chloride	101	mmol/L			96-108	
					Creatinine	80.4	umol/L			56.6-114.9	
					Gamma Glutamyl Transferase	17	IU/L			5-85	
					Globulin	26	g/L			19-39	
					Glucose	6.33	mmol/L		G1	3-6.44	
					Lactate Dehydrogenase	120	IU/L			82-216	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
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Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9095	42/M/W	TPOXX 600 mg	Day 8 - 12 Hours Postdose	06NOV2019 07:06 (8)	Phosphate	1.13	mmol/L			0.68-1.52	
					Potassium	4.7	mmol/L			3.5-5	
					Protein	70	g/L			57-88	
					Sodium	140	mmol/L			132-145	
					Urate	393	umol/L			173-494	
			Day 9	07NOV2019 07:06 (9)	Alanine Aminotransferase	30	IU/L			7-56	
					Albumin	43	g/L			37-55	
					Alkaline Phosphatase	70	IU/L			20-116	
					Anion Gap	10	mmol/L			6-17	
					Aspartate Aminotransferase	19	IU/L			10-40	
					Bilirubin	10.4	umol/L			3.2-28.9	
					Blood Urea Nitrogen	5.21	mmol/L			1.79-9.28	
					Calcium	2.35	mmol/L			2.13-2.58	
					Carbon Dioxide	33	mmol/L			22-34	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
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Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.2
Laboratory Results — Serum Chemistry
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9095	42/M/W	TPOXX 600 mg	Day 9	07NOV2019 07:06 (9)	Chloride	100	mmol/L			96-108	
					Creatinine	78.7	umol/L			56.6-114.9	
					Gamma Glutamyl Transferase	18	IU/L			5-85	
					Globulin	29	g/L			19-39	
					Glucose	6.11	mmol/L		G1	3-6.44	
					Lactate Dehydrogenase	122	IU/L			82-216	
					Phosphate	0.97	mmol/L			0.68-1.52	
					Potassium	5.1	mmol/L	H NCS		3.5-5	
					Protein	72	g/L			57-88	
					Sodium	138	mmol/L			132-145	
					Urate	399	umol/L			173-494	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.3
Laboratory Results — Urinalysis
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9001	41/M/BL		Screening	19JUL2019 11:12 (-26)	Clarity	Clear				Clear	
					Color	Dk Yellow				Yellow,Dk Yellow	
					Ketones	Negative				Negative,Trace	
					Leukocyte Esterase	Negative				Negative	
					Nitrite	Negative				Negative	
					Occult Blood	Negative				Negative	
					Specific Gravity	1.027				1.002-1.03	
					Urine Bilirubin	Negative				Negative	
					Urine Glucose	Negative				Negative	
					Urine Protein	Negative				Negative	
					Urobilinogen	1.69	umol/dL			0.34-1.69	
					pH	5.5				5-7.5	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.3
Laboratory Results — Urinalysis
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9001	41/M/BL	TPOXX 600 mg	Day 9	22AUG2019 08:26 (9)	Clarity	Clear				Clear	
					Color	Dk Yellow				Yellow,Dk Yellow	
					Ketones	Negative				Negative,Trace	
					Leukocyte Esterase	Negative				Negative	
					Nitrite	Negative				Negative	
					Occult Blood	Negative				Negative	
					Specific Gravity	1.028				1.002-1.03	
					Urine Bilirubin	Negative				Negative	
					Urine Glucose	Negative				Negative	
					Urine Protein	Negative				Negative	
					Urobilinogen	0.34	umol/dL			0.34-1.69	
					pH	5.0				5-7.5	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.3
Laboratory Results — Urinalysis
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9002	48/M/W		Screening	19JUL2019 11:13 (-26)	Clarity	Clear				Clear	
					Color	Yellow				Yellow,Dk Yellow	
					Ketones	Negative				Negative,Trace	
					Leukocyte Esterase	Negative				Negative	
					Nitrite	Negative				Negative	
					Occult Blood	Negative				Negative	
					Specific Gravity	1.027				1.002-1.03	
					Urine Bilirubin	Negative				Negative	
					Urine Glucose	Negative				Negative	
					Urine Protein	Negative				Negative	
					Urobilinogen	0.34	umol/dL			0.34-1.69	
					pH	6.5				5-7.5	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.3
Laboratory Results — Urinalysis
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9002	48/M/W	TPOXX 600 mg	Day 9	22AUG2019 08:25 (9)	Clarity	Clear				Clear	
					Color	Yellow				Yellow,Dk Yellow	
					Ketones	Negative				Negative,Trace	
					Leukocyte Esterase	Negative				Negative	
					Nitrite	Negative				Negative	
					Occult Blood	Negative				Negative	
					Specific Gravity	1.011				1.002-1.03	
					Urine Bilirubin	Negative				Negative	
					Urine Glucose	Negative				Negative	
					Urine Protein	Negative				Negative	
					Urobilinogen	0.34	umol/dL			0.34-1.69	
					pH	6.5				5-7.5	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.3
Laboratory Results — Urinalysis
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9005	40/M/W		Screening	23JUL2019 09:37 (-22)	Clarity	Clear				Clear	
					Color	Yellow				Yellow,Dk Yellow	
					Ketones	Negative				Negative,Trace	
					Leukocyte Esterase	Negative				Negative	
					Nitrite	Negative				Negative	
					Occult Blood	Negative				Negative	
					Specific Gravity	1.019				1.002-1.03	
					Urine Bilirubin	Negative				Negative	
					Urine Glucose	Negative				Negative	
					Urine Protein	Negative				Negative	
					Urobilinogen	1.69	umol/dL			0.34-1.69	
					pH	6.0				5-7.5	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.3
Laboratory Results — Urinalysis
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9005	40/M/W	TPOXX 600 mg	Day 9	22AUG2019 08:04 (9)	Clarity	Clear				Clear	
					Color	Yellow				Yellow,Dk Yellow	
					Ketones	Negative				Negative,Trace	
					Leukocyte Esterase	Negative				Negative	
					Nitrite	Negative				Negative	
					Occult Blood	Negative				Negative	
					Specific Gravity	1.019				1.002-1.03	
					Urine Bilirubin	Negative				Negative	
					Urine Glucose	Negative				Negative	
					Urine Protein	Negative				Negative	
					Urobilinogen	1.69	umol/dL			0.34-1.69	
					pH	7.0				5-7.5	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.3
Laboratory Results — Urinalysis
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9009	21/F/BL		Screening	31JUL2019 10:29 (-14)	Clarity	Clear				Clear	
					Color	Yellow				Yellow,Dk Yellow	
					Ketones	Negative				Negative,Trace	
					Leukocyte Esterase	Negative				Negative	
					Nitrite	Negative				Negative	
					Occult Blood	Negative				Negative	
					Specific Gravity	1.020				1.002-1.03	
					Urine Bilirubin	Negative				Negative	
					Urine Glucose	Negative				Negative	
					Urine Protein	Negative				Negative	
					Urobilinogen	1.69	umol/dL			0.34-1.69	
					pH	6.5				5-7.5	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.3
Laboratory Results — Urinalysis
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9009	21/F/BL	TPOXX 600 mg	Day 9	22AUG2019 08:08 (9)	Clarity	Clear				Clear	
					Color	Yellow				Yellow,Dk Yellow	
					Ketones	Negative				Negative,Trace	
					Leukocyte Esterase	Negative				Negative	
					Nitrite	Negative				Negative	
					Occult Blood	Negative				Negative	
					Specific Gravity	1.021				1.002-1.03	
					Urine Bilirubin	Negative				Negative	
					Urine Glucose	Negative				Negative	
					Urine Protein	Negative				Negative	
					Urobilinogen	0.34	umol/dL			0.34-1.69	
					pH	5.5				5-7.5	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.3
Laboratory Results — Urinalysis
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9012	34/M/BL		Screening	06AUG2019 11:05 (-8)	Clarity	Clear				Clear	
					Color	Yellow				Yellow,Dk Yellow	
					Ketones	Negative				Negative,Trace	
					Leukocyte Esterase	Negative				Negative	
					Nitrite	Negative				Negative	
					Occult Blood	Negative				Negative	
					Specific Gravity	1.003				1.002-1.03	
					Urine Bilirubin	Negative				Negative	
					Urine Glucose	Negative				Negative	
					Urine Protein	Negative				Negative	
					Urobilinogen	0.34	umol/dL			0.34-1.69	
					pH	6.5				5-7.5	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.3
Laboratory Results — Urinalysis
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9012	34/M/BL	TPOXX 600 mg	Day 9	22AUG2019 08:12 (9)	Clarity	Clear				Clear	
					Color	Yellow				Yellow,Dk Yellow	
					Ketones	Negative				Negative,Trace	
					Leukocyte Esterase	Negative				Negative	
					Nitrite	Negative				Negative	
					Occult Blood	Negative				Negative	
					Specific Gravity	1.006				1.002-1.03	
					Urine Bilirubin	Negative				Negative	
					Urine Glucose	Negative				Negative	
					Urine Protein	Negative				Negative	
					Urobilinogen	0.34	umol/dL			0.34-1.69	
					pH	6.5				5-7.5	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.3
Laboratory Results — Urinalysis
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9015	29/M/BL		Screening	12AUG2019 10:12 (-2)	Clarity	Clear				Clear	
					Color	Yellow				Yellow,Dk Yellow	
					Ketones	Negative				Negative,Trace	
					Leukocyte Esterase	Negative				Negative	
					Nitrite	Negative				Negative	
					Occult Blood	Negative				Negative	
					Specific Gravity	1.016				1.002-1.03	
					Urine Bilirubin	Negative				Negative	
					Urine Glucose	Negative				Negative	
					Urine Protein	Negative				Negative	
					Urobilinogen	0.34	umol/dL			0.34-1.69	
					pH	6.0				5-7.5	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.3
Laboratory Results — Urinalysis
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9015	29/M/BL	TPOXX 600 mg	Day 9	22AUG2019 08:10 (9)	Clarity	Clear				Clear	
					Color	Yellow				Yellow,Dk Yellow	
					Ketones	Negative				Negative,Trace	
					Leukocyte Esterase	Negative				Negative	
					Nitrite	Negative				Negative	
					Occult Blood	Negative				Negative	
					Specific Gravity	1.016				1.002-1.03	
					Urine Bilirubin	Negative				Negative	
					Urine Glucose	Negative				Negative	
					Urine Protein	Negative				Negative	
					Urobilinogen	0.34	umol/dL			0.34-1.69	
					pH	7.0				5-7.5	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.3
Laboratory Results — Urinalysis
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9016	48/F/W		Screening	12AUG2019 10:26 (-23)	Clarity	Clear				Clear	
					Color	Yellow				Yellow,Dk Yellow	
					Ketones	Negative				Negative,Trace	
					Leukocyte Esterase	Negative				Negative	
					Nitrite	Negative				Negative	
					Occult Blood	Negative				Negative	
					Specific Gravity	1.022				1.002-1.03	
					Urine Bilirubin	Negative				Negative	
					Urine Glucose	Negative				Negative	
					Urine Protein	Negative				Negative	
					Urobilinogen	0.34	umol/dL			0.34-1.69	
					pH	6.0				5-7.5	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.3
Laboratory Results — Urinalysis
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9016	48/F/W	TPOXX 600 mg	Day 9	12SEP2019 07:02 (9)	Bacteria	51-100	/HPF	A NCS		None Seen,0-20	
					Casts	0	/LPF			0	
					Clarity	Clear				Clear	
					Color	Yellow				Yellow,Dk Yellow	
					Crystals	0	/HPF			0	
					Epithelial Cells	Over 20	/HPF	A NCS		0-5	
					Ketones	Negative				Negative,Trace	
					Leukocyte Esterase	Negative				Negative	
					Nitrite	Negative				Negative	
					Occult Blood	1+		A NCS		Negative	
					Specific Gravity	1.024				1.002-1.03	
					Urine Bilirubin	Negative				Negative	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.3
Laboratory Results — Urinalysis
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9016	48/F/W	TPOXX 600 mg	Day 9	12SEP2019 07:02 (9)	Urine Erythrocytes	0-2	/HPF			0-2	
					Urine Glucose	Negative				Negative	
					Urine Leukocytes	0-5	/HPF			0-5	
					Urine Protein	Negative				Negative	
					Urobilinogen	0.34	umol/dL			0.34-1.69	
					pH	5.5				5-7.5	
9019	41/M/BL		Screening	15AUG2019 16:33 (-20)	Clarity	Clear				Clear	
					Color	Yellow				Yellow,Dk Yellow	
					Ketones	Negative				Negative,Trace	
					Leukocyte Esterase	Negative				Negative	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.3
Laboratory Results — Urinalysis
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9019	41/M/BL		Screening	15AUG2019 16:33 (-20)	Nitrite	Negative				Negative	
					Occult Blood	Negative				Negative	
					Specific Gravity	1.006				1.002-1.03	
					Urine Bilirubin	Negative				Negative	
					Urine Glucose	Negative				Negative	
					Urine Protein	Negative				Negative	
					Urobilinogen	0.34	umol/dL			0.34-1.69	
					pH	6.0				5-7.5	
		TPOXX 600 mg	Day 9	12SEP2019 07:06 (9)	Clarity	Clear				Clear	
					Color	Yellow				Yellow,Dk Yellow	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.3
Laboratory Results — Urinalysis
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9019	41/M/BL	TPOXX 600 mg	Day 9	12SEP2019 07:06 (9)	Ketones	Negative				Negative,Trace	
					Leukocyte Esterase	Negative				Negative	
					Nitrite	Negative				Negative	
					Occult Blood	Negative				Negative	
					Specific Gravity	1.020				1.002-1.03	
					Urine Bilirubin	Negative				Negative	
					Urine Glucose	Negative				Negative	
					Urine Protein	Negative				Negative	
					Urobilinogen	0.34	umol/dL			0.34-1.69	
					pH	5.5				5-7.5	
9020	47/F/BL		Screening	21AUG2019 10:03 (-14)	Clarity	Clear				Clear	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.3
Laboratory Results — Urinalysis
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9020	47/F/BL		Screening	21AUG2019 10:03 (-14)	Color	Yellow				Yellow,Dk Yellow	
					Ketones	Negative				Negative,Trace	
					Leukocyte Esterase	Negative				Negative	
					Nitrite	Negative				Negative	
					Occult Blood	Negative				Negative	
					Specific Gravity	1.006				1.002-1.03	
					Urine Bilirubin	Negative				Negative	
					Urine Glucose	Negative				Negative	
					Urine Protein	Negative				Negative	
					Urobilinogen	0.34	umol/dL			0.34-1.69	
					pH	5.5				5-7.5	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.3
Laboratory Results — Urinalysis
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9020	47/F/BL	TPOXX 600 mg	Day 9	12SEP2019 07:08 (9)	Clarity	Clear				Clear	
					Color	Yellow				Yellow,Dk Yellow	
					Ketones	Negative				Negative,Trace	
					Leukocyte Esterase	Negative				Negative	
					Nitrite	Negative				Negative	
					Occult Blood	Negative				Negative	
					Specific Gravity	1.016				1.002-1.03	
					Urine Bilirubin	Negative				Negative	
					Urine Glucose	Negative				Negative	
					Urine Protein	Negative				Negative	
					Urobilinogen	0.34	umol/dL			0.34-1.69	
					pH	6.0				5-7.5	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.3
Laboratory Results — Urinalysis
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9021	39/F/BL		Screening	21AUG2019 10:05 (-14)	Bacteria	0-20	/HPF			None Seen,0-20	
					Casts	0	/LPF			0	
					Clarity	Clear				Clear	
					Color	Yellow				Yellow,Dk Yellow	
					Crystals	0	/HPF			0	
					Epithelial Cells	0-5	/HPF			0-5	
					Ketones	Negative				Negative,Trace	
					Leukocyte Esterase	Negative				Negative	
					Nitrite	Negative				Negative	
					Occult Blood	Trace		A	NCS	Negative	
					Specific Gravity	1.014				1.002-1.03	
					Urine Bilirubin	Negative				Negative	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.3
Laboratory Results — Urinalysis
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9021	39/F/BL		Screening	21AUG2019 10:05 (-14)	Urine Erythrocytes	0-2	/HPF			0-2	
					Urine Glucose	Negative				Negative	
					Urine Leukocytes	0-5	/HPF			0-5	
					Urine Protein	Negative				Negative	
					Urobilinogen	0.34	umol/dL			0.34-1.69	
					pH	5.5				5-7.5	
		TPOXX 600 mg	Day 9	12SEP2019 07:19 (9)	Bacteria	51-100	/HPF	A NCS		None Seen,0-20	
					Casts	6-10	/LPF	A NCS		0	Hyaline casts seen.
					Clarity	Cloudy		A NCS		Clear	
					Color	Dk Yellow				Yellow,Dk Yellow	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.3
Laboratory Results — Urinalysis
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9021	39/F/BL	TPOXX 600 mg	Day 9	12SEP2019 07:19 (9)	Crystals	0	/HPF			0	
					Epithelial Cells	Over 20	/HPF	A NCS		0-5	
					Ketones	Negative				Negative,Trace	
					Leukocyte Esterase	Negative				Negative	
					Nitrite	Negative				Negative	
					Occult Blood	Trace		A NCS		Negative	
					Specific Gravity	1.034		H NCS		1.002-1.03	
					Urine Bilirubin	Negative				Negative	
					Urine Erythrocytes	3-5	/HPF	A NCS		0-2	
					Urine Glucose	Negative				Negative	
					Urine Leukocytes	0-5	/HPF			0-5	
					Urine Protein	Trace		A NCS		Negative	
					Urobilinogen	0.34	umol/dL			0.34-1.69	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.3
Laboratory Results — Urinalysis
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9021	39/F/BL	TPOXX 600 mg	Day 9	12SEP2019 07:19 (9)	pH	5.0				5-7.5	
9022	31/M/W		Screening	21AUG2019 11:12 (-14)	Clarity	Clear				Clear	
					Color	Yellow				Yellow,Dk Yellow	
					Ketones	Negative				Negative,Trace	
					Leukocyte Esterase	Negative				Negative	
					Nitrite	Negative				Negative	
					Occult Blood	Negative				Negative	
					Specific Gravity	1.022				1.002-1.03	
					Urine Bilirubin	Negative				Negative	
					Urine Glucose	Negative				Negative	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.3
Laboratory Results — Urinalysis
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9022	31/M/W		Screening	21AUG2019 11:12 (-14)	Urine Protein	Negative				Negative	
					Urobilinogen	0.34	umol/dL			0.34-1.69	
					pH	5.5				5-7.5	
		TPOXX 600 mg	Day 9	12SEP2019 07:13 (9)	Clarity	Clear				Clear	
					Color	Yellow				Yellow,Dk Yellow	
					Ketones	Negative				Negative,Trace	
					Leukocyte Esterase	Negative				Negative	
					Nitrite	Negative				Negative	
					Occult Blood	Negative				Negative	
					Specific Gravity	1.012				1.002-1.03	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.3
Laboratory Results — Urinalysis
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9022	31/M/W	TPOXX 600 mg	Day 9	12SEP2019 07:13 (9)	Urine Bilirubin	Negative				Negative	
					Urine Glucose	Negative				Negative	
					Urine Protein	Negative				Negative	
					Urobilinogen	0.34	umol/dL			0.34-1.69	
					pH	5.5				5-7.5	
9024	20/M/BL		Screening	23AUG2019 10:02 (-12)	Clarity	Clear				Clear	
					Color	Yellow				Yellow,Dk Yellow	
					Ketones	Negative				Negative,Trace	
					Leukocyte Esterase	Negative				Negative	
					Nitrite	Negative				Negative	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.3
Laboratory Results — Urinalysis
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9024	20/M/BL		Screening	23AUG2019 10:02 (-12)	Occult Blood	Negative				Negative	
					Specific Gravity	1.025				1.002-1.03	
					Urine Bilirubin	Negative				Negative	
					Urine Glucose	Negative				Negative	
					Urine Protein	Negative				Negative	
					Urobilinogen	0.34	umol/dL			0.34-1.69	
					pH	5.0				5-7.5	
		TPOXX 600 mg	Day 9	12SEP2019 07:17 (9)	Clarity	Clear				Clear	
					Color	Yellow				Yellow,Dk Yellow	
					Ketones	Negative				Negative,Trace	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.3
Laboratory Results — Urinalysis
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9024	20/M/BL	TPOXX 600 mg	Day 9	12SEP2019 07:17 (9)	Leukocyte Esterase	Negative				Negative	
					Nitrite	Negative				Negative	
					Occult Blood	Negative				Negative	
					Specific Gravity	1.017				1.002-1.03	
					Urine Bilirubin	Negative				Negative	
					Urine Glucose	Negative				Negative	
					Urine Protein	Negative				Negative	
					Urobilinogen	0.34	umol/dL			0.34-1.69	
					pH	5.5				5-7.5	
9025	50/M/W		Screening	23AUG2019 10:10 (-26)	Clarity	Clear				Clear	
					Color	Yellow				Yellow,Dk Yellow	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.3
Laboratory Results — Urinalysis
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9025	50/M/W		Screening	23AUG2019 10:10 (-26)	Ketones	Negative				Negative,Trace	
					Leukocyte Esterase	Negative				Negative	
					Nitrite	Negative				Negative	
					Occult Blood	Negative				Negative	
					Specific Gravity	1.020				1.002-1.03	
					Urine Bilirubin	Negative				Negative	
					Urine Glucose	Negative				Negative	
					Urine Protein	Negative				Negative	
					Urobilinogen	1.69	umol/dL			0.34-1.69	
					pH	7.0				5-7.5	
		TPOXX 600 mg	Day 9	26SEP2019 07:07 (9)	Bacteria	0-20	/HPF			None Seen,0-20	
					Casts	0	/LPF			0	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.3
Laboratory Results — Urinalysis
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9025	50/M/W	TPOXX 600 mg	Day 9	26SEP2019 07:07 (9)	Clarity	Clear				Clear	
					Color	Yellow				Yellow,Dk Yellow	
					Crystals	0	/HPF			0	
					Epithelial Cells	0-5	/HPF			0-5	
					Ketones	Negative				Negative,Trace	
					Leukocyte Esterase	Negative				Negative	
					Nitrite	Negative				Negative	
					Occult Blood	1+		A NCS		Negative	
					Specific Gravity	1.023				1.002-1.03	
					Urine Bilirubin	Negative				Negative	
					Urine Erythrocytes	0-2	/HPF			0-2	
					Urine Glucose	Negative				Negative	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.3
Laboratory Results — Urinalysis
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9025	50/M/W	TPOXX 600 mg	Day 9	26SEP2019 07:07 (9)	Urine Leukocytes	0-5	/HPF			0-5	
					Urine Protein	Negative				Negative	
					Urobilinogen	0.34	umol/dL			0.34-1.69	
					pH	5.0				5-7.5	
9033	32/M/W		Screening	29AUG2019 09:03 (-6)	Clarity	Clear				Clear	
					Color	Yellow				Yellow,Dk Yellow	
					Ketones	Negative				Negative,Trace	
					Leukocyte Esterase	Negative				Negative	
					Nitrite	Negative				Negative	
					Occult Blood	Negative				Negative	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.3
Laboratory Results — Urinalysis
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9033	32/M/W		Screening	29AUG2019 09:03 (-6)	Specific Gravity	1.018				1.002-1.03	
					Urine Bilirubin	Negative				Negative	
					Urine Glucose	Negative				Negative	
					Urine Protein	Negative				Negative	
					Urobilinogen	0.34	umol/dL			0.34-1.69	
					pH	5.0				5-7.5	
		TPOXX 600 mg	Day 9	12SEP2019 07:21 (9)	Clarity	Clear				Clear	
					Color	Yellow				Yellow,Dk Yellow	
					Ketones	Negative				Negative,Trace	
					Leukocyte Esterase	Negative				Negative	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.3
Laboratory Results — Urinalysis
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9033	32/M/W	TPOXX 600 mg	Day 9	12SEP2019 07:21 (9)	Nitrite	Negative				Negative	
					Occult Blood	Negative				Negative	
					Specific Gravity	1.022				1.002-1.03	
					Urine Bilirubin	Negative				Negative	
					Urine Glucose	Negative				Negative	
					Urine Protein	Negative				Negative	
					Urobilinogen	1.69	umol/dL			0.34-1.69	
					pH	6.5				5-7.5	
9043	22/M/BL		Screening	11SEP2019 08:45 (-7)	Clarity	Clear				Clear	
					Color	Yellow				Yellow,Dk Yellow	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.3
Laboratory Results — Urinalysis
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9043	22/M/BL		Screening	11SEP2019 08:45 (-7)	Ketones	Negative				Negative,Trace	
					Leukocyte Esterase	Negative				Negative	
					Nitrite	Negative				Negative	
					Occult Blood	Negative				Negative	
					Specific Gravity	1.022				1.002-1.03	
					Urine Bilirubin	Negative				Negative	
					Urine Glucose	Negative				Negative	
					Urine Protein	Negative				Negative	
					Urobilinogen	1.69	umol/dL			0.34-1.69	
					pH	6.5				5-7.5	
		TPOXX 600 mg	Unscheduled - 8.01	23SEP2019 10:29 (6)	Bacteria	0-20	/HPF			None Seen,0-20	
					Casts	0	/LPF			0	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.3
Laboratory Results — Urinalysis
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9043	22/M/BL	TPOXX 600 mg	Unscheduled - 8.01	23SEP2019 10:29 (6)	Clarity	Clear				Clear	
					Color	Yellow				Yellow,Dk Yellow	
					Crystals	0	/HPF			0	
					Epithelial Cells	0-5	/HPF			0-5	
					Ketones	Negative				Negative,Trace	
					Leukocyte Esterase	Negative				Negative	
					Nitrite	Negative				Negative	
					Occult Blood	Negative				Negative	
					Specific Gravity	1.002				1.002-1.03	
					Urine Bilirubin	Negative				Negative	
					Urine Erythrocytes	0-2	/HPF			0-2	
					Urine Glucose	Negative				Negative	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.3
Laboratory Results — Urinalysis
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9043	22/M/BL	TPOXX 600 mg	Unscheduled - 8.01	23SEP2019 10:29 (6)	Urine Leukocytes	0-5	/HPF			0-5	
					Urine Protein	Negative				Negative	
					Urobilinogen	0.34	umol/dL			0.34-1.69	
					pH	7.0				5-7.5	
			Day 9	26SEP2019 07:05 (9)	Clarity	Clear				Clear	
					Color	Yellow				Yellow,Dk Yellow	
					Ketones	Negative				Negative,Trace	
					Leukocyte Esterase	Negative				Negative	
					Nitrite	Negative				Negative	
					Occult Blood	Negative				Negative	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.3
Laboratory Results — Urinalysis
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9043	22/M/BL	TPOXX 600 mg	Day 9	26SEP2019 07:05 (9)	Specific Gravity	1.024				1.002-1.03	
					Urine Bilirubin	Negative				Negative	
					Urine Glucose	Negative				Negative	
					Urine Protein	Negative				Negative	
					Urobilinogen	0.34	umol/dL			0.34-1.69	
					pH	5.5				5-7.5	
9046	34/M/BL		Screening	13SEP2019 08:22 (-5)	Clarity	Clear				Clear	
					Color	Yellow				Yellow,Dk Yellow	
					Ketones	Negative				Negative,Trace	
					Leukocyte Esterase	Negative				Negative	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.3
Laboratory Results — Urinalysis
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9046	34/M/BL		Screening	13SEP2019 08:22 (-5)	Nitrite	Negative				Negative	
					Occult Blood	Negative				Negative	
					Specific Gravity	1.023				1.002-1.03	
					Urine Bilirubin	Negative				Negative	
					Urine Glucose	Negative				Negative	
					Urine Protein	Negative				Negative	
					Urobilinogen	1.69	umol/dL			0.34-1.69	
					pH	6.0				5-7.5	
		TPOXX 600 mg	Day 9	26SEP2019 07:08 (9)	Clarity	Clear				Clear	
					Color	Yellow				Yellow,Dk Yellow	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.3
Laboratory Results — Urinalysis
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9046	34/M/BL	TPOXX 600 mg	Day 9	26SEP2019 07:08 (9)	Ketones	Negative				Negative,Trace	
					Leukocyte Esterase	Negative				Negative	
					Nitrite	Negative				Negative	
					Occult Blood	Negative				Negative	
					Specific Gravity	1.011				1.002-1.03	
					Urine Bilirubin	Negative				Negative	
					Urine Glucose	Negative				Negative	
					Urine Protein	Negative				Negative	
					Urobilinogen	0.34	umol/dL			0.34-1.69	
					pH	6.0				5-7.5	
9051	34/M/BL		Screening	19SEP2019 08:40 (-13)	Bacteria	0-20	/HPF			None Seen,0-20	
					Casts	0	/LPF			0	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.3
Laboratory Results — Urinalysis
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9051	34/M/BL		Screening	19SEP2019 08:40 (-13)	Clarity	Clear				Clear	
					Color	Yellow				Yellow,Dk Yellow	
					Crystals	0	/HPF			0	
					Epithelial Cells	0-5	/HPF			0-5	
					Ketones	Negative				Negative,Trace	
					Leukocyte Esterase	Negative				Negative	
					Nitrite	Positive		A NCS		Negative	
					Occult Blood	Negative				Negative	
					Specific Gravity	1.016				1.002-1.03	
					Urine Bilirubin	Negative				Negative	
					Urine Erythrocytes	0-2	/HPF			0-2	
					Urine Glucose	Negative				Negative	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.3
Laboratory Results — Urinalysis
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9051	34/M/BL		Screening	19SEP2019 08:40 (-13)	Urine Leukocytes	0-5	/HPF			0-5	
					Urine Protein	Negative				Negative	
					Urobilinogen	0.34	umol/dL			0.34-1.69	
					pH	6.5				5-7.5	
		TPOXX 600 mg	Day 9	10OCT2019 07:16 (9)	Clarity	Clear				Clear	
					Color	Yellow				Yellow,Dk Yellow	
					Ketones	Negative				Negative,Trace	
					Leukocyte Esterase	Negative				Negative	
					Nitrite	Negative				Negative	
					Occult Blood	Negative				Negative	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.3
Laboratory Results — Urinalysis
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9051	34/M/BL	TPOXX 600 mg	Day 9	10OCT2019 07:16 (9)	Specific Gravity	1.015				1.002-1.03	
					Urine Bilirubin	Negative				Negative	
					Urine Glucose	Negative				Negative	
					Urine Protein	Negative				Negative	
					Urobilinogen	0.34	umol/dL			0.34-1.69	
					pH	6.0				5-7.5	
9052	42/M/BL		Screening	21SEP2019 12:33 (-11)	Clarity	Clear				Clear	
					Color	Yellow				Yellow,Dk Yellow	
					Ketones	Negative				Negative,Trace	
					Leukocyte Esterase	Negative				Negative	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.3
Laboratory Results — Urinalysis
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9052	42/M/BL		Screening	21SEP2019 12:33 (-11)	Nitrite	Negative				Negative	
					Occult Blood	Negative				Negative	
					Specific Gravity	1.021				1.002-1.03	
					Urine Bilirubin	Negative				Negative	
					Urine Glucose	Negative				Negative	
					Urine Protein	Negative				Negative	
					Urobilinogen	0.34	umol/dL			0.34-1.69	
					pH	6.5				5-7.5	
		TPOXX 600 mg	Day 9	10OCT2019 07:20 (9)	Clarity	Clear				Clear	
					Color	Yellow				Yellow,Dk Yellow	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.3
Laboratory Results — Urinalysis
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9052	42/M/BL	TPOXX 600 mg	Day 9	10OCT2019 07:20 (9)	Ketones	Negative				Negative,Trace	
					Leukocyte Esterase	Negative				Negative	
					Nitrite	Negative				Negative	
					Occult Blood	Negative				Negative	
					Specific Gravity	1.021				1.002-1.03	
					Urine Bilirubin	Negative				Negative	
					Urine Glucose	Negative				Negative	
					Urine Protein	Negative				Negative	
					Urobilinogen	0.34	umol/dL			0.34-1.69	
					pH	6.0				5-7.5	
9056	31/F/BL		Screening	24SEP2019 09:20 (-8)	Clarity	Clear				Clear	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.3
Laboratory Results — Urinalysis
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9056	31/F/BL		Screening	24SEP2019 09:20 (-8)	Color	Yellow				Yellow,Dk Yellow	
					Ketones	Negative				Negative,Trace	
					Leukocyte Esterase	Negative				Negative	
					Nitrite	Negative				Negative	
					Occult Blood	Negative				Negative	
					Specific Gravity	1.017				1.002-1.03	
					Urine Bilirubin	Negative				Negative	
					Urine Glucose	Negative				Negative	
					Urine Protein	Negative				Negative	
					Urobilinogen	1.69	umol/dL			0.34-1.69	
					pH	6.0				5-7.5	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.3
Laboratory Results — Urinalysis
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9056	31/F/BL	TPOXX 600 mg	Day 9	10OCT2019 07:08 (9)	Bacteria	51-100	/HPF	A NCS		None Seen,0-20	
					Casts	1-2	/LPF	A NCS		0	Hyaline casts seen.
					Clarity	Clear				Clear	
					Color	Yellow				Yellow,Dk Yellow	
					Crystals	0	/HPF			0	
					Epithelial Cells	6-10	/HPF	A NCS		0-5	
					Ketones	Negative				Negative,Trace	
					Leukocyte Esterase	Trace		A NCS		Negative	
					Nitrite	Negative				Negative	
					Occult Blood	Negative				Negative	
					Specific Gravity	1.027				1.002-1.03	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.3
Laboratory Results — Urinalysis
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9056	31/F/BL	TPOXX 600 mg	Day 9	10OCT2019 07:08 (9)	Urine Bilirubin	Negative				Negative	
					Urine Erythrocytes	0-2	/HPF			0-2	
					Urine Glucose	Negative				Negative	
					Urine Leukocytes	6-10	/HPF	A NCS		0-5	
					Urine Protein	Negative				Negative	
					Urobilinogen	0.34	umol/dL			0.34-1.69	
					pH	6.0				5-7.5	
9057	29/F/W		Screening	25SEP2019 15:56 (-7)	Bacteria	51-100	/HPF	A NCS		None Seen,0-20	
					Casts	0	/LPF			0	
					Clarity	Clear				Clear	
					Color	Dk Yellow				Yellow,Dk Yellow	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.3
Laboratory Results — Urinalysis
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9057	29/F/W		Screening	25SEP2019 15:56 (-7)	Crystals	0	/HPF			0	
					Epithelial Cells	11-20	/HPF	A NCS		0-5	
					Ketones	Negative				Negative,Trace	
					Leukocyte Esterase	Negative				Negative	
					Nitrite	Positive		A NCS		Negative	
					Occult Blood	Negative				Negative	
					Specific Gravity	1.027				1.002-1.03	
					Urine Bilirubin	Negative				Negative	
					Urine Erythrocytes	0-2	/HPF			0-2	
					Urine Glucose	Negative				Negative	
					Urine Leukocytes	0-5	/HPF			0-5	
					Urine Protein	Negative				Negative	
					Urobilinogen	0.34	umol/dL			0.34-1.69	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.3
Laboratory Results — Urinalysis
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9057	29/F/W		Screening	25SEP2019 15:56 (-7)	pH	5.5				5-7.5	
			Screening	30SEP2019 10:10 (-2), R	Bacteria	None Seen	/HPF			None Seen,0-20	
					Casts	0	/LPF			0	
					Clarity	Clear				Clear	
					Color	Yellow				Yellow,Dk Yellow	
					Crystals	0	/HPF			0	
					Epithelial Cells	0-5	/HPF			0-5	
					Ketones	Negative				Negative,Trace	
					Leukocyte Esterase	Negative				Negative	
					Nitrite	Negative				Negative	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.3
Laboratory Results — Urinalysis
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9057	29/F/W		Screening	30SEP2019 10:10 (-2), R	Occult Blood	Negative				Negative	
					Specific Gravity	1.004				1.002-1.03	
					Urine Bilirubin	Negative				Negative	
					Urine Erythrocytes	0-2	/HPF			0-2	
					Urine Glucose	Negative				Negative	
					Urine Leukocytes	0-5	/HPF			0-5	
					Urine Protein	Negative				Negative	
					Urobilinogen	0.34	umol/dL			0.34-1.69	
					pH	6.5				5-7.5	
		TPOXX 600 mg	Day 9	10OCT2019 07:08 (9)	Bacteria	Over 100	/HPF	A NCS		None Seen,0-20	
					Casts	0	/LPF			0	
					Clarity	Clear				Clear	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.3
Laboratory Results — Urinalysis
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9057	29/F/W	TPOXX 600 mg	Day 9	10OCT2019 07:08 (9)	Color	Yellow				Yellow,Dk Yellow	
					Crystals	0	/HPF			0	
					Epithelial Cells	0-5	/HPF			0-5	
					Ketones	Negative				Negative,Trace	
					Leukocyte Esterase	Negative				Negative	
					Nitrite	Positive		A NCS		Negative	
					Occult Blood	Negative				Negative	
					Specific Gravity	1.026				1.002-1.03	
					Urine Bilirubin	Negative				Negative	
					Urine Erythrocytes	0-2	/HPF			0-2	
					Urine Glucose	Negative				Negative	
					Urine Leukocytes	0-5	/HPF			0-5	
					Urine Protein	Negative				Negative	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.3
Laboratory Results — Urinalysis
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9057	29/F/W	TPOXX 600 mg	Day 9	10OCT2019 07:08 (9)	Urobilinogen	0.34	umol/dL			0.34-1.69	
					pH	5.5				5-7.5	
			Day 9	11OCT2019 10:33 (10), R	Bacteria	0-20	/HPF			None Seen,0-20	
					Casts	0	/LPF			0	
					Clarity	Clear				Clear	
					Color	Yellow				Yellow,Dk Yellow	
					Crystals	0	/HPF			0	
					Epithelial Cells	0-5	/HPF			0-5	
					Ketones	Negative				Negative,Trace	
					Leukocyte Esterase	Negative				Negative	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.3
Laboratory Results — Urinalysis
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9057	29/F/W	TPOXX 600 mg	Day 9	11OCT2019 10:33 (10), R	Nitrite	Negative				Negative	
					Occult Blood	Negative				Negative	
					Specific Gravity	1.002				1.002-1.03	
					Urine Bilirubin	Negative				Negative	
					Urine Erythrocytes	0-2	/HPF			0-2	
					Urine Glucose	Negative				Negative	
					Urine Leukocytes	0-5	/HPF			0-5	
					Urine Protein	Negative				Negative	
					Urobilinogen	0.34	umol/dL			0.34-1.69	
					pH	6.0				5-7.5	
9058	32/M/W		Screening	26SEP2019 08:59 (-20)	Clarity	Clear				Clear	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.3
Laboratory Results — Urinalysis
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9058	32/M/W		Screening	26SEP2019 08:59 (-20)	Color	Yellow				Yellow,Dk Yellow	
					Ketones	Negative				Negative,Trace	
					Leukocyte Esterase	Negative				Negative	
					Nitrite	Negative				Negative	
					Occult Blood	Negative				Negative	
					Specific Gravity	1.008				1.002-1.03	
					Urine Bilirubin	Negative				Negative	
					Urine Glucose	Negative				Negative	
					Urine Protein	Negative				Negative	
					Urobilinogen	0.34	umol/dL			0.34-1.69	
					pH	6.0				5-7.5	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.3
Laboratory Results — Urinalysis
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9058	32/M/W	TPOXX 600 mg	Day 9	24OCT2019 07:09 (9)	Clarity	Clear				Clear	
					Color	Yellow				Yellow,Dk Yellow	
					Ketones	Negative				Negative,Trace	
					Leukocyte Esterase	Negative				Negative	
					Nitrite	Negative				Negative	
					Occult Blood	Negative				Negative	
					Specific Gravity	1.030				1.002-1.03	
					Urine Bilirubin	Negative				Negative	
					Urine Glucose	Negative				Negative	
					Urine Protein	Negative				Negative	
					Urobilinogen	0.34	umol/dL			0.34-1.69	
					pH	6.0				5-7.5	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.3
Laboratory Results — Urinalysis
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9061	21/F/BL		Screening	26SEP2019 10:16 (-20)	Bacteria	51-100	/HPF	A NCS		None Seen,0-20	
					Casts	0	/LPF			0	
					Clarity	Clear				Clear	
					Color	Yellow				Yellow,Dk Yellow	
					Crystals	0	/HPF			0	
					Epithelial Cells	11-20	/HPF	A NCS		0-5	
					Ketones	Negative				Negative,Trace	
					Leukocyte Esterase	1+		A NCS		Negative	
					Nitrite	Negative				Negative	
					Occult Blood	1+		A NCS		Negative	
					Specific Gravity	1.029				1.002-1.03	
					Urine Bilirubin	Negative				Negative	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.3
Laboratory Results — Urinalysis
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9061	21/F/BL		Screening	26SEP2019 10:16 (-20)	Urine Erythrocytes	0-2	/HPF			0-2	
					Urine Glucose	Negative				Negative	
					Urine Leukocytes	11-20	/HPF	A NCS		0-5	
					Urine Protein	Negative				Negative	
					Urobilinogen	0.34	umol/dL			0.34-1.69	
					pH	6.0				5-7.5	
		TPOXX 600 mg	Day 9	24OCT2019 07:09 (9)	Bacteria	Over 100	/HPF	A NCS		None Seen,0-20	
					Casts	0	/LPF			0	
					Clarity	Clear				Clear	
					Color	Yellow				Yellow,Dk Yellow	
					Crystals	0	/HPF			0	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.3
Laboratory Results — Urinalysis
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9061	21/F/BL	TPOXX 600 mg	Day 9	24OCT2019 07:09 (9)	Epithelial Cells	Over 20	/HPF	A NCS		0-5	
					Ketones	Negative				Negative,Trace	
					Leukocyte Esterase	1+		A NCS		Negative	
					Nitrite	Negative				Negative	
					Occult Blood	Negative				Negative	
					Specific Gravity	1.026				1.002-1.03	
					Urine Bilirubin	Negative				Negative	
					Urine Erythrocytes	0-2	/HPF			0-2	
					Urine Glucose	Negative				Negative	
					Urine Leukocytes	21-50	/HPF	A NCS		0-5	
					Urine Protein	Negative				Negative	
					Urobilinogen	0.34	umol/dL			0.34-1.69	
					pH	6.0				5-7.5	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.3
Laboratory Results — Urinalysis
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9061	21/F/BL	TPOXX 600 mg	Day 9	31OCT2019 18:11 (16), R	Bacteria	Over 100	/HPF	A NCS		None Seen,0-20	
					Casts	0	/LPF			0	
					Clarity	Cloudy		A NCS		Clear	
					Color	Yellow				Yellow,Dk Yellow	
					Crystals	0	/HPF			0	
					Epithelial Cells	11-20	/HPF	A NCS		0-5	
					Ketones	Trace				Negative,Trace	
					Leukocyte Esterase	1+		A NCS		Negative	
					Nitrite	Positive		A NCS		Negative	
					Occult Blood	Negative				Negative	
					Specific Gravity	1.029				1.002-1.03	
					Urine Bilirubin	Negative				Negative	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.3
Laboratory Results — Urinalysis
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9061	21/F/BL	TPOXX 600 mg	Day 9	31OCT2019 18:11 (16), R	Urine Erythrocytes	0-2	/HPF			0-2	
					Urine Glucose	Negative				Negative	
					Urine Leukocytes	11-20	/HPF	A NCS		0-5	
					Urine Protein	Negative				Negative	
					Urobilinogen	1.69	umol/dL			0.34-1.69	
					pH	6.5				5-7.5	
9062	33/M/BL		Screening	30SEP2019 10:35 (-2)	Clarity	Clear				Clear	
					Color	Yellow				Yellow,Dk Yellow	
					Ketones	Negative				Negative,Trace	
					Leukocyte Esterase	Negative				Negative	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.3
Laboratory Results — Urinalysis
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9062	33/M/BL		Screening	30SEP2019 10:35 (-2)	Nitrite	Negative				Negative	
					Occult Blood	Negative				Negative	
					Specific Gravity	1.003				1.002-1.03	
					Urine Bilirubin	Negative				Negative	
					Urine Glucose	Negative				Negative	
					Urine Protein	Negative				Negative	
					Urobilinogen	0.34	umol/dL			0.34-1.69	
					pH	7.0				5-7.5	
		TPOXX 600 mg	Day 9	10OCT2019 07:11 (9)	Bacteria	0-20	/HPF			None Seen,0-20	
					Casts	0	/LPF			0	
					Clarity	Cloudy		A NCS		Clear	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.3
Laboratory Results — Urinalysis
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9062	33/M/BL	TPOXX 600 mg	Day 9	10OCT2019 07:11 (9)	Color	Yellow				Yellow,Dk Yellow	
					Crystals	0	/HPF			0	
					Epithelial Cells	0-5	/HPF			0-5	
					Ketones	Negative				Negative,Trace	
					Leukocyte Esterase	Negative				Negative	
					Nitrite	Negative				Negative	
					Occult Blood	Trace		A	NCS	Negative	
					Specific Gravity	1.010				1.002-1.03	
					Urine Bilirubin	Negative				Negative	
					Urine Erythrocytes	0-2	/HPF			0-2	
					Urine Glucose	Negative				Negative	
					Urine Leukocytes	0-5	/HPF			0-5	
					Urine Protein	Trace		A	NCS	Negative	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.3
Laboratory Results — Urinalysis
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9062	33/M/BL	TPOXX 600 mg	Day 9	10OCT2019 07:11 (9)	Urobilinogen	0.34	umol/dL			0.34-1.69	
					pH	7.0				5-7.5	
9063	35/M/W		Screening	30SEP2019 08:58 (-2)	Clarity	Clear				Clear	
					Color	Yellow				Yellow,Dk Yellow	
					Ketones	Negative				Negative,Trace	
					Leukocyte Esterase	Negative				Negative	
					Nitrite	Negative				Negative	
					Occult Blood	Negative				Negative	
					Specific Gravity	1.013				1.002-1.03	
					Urine Bilirubin	Negative				Negative	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.3
Laboratory Results — Urinalysis
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9063	35/M/W		Screening	30SEP2019 08:58 (-2)	Urine Glucose	Negative				Negative	
					Urine Protein	Negative				Negative	
					Urobilinogen	0.34	umol/dL			0.34-1.69	
					pH	5.0				5-7.5	
		TPOXX 600 mg	Day 9	10OCT2019 07:10 (9)	Bacteria	21-50	/HPF	A NCS		None Seen,0-20	
					Casts	0	/LPF			0	
					Clarity	Clear				Clear	
					Color	Yellow				Yellow,Dk Yellow	
					Crystals	0	/HPF			0	
					Epithelial Cells	0-5	/HPF			0-5	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.3
Laboratory Results — Urinalysis
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9063	35/M/W	TPOXX 600 mg	Day 9	10OCT2019 07:10 (9)	Ketones	Negative				Negative,Trace	
					Leukocyte Esterase	Trace		A NCS		Negative	
					Nitrite	Negative				Negative	
					Occult Blood	Negative				Negative	
					Specific Gravity	1.021				1.002-1.03	
					Urine Bilirubin	Negative				Negative	
					Urine Erythrocytes	0-2	/HPF			0-2	
					Urine Glucose	Negative				Negative	
					Urine Leukocytes	6-10	/HPF	A NCS		0-5	
					Urine Protein	Negative				Negative	
					Urobilinogen	0.34	umol/dL			0.34-1.69	
					pH	5.5				5-7.5	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.3
Laboratory Results — Urinalysis
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9063	35/M/W	TPOXX 600 mg	Day 9	14OCT2019 09:54 (13), R	Bacteria	None Seen	/HPF			None Seen,0-20	
					Casts	0	/LPF			0	
					Clarity	Clear				Clear	
					Color	Yellow				Yellow,Dk Yellow	
					Crystals	0	/HPF			0	
					Epithelial Cells	0-5	/HPF			0-5	
					Ketones	Negative				Negative,Trace	
					Leukocyte Esterase	Negative				Negative	
					Nitrite	Negative				Negative	
					Occult Blood	Negative				Negative	
					Specific Gravity	1.020				1.002-1.03	
					Urine Bilirubin	Negative				Negative	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.3
Laboratory Results — Urinalysis
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9063	35/M/W	TPOXX 600 mg	Day 9	14OCT2019 09:54 (13), R	Urine Erythrocytes	0-2	/HPF			0-2	
					Urine Glucose	Negative				Negative	
					Urine Leukocytes	0-5	/HPF			0-5	
					Urine Protein	Negative				Negative	
					Urobilinogen	0.34	umol/dL			0.34-1.69	
					pH	5.5				5-7.5	
9069	41/F/BL		Screening	30SEP2019 10:15 (-16)	Clarity	Clear				Clear	
					Color	Yellow				Yellow,Dk Yellow	
					Ketones	Negative				Negative,Trace	
					Leukocyte Esterase	Negative				Negative	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.3
Laboratory Results — Urinalysis
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9069	41/F/BL		Screening	30SEP2019 10:15 (-16)	Nitrite	Negative				Negative	
					Occult Blood	Negative				Negative	
					Specific Gravity	1.012				1.002-1.03	
					Urine Bilirubin	Negative				Negative	
					Urine Glucose	Negative				Negative	
					Urine Protein	Negative				Negative	
					Urobilinogen	0.34	umol/dL			0.34-1.69	
					pH	6.0				5-7.5	
		TPOXX 600 mg	Day 9	24OCT2019 07:10 (9)	Clarity	Clear				Clear	
					Color	Yellow				Yellow,Dk Yellow	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.3
Laboratory Results — Urinalysis
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9069	41/F/BL	TPOXX 600 mg	Day 9	24OCT2019 07:10 (9)	Ketones	Negative				Negative,Trace	
					Leukocyte Esterase	Negative				Negative	
					Nitrite	Negative				Negative	
					Occult Blood	Negative				Negative	
					Specific Gravity	1.018				1.002-1.03	
					Urine Bilirubin	Negative				Negative	
					Urine Glucose	Negative				Negative	
					Urine Protein	Negative				Negative	
					Urobilinogen	0.34	umol/dL			0.34-1.69	
					pH	6.5				5-7.5	
9073	40/M/BL		Screening	04OCT2019 13:25 (-12)	Clarity	Clear				Clear	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.3
Laboratory Results — Urinalysis
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9073	40/M/BL		Screening	04OCT2019 13:25 (-12)	Color	Dk Yellow				Yellow,Dk Yellow	
					Ketones	Negative				Negative,Trace	
					Leukocyte Esterase	Negative				Negative	
					Nitrite	Negative				Negative	
					Occult Blood	Negative				Negative	
					Specific Gravity	1.026				1.002-1.03	
					Urine Bilirubin	Negative				Negative	
					Urine Glucose	Negative				Negative	
					Urine Protein	Negative				Negative	
					Urobilinogen	0.34	umol/dL			0.34-1.69	
					pH	5.5				5-7.5	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.3
Laboratory Results — Urinalysis
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9073	40/M/BL	TPOXX 600 mg	Day 9	24OCT2019 07:18 (9)	Clarity	Clear				Clear	
					Color	Yellow				Yellow,Dk Yellow	
					Ketones	Negative				Negative,Trace	
					Leukocyte Esterase	Negative				Negative	
					Nitrite	Negative				Negative	
					Occult Blood	Negative				Negative	
					Specific Gravity	1.021				1.002-1.03	
					Urine Bilirubin	Negative				Negative	
					Urine Glucose	Negative				Negative	
					Urine Protein	Negative				Negative	
					Urobilinogen	0.34	umol/dL			0.34-1.69	
					pH	5.5				5-7.5	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.3
Laboratory Results — Urinalysis
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9077	37/F/W		Screening	05OCT2019 13:19 (-11)	Clarity	Clear				Clear	
					Color	Yellow				Yellow,Dk Yellow	
					Ketones	Negative				Negative,Trace	
					Leukocyte Esterase	Negative				Negative	
					Nitrite	Negative				Negative	
					Occult Blood	Negative				Negative	
					Specific Gravity	1.007				1.002-1.03	
					Urine Bilirubin	Negative				Negative	
					Urine Glucose	Negative				Negative	
					Urine Protein	Negative				Negative	
					Urobilinogen	0.34	umol/dL			0.34-1.69	
					pH	5.5				5-7.5	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.3
Laboratory Results — Urinalysis
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9077	37/F/W	TPOXX 600 mg	Day 9	24OCT2019 07:15 (9)	Clarity	Clear				Clear	
					Color	Yellow				Yellow,Dk Yellow	
					Ketones	Negative				Negative,Trace	
					Leukocyte Esterase	Negative				Negative	
					Nitrite	Negative				Negative	
					Occult Blood	Negative				Negative	
					Specific Gravity	1.018				1.002-1.03	
					Urine Bilirubin	Negative				Negative	
					Urine Glucose	Negative				Negative	
					Urine Protein	Negative				Negative	
					Urobilinogen	0.34	umol/dL			0.34-1.69	
					pH	6.0				5-7.5	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.3
Laboratory Results — Urinalysis
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9080	41/F/BL		Screening	08OCT2019 11:11 (-8)	Clarity	Clear				Clear	
					Color	Yellow				Yellow,Dk Yellow	
					Ketones	Negative				Negative,Trace	
					Leukocyte Esterase	Negative				Negative	
					Nitrite	Negative				Negative	
					Occult Blood	Negative				Negative	
					Specific Gravity	1.005				1.002-1.03	
					Urine Bilirubin	Negative				Negative	
					Urine Glucose	Negative				Negative	
					Urine Protein	Negative				Negative	
					Urobilinogen	0.34	umol/dL			0.34-1.69	
					pH	6.0				5-7.5	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.3
Laboratory Results — Urinalysis
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9080	41/F/BL	TPOXX 600 mg	Day 9	24OCT2019 07:23 (9)	Clarity	Clear				Clear	
					Color	Yellow				Yellow,Dk Yellow	
					Ketones	Negative				Negative,Trace	
					Leukocyte Esterase	Negative				Negative	
					Nitrite	Negative				Negative	
					Occult Blood	Negative				Negative	
					Specific Gravity	1.020				1.002-1.03	
					Urine Bilirubin	Negative				Negative	
					Urine Glucose	Negative				Negative	
					Urine Protein	Negative				Negative	
					Urobilinogen	0.34	umol/dL			0.34-1.69	
					pH	5.5				5-7.5	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.3
Laboratory Results — Urinalysis
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9081	49/M/BL		Screening	10OCT2019 11:34 (-20)	Clarity	Clear				Clear	
					Color	Dk Yellow				Yellow,Dk Yellow	
					Ketones	Negative				Negative,Trace	
					Leukocyte Esterase	Negative				Negative	
					Nitrite	Negative				Negative	
					Occult Blood	Negative				Negative	
					Specific Gravity	1.025				1.002-1.03	
					Urine Bilirubin	Negative				Negative	
					Urine Glucose	Negative				Negative	
					Urine Protein	Negative				Negative	
					Urobilinogen	1.69	umol/dL			0.34-1.69	
					pH	6.0				5-7.5	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.3
Laboratory Results — Urinalysis
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9081	49/M/BL	TPOXX 600 mg	Day 9	07NOV2019 06:02 (9)	Clarity	Clear				Clear	
					Color	Yellow				Yellow,Dk Yellow	
					Ketones	Negative				Negative,Trace	
					Leukocyte Esterase	Negative				Negative	
					Nitrite	Negative				Negative	
					Occult Blood	Negative				Negative	
					Specific Gravity	1.023				1.002-1.03	
					Urine Bilirubin	Negative				Negative	
					Urine Glucose	Negative				Negative	
					Urine Protein	Negative				Negative	
					Urobilinogen	1.69	umol/dL			0.34-1.69	
					pH	6.5				5-7.5	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.3
Laboratory Results — Urinalysis
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9086	36/M/BL		Screening	11OCT2019 08:56 (-5)	Clarity	Clear				Clear	
					Color	Yellow				Yellow,Dk Yellow	
					Ketones	Negative				Negative,Trace	
					Leukocyte Esterase	Negative				Negative	
					Nitrite	Negative				Negative	
					Occult Blood	Negative				Negative	
					Specific Gravity	1.022				1.002-1.03	
					Urine Bilirubin	Negative				Negative	
					Urine Glucose	Negative				Negative	
					Urine Protein	Negative				Negative	
					Urobilinogen	0.34	umol/dL			0.34-1.69	
					pH	5.0				5-7.5	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.3
Laboratory Results — Urinalysis
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9086	36/M/BL	TPOXX 600 mg	Day 9	24OCT2019 07:19 (9)	Clarity	Clear				Clear	
					Color	Yellow				Yellow,Dk Yellow	
					Ketones	Negative				Negative,Trace	
					Leukocyte Esterase	Negative				Negative	
					Nitrite	Negative				Negative	
					Occult Blood	Negative				Negative	
					Specific Gravity	1.017				1.002-1.03	
					Urine Bilirubin	Negative				Negative	
					Urine Glucose	Negative				Negative	
					Urine Protein	Negative				Negative	
					Urobilinogen	0.34	umol/dL			0.34-1.69	
					pH	6.0				5-7.5	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.3
Laboratory Results — Urinalysis
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9087	34/F/BL		Screening	11OCT2019 10:02 (-5)	Bacteria	0-20	/HPF			None Seen,0-20	
					Casts	0	/LPF			0	
					Clarity	Clear				Clear	
					Color	Yellow				Yellow,Dk Yellow	
					Crystals	0	/HPF			0	
					Epithelial Cells	6-10	/HPF	A NCS		0-5	
					Ketones	Negative				Negative,Trace	
					Leukocyte Esterase	1+		A NCS		Negative	
					Nitrite	Negative				Negative	
					Occult Blood	Negative				Negative	
					Specific Gravity	1.009				1.002-1.03	
					Urine Bilirubin	Negative				Negative	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.3
Laboratory Results — Urinalysis
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9087	34/F/BL		Screening	11OCT2019 10:02 (-5)	Urine Erythrocytes	0-2	/HPF			0-2	
					Urine Glucose	Negative				Negative	
					Urine Leukocytes	6-10	/HPF	A NCS		0-5	
					Urine Protein	Negative				Negative	
					Urobilinogen	0.34	umol/dL			0.34-1.69	
					pH	5.5				5-7.5	
		TPOXX 600 mg	Day 9	24OCT2019 07:20 (9)	Bacteria	51-100	/HPF	A NCS		None Seen,0-20	
					Casts	0	/LPF			0	
					Clarity	Cloudy		A NCS		Clear	
					Color	Yellow				Yellow,Dk Yellow	
					Crystals	0	/HPF			0	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.3
Laboratory Results — Urinalysis
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9087	34/F/BL	TPOXX 600 mg	Day 9	24OCT2019 07:20 (9)	Epithelial Cells	11-20	/HPF	A NCS		0-5	
					Ketones	Negative				Negative,Trace	
					Leukocyte Esterase	1+		A NCS		Negative	
					Nitrite	Negative				Negative	
					Occult Blood	Negative				Negative	
					Specific Gravity	1.009				1.002-1.03	
					Urine Bilirubin	Negative				Negative	
					Urine Erythrocytes	0-2	/HPF			0-2	
					Urine Glucose	Negative				Negative	
					Urine Leukocytes	11-20	/HPF	A NCS		0-5	
					Urine Protein	Negative				Negative	
					Urobilinogen	0.34	umol/dL			0.34-1.69	
					pH	5.5				5-7.5	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.3
Laboratory Results — Urinalysis
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9087	34/F/BL	TPOXX 600 mg	Day 9	07NOV2019 10:36 (23), R	Bacteria	21-50	/HPF	A NCS		None Seen,0-20	
					Casts	0	/LPF			0	
					Clarity	Clear				Clear	
					Color	Yellow				Yellow,Dk Yellow	
					Crystals	0	/HPF			0	
					Epithelial Cells	6-10	/HPF	A NCS		0-5	
					Ketones	Negative				Negative,Trace	
					Leukocyte Esterase	Negative				Negative	
					Nitrite	Negative				Negative	
					Occult Blood	Negative				Negative	
					Specific Gravity	1.001		L NCS		1.002-1.03	
					Urine Bilirubin	Negative				Negative	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.3
Laboratory Results — Urinalysis
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9087	34/F/BL	TPOXX 600 mg	Day 9	07NOV2019 10:36 (23), R	Urine Erythrocytes	0-2	/HPF			0-2	
					Urine Glucose	Negative				Negative	
					Urine Leukocytes	0-5	/HPF			0-5	
					Urine Protein	Negative				Negative	
					Urobilinogen	0.34	umol/dL			0.34-1.69	
					pH	6.5				5-7.5	
9089	29/M/BL		Screening	14OCT2019 08:52 (-2)	Clarity	Clear				Clear	
					Color	Yellow				Yellow,Dk Yellow	
					Ketones	Negative				Negative,Trace	
					Leukocyte Esterase	Negative				Negative	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.3
Laboratory Results — Urinalysis
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9089	29/M/BL		Screening	14OCT2019 08:52 (-2)	Nitrite	Negative				Negative	
					Occult Blood	Negative				Negative	
					Specific Gravity	1.025				1.002-1.03	
					Urine Bilirubin	Negative				Negative	
					Urine Glucose	Negative				Negative	
					Urine Protein	Negative				Negative	
					Urobilinogen	0.34	umol/dL			0.34-1.69	
					pH	6.5				5-7.5	
		TPOXX 600 mg	Day 9	24OCT2019 07:24 (9)	Clarity	Clear				Clear	
					Color	Yellow				Yellow,Dk Yellow	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.3
Laboratory Results — Urinalysis
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9089	29/M/BL	TPOXX 600 mg	Day 9	24OCT2019 07:24 (9)	Ketones	Negative				Negative,Trace	
					Leukocyte Esterase	Negative				Negative	
					Nitrite	Negative				Negative	
					Occult Blood	Negative				Negative	
					Specific Gravity	1.026				1.002-1.03	
					Urine Bilirubin	Negative				Negative	
					Urine Glucose	Negative				Negative	
					Urine Protein	Negative				Negative	
					Urobilinogen	1.69	umol/dL			0.34-1.69	
					pH	6.5				5-7.5	
9092	24/M/W		Screening	14OCT2019 08:56 (-2)	Clarity	Clear				Clear	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.3
Laboratory Results — Urinalysis
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9092	24/M/W		Screening	14OCT2019 08:56 (-2)	Color	Yellow				Yellow,Dk Yellow	
					Ketones	Negative				Negative,Trace	
					Leukocyte Esterase	Negative				Negative	
					Nitrite	Negative				Negative	
					Occult Blood	Negative				Negative	
					Specific Gravity	1.013				1.002-1.03	
					Urine Bilirubin	Negative				Negative	
					Urine Glucose	Negative				Negative	
					Urine Protein	Negative				Negative	
					Urobilinogen	0.34	umol/dL			0.34-1.69	
					pH	6.0				5-7.5	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.3
Laboratory Results — Urinalysis
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9092	24/M/W	TPOXX 600 mg	Day 9	24OCT2019 07:32 (9)	Clarity	Clear				Clear	
					Color	Yellow				Yellow,Dk Yellow	
					Ketones	Negative				Negative,Trace	
					Leukocyte Esterase	Negative				Negative	
					Nitrite	Negative				Negative	
					Occult Blood	Negative				Negative	
					Specific Gravity	1.013				1.002-1.03	
					Urine Bilirubin	Negative				Negative	
					Urine Glucose	Negative				Negative	
					Urine Protein	Negative				Negative	
					Urobilinogen	0.34	umol/dL			0.34-1.69	
					pH	6.5				5-7.5	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.3
Laboratory Results — Urinalysis
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9095	42/M/W		Screening	17OCT2019 13:05 (-13)	Clarity	Clear				Clear	
					Color	Dk Yellow				Yellow,Dk Yellow	
					Ketones	Negative				Negative,Trace	
					Leukocyte Esterase	Negative				Negative	
					Nitrite	Negative				Negative	
					Occult Blood	Negative				Negative	
					Specific Gravity	1.027				1.002-1.03	
					Urine Bilirubin	Negative				Negative	
					Urine Glucose	Negative				Negative	
					Urine Protein	Negative				Negative	
					Urobilinogen	1.69	umol/dL			0.34-1.69	
					pH	6.5				5-7.5	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.3
Laboratory Results — Urinalysis
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9095	42/M/W	TPOXX 600 mg	Day 9	07NOV2019 06:08 (9)	Clarity	Clear				Clear	
					Color	Yellow				Yellow,Dk Yellow	
					Ketones	Negative				Negative,Trace	
					Leukocyte Esterase	Negative				Negative	
					Nitrite	Negative				Negative	
					Occult Blood	Negative				Negative	
					Specific Gravity	1.022				1.002-1.03	
					Urine Bilirubin	Negative				Negative	
					Urine Glucose	Negative				Negative	
					Urine Protein	Negative				Negative	
					Urobilinogen	0.34	umol/dL			0.34-1.69	
					pH	5.5				5-7.5	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.4
Laboratory Results — Other
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Reference Range	Comments
9001	41/M/BL		Screening	19JUL2019 11:12 (-26)	3,4-methylenedioxy methamphetamine	Negative			Negative	
					Amphetamine	Negative			Negative	
					Barbiturates	Negative			Negative	
					Benzodiazepine	Negative			Negative	
					Cannabinoids	Negative			Negative	
					Cocaine	Negative			Negative	
					Ethanol	Negative			Negative	
					Opiate	Negative			Negative	
					Oxycodone	Negative			Negative	
			Screening	19JUL2019 12:06 (-26)	HIV-1/2 Antibody + HIV-1 p24 Antigen	Negative			Negative	
					Hemoglobin A1C	5.2	%		4-6	
					Hepatitis B Virus Surface Antigen	Negative			Negative	
					Hepatitis C Virus Antibody	Negative			Negative	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.

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Listing 16.2.8.4
Laboratory Results — Other
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Reference Range	Comments
9001	41/M/BL		Check-in	13AUG2019 09:00 (-1)	3,4-methylenedioxy methamphetamine	Negative			Negative	
					Amphetamine	Negative			Negative	
					Barbiturates	Negative			Negative	
					Benzodiazepine	Negative			Negative	
					Cannabinoids	Negative			Negative	
					Cocaine	Negative			Negative	
					Ethanol	Negative			Negative	
					Opiate	Negative			Negative	
					Oxycodone	Negative			Negative	
9002	48/M/W		Screening	19JUL2019 11:13 (-26)	3,4-methylenedioxy methamphetamine	Negative			Negative	
					Amphetamine	Negative			Negative	
					Barbiturates	Negative			Negative	
					Benzodiazepine	Negative			Negative	
					Cannabinoids	Negative			Negative	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.

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Listing 16.2.8.4
Laboratory Results — Other
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Reference Range	Comments
9002	48/M/W		Screening	19JUL2019 11:13 (-26)	Cocaine	Negative			Negative	
					Ethanol	Negative			Negative	
					Opiate	Negative			Negative	
					Oxycodone	Negative			Negative	
			Screening	19JUL2019 12:02 (-26)	HIV-1/2 Antibody + HIV-1 p24 Antigen	Negative			Negative	
					Hemoglobin A1C	5.9	%		4-6	
					Hepatitis B Virus Surface Antigen	Negative			Negative	
					Hepatitis C Virus Antibody	Negative			Negative	
			Check-in	13AUG2019 09:11 (-1)	3,4-methylenedioxy methamphetamine	Negative			Negative	
					Amphetamine	Negative			Negative	
					Barbiturates	Negative			Negative	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.

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Listing 16.2.8.4
Laboratory Results — Other
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Reference Range	Comments
9002	48/M/W		Check-in	13AUG2019 09:11 (-1)	Benzodiazepine	Negative			Negative	
					Cannabinoids	Negative			Negative	
					Cocaine	Negative			Negative	
					Ethanol	Negative			Negative	
					Opiate	Negative			Negative	
					Oxycodone	Negative			Negative	
9005	40/M/W		Screening	23JUL2019 09:37 (-22)	3,4-methylenedioxy methamphetamine	Negative			Negative	
					Amphetamine	Negative			Negative	
					Barbiturates	Negative			Negative	
					Benzodiazepine	Negative			Negative	
					Cannabinoids	Negative			Negative	
					Cocaine	Negative			Negative	
					Ethanol	Negative			Negative	
					Opiate	Negative			Negative	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.

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Listing 16.2.8.4
Laboratory Results — Other
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Reference Range	Comments
9005	40/M/W		Screening	23JUL2019 09:37 (-22)	Oxycodone	Negative			Negative	
			Screening	23JUL2019 10:05 (-22)	HIV-1/2 Antibody + HIV-1 p24 Antigen	Negative			Negative	
					Hemoglobin A1C	6.1	%	H NCS	4-6	
					Hepatitis B Virus Surface Antigen	Negative			Negative	
					Hepatitis C Virus Antibody	Negative			Negative	
			Check-in	13AUG2019 08:56 (-1)	3,4-methylenedioxy methamphetamine	Negative			Negative	
					Amphetamine	Negative			Negative	
					Barbiturates	Negative			Negative	
					Benzodiazepine	Negative			Negative	
					Cannabinoids	Negative			Negative	
					Cocaine	Negative			Negative	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.

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Listing 16.2.8.4
Laboratory Results — Other
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Reference Range	Comments
9005	40/M/W		Check-in	13AUG2019 08:56 (-1)	Ethanol	Negative			Negative	
					Opiate	Negative			Negative	
					Oxycodone	Negative			Negative	
9009	21/F/BL		Screening	31JUL2019 10:20 (-14)	Choriogonadotropin Beta	Less than 5.0	IU/L		Less than 5.0	
					HIV-1/2 Antibody + HIV-1 p24 Antigen	Negative			Negative	
					Hemoglobin A1C	5.0	%		4-6	
					Hepatitis B Virus Surface Antigen	Negative			Negative	
					Hepatitis C Virus Antibody	Negative			Negative	
			Screening	31JUL2019 10:29 (-14)	3,4-methylenedioxy methamphetamine	Negative			Negative	
					Amphetamine	Negative			Negative	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.

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Listing 16.2.8.4
Laboratory Results — Other
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Reference Range	Comments
9009	21/F/BL		Screening	31JUL2019 10:29 (-14)	Barbiturates	Negative			Negative	
					Benzodiazepine	Negative			Negative	
					Cannabinoids	Negative			Negative	
					Cocaine	Negative			Negative	
					Ethanol	Negative			Negative	
					Opiate	Negative			Negative	
					Oxycodone	Negative			Negative	
			Check-in	13AUG2019 08:52 (-1)	3,4-methylenedioxy methamphetamine	Negative			Negative	
					Amphetamine	Negative			Negative	
					Barbiturates	Negative			Negative	
					Benzodiazepine	Negative			Negative	
					Cannabinoids	Negative			Negative	
					Cocaine	Negative			Negative	
					Ethanol	Negative			Negative	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.

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Listing 16.2.8.4
Laboratory Results — Other
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Reference Range	Comments
9009	21/F/BL		Check-in	13AUG2019 08:52 (-1)	Opiate	Negative			Negative	
					Oxycodone	Negative			Negative	
			Check-in	13AUG2019 09:32 (-1)	Choriogonadotropin Beta	Less than 5.0	IU/L		Less than 5.0	
9012	34/M/BL		Screening	06AUG2019 10:31 (-8)	HIV-1/2 Antibody + HIV-1 p24 Antigen	Negative			Negative	
					Hemoglobin A1C	4.6	%		4-6	
					Hepatitis B Virus Surface Antigen	Negative			Negative	
					Hepatitis C Virus Antibody	Negative			Negative	
			Screening	06AUG2019 11:05 (-8)	3,4-methylenedioxy methamphetamine	Negative			Negative	
					Amphetamine	Negative			Negative	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.

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Listing 16.2.8.4
Laboratory Results — Other
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Reference Range	Comments
9012	34/M/BL		Screening	06AUG2019 11:05 (-8)	Barbiturates	Negative			Negative	
					Benzodiazepine	Negative			Negative	
					Cannabinoids	Negative			Negative	
					Cocaine	Negative			Negative	
					Ethanol	Negative			Negative	
					Opiate	Negative			Negative	
					Oxycodone	Negative			Negative	
			Check-in	13AUG2019 09:20 (-1)	3,4-methylenedioxy methamphetamine	Negative			Negative	
					Amphetamine	Negative			Negative	
					Barbiturates	Negative			Negative	
					Benzodiazepine	Negative			Negative	
					Cannabinoids	Negative			Negative	
					Cocaine	Negative			Negative	
					Ethanol	Negative			Negative	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.

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Listing 16.2.8.4
Laboratory Results — Other
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Reference Range	Comments
9012	34/M/BL		Check-in	13AUG2019 09:20 (-1)	Opiate	Negative			Negative	
					Oxycodone	Negative			Negative	
9015	29/M/BL		Screening	12AUG2019 10:12 (-2)	3,4-methylenedioxy methamphetamine	Negative			Negative	
					Amphetamine	Negative			Negative	
					Barbiturates	Negative			Negative	
					Benzodiazepine	Negative			Negative	
					Cannabinoids	Negative			Negative	
					Cocaine	Negative			Negative	
					Ethanol	Negative			Negative	
					Opiate	Negative			Negative	
					Oxycodone	Negative			Negative	
			Screening	12AUG2019 11:07 (-2)	HIV-1/2 Antibody + HIV-1 p24 Antigen	Negative			Negative	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.

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Listing 16.2.8.4
Laboratory Results — Other
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Reference Range	Comments
9015	29/M/BL		Screening	12AUG2019 11:07 (-2)	Hemoglobin A1C	5.7	%		4-6	
					Hepatitis B Virus Surface Antigen	Negative			Negative	
					Hepatitis C Virus Antibody	Negative			Negative	
			Check-in	13AUG2019 08:47 (-1)	3,4-methylenedioxy methamphetamine	Negative			Negative	
					Amphetamine	Negative			Negative	
					Barbiturates	Negative			Negative	
					Benzodiazepine	Negative			Negative	
					Cannabinoids	Negative			Negative	
					Cocaine	Negative			Negative	
					Ethanol	Negative			Negative	
					Opiate	Negative			Negative	
					Oxycodone	Negative			Negative	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.

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Listing 16.2.8.4
Laboratory Results — Other
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Reference Range	Comments
9016	48/F/W		Screening	12AUG2019 10:26 (-23)	3,4-methylenedioxy methamphetamine	Negative			Negative	
					Amphetamine	Negative			Negative	
					Barbiturates	Negative			Negative	
					Benzodiazepine	Negative			Negative	
					Cannabinoids	Negative			Negative	
					Cocaine	Negative			Negative	
					Ethanol	Negative			Negative	
					Opiate	Negative			Negative	
					Oxycodone	Negative			Negative	
			Screening	12AUG2019 11:08 (-23)	Choriogonadotropin Beta	Less than 5.0	IU/L		Less than 5.0	
					HIV-1/2 Antibody + HIV-1 p24 Antigen	Negative			Negative	
					Hemoglobin A1C	5.3	%		4-6	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.

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Listing 16.2.8.4
Laboratory Results — Other
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Reference Range	Comments
9016	48/F/W		Screening	12AUG2019 11:08 (-23)	Hepatitis B Virus Surface Antigen	Negative			Negative	
					Hepatitis C Virus Antibody	Negative			Negative	
			Check-in	03SEP2019 08:31 (-1)	3,4-methylenedioxy methamphetamine	Negative			Negative	
					Amphetamine	Negative			Negative	
					Barbiturates	Negative			Negative	
					Benzodiazepine	Negative			Negative	
					Cannabinoids	Negative			Negative	
					Cocaine	Negative			Negative	
					Ethanol	Negative			Negative	
					Opiate	Negative			Negative	
					Oxycodone	Negative			Negative	
			Check-in	03SEP2019 09:04 (-1)	Choriogonadotropin Beta	Less than 5.0	IU/L		Less than 5.0	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.

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Listing 16.2.8.4
Laboratory Results — Other
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Reference Range	Comments
9019	41/M/BL		Screening	15AUG2019 16:33 (-20)	3,4-methylenedioxy methamphetamine	Negative			Negative	
					Amphetamine	Negative			Negative	
					Barbiturates	Negative			Negative	
					Benzodiazepine	Negative			Negative	
					Cannabinoids	Negative			Negative	
					Cocaine	Negative			Negative	
					Ethanol	Negative			Negative	
					Opiate	Negative			Negative	
					Oxycodone	Negative			Negative	
			Screening	15AUG2019 17:21 (-20)	HIV-1/2 Antibody + HIV-1 p24 Antigen	Negative			Negative	
					Hepatitis B Virus Surface Antigen	Negative			Negative	
					Hepatitis C Virus Antibody	Negative			Negative	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.

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Listing 16.2.8.4
Laboratory Results — Other
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Reference Range	Comments
9019	41/M/BL		Screening	15AUG2019 17:29 (-20)	Hemoglobin A1C	5.0	%		4-6	
			Check-in	03SEP2019 11:14 (-1)	3,4-methylenedioxy methamphetamine	Negative			Negative	
					Amphetamine	Negative			Negative	
					Barbiturates	Negative			Negative	
					Benzodiazepine	Negative			Negative	
					Cannabinoids	Negative			Negative	
					Cocaine	Negative			Negative	
					Ethanol	Negative			Negative	
					Opiate	Negative			Negative	
					Oxycodone	Negative			Negative	
9020	47/F/BL		Screening	21AUG2019 10:03 (-14)	3,4-methylenedioxy methamphetamine	Negative			Negative	
					Amphetamine	Negative			Negative	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.

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Listing 16.2.8.4
Laboratory Results — Other
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Reference Range	Comments
9020	47/F/BL		Screening	21AUG2019 10:03 (-14)	Barbiturates	Negative			Negative	
					Benzodiazepine	Negative			Negative	
					Cannabinoids	Negative			Negative	
					Cocaine	Negative			Negative	
					Ethanol	Negative			Negative	
					Opiate	Negative			Negative	
					Oxycodone	Negative			Negative	
			Screening	21AUG2019 10:37 (-14)	Choriogonadotropin Beta	Less than 5.0	IU/L		Less than 5.0	
					HIV-1/2 Antibody + HIV-1 p24 Antigen	Negative			Negative	
					Hemoglobin A1C	5.0	%		4-6	
					Hepatitis B Virus Surface Antigen	Negative			Negative	
					Hepatitis C Virus Antibody	Negative			Negative	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.

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Listing 16.2.8.4
Laboratory Results — Other
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Reference Range	Comments
9020	47/F/BL		Check-in	03SEP2019 08:26 (-1)	3,4-methylenedioxy methamphetamine	Negative			Negative	
					Amphetamine	Negative			Negative	
					Barbiturates	Negative			Negative	
					Benzodiazepine	Negative			Negative	
					Cannabinoids	Negative			Negative	
					Cocaine	Negative			Negative	
					Ethanol	Negative			Negative	
					Opiate	Negative			Negative	
					Oxycodone	Negative			Negative	
			Check-in	03SEP2019 08:56 (-1)	Choriogonadotropin Beta	Less than 5.0	IU/L		Less than 5.0	
9021	39/F/BL		Screening	21AUG2019 10:05 (-14)	3,4-methylenedioxy methamphetamine	Negative			Negative	
					Amphetamine	Negative			Negative	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.

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Listing 16.2.8.4
Laboratory Results — Other
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Reference Range	Comments
9021	39/F/BL		Screening	21AUG2019 10:05 (-14)	Barbiturates	Negative			Negative	
					Benzodiazepine	Negative			Negative	
					Cannabinoids	Negative			Negative	
					Cocaine	Negative			Negative	
					Ethanol	Negative			Negative	
					Opiate	Negative			Negative	
					Oxycodone	Negative			Negative	
			Screening	21AUG2019 10:44 (-14)	Choriogonadotropin Beta	Less than 5.0	IU/L		Less than 5.0	
					HIV-1/2 Antibody + HIV-1 p24 Antigen	Negative			Negative	
					Hemoglobin A1C	5.8	%		4-6	
					Hepatitis B Virus Surface Antigen	Negative			Negative	
					Hepatitis C Virus Antibody	Negative			Negative	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.

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Listing 16.2.8.4
Laboratory Results — Other
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Reference Range	Comments
9021	39/F/BL		Check-in	03SEP2019 08:29 (-1)	3,4-methylenedioxy methamphetamine	Negative			Negative	
					Amphetamine	Negative			Negative	
					Barbiturates	Negative			Negative	
					Benzodiazepine	Negative			Negative	
					Cannabinoids	Negative			Negative	
					Cocaine	Negative			Negative	
					Ethanol	Negative			Negative	
					Opiate	Negative			Negative	
					Oxycodone	Negative			Negative	
			Check-in	03SEP2019 09:00 (-1)	Choriogonadotropin Beta	Less than 5.0	IU/L		Less than 5.0	
9022	31/M/W		Screening	21AUG2019 11:05 (-14)	HIV-1/2 Antibody + HIV-1 p24 Antigen	Negative			Negative	
					Hemoglobin A1C	5.8	%		4-6	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.

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Listing 16.2.8.4
Laboratory Results — Other
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Reference Range	Comments
9022	31/M/W		Screening	21AUG2019 11:05 (-14)	Hepatitis B Virus Surface Antigen	Negative			Negative	
					Hepatitis C Virus Antibody	Negative			Negative	
			Screening	21AUG2019 11:12 (-14)	3,4-methylenedioxy methamphetamine	Negative			Negative	
					Amphetamine	Negative			Negative	
					Barbiturates	Negative			Negative	
					Benzodiazepine	Negative			Negative	
					Cannabinoids	Negative			Negative	
					Cocaine	Negative			Negative	
					Ethanol	Negative			Negative	
					Opiate	Negative			Negative	
					Oxycodone	Negative			Negative	
			Check-in	03SEP2019 09:49 (-1)	3,4-methylenedioxy methamphetamine	Negative			Negative	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.

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Listing 16.2.8.4
Laboratory Results — Other
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Reference Range	Comments
9022	31/M/W		Check-in	03SEP2019 09:49 (-1)	Amphetamine	Negative			Negative	
					Barbiturates	Negative			Negative	
					Benzodiazepine	Negative			Negative	
					Cannabinoids	Negative			Negative	
					Cocaine	Negative			Negative	
					Ethanol	Negative			Negative	
					Opiate	Negative			Negative	
					Oxycodone	Negative			Negative	
9024	20/M/BL		Screening	23AUG2019 10:02 (-12)	3,4-methylenedioxy methamphetamine	Negative			Negative	
					Amphetamine	Negative			Negative	
					Barbiturates	Negative			Negative	
					Benzodiazepine	Negative			Negative	
					Cannabinoids	Negative			Negative	
					Cocaine	Negative			Negative	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.

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Listing 16.2.8.4
Laboratory Results — Other
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Reference Range	Comments
9024	20/M/BL		Screening	23AUG2019 10:02 (-12)	Ethanol	Negative			Negative	
					Opiate	Negative			Negative	
					Oxycodone	Negative			Negative	
			Screening	23AUG2019 10:48 (-12)	HIV-1/2 Antibody + HIV-1 p24 Antigen	Negative			Negative	
					Hemoglobin A1C	5.2	%		4-6	
					Hepatitis B Virus Surface Antigen	Negative			Negative	
					Hepatitis C Virus Antibody	Negative			Negative	
			Check-in	03SEP2019 08:42 (-1)	3,4-methylenedioxy methamphetamine	Negative			Negative	
					Amphetamine	Negative			Negative	
					Barbiturates	Negative			Negative	
					Benzodiazepine	Negative			Negative	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.

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Listing 16.2.8.4
Laboratory Results — Other
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Reference Range	Comments
9024	20/M/BL		Check-in	03SEP2019 08:42 (-1)	Cannabinoids	Negative			Negative	
					Cocaine	Negative			Negative	
					Ethanol	Negative			Negative	
					Opiate	Negative			Negative	
					Oxycodone	Negative			Negative	
9025	50/M/W		Screening	23AUG2019 10:10 (-26)	3,4-methylenedioxy methamphetamine	Negative			Negative	
					Amphetamine	Negative			Negative	
					Barbiturates	Negative			Negative	
					Benzodiazepine	Negative			Negative	
					Cannabinoids	Negative			Negative	
					Cocaine	Negative			Negative	
					Ethanol	Negative			Negative	
					Opiate	Negative			Negative	
					Oxycodone	Negative			Negative	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.

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Listing 16.2.8.4
Laboratory Results — Other
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Reference Range	Comments
9025	50/M/W		Screening	23AUG2019 10:59 (-26)	HIV-1/2 Antibody + HIV-1 p24 Antigen	Negative			Negative	
					Hemoglobin A1C	5.9	%		4-6	
					Hepatitis B Virus Surface Antigen	Negative			Negative	
					Hepatitis C Virus Antibody	Negative			Negative	
			Check-in	17SEP2019 08:40 (-1)	3,4-methylenedioxy methamphetamine	Negative			Negative	
					Amphetamine	Negative			Negative	
					Barbiturates	Negative			Negative	
					Benzodiazepine	Negative			Negative	
					Cannabinoids	Negative			Negative	
					Cocaine	Negative			Negative	
					Ethanol	Negative			Negative	
					Opiate	Negative			Negative	
					Oxycodone	Negative			Negative	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.

Listing 16.2.8.4
Laboratory Results — Other
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Reference Range	Comments
9033	32/M/W		Screening	29AUG2019 09:03 (-6)	3,4-methylenedioxy methamphetamine	Negative			Negative	
					Amphetamine	Negative			Negative	
					Barbiturates	Negative			Negative	
					Benzodiazepine	Negative			Negative	
					Cannabinoids	Negative			Negative	
					Cocaine	Negative			Negative	
					Ethanol	Negative			Negative	
					Opiate	Negative			Negative	
					Oxycodone	Negative			Negative	
			Screening	29AUG2019 09:53 (-6)	HIV-1/2 Antibody + HIV-1 p24 Antigen	Negative			Negative	
					Hemoglobin A1C	5.9	%		4-6	
					Hepatitis B Virus Surface Antigen	Negative			Negative	
					Hepatitis C Virus Antibody	Negative			Negative	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.

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Listing 16.2.8.4
Laboratory Results — Other
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Reference Range	Comments
9033	32/M/W		Check-in	03SEP2019 08:39 (-1)	3,4-methylenedioxy methamphetamine	Negative			Negative	
					Amphetamine	Negative			Negative	
					Barbiturates	Negative			Negative	
					Benzodiazepine	Negative			Negative	
					Cannabinoids	Negative			Negative	
					Cocaine	Negative			Negative	
					Ethanol	Negative			Negative	
					Opiate	Negative			Negative	
					Oxycodone	Negative			Negative	
9043	22/M/BL		Screening	11SEP2019 08:45 (-7)	3,4-methylenedioxy methamphetamine	Negative			Negative	
					Amphetamine	Negative			Negative	
					Barbiturates	Negative			Negative	
					Benzodiazepine	Negative			Negative	
					Cannabinoids	Negative			Negative	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.

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Listing 16.2.8.4
Laboratory Results — Other
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Reference Range	Comments
9043	22/M/BL		Screening	11SEP2019 08:45 (-7)	Cocaine	Negative			Negative	
					Ethanol	Negative			Negative	
					Opiate	Negative			Negative	
					Oxycodone	Negative			Negative	
			Screening	11SEP2019 09:38 (-7)	HIV-1/2 Antibody + HIV-1 p24 Antigen	Negative			Negative	
					Hemoglobin A1C	5.6	%		4-6	
					Hepatitis B Virus Surface Antigen	Negative			Negative	
					Hepatitis C Virus Antibody	Negative			Negative	
			Check-in	17SEP2019 08:38 (-1)	3,4-methylenedioxy methamphetamine	Negative			Negative	
					Amphetamine	Negative			Negative	
					Barbiturates	Negative			Negative	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.

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Listing 16.2.8.4
Laboratory Results — Other
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Reference Range	Comments
9043	22/M/BL		Check-in	17SEP2019 08:38 (-1)	Benzodiazepine	Negative			Negative	
					Cannabinoids	Negative			Negative	
					Cocaine	Negative			Negative	
					Ethanol	Negative			Negative	
					Opiate	Negative			Negative	
					Oxycodone	Negative			Negative	
9046	34/M/BL		Screening	13SEP2019 08:22 (-5)	3,4-methylenedioxy methamphetamine	Negative			Negative	
					Amphetamine	Negative			Negative	
					Barbiturates	Negative			Negative	
					Benzodiazepine	Negative			Negative	
					Cannabinoids	Negative			Negative	
					Cocaine	Negative			Negative	
					Ethanol	Negative			Negative	
					Opiate	Negative			Negative	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.

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Listing 16.2.8.4
Laboratory Results — Other
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Reference Range	Comments
9046	34/M/BL		Screening	13SEP2019 08:22 (-5)	Oxycodone	Negative			Negative	
			Screening	13SEP2019 09:12 (-5)	HIV-1/2 Antibody + HIV-1 p24 Antigen	Negative			Negative	
					Hemoglobin A1C	4.4	%		4-6	
					Hepatitis B Virus Surface Antigen	Negative			Negative	
					Hepatitis C Virus Antibody	Negative			Negative	
			Check-in	17SEP2019 08:42 (-1)	3,4-methylenedioxy methamphetamine	Negative			Negative	
					Amphetamine	Negative			Negative	
					Barbiturates	Negative			Negative	
					Benzodiazepine	Negative			Negative	
					Cannabinoids	Negative			Negative	
					Cocaine	Negative			Negative	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.

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Listing 16.2.8.4
Laboratory Results — Other
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Reference Range	Comments
9046	34/M/BL		Check-in	17SEP2019 08:42 (-1)	Ethanol	Negative			Negative	
					Opiate	Negative			Negative	
					Oxycodone	Negative			Negative	
9051	34/M/BL		Screening	19SEP2019 08:40 (-13)	3,4-methylenedioxy methamphetamine	Negative			Negative	
					Amphetamine	Negative			Negative	
					Barbiturates	Negative			Negative	
					Benzodiazepine	Negative			Negative	
					Cannabinoids	Negative			Negative	
					Cocaine	Negative			Negative	
					Ethanol	Negative			Negative	
					Opiate	Negative			Negative	
					Oxycodone	Negative			Negative	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.

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Listing 16.2.8.4
Laboratory Results — Other
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Reference Range	Comments
9051	34/M/BL		Screening	19SEP2019 09:10 (-13)	HIV-1/2 Antibody + HIV-1 p24 Antigen	Negative			Negative	
					Hemoglobin A1C	5.7	%		4-6	
					Hepatitis B Virus Surface Antigen	Negative			Negative	
					Hepatitis C Virus Antibody	Negative			Negative	
			Check-in	01OCT2019 08:22 (-1)	3,4-methylenedioxy methamphetamine	Negative			Negative	
					Amphetamine	Negative			Negative	
					Barbiturates	Negative			Negative	
					Benzodiazepine	Negative			Negative	
					Cannabinoids	Negative			Negative	
					Cocaine	Negative			Negative	
					Ethanol	Negative			Negative	
					Opiate	Negative			Negative	
					Oxycodone	Negative			Negative	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.

Listing 16.2.8.4
Laboratory Results — Other
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Reference Range	Comments
9052	42/M/BL		Screening	21SEP2019 12:33 (-11)	3,4-methylenedioxy methamphetamine	Negative			Negative	
					Amphetamine	Negative			Negative	
					Barbiturates	Negative			Negative	
					Benzodiazepine	Negative			Negative	
					Cannabinoids	Negative			Negative	
					Cocaine	Negative			Negative	
					Ethanol	Negative			Negative	
					Opiate	Negative			Negative	
					Oxycodone	Negative			Negative	
			Screening	21SEP2019 13:12 (-11)	HIV-1/2 Antibody + HIV-1 p24 Antigen	Negative			Negative	
					Hemoglobin A1C	6.0	%		4-6	
					Hepatitis B Virus Surface Antigen	Negative			Negative	
					Hepatitis C Virus Antibody	Negative			Negative	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.

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Listing 16.2.8.4
Laboratory Results — Other
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Reference Range	Comments
9052	42/M/BL		Check-in	01OCT2019 08:25 (-1)	3,4-methylenedioxy methamphetamine	Negative			Negative	
					Amphetamine	Negative			Negative	
					Barbiturates	Negative			Negative	
					Benzodiazepine	Negative			Negative	
					Cannabinoids	Negative			Negative	
					Cocaine	Negative			Negative	
					Ethanol	Negative			Negative	
					Opiate	Negative			Negative	
					Oxycodone	Negative			Negative	
9056	31/F/BL		Screening	24SEP2019 09:20 (-8)	3,4-methylenedioxy methamphetamine	Negative			Negative	
					Amphetamine	Negative			Negative	
					Barbiturates	Negative			Negative	
					Benzodiazepine	Negative			Negative	
					Cannabinoids	Negative			Negative	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.

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Listing 16.2.8.4
Laboratory Results — Other
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Reference Range	Comments
9056	31/F/BL		Screening	24SEP2019 09:20 (-8)	Cocaine	Negative			Negative	
					Ethanol	Negative			Negative	
					Opiate	Negative			Negative	
					Oxycodone	Negative			Negative	
			Screening	24SEP2019 10:06 (-8)	Choriogonadotropin Beta	Less than 5.0	IU/L		Less than 5.0	
					HIV-1/2 Antibody + HIV-1 p24 Antigen	Negative			Negative	
					Hemoglobin A1C	5.7	%		4-6	
					Hepatitis B Virus Surface Antigen	Negative			Negative	
					Hepatitis C Virus Antibody	Negative			Negative	
			Check-in	01OCT2019 08:55 (-1)	3,4-methylenedioxy methamphetamine	Negative			Negative	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.

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Listing 16.2.8.4
Laboratory Results — Other
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Reference Range	Comments
9056	31/F/BL		Check-in	01OCT2019 08:55 (-1)	Amphetamine	Negative			Negative	
					Barbiturates	Negative			Negative	
					Benzodiazepine	Negative			Negative	
					Cannabinoids	Negative			Negative	
					Cocaine	Negative			Negative	
					Ethanol	Negative			Negative	
					Opiate	Negative			Negative	
					Oxycodone	Negative			Negative	
			Check-in	01OCT2019 09:26 (-1)	Choriogonadotropin Beta	Less than 5.0	IU/L		Less than 5.0	
9057	29/F/W		Screening	25SEP2019 15:56 (-7)	3,4-methylenedioxy methamphetamine	Negative			Negative	
					Amphetamine	Negative			Negative	
					Barbiturates	Negative			Negative	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.

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Listing 16.2.8.4
Laboratory Results — Other
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Reference Range	Comments
9057	29/F/W		Screening	25SEP2019 15:56 (-7)	Benzodiazepine	Negative			Negative	
					Cannabinoids	Negative			Negative	
					Cocaine	Negative			Negative	
					Ethanol	Negative			Negative	
					Opiate	Negative			Negative	
					Oxycodone	Negative			Negative	
			Screening	25SEP2019 16:27 (-7)	Choriogonadotropin Beta	Less than 5.0	IU/L		Less than 5.0	
					HIV-1/2 Antibody + HIV-1 p24 Antigen	Negative			Negative	
					Hemoglobin A1C	5.5	%		4-6	
					Hepatitis B Virus Surface Antigen	Negative			Negative	
					Hepatitis C Virus Antibody	Negative			Negative	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.

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Listing 16.2.8.4
Laboratory Results — Other
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Reference Range	Comments
9057	29/F/W		Check-in	01OCT2019 08:23 (-1)	3,4-methylenedioxy methamphetamine	Negative			Negative	
					Amphetamine	Negative			Negative	
					Barbiturates	Negative			Negative	
					Benzodiazepine	Negative			Negative	
					Cannabinoids	Negative			Negative	
					Cocaine	Negative			Negative	
					Ethanol	Negative			Negative	
					Opiate	Negative			Negative	
					Oxycodone	Negative			Negative	
			Check-in	01OCT2019 09:22 (-1)	Choriogonadotropin Beta	Less than 5.0	IU/L		Less than 5.0	
9058	32/M/W		Screening	26SEP2019 08:59 (-20)	3,4-methylenedioxy methamphetamine	Negative			Negative	
					Amphetamine	Negative			Negative	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.

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Listing 16.2.8.4
Laboratory Results — Other
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Reference Range	Comments
9058	32/M/W		Screening	26SEP2019 08:59 (-20)	Barbiturates	Negative			Negative	
					Benzodiazepine	Negative			Negative	
					Cannabinoids	Negative			Negative	
					Cocaine	Negative			Negative	
					Ethanol	Negative			Negative	
					Opiate	Negative			Negative	
					Oxycodone	Negative			Negative	
			Screening	26SEP2019 09:26 (-20)	Erythrocyte Cell Morphology	Abnormal		A NCS	Normal	2+ Microcytosis, Unrequested Test
					HIV-1/2 Antibody + HIV-1 p24 Antigen	Negative			Negative	
					Hemoglobin A1C	5.5	%		4-6	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.

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Listing 16.2.8.4
Laboratory Results — Other
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Reference Range	Comments
9058	32/M/W		Screening	26SEP2019 09:26 (-20)	Hepatitis B Virus Surface Antigen	Negative			Negative	
					Hepatitis C Virus Antibody	Negative			Negative	
			Check-in	15OCT2019 08:27 (-1)	3,4-methylenedioxy methamphetamine	Negative			Negative	
					Amphetamine	Negative			Negative	
					Barbiturates	Negative			Negative	
					Benzodiazepine	Negative			Negative	
					Cannabinoids	Negative			Negative	
					Cocaine	Negative			Negative	
					Ethanol	Negative			Negative	
					Opiate	Negative			Negative	
					Oxycodone	Negative			Negative	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.

Listing 16.2.8.4
Laboratory Results — Other
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Reference Range	Comments
9058	32/M/W		Check-in	15OCT2019 09:07 (-1)	Erythrocyte Cell Morphology	Abnormal		A NCS	Normal	2+ Microcytosis, Unrequested Test
		TPOXX 600 mg	Day 4	19OCT2019 07:32 (4)	Erythrocyte Cell Morphology	Abnormal		A NCS	Normal	2+ Microcytosis, Unrequested Test
			Day 8 - 12 Hours Postdose	23OCT2019 08:29 (8)	Erythrocyte Cell Morphology	Abnormal		A NCS	Normal	2+ Microcytosis, Unrequested Test

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.

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Listing 16.2.8.4
Laboratory Results — Other
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Reference Range	Comments
9058	32/M/W	TPOXX 600 mg	Day 9	24OCT2019 08:08 (9)	Erythrocyte Cell Morphology	Abnormal		A NCS	Normal	2+ Microcytosis, Unrequested Test
9061	21/F/BL		Screening	26SEP2019 10:16 (-20)	3,4-methylenedioxy methamphetamine	Negative			Negative	
					Amphetamine	Negative			Negative	
					Barbiturates	Negative			Negative	
					Benzodiazepine	Negative			Negative	
					Cannabinoids	Negative			Negative	
					Cocaine	Negative			Negative	
					Ethanol	Negative			Negative	
					Opiate	Negative			Negative	
					Oxycodone	Negative			Negative	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.

Listing 16.2.8.4
Laboratory Results — Other
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Reference Range	Comments
9061	21/F/BL		Screening	26SEP2019 11:06 (-20)	Choriogonadotropin Beta	Less than 5.0	IU/L		Less than 5.0	
					HIV-1/2 Antibody + HIV-1 p24 Antigen	Negative			Negative	
					Hemoglobin A1C	5.4	%		4-6	
					Hepatitis B Virus Surface Antigen	Negative			Negative	
					Hepatitis C Virus Antibody	Negative			Negative	
			Check-in	15OCT2019 08:34 (-1)	3,4-methylenedioxy methamphetamine	Negative			Negative	
					Amphetamine	Negative			Negative	
					Barbiturates	Negative			Negative	
					Benzodiazepine	Negative			Negative	
					Cannabinoids	Negative			Negative	
					Cocaine	Negative			Negative	
					Ethanol	Negative			Negative	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.

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Listing 16.2.8.4
Laboratory Results — Other
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Reference Range	Comments
9061	21/F/BL		Check-in	15OCT2019 08:34 (-1)	Opiate	Negative			Negative	
					Oxycodone	Negative			Negative	
			Check-in	15OCT2019 09:01 (-1)	Choriogonadotropin Beta	Less than 5.0	IU/L		Less than 5.0	
9062	33/M/BL		Screening	30SEP2019 10:25 (-2)	HIV-1/2 Antibody + HIV-1 p24 Antigen	Negative			Negative	
					Hemoglobin A1C	5.6	%		4-6	
					Hepatitis B Virus Surface Antigen	Negative			Negative	
					Hepatitis C Virus Antibody	Negative			Negative	
			Screening	30SEP2019 10:35 (-2)	3,4-methylenedioxy methamphetamine	Negative			Negative	
					Amphetamine	Negative			Negative	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.

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Listing 16.2.8.4
Laboratory Results — Other
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Reference Range	Comments
9062	33/M/BL		Screening	30SEP2019 10:35 (-2)	Barbiturates	Negative			Negative	
					Benzodiazepine	Negative			Negative	
					Cannabinoids	Negative			Negative	
					Cocaine	Negative			Negative	
					Ethanol	Negative			Negative	
					Opiate	Negative			Negative	
					Oxycodone	Negative			Negative	
			Check-in	01OCT2019 09:25 (-1)	3,4-methylenedioxy methamphetamine	Negative			Negative	
					Amphetamine	Negative			Negative	
					Barbiturates	Negative			Negative	
					Benzodiazepine	Negative			Negative	
					Cannabinoids	Negative			Negative	
					Cocaine	Negative			Negative	
					Ethanol	Negative			Negative	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.

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Listing 16.2.8.4
Laboratory Results — Other
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Reference Range	Comments
9062	33/M/BL		Check-in	01OCT2019 09:25 (-1)	Opiate	Negative			Negative	
					Oxycodone	Negative			Negative	
9063	35/M/W		Screening	30SEP2019 08:58 (-2)	3,4-methylenedioxy methamphetamine	Negative			Negative	
					Amphetamine	Negative			Negative	
					Barbiturates	Negative			Negative	
					Benzodiazepine	Negative			Negative	
					Cannabinoids	Negative			Negative	
					Cocaine	Negative			Negative	
					Ethanol	Negative			Negative	
					Opiate	Negative			Negative	
					Oxycodone	Negative			Negative	
			Screening	30SEP2019 09:38 (-2)	HIV-1/2 Antibody + HIV-1 p24 Antigen	Negative			Negative	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.

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Listing 16.2.8.4
Laboratory Results — Other
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Reference Range	Comments
9063	35/M/W		Screening	30SEP2019 09:38 (-2)	Hemoglobin A1C	4.9	%		4-6	
					Hepatitis B Virus Surface Antigen	Negative			Negative	
					Hepatitis C Virus Antibody	Negative			Negative	
			Check-in	01OCT2019 08:19 (-1)	3,4-methylenedioxy methamphetamine	Negative			Negative	
					Amphetamine	Negative			Negative	
					Barbiturates	Negative			Negative	
					Benzodiazepine	Negative			Negative	
					Cannabinoids	Negative			Negative	
					Cocaine	Negative			Negative	
					Ethanol	Negative			Negative	
					Opiate	Negative			Negative	
					Oxycodone	Negative			Negative	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.

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Listing 16.2.8.4
Laboratory Results — Other
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Reference Range	Comments
9069	41/F/BL		Screening	30SEP2019 10:15 (-16)	3,4-methylenedioxy methamphetamine	Negative			Negative	
					Amphetamine	Negative			Negative	
					Barbiturates	Negative			Negative	
					Benzodiazepine	Negative			Negative	
					Cannabinoids	Negative			Negative	
					Cocaine	Negative			Negative	
					Ethanol	Negative			Negative	
					Opiate	Negative			Negative	
					Oxycodone	Negative			Negative	
			Screening	30SEP2019 11:19 (-16)	Choriogonadotropin Beta	Less than 5.0	IU/L		Less than 5.0	
					HIV-1/2 Antibody + HIV-1 p24 Antigen	Negative			Negative	
					Hemoglobin A1C	5.7	%		4-6	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.

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Listing 16.2.8.4
Laboratory Results — Other
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Reference Range	Comments
9069	41/F/BL		Screening	30SEP2019 11:19 (-16)	Hepatitis B Virus Surface Antigen	Negative			Negative	
					Hepatitis C Virus Antibody	Negative			Negative	
			Check-in	15OCT2019 11:40 (-1)	3,4-methylenedioxy methamphetamine	Negative			Negative	
					Amphetamine	Negative			Negative	
					Barbiturates	Negative			Negative	
					Benzodiazepine	Negative			Negative	
					Cannabinoids	Negative			Negative	
					Cocaine	Negative			Negative	
					Ethanol	Negative			Negative	
					Opiate	Negative			Negative	
					Oxycodone	Negative			Negative	
			Check-in	15OCT2019 12:32 (-1)	Choriogonadotropin Beta	Less than 5.0	IU/L		Less than 5.0	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.

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Listing 16.2.8.4
Laboratory Results — Other
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Reference Range	Comments
9073	40/M/BL		Screening	04OCT2019 13:25 (-12)	3,4-methylenedioxy methamphetamine	Negative			Negative	
					Amphetamine	Negative			Negative	
					Barbiturates	Negative			Negative	
					Benzodiazepine	Negative			Negative	
					Cannabinoids	Negative			Negative	
					Cocaine	Negative			Negative	
					Ethanol	Negative			Negative	
					Opiate	Negative			Negative	
					Oxycodone	Negative			Negative	
			Screening	04OCT2019 13:56 (-12)	HIV-1 Antibody	Nonreactive			Nonreactive	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.

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Listing 16.2.8.4
Laboratory Results — Other
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Reference Range	Comments
9073	40/M/BL		Screening	04OCT2019 13:56 (-12)	HIV-1/2 Antibody + HIV-1 p24 Antigen	*** SENT TO LAB		A NCS	Negative	Sample sent to LabCorp for confirmatory testing.
					HIV-2 Antibody	Nonreactive			Nonreactive	
					HIV1-RNA	Negative			Negative	
					Hemoglobin A1C	6.0	%		4-6	
					Hepatitis B Virus Surface Antigen	Negative			Negative	
					Hepatitis C Virus Antibody	Negative			Negative	
			Check-in	15OCT2019 08:53 (-1)	3,4-methylenedioxy methamphetamine	Negative			Negative	
					Amphetamine	Negative			Negative	
					Barbiturates	Negative			Negative	
					Benzodiazepine	Negative			Negative	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.

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Listing 16.2.8.4
Laboratory Results — Other
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Reference Range	Comments
9073	40/M/BL		Check-in	15OCT2019 08:53 (-1)	Cannabinoids	Negative			Negative	
					Cocaine	Negative			Negative	
					Ethanol	Negative			Negative	
					Opiate	Negative			Negative	
					Oxycodone	Negative			Negative	
9077	37/F/W		Screening	05OCT2019 13:15 (-11)	Choriogonadotropin Beta	Less than 5.0	IU/L		Less than 5.0	
					HIV-1/2 Antibody + HIV-1 p24 Antigen	Negative			Negative	
					Hemoglobin A1C	5.5	%		4-6	
					Hepatitis B Virus Surface Antigen	Negative			Negative	
					Hepatitis C Virus Antibody	Negative			Negative	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.

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Listing 16.2.8.4
Laboratory Results — Other
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Reference Range	Comments
9077	37/F/W		Screening	05OCT2019 13:19 (-11)	3,4-methylenedioxy methamphetamine	Negative			Negative	
					Amphetamine	Negative			Negative	
					Barbiturates	Negative			Negative	
					Benzodiazepine	Negative			Negative	
					Cannabinoids	Negative			Negative	
					Cocaine	Negative			Negative	
					Ethanol	Negative			Negative	
					Opiate	Negative			Negative	
					Oxycodone	Negative			Negative	
			Check-in	15OCT2019 09:25 (-1)	3,4-methylenedioxy methamphetamine	Negative			Negative	
					Amphetamine	Negative			Negative	
					Barbiturates	Negative			Negative	
					Benzodiazepine	Negative			Negative	
					Cannabinoids	Negative			Negative	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.

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Listing 16.2.8.4
Laboratory Results — Other
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Reference Range	Comments
9077	37/F/W		Check-in	15OCT2019 09:25 (-1)	Cocaine	Negative			Negative	
					Ethanol	Negative			Negative	
					Opiate	Negative			Negative	
					Oxycodone	Negative			Negative	
			Check-in	15OCT2019 09:28 (-1)	Choriogonadotropin Beta	Less than 5.0	IU/L		Less than 5.0	
9080	41/F/BL		Screening	08OCT2019 11:11 (-8)	3,4-methylenedioxy methamphetamine	Negative			Negative	
					Amphetamine	Negative			Negative	
					Barbiturates	Negative			Negative	
					Benzodiazepine	Negative			Negative	
					Cannabinoids	Negative			Negative	
					Cocaine	Negative			Negative	
					Ethanol	Negative			Negative	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.

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Listing 16.2.8.4
Laboratory Results — Other
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Reference Range	Comments
9080	41/F/BL		Screening	08OCT2019 11:11 (-8)	Opiate	Negative			Negative	
					Oxycodone	Negative			Negative	
			Screening	08OCT2019 11:46 (-8)	Choriogonadotropin Beta	Less than 5.0	IU/L		Less than 5.0	
					HIV-1/2 Antibody + HIV-1 p24 Antigen	Negative			Negative	
					Hemoglobin A1C	5.5	%		4-6	
					Hepatitis B Virus Surface Antigen	Negative			Negative	
					Hepatitis C Virus Antibody	Negative			Negative	
			Check-in	15OCT2019 08:58 (-1)	3,4-methylenedioxy methamphetamine	Negative			Negative	
					Amphetamine	Negative			Negative	
					Barbiturates	Negative			Negative	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.

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Listing 16.2.8.4
Laboratory Results — Other
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Reference Range	Comments
9080	41/F/BL		Check-in	15OCT2019 08:58 (-1)	Benzodiazepine	Negative			Negative	
					Cannabinoids	Negative			Negative	
					Cocaine	Negative			Negative	
					Ethanol	Negative			Negative	
					Opiate	Negative			Negative	
					Oxycodone	Negative			Negative	
			Check-in	15OCT2019 09:30 (-1)	Choriogonadotropin Beta	Less than 5.0	IU/L		Less than 5.0	
9081	49/M/BL		Screening	10OCT2019 11:34 (-20)	3,4-methylenedioxy methamphetamine	Negative			Negative	
					Amphetamine	Negative			Negative	
					Barbiturates	Negative			Negative	
					Benzodiazepine	Negative			Negative	
					Cannabinoids	Negative			Negative	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.

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Listing 16.2.8.4
Laboratory Results — Other
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Reference Range	Comments
9081	49/M/BL		Screening	10OCT2019 11:34 (-20)	Cocaine	Negative			Negative	
					Ethanol	Negative			Negative	
					Opiate	Negative			Negative	
					Oxycodone	Negative			Negative	
			Screening	10OCT2019 12:25 (-20)	HIV-1/2 Antibody + HIV-1 p24 Antigen	Negative			Negative	
					Hemoglobin A1C	6.2	%	H NCS	4-6	
					Hepatitis B Virus Surface Antigen	Negative			Negative	
					Hepatitis C Virus Antibody	Negative			Negative	
			Check-in	29OCT2019 09:47 (-1)	3,4-methylenedioxy methamphetamine	Negative			Negative	
					Amphetamine	Negative			Negative	
					Barbiturates	Negative			Negative	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.

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Listing 16.2.8.4
Laboratory Results — Other
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Reference Range	Comments
9081	49/M/BL		Check-in	29OCT2019 09:47 (-1)	Benzodiazepine	Negative			Negative	
					Cannabinoids	Negative			Negative	
					Cocaine	Negative			Negative	
					Ethanol	Negative			Negative	
					Opiate	Negative			Negative	
					Oxycodone	Negative			Negative	
9086	36/M/BL		Screening	11OCT2019 08:56 (-5)	3,4-methylenedioxy methamphetamine	Negative			Negative	
					Amphetamine	Negative			Negative	
					Barbiturates	Negative			Negative	
					Benzodiazepine	Negative			Negative	
					Cannabinoids	Negative			Negative	
					Cocaine	Negative			Negative	
					Ethanol	Negative			Negative	
					Opiate	Negative			Negative	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.

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Listing 16.2.8.4
Laboratory Results — Other
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Reference Range	Comments
9086	36/M/BL		Screening	11OCT2019 08:56 (-5)	Oxycodone	Negative			Negative	
			Screening	11OCT2019 10:03 (-5)	HIV-1/2 Antibody + HIV-1 p24 Antigen	Negative			Negative	
					Hemoglobin A1C	5.7	%		4-6	
					Hepatitis B Virus Surface Antigen	Negative			Negative	
					Hepatitis C Virus Antibody	Negative			Negative	
			Check-in	15OCT2019 09:03 (-1)	3,4-methylenedioxy methamphetamine	Negative			Negative	
					Amphetamine	Negative			Negative	
					Barbiturates	Negative			Negative	
					Benzodiazepine	Negative			Negative	
					Cannabinoids	Negative			Negative	
					Cocaine	Negative			Negative	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.

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Listing 16.2.8.4
Laboratory Results — Other
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Reference Range	Comments
9086	36/M/BL		Check-in	15OCT2019 09:03 (-1)	Ethanol	Negative			Negative	
					Opiate	Negative			Negative	
					Oxycodone	Negative			Negative	
9087	34/F/BL		Screening	11OCT2019 09:47 (-5)	Choriogonadotropin Beta	Less than 5.0	IU/L		Less than 5.0	
					HIV-1/2 Antibody + HIV-1 p24 Antigen	Negative			Negative	
					Hemoglobin A1C	5.3	%		4-6	
					Hepatitis B Virus Surface Antigen	Negative			Negative	
					Hepatitis C Virus Antibody	Negative			Negative	
			Screening	11OCT2019 10:02 (-5)	3,4-methylenedioxy methamphetamine	Negative			Negative	
					Amphetamine	Negative			Negative	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.

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Listing 16.2.8.4
Laboratory Results — Other
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Reference Range	Comments
9087	34/F/BL		Screening	11OCT2019 10:02 (-5)	Barbiturates	Negative			Negative	
					Benzodiazepine	Negative			Negative	
					Cannabinoids	Negative			Negative	
					Cocaine	Negative			Negative	
					Ethanol	Negative			Negative	
					Opiate	Negative			Negative	
					Oxycodone	Negative			Negative	
			Check-in	15OCT2019 08:43 (-1)	3,4-methylenedioxy methamphetamine	Negative			Negative	
					Amphetamine	Negative			Negative	
					Barbiturates	Negative			Negative	
					Benzodiazepine	Negative			Negative	
					Cannabinoids	Negative			Negative	
					Cocaine	Negative			Negative	
					Ethanol	Negative			Negative	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.

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Listing 16.2.8.4
Laboratory Results — Other
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Reference Range	Comments
9087	34/F/BL		Check-in	15OCT2019 08:43 (-1)	Opiate	Negative			Negative	
					Oxycodone	Negative			Negative	
			Check-in	15OCT2019 09:17 (-1)	Choriogonadotropin Beta	Less than 5.0	IU/L		Less than 5.0	
9089	29/M/BL		Screening	14OCT2019 08:52 (-2)	3,4-methylenedioxy methamphetamine	Negative			Negative	
					Amphetamine	Negative			Negative	
					Barbiturates	Negative			Negative	
					Benzodiazepine	Negative			Negative	
					Cannabinoids	Negative			Negative	
					Cocaine	Negative			Negative	
					Ethanol	Negative			Negative	
					Opiate	Negative			Negative	
					Oxycodone	Negative			Negative	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.

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Listing 16.2.8.4
Laboratory Results — Other
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Reference Range	Comments
9089	29/M/BL		Screening	14OCT2019 09:26 (-2)	HIV-1/2 Antibody + HIV-1 p24 Antigen	Negative			Negative	
					Hemoglobin A1C	5.8	%		4-6	
					Hepatitis B Virus Surface Antigen	Negative			Negative	
					Hepatitis C Virus Antibody	Negative			Negative	
			Check-in	15OCT2019 08:28 (-1)	3,4-methylenedioxy methamphetamine	Negative			Negative	
					Amphetamine	Negative			Negative	
					Barbiturates	Negative			Negative	
					Benzodiazepine	Negative			Negative	
					Cannabinoids	Negative			Negative	
					Cocaine	Negative			Negative	
					Ethanol	Negative			Negative	
					Opiate	Negative			Negative	
					Oxycodone	Negative			Negative	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.

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Listing 16.2.8.4
Laboratory Results — Other
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Reference Range	Comments
9092	24/M/W		Screening	14OCT2019 08:56 (-2)	3,4-methylenedioxy methamphetamine	Negative			Negative	
					Amphetamine	Negative			Negative	
					Barbiturates	Negative			Negative	
					Benzodiazepine	Negative			Negative	
					Cannabinoids	Negative			Negative	
					Cocaine	Negative			Negative	
					Ethanol	Negative			Negative	
					Opiate	Negative			Negative	
					Oxycodone	Negative			Negative	
			Screening	14OCT2019 09:33 (-2)	HIV-1/2 Antibody + HIV-1 p24 Antigen	Negative			Negative	
					Hemoglobin A1C	5.6	%		4-6	
					Hepatitis B Virus Surface Antigen	Negative			Negative	
					Hepatitis C Virus Antibody	Negative			Negative	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.

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Listing 16.2.8.4
Laboratory Results — Other
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Reference Range	Comments
9092	24/M/W		Check-in	15OCT2019 08:48 (-1)	3,4-methylenedioxy methamphetamine	Negative			Negative	
					Amphetamine	Negative			Negative	
					Barbiturates	Negative			Negative	
					Benzodiazepine	Negative			Negative	
					Cannabinoids	Negative			Negative	
					Cocaine	Negative			Negative	
					Ethanol	Negative			Negative	
					Opiate	Negative			Negative	
					Oxycodone	Negative			Negative	
9095	42/M/W		Screening	17OCT2019 13:05 (-13)	3,4-methylenedioxy methamphetamine	Negative			Negative	
					Amphetamine	Negative			Negative	
					Barbiturates	Negative			Negative	
					Benzodiazepine	Negative			Negative	
					Cannabinoids	Negative			Negative	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.

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Listing 16.2.8.4
Laboratory Results — Other
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Reference Range	Comments
9095	42/M/W		Screening	17OCT2019 13:05 (-13)	Cocaine	Negative			Negative	
					Ethanol	Negative			Negative	
					Opiate	Negative			Negative	
					Oxycodone	Negative			Negative	
			Screening	17OCT2019 13:31 (-13)	HIV-1/2 Antibody + HIV-1 p24 Antigen	Negative			Negative	
					Hemoglobin A1C	5.3	%		4-6	
					Hepatitis B Virus Surface Antigen	Negative			Negative	
					Hepatitis C Virus Antibody	Negative			Negative	
			Check-in	29OCT2019 08:27 (-1)	3,4-methylenedioxy methamphetamine	Negative			Negative	
					Amphetamine	Negative			Negative	
					Barbiturates	Negative			Negative	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.

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Listing 16.2.8.4
Laboratory Results — Other
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Reference Range	Comments
9095	42/M/W		Check-in	29OCT2019 08:27 (-1)	Benzodiazepine	Negative			Negative	
					Cannabinoids	Negative			Negative	
					Cocaine	Negative			Negative	
					Ethanol	Negative			Negative	
					Opiate	Negative			Negative	
					Oxycodone	Negative			Negative	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.

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Listing 16.2.8.5
Laboratory Results Meeting Toxicity Grade of 1 or Higher
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9001	41/M/BL		Screening	19JUL2019 12:06 (-26)	Triglycerides	2.17	mmol/L		G1	0-4.52	
9002	48/M/W	TPOXX 600 mg	Day 4	17AUG2019 08:49 (4)	Glucose	6.11	mmol/L		G1	3-6.44	
		TPOXX 600 mg	Day 9	22AUG2019 09:27 (9)	Sodium	134	mmol/L		G1	132-145	
			Screening	19JUL2019 12:02 (-26)	Triglycerides	2.28	mmol/L		G1	0-4.52	
9005	40/M/W		Screening	23JUL2019 10:05 (-22)	Glucose	6.44	mmol/L		G1	3-6.44	
			Check-in	13AUG2019 09:35 (-1)	Glucose	6.33	mmol/L		G1	3-6.44	
		TPOXX 600 mg	Day 4	17AUG2019 08:27 (4)	Glucose	6.11	mmol/L		G1	3-6.44	
			Screening	23JUL2019 10:05 (-22)	Urate	458	umol/L		G1	173-494	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.5
Laboratory Results Meeting Toxicity Grade of 1 or Higher
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9005	40/M/W	TPOXX 600 mg	Day 4	17AUG2019 08:27 (4)	Urate	464	umol/L		G1	173-494	
		TPOXX 600 mg	Day 8 - 12 Hours Postdose	21AUG2019 09:02 (8)	Urate	458	umol/L		G1	173-494	
9009	21/F/BL	TPOXX 600 mg	Day 4	17AUG2019 08:31 (4)	Albumin	37	g/L	L NCS	G1	38-49	
		TPOXX 600 mg	Day 8 - 12 Hours Postdose	21AUG2019 09:06 (8)	Albumin	37	g/L	L NCS	G1	38-49	
			Screening	31JUL2019 10:20 (-14)	Cholesterol	5.26	mmol/L		G1	2.2-6.22	
			Screening	31JUL2019 10:20 (-14)	LDL Cholesterol	3.50	mmol/L		G1	0.96-4.22	
			Screening	31JUL2019 10:20 (-14)	Sodium	134	mmol/L		G1	132-145	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.5
Laboratory Results Meeting Toxicity Grade of 1 or Higher
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9012	34/M/BL		Screening	06AUG2019 10:31 (-8)	Triglycerides	1.83	mmol/L		G1	0-4.52	
9015	29/M/BL		Screening	12AUG2019 11:07 (-2)	Triglycerides	2.90	mmol/L		G1	0-4.52	
9016	48/F/W		Screening	12AUG2019 11:08 (-23)	Cholesterol	6.84	mmol/L	H NCS	G2	2.2-6.22	
			Screening	12AUG2019 11:08 (-23)	LDL Cholesterol	4.45	mmol/L	H NCS	G2	0.96-4.22	
9019	41/M/BL		Screening	15AUG2019 17:21 (-20)	Cholesterol	5.18	mmol/L		G1	2.2-6.22	
			Screening	15AUG2019 17:21 (-20)	LDL Cholesterol	3.55	mmol/L		G1	0.96-4.22	
			Screening	15AUG2019 17:21 (-20)	Urate	512	umol/L	H NCS	G1	173-494	
			Check-in	03SEP2019 11:40 (-1)	Urate	506	umol/L	H NCS	G1	173-494	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.5
Laboratory Results Meeting Toxicity Grade of 1 or Higher
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9019	41/M/BL	TPOXX 600 mg	Day 4	07SEP2019 07:32 (4)	Urate	458	umol/L		G1	173-494	
		TPOXX 600 mg	Day 9	12SEP2019 08:08 (9)	Urate	452	umol/L		G1	173-494	
9020	47/F/BL	TPOXX 600 mg	Day 4	07SEP2019 07:31 (4)	Albumin	37	g/L	L NCS	G1	38-49	
9021	39/F/BL		Screening	21AUG2019 10:44 (-14)	Cholesterol	5.72	mmol/L		G1	2.2-6.22	
			Check-in	03SEP2019 09:00 (-1)	Glucose	6.11	mmol/L		G1	3-6.44	
			Screening	21AUG2019 10:44 (-14)	LDL Cholesterol	4.14	mmol/L		G2	0.96-4.22	
			Check-in	03SEP2019 09:00 (-1)	Urate	458	umol/L	H NCS	G1	119-345	
		TPOXX 600 mg	Day 4	07SEP2019 07:34 (4)	Urate	482	umol/L	H NCS	G1	119-345	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.5
Laboratory Results Meeting Toxicity Grade of 1 or Higher
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9021	39/F/BL	TPOXX 600 mg	Day 8 - 12 Hours Postdose	11SEP2019 08:09 (8)	Urate	464	umol/L	H NCS	G1	119-345	
		TPOXX 600 mg	Day 9	12SEP2019 08:09 (9)	Urate	452	umol/L	H NCS	G1	119-345	
9022	31/M/W		Screening	21AUG2019 11:05 (-14)	Triglycerides	2.45	mmol/L		G1	0-4.52	
			Screening	21AUG2019 11:05 (-14)	Urate	494	umol/L		G1	173-494	
			Check-in	03SEP2019 09:54 (-1)	Urate	464	umol/L		G1	173-494	
		TPOXX 600 mg	Day 4	07SEP2019 07:44 (4)	Urate	589	umol/L	H NCS	G1	173-494	
		TPOXX 600 mg	Day 8 - 12 Hours Postdose	11SEP2019 08:12 (8)	Urate	571	umol/L	H NCS	G1	173-494	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.5
Laboratory Results Meeting Toxicity Grade of 1 or Higher
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9022	31/M/W	TPOXX 600 mg	Day 9	12SEP2019 08:12 (9)	Urate	577	umol/L	H NCS	G1	173-494	
9033	32/M/W		Screening	29AUG2019 09:53 (-6)	Urate	488	umol/L		G1	173-494	
			Check-in	03SEP2019 09:15 (-1)	Urate	500	umol/L	H NCS	G1	173-494	
		TPOXX 600 mg	Day 4	07SEP2019 07:48 (4)	Urate	518	umol/L	H NCS	G1	173-494	
		TPOXX 600 mg	Day 8 - 12 Hours Postdose	11SEP2019 08:18 (8)	Urate	494	umol/L		G1	173-494	
		TPOXX 600 mg	Day 9	12SEP2019 08:18 (9)	Urate	488	umol/L		G1	173-494	
9043	22/M/BL		Screening	11SEP2019 09:38 (-7)	Urate	452	umol/L		G1	173-494	
			Check-in	17SEP2019 09:06 (-1)	Urate	535	umol/L	H NCS	G1	173-494	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.5
Laboratory Results Meeting Toxicity Grade of 1 or Higher
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9043	22/M/BL	TPOXX 600 mg	Day 4	21SEP2019 07:28 (4)	Urate	470	umol/L		G1	173-494	
9051	34/M/BL		Screening	19SEP2019 09:10 (-13)	Cholesterol	6.58	mmol/L	H NCS	G2	2.2-6.22	
			Screening	19SEP2019 09:10 (-13)	LDL Cholesterol	4.27	mmol/L	H NCS	G2	0.96-4.22	
			Screening	19SEP2019 09:10 (-13)	Triglycerides	1.84	mmol/L		G1	0-4.52	
9057	29/F/W		Screening	25SEP2019 16:27 (-7)	Cholesterol	6.53	mmol/L	H NCS	G2	2.2-6.22	
			Screening	25SEP2019 16:27 (-7)	LDL Cholesterol	3.68	mmol/L		G1	0.96-4.22	
			Screening	25SEP2019 16:27 (-7)	Triglycerides	4.19	mmol/L		G2	0-4.52	
9058	32/M/W		Screening	26SEP2019 09:26 (-20)	Cholesterol	6.66	mmol/L	H NCS	G2	2.2-6.22	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.5
Laboratory Results Meeting Toxicity Grade of 1 or Higher
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treat-ment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9058	32/M/W		Screening	26SEP2019 09:26 (-20)	LDL Cholesterol	4.77	mmol/L	H NCS	G2	0.96-4.22	
9063	35/M/W		Screening	30SEP2019 09:38 (-2)	Triglycerides	2.71	mmol/L		G1	0-4.52	
9073	40/M/BL		Screening	04OCT2019 13:56 (-12)	Glucose	6.38	mmol/L		G1	3-6.44	
		TPOXX 600 mg	Day 4	19OCT2019 07:41 (4)	Urate	452	umol/L		G1	173-494	
9077	37/F/W		Screening	05OCT2019 13:15 (-11)	Sodium	134	mmol/L		G1	132-145	
9080	41/F/BL	TPOXX 600 mg	Day 9	24OCT2019 08:21 (9)	Sodium	133	mmol/L		G1	132-145	
9086	36/M/BL		Screening	11OCT2019 10:03 (-5)	Cholesterol	6.06	mmol/L		G1	2.2-6.22	
			Screening	11OCT2019 10:03 (-5)	LDL Cholesterol	4.53	mmol/L	H NCS	G2	0.96-4.22	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.5
Laboratory Results Meeting Toxicity Grade of 1 or Higher
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9086	36/M/BL		Screening	11OCT2019 10:03 (-5)	Urate	529	umol/L	H NCS	G1	173-494	
			Check-in	15OCT2019 09:28 (-1)	Urate	523	umol/L	H NCS	G1	173-494	
		TPOXX 600 mg	Day 4	19OCT2019 07:40 (4)	Urate	518	umol/L	H NCS	G1	173-494	
		TPOXX 600 mg	Day 8 - 12 Hours Postdose	23OCT2019 08:15 (8)	Urate	488	umol/L		G1	173-494	
		TPOXX 600 mg	Day 9	24OCT2019 08:15 (9)	Urate	482	umol/L		G1	173-494	
9087	34/F/BL	TPOXX 600 mg	Day 9	24OCT2019 08:18 (9)	Sodium	134	mmol/L		G1	132-145	
9089	29/M/BL		Screening	14OCT2019 09:26 (-2)	Cholesterol	5.57	mmol/L		G1	2.2-6.22	
			Screening	14OCT2019 09:26 (-2)	Triglycerides	3.48	mmol/L		G2	0-4.52	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.5
Laboratory Results Meeting Toxicity Grade of 1 or Higher
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9092	24/M/W	TPOXX 600 mg	Day 4	19OCT2019 07:52 (4)	Urate	476	umol/L		G1	173-494	
9095	42/M/W		Screening	17OCT2019 13:31 (-13)	Cholesterol	6.06	mmol/L		G1	2.2-6.22	
			Screening	17OCT2019 13:31 (-13)	Glucose	6.38	mmol/L		G1	3-6.44	
		TPOXX 600 mg	Day 8 - 12 Hours Postdose	06NOV2019 07:06 (8)	Glucose	6.33	mmol/L		G1	3-6.44	
		TPOXX 600 mg	Day 9	07NOV2019 07:06 (9)	Glucose	6.11	mmol/L		G1	3-6.44	
			Screening	17OCT2019 13:31 (-13)	LDL Cholesterol	4.22	mmol/L		G2	0.96-4.22	
9087	34/F/BL		Screening	11OCT2019 09:47 (-5)	Hemoglobin	104	g/L	L NCS	G1	108-150	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.5
Laboratory Results Meeting Toxicity Grade of 1 or Higher
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Treatment	Visit	Collection Date Time (Day)	Laboratory Test	Result	Units	Flag [1]	Toxicity Grade [1]	Reference Range	Comments
9087	34/F/BL		Check-in	15OCT2019 09:17 (-1)	Hemoglobin	104	g/L	L NCS	G1	108-150	
		TPOXX 600 mg	Day 4	19OCT2019 07:43 (4)	Hemoglobin	102	g/L	L NCS	G1	108-150	
		TPOXX 600 mg	Day 9	24OCT2019 08:18 (9)	Hemoglobin	104	g/L	L NCS	G1	108-150	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
[1] L = Low, H = High, CS = Clinically Significant, NCS = Not Clinically Significant
[2] G = Grade; Laboratory parameters were graded using the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, verions 2.1.
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Listing 16.2.8.6
Vital Sign Results
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Time Point	Date Time (Day)	Position	Sys BP (mmHg)	Dias BP (mmHg)	Heart Rate (bpm)	Resp Rate (bpm)	Temp (C)
9001	41/M/BL	Screening	19JUL2019 11:27 (-26)	SITTING	154	85	57	14	36.4
		Screening	19JUL2019 11:34 (-26) R	SITTING	155	86	68		
		Screening	19JUL2019 12:50 (-26) R	SITTING	138	100	60		
		Check-in	13AUG2019 09:38 (-1)	SITTING	139	79	71	18	36.2
		Day 1- Predose	14AUG2019 08:28 (1)	SITTING	169	99	66	20	36
		Day 1- Predose	14AUG2019 08:35 (1) R	SITTING	177	98	64		
		Day 1- Predose	14AUG2019 08:37 (1) R	SITTING	150	98	64		
		Day 1- 4 Hour Postdose	14AUG2019 13:20 (1)	SITTING	134	83	61	18	36.3

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date – First dose date + 1
Sys=Systolic, Dias=Diastolic, BP=Blood Pressure, bpm=beats per minute, Resp=Respiration, Temp=Temperature
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.6
Vital Sign Results
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Time Point	Date Time (Day)	Position	Sys BP (mmHg)	Dias BP (mmHg)	Heart Rate (bpm)	Resp Rate (bpm)	Temp (C)
9001	41/M/BL	Day 4- 4 Hour Postdose	17AUG2019 13:21 (4)	SITTING	132	79	64	16	36.2
		Day 7- Predose	20AUG2019 08:45 (7)	SITTING	162	95	68	20	35.7
		Day 7- Predose	20AUG2019 08:52 (7) R	SITTING	158	96	72		
		Day 7- 4 Hour Postdose	20AUG2019 13:20 (7)	SITTING	154	90	66	18	36.5
		Day 8	21AUG2019 09:10 (8)	SITTING	144	91	66	10	36.2
		Day 9	22AUG2019 09:20 (9)	SITTING	131	80	71	16	36.4
9002	48/M/W	Screening	19JUL2019 11:46 (-26)	SITTING	152	96	89	18	36.4
		Screening	19JUL2019 11:52 (-26) R	SITTING	147	90	89		

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date – First dose date + 1
Sys=Systolic, Dias=Diastolic, BP=Blood Pressure, bpm=beats per minute, Resp=Respiration, Temp=Temperature
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.6
Vital Sign Results
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Time Point	Date Time (Day)	Position	Sys BP (mmHg)	Dias BP (mmHg)	Heart Rate (bpm)	Resp Rate (bpm)	Temp (C)
9002	48/M/W	Screening	19JUL2019 12:48 (-26) R	SITTING	140	106	88		
		Check-in	13AUG2019 09:57 (-1)	SITTING	137	77	98	18	36.3
		Day 1- Predose	14AUG2019 08:20 (1)	SITTING	138	92	89	16	36.2
		Day 1- Predose	14AUG2019 08:27 (1) R	SITTING	145	78	88	16	36.5
		Day 1- Predose	14AUG2019 08:35 (1) R	SITTING	138	100	88		
		Day 1- 4 Hour Postdose	14AUG2019 13:21 (1)	SITTING	182	82	81	18	35.2
		Day 1- 4 Hour Postdose	14AUG2019 13:30 (1) R	SITTING	160	100	80		
		Day 4- 4 Hour Postdose	17AUG2019 13:20 (4)	SITTING	166	100	84	16	36.4

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
Sys=Systolic, Dias=Diastolic, BP=Blood Pressure, bpm=beats per minute, Resp=Respiration, Temp=Temperature
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.6
Vital Sign Results
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Time Point	Date Time (Day)	Position	Sys BP (mmHg)	Dias BP (mmHg)	Heart Rate (bpm)	Resp Rate (bpm)	Temp (C)
9002	48/M/W	Day 4- 4 Hour Postdose	17AUG2019 13:26 (4) R	SITTING	167	86	85		
		Day 4- 4 Hour Postdose	17AUG2019 13:32 (4) R	SITTING	162	100	88		
		Day 7- Predose	20AUG2019 08:44 (7)	SITTING	147	68	87	14	36.2
		Day 7- 4 Hour Postdose	20AUG2019 13:22 (7)	SITTING	152	77	79	16	35.9
		Day 8	21AUG2019 09:09 (8)	SITTING	172	84	78	12	35.1
		Day 8	21AUG2019 09:16 (8) R	SITTING	160	78	76		
		Day 9	22AUG2019 09:19 (9)	SITTING	144	88	85	16	36
9005	40/M/W	Screening	23JUL2019 09:45 (-22)	SITTING	139	86	63	16	35.9

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date – First dose date + 1
Sys=Systolic, Dias=Diastolic, BP=Blood Pressure, bpm=beats per minute, Resp=Respiration, Temp=Temperature
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.6
Vital Sign Results
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Time Point	Date Time (Day)	Position	Sys BP (mmHg)	Dias BP (mmHg)	Heart Rate (bpm)	Resp Rate (bpm)	Temp (C)
9005	40/M/W	Check-in	13AUG2019 09:30 (-1)	SITTING	128	74	67	20	36.1
		Day 1- Predose	14AUG2019 08:22 (1)	SITTING	120	75	68	14	36.2
		Day 1- 4 Hour Postdose	14AUG2019 12:57 (1)	SITTING	112	72	69	18	36.1
		Day 4- 4 Hour Postdose	17AUG2019 12:57 (4)	SITTING	122	74	59	16	36.1
		Day 7- Predose	20AUG2019 08:22 (7)	SITTING	103	50	59	14	36.4
		Day 7- 4 Hour Postdose	20AUG2019 12:57 (7)	SITTING	106	72	63	18	36.6
		Day 8	21AUG2019 08:48 (8)	SITTING	110	65	63	14	35.9
		Day 9	22AUG2019 08:57 (9)	SITTING	118	72	64	18	36.1

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date – First dose date + 1
Sys=Systolic, Dias=Diastolic, BP=Blood Pressure, bpm=beats per minute, Resp=Respiration, Temp=Temperature
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.6
Vital Sign Results
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Time Point	Date Time (Day)	Position	Sys BP (mmHg)	Dias BP (mmHg)	Heart Rate (bpm)	Resp Rate (bpm)	Temp (C)
9009	21/F/BL	Screening	31JUL2019 09:57 (-14)	SITTING	96	71	75	12	36.4
		Screening	31JUL2019 10:05 (-14) R	SITTING	94	74	79		
		Screening	31JUL2019 11:18 (-14) R	SITTING	112	62	88		
		Check-in	13AUG2019 09:27 (-1)	SITTING	123	67	87	18	36.8
		Day 1- Predose	14AUG2019 08:26 (1)	SITTING	121	69	85	12	36.3
		Day 1- 4 Hour Postdose	14AUG2019 13:01 (1)	SITTING	98	57	79	14	35.9
		Day 4- 4 Hour Postdose	17AUG2019 13:01 (4)	SITTING	109	57	71	12	36.4
		Day 7- Predose	20AUG2019 08:26 (7)	SITTING	124	57	107	18	36.4

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date – First dose date + 1
Sys=Systolic, Dias=Diastolic, BP=Blood Pressure, bpm=beats per minute, Resp=Respiration, Temp=Temperature
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.6
Vital Sign Results
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Time Point	Date Time (Day)	Position	Sys BP (mmHg)	Dias BP (mmHg)	Heart Rate (bpm)	Resp Rate (bpm)	Temp (C)
9009	21/F/BL	Day 7- 4 Hour Postdose	20AUG2019 13:04 (7)	SITTING	120	50	91	12	35.9
		Day 8	21AUG2019 08:51 (8)	SITTING	102	56	101	12	36.5
		Day 9	22AUG2019 09:01 (9)	SITTING	105	56	88	16	36.4
9012	34/M/BL	Screening	06AUG2019 10:06 (-8)	SITTING	121	75	68	14	36
		Check-in	13AUG2019 09:50 (-1)	SITTING	113	70	77	16	36.6
		Day 1- Predose	14AUG2019 08:32 (1)	SITTING	117	74	76	16	36.6
		Day 1- 4 Hour Postdose	14AUG2019 13:05 (1)	SITTING	119	77	75	16	36.2
		Day 4- 4 Hour Postdose	17AUG2019 13:05 (4)	SITTING	115	75	68	14	35.7

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date – First dose date + 1
Sys=Systolic, Dias=Diastolic, BP=Blood Pressure, bpm=beats per minute, Resp=Respiration, Temp=Temperature
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.6
Vital Sign Results
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Time Point	Date Time (Day)	Position	Sys BP (mmHg)	Dias BP (mmHg)	Heart Rate (bpm)	Resp Rate (bpm)	Temp (C)
9012	34/M/BL	Day 7- Predose	20AUG2019 08:30 (7)	SITTING	121	76	68	18	36.4
		Day 7- 4 Hour Postdose	20AUG2019 13:05 (7)	SITTING	133	64	80	16	36.4
		Day 8	21AUG2019 08:55 (8)	SITTING	128	64	69	14	36.3
		Day 9	22AUG2019 09:05 (9)	SITTING	122	80	71	14	36.6
9015	29/M/BL	Screening	12AUG2019 10:57 (-2)	SITTING	130	73	46	16	36.6
		Check-in	13AUG2019 09:15 (-1)	SITTING	129	74	50	12	35.9
		Day 1- Predose	14AUG2019 08:24 (1)	SITTING	119	66	44	16	36.2
		Day 1- 4 Hour Postdose	14AUG2019 13:03 (1)	SITTING	116	67	46	18	36.3

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date – First dose date + 1
Sys=Systolic, Dias=Diastolic, BP=Blood Pressure, bpm=beats per minute, Resp=Respiration, Temp=Temperature
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.6
Vital Sign Results
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Time Point	Date Time (Day)	Position	Sys BP (mmHg)	Dias BP (mmHg)	Heart Rate (bpm)	Resp Rate (bpm)	Temp (C)
9015	29/M/BL	Day 4- 4 Hour Postdose	17AUG2019 13:03 (4)	SITTING	114	65	50	12	36.5
		Day 7- Predose	20AUG2019 08:28 (7)	SITTING	113	59	44	12	36.2
		Day 7- 4 Hour Postdose	20AUG2019 13:03 (7)	SITTING	113	66	47	18	36.4
		Day 8	21AUG2019 08:53 (8)	SITTING	108	63	57	12	36.1
		Day 9	22AUG2019 09:03 (9)	SITTING	118	65	49	16	36.4
9016	48/F/W	Screening	12AUG2019 11:22 (-23)	SITTING	149	85	88	16	36.5
		Screening	12AUG2019 11:29 (-23) R	SITTING	130	73	81		
		Check-in	03SEP2019 08:57 (-1)	SITTING	138	64	87	14	36.4

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date – First dose date + 1
Sys=Systolic, Dias=Diastolic, BP=Blood Pressure, bpm=beats per minute, Resp=Respiration, Temp=Temperature
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.6
Vital Sign Results
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Time Point	Date Time (Day)	Position	Sys BP (mmHg)	Dias BP (mmHg)	Heart Rate (bpm)	Resp Rate (bpm)	Temp (C)
9016	48/F/W	Day 1- Predose	04SEP2019 07:20 (1)	SITTING	143	76	92	18	36.9
		Day 1- Predose	04SEP2019 07:28 (1) R	SITTING	137	65	93		
		Day 1- 4 Hour Postdose	04SEP2019 11:55 (1)	SITTING	125	72	82	12	35.8
		Day 4- 4 Hour Postdose	07SEP2019 11:55 (4)	SITTING	137	70	75	18	35.9
		Day 7- Predose	10SEP2019 07:20 (7)	SITTING	128	73	91	18	36.3
		Day 7- 4 Hour Postdose	10SEP2019 11:55 (7)	SITTING	143	71	71	18	36.6
		Day 8	11SEP2019 07:45 (8)	SITTING	134	75	77	16	36.7
		Day 9	12SEP2019 07:55 (9)	SITTING	139	74	81	16	36.3

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date – First dose date + 1
Sys=Systolic, Dias=Diastolic, BP=Blood Pressure, bpm=beats per minute, Resp=Respiration, Temp=Temperature
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.6
Vital Sign Results
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Time Point	Date Time (Day)	Position	Sys BP (mmHg)	Dias BP (mmHg)	Heart Rate (bpm)	Resp Rate (bpm)	Temp (C)
9019	41/M/BL	Screening	15AUG2019 16:58 (-20)	SITTING	132	71	85	14	36.3
		Check-in	03SEP2019 11:37 (-1)	SITTING	137	78	88	16	36.4
		Day 1- Predose	04SEP2019 07:23 (1)	SITTING	123	67	72	14	36.2
		Day 1- 4 Hour Postdose	04SEP2019 11:58 (1)	SITTING	122	72	76	16	36.1
		Day 4- 4 Hour Postdose	07SEP2019 12:04 (4)	SITTING	129	76	71	16	36.3
		Day 7- Predose	10SEP2019 07:23 (7)	SITTING	114	80	77	16	35.8
		Day 7- 4 Hour Postdose	10SEP2019 11:58 (7)	SITTING	119	75	70	16	36.5
		Day 8	11SEP2019 07:48 (8)	SITTING	119	76	70	14	35.9

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date – First dose date + 1
Sys=Systolic, Dias=Diastolic, BP=Blood Pressure, bpm=beats per minute, Resp=Respiration, Temp=Temperature
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.6
Vital Sign Results
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Time Point	Date Time (Day)	Position	Sys BP (mmHg)	Dias BP (mmHg)	Heart Rate (bpm)	Resp Rate (bpm)	Temp (C)
9019	41/M/BL	Day 9	12SEP2019 07:58 (9)	SITTING	119	70	77	18	36.3
9020	47/F/BL	Screening	21AUG2019 10:32 (-14)	SITTING	119	63	59	16	35.9
		Check-in	03SEP2019 08:49 (-1)	SITTING	137	62	53	18	36.3
		Day 1- Predose	04SEP2019 07:26 (1)	SITTING	123	65	57	14	36.3
		Day 1- 4 Hour Postdose	04SEP2019 12:01 (1)	SITTING	126	68	56	12	35.9
		Day 4- 4 Hour Postdose	07SEP2019 12:01 (4)	SITTING	130	63	51	18	36.1
		Day 7- Predose	10SEP2019 07:26 (7)	SITTING	106	55	61	18	36.6
		Day 7- 4 Hour Postdose	10SEP2019 12:01 (7)	SITTING	120	61	60	16	36.4

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
Sys=Systolic, Dias=Diastolic, BP=Blood Pressure, bpm=beats per minute, Resp=Respiration, Temp=Temperature
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.6
Vital Sign Results
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Time Point	Date Time (Day)	Position	Sys BP (mmHg)	Dias BP (mmHg)	Heart Rate (bpm)	Resp Rate (bpm)	Temp (C)
9020	47/F/BL	Day 8	11SEP2019 07:51 (8)	SITTING	122	71	59	14	36.6
		Day 9	12SEP2019 08:03 (9)	SITTING	110	59	57	18	36.4
9021	39/F/BL	Screening	21AUG2019 10:19 (-14)	SITTING	133	63	86	12	37.4
		Check-in	03SEP2019 08:50 (-1)	SITTING	114	55	88	14	37.1
		Day 1- Predose	04SEP2019 07:29 (1)	SITTING	124	60	58	14	36.6
		Day 1- 4 Hour Postdose	04SEP2019 12:04 (1)	SITTING	114	57	67	14	36.4
		Day 4- 4 Hour Postdose	07SEP2019 12:04 (4)	SITTING	126	59	69	16	36.5
		Day 7- Predose	10SEP2019 07:29 (7)	SITTING	124	61	71	16	36.7

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date – First dose date + 1
Sys=Systolic, Dias=Diastolic, BP=Blood Pressure, bpm=beats per minute, Resp=Respiration, Temp=Temperature
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.6
Vital Sign Results
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Time Point	Date Time (Day)	Position	Sys BP (mmHg)	Dias BP (mmHg)	Heart Rate (bpm)	Resp Rate (bpm)	Temp (C)
9021	39/F/BL	Day 7- 4 Hour Postdose	10SEP2019 12:04 (7)	SITTING	119	57	63	16	36.4
		Day 8	11SEP2019 07:54 (8)	SITTING	127	60	73	18	36.6
		Day 9	12SEP2019 08:04 (9)	SITTING	108	54	83	18	36.6
9022	31/M/W	Screening	21AUG2019 10:53 (-14)	SITTING	127	69	83	16	36.1
		Check-in	03SEP2019 09:43 (-1)	SITTING	122	64	80	18	36.4
		Day 1- Predose	04SEP2019 07:32 (1)	SITTING	110	64	76	16	35.7
		Day 1- 4 Hour Postdose	04SEP2019 12:07 (1)	SITTING	119	67	77	12	36
		Day 4- 4 Hour Postdose	07SEP2019 12:13 (4)	SITTING	116	66	77	18	36.4

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date – First dose date + 1
Sys=Systolic, Dias=Diastolic, BP=Blood Pressure, bpm=beats per minute, Resp=Respiration, Temp=Temperature
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.6
Vital Sign Results
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Time Point	Date Time (Day)	Position	Sys BP (mmHg)	Dias BP (mmHg)	Heart Rate (bpm)	Resp Rate (bpm)	Temp (C)
9022	31/M/W	Day 7- Predose	10SEP2019 07:32 (7)	SITTING	102	57	74	14	35.8
		Day 7- 4 Hour Postdose	10SEP2019 12:07 (7)	SITTING	122	61	69	16	36.1
		Day 8	11SEP2019 07:57 (8)	SITTING	122	69	79	16	35.9
		Day 9	12SEP2019 08:07 (9)	SITTING	119	59	80	16	36.2
9024	20/M/BL	Screening	23AUG2019 10:18 (-12)	SITTING	108	72	94	18	36.6
		Check-in	03SEP2019 09:10 (-1)	SITTING	115	66	75	12	36.7
		Day 1- Predose	04SEP2019 07:35 (1)	SITTING	98	63	67	14	36.3
		Day 1- Predose	04SEP2019 07:41 (1) R	SITTING	101	66	68	14	36

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date – First dose date + 1
Sys=Systolic, Dias=Diastolic, BP=Blood Pressure, bpm=beats per minute, Resp=Respiration, Temp=Temperature
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.6
Vital Sign Results
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Time Point	Date Time (Day)	Position	Sys BP (mmHg)	Dias BP (mmHg)	Heart Rate (bpm)	Resp Rate (bpm)	Temp (C)
9024	20/M/BL	Day 1- 4 Hour Postdose	04SEP2019 12:10 (1)	SITTING	103	67	78	16	36
		Day 4- 4 Hour Postdose	07SEP2019 12:10 (4)	SITTING	122	68	82	16	36.7
		Day 7- Predose	10SEP2019 07:35 (7)	SITTING	115	71	69	16	35.9
		Day 7- 4 Hour Postdose	10SEP2019 12:10 (7)	SITTING	121	72	75	12	36.3
		Day 8	11SEP2019 08:00 (8)	SITTING	114	70	70	14	36.2
		Day 9	12SEP2019 08:10 (9)	SITTING	131	67	91	14	36.4
9025	50/M/W	Screening	23AUG2019 10:29 (-26)	SITTING	113	74	74	12	36.8
		Check-in	17SEP2019 09:01 (-1)	SITTING	133	82	72	18	37.1

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date – First dose date + 1
Sys=Systolic, Dias=Diastolic, BP=Blood Pressure, bpm=beats per minute, Resp=Respiration, Temp=Temperature
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.6
Vital Sign Results
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Time Point	Date Time (Day)	Position	Sys BP (mmHg)	Dias BP (mmHg)	Heart Rate (bpm)	Resp Rate (bpm)	Temp (C)
9025	50/M/W	Day 1- Predose	18SEP2019 07:21 (1)	SITTING	111	70	73	12	36.8
		Day 1- 4 Hour Postdose	18SEP2019 11:55 (1)	SITTING	123	82	70	14	36.7
		Day 4- 4 Hour Postdose	21SEP2019 11:55 (4)	SITTING	122	69	69	18	36.5
		Day 7- Predose	24SEP2019 07:20 (7)	SITTING	120	74	82	14	36.3
		Day 7- 4 Hour Postdose	24SEP2019 11:55 (7)	SITTING	124	66	69	14	35.8
		Day 8	25SEP2019 07:45 (8)	SITTING	109	71	90	16	36.7
		Day 9	26SEP2019 07:55 (9)	SITTING	101	58	85	14	36.6
9033	32/M/W	Screening	29AUG2019 09:13 (-6)	SITTING	146	88	76	18	37.5

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date – First dose date + 1
Sys=Systolic, Dias=Diastolic, BP=Blood Pressure, bpm=beats per minute, Resp=Respiration, Temp=Temperature
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.6
Vital Sign Results
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Time Point	Date Time (Day)	Position	Sys BP (mmHg)	Dias BP (mmHg)	Heart Rate (bpm)	Resp Rate (bpm)	Temp (C)
9033	32/M/W	Screening	29AUG2019 09:20 (-6) R	SITTING	138	86	76		
		Check-in	03SEP2019 09:03 (-1)	SITTING	135	73	78	14	37.1
		Day 1- Predose	04SEP2019 07:38 (1)	SITTING	139	85	71	16	36.6
		Day 1- 4 Hour Postdose	04SEP2019 12:13 (1)	SITTING	134	87	60	12	36.3
		Day 4- 4 Hour Postdose	07SEP2019 12:16 (4)	SITTING	143	79	70	18	36.8
		Day 7- Predose	10SEP2019 07:38 (7)	SITTING	146	87	69	16	36.8
		Day 7- 4 Hour Postdose	10SEP2019 12:13 (7)	SITTING	143	84	60	16	37.2
		Day 8	11SEP2019 08:03 (8)	SITTING	130	79	77	14	37.2

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date – First dose date + 1
Sys=Systolic, Dias=Diastolic, BP=Blood Pressure, bpm=beats per minute, Resp=Respiration, Temp=Temperature
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.6
Vital Sign Results
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Time Point	Date Time (Day)	Position	Sys BP (mmHg)	Dias BP (mmHg)	Heart Rate (bpm)	Resp Rate (bpm)	Temp (C)
9033	32/M/W	Day 9	12SEP2019 08:13 (9)	SITTING	136	77	71	18	36.8
9043	22/M/BL	Screening	11SEP2019 09:13 (-7)	SITTING	130	61	55	20	37.3
		Check-in	17SEP2019 08:58 (-1)	SITTING	121	69	61	18	36.7
		Day 1- Predose	18SEP2019 07:23 (1)	SITTING	132	71	62	14	36.8
		Day 1- 4 Hour Postdose	18SEP2019 11:58 (1)	SITTING	124	72	54	12	35.9
		Day 4- 4 Hour Postdose	21SEP2019 11:58 (4)	SITTING	123	65	60	16	36.3
		Day 7- Predose	24SEP2019 07:23 (7)	SITTING	124	71	67	18	36.3
		Day 7- 4 Hour Postdose	24SEP2019 11:58 (7)	SITTING	122	78	62	16	36.6

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date – First dose date + 1
Sys=Systolic, Dias=Diastolic, BP=Blood Pressure, bpm=beats per minute, Resp=Respiration, Temp=Temperature
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.6
Vital Sign Results
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Time Point	Date Time (Day)	Position	Sys BP (mmHg)	Dias BP (mmHg)	Heart Rate (bpm)	Resp Rate (bpm)	Temp (C)
9043	22/M/BL	Day 8	25SEP2019 07:48 (8)	SITTING	113	72	67	12	36.5
		Day 9	26SEP2019 07:58 (9)	SITTING	119	62	72	16	36.8
9046	34/M/BL	Screening	13SEP2019 08:51 (-5)	SITTING	121	82	60	14	36.6
		Check-in	17SEP2019 09:02 (-1)	SITTING	136	81	56	16	36.8
		Day 1- Predose	18SEP2019 07:26 (1)	SITTING	122	82	55	14	36.4
		Day 1- 4 Hour Postdose	18SEP2019 12:01 (1)	SITTING	124	82	50	12	35.9
		Day 4- 4 Hour Postdose	21SEP2019 12:01 (4)	SITTING	122	76	57	14	36.4
		Day 7- Predose	24SEP2019 07:26 (7)	SITTING	118	68	62	16	36.3

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date – First dose date + 1
Sys=Systolic, Dias=Diastolic, BP=Blood Pressure, bpm=beats per minute, Resp=Respiration, Temp=Temperature
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.6
Vital Sign Results
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Time Point	Date Time (Day)	Position	Sys BP (mmHg)	Dias BP (mmHg)	Heart Rate (bpm)	Resp Rate (bpm)	Temp (C)
9046	34/M/BL	Day 7- 4 Hour Postdose	24SEP2019 12:03 (7)	SITTING	131	73	53	16	36.3
		Day 8	25SEP2019 07:51 (8)	SITTING	119	66	59	16	36.2
		Day 9	26SEP2019 08:01 (9)	SITTING	123	67	62	14	36.5
9051	34/M/BL	Screening	19SEP2019 09:04 (-13)	SITTING	135	70	75	16	36.8
		Check-in	01OCT2019 08:58 (-1)	SITTING	111	54	73	16	36.9
		Day 1- Predose	02OCT2019 07:35 (1)	SITTING	127	73	71	16	36.4
		Day 1- 4 Hour Postdose	02OCT2019 12:10 (1)	SITTING	120	59	66	18	36.6
		Day 4- 4 Hour Postdose	05OCT2019 12:10 (4)	SITTING	121	58	70	14	36.7

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date – First dose date + 1
Sys=Systolic, Dias=Diastolic, BP=Blood Pressure, bpm=beats per minute, Resp=Respiration, Temp=Temperature
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.6
Vital Sign Results
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Time Point	Date Time (Day)	Position	Sys BP (mmHg)	Dias BP (mmHg)	Heart Rate (bpm)	Resp Rate (bpm)	Temp (C)
9051	34/M/BL	Day 7- Predose	08OCT2019 07:36 (7)	SITTING	133	74	73	16	36.6
		Day 7- 4 Hour Postdose	08OCT2019 12:10 (7)	SITTING	122	72	63	16	36.7
		Day 8	09OCT2019 08:00 (8)	SITTING	107	62	75	14	36.4
		Day 9	10OCT2019 08:10 (9)	SITTING	127	68	78	16	37.2
9052	42/M/BL	Screening	21SEP2019 13:00 (-11)	SITTING	145	91	63	12	36.4
		Screening	21SEP2019 13:06 (-11) R	SITTING	158	85	70		
		Screening	30SEP2019 12:29 (-2) R	SITTING	134	76	71		
		Check-in	01OCT2019 08:58 (-1)	SITTING	148	83	80	14	36.9

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date – First dose date + 1
Sys=Systolic, Dias=Diastolic, BP=Blood Pressure, bpm=beats per minute, Resp=Respiration, Temp=Temperature
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.6
Vital Sign Results
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Time Point	Date Time (Day)	Position	Sys BP (mmHg)	Dias BP (mmHg)	Heart Rate (bpm)	Resp Rate (bpm)	Temp (C)
9052	42/M/BL	Check-in	01OCT2019 09:04 (-1) R	SITTING	143	94	87		
		Check-in	01OCT2019 09:09 (-1) R	SITTING	132	60	88		
		Day 1- Predose	02OCT2019 07:32 (1)	SITTING	156	84	94	12	36.6
		Day 1- Predose	02OCT2019 07:38 (1) R	SITTING	141	84	87		
		Day 1- Predose	02OCT2019 07:45 (1) R	SITTING	144	92	84		
		Day 1- 4 Hour Postdose	02OCT2019 12:14 (1)	SITTING	141	79	75	18	36.5
		Day 4- 4 Hour Postdose	05OCT2019 12:14 (4)	SITTING	145	84	70	16	36.8
		Day 7- Predose	08OCT2019 07:39 (7)	SITTING	130	73	77	16	36.6

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date – First dose date + 1
Sys=Systolic, Dias=Diastolic, BP=Blood Pressure, bpm=beats per minute, Resp=Respiration, Temp=Temperature
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.6
Vital Sign Results
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Time Point	Date Time (Day)	Position	Sys BP (mmHg)	Dias BP (mmHg)	Heart Rate (bpm)	Resp Rate (bpm)	Temp (C)
9052	42/M/BL	Day 7- 4 Hour Postdose	08OCT2019 12:14 (7)	SITTING	151	87	69	12	36.6
		Day 8	09OCT2019 08:04 (8)	SITTING	126	79	84	14	36.4
		Day 9	10OCT2019 08:14 (9)	SITTING	149	82	73	12	36.6
9056	31/F/BL	Screening	24SEP2019 09:27 (-8)	SITTING	114	61	84	16	36.5
		Check-in	01OCT2019 09:23 (-1)	SITTING	120	65	85	16	37
		Day 1- Predose	02OCT2019 07:20 (1)	SITTING	125	70	86	18	36.6
		Day 1- 4 Hour Postdose	02OCT2019 11:55 (1)	SITTING	122	65	80	14	36.1
		Day 4- 4 Hour Postdose	05OCT2019 11:55 (4)	SITTING	136	64	80	12	36.2

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
Sys=Systolic, Dias=Diastolic, BP=Blood Pressure, bpm=beats per minute, Resp=Respiration, Temp=Temperature
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.6
Vital Sign Results
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Time Point	Date Time (Day)	Position	Sys BP (mmHg)	Dias BP (mmHg)	Heart Rate (bpm)	Resp Rate (bpm)	Temp (C)
9056	31/F/BL	Day 7- Predose	08OCT2019 07:20 (7)	SITTING	121	62	91	14	37.1
		Day 7- 4 Hour Postdose	08OCT2019 11:55 (7)	SITTING	131	67	88	14	37.2
		Day 8	09OCT2019 07:45 (8)	SITTING	126	63	89	10	36.5
		Day 9	10OCT2019 07:55 (9)	SITTING	125	59	89	12	36.9
9057	29/F/W	Screening	25SEP2019 16:09 (-7)	SITTING	115	71	80	14	36.1
		Check-in	01OCT2019 09:19 (-1)	SITTING	116	57	68	14	36.3
		Day 1- Predose	02OCT2019 07:23 (1)	SITTING	118	66	85	16	36.5
		Day 1- 4 Hour Postdose	02OCT2019 11:58 (1)	SITTING	147	64	80	12	36

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date – First dose date + 1
Sys=Systolic, Dias=Diastolic, BP=Blood Pressure, bpm=beats per minute, Resp=Respiration, Temp=Temperature
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.6
Vital Sign Results
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Time Point	Date Time (Day)	Position	Sys BP (mmHg)	Dias BP (mmHg)	Heart Rate (bpm)	Resp Rate (bpm)	Temp (C)
9057	29/F/W	Day 4- 4 Hour Postdose	05OCT2019 11:58 (4)	SITTING	112	68	76	12	36.3
		Day 7- Predose	08OCT2019 07:23 (7)	SITTING	115	58	86	14	36.5
		Day 7- 4 Hour Postdose	08OCT2019 11:58 (7)	SITTING	109	66	75	10	36.3
		Day 8	09OCT2019 07:48 (8)	SITTING	116	70	89	12	36.5
		Day 9	10OCT2019 07:58 (9)	SITTING	119	67	88	14	36.7
9058	32/M/W	Screening	26SEP2019 09:05 (-20)	SITTING	118	64	73	12	36.2
		Check-in	15OCT2019 09:01 (-1)	SITTING	123	57	68	16	36.7
		Day 1- Predose	16OCT2019 07:20 (1)	SITTING	130	59	66	14	35.7

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date – First dose date + 1
Sys=Systolic, Dias=Diastolic, BP=Blood Pressure, bpm=beats per minute, Resp=Respiration, Temp=Temperature
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.6
Vital Sign Results
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Time Point	Date Time (Day)	Position	Sys BP (mmHg)	Dias BP (mmHg)	Heart Rate (bpm)	Resp Rate (bpm)	Temp (C)
9058	32/M/W	Day 1- 4 Hour Postdose	16OCT2019 12:05 (1)	SITTING	127	58	69	14	36.4
		Day 4- 4 Hour Postdose	19OCT2019 12:02 (4)	SITTING	107	47	71	16	36.7
		Day 7- Predose	22OCT2019 07:27 (7)	SITTING	107	53	71	10	35.9
		Day 7- 4 Hour Postdose	22OCT2019 12:02 (7)	SITTING	111	53	70	16	36.7
		Day 8	23OCT2019 08:02 (8)	SITTING	130	58	65	14	35.7
		Day 9	24OCT2019 08:02 (9)	SITTING	108	55	69	12	36.4
9061	21/F/BL	Screening	26SEP2019 10:44 (-20)	SITTING	115	64	75	16	36.7
		Check-in	15OCT2019 08:56 (-1)	SITTING	124	57	81	14	37.1

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date – First dose date + 1
Sys=Systolic, Dias=Diastolic, BP=Blood Pressure, bpm=beats per minute, Resp=Respiration, Temp=Temperature
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.6
Vital Sign Results
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Time Point	Date Time (Day)	Position	Sys BP (mmHg)	Dias BP (mmHg)	Heart Rate (bpm)	Resp Rate (bpm)	Temp (C)
9061	21/F/BL	Day 1- Predose	16OCT2019 07:23 (1)	SITTING	116	72	72	10	36.6
		Day 1- 4 Hour Postdose	16OCT2019 11:58 (1)	SITTING	120	60	75	12	36.4
		Day 4- 4 Hour Postdose	19OCT2019 11:58 (4)	SITTING	84	52	75	16	36.7
		Day 4- 4 Hour Postdose	19OCT2019 12:05 (4) R	SITTING	108	59	78	16	36.9
		Day 7- Predose	22OCT2019 07:23 (7)	SITTING	100	61	85	14	36.6
		Day 7- 4 Hour Postdose	22OCT2019 11:58 (7)	SITTING	111	58	75	14	37.2
		Day 8	23OCT2019 07:48 (8)	SITTING	114	66	82	14	36.4
		Day 9	24OCT2019 07:59 (9)	SITTING	123	80	92	12	36.8

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date – First dose date + 1
Sys=Systolic, Dias=Diastolic, BP=Blood Pressure, bpm=beats per minute, Resp=Respiration, Temp=Temperature
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.6
Vital Sign Results
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Time Point	Date Time (Day)	Position	Sys BP (mmHg)	Dias BP (mmHg)	Heart Rate (bpm)	Resp Rate (bpm)	Temp (C)
9062	33/M/BL	Screening	30SEP2019 10:07 (-2)	SITTING	118	61	79	14	36.2
		Check-in	01OCT2019 09:15 (-1)	SITTING	134	81	78	18	36.3
		Day 1- Predose	02OCT2019 07:26 (1)	SITTING	122	65	76	14	36.4
		Day 1- 4 Hour Postdose	02OCT2019 12:01 (1)	SITTING	129	76	74	14	36.2
		Day 4- 4 Hour Postdose	05OCT2019 12:01 (4)	SITTING	125	70	78	10	36.4
		Day 7- Predose	08OCT2019 07:26 (7)	SITTING	121	57	80	14	36.3
		Day 7- 4 Hour Postdose	08OCT2019 12:05 (7)	SITTING	132	72	74	12	36.4
		Day 8	09OCT2019 07:51 (8)	SITTING	118	67	85	10	36.4

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date – First dose date + 1
Sys=Systolic, Dias=Diastolic, BP=Blood Pressure, bpm=beats per minute, Resp=Respiration, Temp=Temperature
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.6
Vital Sign Results
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Time Point	Date Time (Day)	Position	Sys BP (mmHg)	Dias BP (mmHg)	Heart Rate (bpm)	Resp Rate (bpm)	Temp (C)
9062	33/M/BL	Day 9	10OCT2019 08:01 (9)	SITTING	120	56	75	14	36.1
9063	35/M/W	Screening	30SEP2019 09:21 (-2)	SITTING	154	80	77	12	36.8
		Screening	30SEP2019 09:28 (-2) R	SITTING	141	82	91		
		Check-in	01OCT2019 08:45 (-1)	SITTING	135	83	76	16	36.4
		Day 1- Predose	02OCT2019 07:29 (1)	SITTING	140	78	84	14	36.4
		Day 1- 4 Hour Postdose	02OCT2019 12:05 (1)	SITTING	129	76	70	14	36
		Day 4- 4 Hour Postdose	05OCT2019 12:04 (4)	SITTING	133	67	78	10	37.2
		Day 7- Predose	08OCT2019 07:29 (7)	SITTING	119	71	73	16	36.3

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date – First dose date + 1
Sys=Systolic, Dias=Diastolic, BP=Blood Pressure, bpm=beats per minute, Resp=Respiration, Temp=Temperature
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.6
Vital Sign Results
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Time Point	Date Time (Day)	Position	Sys BP (mmHg)	Dias BP (mmHg)	Heart Rate (bpm)	Resp Rate (bpm)	Temp (C)
9063	35/M/W	Day 7- 4 Hour Postdose	08OCT2019 12:06 (7)	SITTING	145	63	74	12	36.4
		Day 8	09OCT2019 07:54 (8)	SITTING	123	68	82	14	35.8
		Day 9	10OCT2019 08:04 (9)	SITTING	126	72	79	12	36.4
9069	41/F/BL	Screening	30SEP2019 10:52 (-16)	SITTING	142	71	72	12	36.1
		Screening	30SEP2019 11:05 (-16) R	SITTING	154	72	68		
		Check-in	15OCT2019 12:18 (-1)	SITTING	133	90	77	16	36.4
		Day 1- Predose	16OCT2019 07:26 (1)	SITTING	137	65	67	16	36.1
		Day 1- 4 Hour Postdose	16OCT2019 12:01 (1)	SITTING	162	77	71	14	36

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date – First dose date + 1
Sys=Systolic, Dias=Diastolic, BP=Blood Pressure, bpm=beats per minute, Resp=Respiration, Temp=Temperature
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.6
Vital Sign Results
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Time Point	Date Time (Day)	Position	Sys BP (mmHg)	Dias BP (mmHg)	Heart Rate (bpm)	Resp Rate (bpm)	Temp (C)
9069	41/F/BL	Day 1- 4 Hour Postdose	16OCT2019 12:09 (1) R	SITTING	153	82	71		
		Day 4- 4 Hour Postdose	19OCT2019 12:10 (4)	SITTING	140	65	70	18	36.2
		Day 7- Predose	22OCT2019 07:26 (7)	SITTING	131	85	75	16	36.8
		Day 7- 4 Hour Postdose	22OCT2019 12:03 (7)	SITTING	133	63	70	12	35.9
		Day 8	23OCT2019 07:51 (8)	SITTING	138	64	71	14	36.8
		Day 9	24OCT2019 08:01 (9)	SITTING	138	65	83	12	36.6
9073	40/M/BL	Screening	04OCT2019 13:51 (-12)	SITTING	129	77	80	16	36.6
		Check-in	15OCT2019 09:14 (-1)	SITTING	125	68	78	18	36.4

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date – First dose date + 1
Sys=Systolic, Dias=Diastolic, BP=Blood Pressure, bpm=beats per minute, Resp=Respiration, Temp=Temperature
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.6
Vital Sign Results
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Time Point	Date Time (Day)	Position	Sys BP (mmHg)	Dias BP (mmHg)	Heart Rate (bpm)	Resp Rate (bpm)	Temp (C)
9073	40/M/BL	Day 1- Predose	16OCT2019 07:29 (1)	SITTING	142	67	79	12	35.9
		Day 1- Predose	16OCT2019 07:36 (1) R	SITTING	130	68	73		
		Day 1- 4 Hour Postdose	16OCT2019 12:11 (1)	SITTING	124	67	78	14	36.2
		Day 4- 4 Hour Postdose	19OCT2019 12:11 (4)	SITTING	133	76	70	8	36.3
		Day 7- Predose	22OCT2019 07:36 (7)	SITTING	130	73	79	16	35.8
		Day 7- 4 Hour Postdose	22OCT2019 12:11 (7)	SITTING	117	73	67	16	36.3
		Day 8	23OCT2019 08:01 (8)	SITTING	123	71	81	14	36.3
		Day 9	24OCT2019 08:11 (9)	SITTING	122	58	77	16	36.7

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date – First dose date + 1
Sys=Systolic, Dias=Diastolic, BP=Blood Pressure, bpm=beats per minute, Resp=Respiration, Temp=Temperature
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.6
Vital Sign Results
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Time Point	Date Time (Day)	Position	Sys BP (mmHg)	Dias BP (mmHg)	Heart Rate (bpm)	Resp Rate (bpm)	Temp (C)
9077	37/F/W	Screening	05OCT2019 13:01 (-11)	SITTING	129	77	71	12	36.4
		Check-in	15OCT2019 08:52 (-1)	SITTING	150	91	78		35.9
		Check-in	15OCT2019 08:58 (-1) R	SITTING	136	80	77	12	36.1
		Day 1- Predose	16OCT2019 07:32 (1)	SITTING	123	76	78	14	36.3
		Day 1- 4 Hour Postdose	16OCT2019 12:07 (1)	SITTING	131	81	73	12	36
		Day 4- 4 Hour Postdose	19OCT2019 12:07 (4)	SITTING	131	78	72	14	35.9
		Day 7- Predose	22OCT2019 07:32 (7)	SITTING	120	77	77	14	36.6
		Day 7- 4 Hour Postdose	22OCT2019 12:28 (7)	SITTING	137	80	70	18	36.2

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date – First dose date + 1
Sys=Systolic, Dias=Diastolic, BP=Blood Pressure, bpm=beats per minute, Resp=Respiration, Temp=Temperature
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.6
Vital Sign Results
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Time Point	Date Time (Day)	Position	Sys BP (mmHg)	Dias BP (mmHg)	Heart Rate (bpm)	Resp Rate (bpm)	Temp (C)
9077	37/F/W	Day 8	23OCT2019 07:57 (8)	SITTING	131	83	82	16	35.7
		Day 9	24OCT2019 08:07 (9)	SITTING	116	77	80	14	36.4
9080	41/F/BL	Screening	08OCT2019 11:38 (-8)	SITTING	122	62	68	14	35.7
		Check-in	15OCT2019 09:06 (-1)	SITTING	119	63	68	14	36.2
		Day 1- Predose	16OCT2019 07:41 (1)	SITTING	100	57	64	16	36.2
		Day 1- 4 Hour Postdose	16OCT2019 12:18 (1)	SITTING	120	68	69	14	36.3
		Day 4- 4 Hour Postdose	19OCT2019 12:23 (4)	SITTING	127	60	77	16	36.6
		Day 7- Predose	22OCT2019 07:41 (7)	SITTING	128	61	81	16	36

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date – First dose date + 1
Sys=Systolic, Dias=Diastolic, BP=Blood Pressure, bpm=beats per minute, Resp=Respiration, Temp=Temperature
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.6
Vital Sign Results
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Time Point	Date Time (Day)	Position	Sys BP (mmHg)	Dias BP (mmHg)	Heart Rate (bpm)	Resp Rate (bpm)	Temp (C)
9080	41/F/BL	Day 7- 4 Hour Postdose	22OCT2019 12:16 (7)	SITTING	121	67	75	14	36.6
		Day 8	23OCT2019 08:06 (8)	SITTING	129	76	84	16	35.9
		Day 9	24OCT2019 08:16 (9)	SITTING	131	64	85	12	36.7
9081	49/M/BL	Screening	10OCT2019 12:17 (-20)	SITTING	111	61	81	18	36.8
		Check-in	29OCT2019 09:41 (-1)	SITTING	135	76	80	12	36.4
		Day 1- Predose	30OCT2019 07:22 (1)	SITTING	137	72	90	16	36.2
		Day 1- 4 Hour Postdose	30OCT2019 11:55 (1)	SITTING	133	83	83	16	36.5
		Day 4- 4 Hour Postdose	02NOV2019 11:55 (4)	SITTING	137	78	79	14	35.8

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date – First dose date + 1
Sys=Systolic, Dias=Diastolic, BP=Blood Pressure, bpm=beats per minute, Resp=Respiration, Temp=Temperature
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.6
Vital Sign Results
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Time Point	Date Time (Day)	Position	Sys BP (mmHg)	Dias BP (mmHg)	Heart Rate (bpm)	Resp Rate (bpm)	Temp (C)
9081	49/M/BL	Day 7- Predose	05NOV2019 06:20 (7)	SITTING	132	71	79	16	36.3
		Day 7- 4 Hour Postdose	05NOV2019 10:55 (7)	SITTING	134	71	73	14	35.7
		Day 8	06NOV2019 06:45 (8)	SITTING	128	73	81	12	36.4
		Day 9	07NOV2019 06:55 (9)	SITTING	138	69	79	18	36.2
9086	36/M/BL	Screening	11OCT2019 09:13 (-5)	SITTING	120	73	77	14	36.3
		Check-in	15OCT2019 09:25 (-1)	SITTING	123	73	75	14	36.4
		Day 1- Predose	16OCT2019 07:35 (1)	SITTING	121	77	75	10	36.1
		Day 1- 4 Hour Postdose	16OCT2019 12:10 (1)	SITTING	116	66	66	12	35.9

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date – First dose date + 1
Sys=Systolic, Dias=Diastolic, BP=Blood Pressure, bpm=beats per minute, Resp=Respiration, Temp=Temperature
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.6
Vital Sign Results
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Time Point	Date Time (Day)	Position	Sys BP (mmHg)	Dias BP (mmHg)	Heart Rate (bpm)	Resp Rate (bpm)	Temp (C)
9086	36/M/BL	Day 4- 4 Hour Postdose	19OCT2019 12:10 (4)	SITTING	121	78	72	14	36.2
		Day 7- Predose	22OCT2019 07:35 (7)	SITTING	126	79	75	14	36
		Day 7- 4 Hour Postdose	22OCT2019 12:10 (7)	SITTING	123	85	68	14	35.7
		Day 8	23OCT2019 08:00 (8)	SITTING	124	79	81	14	35.8
		Day 9	24OCT2019 08:10 (9)	SITTING	120	74	79	12	35.9
9087	34/F/BL	Screening	11OCT2019 09:31 (-5)	SITTING	149	76	87	20	36.8
		Screening	11OCT2019 09:39 (-5) R	SITTING	143	76	88		
		Check-in	15OCT2019 08:51 (-1)	SITTING	150	88	91	14	37.2

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date – First dose date + 1
Sys=Systolic, Dias=Diastolic, BP=Blood Pressure, bpm=beats per minute, Resp=Respiration, Temp=Temperature
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.6
Vital Sign Results
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Time Point	Date Time (Day)	Position	Sys BP (mmHg)	Dias BP (mmHg)	Heart Rate (bpm)	Resp Rate (bpm)	Temp (C)
9087	34/F/BL	Check-in	15OCT2019 08:57 (-1) R	SITTING	138	72	91		
		Day 1- Predose	16OCT2019 07:38 (1)	SITTING	132	62	81	12	36.7
		Day 1- 4 Hour Postdose	16OCT2019 12:13 (1)	SITTING	145	81	76	14	36.6
		Day 4- 4 Hour Postdose	19OCT2019 12:15 (4)	SITTING	136	69	78	14	36.6
		Day 7- Predose	22OCT2019 07:38 (7)	SITTING	129	62	78	16	36.5
		Day 7- 4 Hour Postdose	22OCT2019 12:13 (7)	SITTING	139	65	75	14	36.5
		Day 8	23OCT2019 08:03 (8)	SITTING	130	71	80	12	36.7
		Day 9	24OCT2019 08:13 (9)	SITTING	116	58	80	16	36.7

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date – First dose date + 1
Sys=Systolic, Dias=Diastolic, BP=Blood Pressure, bpm=beats per minute, Resp=Respiration, Temp=Temperature
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.6
Vital Sign Results
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Time Point	Date Time (Day)	Position	Sys BP (mmHg)	Dias BP (mmHg)	Heart Rate (bpm)	Resp Rate (bpm)	Temp (C)
9089	29/M/BL	Screening	14OCT2019 09:20 (-2)	SITTING	116	65	73	12	36.3
		Check-in	15OCT2019 08:49 (-1)	SITTING	110	62	75	14	36.4
		Day 1- Predose	16OCT2019 07:45 (1)	SITTING	112	73	71	12	36.1
		Day 1- 4 Hour Postdose	16OCT2019 12:19 (1)	SITTING	104	56	75	14	36.3
		Day 4- 4 Hour Postdose	19OCT2019 12:19 (4)	SITTING	108	65	70	14	36.1
		Day 7- Predose	22OCT2019 07:44 (7)	SITTING	106	54	64	16	36.4
		Day 7- 4 Hour Postdose	22OCT2019 12:19 (7)	SITTING	106	57	65	14	36.6
		Day 8	23OCT2019 08:09 (8)	SITTING	103	68	74	12	36.6

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date – First dose date + 1
Sys=Systolic, Dias=Diastolic, BP=Blood Pressure, bpm=beats per minute, Resp=Respiration, Temp=Temperature
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.6
Vital Sign Results
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Time Point	Date Time (Day)	Position	Sys BP (mmHg)	Dias BP (mmHg)	Heart Rate (bpm)	Resp Rate (bpm)	Temp (C)
9089	29/M/BL	Day 9	24OCT2019 08:19 (9)	SITTING	106	60	71	14	36.3
9092	24/M/W	Screening	14OCT2019 09:24 (-2)	SITTING	121	58	74	16	36.3
		Check-in	15OCT2019 09:11 (-1)	SITTING	134	63	61	16	36.7
		Day 1- Predose	16OCT2019 07:47 (1)	SITTING	131	66	70	14	36.9
		Day 1- 4 Hour Postdose	16OCT2019 12:22 (1)	SITTING	127	65	55	16	36.6
		Day 4- 4 Hour Postdose	19OCT2019 12:22 (4)	SITTING	128	67	50	18	36.9
		Day 7- Predose	22OCT2019 07:47 (7)	SITTING	132	64	70	18	37
		Day 7- 4 Hour Postdose	22OCT2019 12:22 (7)	SITTING	133	63	57	12	36.4

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date – First dose date + 1
Sys=Systolic, Dias=Diastolic, BP=Blood Pressure, bpm=beats per minute, Resp=Respiration, Temp=Temperature
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.6
Vital Sign Results
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Time Point	Date Time (Day)	Position	Sys BP (mmHg)	Dias BP (mmHg)	Heart Rate (bpm)	Resp Rate (bpm)	Temp (C)
9092	24/M/W	Day 8	23OCT2019 08:12 (8)	SITTING	136	72	57	14	36.7
		Day 9	24OCT2019 08:22 (9)	SITTING	133	66	64	12	36.9
9095	42/M/W	Screening	17OCT2019 13:14 (-13)	SITTING	136	82	76	14	36.2
		Check-in	29OCT2019 08:49 (-1)	SITTING	120	76	82	14	36.4
		Day 1- Predose	30OCT2019 07:26 (1)	SITTING	115	72	83	12	36.8
		Day 1- 4 Hour Postdose	30OCT2019 12:01 (1)	SITTING	129	70	79	14	36.5
		Day 4- 4 Hour Postdose	02NOV2019 12:01 (4)	SITTING	125	76	84	16	36.7
		Day 7- Predose	05NOV2019 06:26 (7)	SITTING	123	61	83	14	36.4

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date – First dose date + 1
Sys=Systolic, Dias=Diastolic, BP=Blood Pressure, bpm=beats per minute, Resp=Respiration, Temp=Temperature
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.6
Vital Sign Results
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Time Point	Date Time (Day)	Position	Sys BP (mmHg)	Dias BP (mmHg)	Heart Rate (bpm)	Resp Rate (bpm)	Temp (C)
9095	42/M/W	Day 7- 4 Hour Postdose	05NOV2019 11:01 (7)	SITTING	117	74	79	12	36.7
		Day 8	06NOV2019 06:51 (8)	SITTING	106	66	86	14	36.7
		Day 9	07NOV2019 07:01 (9)	SITTING	117	65	89	14	36.6

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date – First dose date + 1
Sys=Systolic, Dias=Diastolic, BP=Blood Pressure, bpm=beats per minute, Resp=Respiration, Temp=Temperature
R=Repeat
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.7
Electrocardiogram Results
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ ECG Date Time (Day)	Heart Rate (bpm)	PR Int (msec)	QRS Dur (msec)	QTcB Int (msec)	QTcF Int (msec)	RR Int (msec)	Interpretation/ Clinically Significant	Abnormal Finding
9001	41/M/BL	Screening/ 19JUL2019 11:47 (-26)	63	140	88	412	408	940	N	
		Check-In/ 13AUG2019 09:26 (-1)	60	150	93	397	396	986	N	
		Day 1 - 4 Hour Postdose/ 14AUG2019 13:10 (1)	56	156	93	396	400	1071	N	
		Day 4 - 4 Hour Postdose/ 17AUG2019 13:11 (4)	61	147	90	401	399	980	N	
		Day 7 - 4 Hour Postdose/ 20AUG2019 13:10 (7)	69	166	86	418	408	869	N	
		Day 9/ 22AUG2019 09:10 (9)	63	158	92	402	399	951	N	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date – First dose date + 1
bpm=beats per minute, msec=milliseconds, Int=Interval
R=Repeat; N=Normal, AB=Abnormal; CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.7
Electrocardiogram Results
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ ECG Date Time (Day)	Heart Rate (bpm)	PR Int (msec)	QRS Dur (msec)	QTcB Int (msec)	QTcF Int (msec)	RR Int (msec)	Interpretation/ Clinically Significant	Abnormal Finding
9002	48/M/W	Screening/ 19JUL2019 11:38 (-26)	80	155	101	407	388	746	N	
		Check-In/ 13AUG2019 09:48 (-1)	93	163	97	413	384	645	N	
		Day 1 - 4 Hour Postdose/ 14AUG2019 13:12 (1)	76	178	104	424	407	786	N	
		Day 4 - 4 Hour Postdose/ 17AUG2019 13:10 (4)	77	172	94	411	394	774	N	
		Day 7 - 4 Hour Postdose/ 20AUG2019 13:13 (7)	75	173	92	406	392	800	N	
		Day 9/ 22AUG2019 09:09 (9)	72	181	101	410	397	822	N	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date – First dose date + 1
bpm=beats per minute, msec=milliseconds, Int=Interval
R=Repeat; N=Normal, AB=Abnormal; CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.7
Electrocardiogram Results
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ ECG Date Time (Day)	Heart Rate (bpm)	PR Int (msec)	QRS Dur (msec)	QTcB Int (msec)	QTcF Int (msec)	RR Int (msec)	Interpretation/ Clinically Significant	Abnormal Finding
9005	40/M/W	Screening/ 23JUL2019 09:58 (-22)	58	135	90	417	419	1020	N	
		Check-In/ 13AUG2019 09:21 (-1)	58	130	88	412	414	1021	N	
		Day 1 - 4 Hour Postdose/ 14AUG2019 12:47 (1)	55	134	84	409	415	1087	N	
		Day 4 - 4 Hour Postdose/ 17AUG2019 12:47 (4)	56	137	90	416	421	1064	N	
		Day 7 - 4 Hour Postdose/ 20AUG2019 12:47 (7)	52	140	97	408	417	1151	N	
		Day 9/ 22AUG2019 08:47 (9)	56	143	87	395	399	1058	N	

Sex: M=Male, F=Female;
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Day = The presented date — First dose date + 1
bpm=beats per minute, msec=milliseconds, Int=Interval
R=Repeat; N=Normal, AB=Abnormal; CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.7
Electrocardiogram Results
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ ECG Date Time (Day)	Heart Rate (bpm)	PR Int (msec)	QRS Dur (msec)	QTcB Int (msec)	QTcF Int (msec)	RR Int (msec)	Interpretation/ Clinically Significant	Abnormal Finding
9009	21/F/BL	Screening/ 31JUL2019 09:48 (-14)	84	160	94	416	394	713	N	
		Check-In/ 13AUG2019 09:17 (-1)	91	147	94	433	404	659	N	
		Day 1 - 4 Hour Postdose/ 14AUG2019 12:51 (1)	64	153	93	406	402	933	N	
		Day 4 - 4 Hour Postdose/ 17AUG2019 12:51 (4)	84	161	94	424	400	708	N	
		Day 7 - 4 Hour Postdose/ 20AUG2019 12:56 (7)	83	146	94	407	385	717	N	
		Day 9/ 22AUG2019 08:51 (9)	92	156	98	428	398	647	N	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
bpm=beats per minute, msec=milliseconds, Int=Interval
R=Repeat; N=Normal, AB=Abnormal; CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.7
Electrocardiogram Results
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ ECG Date Time (Day)	Heart Rate (bpm)	PR Int (msec)	QRS Dur (msec)	QTcB Int (msec)	QTcF Int (msec)	RR Int (msec)	Interpretation/ Clinically Significant	Abnormal Finding
9012	34/M/BL	Screening/ 06AUG2019 09:57 (-8)	73	203	84	421	407	817	AB, NCS	FIRST DEGREE AV BLOCK
		Check-In/ 13AUG2019 09:41 (-1)	80	205	87	438	417	742	AB, NCS	FIRST DEGREE AV BLOCK
		Day 1 - 4 Hour Postdose/ 14AUG2019 12:55 (1)	74	195	88	443	428	808	N	
		Day 4 - 4 Hour Postdose/ 17AUG2019 12:55 (4)	69	195	91	411	401	865	N	
		Day 7 - 4 Hour Postdose/ 20AUG2019 12:59 (7)	73	199	97	420	406	818	N	
		Day 9/ 22AUG2019 08:55 (9)	63	191	89	420	417	950	N	

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Day = The presented date – First dose date + 1
bpm=beats per minute, msec=milliseconds, Int=Interval
R=Repeat; N=Normal, AB=Abnormal; CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.7
Electrocardiogram Results
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ ECG Date Time (Day)	Heart Rate (bpm)	PR Int (msec)	QRS Dur (msec)	QTcB Int (msec)	QTcF Int (msec)	RR Int (msec)	Interpretation/ Clinically Significant	Abnormal Finding
9015	29/M/BL	Screening/ 12AUG2019 10:46 (-2)	47	216	109	386	402	1258	AB, NCS	SINUS BRADYCARDIA, FIRST DEGREE AV BLOCK
		Check-In/ 13AUG2019 09:07 (-1)	47	219	111	380	395	1272	AB, NCS	SINUS BRADYCARDIA, FIRST DEGREE AV BLOCK
		Day 1 - 4 Hour Postdose/ 14AUG2019 12:53 (1)	48	211	108	365	379	1237	AB, NCS	SINUS BRADYCARDIA, FIRST DEGREE AV BLOCK
		Day 4 - 4 Hour Postdose/ 17AUG2019 12:53 (4)	50	220	105	363	374	1185	AB, NCS	FIRST DEGREE AV BLOCK, NONSPECIFIC T WAVE ABNORMALITY
		Day 7 - 4 Hour Postdose/ 20AUG2019 12:53 (7)	50	215	109	366	377	1198	AB, NCS	FIRST DEGREE AV BLOCK, NONSPECIFIC T WAVE ABNORMALITY
		Day 9/ 22AUG2019 08:53 (9)	48	163	106	366	379	1230	AB, NCS	SINUS BRADYCARDIA, NONSPECIFIC T WAVE ABNORMALITY

Sex: M=Male, F=Female;
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Day = The presented date — First dose date + 1
bpm=beats per minute, msec=milliseconds, Int=Interval
R=Repeat; N=Normal, AB=Abnormal; CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.7
Electrocardiogram Results
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ ECG Date Time (Day)	Heart Rate (bpm)	PR Int (msec)	QRS Dur (msec)	QTcB Int (msec)	QTcF Int (msec)	RR Int (msec)	Interpretation/ Clinically Significant	Abnormal Finding
9016	48/F/W	Screening/ 12AUG2019 10:56 (-23)	87	155	101	457	429	684	N	
		Check-In/ 03SEP2019 08:46 (-1)	89	161	94	455	425	667	N	
		Day 1 - 4 Hour Postdose/ 04SEP2019 11:45 (1)	78	170	96	442	423	764	N	
		Day 4 - 4 Hour Postdose/ 07SEP2019 11:45 (4)	80	173	96	453	432	750	N	
		Day 7 - 4 Hour Postdose/ 10SEP2019 11:45 (7)	71	174	96	438	426	844	N	
		Day 9/ 12SEP2019 07:45 (9)	85	165	99	454	429	705	N	

Sex: M=Male, F=Female;
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Day = The presented date – First dose date + 1
bpm=beats per minute, msec=milliseconds, Int=Interval
R=Repeat; N=Normal, AB=Abnormal; CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.7
Electrocardiogram Results
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ ECG Date Time (Day)	Heart Rate (bpm)	PR Int (msec)	QRS Dur (msec)	QTcB Int (msec)	QTcF Int (msec)	RR Int (msec)	Interpretation/ Clinically Significant	Abnormal Finding
9019	41/M/BL	Screening/ 15AUG2019 16:49 (-20)	76	178	76	422	405	789	N	
		Check-In/ 03SEP2019 11:26 (-1)	82	166	89	411	390	729	N	
		Day 1 - 4 Hour Postdose/ 04SEP2019 11:48 (1)	70	185	74	408	397	851	N	
		Day 4 - 4 Hour Postdose/ 07SEP2019 11:54 (4)	63	176	84	407	403	945	N	
		Day 7 - 4 Hour Postdose/ 10SEP2019 11:48 (7)	64	179	80	397	392	929	N	
		Day 9/ 12SEP2019 07:48 (9)	71	178	73	400	389	838	N	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date – First dose date + 1
bpm=beats per minute, msec=milliseconds, Int=Interval
R=Repeat; N=Normal, AB=Abnormal; CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.7
Electrocardiogram Results
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ ECG Date Time (Day)	Heart Rate (bpm)	PR Int (msec)	QRS Dur (msec)	QTcB Int (msec)	QTcF Int (msec)	RR Int (msec)	Interpretation/ Clinically Significant	Abnormal Finding
9020	47/F/BL	Screening/ 21AUG2019 10:23 (-14)	58	171	86	435	438	1034	N	
		Check-In/ 03SEP2019 08:40 (-1)	53	177	82	417	425	1116	N	
		Day 1 - 4 Hour Postdose/ 04SEP2019 11:51 (1)	49	170	81	416	429	1217	AB, NCS	SINUS BRADYCARDIA
		Day 4 - 4 Hour Postdose/ 07SEP2019 11:51 (4)	56	172	81	419	423	1054	N	
		Day 7 - 4 Hour Postdose/ 10SEP2019 11:51 (7)	54	168	83	426	433	1091	N	
		Day 9/ 12SEP2019 07:54 (9)	54	186	77	417	424	1098	N	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
bpm=beats per minute, msec=milliseconds, Int=Interval
R=Repeat; N=Normal, AB=Abnormal; CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.7
Electrocardiogram Results
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ ECG Date Time (Day)	Heart Rate (bpm)	PR Int (msec)	QRS Dur (msec)	QTcB Int (msec)	QTcF Int (msec)	RR Int (msec)	Interpretation/ Clinically Significant	Abnormal Finding
9021	39/F/BL	Screening/ 21AUG2019 10:37 (-14)	85	141	82	466	439	699	AB, NCS	NONSPECIFIC T WAVE ABNORMALITIES
		Check-In/ 03SEP2019 08:42 (-1)	76	151	84	464	446	786	AB, NCS	NONSPECIFIC T WAVE ABNORMALITY
		Day 1 - 4 Hour Postdose/ 04SEP2019 11:56 (1)	60	143	86	463	462	984	AB, NCS	NONSPECIFIC T WAVE ABNORMALITY
		Day 4 - 4 Hour Postdose/ 07SEP2019 11:54 (4)	64	158	83	449	444	932	AB, NCS	NONSPECIFIC T WAVE ABNORMALITY
		Day 7 - 4 Hour Postdose/ 10SEP2019 11:54 (7)	57	152	90	435	438	1049	AB, NCS	NONSPECIFIC T WAVE ABNORMALITY
		Day 9/ 12SEP2019 07:55 (9)	74	160	85	444	429	810	N	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
bpm=beats per minute, msec=milliseconds, Int=Interval
R=Repeat; N=Normal, AB=Abnormal; CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.7
Electrocardiogram Results
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ ECG Date Time (Day)	Heart Rate (bpm)	PR Int (msec)	QRS Dur (msec)	QTcB Int (msec)	QTcF Int (msec)	RR Int (msec)	Interpretation/ Clinically Significant	Abnormal Finding
9022	31/M/W	Screening/ 21AUG2019 10:43 (-14)	76	171	94	417	401	785	N	
		Check-In/ 03SEP2019 09:33 (-1)	78	169	93	441	421	760	N	
		Day 1 - 4 Hour Postdose/ 04SEP2019 11:57 (1)	74	176	92	446	430	803	N	
		Day 4 - 4 Hour Postdose/ 07SEP2019 12:03 (4)	71	175	86	416	404	837	N	
		Day 7 - 4 Hour Postdose/ 10SEP2019 11:57 (7)	67	179	90	434	426	893	N	
		Day 9/ 12SEP2019 07:57 (9)	77	171	106	426	408	779	N	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date – First dose date + 1
bpm=beats per minute, msec=milliseconds, Int=Interval
R=Repeat; N=Normal, AB=Abnormal; CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.7
Electrocardiogram Results
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ ECG Date Time (Day)	Heart Rate (bpm)	PR Int (msec)	QRS Dur (msec)	QTcB Int (msec)	QTcF Int (msec)	RR Int (msec)	Interpretation/ Clinically Significant	Abnormal Finding
9024	20/M/BL	Screening/ 23AUG2019 10:33 (-12)	66	156	88	367	360	896	AB, NCS	EARLY REPOLARIZATION
		Check-In/ 03SEP2019 09:02 (-1)	58	158	91	388	390	1033	AB, NCS	EARLY REPOLARIZATION
		Day 1 - 4 Hour Postdose/ 04SEP2019 12:00 (1)	58	144	93	388	390	1030	AB, NCS	EARLY REPOLARIZATION
		Day 4 - 4 Hour Postdose/ 07SEP2019 12:03 (4)	68	158	90	385	377	882	AB, NCS	EARLY REPOLARIZATION
		Day 7 - 4 Hour Postdose/ 10SEP2019 12:00 (7)	60	163	94	380	379	989	AB, NCS	EARLY REPOLARIZATION
		Day 9/ 12SEP2019 08:00 (9)	70	159	89	383	373	854	AB, NCS	EARLY REPOLARIZATION

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date – First dose date + 1
bpm=beats per minute, msec=milliseconds, Int=Interval
R=Repeat; N=Normal, AB=Abnormal; CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.7
Electrocardiogram Results
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ ECG Date Time (Day)	Heart Rate (bpm)	PR Int (msec)	QRS Dur (msec)	QTcB Int (msec)	QTcF Int (msec)	RR Int (msec)	Interpretation/ Clinically Significant	Abnormal Finding
9025	50/M/W	Screening/ 23AUG2019 10:48 (-26)	60	157	93	397	396	989	N	
		Check-In/ 17SEP2019 08:53 (-1)	67	146	94	405	397	886	N	
		Day 1 - 4 Hour Postdose/ 18SEP2019 11:46 (1)	62	150	102	421	418	960	AB, NCS	SINGLE PVC
		Unscheduled - 3.01/ 18SEP2019 11:47 (1)	59	145	98	410	411	1010	N	
		Day 4 - 4 Hour Postdose/ 21SEP2019 11:46 (4)	62	148	98	411	408	961	N	
		Day 7 - 4 Hour Postdose/ 24SEP2019 11:46 (7)	64	142	101	420	415	934	N	
		Day 9/ 26SEP2019 07:45 (9)	77	143	97	417	399	773	N	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
bpm=beats per minute, msec=milliseconds, Int=Interval
R=Repeat; N=Normal, AB=Abnormal; CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.7
Electrocardiogram Results
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ ECG Date Time (Day)	Heart Rate (bpm)	PR Int (msec)	QRS Dur (msec)	QTcB Int (msec)	QTcF Int (msec)	RR Int (msec)	Interpretation/ Clinically Significant	Abnormal Finding
9033	32/M/W	Screening/ 29AUG2019 09:43 (-6)	71	159	103	427	414	837	N	
		Check-In/ 03SEP2019 08:55 (-1)	70	150	107	419	408	857	N	
		Day 1 - 4 Hour Postdose/ 04SEP2019 12:03 (1)	57	155	107	428	431	1046	N	
		Day 4 - 4 Hour Postdose/ 07SEP2019 12:06 (4)	65	141	102	416	410	911	N	
		Day 7 - 4 Hour Postdose/ 10SEP2019 12:03 (7)	62	146	108	427	424	955	N	
		Day 9/ 12SEP2019 08:03 (9)	67	172	108	426	417	890	N	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date – First dose date + 1
bpm=beats per minute, msec=milliseconds, Int=Interval
R=Repeat; N=Normal, AB=Abnormal; CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.7
Electrocardiogram Results
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ ECG Date Time (Day)	Heart Rate (bpm)	PR Int (msec)	QRS Dur (msec)	QTcB Int (msec)	QTcF Int (msec)	RR Int (msec)	Interpretation/ Clinically Significant	Abnormal Finding
9043	22/M/BL	Screening/ 11SEP2019 09:04 (-7)	55	142	105	399	405	1088	N	
		Check-In/ 17SEP2019 08:50 (-1)	61	150	107	408	406	974	N	
		Day 1 - 4 Hour Postdose/ 18SEP2019 11:48 (1)	50	145	108	402	414	1182	N	
		Day 4 - 4 Hour Postdose/ 21SEP2019 11:48 (4)	60	149	106	403	402	985	N	
		Day 7 - 4 Hour Postdose/ 24SEP2019 11:48 (7)	64	152	106	424	419	934	N	
		Day 9/ 26SEP2019 07:48 (9)	66	150	106	402	395	901	N	

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Day = The presented date – First dose date + 1
bpm=beats per minute, msec=milliseconds, Int=Interval
R=Repeat; N=Normal, AB=Abnormal; CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.7
Electrocardiogram Results
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ ECG Date Time (Day)	Heart Rate (bpm)	PR Int (msec)	QRS Dur (msec)	QTcB Int (msec)	QTcF Int (msec)	RR Int (msec)	Interpretation/ Clinically Significant	Abnormal Finding
9046	34/M/BL	Screening/ 13SEP2019 10:31 (-5)	68	211	113	396	388	880	AB, NCS	FIRST DEGREE AV BLOCK, NCS NONSPECIFIC INTRAVENTRICULAR CONDUCTION DELAY, NCS
		Check-In/ 17SEP2019 08:53 (-1)	55	209	110	367	372	1074	AB, NCS	FIRST DEGREE AV BLOCK
		Day 1 - 4 Hour Postdose/ 18SEP2019 11:51 (1)	48	198	109	364	378	1239	AB, NCS	SINUS BRADYCARDIA,NCS
		Day 4 - 4 Hour Postdose/ 21SEP2019 11:51 (4)	52	207	110	363	371	1134	AB, NCS	FIRST DEGREE AV BLOCK, NCS
		Day 7 - 4 Hour Postdose/ 24SEP2019 11:53 (7)	51	201	109	365	375	1159	AB, NCS	FIRST DEGREE AV BLOCK
		Day 9/ 26SEP2019 07:54 (9)	58	204	105	375	377	1024	AB, NCS	FIRST DEGREE AV BLOCK

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Day = The presented date — First dose date + 1
bpm=beats per minute, msec=milliseconds, Int=Interval
R=Repeat; N=Normal, AB=Abnormal; CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.7
Electrocardiogram Results
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ ECG Date Time (Day)	Heart Rate (bpm)	PR Int (msec)	QRS Dur (msec)	QTcB Int (msec)	QTcF Int (msec)	RR Int (msec)	Interpretation/ Clinically Significant	Abnormal Finding
9051	34/M/BL	Screening/ 19SEP2019 08:56 (-13)	61	160	88	413	411	979	AB, NCS	NONSPECIFIC T WAVE ABNORMALITY
		Check-In/ 01OCT2019 08:50 (-1)	65	169	92	414	409	921	AB, NCS	SINUS ARRHYTHMIA, WNL NONSPECIFIC T WAVE ABNORMALITY
		Day 1 - 4 Hour Postdose/ 02OCT2019 12:00 (1)	65	170	90	427	421	920	AB, NCS	NONSPECIFIC T WAVE ABNORMALITY. SINGLE PAC.
		Day 4 - 4 Hour Postdose/ 05OCT2019 12:00 (4)	61	171	90	400	398	971	AB, NCS	NONSPECIFIC T WAVE ABNORMALITY
		Day 7 - 4 Hour Postdose/ 08OCT2019 12:03 (7)	60	170	89	393	393	1000	AB, NCS	NONSPECIFIC T WAVE ABNORMALITY
		Day 9/ 10OCT2019 08:00 (9)	72	167	90	405	393	827	AB, NCS	INFEROLATERAL T WAVE ABNORMALITIES

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Day = The presented date — First dose date + 1
bpm=beats per minute, msec=milliseconds, Int=Interval
R=Repeat; N=Normal, AB=Abnormal; CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.7
Electrocardiogram Results
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ ECG Date Time (Day)	Heart Rate (bpm)	PR Int (msec)	QRS Dur (msec)	QTcB Int (msec)	QTcF Int (msec)	RR Int (msec)	Interpretation/ Clinically Significant	Abnormal Finding
9051	34/M/BL	Day 9/ 10OCT2019 09:35 (9) R	72	170	91	403	391	833	AB, NCS	NONSPECIFIC TWAVE ABNORMALITIES.
9052	42/M/BL	Screening/ 21SEP2019 12:52 (-11)	60	199	96	389	389	996	N	
		Check-In/ 01OCT2019 08:50 (-1)	87	168	91	422	397	689	AB, NCS	ARTIFACT NOTED, NO NEED FOR REPEAT NONSPECIFIC T WAVE ABNORMALITY
		Day 1 - 4 Hour Postdose/ 02OCT2019 12:04 (1)	61	194	93	391	390	976	N	
		Day 4 - 4 Hour Postdose/ 05OCT2019 12:07 (4)	64	192	90	385	380	933	N	

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Day = The presented date — First dose date + 1
bpm=beats per minute, msec=milliseconds, Int=Interval
R=Repeat; N=Normal, AB=Abnormal; CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.7
Electrocardiogram Results
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ ECG Date Time (Day)	Heart Rate (bpm)	PR Int (msec)	QRS Dur (msec)	QTcB Int (msec)	QTcF Int (msec)	RR Int (msec)	Interpretation/ Clinically Significant	Abnormal Finding
9052	42/M/BL	Day 7 - 4 Hour Postdose/ 08OCT2019 12:04 (7)	66	194	96	386	380	900	N	
		Day 9/ 10OCT2019 08:04 (9)	68	202	97	398	390	880	AB, NCS	FIRST DEGREE AV BLOCK
9056	31/F/BL	Screening/ 24SEP2019 09:47 (-8)	76	166	85	407	390	781	N	
		Check-In/ 01OCT2019 09:15 (-1)	84	161	75	401	379	712	N	
		Day 1 - 4 Hour Postdose/ 02OCT2019 11:45 (1)	72	157	88	393	381	829	N	
		Day 4 - 4 Hour Postdose/ 05OCT2019 11:45 (4)	77	159	86	390	374	771	N	

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Day = The presented date — First dose date + 1
bpm=beats per minute, msec=milliseconds, Int=Interval
R=Repeat; N=Normal, AB=Abnormal; CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.7
Electrocardiogram Results
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ ECG Date Time (Day)	Heart Rate (bpm)	PR Int (msec)	QRS Dur (msec)	QTcB Int (msec)	QTcF Int (msec)	RR Int (msec)	Interpretation/ Clinically Significant	Abnormal Finding
9056	31/F/BL	Day 7 - 4 Hour Postdose/ 08OCT2019 11:45 (7)	86	156	77	404	381	697	N	
		Day 9/ 10OCT2019 07:45 (9)	90	159	78	404	378	665	N	
9057	29/F/W	Check-In/ 01OCT2019 09:03 (-1)	75	160	93	440	424	799	N	
		Screening/ 01OCT2019 16:21 (-1)	79	155	89	449	429	759	N	
		Day 1 - 4 Hour Postdose/ 02OCT2019 11:48 (1)	71	158	93	446	433	835	N	
		Day 4 - 4 Hour Postdose/ 05OCT2019 11:48 (4)	68	166	90	427	418	879	N	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
bpm=beats per minute, msec=milliseconds, Int=Interval
R=Repeat; N=Normal, AB=Abnormal; CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.7
Electrocardiogram Results
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ ECG Date Time (Day)	Heart Rate (bpm)	PR Int (msec)	QRS Dur (msec)	QTcB Int (msec)	QTcF Int (msec)	RR Int (msec)	Interpretation/ Clinically Significant	Abnormal Finding
9057	29/F/W	Day 7 - 4 Hour Postdose/ 08OCT2019 11:48 (7)	67	168	93	423	414	885	N	
		Day 9/ 10OCT2019 07:48 (9)	83	153	94	439	416	719	N	
9058	32/M/W	Screening/ 26SEP2019 09:17 (-20)	66	191	119	431	423	896	AB, NCS	INCOMPLETE RIGHT BUNDLE BRANCH BLOCK
		Check-In/ 15OCT2019 08:50 (-1)	61	189	124	424	422	972	AB, NCS	RIGHT BUNDLE BRANCH BLOCK
		Day 1 - 4 Hour Postdose/ 16OCT2019 11:52 (1)	63	187	114	430	426	947	AB, NCS	INCOMPLETE RIGHT BUNDLE BRANCH BLOCK
		Day 4 - 4 Hour Postdose/ 19OCT2019 11:52 (4)	64	186	112	419	414	927	AB, NCS	INCOMPLETE RIGHT BUNDLE BRANCH BLOCK

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
bpm=beats per minute, msec=milliseconds, Int=Interval
R=Repeat; N=Normal, AB=Abnormal; CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.7
Electrocardiogram Results
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ ECG Date Time (Day)	Heart Rate (bpm)	PR Int (msec)	QRS Dur (msec)	QTcB Int (msec)	QTcF Int (msec)	RR Int (msec)	Interpretation/ Clinically Significant	Abnormal Finding
9058	32/M/W	Day 7 - 4 Hour Postdose/ 22OCT2019 11:52 (7)	64	189	121	422	416	930	AB, NCS	RIGHT BUNDLE BRANCH BLOCK
		Day 9/ 24OCT2019 07:53 (9)	62	188	116	417	414	959	AB, NCS	INCOMPLETE RIGHT BUNDLE BRANCH BLOCK
9061	21/F/BL	Screening/ 26SEP2019 10:35 (-20)	73	199	83	415	401	814	N	
		Check-In/ 15OCT2019 08:47 (-1)	74	192	87	410	396	809	N	
		Day 1 - 4 Hour Postdose/ 16OCT2019 11:48 (1)	70	191	88	413	402	849	N	
		Day 4 - 4 Hour Postdose/ 19OCT2019 11:48 (4)	73	178	79	412	399	821	N	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
bpm=beats per minute, msec=milliseconds, Int=Interval
R=Repeat; N=Normal, AB=Abnormal; CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.7
Electrocardiogram Results
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ ECG Date Time (Day)	Heart Rate (bpm)	PR Int (msec)	QRS Dur (msec)	QTcB Int (msec)	QTcF Int (msec)	RR Int (msec)	Interpretation/ Clinically Significant	Abnormal Finding
9061	21/F/BL	Day 7 - 4 Hour Postdose/ 22OCT2019 11:48 (7)	76	188	85	419	403	789	N	
		Day 9/ 24OCT2019 07:49 (9)	71	188	85	401	389	842	N	
9062	33/M/BL	Screening/ 30SEP2019 09:53 (-2)	77	162	93	436	418	775	N	
		Check-In/ 01OCT2019 09:08 (-1)	70	161	92	418	407	849	N	
		Day 1 - 4 Hour Postdose/ 02OCT2019 11:51 (1)	68	160	88	432	422	874	N	
		Day 4 - 4 Hour Postdose/ 05OCT2019 11:51 (4)	69	161	95	424	414	869	N	

Sex: M=Male, F=Female;
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Day = The presented date — First dose date + 1
bpm=beats per minute, msec=milliseconds, Int=Interval
R=Repeat; N=Normal, AB=Abnormal; CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.7
Electrocardiogram Results
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ ECG Date Time (Day)	Heart Rate (bpm)	PR Int (msec)	QRS Dur (msec)	QTcB Int (msec)	QTcF Int (msec)	RR Int (msec)	Interpretation/ Clinically Significant	Abnormal Finding
9062	33/M/BL	Day 7 - 4 Hour Postdose/ 08OCT2019 11:58 (7)	72	157	93	430	417	832	N	
		Day 9/ 10OCT2019 07:51 (9)	70	167	89	411	401	856	N	
9063	35/M/W	Screening/ 30SEP2019 09:14 (-2)	78	178	98	408	390	763	N	
		Check-In/ 01OCT2019 08:38 (-1)	74	168	101	424	409	809	N	
		Day 1 - 4 Hour Postdose/ 02OCT2019 11:56 (1)	66	177	98	408	400	899	N	
		Day 4 - 4 Hour Postdose/ 05OCT2019 11:54 (4)	72	162	98	394	382	831	N	

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bpm=beats per minute, msec=milliseconds, Int=Interval
R=Repeat; N=Normal, AB=Abnormal; CS=Clinically Significant, NCS=Not clinically significant
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Listing 16.2.8.7
Electrocardiogram Results
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ ECG Date Time (Day)	Heart Rate (bpm)	PR Int (msec)	QRS Dur (msec)	QTcB Int (msec)	QTcF Int (msec)	RR Int (msec)	Interpretation/ Clinically Significant	Abnormal Finding
9063	35/M/W	Day 7 - 4 Hour Postdose/ 08OCT2019 11:59 (7)	66	181	98	404	397	896	N	
		Day 9/ 10OCT2019 07:54 (9)	75	184	98	404	390	799	N	
9069	41/F/BL	Screening/ 30SEP2019 10:36 (-16)	70	187	85	436	424	848	N	
		Check-In/ 15OCT2019 12:08 (-1)	73	194	92	437	422	711	N	
		Day 1 - 4 Hour Postdose/ 16OCT2019 11:51 (1)	70	174	89	425	414	855	N	
		Day 4 - 4 Hour Postdose/ 19OCT2019 11:59 (4)	69	194	87	407	397	860	N	

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Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.7
Electrocardiogram Results
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ ECG Date Time (Day)	Heart Rate (bpm)	PR Int (msec)	QRS Dur (msec)	QTcB Int (msec)	QTcF Int (msec)	RR Int (msec)	Interpretation/ Clinically Significant	Abnormal Finding
9069	41/F/BL	Day 7 - 4 Hour Postdose/ 22OCT2019 11:52 (7)	72	186	86	411	398	823	N	
		Day 9/ 24OCT2019 07:51 (9)	76	194	86	409	393	789	N	
9073	40/M/BL	Screening/ 04OCT2019 13:44 (-12)	72	158	106	427	414	828	N	
		Check-In/ 15OCT2019 09:06 (-1)	75	165	101	446	429	794	N	
		Day 1 - 4 Hour Postdose/ 16OCT2019 12:01 (1)	71	166	96	454	441	837	N	
		Day 4 - 4 Hour Postdose/ 19OCT2019 12:01 (4)	67	166	95	454	445	888	N	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
bpm=beats per minute, msec=milliseconds, Int=Interval
R=Repeat; N=Normal, AB=Abnormal; CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.7
Electrocardiogram Results
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ ECG Date Time (Day)	Heart Rate (bpm)	PR Int (msec)	QRS Dur (msec)	QTcB Int (msec)	QTcF Int (msec)	RR Int (msec)	Interpretation/ Clinically Significant	Abnormal Finding
9073	40/M/BL	Day 7 - 4 Hour Postdose/ 22OCT2019 12:02 (7)	69	166	93	436	426	868	N	
		Day 9/ 24OCT2019 08:01 (9)	68	177	96	438	429	877	N	
9077	37/F/W	Screening/ 05OCT2019 12:52 (-11)	67	142	94	432	424	884	N	
		Check-In/ 15OCT2019 09:16 (-1)	74	140	90	420	405	810	N	
		Day 1 - 4 Hour Postdose/ 16OCT2019 11:57 (1)	73	138	98	430	416	819	N	
		Day 4 - 4 Hour Postdose/ 19OCT2019 11:58 (4)	71	166	94	437	424	840	N	

Sex: M=Male, F=Female;
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Day = The presented date — First dose date + 1
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R=Repeat; N=Normal, AB=Abnormal; CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Electrocardiogram Results
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ ECG Date Time (Day)	Heart Rate (bpm)	PR Int (msec)	QRS Dur (msec)	QTcB Int (msec)	QTcF Int (msec)	RR Int (msec)	Interpretation/ Clinically Significant	Abnormal Finding
9077	37/F/W	Day 7 - 4 Hour Postdose/ 22OCT2019 12:20 (7)	66	135	93	426	419	901	N	
		Day 9/ 24OCT2019 07:57 (9)	74	162	92	429	414	808	N	
9080	41/F/BL	Screening/ 08OCT2019 11:29 (-8)	66	139	82	431	423	898	N	
		Check-In/ 15OCT2019 09:26 (-1)	66	144	100	416	409	903	N	
		Day 1 - 4 Hour Postdose/ 16OCT2019 12:10 (1)	66	142	86	402	395	905	N	
		Day 4 - 4 Hour Postdose/ 19OCT2019 12:15 (4)	80	136	81	419	399	744	N	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
bpm=beats per minute, msec=milliseconds, Int=Interval
R=Repeat; N=Normal, AB=Abnormal; CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.7
Electrocardiogram Results
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ ECG Date Time (Day)	Heart Rate (bpm)	PR Int (msec)	QRS Dur (msec)	QTcB Int (msec)	QTcF Int (msec)	RR Int (msec)	Interpretation/ Clinically Significant	Abnormal Finding
9080	41/F/BL	Day 7 - 4 Hour Postdose/ 22OCT2019 12:09 (7)	72	126	80	399	387	824	N	
		Day 9/ 24OCT2019 08:06 (9)	80	128	97	412	392	744	N	
9081	49/M/BL	Screening/ 10OCT2019 11:54 (-20)	80	190	107	452	430	747	AB, NCS	LEFT AXIS DEVIATION AND NONSPECIFIC INTRAVENTRICULAR CONDUCTION DELAY OF UNCERTAIN SIGNIFICANCE. NO SIGNS OF ACUTE ISCHEMIA OR INFARCT
		Check-In/ 29OCT2019 09:32 (-1)	75	191	110	440	424	800	AB, NCS	LEFT AXIS DEVIATION

Sex: M=Male, F=Female;
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Day = The presented date — First dose date + 1
bpm=beats per minute, msec=milliseconds, Int=Interval
R=Repeat; N=Normal, AB=Abnormal; CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.7
Electrocardiogram Results
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ ECG Date Time (Day)	Heart Rate (bpm)	PR Int (msec)	QRS Dur (msec)	QTcB Int (msec)	QTcF Int (msec)	RR Int (msec)	Interpretation/ Clinically Significant	Abnormal Finding
9081	49/M/BL	Day 1 - 4 Hour Postdose/ 30OCT2019 11:45 (1)	74	193	109	442	426	805	AB, NCS	LEFT AXIS DEVIATION
		Day 4 - 4 Hour Postdose/ 02NOV2019 11:45 (4)	72	194	109	442	428	830	AB, NCS	LEFT AXIS DEVIATION
		Day 7 - 4 Hour Postdose/ 05NOV2019 10:45 (7)	66	197	108	428	421	901	AB, NCS	LEFT AXIS DEVIATION
		Day 9/ 07NOV2019 06:45 (9)	70	206	110	429	418	856	AB, NCS	FIRST DEGREE AV BLOCK, LEFT AXIS DEVIATION
9086	36/M/BL	Screening/ 11OCT2019 09:33 (-5)	77	216	112	446	428	773	AB, NCS	FIRST DEGREE AV BLOCK, INCOMPLETE RIGHT BUNDLE BRANCH BLOCK
		Check-In/ 15OCT2019 09:17 (-1)	75	211	110	446	429	791	AB, NCS	FIRST DEGREE AV BLOCK

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Day = The presented date — First dose date + 1
bpm=beats per minute, msec=milliseconds, Int=Interval
R=Repeat; N=Normal, AB=Abnormal; CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.7
Electrocardiogram Results
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ ECG Date Time (Day)	Heart Rate (bpm)	PR Int (msec)	QRS Dur (msec)	QTcB Int (msec)	QTcF Int (msec)	RR Int (msec)	Interpretation/ Clinically Significant	Abnormal Finding
9086	36/M/BL	Day 1 - 4 Hour Postdose/ 16OCT2019 12:00 (1)	58	217	111	419	421	1025	AB, NCS	FIRST DEGREE AV BLOCK, INCOMPLETE RIGHT BUNDLE BRANCH BLOCK.
		Day 4 - 4 Hour Postdose/ 19OCT2019 12:00 (4)	63	217	110	416	412	941	AB, NCS	FIRST DEGREE AV BLOCK
		Day 7 - 4 Hour Postdose/ 22OCT2019 12:00 (7)	60	217	110	422	421	985	AB, NCS	FIRST DEGREE AV BLOCK, NCS
		Day 9/ 24OCT2019 08:00 (9)	73	221	108	433	418	815	AB, NCS	FIRST DEGREE AV BLOCK, NCS
9087	34/F/BL	Screening/ 11OCT2019 09:14 (-5)	78	184	86	432	414	767	N	
		Check-In/ 15OCT2019 09:11 (-1)	79	196	88	442	422	753	N	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date – First dose date + 1
bpm=beats per minute, msec=milliseconds, Int=Interval
R=Repeat; N=Normal, AB=Abnormal; CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.7
Electrocardiogram Results
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ ECG Date Time (Day)	Heart Rate (bpm)	PR Int (msec)	QRS Dur (msec)	QTcB Int (msec)	QTcF Int (msec)	RR Int (msec)	Interpretation/ Clinically Significant	Abnormal Finding
9087	34/F/BL	Day 1 - 4 Hour Postdose/ 16OCT2019 12:06 (1)	77	188	100	444	425	770	N	
		Day 4 - 4 Hour Postdose/ 19OCT2019 12:07 (4)	76	188	88	430	413	783	AB, NCS	NONSPECIFIC T-WAVE ANORMALITY
		Day 7 - 4 Hour Postdose/ 22OCT2019 12:03 (7)	81	184	89	444	422	734	N	
		Day 9/ 24OCT2019 08:06 (9)	78	160	101	422	403	760	N	
9089	29/M/BL	Screening/ 14OCT2019 09:08 (-2)	61	143	92	388	386	972	N	
		Check-In/ 15OCT2019 08:40 (-1)	70	155	96	397	386	849	N	

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Day = The presented date — First dose date + 1
bpm=beats per minute, msec=milliseconds, Int=Interval
R=Repeat; N=Normal, AB=Abnormal; CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.7
Electrocardiogram Results
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ ECG Date Time (Day)	Heart Rate (bpm)	PR Int (msec)	QRS Dur (msec)	QTcB Int (msec)	QTcF Int (msec)	RR Int (msec)	Interpretation/ Clinically Significant	Abnormal Finding
9089	29/M/BL	Day 1 - 4 Hour Postdose/ 16OCT2019 12:09 (1)	67	164	90	399	391	890	N	
		Day 4 - 4 Hour Postdose/ 19OCT2019 12:09 (4)	63	152	91	393	389	941	N	
		Day 7 - 4 Hour Postdose/ 22OCT2019 12:09 (7)	61	164	89	374	372	978	N	
		Day 9/ 24OCT2019 08:09 (9)	66	164	91	382	375	898	N	
9092	24/M/W	Screening/ 14OCT2019 09:14 (-2)	73	163	110	392	379	816	N	
		Check-In/ 15OCT2019 09:03 (-1)	66	160	103	391	384	905	N	

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Day = The presented date — First dose date + 1
bpm=beats per minute, msec=milliseconds, Int=Interval
R=Repeat; N=Normal, AB=Abnormal; CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.7
Electrocardiogram Results
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ ECG Date Time (Day)	Heart Rate (bpm)	PR Int (msec)	QRS Dur (msec)	QTcB Int (msec)	QTcF Int (msec)	RR Int (msec)	Interpretation/ Clinically Significant	Abnormal Finding
9092	24/M/W	Day 1 - 4 Hour Postdose/ 16OCT2019 12:13 (1)	55	160	108	390	395	1075	N	
		Day 4 - 4 Hour Postdose/ 19OCT2019 12:12 (4)	54	152	113	395	401	1095	AB, NCS	INCOMPLETE RIGHT BUNDLE BRANCH BLOCK
		Day 7 - 4 Hour Postdose/ 22OCT2019 12:12 (7)	54	158	112	381	388	1102	AB, NCS	INCOMPLETE RIGHT BUNDLE BRANCH BLOCK
		Day 9/ 24OCT2019 08:12 (9)	63	168	114	384	380	943	AB, NCS	INCOMPLETE RIGHT BUNDLE BRANCH BLOCK
9095	42/M/W	Screening/ 17OCT2019 12:56 (-13)	75	139	106	442	425	793	AB, NCS	NONSPECIFIC T WAVE ABNORMALITY, NCS
		Check-In/ 29OCT2019 08:40 (-1)	80	147	105	439	418	746	AB, NCS	NOSPECIFIC T WAVE ABNORMAILITY, NCS

Sex: M=Male, F=Female;
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Day = The presented date — First dose date + 1
bpm=beats per minute, msec=milliseconds, Int=Interval
R=Repeat; N=Normal, AB=Abnormal; CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.7
Electrocardiogram Results
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ ECG Date Time (Day)	Heart Rate (bpm)	PR Int (msec)	QRS Dur (msec)	QTcB Int (msec)	QTcF Int (msec)	RR Int (msec)	Interpretation/ Clinically Significant	Abnormal Finding
9095	42/M/W	Day 1 - 4 Hour Postdose/ 30OCT2019 11:51 (1)	71	150	99	425	413	834	AB, NCS	NONSPECIFIC T WAVE ABNORMALITY
		Day 4 - 4 Hour Postdose/ 02NOV2019 11:51 (4)	77	151	100	411	429	770	AB, NCS	NONSPECIFIC T WAVE ABNORMALITY
		Day 7 - 4 Hour Postdose/ 05NOV2019 10:51 (7)	77	152	105	433	414	774	AB, NCS	SINGLE PVC.
		Day 9/ 07NOV2019 06:51 (9)	81	148	100	431	410	734	AB, NCS	NONSPECIFIC T-WAVE ABNORMALITY

Sex: M=Male, F=Female;
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Day = The presented date — First dose date + 1
bpm=beats per minute, msec=milliseconds, Int=Interval
R=Repeat; N=Normal, AB=Abnormal; CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.8
Physical Exam
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Exam Date (Day)	Body System	Interpretation and Significance	Findings
9001	41/M/BL	Screening/ 12AUG2019 (-2)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Check-in/ 13AUG2019 (-1)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Day 2	PE All	NOT DONE	
		Day 3	PE All	NOT DONE	
		Day 4	PE All	NOT DONE	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.8
Physical Exam
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Exam Date (Day)	Body System	Interpretation and Significance	Findings
9001	41/M/BL	Day 5	PE All	NOT DONE	
		Day 6	PE All	NOT DONE	
		Day 7/ 20AUG2019 (7)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Day 9/ 22AUG2019 (9)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.8
Physical Exam
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Exam Date (Day)	Body System	Interpretation and Significance	Findings
9002	48/M/W	Screening/ 06AUG2019 (-8)	SKIN	ABNORMAL, NCS	MILD SCATTERED TINEA VERSICOLOR
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Check-in/ 13AUG2019 (-1)	SKIN	ABNORMAL, NCS	TINEA VERSICOLOR, UNCHANGED
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Day 2	PE All	NOT DONE	
		Day 3	PE All	NOT DONE	
		Day 4	PE All	NOT DONE	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.8
Physical Exam
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Exam Date (Day)	Body System	Interpretation and Significance	Findings
9002	48/M/W	Day 5	PE All	NOT DONE	
		Day 6	PE All	NOT DONE	
		Day 7/ 20AUG2019 (7)	SKIN	ABNORMAL, NCS	TINEA VERSICOLOR
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Day 9/ 22AUG2019 (9)	SKIN	ABNORMAL, NCS	TINEA VERSICOLOR
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.8
Physical Exam
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Exam Date (Day)	Body System	Interpretation and Significance	Findings
9005	40/M/W	Screening/ 23JUL2019 (-22)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Check-in/ 13AUG2019 (-1)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Day 2	PE All	NOT DONE	
		Day 3	PE All	NOT DONE	
		Day 4	PE All	NOT DONE	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.8
Physical Exam
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Exam Date (Day)	Body System	Interpretation and Significance	Findings
9005	40/M/W	Day 5	PE All	NOT DONE	
		Day 6	PE All	NOT DONE	
		Day 7/ 20AUG2019 (7)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Day 9/ 22AUG2019 (9)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.8
Physical Exam
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Exam Date (Day)	Body System	Interpretation and Significance	Findings
9009	21/F/BL	Screening/ 31JUL2019 (-14)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Check-in/ 13AUG2019 (-1)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Day 2	PE All	NOT DONE	
		Day 3	PE All	NOT DONE	
		Day 4	PE All	NOT DONE	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.8
Physical Exam
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Exam Date (Day)	Body System	Interpretation and Significance	Findings
9009	21/F/BL	Day 5	PE All	NOT DONE	
		Day 6	PE All	NOT DONE	
		Day 7/ 20AUG2019 (7)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Day 9/ 22AUG2019 (9)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.8
Physical Exam
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Exam Date (Day)	Body System	Interpretation and Significance	Findings
9012	34/M/BL	Screening/ 06AUG2019 (-8)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Check-in/ 13AUG2019 (-1)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Day 2	PE All	NOT DONE	
		Day 3	PE All	NOT DONE	
		Day 4	PE All	NOT DONE	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.8
Physical Exam
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Exam Date (Day)	Body System	Interpretation and Significance	Findings
9012	34/M/BL	Day 5	PE All	NOT DONE	
		Day 6	PE All	NOT DONE	
		Day 7/ 20AUG2019 (7)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Day 9/ 22AUG2019 (9)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.8
Physical Exam
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Exam Date (Day)	Body System	Interpretation and Significance	Findings
9015	29/M/BL	Screening/ 12AUG2019 (-2)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Check-in/ 13AUG2019 (-1)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Day 2	PE All	NOT DONE	
		Day 3	PE All	NOT DONE	
		Day 4	PE All	NOT DONE	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.8
Physical Exam
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Exam Date (Day)	Body System	Interpretation and Significance	Findings
9015	29/M/BL	Day 5	PE All	NOT DONE	
		Day 6	PE All	NOT DONE	
		Day 7/ 20AUG2019 (7)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Day 9/ 22AUG2019 (9)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.8
Physical Exam
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Exam Date (Day)	Body System	Interpretation and Significance	Findings
9016	48/F/W	Screening/ 12AUG2019 (-23)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Check-in/ 03SEP2019 (-1)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Day 2	PE All	NOT DONE	
		Day 3	PE All	NOT DONE	
		Day 4	PE All	NOT DONE	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.8
Physical Exam
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Exam Date (Day)	Body System	Interpretation and Significance	Findings
9016	48/F/W	Day 5	PE All	NOT DONE	
		Day 6	PE All	NOT DONE	
		Day 7/ 10SEP2019 (7)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Day 9/ 12SEP2019 (9)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.8
Physical Exam
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Exam Date (Day)	Body System	Interpretation and Significance	Findings
9019	41/M/BL	Screening/ 23AUG2019 (-12)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Check-in/ 03SEP2019 (-1)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Day 2	PE All	NOT DONE	
		Day 3	PE All	NOT DONE	
		Day 4	PE All	NOT DONE	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.8
Physical Exam
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Exam Date (Day)	Body System	Interpretation and Significance	Findings
9019	41/M/BL	Day 5	PE All	NOT DONE	
		Day 6	PE All	NOT DONE	
		Day 7/ 10SEP2019 (7)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Day 9/ 12SEP2019 (9)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.8
Physical Exam
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Exam Date (Day)	Body System	Interpretation and Significance	Findings
9020	47/F/BL	Screening/ 21AUG2019 (-14)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Check-in/ 03SEP2019 (-1)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Day 2	PE All	NOT DONE	
		Day 3	PE All	NOT DONE	
		Day 4	PE All	NOT DONE	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.8
Physical Exam
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Exam Date (Day)	Body System	Interpretation and Significance	Findings
9020	47/F/BL	Day 5	PE All	NOT DONE	
		Day 6	PE All	NOT DONE	
		Day 7/ 10SEP2019 (7)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Day 9/ 12SEP2019 (9)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.8
Physical Exam
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Exam Date (Day)	Body System	Interpretation and Significance	Findings
9021	39/F/BL	Screening/ 21AUG2019 (-14)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Check-in/ 03SEP2019 (-1)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Day 2	PE All	NOT DONE	
		Day 3	PE All	NOT DONE	
		Day 4	PE All	NOT DONE	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.8
Physical Exam
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Exam Date (Day)	Body System	Interpretation and Significance	Findings
9021	39/F/BL	Day 5	PE All	NOT DONE	
		Day 6	PE All	NOT DONE	
		Day 7/ 10SEP2019 (7)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Day 9/ 12SEP2019 (9)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.8
Physical Exam
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Exam Date (Day)	Body System	Interpretation and Significance	Findings
9022	31/M/W	Screening/ 21AUG2019 (-14)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Check-in/ 03SEP2019 (-1)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Day 2	PE All	NOT DONE	
		Day 3	PE All	NOT DONE	
		Day 4	PE All	NOT DONE	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.8
Physical Exam
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Exam Date (Day)	Body System	Interpretation and Significance	Findings
9022	31/M/W	Day 5	PE All	NOT DONE	
		Day 6	PE All	NOT DONE	
		Day 7/ 10SEP2019 (7)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Day 9/ 12SEP2019 (9)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.8
Physical Exam
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Exam Date (Day)	Body System	Interpretation and Significance	Findings
9024	20/M/BL	Screening/ 23AUG2019 (-12)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Check-in/ 03SEP2019 (-1)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Day 2	PE All	NOT DONE	
		Day 3	PE All	NOT DONE	
		Day 4	PE All	NOT DONE	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.8
Physical Exam
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Exam Date (Day)	Body System	Interpretation and Significance	Findings
9024	20/M/BL	Day 5	PE All	NOT DONE	
		Day 6	PE All	NOT DONE	
		Day 7/ 10SEP2019 (7)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Day 9/ 12SEP2019 (9)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.8
Physical Exam
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Exam Date (Day)	Body System	Interpretation and Significance	Findings
9025	50/M/W	Screening/ 23AUG2019 (-26)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Check-in/ 17SEP2019 (-1)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Day 2	PE All	NOT DONE	
		Day 3	PE All	NOT DONE	
		Day 4	PE All	NOT DONE	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.8
Physical Exam
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Exam Date (Day)	Body System	Interpretation and Significance	Findings
9025	50/M/W	Day 5	PE All	NOT DONE	
		Day 6	PE All	NOT DONE	
		Day 7/ 24SEP2019 (7)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Day 9/ 26SEP2019 (9)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.8
Physical Exam
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Exam Date (Day)	Body System	Interpretation and Significance	Findings
9033	32/M/W	Screening/ 29AUG2019 (-6)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Check-in/ 03SEP2019 (-1)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Day 2	PE All	NOT DONE	
		Day 3	PE All	NOT DONE	
		Day 4	PE All	NOT DONE	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.8
Physical Exam
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Exam Date (Day)	Body System	Interpretation and Significance	Findings
9033	32/M/W	Day 5	PE All	NOT DONE	
		Day 6	PE All	NOT DONE	
		Day 7/ 10SEP2019 (7)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Day 9/ 12SEP2019 (9)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.8
Physical Exam
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Exam Date (Day)	Body System	Interpretation and Significance	Findings
9043	22/M/BL	Screening/ 11SEP2019 (-7)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Check-in/ 17SEP2019 (-1)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Day 2	PE All	NOT DONE	
		Day 3	PE All	NOT DONE	
		Day 4	PE All	NOT DONE	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.8
Physical Exam
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Exam Date (Day)	Body System	Interpretation and Significance	Findings
9043	22/M/BL	Day 5	PE All	NOT DONE	
		Day 6	PE All	NOT DONE	
		Day 7/ 24SEP2019 (7)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Day 9/ 26SEP2019 (9)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.8
Physical Exam
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Exam Date (Day)	Body System	Interpretation and Significance	Findings
9046	34/M/BL	Screening/ 13SEP2019 (-5)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Check-in/ 17SEP2019 (-1)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Day 2	PE All	NOT DONE	
		Day 3	PE All	NOT DONE	
		Day 4	PE All	NOT DONE	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.8
Physical Exam
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Exam Date (Day)	Body System	Interpretation and Significance	Findings
9046	34/M/BL	Day 5	PE All	NOT DONE	
		Day 6	PE All	NOT DONE	
		Day 7/ 24SEP2019 (7)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Day 9/ 26SEP2019 (9)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.8
Physical Exam
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Exam Date (Day)	Body System	Interpretation and Significance	Findings
9051	34/M/BL	Screening/ 30SEP2019 (-2)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Check-in/ 01OCT2019 (-1)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Day 2	PE All	NOT DONE	
		Day 3	PE All	NOT DONE	
		Day 4	PE All	NOT DONE	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.8
Physical Exam
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Exam Date (Day)	Body System	Interpretation and Significance	Findings
9051	34/M/BL	Day 5	PE All	NOT DONE	
		Day 6	PE All	NOT DONE	
		Day 7/ 08OCT2019 (7)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Day 9/ 10OCT2019 (9)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.8
Physical Exam
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Exam Date (Day)	Body System	Interpretation and Significance	Findings
9052	42/M/BL	Screening/ 30SEP2019 (-2)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Check-in/ 01OCT2019 (-1)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Day 2	PE All	NOT DONE	
		Day 3	PE All	NOT DONE	
		Day 4	PE All	NOT DONE	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.8
Physical Exam
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Exam Date (Day)	Body System	Interpretation and Significance	Findings
9052	42/M/BL	Day 5	PE All	NOT DONE	
		Day 6	PE All	NOT DONE	
		Day 7/ 08OCT2019 (7)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Day 9/ 10OCT2019 (9)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.8
Physical Exam
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Exam Date (Day)	Body System	Interpretation and Significance	Findings
9056	31/F/BL	Screening/ 26SEP2019 (-6)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Check-in/ 01OCT2019 (-1)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Day 2	PE All	NOT DONE	
		Day 3	PE All	NOT DONE	
		Day 4	PE All	NOT DONE	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.8
Physical Exam
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Exam Date (Day)	Body System	Interpretation and Significance	Findings
9056	31/F/BL	Day 5	PE All	NOT DONE	
		Day 6	PE All	NOT DONE	
		Day 7/ 08OCT2019 (7)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Day 9/ 10OCT2019 (9)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.8
Physical Exam
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Exam Date (Day)	Body System	Interpretation and Significance	Findings
9057	29/F/W	Screening/ 30SEP2019 (-2)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Check-in/ 01OCT2019 (-1)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Day 2	PE All	NOT DONE	
		Day 3	PE All	NOT DONE	
		Day 4	PE All	NOT DONE	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.8
Physical Exam
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Exam Date (Day)	Body System	Interpretation and Significance	Findings
9057	29/F/W	Day 5	PE All	NOT DONE	
		Day 6	PE All	NOT DONE	
		Day 7/ 08OCT2019 (7)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Day 9/ 10OCT2019 (9)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.8
Physical Exam
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Exam Date (Day)	Body System	Interpretation and Significance	Findings
9058	32/M/W	Screening/ 26SEP2019 (-20)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Check-in/ 15OCT2019 (-1)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Day 2	PE All	NOT DONE	
		Day 3	PE All	NOT DONE	
		Day 4	PE All	NOT DONE	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.8
Physical Exam
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Exam Date (Day)	Body System	Interpretation and Significance	Findings
9058	32/M/W	Day 5	PE All	NOT DONE	
		Day 6	PE All	NOT DONE	
		Day 7/ 22OCT2019 (7)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Day 9/ 24OCT2019 (9)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.8
Physical Exam
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Exam Date (Day)	Body System	Interpretation and Significance	Findings
9061	21/F/BL	Screening/ 26SEP2019 (-20)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Check-in/ 15OCT2019 (-1)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Day 2	PE All	NOT DONE	
		Day 3	PE All	NOT DONE	
		Day 4	PE All	NOT DONE	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.8
Physical Exam
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Exam Date (Day)	Body System	Interpretation and Significance	Findings
9061	21/F/BL	Day 5	PE All	NOT DONE	
		Day 6	PE All	NOT DONE	
		Day 7/ 22OCT2019 (7)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Day 9/ 24OCT2019 (9)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.8
Physical Exam
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Exam Date (Day)	Body System	Interpretation and Significance	Findings
9062	33/M/BL	Screening/ 30SEP2019 (-2)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Check-in/ 01OCT2019 (-1)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Day 2	PE All	NOT DONE	
		Day 3	PE All	NOT DONE	
		Day 4	PE All	NOT DONE	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.8
Physical Exam
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Exam Date (Day)	Body System	Interpretation and Significance	Findings
9062	33/M/BL	Day 5	PE All	NOT DONE	
		Day 6	PE All	NOT DONE	
		Day 7/ 08OCT2019 (7)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Day 9/ 10OCT2019 (9)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.8
Physical Exam
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Exam Date (Day)	Body System	Interpretation and Significance	Findings
9063	35/M/W	Screening/ 30SEP2019 (-2)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Check-in/ 01OCT2019 (-1)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Day 2	PE All	NOT DONE	
		Day 3	PE All	NOT DONE	
		Day 4	PE All	NOT DONE	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.8
Physical Exam
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Exam Date (Day)	Body System	Interpretation and Significance	Findings
9063	35/M/W	Day 5	PE All	NOT DONE	
		Day 6	PE All	NOT DONE	
		Day 7/ 08OCT2019 (7)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Day 9/ 10OCT2019 (9)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.8
Physical Exam
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Exam Date (Day)	Body System	Interpretation and Significance	Findings
9069	41/F/BL	Screening/ 30SEP2019 (-16)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Check-in/ 15OCT2019 (-1)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Day 2	PE All	NOT DONE	
		Day 3	PE All	NOT DONE	
		Day 4	PE All	NOT DONE	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.8
Physical Exam
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Exam Date (Day)	Body System	Interpretation and Significance	Findings
9069	41/F/BL	Day 5	PE All	NOT DONE	
		Day 6	PE All	NOT DONE	
		Day 7/ 22OCT2019 (7)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Day 9/ 24OCT2019 (9)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.8
Physical Exam
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Exam Date (Day)	Body System	Interpretation and Significance	Findings
9073	40/M/BL	Screening/ 14OCT2019 (-2)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Check-in/ 15OCT2019 (-1)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Day 2	PE All	NOT DONE	
		Day 3	PE All	NOT DONE	
		Day 4	PE All	NOT DONE	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.8
Physical Exam
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Exam Date (Day)	Body System	Interpretation and Significance	Findings
9073	40/M/BL	Day 5	PE All	NOT DONE	
		Day 6	PE All	NOT DONE	
		Day 7/ 22OCT2019 (7)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Day 9/ 24OCT2019 (9)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.8
Physical Exam
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Exam Date (Day)	Body System	Interpretation and Significance	Findings
9077	37/F/W	Screening/ 11OCT2019 (-5)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Check-in/ 15OCT2019 (-1)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Day 2	PE All	NOT DONE	
		Day 3	PE All	NOT DONE	
		Day 4	PE All	NOT DONE	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.8
Physical Exam
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Exam Date (Day)	Body System	Interpretation and Significance	Findings
9077	37/F/W	Day 5	PE All	NOT DONE	
		Day 6	PE All	NOT DONE	
		Day 7/ 22OCT2019 (7)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Day 9/ 24OCT2019 (9)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.8
Physical Exam
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Exam Date (Day)	Body System	Interpretation and Significance	Findings
9080	41/F/BL	Screening/ 14OCT2019 (-2)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Check-in/ 15OCT2019 (-1)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Day 2	PE All	NOT DONE	
		Day 3	PE All	NOT DONE	
		Day 4	PE All	NOT DONE	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.8
Physical Exam
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Exam Date (Day)	Body System	Interpretation and Significance	Findings
9080	41/F/BL	Day 5	PE All	NOT DONE	
		Day 6	PE All	NOT DONE	
		Day 7/ 22OCT2019 (7)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Day 9/ 24OCT2019 (9)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.8
Physical Exam
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Exam Date (Day)	Body System	Interpretation and Significance	Findings
9081	49/M/BL	Screening/ 11OCT2019 (-19)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	ABNORMAL, NCS	LEFT LOWER LEG LYMPHEDEMA 2/2 SEQUELLAE OF SURGICAL REPAIR
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Check-in/ 29OCT2019 (-1)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	ABNORMAL, NCS	LEFT LEG LYMPHEDEMA 2/2 SEQUELLAE OF SURGICAL REPAIR

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.8
Physical Exam
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Exam Date (Day)	Body System	Interpretation and Significance	Findings
9081	49/M/BL	Check-in/ 29OCT2019 (-1)	NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Day 2	PE All	NOT DONE	
		Day 3	PE All	NOT DONE	
		Day 4	PE All	NOT DONE	
		Day 5	PE All	NOT DONE	
		Day 6	PE All	NOT DONE	
		Day 7/ 05NOV2019 (7)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	ABNORMAL, NCS	LEFT LEG LYMPHEDEMA UNCHANGED
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Day 9/ 07NOV2019 (9)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date − First dose date + 1
CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.8
Physical Exam
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Exam Date (Day)	Body System	Interpretation and Significance	Findings
9081	49/M/BL	Day 9/ 07NOV2019 (9)	CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	ABNORMAL, NCS	LEFT LEG LYMPHEDEMA 2/2 SEQUELLAE OF SURGICAL REPAIR- NO CHANGE DURING STUDY
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
9086	36/M/BL	Screening/ 11OCT2019 (-5)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Check-in/ 15OCT2019 (-1)	SKIN	NORMAL	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.8
Physical Exam
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Exam Date (Day)	Body System	Interpretation and Significance	Findings
9086	36/M/BL	Check-in/ 15OCT2019 (-1)	HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Day 2	PE All	NOT DONE	
		Day 3	PE All	NOT DONE	
		Day 4	PE All	NOT DONE	
		Day 5	PE All	NOT DONE	
		Day 6	PE All	NOT DONE	
		Day 7/ 22OCT2019 (7)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.8
Physical Exam
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Exam Date (Day)	Body System	Interpretation and Significance	Findings
9086	36/M/BL	Day 7/ 22OCT2019 (7)	OTHER	NOT DONE	
		Day 9/ 24OCT2019 (9)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
9087	34/F/BL	Screening/ 11OCT2019 (-5)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.8
Physical Exam
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Exam Date (Day)	Body System	Interpretation and Significance	Findings
9087	34/F/BL	Check-in/ 15OCT2019 (-1)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Day 2	PE All	NOT DONE	
		Day 3	PE All	NOT DONE	
		Day 4	PE All	NOT DONE	
		Day 5	PE All	NOT DONE	
		Day 6	PE All	NOT DONE	
		Day 7/ 22OCT2019 (7)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.8
Physical Exam
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Exam Date (Day)	Body System	Interpretation and Significance	Findings
9087	34/F/BL	Day 7/ 22OCT2019 (7)	NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Day 9/ 24OCT2019 (9)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
9089	29/M/BL	Screening/ 14OCT2019 (-2)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.8
Physical Exam
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Exam Date (Day)	Body System	Interpretation and Significance	Findings
9089	29/M/BL	Screening/ 14OCT2019 (-2)	OTHER	NOT DONE	
		Check-in/ 15OCT2019 (-1)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Day 2	PE All	NOT DONE	
		Day 3	PE All	NOT DONE	
		Day 4	PE All	NOT DONE	
		Day 5	PE All	NOT DONE	
		Day 6	PE All	NOT DONE	
		Day 7/ 22OCT2019 (7)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.8
Physical Exam
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Exam Date (Day)	Body System	Interpretation and Significance	Findings
9089	29/M/BL	Day 7/ 22OCT2019 (7)	LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Day 9/ 24OCT2019 (9)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
9092	24/M/W	Screening/ 14OCT2019 (-2)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.8
Physical Exam
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Exam Date (Day)	Body System	Interpretation and Significance	Findings
9092	24/M/W	Screening/ 14OCT2019 (-2)	MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Check-in/ 15OCT2019 (-1)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Day 2	PE All	NOT DONE	
		Day 3	PE All	NOT DONE	
		Day 4	PE All	NOT DONE	
		Day 5	PE All	NOT DONE	
		Day 6	PE All	NOT DONE	
		Day 7/ 22OCT2019 (7)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.8
Physical Exam
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Exam Date (Day)	Body System	Interpretation and Significance	Findings
9092	24/M/W	Day 7/ 22OCT2019 (7)	CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Day 9/ 24OCT2019 (9)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
9095	42/M/W	Screening/ 28OCT2019 (-2)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.8
Physical Exam
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Exam Date (Day)	Body System	Interpretation and Significance	Findings
9095	42/M/W	Screening/ 28OCT2019 (-2)	ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Check-in/ 29OCT2019 (-1)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Day 2	PE All	NOT DONE	
		Day 3	PE All	NOT DONE	
		Day 4	PE All	NOT DONE	
		Day 5	PE All	NOT DONE	
		Day 6	PE All	NOT DONE	
		Day 7/ 05NOV2019 (7)	SKIN	NORMAL	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.8
Physical Exam
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Visit/ Exam Date (Day)	Body System	Interpretation and Significance	Findings
9095	42/M/W	Day 7/ 05NOV2019 (7)	HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	
		Day 9/ 07NOV2019 (9)	SKIN	NORMAL	
			HEENT	NORMAL	
			PULMONARY	NORMAL	
			CARDIOVASCULAR	NORMAL	
			ABDOMEN	NORMAL	
			LYMPH NODES	NORMAL	
			MUSCULOSKELETAL	NORMAL	
			NEUROLOGIC SYSTEM	NORMAL	
			OTHER	NOT DONE	

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
CS=Clinically Significant, NCS=Not clinically significant
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.9
Physical Measurements
Safety Population

Subject ID	Age(yrs)/Sex/Race	Visit	Date Time (Day)	Height (cm)	Weight (kg)
9001	41/M/BL	Screening	19JUL2019 11:16(-26)		128
		Check-in	13AUG2019 09:03(-1)	174.3	129.9
		Day 1	14AUG2019 07:33(1)		129.6
		Day 9	22AUG2019 10:08(9)		126.8
9002	48/M/W	Screening	19JUL2019 11:18(-26)		160.4
		Check-in	13AUG2019 09:17(-1)	178.5	159.7
		Day 1	14AUG2019 07:17(1)		159.1
		Day 9	22AUG2019 10:11(9)		154.9
9005	40/M/W	Screening	23JUL2019 09:26(-22)		140.9
		Check-in	13AUG2019 09:02(-1)	176.8	141.9
		Day 1	14AUG2019 07:13(1)		140.3
		Day 9	22AUG2019 10:16(9)		138.2
9009	21/F/BL	Screening	31JUL2019 09:33(-14)		138.3
		Check-in	13AUG2019 08:53(-1)	174	137.2
		Day 1	14AUG2019 07:36(1)		136.1
		Day 9	22AUG2019 10:05(9)		136.8
9012	34/M/BL	Screening	06AUG2019 09:34(-8)		130.7

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.9
Physical Measurements
Safety Population

Subject ID	Age(yrs)/Sex/Race	Visit	Date Time (Day)	Height (cm)	Weight (kg)
9012	34/M/BL	Check-in	13AUG2019 09:09(-1)	177	130.4
		Day 1	14AUG2019 07:29(1)		128.6
		Day 9	22AUG2019 10:03(9)		126.4
9015	29/M/BL	Screening	12AUG2019 10:29(-2)		121.2
		Check-in	13AUG2019 09:22(-1)	195.3	120.4
		Day 1	14AUG2019 07:31(1)		120.1
		Day 9	22AUG2019 10:14(9)		115.9
9016	48/F/W	Screening	12AUG2019 10:30(-23)		143.1
		Check-in	03SEP2019 08:26(-1)	173.6	144.9
		Day 1	04SEP2019 06:04(1)		143.5
		Day 9	12SEP2019 09:37(9)		142.7
9019	41/M/BL	Screening	15AUG2019 16:38(-20)		134.6
		Check-in	03SEP2019 11:02(-1)	181.6	133.5
		Day 1	04SEP2019 06:07(1)		133.1
		Day 9	12SEP2019 09:42(9)		131
9020	47/F/BL	Screening	21AUG2019 10:08(-14)		134.7
		Check-in	03SEP2019 08:19(-1)	164.8	135

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.9
Physical Measurements
Safety Population

Subject ID	Age(yrs)/Sex/Race	Visit	Date Time (Day)	Height (cm)	Weight (kg)
9020	47/F/BL	Day 1	04SEP2019 06:10(1)		133.7
		Day 9	12SEP2019 09:35(9)		133.4
9021	39/F/BL	Screening	21AUG2019 10:10(-14)		122.5
		Check-in	03SEP2019 08:22(-1)	172.8	123.4
		Day 1	04SEP2019 06:12(1)		122.3
		Day 9	12SEP2019 09:34(9)		120.9
9022	31/M/W	Screening	21AUG2019 10:28(-14)		170.6
		Check-in	03SEP2019 09:11(-1)	177.3	172.1
		Day 1	04SEP2019 06:25(1)		170.2
		Day 9	12SEP2019 09:52(9)		165.8
9024	20/M/BL	Screening	23AUG2019 10:06(-12)		133.8
		Check-in	03SEP2019 08:37(-1)	186.4	133.3
		Day 1	04SEP2019 06:22(1)		133.7
		Day 9	12SEP2019 09:46(9)		131.9
9025	50/M/W	Screening	23AUG2019 10:17(-26)		122.9
		Check-in	17SEP2019 08:34(-1)	175.5	123.5
		Day 1	18SEP2019 06:36(1)		121.1

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.9
Physical Measurements
Safety Population

Subject ID	Age(yrs)/Sex/Race	Visit	Date Time (Day)	Height (cm)	Weight (kg)
9025	50/M/W	Day 9	26SEP2019 08:27(9)		120
9033	32/M/W	Screening	29AUG2019 09:05(-6)		147.4
		Check-in	03SEP2019 08:30(-1)	172.7	148
		Day 1	04SEP2019 06:19(1)		146.2
		Day 9	12SEP2019 09:40(9)		142.6
9043	22/M/BL	Screening	11SEP2019 08:51(-7)		159.1
		Check-in	17SEP2019 08:31(-1)	186.4	158.9
		Day 1	18SEP2019 06:41(1)		157.1
		Day 9	26SEP2019 08:23(9)		156.4
9046	34/M/BL	Screening	13SEP2019 08:42(-5)		121.6
		Check-in	17SEP2019 08:37(-1)	190.4	121.3
		Day 1	18SEP2019 06:39(1)		120.6
		Day 9	26SEP2019 08:20(9)		118.7
9051	34/M/BL	Screening	19SEP2019 08:44(-13)		129.2
		Check-in	01OCT2019 08:25(-1)	182	130
		Day 1	02OCT2019 06:08(1)		129
		Day 9	10OCT2019 08:27(9)		125.6

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.9
Physical Measurements
Safety Population

Subject ID	Age(yrs)/Sex/Race	Visit	Date Time (Day)	Height (cm)	Weight (kg)
9052	42/M/BL	Screening	21SEP2019 12:39(-11)		121.1
		Check-in	01OCT2019 08:32(-1)	179.4	121.6
		Day 1	02OCT2019 06:19(1)		122.9
		Day 9	10OCT2019 08:37(9)		120.2
9056	31/F/BL	Screening	24SEP2019 09:14(-8)		122.4
		Check-in	01OCT2019 08:50(-1)	171	120.9
		Day 1	02OCT2019 05:59(1)		121.4
		Day 9	10OCT2019 08:19(9)		120.3
9057	29/F/W	Screening	25SEP2019 16:01(-7)		127.9
		Check-in	01OCT2019 08:43(-1)	151.2	127.6
		Day 1	02OCT2019 06:01(1)		127.5
		Day 9	10OCT2019 08:22(9)		125
9058	32/M/W	Screening	26SEP2019 08:51(-20)		122.4
		Check-in	15OCT2019 08:32(-1)	185.9	121.3
		Day 1	16OCT2019 06:14(1)		120.6
		Day 9	24OCT2019 08:27(9)		119.5
9061	21/F/BL	Screening	26SEP2019 10:21(-20)		125.3

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.9
Physical Measurements
Safety Population

Subject ID	Age(yrs)/Sex/Race	Visit	Date Time (Day)	Height (cm)	Weight (kg)
9061	21/F/BL	Check-in	15OCT2019 08:27(-1)	169.8	127.2
		Day 1	16OCT2019 06:06(1)		126.3
		Day 9	24OCT2019 08:14(9)		124.5
9062	33/M/BL	Screening	30SEP2019 09:18(-2)		133.7
		Check-in	01OCT2019 08:47(-1)	173.5	131.9
		Day 1	02OCT2019 06:05(1)		131.5
		Day 9	10OCT2019 08:24(9)		130
9063	35/M/W	Screening	30SEP2019 09:06(-2)		124.5
		Check-in	01OCT2019 08:21(-1)	189	120.3
		Day 1	02OCT2019 06:15(1)		120.3
		Day 9	10OCT2019 08:34(9)		115.7
9069	41/F/BL	Screening	30SEP2019 10:22(-16)		150.9
		Check-in	15OCT2019 11:48(-1)	160	151.4
		Day 1	16OCT2019 06:08(1)		151
		Day 9	24OCT2019 08:17(9)		148.4
9073	40/M/BL	Screening	04OCT2019 13:30(-12)		158.4
		Check-in	15OCT2019 08:46(-1)	182.5	161.5

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.9
Physical Measurements
Safety Population

Subject ID	Age(yrs)/Sex/Race	Visit	Date Time (Day)	Height (cm)	Weight (kg)
9073	40/M/BL	Day 1	16OCT2019 06:12(1)		159.2
		Day 9	24OCT2019 08:43(9)		156.6
9077	37/F/W	Screening	05OCT2019 12:36(-11)		126.6
		Check-in	15OCT2019 08:29(-1)	167.4	125.7
		Day 1	16OCT2019 06:03(1)		125.2
		Day 9	24OCT2019 08:29(9)		124.6
9080	41/F/BL	Screening	08OCT2019 11:14(-8)		120.6
		Check-in	15OCT2019 08:50(-1)	161.8	121.2
		Day 1	16OCT2019 06:27(1)		120.3
		Day 9	24OCT2019 08:46(9)		119.5
9081	49/M/BL	Screening	10OCT2019 11:37(-20)		218.8
		Check-in	29OCT2019 09:09(-1)	192	220.4
		Day 1	30OCT2019 07:02(1)		219.4
		Day 9	07NOV2019 08:01(9)		215.1
9086	36/M/BL	Screening	11OCT2019 09:02(-5)		140.5
		Check-in	15OCT2019 08:55(-1)	186.4	139.9
		Day 1	16OCT2019 06:20(1)		140

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.9
Physical Measurements
Safety Population

Subject ID	Age(yrs)/Sex/Race	Visit	Date Time (Day)	Height (cm)	Weight (kg)
9086	36/M/BL	Day 9	24OCT2019 08:32(9)		139
9087	34/F/BL	Screening	11OCT2019 08:59(-5)		124.3
		Check-in	15OCT2019 08:35(-1)	167.2	123
		Day 1	16OCT2019 06:22(1)		123.3
		Day 9	24OCT2019 08:27(9)		121.6
9089	29/M/BL	Screening	14OCT2019 08:55(-2)		123
		Check-in	15OCT2019 08:22(-1)	167.9	122
		Day 1	16OCT2019 06:30(1)		121.6
		Day 9	24OCT2019 08:52(9)		120.1
9092	24/M/W	Screening	14OCT2019 08:58(-2)		167.8
		Check-in	15OCT2019 08:43(-1)	176.5	168.6
		Day 1	16OCT2019 06:25(1)		166.7
		Day 9	24OCT2019 08:40(9)		162.1
9095	42/M/W	Screening	17OCT2019 12:41(-13)		149.6
		Check-in	29OCT2019 08:22(-1)	176.6	148.6
		Day 1	30OCT2019 06:51(1)		149
		Day 9	07NOV2019 08:04(9)		146.9

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
Day = The presented date — First dose date + 1
Note: TPOXX 600 mg (3 x 200-mg capsules) was administered orally twice a day on Days 1 to 7, approximately 12 hours (±30 minutes) apart.
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Listing 16.2.8.10
Follow-Up Visit/Call
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Type of Follow-Up/ Reason for Site Visit	Contact Made/ If 'NO', Reason	Date of Contact Attempt or Visit	AEs/Medications Since Last Visit
9001	41/M/BL	CALL	YES	27AUG2019	NO/NO
		CALL	YES	19SEP2019	NO/NO
9002	48/M/W	CALL	YES	27AUG2019	NO/NO
		CALL	YES	19SEP2019	NO/NO
9005	40/M/W	CALL	YES	27AUG2019	NO/NO
		CALL	YES	19SEP2019	NO/NO
9009	21/F/BL	CALL	YES	27AUG2019	NO/NO
		CALL	YES	19SEP2019	NO/NO
9012	34/M/BL	CALL	YES	27AUG2019	NO/NO
		CALL	YES	19SEP2019	NO/NO
9015	29/M/BL	CALL	YES	27AUG2019	NO/NO
		CALL	YES	19SEP2019	NO/NO
9016	48/F/W	CALL	YES	17SEP2019	NO/NO
		CALL	YES	10OCT2019	NO/NO
9019	41/M/BL	CALL	YES	17SEP2019	NO/NO
		CALL	YES	10OCT2019	NO/NO
9020	47/F/BL	CALL	YES	17SEP2019	NO/NO
		CALL	YES	10OCT2019	NO/NO

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
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Listing 16.2.8.10
Follow-Up Visit/Call
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Type of Follow-Up/ Reason for Site Visit	Contact Made/ If 'NO', Reason	Date of Contact Attempt or Visit	AEs/Medications Since Last Visit
9021	39/F/BL	CALL	YES	17SEP2019	NO/NO
		CALL	YES	10OCT2019	NO/NO
9022	31/M/W	CALL	YES	17SEP2019	NO/NO
		CALL	YES	10OCT2019	NO/NO
9024	20/M/BL	CALL	YES	17SEP2019	NO/NO
		CALL	YES	10OCT2019	NO/NO
9025	50/M/W	CALL	YES	01OCT2019	NO/YES
		CALL	YES	24OCT2019	NO/NO
9033	32/M/W	CALL	YES	17SEP2019	NO/NO
		CALL	YES	10OCT2019	NO/NO
9043	22/M/BL	CALL	YES	01OCT2019	NO/NO
		CALL	YES	24OCT2019	NO/NO
9046	34/M/BL	CALL	YES	01OCT2019	NO/NO
		CALL	YES	24OCT2019	NO/NO
9051	34/M/BL	CALL	YES	15OCT2019	NO/NO
		CALL	YES	07NOV2019	NO/NO
9052	42/M/BL	CALL	YES	15OCT2019	NO/NO
		CALL	YES	07NOV2019	NO/NO

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
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Listing 16.2.8.10
Follow-Up Visit/Call
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Type of Follow-Up/ Reason for Site Visit	Contact Made/ If 'NO', Reason	Date of Contact Attempt or Visit	AEs/Medications Since Last Visit
9056	31/F/BL	CALL	YES	15OCT2019	NO/NO
		CALL	YES	07NOV2019	NO/NO
9057	29/F/W	CALL	YES	15OCT2019	NO/NO
		CALL	YES	07NOV2019	NO/NO
9058	32/M/W	CALL	YES	29OCT2019	NO/NO
		CALL	YES	21NOV2019	NO/NO
9061	21/F/BL	CALL	YES	29OCT2019	NO/NO
		CALL	YES	21NOV2019	NO/NO
9062	33/M/BL	CALL	YES	15OCT2019	NO/NO
		CALL	YES	07NOV2019	NO/NO
9063	35/M/W	CALL	YES	15OCT2019	NO/NO
		CALL	YES	07NOV2019	NO/NO
9069	41/F/BL	CALL	YES	29OCT2019	NO/NO
		CALL	YES	21NOV2019	NO/NO
9073	40/M/BL	CALL	YES	29OCT2019	NO/NO
		CALL	YES	21NOV2019	NO/NO
9077	37/F/W	CALL	YES	29OCT2019	NO/NO
		CALL	YES	21NOV2019	NO/NO

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
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Listing 16.2.8.10
Follow-Up Visit/Call
Safety Population

Subject ID	Age(yrs)/ Sex/ Race	Type of Follow-Up/ Reason for Site Visit	Contact Made/ If 'NO', Reason	Date of Contact Attempt or Visit	AEs/Medications Since Last Visit
9080	41/F/BL	CALL	YES	29OCT2019	NO/NO
		CALL	YES	21NOV2019	NO/NO
9081	49/M/BL	CALL	YES	12NOV2019	NO/NO
		CALL	YES	05DEC2019	NO/NO
9086	36/M/BL	CALL	YES	29OCT2019	NO/NO
		CALL	YES	21NOV2019	NO/NO
9087	34/F/BL	CALL	YES	29OCT2019	NO/NO
		CALL	YES	21NOV2019	NO/NO
9089	29/M/BL	CALL	YES	29OCT2019	NO/NO
		CALL	YES	21NOV2019	NO/NO
9092	24/M/W	CALL	YES	29OCT2019	NO/NO
		CALL	YES	21NOV2019	NO/NO
9095	42/M/W	CALL	YES	12NOV2019	NO/YES
		CALL	YES	05DEC2019	NO/NO

Sex: M=Male, F=Female;
Race: W=White, BL=Black or African American, AS=Asian, AI=American Indian or Alaska Native, PI=Native Hawaiian or Other Pacific Islander, O=Other
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16.3 CASE REPORT FORMS

16.3.1 Case Report Forms for Deaths, Serious Adverse Events, and Withdrawals for Adverse Events

There were no deaths, serious adverse events, or adverse events leading to study discontinuation.

16.3.2 Other Case Report Forms Submitted

No other case report forms were submitted.

16.4 INDIVIDUAL SUBJECT DATA LISTINGS

Please refer to Appendix 16.2 for the data listings.

16.5 BIOANALYTICAL REPORT

This section contains the following document:

Bioanalytical Sample Analysis for the Determination of Tecovirimat in Human Plasma by HPLC/MS/MS dated 23 January 2020

Bioanalytical Sample Analysis for the Determination of Tecovirimat in Human Plasma by HPLC/MS/MS

Prepared For:

SIGA Technologies, Inc.
4575 SW Research Way, Suite 110
Corvallis, Oregon 97333

Prepared By:

Alturas Analytics, Inc.
1324 Alturas Drive
Moscow, ID 83843

Alturas Report Number: AD19-982
Study Number: SIGA-246-022
IND Number: 69,019
Version Date: 23 Jan 2020
Report Status: Final

Quality Assurance Statement

Study Number: SIGA-246-022

Performed For: SIGA Technologies, Inc.

The bioanalytical phase of this study has been inspected by the Alturas Analytics, Inc. Quality Assurance Unit. Listed below are the types of inspections conducted, the inspection dates, the dates the inspections were reported to the Alturas Analytics, Inc. Principal Investigator and Test Facility Management.

Type of Inspection	Inspection Date	Date Reported to	
		Principal Investigator	Management
Sample Analysis Plan Review	22 Jul 2019	22 Jul 2019	23 Jul 2019
In-Process Inspection; Sample Sorting	15 Nov 2019	15 Nov 2019	15 Nov 2019
In-Process Inspection; Curve and QC Preparation	15 Nov 2019	15 Nov 2019	18 Nov 2019
Data Audit; Batches 1-18	18 Dec 2019	18 Dec 2019	24 Dec 2019
Report Audit	13-14 Jan 2020	14 Jan 2020	23 Jan 2020

The Quality Assurance Unit has confirmed that this report accurately describes the Alturas Analytics, Inc. methods and Standard Operating Procedures, and that the reported results accurately reflect the raw data of the study.

Rachel Walker, B.S.
Quality Assurance Associate
Alturas Analytics, Inc.

23 Jan 2020
Date

Key Personnel

Principal Investigator:	Jennifer Zimmer, Ph.D.
Analysts:	Ashley Davie, B.S. Winston Slocumb, B.S.
Quality Control Reviewers:	Timberly Maddox, B.S. Rebecca Brainard, B.S.
Author:	Sara Underwood, B.S.
Quality Assurance Unit:	David Schumacher, B.S., RQAP-GLP Staci Loughney, B.A. Rachel Walker, B.S.

Principal Investigator and GLP Compliance Statement

I, the undersigned, hereby declare that the work was performed by me or under my direction and that the findings provide a true and accurate record of the results obtained.

The bioanalytical phase of this study (SIGA-246-022) was performed in compliance with the agreed protocol and Alturas Standard Operating Procedures and the study objectives were achieved. The bioanalysis was conducted in compliance with applicable provisions of the Food and Drug Administration (FDA) Good Laboratory Practice (GLP) Regulations as described in the Code of Federal Regulations, 21 CFR Part 58. For any deviations from protocol or procedures please see the Study Deviations section of the report.

Principal Investigator:

Jennifer Zimmer, Ph.D.
Laboratory Director
Alturas Analytics, Inc.

23 Jan 2020
Date

STUDY SCHEDULE

Bioanalytical Sample Analysis for the Determination of Tecovirimat in Human Plasma by HPLC/MS/MS

Bioanalytical Study Phase Initiation Date:	29 Jul 2019
Total Number of Samples Received:	1962
Primary:	981
Duplicate:	981
Total Number of Samples Analyzed:	981
Analysis Start Date:	14 Nov 2019
Analysis Completion Date:	06 Dec 2019
Draft Report Issue Date:	16 Jan 2020
Final Report Issue Date:	23 Jan 2020

List of Abbreviations

CIMS	Chemical Inventory Management System
DMSO	Dimethyl sulfoxide
DQC	Dilution quality control
IS or Int.Std.	Internal standard
ISR	Incurred sample reanalysis
HPLC/MS/MS	Liquid chromatography tandem mass spectrometry
HQC	High-level quality control
LLOQ	Lower limit of quantitation
LQC	Low-level quality control
MQC	Mid-level quality control
mg/mL	Milligrams per milliliter
ng/mL	Nanograms per milliliter
QC	Quality control
SD	Standard deviation
SOP	Standard operating procedure
ULOQ	Upper limit of quantitation
µg/mL	Micrograms per milliliter
% Bias	((experimental value - theoretical value)/theoretical value) x 100
% CV	Coefficient of variation x 100

Table of Contents

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List of Tables

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1. SUMMARY

This report summarizes the bioanalytical results for the quantitation of TPOXX® (tecovirimat, also known as ST-246) in human K_3DTA plasma samples for SIGA Technologies, Inc. in support of study number SIGA-246-022 entitled "A Post Marketing Study of the Safety, Tolerability, and Pharmacokinetics of TPOXX® in Adult Subjects Weighing More than 120 kg." Human K_3DTA plasma samples were analyzed for tecovirimat according to Alturas Analytics' Procedure TM19-535 described in the validation report (AV15-ST246-03 Addendum 2). The FDA 2018 guidance for industry on Bioanalytical Method Validation was followed for the sample analysis procedures throughout the report.

Acetonitrile precipitation and HPLC/MS/MS were used to determine the concentration of tecovirimat from human K_3DTA plasma. An aliquot of the extract was injected onto an HPLC/MS/MS triple quadrupole mass spectrometer (Sciex API4000). A C18 HPLC column was used to separate tecovirimat and the internal standard (IS), ST-247, from interfering compounds that may be present in the sample extract. The peak area of the product ion of the compound (tecovirimat) was measured against the peak area of the product ion of the IS. A calibration curve ranging from 5.00 to 2000 ng/mL (eight concentrations in duplicate) was used to quantify tecovirimat in the samples.

2. MATERIALS AND METHODS

2.1 STANDARD PURITY

A summary of the reference standards used throughout sample analysis is presented in Table 2-1. Purities were corrected for in all calculations. Supporting documentation of the reference standard(s), including expiration date, certificates of analysis, and evidence of purity is the responsibility of the manufacturer/supplier or Sponsor; see Certificates of Analysis in the Appendices.

Table 2-1 Summary of Reference Standards for SIGA-246-022

Reference Standard (Synonym)	Lot Number	Purity	Expiration/Retest Date	Batch Numbers
Tpoxx® (Tecovirimat, ST-246 Monohydrate)	20AZ10B-4837	0.9551	15 Jan 2020	1-18
ST-247	1244-TRB-4	1.00	Not assigned	1-18

2.2 BIOLOGICAL MATRIX

Blank human plasma was purchased from BioIVT, (Westbury, New York). Table 2-2 summarizes the lot numbers and receipt dates of the matrices used throughout sample analysis.

Table 2-2 Blank Biological Matrix for SIGA-246-022

Description	Lot Number	Receipt Date
Human K_3DTA Plasma	BRH1353066	11 Jul 2017
	BRH1625452	30 Jan 2019

2.3 PREPARATION OF SOLUTIONS

A summary of solution preparation dates used throughout sample analysis is presented in Table 2-3.

2.3.1 Stock Solutions

Stock solutions of tecovirimat were prepared in dimethyl sulfoxide (DMSO) and ST-247 was prepared in methanol at 1.00 mg/mL. The weight (in milligrams) and other related details for all of the solutions were recorded individually for each day of stock solution preparation in Alturas Analytics Chemical Inventory Management System (CIMS). Separate stock solutions of tecovirimat were weighed and used in the preparation of curve and quality control (QC) working

solutions and stored at nominal -20 °C. Long term stability of tecovirimat stock solution has been demonstrated for up to 285 days at nominal -20 °C; see AV15-ST246-03 Addendum 2.

2.3.2 Working Solutions

Standard curve working solutions were prepared by diluting the respective stock solution of tecovirimat in DMSO and stored in single-use aliquots at nominal -20 °C. Blank human K_3DTA plasma was spiked on the day of analysis with the working solutions to yield standard concentrations of 5.00, 10.0, 25.0, 100, 350, 700, 1500, and 2000 ng/mL. Long term stability of the LLOQ working solution has been demonstrated for up to 56 days at nominal -20 °C; see AV15-ST246-03 Addendum 2.

QC working solutions were prepared by diluting the respective tecovirimat stock solution in DMSO and stored in single-use aliquots at nominal -20 °C. QC samples were prepared by spiking blank human K_3DTA plasma with the QC working solutions to yield concentrations of 15.0, 150, and 1600 ng/mL. On each day of analysis, QC samples were analyzed with incurred samples. Any remaining volume of QC aliquots thawed for analysis were discarded after each day of use.

Table 2-3 Preparation Dates of Calibration Curve and QC Solutions for SIGA-246-022

Analyte	Solution Preparation Date			Plasma QC [a]	Batch Number(s)
	Stock Solution	Working Solution			
		Calibration Curve	QCs		
Tecovirimat	13 Nov 2019	13 Nov 2019	13 Nov 2019	14 Nov 2019	1
				15 Nov 2019	2-5
				26 Nov 2019	6-8
				27 Nov 2019	9, 10
				28 Nov 2019	11, 12
				03 Dec 2019	13, 14
				04 Dec 2019	16
				05 Dec 2019	17
				06 Dec 2019	15, 18

[a] = If not prepared on batch extraction date, QC was stored at -70 °C

3. SAMPLE ANALYSIS

3.1 SAMPLE RECEIPT

Study samples were received as shown in Table 3-1. Samples were stored at nominal -70 °C. Study samples were analyzed within 24 days from receipt. Long term stability for tecovirimat in human plasma has been validated for up to 757 days at nominal -70 °C; see AV15-ST246-03, report addendum 3.

Table 3-1 SIGA-246-022 Human K_3DTA Plasma Sample Receipt

Date Received	Sample Count	Storage Temperature (°C)	Sample Condition
13 Nov 2019	981 primary	-70 ± 10	Frozen/intact on dry ice
05 Dec 2019	981 duplicate	-70 ± 10	Frozen/intact on dry ice

3.2 SUMMARY OF ANALYSIS

Study samples were analyzed in 18 batches in accordance with SOP AA-301, the Bioanalytical Sample Analysis Plan, and test method TM19-535. Each batch included at least duplicate QC samples at three concentrations within the calibration range. A summary of all analytical batches can be found in Table 3-2.

Table 3-2 Summary of Analytical Batches for Tecovirimat

Batch Number	Extraction Date	Instrument ID	Batch Status	Description of Samples Analyzed
1	14 Nov 2019	API4000-06	Accepted	Incurred samples
2	15 Nov 2019	API4000-06	Accepted	Incurred samples
3	15 Nov 2019	API4000-06	Accepted	Incurred samples
4	15 Nov 2019	API4000-06	Accepted	Incurred samples
5	15 Nov 2019	API4000-06	Accepted	Incurred samples
6	26 Nov 2019	API4000-04	Accepted	Incurred samples
7	26 Nov 2019	API4000-04	Accepted	Incurred samples
8	26 Nov 2019	API4000-04	Accepted	Incurred samples
9	27 Nov 2019	API4000-04	Accepted	Incurred samples
10	27 Nov 2019	API4000-04	Accepted	Incurred samples
11	28 Nov 2019	API4000-04	Accepted	Incurred samples
12	28 Nov 2019	API4000-04	Accepted	Incurred samples
13	03 Dec 2019	API4000-04	Accepted	Incurred samples
14	03 Dec 2019	API4000-04	Accepted	Incurred samples
15	06 Dec 2019	API4000-06	Accepted	Incurred samples Reassay samples
16	04 Dec 2019	API4000-06	Accepted	ISR
17	05 Dec 2019	API4000-06	Accepted	ISR
18	06 Dec 2019	API4000-06	Accepted	Incurred samples

ISR = Incurred sample reanalysis

3.3 STUDY SAMPLE RESULTS

Study sample concentrations are displayed in Table 3-3. Information about reassayed study samples is shown in Table 3-4.

Table 3-3 Concentration of Tecovirimat in Human Plasma

Subject	Day Nominal	Hour Nominal	Batch Number	Calculated Concentration (ng/mL)	Dilution Factor
9001	1	0	1	LLOQ(<5.00)	1
9001	1	0.5	1	10.8	1
9001	1	1	1	104	1
9001	1	2	1	469	1
9001	1	4	1	1100	1
9001	1	6	1	759	1
9001	1	8	1	397	1
9001	1	12	1	240	1
9001	1	14	1	173	1
9001	2	16	5	485	1
9001	2	18	5	688	1
9001	2	20	5	695	1
9001	2	24	5	455	1
9001	6	0	8	630	1
9001	6	4	8	1580	1
9001	7	0	9	555	1
9001	7	0.5	9	387	1
9001	7	1	9	345	1
9001	7	2	9	603	1
9001	7	4	9	1600	1
9001	7	6	9	1270	1
9001	7	8	9	691	1
9001	7	12	9	481	1
9001	7	14	9	568	1
9001	8	16	12	1020	1
9001	8	18	12	1070	1
9001	8	20	12	717	1
9001	8	24	12	488	1
9001	9	48	14	121	1
9002	1	0	1	LLOQ(<5.00)	1
9002	1	0.5	1	LLOQ(<5.00)	1
9002	1	1	1	33.4	1
9002	1	2	1	323	1
9002	1	4	1	717	1
9002	1	6	1	548	1
9002	1	8	1	355	1
9002	1	12	1	216	1
9002	1	14	1	273	1

LLOQ = Lower Limit of Quantitation

Continued on next page

Table 3-3 Concentration of Tecovirimat in Human Plasma

Subject	Day Nominal	Hour Nominal	Batch Number	Calculated Concentration (ng/mL)	Dilution Factor
9002	2	16	5	471	1
9002	2	18	5	674	1
9002	2	20	5	865	1
9002	2	24	5	637	1
9002	6	0	8	537	1
9002	6	4	8	1180	1
9002	7	0	9	533	1
9002	7	0.5	9	429	1
9002	7	1	9	410	1
9002	7	2	9	907	1
9002	7	4	9	1290	1
9002	7	6	9	839	1
9002	7	8	9	509	1
9002	7	12	9	567	1
9002	7	14	9	854	1
9002	8	16	12	1140	1
9002	8	18	12	934	1
9002	8	20	12	862	1
9002	8	24	12	624	1
9002	9	48	14	203	1
9005	1	0	1	LLOQ(<5.00)	1
9005	1	0.5	1	22.2	1
9005	1	1	1	164	1
9005	1	2	1	840	1
9005	1	4	1	1080	1
9005	1	6	1	578	1
9005	1	8	1	360	1
9005	1	12	1	233	1
9005	1	14	1	579	1
9005	2	16	6	1110	1
9005	2	18	6	1190	1
9005	2	20	6	811	1
9005	2	24	6	555	1
9005	6	0	8	827	1
9005	6	4	8	1800	1
9005	7	0	9	719	1
9005	7	0.5	9	655	1
9005	7	1	9	572	1
9005	7	2	9	1410	1
9005	7	4	15	2270	5
9005	7	6	15	1170	1
9005	7	8	9	748	1
9005	7	12	9	607	1
9005	7	14	9	1270	1

LLOQ = Lower Limit of Quantitation

Continued on next page

Table 3-3 Concentration of Tecovirimat in Human Plasma

Subject	Day Nominal	Hour Nominal	Batch Number	Calculated Concentration (ng/mL)	Dilution Factor
9005	8	16	12	1660	1
9005	8	18	12	1490	1
9005	8	20	12	997	1
9005	8	24	12	810	1
9005	9	48	14	314	1
9009	1	0	1	LLOQ(<5.00)	1
9009	1	0.5	1	LLOQ(<5.00)	1
9009	1	1	1	LLOQ(<5.00)	1
9009	1	2	1	72.3	1
9009	1	4	1	523	1
9009	1	6	1	378	1
9009	1	12	1	274	1
9009	1	14	1	346	1
9009	2	16	6	899	1
9009	2	18	6	1520	1
9009	2	20	6	935	1
9009	2	24	6	550	1
9009	6	0	8	750	1
9009	6	4	8	1620	1
9009	7	0	9	650	1
9009	7	0.5	9	516	1
9009	7	1	9	471	1
9009	7	2	9	630	1
9009	7	4	9	1190	1
9009	7	6	9	1030	1
9009	7	8	9	860	1
9009	7	12	9	922	1
9009	7	14	9	962	1
9009	8	16	12	1260	1
9009	8	18	12	1350	1
9009	8	20	12	1070	1
9009	8	24	12	849	1
9009	9	48	14	273	1
9012	1	0	1	LLOQ(<5.00)	1
9012	1	0.5	1	10.7	1
9012	1	1	1	78.9	1
9012	1	2	1	683	1
9012	1	4	1	757	1
9012	1	6	1	657	1
9012	1	8	1	367	1
9012	1	12	1	193	1
9012	1	14	1	265	1
9012	2	16	6	667	1
9012	2	18	6	648	1

LLOQ = Lower Limit of Quantitation

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Table 3-3 Concentration of Tecovirimat in Human Plasma

Subject	Day Nominal	Hour Nominal	Batch Number	Calculated Concentration (ng/mL)	Dilution Factor
9012	2	20	6	685	1
9012	2	24	6	451	1
9012	6	0	8	815	1
9012	6	4	8	982	1
9012	7	0	9	490	1
9012	7	0.5	9	435	1
9012	7	1	9	354	1
9012	7	2	9	334	1
9012	7	4	9	810	1
9012	7	6	9	1060	1
9012	7	8	9	662	1
9012	7	12	9	424	1
9012	7	14	9	481	1
9012	8	16	12	675	1
9012	8	18	12	979	1
9012	8	20	12	1180	1
9012	8	24	12	603	1
9012	9	48	14	131	1
9015	1	0	1	LLOQ(<5.00)	1
9015	1	0.5	1	5.35	1
9015	1	1	1	69.1	1
9015	1	2	1	212	1
9015	1	4	1	331	1
9015	1	6	1	900	1
9015	1	8	1	544	1
9015	1	12	1	256	1
9015	1	14	1	246	1
9015	2	16	6	393	1
9015	2	18	6	642	1
9015	2	20	6	741	1
9015	2	24	6	507	1
9015	6	0	8	563	1
9015	6	4	8	1320	1
9015	7	0	9	727	1
9015	7	0.5	9	612	1
9015	7	1	9	524	1
9015	7	2	9	618	1
9015	7	4	9	878	1
9015	7	6	9	858	1
9015	7	8	9	612	1
9015	7	12	9	305	1
9015	7	14	9	632	1
9015	8	16	12	746	1
9015	8	18	12	865	1

LLOQ = Lower Limit of Quantitation

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Table 3-3 Concentration of Tecovirimat in Human Plasma

Subject	Day Nominal	Hour Nominal	Batch Number	Calculated Concentration (ng/mL)	Dilution Factor
9015	8	20	12	742	1
9015	8	24	12	471	1
9015	9	48	14	107	1
9016	1	0	1	LLOQ(<5.00)	1
9016	1	0.5	1	LLOQ(<5.00)	1
9016	1	1	1	91.5	1
9016	1	2	1	205	1
9016	1	4	1	711	1
9016	1	6	1	547	1
9016	1	8	1	408	1
9016	1	12	1	327	1
9016	1	14	1	321	1
9016	2	16	6	528	1
9016	2	18	6	624	1
9016	2	20	6	613	1
9016	2	24	6	534	1
9016	6	0	8	831	1
9016	6	4	8	1700	1
9016	7	0	15	773	1
9016	7	0.5	15	569	1
9016	7	1	15	621	1
9016	7	2	15	870	1
9016	7	4	15	1750	1
9016	7	6	15	1430	1
9016	7	8	15	913	1
9016	7	12	15	811	1
9016	7	14	15	739	1
9016	8	16	12	1090	1
9016	8	18	12	992	1
9016	8	20	12	1180	1
9016	8	24	12	1020	1
9016	9	48	14	205	1
9019	1	0	2	LLOQ(<5.00)	1
9019	1	0.5	2	LLOQ(<5.00)	1
9019	1	1	2	16.6	1
9019	1	2	2	641	1
9019	1	4	2	922	1
9019	1	6	2	771	1
9019	1	8	2	511	1
9019	1	12	2	271	1
9019	1	14	2	225	1
9019	2	16	6	493	1
9019	2	18	6	568	1
9019	2	20	6	761	1

LLOQ = Lower Limit of Quantitation

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Table 3-3 Concentration of Tecovirimat in Human Plasma

Subject	Day Nominal	Hour Nominal	Batch Number	Calculated Concentration (ng/mL)	Dilution Factor
9019	2	24	6	417	1
9019	6	0	8	555	1
9019	6	4	8	1210	1
9019	7	0	15	526	1
9019	7	0.5	15	465	1
9019	7	1	15	406	1
9019	7	2	15	617	1
9019	7	4	15	950	1
9019	7	6	15	1130	1
9019	7	8	15	846	1
9019	7	12	15	557	1
9019	7	14	15	650	1
9019	8	16	12	992	1
9019	8	18	12	1020	1
9019	8	20	12	920	1
9019	8	24	12	574	1
9019	9	48	14	130	1
9020	1	0	2	LLOQ(<5.00)	1
9020	1	0.5	2	LLOQ(<5.00)	1
9020	1	1	2	LLOQ(<5.00)	1
9020	1	2	2	25.6	1
9020	1	4	2	740	1
9020	1	6	2	684	1
9020	1	8	2	740	1
9020	1	12	2	444	1
9020	1	14	2	334	1
9020	2	16	6	603	1
9020	2	18	6	801	1
9020	2	20	6	721	1
9020	2	24	6	429	1
9020	6	0	8	550	1
9020	6	4	8	1090	1
9020	7	0	15	506	1
9020	7	0.5	15	506	1
9020	7	1	15	450	1
9020	7	2	15	498	1
9020	7	4	15	1060	1
9020	7	6	15	1110	1
9020	7	8	15	678	1
9020	7	12	15	627	1
9020	7	14	15	610	1
9020	8	16	12	920	1
9020	8	18	12	1010	1
9020	8	20	12	886	1

LLOQ = Lower Limit of Quantitation

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Table 3-3 Concentration of Tecovirimat in Human Plasma

Subject	Day Nominal	Hour Nominal	Batch Number	Calculated Concentration (ng/mL)	Dilution Factor
9020	8	24	12	601	1
9020	9	48	14	245	1
9021	1	0	2	LLOQ(<5.00)	1
9021	1	0.5	2	LLOQ(<5.00)	1
9021	1	1	2	21.9	1
9021	1	2	2	774	1
9021	1	4	2	890	1
9021	1	6	2	511	1
9021	1	8	2	292	1
9021	1	12	2	272	1
9021	1	14	2	722	1
9021	2	16	6	748	1
9021	2	18	6	713	1
9021	2	20	6	714	1
9021	2	24	6	336	1
9021	6	0	8	434	1
9021	6	4	8	1330	1
9021	7	0	15	247	1
9021	7	0.5	15	192	1
9021	7	1	15	157	1
9021	7	2	15	451	1
9021	7	4	15	1050	1
9021	7	6	15	459	1
9021	7	8	15	288	1
9021	7	12	15	527	1
9021	7	14	15	638	1
9021	8	16	13	663	1
9021	8	18	13	670	1
9021	8	20	13	532	1
9021	8	24	13	307	1
9021	9	48	14	58.0	1
9022	1	0	2	LLOQ(<5.00)	1
9022	1	0.5	2	LLOQ(<5.00)	1
9022	1	1	2	40.6	1
9022	1	2	2	309	1
9022	1	4	2	624	1
9022	1	6	2	648	1
9022	1	8	2	396	1
9022	1	12	2	304	1
9022	1	14	2	402	1
9022	2	16	6	668	1
9022	2	18	6	632	1
9022	2	20	6	637	1
9022	2	24	6	513	1

LLOQ = Lower Limit of Quantitation

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Table 3-3 Concentration of Tecovirimat in Human Plasma

Subject	Day Nominal	Hour Nominal	Batch Number	Calculated Concentration (ng/mL)	Dilution Factor
9022	6	0	8	511	1
9022	6	4	8	1150	1
9022	7	0	15	669	1
9022	7	0.5	15	582	1
9022	7	1	15	581	1
9022	7	2	15	920	1
9022	7	4	15	1170	1
9022	7	6	15	1200	1
9022	7	8	15	727	1
9022	7	12	15	577	1
9022	7	14	15	839	1
9022	8	16	13	1350	1
9022	8	18	13	1300	1
9022	8	20	13	931	1
9022	8	24	13	582	1
9022	9	48	14	148	1
9024	1	0	2	LLOQ(<5.00)	1
9024	1	0.5	2	LLOQ(<5.00)	1
9024	1	1	2	23.5	1
9024	1	2	2	251	1
9024	1	4	2	840	1
9024	1	6	2	885	1
9024	1	8	2	845	1
9024	1	12	2	456	1
9024	1	14	2	328	1
9024	2	16	6	835	1
9024	2	18	6	647	1
9024	2	20	6	1070	1
9024	2	24	6	630	1
9024	6	0	8	921	1
9024	6	4	8	1940	1
9024	7	0	15	862	1
9024	7	0.5	15	711	1
9024	7	1	15	621	1
9024	7	2	15	774	1
9024	7	4	15	1860	1
9024	7	6	15	1440	1
9024	7	8	15	902	1
9024	7	12	15	733	1
9024	7	14	15	1090	1
9024	8	16	13	1300	1
9024	8	18	13	1430	1
9024	8	20	13	1300	1
9024	8	24	13	804	1

LLOQ = Lower Limit of Quantitation

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Table 3-3 Concentration of Tecovirimat in Human Plasma

Subject	Day Nominal	Hour Nominal	Batch Number	Calculated Concentration (ng/mL)	Dilution Factor
9024	9	48	14	271	1
9025	1	0	2	LLOQ(<5.00)	1
9025	1	0.5	2	LLOQ(<5.00)	1
9025	1	1	2	LLOQ(<5.00)	1
9025	1	2	2	50.1	1
9025	1	4	2	192	1
9025	1	6	2	628	1
9025	1	8	2	1330	1
9025	1	12	2	758	1
9025	1	14	2	554	1
9025	2	16	6	1050	1
9025	2	18	6	936	1
9025	2	20	6	958	1
9025	2	24	6	1110	1
9025	6	0	8	1200	1
9025	6	4	8	1440	1
9025	7	0	18	1090	1
9025	7	0.5	18	978	1
9025	7	1	18	728	1
9025	7	2	18	884	1
9025	7	4	18	1200	1
9025	7	6	18	1480	1
9025	7	8	18	1210	1
9025	7	12	18	760	1
9025	7	14	18	1060	1
9025	8	16	13	1510	1
9025	8	18	13	1300	1
9025	8	20	13	1170	1
9025	8	24	13	815	1
9025	9	48	14	236	1
9033	1	0	2	LLOQ(<5.00)	1
9033	1	0.5	2	15.5	1
9033	1	1	2	129	1
9033	1	2	2	497	1
9033	1	4	2	574	1
9033	1	6	2	347	1
9033	1	8	2	191	1
9033	1	12	2	160	1
9033	1	14	2	339	1
9033	2	16	6	631	1
9033	2	18	6	528	1
9033	2	20	6	467	1
9033	2	24	6	292	1
9033	6	0	8	356	1

LLOQ = Lower Limit of Quantitation

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Table 3-3 Concentration of Tecovirimat in Human Plasma

Subject	Day Nominal	Hour Nominal	Batch Number	Calculated Concentration (ng/mL)	Dilution Factor
9033	6	4	8	1590	1
9033	7	0	18	365	1
9033	7	0.5	18	283	1
9033	7	1	18	402	1
9033	7	2	18	701	1
9033	7	4	18	1160	1
9033	7	6	18	845	1
9033	7	8	18	535	1
9033	7	12	18	463	1
9033	7	14	18	1020	1
9033	8	16	13	916	1
9033	8	18	13	844	1
9033	8	20	13	612	1
9033	8	24	13	411	1
9033	9	48	14	117	1
9043	1	0	3	LLOQ(<5.00)	1
9043	1	0.5	3	LLOQ(<5.00)	1
9043	1	1	3	14.9	1
9043	1	2	3	711	1
9043	1	4	3	909	1
9043	1	6	3	571	1
9043	1	8	3	361	1
9043	1	14	3	269	1
9043	2	16	6	421	1
9043	2	18	6	635	1
9043	2	20	6	1100	1
9043	2	24	6	504	1
9043	6	0	8	958	1
9043	6	4	8	1100	1
9043	7	0	18	840	1
9043	7	0.5	18	451	1
9043	7	1	18	442	1
9043	7	2	18	1050	1
9043	7	4	18	1640	1
9043	7	6	18	1020	1
9043	7	8	18	543	1
9043	7	12	18	501	1
9043	7	14	18	468	1
9043	8	16	13	1120	1
9043	8	18	13	960	1
9043	8	20	13	859	1
9043	8	24	13	570	1
9043	9	48	14	237	1
9046	1	0	3	LLOQ(<5.00)	1

LLOQ = Lower Limit of Quantitation

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Table 3-3 Concentration of Tecovirimat in Human Plasma

Subject	Day Nominal	Hour Nominal	Batch Number	Calculated Concentration (ng/mL)	Dilution Factor
9046	1	0.5	3	LLOQ(<5.00)	1
9046	1	1	3	11.8	1
9046	1	2	3	370	1
9046	1	4	3	1030	1
9046	1	6	3	498	1
9046	1	8	3	331	1
9046	1	12	3	265	1
9046	1	14	3	535	1
9046	2	16	6	1090	1
9046	2	18	6	951	1
9046	2	20	6	832	1
9046	2	24	6	506	1
9046	6	0	8	702	1
9046	6	4	8	1440	1
9046	7	0	18	909	1
9046	7	0.5	18	694	1
9046	7	1	18	629	1
9046	7	2	18	721	1
9046	7	4	18	1350	1
9046	7	6	18	833	1
9046	7	8	18	567	1
9046	7	12	18	523	1
9046	7	14	18	1330	1
9046	8	16	13	1470	1
9046	8	18	13	1170	1
9046	8	20	13	1070	1
9046	8	24	13	802	1
9046	9	48	14	264	1
9051	1	0	3	LLOQ(<5.00)	1
9051	1	0.5	3	LLOQ(<5.00)	1
9051	1	1	3	26.7	1
9051	1	2	3	453	1
9051	1	4	3	811	1
9051	1	6	3	232	1
9051	1	8	3	136	1
9051	1	12	3	149	1
9051	1	14	3	171	1
9051	2	16	6	553	1
9051	2	18	6	475	1
9051	2	20	6	409	1
9051	2	24	6	294	1
9051	6	0	8	241	1
9051	6	4	8	816	1
9051	7	0	18	282	1

LLOQ = Lower Limit of Quantitation

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Table 3-3 Concentration of Tecovirimat in Human Plasma

Subject	Day Nominal	Hour Nominal	Batch Number	Calculated Concentration (ng/mL)	Dilution Factor
9051	7	0.5	18	239	1
9051	7	1	18	449	1
9051	7	2	18	937	1
9051	7	4	18	1020	1
9051	7	6	18	513	1
9051	7	8	18	285	1
9051	7	12	18	352	1
9051	7	14	18	512	1
9051	8	16	13	641	1
9051	8	18	13	539	1
9051	8	20	13	322	1
9051	8	24	13	284	1
9051	9	48	14	27.9	1
9052	1	0	3	LLOQ(<5.00)	1
9052	1	0.5	3	15.0	1
9052	1	1	3	54.2	1
9052	1	2	3	256	1
9052	1	4	3	556	1
9052	1	6	3	941	1
9052	1	8	3	522	1
9052	1	12	3	346	1
9052	1	14	3	458	1
9052	2	16	7	1040	1
9052	2	18	7	1040	1
9052	2	20	7	958	1
9052	2	24	7	705	1
9052	6	0	8	632	1
9052	6	4	8	1470	1
9052	7	0	10	575	1
9052	7	0.5	10	440	1
9052	7	1	10	450	1
9052	7	2	10	745	1
9052	7	4	10	1930	1
9052	7	6	10	1160	1
9052	7	8	10	750	1
9052	7	12	10	494	1
9052	7	14	10	890	1
9052	8	16	13	1850	1
9052	8	18	13	1310	1
9052	8	20	13	909	1
9052	8	24	13	622	1
9052	9	48	14	146	1
9056	1	0	3	LLOQ(<5.00)	1
9056	1	0.5	3	9.22	1

LLOQ = Lower Limit of Quantitation

Continued on next page

Table 3-3 Concentration of Tecovirimat in Human Plasma

Subject	Day Nominal	Hour Nominal	Batch Number	Calculated Concentration (ng/mL)	Dilution Factor
9056	1	1	3	33.0	1
9056	1	2	3	123	1
9056	1	4	3	938	1
9056	1	6	3	519	1
9056	1	8	3	327	1
9056	1	12	3	213	1
9056	1	14	3	158	1
9056	2	16	7	398	1
9056	2	18	7	1140	1
9056	2	20	7	916	1
9056	2	24	7	555	1
9056	6	0	8	738	1
9056	6	4	8	1140	1
9056	7	0	10	653	1
9056	7	0.5	10	458	1
9056	7	1	10	384	1
9056	7	2	10	323	1
9056	7	4	10	901	1
9056	7	6	10	1130	1
9056	7	8	10	794	1
9056	7	12	10	1220	1
9056	7	14	10	853	1
9056	8	16	13	1210	1
9056	8	18	13	1020	1
9056	8	20	13	894	1
9056	8	24	13	707	1
9056	9	48	14	257	1
9057	1	0	3	LLOQ(<5.00)	1
9057	1	0.5	3	LLOQ(<5.00)	1
9057	1	1	3	45.8	1
9057	1	2	3	239	1
9057	1	4	3	489	1
9057	1	6	3	557	1
9057	1	8	3	362	1
9057	1	12	3	210	1
9057	1	14	3	178	1
9057	2	16	7	457	1
9057	2	18	7	451	1
9057	2	20	7	504	1
9057	2	24	7	472	1
9057	6	0	8	618	1
9057	6	4	8	940	1
9057	7	0	10	635	1
9057	7	0.5	10	421	1

LLOQ = Lower Limit of Quantitation

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Table 3-3 Concentration of Tecovirimat in Human Plasma

Subject	Day Nominal	Hour Nominal	Batch Number	Calculated Concentration (ng/mL)	Dilution Factor
9057	7	1	10	368	1
9057	7	2	10	512	1
9057	7	4	10	1270	1
9057	7	6	10	931	1
9057	7	8	10	760	1
9057	7	12	10	761	1
9057	7	14	10	797	1
9057	8	16	13	977	1
9057	8	18	13	853	1
9057	8	20	13	913	1
9057	8	24	13	648	1
9057	9	48	14	182	1
9058	1	0	3	LLOQ(<5.00)	1
9058	1	0.5	3	14.0	1
9058	1	1	3	355	1
9058	1	2	3	894	1
9058	1	4	3	881	1
9058	1	6	3	623	1
9058	1	8	3	359	1
9058	1	12	3	192	1
9058	1	14	3	248	1
9058	2	16	7	513	1
9058	2	18	7	588	1
9058	2	20	7	702	1
9058	2	24	7	746	1
9058	6	0	8	573	1
9058	6	4	8	1400	1
9058	7	0	10	645	1
9058	7	0.5	10	488	1
9058	7	1	10	897	1
9058	7	2	10	1710	1
9058	7	4	10	1470	1
9058	7	6	10	1270	1
9058	7	8	10	837	1
9058	7	12	10	621	1
9058	7	14	10	481	1
9058	8	16	13	704	1
9058	8	18	13	854	1
9058	8	20	13	743	1
9058	8	24	13	742	1
9058	9	48	14	141	1
9061	1	0	4	LLOQ(<5.00)	1
9061	1	0.5	4	5.77	1
9061	1	1	4	288	1

LLOQ = Lower Limit of Quantitation

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Table 3-3 Concentration of Tecovirimat in Human Plasma

Subject	Day Nominal	Hour Nominal	Batch Number	Calculated Concentration (ng/mL)	Dilution Factor
9061	1	2	4	940	1
9061	1	4	4	965	1
9061	1	6	4	440	1
9061	1	8	4	311	1
9061	1	12	4	325	1
9061	1	14	4	745	1
9061	2	16	7	833	1
9061	2	24	7	448	1
9061	6	0	8	415	1
9061	6	4	8	1020	1
9061	7	0	10	572	1
9061	7	0.5	10	439	1
9061	7	1	10	413	1
9061	7	2	10	606	1
9061	7	4	10	1290	1
9061	7	6	10	1000	1
9061	7	8	10	603	1
9061	7	12	10	554	1
9061	7	14	10	614	1
9061	8	16	13	888	1
9061	8	18	13	936	1
9061	8	20	13	734	1
9061	8	24	13	460	1
9061	9	48	14	129	1
9062	1	0	4	LLOQ(<5.00)	1
9062	1	0.5	4	14.3	1
9062	1	1	4	127	1
9062	1	2	4	609	1
9062	1	4	4	583	1
9062	1	6	4	368	1
9062	1	8	4	232	1
9062	1	12	4	157	1
9062	1	14	4	245	1
9062	2	16	7	467	1
9062	2	18	7	407	1
9062	2	20	7	441	1
9062	2	24	7	370	1
9062	6	0	8	438	1
9062	6	4	8	997	1
9062	7	0	10	462	1
9062	7	0.5	10	386	1
9062	7	1	10	359	1
9062	7	2	10	692	1
9062	7	4	10	941	1

LLOQ = Lower Limit of Quantitation

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Table 3-3 Concentration of Tecovirimat in Human Plasma

Subject	Day Nominal	Hour Nominal	Batch Number	Calculated Concentration (ng/mL)	Dilution Factor
9062	7	6	10	1020	1
9062	7	8	10	736	1
9062	7	12	10	647	1
9062	7	14	10	561	1
9062	8	16	13	849	1
9062	8	18	13	901	1
9062	8	20	13	598	1
9062	8	24	13	381	1
9062	9	48	14	128	1
9063	1	0	4	LLOQ(<5.00)	1
9063	1	0.5	4	10.2	1
9063	1	1	4	41.2	1
9063	1	2	4	455	1
9063	1	4	4	762	1
9063	1	6	4	571	1
9063	1	8	4	382	1
9063	1	12	4	170	1
9063	1	14	4	200	1
9063	2	16	7	653	1
9063	2	18	7	674	1
9063	2	20	7	761	1
9063	2	24	7	469	1
9063	6	0	8	532	1
9063	6	4	8	1800	1
9063	7	0	10	687	1
9063	7	0.5	10	539	1
9063	7	1	10	721	1
9063	7	2	10	1860	1
9063	7	4	15	2180	5
9063	7	6	15	1450	1
9063	7	8	10	823	1
9063	7	12	10	635	1
9063	7	14	10	962	1
9063	8	16	13	1440	1
9063	8	18	13	1150	1
9063	8	20	13	955	1
9063	8	24	13	690	1
9063	9	48	14	190	1
9069	1	0	4	LLOQ(<5.00)	1
9069	1	0.5	4	73.2	1
9069	1	1	4	102	1
9069	1	2	4	537	1
9069	1	4	4	957	1
9069	1	6	4	402	1

LLOQ = Lower Limit of Quantitation

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Table 3-3 Concentration of Tecovirimat in Human Plasma

Subject	Day Nominal	Hour Nominal	Batch Number	Calculated Concentration (ng/mL)	Dilution Factor
9069	1	8	4	331	1
9069	1	12	4	283	1
9069	1	14	4	629	1
9069	2	16	7	933	1
9069	2	18	7	831	1
9069	2	20	7	592	1
9069	2	24	7	407	1
9069	6	0	8	634	1
9069	6	4	8	1220	1
9069	7	0	11	689	1
9069	7	0.5	11	511	1
9069	7	1	11	472	1
9069	7	2	11	560	1
9069	7	4	11	1270	1
9069	7	6	11	709	1
9069	7	8	11	501	1
9069	7	12	11	543	1
9069	7	14	11	987	1
9069	8	16	13	861	1
9069	8	18	13	772	1
9069	8	20	13	647	1
9069	8	24	13	517	1
9069	9	48	14	232	1
9073	1	0	4	LLOQ(<5.00)	1
9073	1	0.5	4	11.1	1
9073	1	1	4	127	1
9073	1	2	4	702	1
9073	1	4	4	630	1
9073	1	6	4	237	1
9073	1	8	4	225	1
9073	1	12	4	164	1
9073	1	14	4	208	1
9073	2	16	7	504	1
9073	2	18	7	540	1
9073	2	20	7	452	1
9073	2	24	7	294	1
9073	6	0	8	599	1
9073	6	4	8	1290	1
9073	7	0	11	502	1
9073	7	0.5	11	397	1
9073	7	1	11	350	1
9073	7	2	11	847	1
9073	7	4	11	1300	1
9073	7	6	11	931	1

LLOQ = Lower Limit of Quantitation

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Table 3-3 Concentration of Tecovirimat in Human Plasma

Subject	Day Nominal	Hour Nominal	Batch Number	Calculated Concentration (ng/mL)	Dilution Factor
9073	7	8	11	637	1
9073	7	12	11	505	1
9073	7	14	11	1030	1
9073	8	16	14	959	1
9073	8	18	14	811	1
9073	8	20	14	696	1
9073	8	24	14	522	1
9073	9	48	14	195	1
9077	1	0	4	LLOQ(<5.00)	1
9077	1	0.5	4	LLOQ(<5.00)	1
9077	1	1	4	15.2	1
9077	1	2	4	586	1
9077	1	4	4	1310	1
9077	1	6	4	810	1
9077	1	8	4	436	1
9077	1	12	4	343	1
9077	1	14	4	694	1
9077	2	16	7	1220	1
9077	2	18	7	1060	1
9077	2	20	7	1100	1
9077	2	24	7	1170	1
9077	6	0	8	1010	1
9077	6	4	8	2000	1
9077	7	0	11	969	1
9077	7	0.5	11	739	1
9077	7	1	11	750	1
9077	7	2	11	847	1
9077	7	4	15	2120	5
9077	7	6	15	1230	1
9077	7	8	11	875	1
9077	7	12	11	925	1
9077	7	14	11	1000	1
9077	8	16	14	1360	1
9077	8	18	14	1290	1
9077	8	20	14	1210	1
9077	8	24	14	1090	1
9077	9	48	14	381	1
9080	1	0	4	LLOQ(<5.00)	1
9080	1	0.5	4	5.31	1
9080	1	1	4	75.1	1
9080	1	2	4	454	1
9080	1	4	4	1130	1
9080	1	6	4	771	1
9080	1	8	4	494	1

LLOQ = Lower Limit of Quantitation

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Table 3-3 Concentration of Tecovirimat in Human Plasma

Subject	Day Nominal	Hour Nominal	Batch Number	Calculated Concentration (ng/mL)	Dilution Factor
9080	1	12	4	407	1
9080	1	14	4	269	1
9080	2	16	7	382	1
9080	2	18	7	538	1
9080	2	20	7	771	1
9080	2	24	7	584	1
9080	6	0	8	724	1
9080	6	4	8	1360	1
9080	7	0	11	797	1
9080	7	0.5	11	613	1
9080	7	1	11	481	1
9080	7	2	11	474	1
9080	7	4	11	1120	1
9080	7	6	11	1370	1
9080	7	8	11	886	1
9080	7	12	11	1280	1
9080	7	14	11	1110	1
9080	8	16	14	1500	1
9080	8	20	14	1290	1
9080	8	24	14	1030	1
9080	9	48	18	206	1
9081	1	0	5	LLOQ(<5.00)	1
9081	1	0.5	5	31.4	1
9081	1	1	5	105	1
9081	1	2	5	628	1
9081	1	4	5	527	1
9081	1	6	5	361	1
9081	1	8	5	223	1
9081	1	12	5	152	1
9081	1	14	5	258	1
9081	2	16	7	471	1
9081	2	18	7	473	1
9081	2	20	7	496	1
9081	2	24	7	340	1
9081	6	0	8	471	1
9081	6	4	8	982	1
9081	7	0	11	491	1
9081	7	0.5	11	420	1
9081	7	1	11	409	1
9081	7	2	11	769	1
9081	7	4	11	1030	1
9081	7	6	11	906	1
9081	7	8	11	579	1
9081	7	12	11	491	1

LLOQ = Lower Limit of Quantitation

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Table 3-3 Concentration of Tecovirimat in Human Plasma

Subject	Day Nominal	Hour Nominal	Batch Number	Calculated Concentration (ng/mL)	Dilution Factor
9081	7	14	11	851	1
9081	8	16	14	808	1
9081	8	18	14	708	1
9081	8	20	14	638	1
9081	8	24	14	461	1
9081	9	48	18	160	1
9086	1	0	5	LLOQ(<5.00)	1
9086	1	0.5	5	LLOQ(<5.00)	1
9086	1	1	5	21.9	1
9086	1	2	5	215	1
9086	1	4	5	634	1
9086	1	6	5	324	1
9086	1	8	5	154	1
9086	1	12	5	121	1
9086	1	14	5	148	1
9086	2	16	7	240	1
9086	2	18	7	382	1
9086	2	20	7	395	1
9086	2	24	7	215	1
9086	6	0	9	227	1
9086	6	4	9	633	1
9086	7	0	11	339	1
9086	7	0.5	11	230	1
9086	7	1	11	357	1
9086	7	2	11	531	1
9086	7	4	11	690	1
9086	7	6	11	626	1
9086	7	8	11	286	1
9086	7	12	11	265	1
9086	7	14	11	632	1
9086	8	16	14	654	1
9086	8	18	14	548	1
9086	8	20	14	391	1
9086	8	24	14	263	1
9086	9	48	18	114	1
9087	1	0	5	LLOQ(<5.00)	1
9087	1	0.5	5	LLOQ(<5.00)	1
9087	1	1	5	23.4	1
9087	1	2	5	304	1
9087	1	4	5	1160	1
9087	1	6	5	557	1
9087	1	8	5	296	1
9087	1	12	5	177	1
9087	1	14	5	173	1

LLOQ = Lower Limit of Quantitation

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Table 3-3 Concentration of Tecovirimat in Human Plasma

Subject	Day Nominal	Hour Nominal	Batch Number	Calculated Concentration (ng/mL)	Dilution Factor
9087	2	16	7	478	1
9087	2	18	7	867	1
9087	2	20	7	704	1
9087	2	24	7	436	1
9087	6	0	9	474	1
9087	6	4	9	744	1
9087	7	0	11	449	1
9087	7	0.5	11	364	1
9087	7	1	11	329	1
9087	7	2	11	291	1
9087	7	4	11	516	1
9087	7	6	11	751	1
9087	7	8	11	638	1
9087	7	12	11	549	1
9087	7	14	11	712	1
9087	8	16	14	1010	1
9087	8	18	14	868	1
9087	8	20	14	782	1
9087	8	24	14	514	1
9087	9	48	18	121	1
9089	1	0	5	LLOQ(<5.00)	1
9089	1	0.5	5	LLOQ(<5.00)	1
9089	1	1	5	65.9	1
9089	1	2	5	237	1
9089	1	4	5	802	1
9089	1	6	5	649	1
9089	1	8	5	407	1
9089	1	12	5	241	1
9089	1	14	5	252	1
9089	2	16	7	513	1
9089	2	18	7	638	1
9089	2	20	7	698	1
9089	2	24	7	457	1
9089	6	0	9	468	1
9089	6	4	9	941	1
9089	7	0	12	563	1
9089	7	0.5	12	450	1
9089	7	1	12	387	1
9089	7	2	12	355	1
9089	7	4	12	950	1
9089	7	6	12	972	1
9089	7	8	12	566	1
9089	7	12	12	444	1
9089	7	14	12	439	1

LLOQ = Lower Limit of Quantitation

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Table 3-3 Concentration of Tecovirimat in Human Plasma

Subject	Day Nominal	Hour Nominal	Batch Number	Calculated Concentration (ng/mL)	Dilution Factor
9089	8	16	14	786	1
9089	8	18	14	998	1
9089	8	20	14	752	1
9089	8	24	14	480	1
9089	9	48	18	142	1
9092	1	0	5	LLOQ(<5.00)	1
9092	1	0.5	5	26.8	1
9092	1	1	5	196	1
9092	1	2	5	596	1
9092	1	4	5	521	1
9092	1	6	5	439	1
9092	1	8	5	217	1
9092	1	12	5	160	1
9092	1	14	5	300	1
9092	2	16	7	442	1
9092	2	18	7	427	1
9092	2	20	7	484	1
9092	2	24	7	370	1
9092	6	0	9	442	1
9092	6	4	9	1200	1
9092	7	0	12	460	1
9092	7	0.5	12	376	1
9092	7	1	12	590	1
9092	7	2	12	1530	1
9092	7	4	12	1390	1
9092	7	6	12	688	1
9092	7	8	12	444	1
9092	7	12	12	598	1
9092	7	14	12	842	1
9092	8	16	14	960	1
9092	8	18	14	774	1
9092	8	20	14	638	1
9092	8	24	14	270	1
9092	9	48	18	129	1
9095	1	0	5	LLOQ(<5.00)	1
9095	1	0.5	5	LLOQ(<5.00)	1
9095	1	1	5	13.3	1
9095	1	2	5	178	1
9095	1	4	5	697	1
9095	1	6	5	612	1
9095	1	8	5	396	1
9095	1	12	5	331	1
9095	1	14	5	266	1
9095	2	16	8	554	1

LLOQ = Lower Limit of Quantitation

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Table 3-3 Concentration of Tecovirimat in Human Plasma

Subject	Day Nominal	Hour Nominal	Batch Number	Calculated Concentration (ng/mL)	Dilution Factor
9095	2	18	8	549	1
9095	2	20	8	582	1
9095	2	24	8	810	1
9095	6	0	9	717	1
9095	6	4	9	1040	1
9095	7	0	12	662	1
9095	7	0.5	12	579	1
9095	7	1	12	318	1
9095	7	2	12	527	1
9095	7	4	12	863	1
9095	7	6	12	1340	1
9095	7	8	12	1030	1
9095	7	12	12	706	1
9095	7	14	12	905	1
9095	8	16	14	1300	1
9095	8	18	14	996	1
9095	8	20	14	976	1
9095	8	24	14	719	1
9095	9	48	18	252	1

Table 3-4 Summary of Tecovirimat Reassayed Samples

Subject	Day Nominal	Hour Nominal	Original Conc. (ng/mL)	Original Batch No.	Reason for Reassay	Reassay Conc. (ng/mL)	Reassayed Batch No.	Reported Conc. (ng/mL)	Reason for Reported Conc.
9005	7	4	ULOQ(>2000)	9	1	2270	15	2270	1
9005	7	6	Follows >ULOQ sample	9	2	1170	15	1170	2
9063	7	4	ULOQ(>2000)	10	1	2180	15	2180	1
9063	7	6	Follows >ULOQ sample	10	2	1450	15	1450	2
9077	7	4	ULOQ(>2000)	11	1	2120	15	2120	1
9077	7	6	Follows >ULOQ sample	11	2	1230	15	1230	2

ULOQ = Upper Limit of Quantitation

REASON FOR REASSAY:
1 = Sample > ULOQ
2 = Sample injected immediately following a >ULOQ sample

REASON FOR REPORTED CONCENTRATION:
1 = Original value > ULOQ
2 = Original value invalid due to possible carryover

3.4 CALIBRATION DATA

The calibration curve was found to be best modeled by a least-squares linear fit from 5.00 to 2000 ng/mL for tecovirimat. During method validation, it was found that $1/x^2$ weighting gave the most accurate results for the quantitative analysis of tecovirimat.

A calibration curve was made with tecovirimat and back-calculated concentrations were generated using the derived equation from the weighted least-squares linear regression line of the peak area ratios. Per SOP, the accuracy (% bias) for the back-calculated concentrations for each standard point should be within 15% (20% at the LLOQ) of the nominal value to be considered acceptable. At least 75% of the calibration standards in each batch must meet these accuracy criteria in order for the batch to be considered acceptable per SOP. Back-calculated concentration values are shown in Table 3-5 together with calibration curve parameters and overall precision and accuracy values for the curves.

Table 3-5 Calibration Curve Data for Tecovirimat in Human K_3EDTA Plasma

Batch Number	Nominal Concentrations 5.00 (ng/mL)	10.0 (ng/mL)	25.0 (ng/mL)	100 (ng/mL)	350 (ng/mL)	700 (ng/mL)	1500 (ng/mL)	2000 (ng/mL)	Calibration Curve Parameters A [a]	B [a]	RSQ [b]
1	5.27	9.60	23.3	102	329	820 [c]	1590	2170			
	4.97	9.60	26.0	95.6	368	714	1410	1980	1.13E-02	6.78E-03	9.965E-01
2	4.93	10.4	24.3	96.7	352	752	1490	1820			
	4.78	11.0	23.9	104	355	732	1400	2020	1.07E-02	2.12E-03	9.964E-01
3	5.13	9.93	25.9	97.8	355	716	1530	2080			
	5.12	8.96	25.2	92.1	355	754	1380	2030	1.05E-02	4.34E-05	9.968E-01
4	4.89	9.70	25.4	95.5	508 [c]	669	1500	1920			
	5.04	10.6	24.4	101	340	779	1420	2160	1.11E-02	1.22E-03	9.966E-01
5	4.50	10.0	23.2	97.5	381	788	1490	1940			
	5.50	10.1	26.0	97.1	343	698	1430	1920	1.07E-02	9.97E-03	9.949E-01
6	5.44	11.0	24.5	103	345	690	1460	1950			
	4.66	8.88	23.7	98.2	391	712	1490	2010	1.05E-02	-8.59E-03	9.951E-01
7	5.21	14.0 [c]	25.4	94.9	365	710	1420	2590 [c]			
	6.74 [d]	9.18	25.0	95.7	353	708	1540	2140	9.68E-03	-9.70E-03	9.976E-01
8	4.73	9.76	26.0	101	355	719	1490	2120			
	5.46	9.71	22.7	95.5	334	721	1520	2000	9.88E-03	3.70E-05	9.971E-01

[a] = Linear Regression: y = Ax + B where y is the peak area ratio of Tecovirimat to Int. Std., x is the concentration of Tecovirimat, and A and B are regression constants. Regression weighted $1/x^2$.
[b] = RSQ = R-Squared
[c] = >15% (± 15% theoretical). Value excluded from regression and summary statistics.
[d] = >20% (± 20% theoretical). Value excluded from regression and summary statistics.

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Table 3-5 Calibration Curve Data for Tecovirimat in Human K_3EDTA Plasma

Batch Number	Nominal Concentrations 5.00 (ng/mL)	10.0 (ng/mL)	25.0 (ng/mL)	100 (ng/mL)	350 (ng/mL)	700 (ng/mL)	1500 (ng/mL)	2000 (ng/mL)	Calibration Curve Parameters A [a]	B [a]	RSQ [b]
9	4.92	10.1	23.2	99.4	358	714	1530	1990			
	5.20	12.2 [c]	23.4	97.7	345	674	1660	2030	9.81E-03	-4.48E-03	9.976E-01
10	4.96	11.5	24.6	96.1	355	675	1540	2140			
	5.02	8.98	23.5	91.5	342	702	1540	2150	9.32E-03	-8.68E-04	9.948E-01
11	5.70	9.66	25.2	104	334	734	1550	2100			
	4.34	10.3	23.5	107	319	689	1520	1890	8.81E-03	8.37E-05	9.939E-01
12	5.39	10.3	25.1	97.7	337	717	1550	2140			
	4.54	9.61	27.6	97.5	185 [c]	655	1460	1930	8.51E-03	4.67E-04	9.957E-01
13	5.19	10.1	25.7	102	378	717	1490	2050			
	5.03	9.19	23.3	98.2	335	710	1480	1960	9.16E-03	-4.01E-03	9.978E-01
14	4.67	8.66	25.9	90.5	340	751	1550	2080			
	5.69	9.91	30.1 [c]	92.2	354	713	1610	1970	8.93E-03	-2.68E-03	9.932E-01
15	4.56	10.9	24.2	103	356	645	1240 [c]	1750			
	5.17	9.92	26.8	111	328	799	1370	1970	9.80E-03	-4.42E-04	9.912E-01
16	4.89	9.46	26.6	94.3	373	735	1500	2070			
	4.99	11.0	24.2	93.7	346	677	1470	1950	9.18E-03	-5.24E-04	9.968E-01

[a] = Linear Regression: y = Ax + B where y is the peak area ratio of Tecovirimat to Int. Std., x is the concentration of Tecovirimat, and A and B are regression constants. Regression weighted $1/x^2$.

[b] = RSQ = R-Squared

[c] = >15% (± 15% theoretical). Value excluded from regression and summary statistics.

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Table 3-5 Calibration Curve Data for Tecovirimat in Human K_3EDTA Plasma

Batch Number	Nominal Concentrations 5.00 (ng/mL)	10.0 (ng/mL)	25.0 (ng/mL)	100 (ng/mL)	350 (ng/mL)	700 (ng/mL)	1500 (ng/mL)	2000 (ng/mL)	Calibration Curve Parameters A [a]	B [a]	RSQ [b]
17	5.60	9.57	27.0	96.9	350	653	1410	1910			
	4.63	9.31	24.0	104	382	716	1520	2130	9.02E-03	2.22E-03	9.946E-01
18	5.44	10.4	24.5	105	352	698	1460	1980			
	4.60	9.48	24.6	110	337	652	1510	2070	9.91E-03	-1.58E-03	9.965E-01
Mean	5.03	9.91	24.8	98.9	351	711	1490	2010	9.82E-03	-5.52E-04	9.957E-01
S.D.	0.356	0.679	1.24	4.97	16.6	37.0	64.5	100			
%CV	7.1	6.9	5.0	5.0	4.7	5.2	4.3	5.0			
%Bias	0.6	-0.9	-0.8	-1.1	0.3	1.6	-0.7	0.5			
n	35	34	35	36	34	35	35	35	18	18	18

[a] = Linear Regression: y = Ax + B where y is the peak area ratio of Tecovirimat to Int. Std., x is the concentration of Tecovirimat, and A and B are regression constants. Regression weighted $1/x^2$.

[b] = RSQ = R-Squared

3.5 QUALITY CONTROL SAMPLES

The QC samples were prepared in human plasma, as described in Section 2.3, extracted following the test method (TM19-535), and analyzed along with calibration standards. Two-thirds (66.7%) of all QC samples must be within 15% of their respective nominal values to meet acceptance criteria. In addition, no more than one-half of the QC samples at each level may fail these criteria (± 15% of nominal). Dilution QC (DQC) samples were also evaluated in each batch that included diluted incurred samples. Two-thirds (66.7%) of the DQC samples must be within 15% of their respective nominal values to meet run acceptance criteria. The QCs and DQC sample results are shown in Table 3-6.

Table 3-6 Quality Control Evaluation Data for Tecovirimat in Human Plasma

	Nominal Concentration			
Batch Number	LQC (15.0 ng/mL)	MQC (150 ng/mL)	HQC (1600 ng/mL)	DQC [a] (1600 ng/mL)
1	16.2	155	1650	
	15.7	166	1490	
2	17.2	155	1600	
	16.1	146	1570	
3	14.6	169	1660	
	16.4	155	1560	
4	14.8	165	1620	
	17.3 [b]	166	1650	
5	14.0	155	1700	
	13.0	146	1680	
6	15.8	161	1500	
	15.0	193 [b]	1870 [b]	
7	19.9 [b]	160	1750	
	16.8	154	1750	
8	15.3	161	1690	
	14.9	156	1570	
9	16.5	157	1580	
	14.8	148	1430	
10	16.5	150	1710	
	14.9	146	1540	
11	16.9	159	1700	
	16.5	145	1640	
12	16.1	152	1600	
	18.3 [b]	149	1880 [b]	
13	16.5	144	1630	
	15.0	143	1510	
14	12.9	142	1490	
	15.3	142	1770	

[a] = Dilution QCs undiluted concentration 1600 ng/mL; a 5-fold dilution with blank matrix was performed prior to extraction and analysis.

[b] = Value outside of acceptance criteria (± 15% theoretical) but included in summary statistics.

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Table 3-6 Quality Control Evaluation Data for Tecovirimat in Human Plasma

	Nominal Concentration			
Batch Number	LQC (15.0 ng/mL)	MQC (150 ng/mL)	HQC (1600 ng/mL)	DQC [a] (1600 ng/mL)
15	16.7	205 [b]	1600	1680
	13.8	141	1700	1470
				1750
16	16.5	147	1550	
	15.0	155	1590	
17	15.8	147	1530	
	13.2	162	1500	
18	15.8	149	1570	
	15.1	145	1650	
Mean	15.7	155	1620	1630
S.D.	1.43	13.3	103	146
%CV	9.1	8.6	6.4	9.0
%Bias	4.7	3.3	1.3	1.9
n	36	36	36	3

[a] = Dilution QCs undiluted concentration 1600 ng/mL; a 5-fold dilution with blank matrix was performed prior to extraction and analysis.

[b] = Value outside of acceptance criteria (± 15% theoretical) but included in summary statistics.

3.6 INCURRED SAMPLE REANALYSIS

Incurred sample reanalysis (ISR) was performed in batches 16 and 17 for a total of 116 samples. Per SOP, two-thirds (66.7%) of the ISR samples must exhibit a percent difference of less than 20% from their respective original values to meet acceptance criteria using the equation:

$$\%\ Difference = 100\left(\frac{Repeat\ Conc. - Original\ Conc.}{Mean}\right)$$

The ISR data for tecovirimat is presented in Table 3-7. The results show that 103 of 116 (88.8%) ISR samples pass per Alturas Analytics' SOP AA-312.

Table 3-7 Incurred Sample Reanalysis Data for Tecovirimat in Human Plasma

Subject	Day Nominal	Hour Nominal	Original Batch Number	Original Concentration (ng/mL)	Repeat Batch Number	Repeat Concentration (ng/mL)	% Difference	Pass/ Fail
9001	1	4h	1	1100	16	1100	0.0	Pass
9001	6	4h	8	1580	16	1660	4.9	Pass
9001	7	1h	9	345	17	394	13.3	Pass
9001	8	18h	12	1070	16	982	-8.6	Pass
9002	1	1h	1	33.4	17	43.0	25.1	Fail
9002	1	12h	1	216	16	231	6.7	Pass
9002	7	4h	9	1290	16	1310	1.5	Pass
9002	8	16h	12	1140	16	1020	-11.1	Pass
9005	1	1h	1	164	16	173	5.3	Pass
9005	2	18h	6	1190	16	1160	-2.6	Pass
9005	8	16h	12	1660	16	1620	-2.4	Pass
9009	1	14h	1	346	17	424	20.3	Fail
9009	2	18h	6	1520	16	842	-57.4	Fail
9009	7	6h	9	1030	16	1200	15.2	Pass
9012	7	6h	9	1060	16	1020	-3.8	Pass
9015	6	4h	8	1320	16	1220	-7.9	Pass
9016	8	24h	12	1020	16	968	-5.2	Pass
9019	1	4h	2	922	17	901	-2.3	Pass
9019	1	12h	2	271	16	229	-16.8	Pass
9019	2	24h	6	417	17	442	5.8	Pass
9019	8	16h	12	992	17	930	-6.5	Pass
9019	8	18h	12	1020	16	959	-6.2	Pass
9019	8	24h	12	574	17	584	1.7	Pass
9020	1	4h	2	740	17	768	3.7	Pass
9020	1	8h	2	740	17	661	-11.3	Pass
9020	1	12h	2	444	17	454	2.2	Pass
9021	1	12h	2	272	16	249	-8.8	Pass
9022	2	18h	6	632	17	713	12.0	Pass
9022	2	20h	6	637	17	643	0.9	Pass
9024	1	2h	2	251	16	209	-18.3	Pass
9024	1	14h	2	328	17	329	0.3	Pass
9025	1	14h	2	554	17	532	-4.1	Pass
9025	6	0h	8	1200	16	1230	2.5	Pass
9025	6	4h	8	1440	16	1420	-1.4	Pass
9033	1	1h	2	129	16	112	-14.1	Pass
9033	2	20h	6	467	17	482	3.2	Pass
9033	6	4h	8	1590	16	900	-55.4	Fail
9043	2	20h	6	1100	16	1150	4.4	Pass
9043	6	4h	8	1100	16	1060	-3.7	Pass
9046	1	4h	3	1030	16	765	-29.5	Fail
9051	1	4h	3	811	17	720	-11.9	Pass
9051	1	6h	3	232	16	253	8.7	Pass
9051	2	18h	6	475	17	477	0.4	Pass
9052	1	2h	3	256	16	248	-3.2	Pass
9052	2	16h	7	1040	16	946	-9.5	Pass

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Table 3-7 Incurred Sample Reanalysis Data for Tecovirimat in Human Plasma

Subject	Day Nominal	Hour Nominal	Original Batch Number	Original Concentration (ng/mL)	Repeat Batch Number	Repeat Concentration (ng/mL)	% Difference	Pass/ Fail
9052	2	18h	7	1040	16	903	-14.1	Pass
9052	2	24h	7	705	17	694	-1.6	Pass
9052	6	0h	8	632	17	690	8.8	Pass
9052	6	4h	8	1470	16	1440	-2.1	Pass
9052	7	6h	10	1160	16	1130	-2.6	Pass
9052	7	8h	10	750	17	787	4.8	Pass
9056	1	1h	3	33.0	17	31.6	-4.3	Pass
9056	1	6h	3	519	17	500	-3.7	Pass
9056	7	0h	10	653	17	710	8.4	Pass
9056	7	6h	10	1130	16	1230	8.5	Pass
9056	7	12h	10	1220	16	1060	-14.0	Pass
9057	1	4h	3	489	17	487	-0.4	Pass
9057	6	0h	8	618	17	587	-5.1	Pass
9058	6	0h	8	573	17	616	7.2	Pass
9058	7	4h	10	1470	16	1540	4.7	Pass
9061	1	8h	4	311	16	280	-10.5	Pass
9061	2	24h	7	448	17	386	-14.9	Pass
9061	6	0h	8	415	17	450	8.1	Pass
9061	6	4h	8	1020	16	981	-3.9	Pass
9061	7	0h	10	572	17	550	-3.9	Pass
9061	7	1h	10	413	17	424	2.6	Pass
9061	7	6h	10	1000	16	937	-6.5	Pass
9061	7	14h	10	614	17	626	1.9	Pass
9062	1	1h	4	127	16	123	-3.2	Pass
9062	1	8h	4	232	16	169	-31.4	Fail
9062	2	16h	7	467	17	547	15.8	Pass
9062	6	4h	8	997	17	1110	10.7	Pass
9062	7	0h	10	462	17	501	8.1	Pass
9063	2	16h	7	653	17	1010	42.9	Fail
9063	7	0.5h	10	539	17	556	3.1	Pass
9069	6	4h	8	1220	16	739	-49.1	Fail
9069	7	4h	11	1270	16	1200	-5.7	Pass
9069	7	6h	11	709	17	737	3.9	Pass
9073	1	1h	4	127	16	113	-11.7	Pass
9073	1	12h	4	164	16	179	8.7	Pass
9073	6	0h	8	599	17	633	5.5	Pass
9073	6	4h	8	1290	16	1010	-24.3	Fail
9073	7	4h	11	1300	16	1210	-7.2	Pass
9077	1	4h	4	1310	16	1240	-5.5	Pass
9077	1	12h	4	343	17	357	4.0	Pass
9077	1	14h	4	694	17	611	-12.7	Pass
9077	2	16h	7	1220	16	1170	-4.2	Pass
9077	2	18h	7	1060	16	882	-18.3	Pass
9077	2	24h	7	1170	16	733	-45.9	Fail
9077	6	0h	8	1010	16	1030	2.0	Pass

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Table 3-7 Incurred Sample Reanalysis Data for Tecovirimat in Human Plasma

Subject	Day Nominal	Hour Nominal	Original Batch Number	Original Concentration (ng/mL)	Repeat Batch Number	Repeat Concentration (ng/mL)	% Difference	Pass/ Fail
9077	7	0.5h	11	739	17	878	17.2	Pass
9077	7	1h	11	750	17	743	-0.9	Pass
9077	7	12h	11	925	17	919	-0.7	Pass
9077	7	14h	11	1000	16	923	-8.0	Pass
9080	1	4h	4	1130	16	1080	-4.5	Pass
9080	2	18h	7	538	17	521	-3.2	Pass
9080	7	2h	11	474	17	486	2.5	Pass
9081	2	24h	7	340	17	361	6.0	Pass
9081	7	0h	11	491	17	541	9.7	Pass
9086	1	8h	5	154	16	133	-14.6	Pass
9086	7	0.5h	11	230	16	281	20.0	Pass
9087	1	4h	5	1160	16	669	-53.7	Fail
9087	2	16h	7	478	17	373	-24.7	Fail
9087	2	20h	7	704	17	682	-3.2	Pass
9087	7	1h	11	329	17	321	-2.5	Pass
9087	7	4h	11	516	17	577	11.2	Pass
9087	7	8h	11	638	17	669	4.7	Pass
9089	1	14h	5	252	16	260	3.1	Pass
9089	7	12h	12	444	17	442	-0.5	Pass
9092	1	8h	5	217	16	234	7.5	Pass
9092	1	12h	5	160	16	161	0.6	Pass
9092	6	4h	9	1200	16	1190	-0.8	Pass
9092	7	2h	12	1530	16	1480	-3.3	Pass
9095	6	4h	9	1040	16	1080	3.8	Pass
9095	7	1h	12	318	16	447	33.7	Fail
9095	7	8h	12	1030	16	989	-4.1	Pass

4. SELECTIVITY

4.1 BLANKS

Double blank and blank + IS samples in human plasma were analyzed in each batch to determine if there were any interfering peaks present during chromatographic analysis. For double blank samples to be considered acceptable, the analyte peak area must be less than or equal to 20% and the IS peak area must be less than or equal to 5% of the mean of the valid LLOQ curve points. For blank + IS samples to be considered acceptable, the peak area ratio must be less than or equal to 20% of the mean of the valid LLOQ curve points. No substantial interfering peaks were observed that eluted at the retention times of tecovirimat or ST-247 in any of the blank plasma samples analyzed during valid sample analysis batches; see Table 4-1.

4.2 CARRYOVER

On each day of analysis a double blank sample was injected after a ULOQ point. If the double blank sample had an analyte peak area response less than or equal to 20% of the passing LLOQ curve point(s), carryover was not considered to be a factor in that day's analysis and carryover factor (COF) was not evaluated. Carryover met acceptance criteria in all batches; see Table 4-2.

Table 4-1 Tecovirimat and ST-247 in Double Blank and Blank + IS Samples in Human Plasma

Batch Number	Analyte Peak Area		% Analyte Peak Area	IS Peak Area		%IS Peak Area	Peak Area Ratio		% Peak Area Ratio
	Double Blank	LLOQ Curve Values		Double Blank	LLOQ Curve Values		Blank + IS	LLOQ Curve Values	
1	8.05E+00	2.09E+03 2.33E+03	0.4	1.75E+01	3.17E+04 3.72E+04	0.1	4.06E-04	6.61E-02 6.27E-02	0.6
2	6.30E+00	1.79E+03 1.92E+03	0.3	8.76E+01	3.26E+04 3.60E+04	0.3	0.00E+00	5.50E-02 5.34E-02	0.0
3	1.09E+01	1.90E+03 1.92E+03	0.6	4.04E+02	3.54E+04 3.58E+04	1.1	4.14E-04	5.37E-02 5.37E-02	0.8
4	5.95E+00	2.17E+03 2.22E+03	0.3	1.32E+02	3.91E+04 3.88E+04	0.3	3.96E-04	5.54E-02 5.71E-02	0.7
5	2.87E+01	2.29E+03 2.51E+03	1.2	9.94E+01	3.95E+04 3.65E+04	0.3	1.08E-04	5.79E-02 6.86E-02	0.2
6	8.19E+01	2.58E+03 2.40E+03	3.3	8.41E+00	5.33E+04 5.97E+04	0.0	2.26E-03	4.84E-02 4.03E-02	5.1
7	2.64E+01	2.42E+03 -- [a]	1.1	4.20E+00	5.94E+04 -- [a]	0.0	2.41E-04	4.07E-02 -- [a]	0.6
8	1.13E+02	2.79E+03 3.42E+03	3.7	4.55E+01	5.97E+04 6.33E+04	0.1	8.21E-04	4.68E-02 5.39E-02	1.6
9	3.78E+01	2.69E+03 2.70E+03	1.4	1.47E+01	6.14E+04 5.81E+04	0.0	8.24E-04	4.37E-02 4.65E-02	1.8
10	3.78E+01	2.27E+03 1.51E+03	2.0	1.47E+01	4.99E+04 3.29E+04	0.0	7.41E-04	4.54E-02 4.59E-02	1.6
11	1.89E+01	2.01E+03 1.19E+03	1.2	2.52E+01	4.01E+04 3.12E+04	0.1	9.59E-04	5.02E-02 3.83E-02	2.2
12	1.05E+01	1.30E+03 8.91E+02	1.0	1.89E+01	2.80E+04 2.28E+04	0.1	2.15E-03	4.63E-02 3.91E-02	5.0
13	2.73E+01	2.60E+03 1.58E+03	1.3	1.68E+01	5.97E+04 3.76E+04	0.0	1.12E-03	4.35E-02 4.21E-02	2.6

[a] = Only one valid LLOQ curve point obtained for this batch; see Table 3-5 for details.

Continued on next page

Table 4-1 Tecovirimat and ST-247 in Double Blank and Blank + IS Samples in Human Plasma

Batch Number	Analyte Peak Area		% Analyte Peak Area	IS Peak Area		%IS Peak Area	Peak Area Ratio		% Peak Area Ratio
	Double Blank	LLOQ Curve Values		Double Blank	LLOQ Curve Values		Blank + IS	LLOQ Curve Values	
14	1.89E+01	1.39E+03 2.01E+03	1.1	1.47E+01	3.55E+04 4.17E+04	0.0	6.55E-04	3.91E-02 4.81E-02	1.5
15	2.16E+02	1.55E+03 1.68E+03	13.4	3.08E+01	3.49E+04 3.34E+04	0.1	4.81E-03	4.43E-02 5.02E-02	10.2
16	7.00E-01	1.83E+03 1.85E+03	0.0	8.40E+00	4.12E+04 4.09E+04	0.0	1.57E-04	4.44E-02 4.52E-02	0.4
17	3.47E+01	1.88E+03 1.52E+03	2.0	3.43E+01	3.56E+04 3.45E+04	0.1	3.91E-04	5.28E-02 4.40E-02	0.8
18	1.49E+02	1.74E+03 1.56E+03	9.0	3.15E+01	3.33E+04 3.55E+04	0.1	2.55E-04	5.23E-02 4.40E-02	0.5

Table 4-2 Carryover Calculations for Tecovirimat in Human Plasma

Batch Number	LLOQ Peak Area	Carryover DoubleBlank Peak Area	% Carryover
1	2090 2330	165	7.4
2	1790 1920	57.4	3.1
3	1900 1920	121	6.3
4	2170 2220	95.2	4.3
5	2290 2510	131	5.5
6	2580 2400	28.8	1.2
7	2420 -- [a]	84.8	3.5
8	2790 3420	16.8	0.5
9	2690 2700	28.7	1.1
10	2270 1510	18.9	1.0
11	2010 1190	63.0	3.9
12	1300 891	66.5	6.1
13	2600 1580	33.6	1.6
14	1390 2010	12.6	0.7
15	1550 1680	169	10.5

[a] = Only one valid LLOQ curve point obtained for this batch; see Table 3-5 for details.

Continued on next page

Table 4-2 Carryover Calculations for Tecovirimat in Human Plasma

Batch Number	LLOQ Peak Area	Carryover DoubleBlank Peak Area	% Carryover
16	1830 1850	180	9.8
17	1880 1520	151	8.9
18	1740 1560	218	13.2

5. CONCLUSION

The calibration curves and QC sample data from the reported batches indicate that the method met the acceptance criteria for these batches.

6. ARCHIVAL

All raw data, documentation, records and a signed copy of the final report are archived at Alturas Analytics, Inc. for a period of at least five years in accordance with Alturas' SOPs.

7. STUDY DEVIATIONS

No deviations were noted in this study.

8. COMPUTER SYSTEMS

All data were acquired using Analyst version 1.6 or higher and all calculations were performed with Watson version 7.5 SP1 or higher and Microsoft Excel 2010. Per Alturas Analytics' SOP AA-217, three significant figures are reported for all concentrations and percentages are reported to one decimal place.

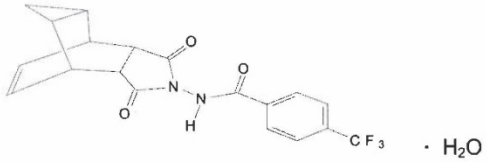
9. REFERENCES

1. Alturas Analytics, Inc. Validation Study: AV15-ST246-03 Addendum 2, "Addendum 2 to HPLC/MS/MS Assay Validation for the Determination of ST-246, M4, M5, and TFMBA from Human Plasma."
2. Alturas Analytics, Inc. Validation Study: AV15-ST246-03, " Addendum 3 to HPLC/MS/MS Assay Validation for the Determination of ST-246, M4, M5, and TFMBA from Human Plasma."
3. Food and Drug Administration. *Guidance for Industry: Bioanalytical Method Validation*. Silver Spring, MD: US Department of Health and Human Services, FDA, Center for Drug Evaluation and Research; 2018.

10. APPENDICES

10.1 CERTIFICATES OF ANALYSIS

ST-246 (MONOHYDRATE) REFERENCE STANDARD



Chemical Name: 4-trifluoromethyl-N-(3,3a,4,4a,5,5a,6,6a-octahydro-1,3-dioxo-4,6-etheno-cycloprop[f]isoindol-2-(1H)-yl)-benzamide (monohydrate)

Molecular Formula: $C_{19}H_{15}F_3N_2O_3 \cdot H_2O$
Molecular Weight: 394.3

LOT #: 20AZ10B-4837

SOURCE: Albemarle Corporation; synthesized in R&D laboratory by unambiguous route; micronized
RECOMMENDED STORAGE: Room temperature in closed container.

CERTIFICATION TESTING

RETEST DATE:	**01-15-20**
APPEARANCE:	White solid free of visible contamination
IDENTIFICATION:	FTIR spectrum conforms to structure Mass spectrum is consistent with molecular structure NMR spectrum is consistent with molecular structure Sample retention time compares to standard within ± 0.5 minutes by HPLC
HPLC PURITY:	99.96% by internal normalization
RELATED SUBSTANCES:	Unknown 1: 0.01% ; Unknown RRT 1.18: 0.03%
SG1 / SG1 EXO ISOMER:	SG1: None detected ≥ 0.05%; SG1 Exo Isomer: None detected ≥ 0.05%
SG2 DIMER	None detected ≥ 0.01%
HYDRAZINE	None detected ≥ 0.1 ppm
RESIDUAL SOLVENTS:	Ethyl Acetate: 0.006%
WATER CONTENT:	4.434%*
RESIDUE ON IGNITION:	0.014%
HEAVY METALS:	NMT 0.002%
PARTICLE SIZE:	d90 < 4.370 microns
DSC:	Minor Endotherm at 125°C, Major Endotherm at 196°C
X-RAY DIFFRACTION:	XRD pattern is consistent with ST-246 designated Polymorph Form I
PURITY FACTOR:	**A. 95.51% as is basis*** [Purity Factor = Purity based on anhydrous basis (99.94%) – Water Content] **B. 99.94% anhydrous basis*** [Purity Factor = HPLC Purity – Residual Solvents – Residue on Ignition]

* The water content value reported on this Certificate of Analysis is the result obtained during the original testing. Water content can be influenced by variability of storage and frequency of exposure to the environment, therefore, Albemarle cannot certify the accuracy of the water content over time. If the water content is critical for the intended application, it is recommended that the water content be determined at the time of use.

Signature Manifest

Document Number: Ref Cpd COA-0029 **Revision:** 5
Title: SG ST-246 Primary Reference Standard, Lot 20AZ10B-4837, Retest Date 01-15-20

All dates and times are in GMT Zone.

SG ST-246 Primary Ref Std Lot 20AZ10B-4837 CofA update

Approve to begin

Name/Signature	Title	Date	Meaning/Reason
Dorota Romanowski (ROMANDB)	R&D Chemist	16 Jan 2019, 03:31:58 PM	Approved

Analytical Services Approve

Name/Signature	Title	Date	Meaning/Reason
Paul Byers (BYERSP2)	Sr. Specialist R&D		
Bethany Gross (GROSSBG)	Analytical Chemist		
Steve Halpin (HALPIST)	Analytical Chemist		
Dorota Romanowski (ROMANDB)	R&D Chemist		
Geoff Bohren (BOHREGB)	Analytical Chemist		
Patricia Tribby (TRIBBPJ)	Sr. Chemist R&D		
David Grossens (GROSSDE)	Analytical Chemist		
Scott Buckley (BUCKLSA)	Analytical Chemist		
Kari Engelkemier (ENGELKB)	Analytical Chemist	16 Jan 2019, 04:46:20 PM	Approved

Originator Approve

Name/Signature	Title	Date	Meaning/Reason
Dorota Romanowski (ROMANDB)	R&D Chemist	16 Jan 2019, 04:05:28 PM	Approved

Quality Assurance Approval

Name/Signature	Title	Date	Meaning/Reason
Franklin Fetzer (FETZEFG)	Sr. Specialist Process		
Robert Hayes (HAYESRF)	QA Specialist		
Kevin McIntosh (MCINTKB)	Quality Specialist		
Angela Lockwood (LOCKWAL)	Quality Specialist		
Erika Ballman (BALLMEA)	Quality Manager		
Macy Siemen (PRZYBML)	QA Specialist		
Lindsay Cunningham (CUNNILA)	QA Specialist		
Joy Denny (DENNYBJ)	Sr. Quality Assurance Advisor	17 Jan 2019, 03:09:06 PM	Approved

Final Release

Name/Signature	Title	Date	Meaning/Reason
Joy Denny (DENNYBJ)	Sr. Quality Assurance Advisor		
Phil Kenreich (KENREPR)	Quality Engineer		
Sherie Middleton (MIDDLSL)	QA Auditor	17 Jan 2019, 03:41:44 PM	Approved

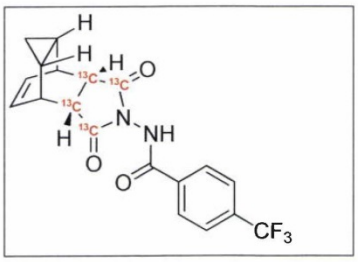
Ref Cpd COA-0029, Revision # 5, Effective 17 Jan 2019
Approved by Quality Assurance via 21 CFR Part 11 compliant electronic system.
Strictly Confidential - Proprietary Information of Albemarle Corporation

Kalexsyn
medicinal chemistry

Certificate of Analysis
SIGA Project

Name: $^{13}C_4$-N-[(3aR,6aS)-1,3-dioxooctahydro-4,6-ethenocyclopropa[f]isoindol-2(1H)-yl]-4-(trifluoromethyl)benzamide (ST-247)

Kalexsyn Reg No.:	KXN-2327
Kalexsyn Project No.:	**1244**
Date:	May 16, 2012
Lot Number:	1244-TRB-4
Molecular Formula:	$^{13}C_4C_{15}H_{15}F_3N_2O_3$
Molecular Weight:	380.3
Exact Mass:	380.1168
Quantity Shipped:	6.9g
Purity:	> 98% by HPLC. No detectable exo isomer.
Kalexsyn Chemist:	Tom Belliotti



Test	Results
Physical Appearance	White solid
Identification: ^{1}H NMR Spectrum	Attached: Consistent with structure of molecule.
HPLC Analysis	Attached: Agilent XDB C18 50 x 4.6 mm 1.8 micron column, Solvent A – Water (0.1% TFA) Solvent B – Acetonitrile (0.07% TFA). Gradient – 5 min 95%A to 95%B; 1.0 min hold; then recycle. UV Detection @ 210 and 254 nm. Retention time = 3.83 min. 100 area % at 210 nm and 100 area % at 254 nm.
Mass Spectrum	MS (ESI+) for $^{13}C_4C_{15}H_{15}F_3N_2O_3$ *m/z* 381.14 $(M+H)^+$. Abundance analysis indicates 99.6% M+4, 0.4%M+2. M+3, M+1, and M+0 were not detected.

Spectral Data are attached.

RECEIVED
MAY 23 2012
BY: Elizabeth Walker

Note: Spectral data on file at Alturas Analytics, Inc.

10.2 REPRESENTATIVE CHROMATOGRAMS

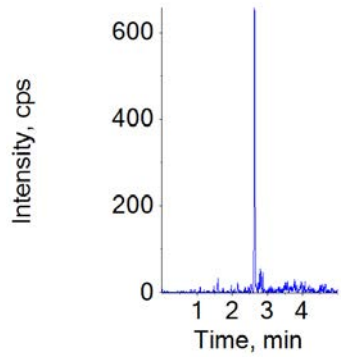
Representative chromatograms are attached below from batch 4 for tecovirimat in human K_3DTA plasma. Attached are the blanks, standards, QCs, and 63 incurred sample chromatograms; which is greater than 5% of the total samples analyzed for this study. Study samples are named using the naming convention below:

4	019	SIGA-246-022	085P813	9061	A	Day 1 0h	PLM-1	1
Batch Number	Sample Number	Study Number	Custom ID	Subject	Treatment ID	Time	Matrix-Replicate	Dilution Factor

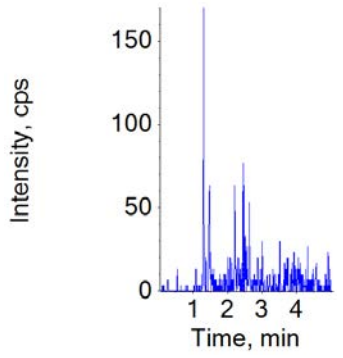
Batch 4: Tecovirimat (ST-246) in Human K_3EDTA Plasma

Data File Name	SIGA-246-022\B4.wiff	Result Table	SIGA-246-022_B4.rdb
Acquisition Method	ST-246_HumanK3.dam	Algorithm Used	MQL
Project	AlturasData\SIG	Instrument Name	API 4000

Sample Name:	4 005 SIGA-246-022 Double Blank 1 1			Plate Number:	7
Acquisition Date:	11/16/2019 10:09:09 AM	Sample Type:	Quality Control	Vial Position:	5

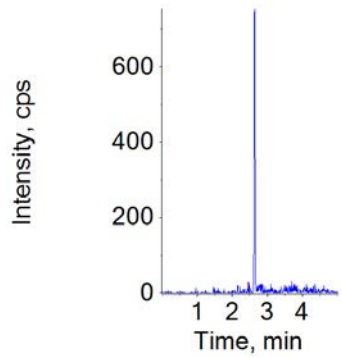


Analyte:	
ST-246	
Analyte Masses:	
375.300/283.300 Da	
Analyte Peak Area:	
5.950000067e+000	
Peak Area Ratio:	
4.49e-002	

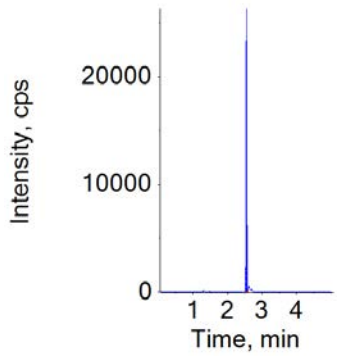


IS:	
ST-247	
IS Masses:	
379.000/287.100 Da	
IS Peak Area:	
1.323716667e+002	

Sample Name:	4 006 SIGA-246-022 Blank IS 1 1			Plate Number:	7
Acquisition Date:	11/16/2019 10:14:43 AM	Sample Type:	Quality Control	Vial Position:	6

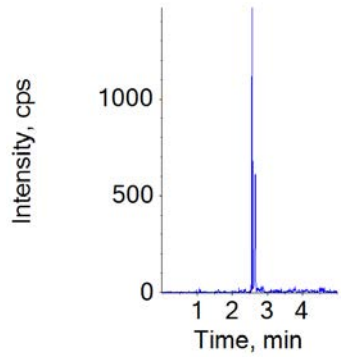


Analyte:	
ST-246	
Analyte Masses:	
375.300/283.300 Da	
Analyte Peak Area:	
1.610000007e+001	
Peak Area Ratio:	
3.96e-004	

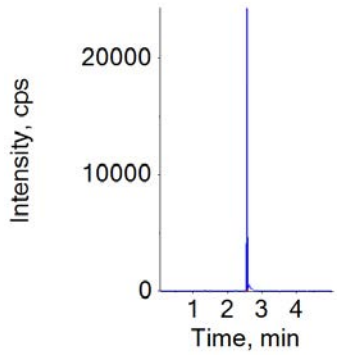


IS:	
ST-247	
IS Masses:	
379.000/287.100 Da	
IS Peak Area:	
4.063853514e+004	

Sample Name:	4 007 SIGA-246-022 STD 1 1 1			Plate Number:	7
Acquisition Date:	11/16/2019 10:20:17 AM	Sample Type:	Standard	Vial Position:	7

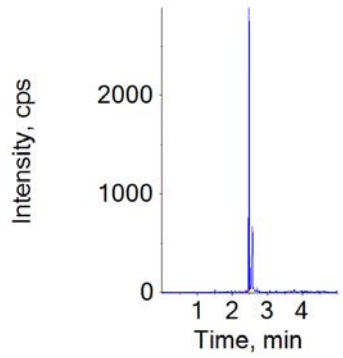


Analyte:
ST-246
Analyte Masses:
375.300/283.300 Da
Analyte Peak Area:
2.166140001e+003
Peak Area Ratio:
5.54e-002

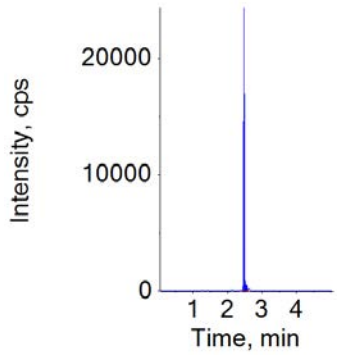


IS:
ST-247
IS Masses:
379.000/287.100 Da
IS Peak Area:
3.911700295e+004

Sample Name:	4 008 SIGA-246-022 STD 2 1 1			Plate Number:	7
Acquisition Date:	11/16/2019 10:25:50 AM	Sample Type:	Standard	Vial Position:	8

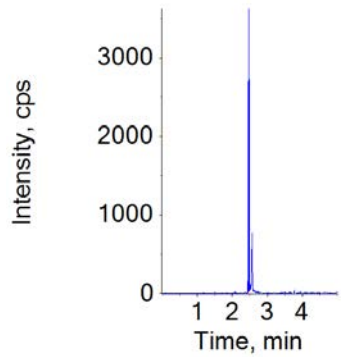


Analyte:
ST-246
Analyte Masses:
375.300/283.300 Da
Analyte Peak Area:
4.416379997e+003
Peak Area Ratio:
1.09e-001

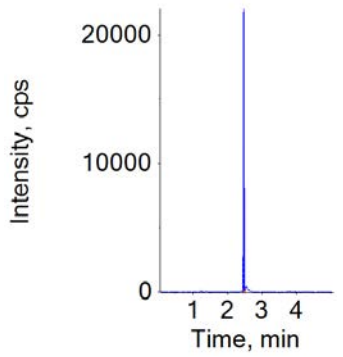


IS:
ST-247
IS Masses:
379.000/287.100 Da
IS Peak Area:
4.062092150e+004

Sample Name:	4 009 SIGA-246-022 LQC 1 1			Plate Number:	7
Acquisition Date:	11/16/2019 10:31:24 AM	Sample Type:	Quality Control	Vial Position:	9

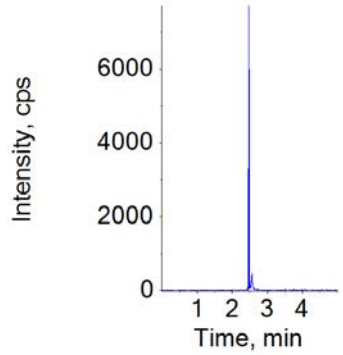


Analyte:
ST-246
Analyte Masses:
375.300/283.300 Da
Analyte Peak Area:
6.338338337e+003
Peak Area Ratio:
1.65e-001

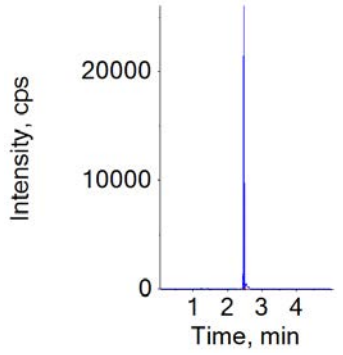


IS:
ST-247
IS Masses:
379.000/287.100 Da
IS Peak Area:
3.839296556e+004

Sample Name:	4 010 SIGA-246-022 STD 3 1 1			Plate Number:	7
Acquisition Date:	11/16/2019 10:36:57 AM	Sample Type:	Standard	Vial Position:	10

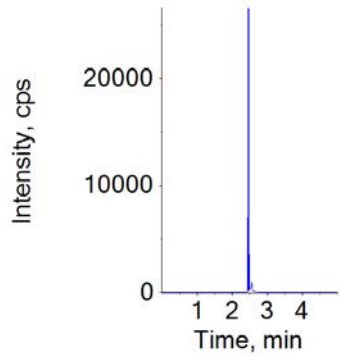


Analyte:
ST-246
Analyte Masses:
375.300/283.300 Da
Analyte Peak Area:
1.132302833e+004
Peak Area Ratio:
2.83e-001

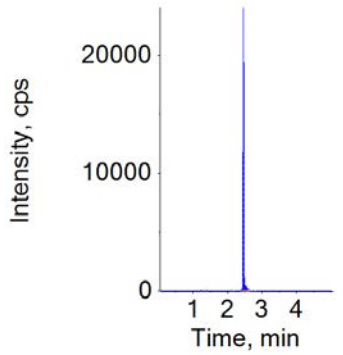


IS:
ST-247
IS Masses:
379.000/287.100 Da
IS Peak Area:
4.001269170e+004

Sample Name:	4 011 SIGA-246-022 STD 4 1 1			Plate Number:	7
Acquisition Date:	11/16/2019 10:42:29 AM	Sample Type:	Standard	Vial Position:	11

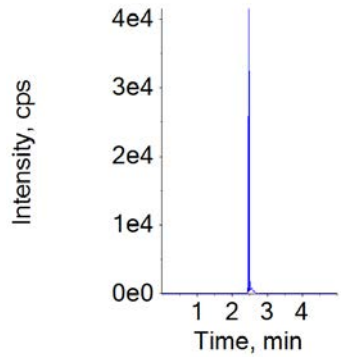


Analyte:
ST-246
Analyte Masses:
375.300/283.300 Da
Analyte Peak Area:
4.225579169e+004
Peak Area Ratio:
1.06e+000

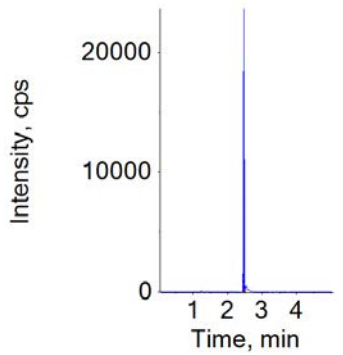


IS:
ST-247
IS Masses:
379.000/287.100 Da
IS Peak Area:
3.989837236e+004

Sample Name:	4 012 SIGA-246-022 MQC 1 1			Plate Number:	7
Acquisition Date:	11/16/2019 10:48:02 AM	Sample Type:	Quality Control	Vial Position:	12

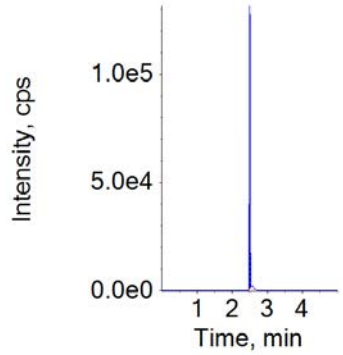


Analyte:
ST-246
Analyte Masses:
375.300/283.300 Da
Analyte Peak Area:
6.966962328e+004
Peak Area Ratio:
1.83e+000

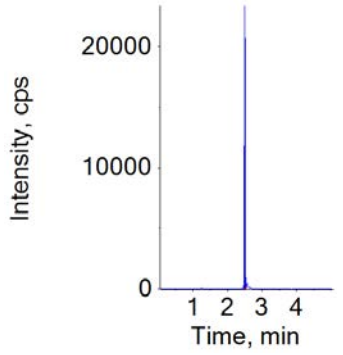


IS:
ST-247
IS Masses:
379.000/287.100 Da
IS Peak Area:
3.809022073e+004

Sample Name:	4 013 SIGA-246-022 STD 5 1 1			Plate Number:	7
Acquisition Date:	11/16/2019 10:53:35 AM	Sample Type:	Standard	Vial Position:	13

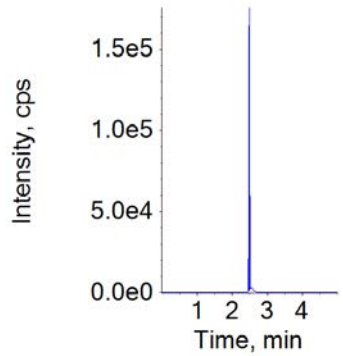


Analyte:
ST-246
Analyte Masses:
375.300/283.300 Da
Analyte Peak Area:
2.120005999e+005
Peak Area Ratio:
5.63e+000

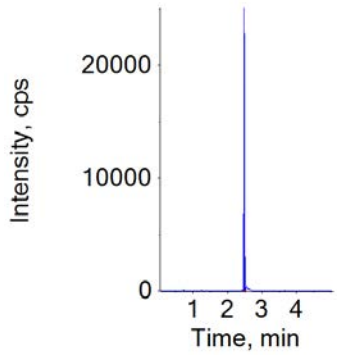


IS:
ST-247
IS Masses:
379.000/287.100 Da
IS Peak Area:
3.762778318e+004

Sample Name:	4 014 SIGA-246-022 STD 6 1 1			Plate Number:	7
Acquisition Date:	11/16/2019 10:59:10 AM	Sample Type:	Standard	Vial Position:	14

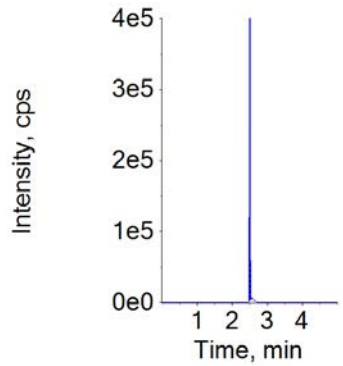


Analyte:
ST-246
Analyte Masses:
375.300/283.300 Da
Analyte Peak Area:
2.911011198e+005
Peak Area Ratio:
7.41e+000

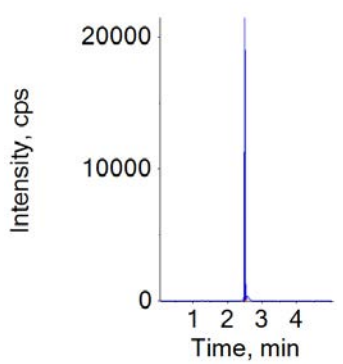


IS:
ST-247
IS Masses:
379.000/287.100 Da
IS Peak Area:
3.928978321e+004

Sample Name:	4 015 SIGA-246-022 HQC 1 1			Plate Number:	7
Acquisition Date:	11/16/2019 11:04:44 AM	Sample Type:	Quality Control	Vial Position:	15

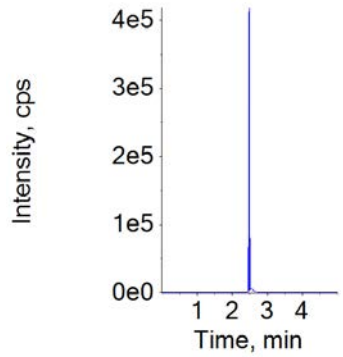


Analyte:
ST-246
Analyte Masses:
375.300/283.300 Da
Analyte Peak Area:
6.319176504e+005
Peak Area Ratio:
1.79e+001

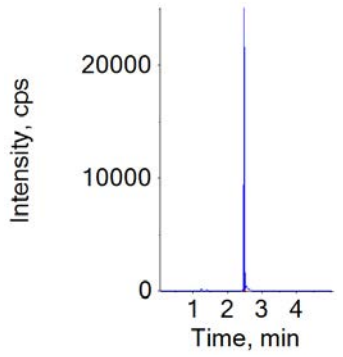


IS:
ST-247
IS Masses:
379.000/287.100 Da
IS Peak Area:
3.526737816e+004

Sample Name:	4 016 SIGA-246-022 STD 7 1 1			Plate Number:	7
Acquisition Date:	11/16/2019 11:10:17 AM	Sample Type:	Standard	Vial Position:	16

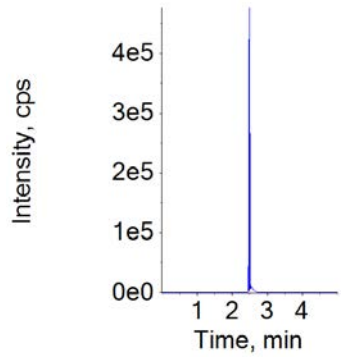


Analyte:
ST-246
Analyte Masses:
375.300/283.300 Da
Analyte Peak Area:
6.523013345e+005
Peak Area Ratio:
1.66e+001

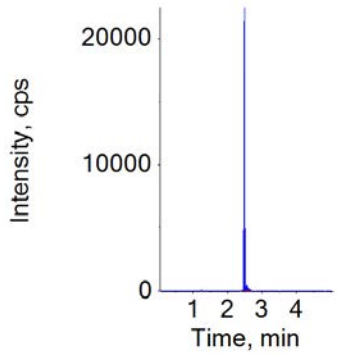


IS:
ST-247
IS Masses:
379.000/287.100 Da
IS Peak Area:
3.918546228e+004

Sample Name:	4 017 SIGA-246-022 STD 8 1 1			Plate Number:	7
Acquisition Date:	11/16/2019 11:15:51 AM	Sample Type:	Standard	Vial Position:	17

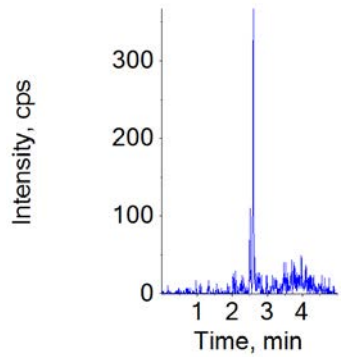


Analyte:
ST-246
Analyte Masses:
375.300/283.300 Da
Analyte Peak Area:
8.255530467e+005
Peak Area Ratio:
2.12e+001

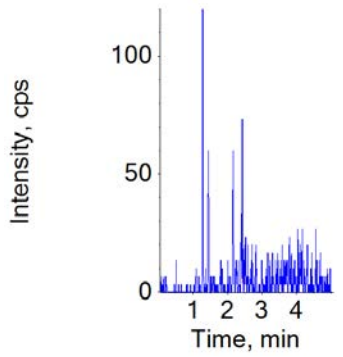


IS:
ST-247
IS Masses:
379.000/287.100 Da
IS Peak Area:
3.889533000e+004

Sample Name:	4 018 SIGA-246-022 CO DB 1 1			Plate Number:	7
Acquisition Date:	11/16/2019 11:21:24 AM	Sample Type:	Quality Control	Vial Position:	18

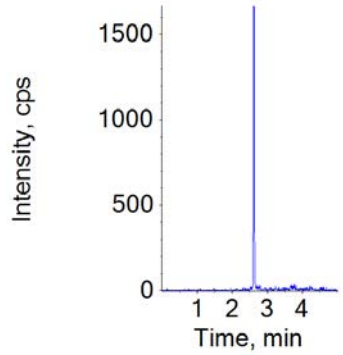


Analyte:
ST-246
Analyte Masses:
375.300/283.300 Da
Analyte Peak Area:
9.520000160e+001
Peak Area Ratio:
1.60e+000

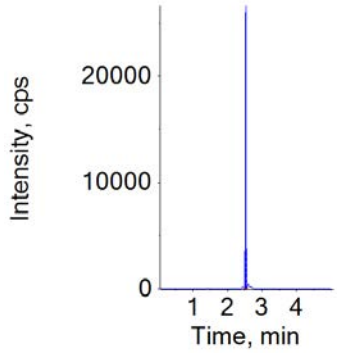


IS:
ST-247
IS Masses:
379.000/287.100 Da
IS Peak Area:
5.950333361e+001

Sample Name:	4 019 SIGA-246-022 085P813 9061 A Day 1 0h PLM-1 1			Plate Number:	7
Acquisition Date:	11/16/2019 11:26:58 AM	Sample Type:	Unknown	Vial Position:	19

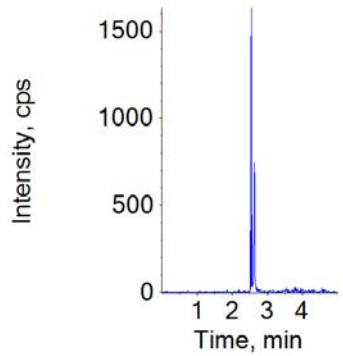


Analyte:
ST-246
Analyte Masses:
375.300/283.300 Da
Analyte Peak Area:
1.120000021e+001
Peak Area Ratio:
2.97e-004

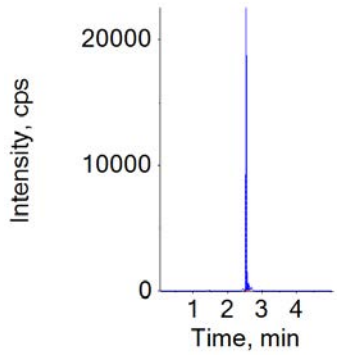


IS:
ST-247
IS Masses:
379.000/287.100 Da
IS Peak Area:
3.768111551e+004

Sample Name:	4 020 SIGA-246-022 085P814 9061 A Day 1 0.5h PLM-1 1			Plate Number:	7
Acquisition Date:	11/16/2019 11:32:33 AM	Sample Type:	Unknown	Vial Position:	20

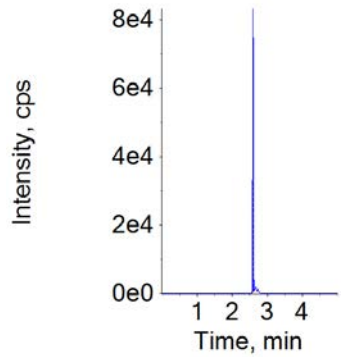


Analyte:
ST-246
Analyte Masses:
375.300/283.300 Da
Analyte Peak Area:
2.531200003e+003
Peak Area Ratio:
6.52e-002

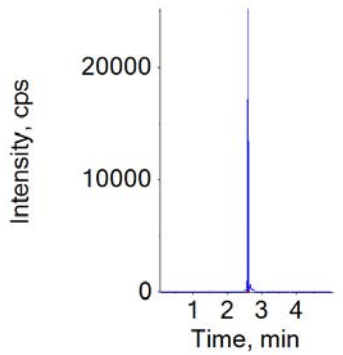


IS:
ST-247
IS Masses:
379.000/287.100 Da
IS Peak Area:
3.884336603e+004

Sample Name:	4 021 SIGA-246-022 085P815 9061 A Day 1 1h PLM-1 1			Plate Number:	7
Acquisition Date:	11/16/2019 11:38:07 AM	Sample Type:	Unknown	Vial Position:	21

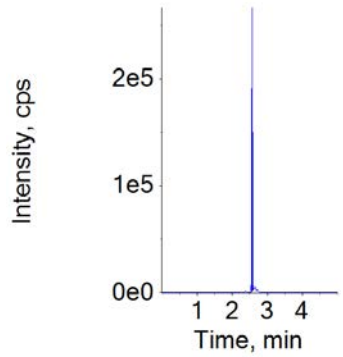


Analyte:
ST-246
Analyte Masses:
375.300/283.300 Da
Analyte Peak Area:
1.237124034e+005
Peak Area Ratio:
3.20e+000

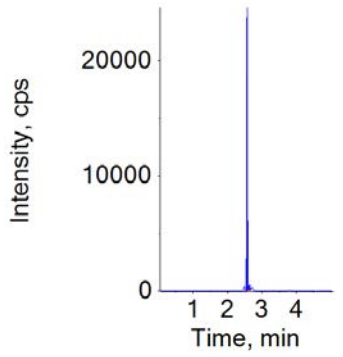


IS:
ST-247
IS Masses:
379.000/287.100 Da
IS Peak Area:
3.869524475e+004

Sample Name:	4 022 SIGA-246-022 085P816 9061 A Day 1 2h PLM-1 1			Plate Number:	7
Acquisition Date:	11/16/2019 11:43:40 AM	Sample Type:	Unknown	Vial Position:	22

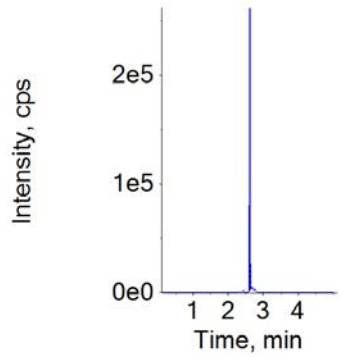


Analyte:
ST-246
Analyte Masses:
375.300/283.300 Da
Analyte Peak Area:
4.073956565e+005
Peak Area Ratio:
1.04e+001

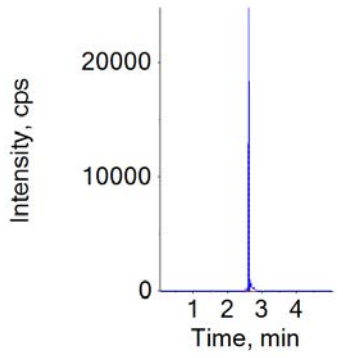


IS:
ST-247
IS Masses:
379.000/287.100 Da
IS Peak Area:
3.910999266e+004

Sample Name:	4 023 SIGA-246-022 085P817 9061 A Day 1 4h PLM-1 1			Plate Number:	7
Acquisition Date:	11/16/2019 11:49:14 AM	Sample Type:	Unknown	Vial Position:	23

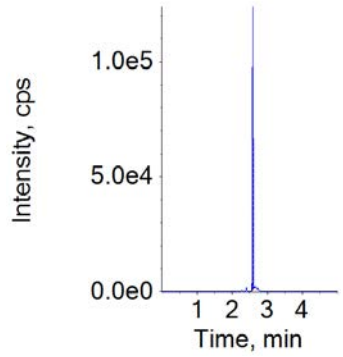


Analyte:
ST-246
Analyte Masses:
375.300/283.300 Da
Analyte Peak Area:
4.153275002e+005
Peak Area Ratio:
1.07e+001

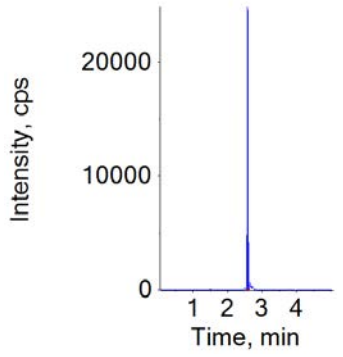


IS:
ST-247
IS Masses:
379.000/287.100 Da
IS Peak Area:
3.885607379e+004

Sample Name:	4 024 SIGA-246-022 085P818 9061 A Day 1 6h PLM-1 1			Plate Number:	7
Acquisition Date:	11/16/2019 11:54:48 AM	Sample Type:	Unknown	Vial Position:	24

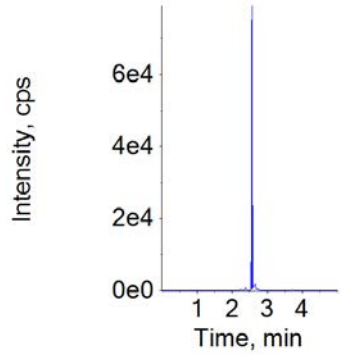


Analyte:
ST-246
Analyte Masses:
375.300/283.300 Da
Analyte Peak Area:
1.876873751e+005
Peak Area Ratio:
4.88e+000

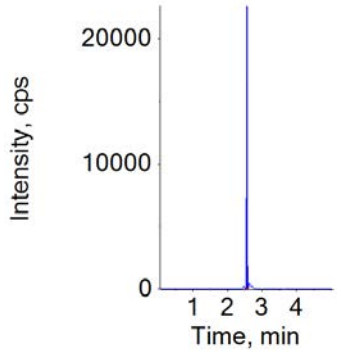


IS:
ST-247
IS Masses:
379.000/287.100 Da
IS Peak Area:
3.847659143e+004

Sample Name:	4 025 SIGA-246-022 085P819 9061 A Day 1 8h PLM-1 1			Plate Number:	7
Acquisition Date:	11/16/2019 12:00:21 PM	Sample Type:	Unknown	Vial Position:	25

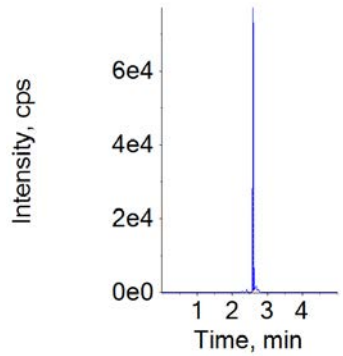


Analyte:
ST-246
Analyte Masses:
375.300/283.300 Da
Analyte Peak Area:
1.216227883e+005
Peak Area Ratio:
3.44e+000

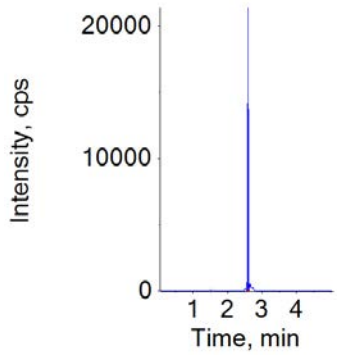


IS:
ST-247
IS Masses:
379.000/287.100 Da
IS Peak Area:
3.532737671e+004

Sample Name:	4 026 SIGA-246-022 085P820 9061 A Day 1 12h PLM-1 1			Plate Number:	7
Acquisition Date:	11/16/2019 12:05:55 PM	Sample Type:	Unknown	Vial Position:	26

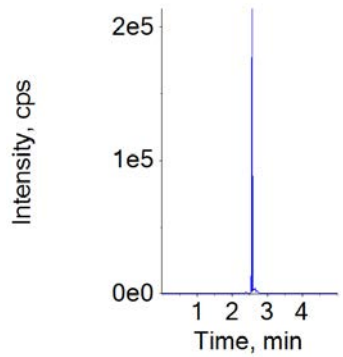


Analyte:
ST-246
Analyte Masses:
375.300/283.300 Da
Analyte Peak Area:
1.248485251e+005
Peak Area Ratio:
3.60e+000

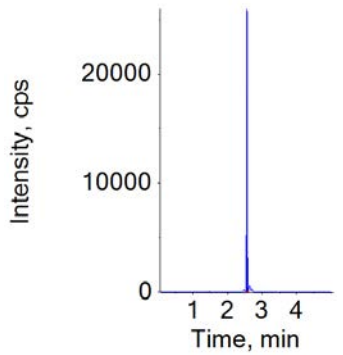


IS:
ST-247
IS Masses:
379.000/287.100 Da
IS Peak Area:
3.468694154e+004

Sample Name:	4 027 SIGA-246-022 085P821 9061 A Day 1 14h PLM-1 1			Plate Number:	7
Acquisition Date:	11/16/2019 12:11:31 PM	Sample Type:	Unknown	Vial Position:	27

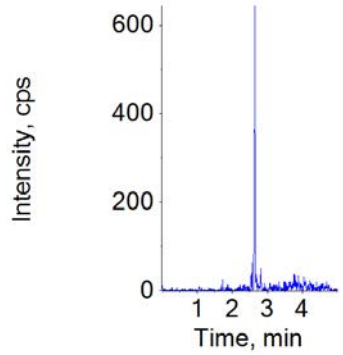


Analyte:
ST-246
Analyte Masses:
375.300/283.300 Da
Analyte Peak Area:
3.309478300e+005
Peak Area Ratio:
8.26e+000

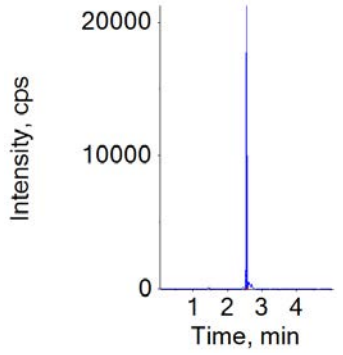


IS:
ST-247
IS Masses:
379.000/287.100 Da
IS Peak Area:
4.006866606e+004

Sample Name:	4 028 SIGA-246-022 085P610 9062 A Day 1 0h PLM-1 1			Plate Number:	7
Acquisition Date:	11/16/2019 12:17:06 PM	Sample Type:	Unknown	Vial Position:	28

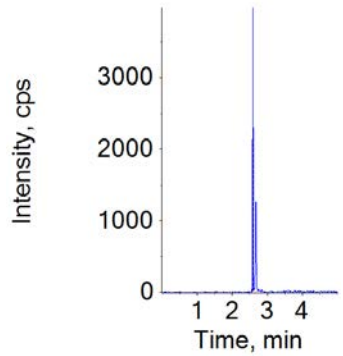


Analyte:	
ST-246	
Analyte Masses:	
375.300/283.300 Da	
Analyte Peak Area:	
4.586666667e+001	
Peak Area Ratio:	
1.27e-003	

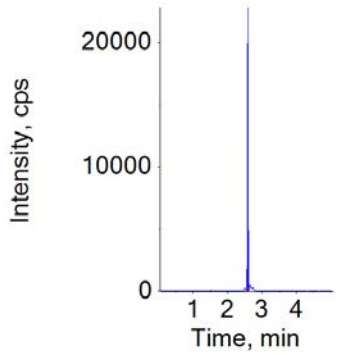


IS:	
ST-247	
IS Masses:	
379.000/287.100 Da	
IS Peak Area:	
3.606442810e+004	

Sample Name:	4 029 SIGA-246-022 085P611 9062 A Day 1 0.5h PLM-1 1			Plate Number:	7
Acquisition Date:	11/16/2019 12:22:39 PM	Sample Type:	Unknown	Vial Position:	29

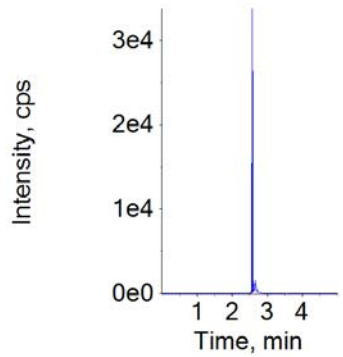


Analyte:	
ST-246	
Analyte Masses:	
375.300/283.300 Da	
Analyte Peak Area:	
5.751781669e+003	
Peak Area Ratio:	
1.59e-001	

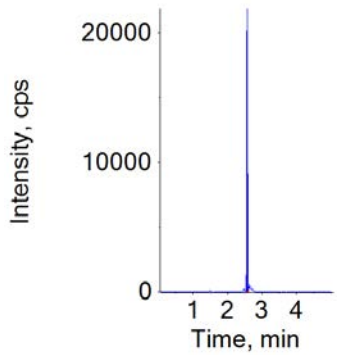


IS:	
ST-247	
IS Masses:	
379.000/287.100 Da	
IS Peak Area:	
3.611766623e+004	

Sample Name:	4 030 SIGA-246-022 085P612 9062 A Day 1 1h PLM-1 1			Plate Number:	7
Acquisition Date:	11/16/2019 12:28:13 PM	Sample Type:	Unknown	Vial Position:	30

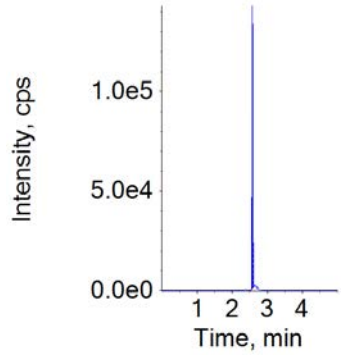


Analyte:	
ST-246	
Analyte Masses:	
375.300/283.300 Da	
Analyte Peak Area:	
4.961209000e+004	
Peak Area Ratio:	
1.41e+000	

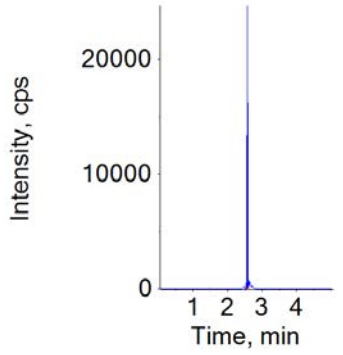


IS:	
ST-247	
IS Masses:	
379.000/287.100 Da	
IS Peak Area:	
3.514948914e+004	

Sample Name:	4 031 SIGA-246-022 085P613 9062 A Day 1 2h PLM-1 1			Plate Number:	7
Acquisition Date:	11/16/2019 12:33:48 PM	Sample Type:	Unknown	Vial Position:	31

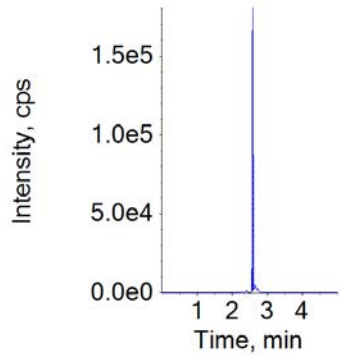


Analyte:
ST-246
Analyte Masses:
375.300/283.300 Da
Analyte Peak Area:
2.456151068e+005
Peak Area Ratio:
6.75e+000

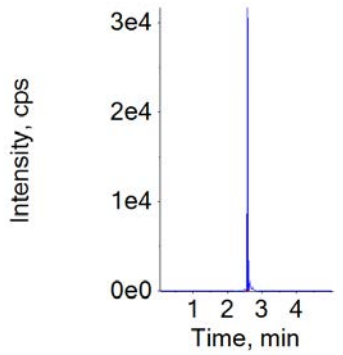


IS:
ST-247
IS Masses:
379.000/287.100 Da
IS Peak Area:
3.640597137e+004

Sample Name:	4 032 SIGA-246-022 085P614 9062 A Day 1 4h PLM-1 1			Plate Number:	7
Acquisition Date:	11/16/2019 12:39:24 PM	Sample Type:	Unknown	Vial Position:	32

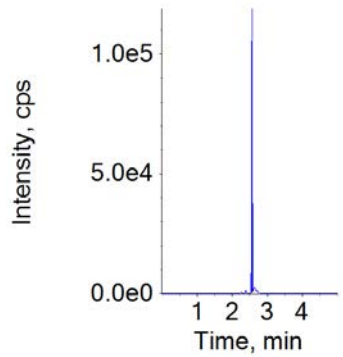


Analyte:
ST-246
Analyte Masses:
375.300/283.300 Da
Analyte Peak Area:
3.088776431e+005
Peak Area Ratio:
6.46e+000

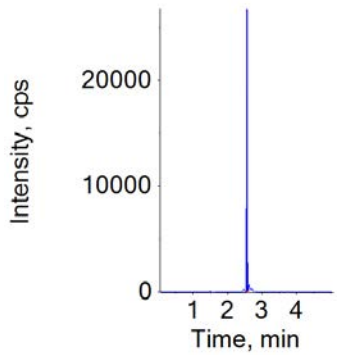


IS:
ST-247
IS Masses:
379.000/287.100 Da
IS Peak Area:
4.785036711e+004

Sample Name:	4 033 SIGA-246-022 085P615 9062 A Day 1 6h PLM-1 1			Plate Number:	7
Acquisition Date:	11/16/2019 12:44:57 PM	Sample Type:	Unknown	Vial Position:	33

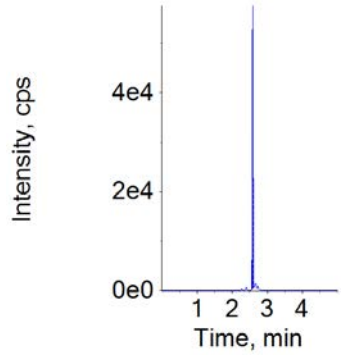


Analyte:
ST-246
Analyte Masses:
375.300/283.300 Da
Analyte Peak Area:
1.755102501e+005
Peak Area Ratio:
4.07e+000

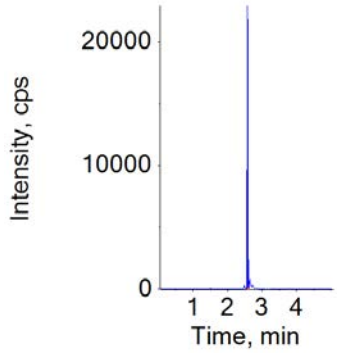


IS:
ST-247
IS Masses:
379.000/287.100 Da
IS Peak Area:
4.307469823e+004

Sample Name:	4 034 SIGA-246-022 085P616 9062 A Day 1 8h PLM-1 1			Plate Number:	7
Acquisition Date:	11/16/2019 12:50:31 PM	Sample Type:	Unknown	Vial Position:	34

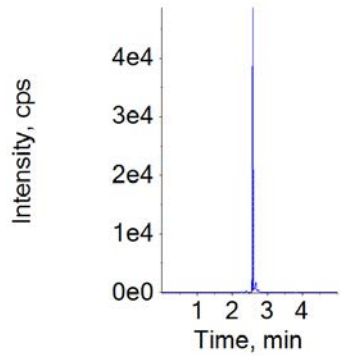


Analyte:
ST-246
Analyte Masses:
375.300/283.300 Da
Analyte Peak Area:
9.641593839e+004
Peak Area Ratio:
2.57e+000

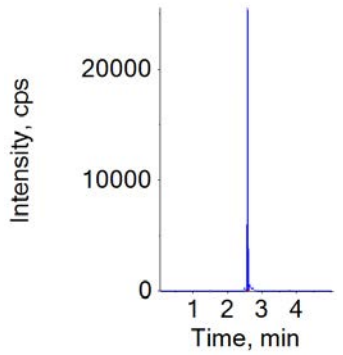


IS:
ST-247
IS Masses:
379.000/287.100 Da
IS Peak Area:
3.754572217e+004

Sample Name:	4 035 SIGA-246-022 085P617 9062 A Day 1 12h PLM-1 1			Plate Number:	7
Acquisition Date:	11/16/2019 12:56:05 PM	Sample Type:	Unknown	Vial Position:	35

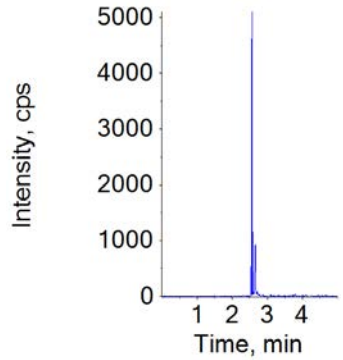


Analyte:
ST-246
Analyte Masses:
375.300/283.300 Da
Analyte Peak Area:
7.025529495e+004
Peak Area Ratio:
1.74e+000

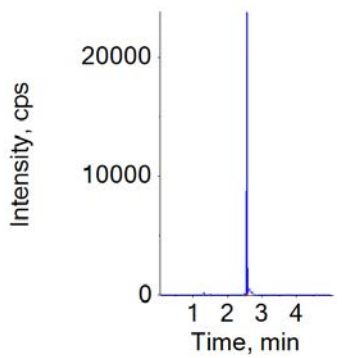


IS:
ST-247
IS Masses:
379.000/287.100 Da
IS Peak Area:
4.033016607e+004

Sample Name:	4 036 SIGA-246-022 LQC 2 1			Plate Number:	7
Acquisition Date:	11/16/2019 1:01:38 PM	Sample Type:	Quality Control	Vial Position:	36

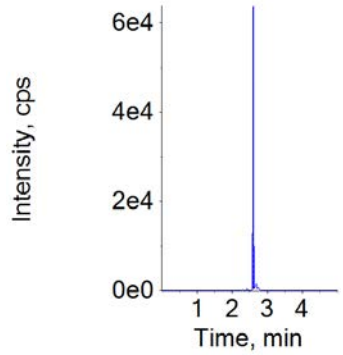


Analyte:
ST-246
Analyte Masses:
375.300/283.300 Da
Analyte Peak Area:
7.604598334e+003
Peak Area Ratio:
1.93e-001

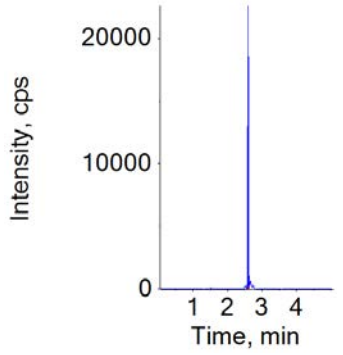


IS:
ST-247
IS Masses:
379.000/287.100 Da
IS Peak Area:
3.939302108e+004

Sample Name:	4 037 SIGA-246-022 085P618 9062 A Day 1 14h PLM-1 1			Plate Number:	7
Acquisition Date:	11/16/2019 1:07:13 PM	Sample Type:	Unknown	Vial Position:	37

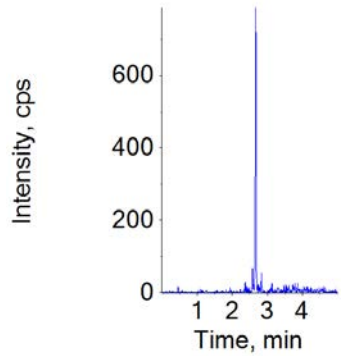


Analyte:
ST-246
Analyte Masses:
375.300/283.300 Da
Analyte Peak Area:
1.006860800e+005
Peak Area Ratio:
2.72e+000

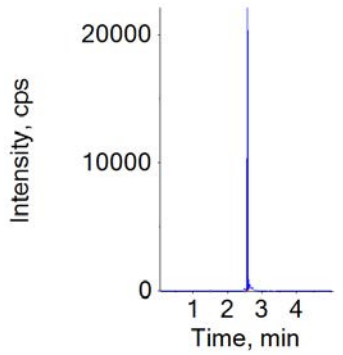


IS:
ST-247
IS Masses:
379.000/287.100 Da
IS Peak Area:
3.704987913e+004

Sample Name:	4 038 SIGA-246-022 085P639 9063 A Day 1 0h PLM-1 1			Plate Number:	7
Acquisition Date:	11/16/2019 1:12:47 PM	Sample Type:	Unknown	Vial Position:	38

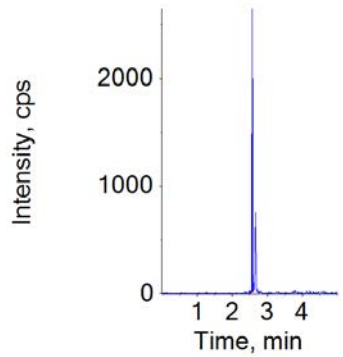


Analyte:
ST-246
Analyte Masses:
375.300/283.300 Da
Analyte Peak Area:
8.369833373e+001
Peak Area Ratio:
2.32e-003

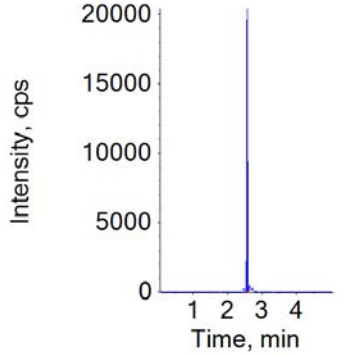


IS:
ST-247
IS Masses:
379.000/287.100 Da
IS Peak Area:
3.605918192e+004

Sample Name:	4 039 SIGA-246-022 085P640 9063 A Day 1 0.5h PLM-1 1			Plate Number:	7
Acquisition Date:	11/16/2019 1:18:23 PM	Sample Type:	Unknown	Vial Position:	39

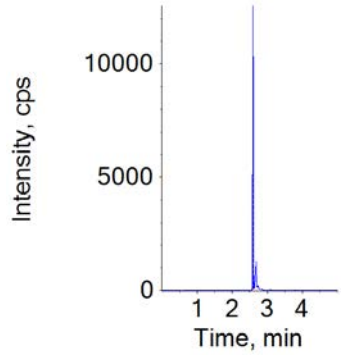


Analyte:
ST-246
Analyte Masses:
375.300/283.300 Da
Analyte Peak Area:
4.109446668e+003
Peak Area Ratio:
1.14e-001

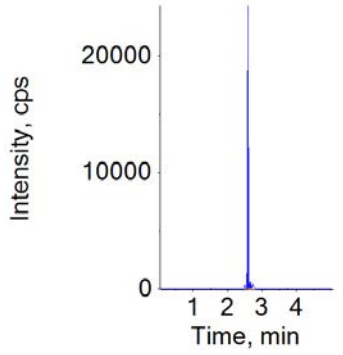


IS:
ST-247
IS Masses:
379.000/287.100 Da
IS Peak Area:
3.600564543e+004

Sample Name:	4 040 SIGA-246-022 085P641 9063 A Day 1 1h PLM-1 1			Plate Number:	7
Acquisition Date:	11/16/2019 1:23:57 PM	Sample Type:	Unknown	Vial Position:	40

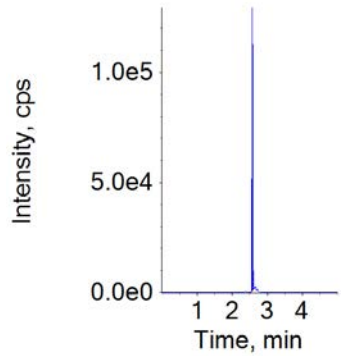


Analyte:
ST-246
Analyte Masses:
375.300/283.300 Da
Analyte Peak Area:
1.844668501e+004
Peak Area Ratio:
4.58e-001

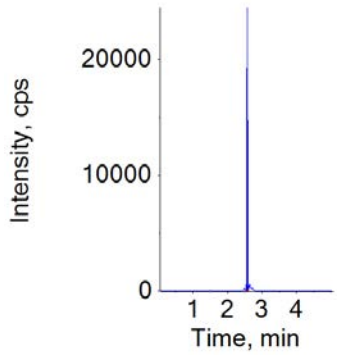


IS:
ST-247
IS Masses:
379.000/287.100 Da
IS Peak Area:
4.031398692e+004

Sample Name:	4 041 SIGA-246-022 085P642 9063 A Day 1 2h PLM-1 1			Plate Number:	7
Acquisition Date:	11/16/2019 1:29:32 PM	Sample Type:	Unknown	Vial Position:	41

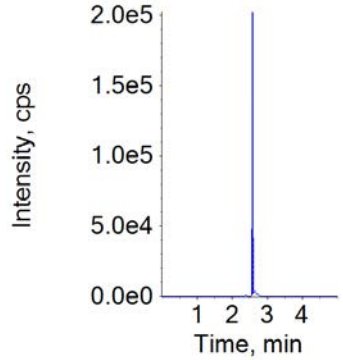


Analyte:
ST-246
Analyte Masses:
375.300/283.300 Da
Analyte Peak Area:
1.925715284e+005
Peak Area Ratio:
5.04e+000

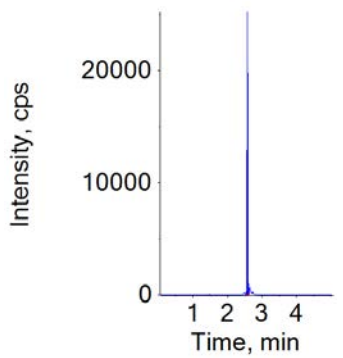


IS:
ST-247
IS Masses:
379.000/287.100 Da
IS Peak Area:
3.822959459e+004

Sample Name:	4 042 SIGA-246-022 085P643 9063 A Day 1 4h PLM-1 1			Plate Number:	7
Acquisition Date:	11/16/2019 1:35:06 PM	Sample Type:	Unknown	Vial Position:	42

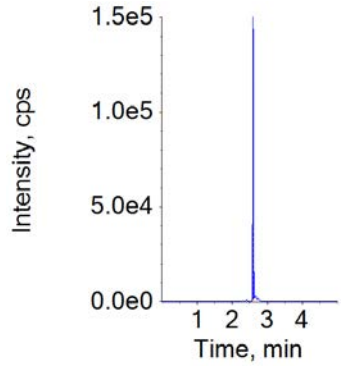


Analyte:
ST-246
Analyte Masses:
375.300/283.300 Da
Analyte Peak Area:
3.335186215e+005
Peak Area Ratio:
8.45e+000

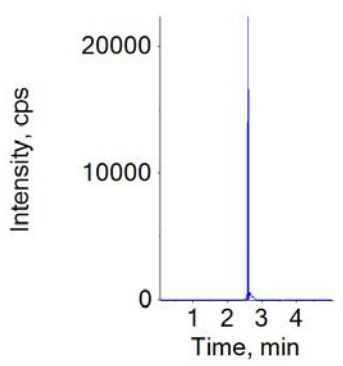


IS:
ST-247
IS Masses:
379.000/287.100 Da
IS Peak Area:
3.947829538e+004

Sample Name:	4 043 SIGA-246-022 085P644 9063 A Day 1 6h PLM-1 1			Plate Number:	7
Acquisition Date:	11/16/2019 1:40:41 PM	Sample Type:	Unknown	Vial Position:	43

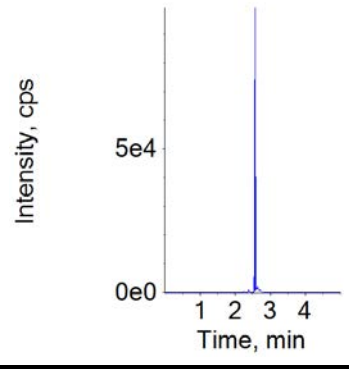


Analyte:
ST-246
Analyte Masses:
375.300/283.300 Da
Analyte Peak Area:
2.290863519e+005
Peak Area Ratio:
6.33e+000

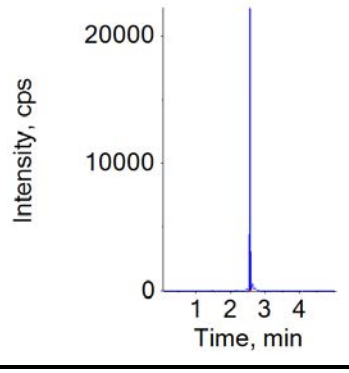


IS:
ST-247
IS Masses:
379.000/287.100 Da
IS Peak Area:
3.617875974e+004

Sample Name:	4 044 SIGA-246-022 085P645 9063 A Day 1 8h PLM-1 1			Plate Number:	7
Acquisition Date:	11/16/2019 1:46:15 PM	Sample Type:	Unknown	Vial Position:	44

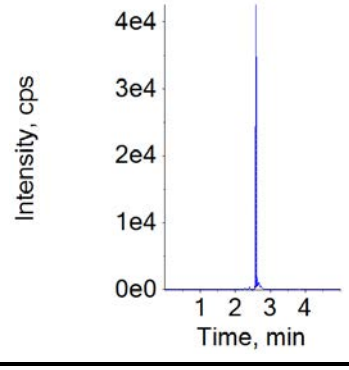


Analyte:
ST-246
Analyte Masses:
375.300/283.300 Da
Analyte Peak Area:
1.471833100e+005
Peak Area Ratio:
4.23e+000

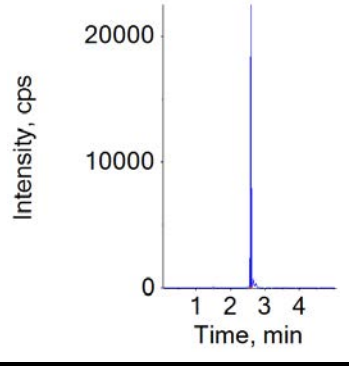


IS:
ST-247
IS Masses:
379.000/287.100 Da
IS Peak Area:
3.480711329e+004

Sample Name:	4 045 SIGA-246-022 085P646 9063 A Day 1 12h PLM-1 1			Plate Number:	7
Acquisition Date:	11/16/2019 1:51:50 PM	Sample Type:	Unknown	Vial Position:	45

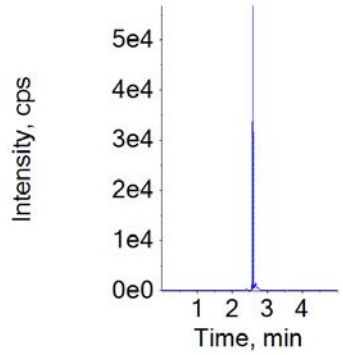


Analyte:
ST-246
Analyte Masses:
375.300/283.300 Da
Analyte Peak Area:
6.700168661e+004
Peak Area Ratio:
1.88e+000

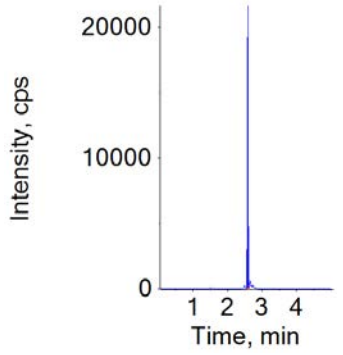


IS:
ST-247
IS Masses:
379.000/287.100 Da
IS Peak Area:
3.559079725e+004

Sample Name:	4 046 SIGA-246-022 085P647 9063 A Day 1 14h PLM-1 1			Plate Number:	7
Acquisition Date:	11/16/2019 1:57:24 PM	Sample Type:	Unknown	Vial Position:	46

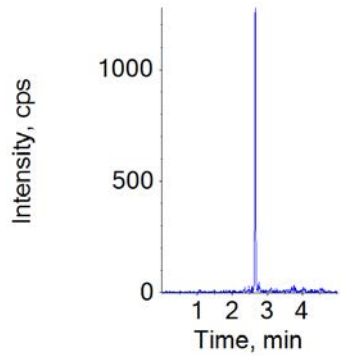


Analyte:
ST-246
Analyte Masses:
375.300/283.300 Da
Analyte Peak Area:
7.855134838e+004
Peak Area Ratio:
2.21e+000

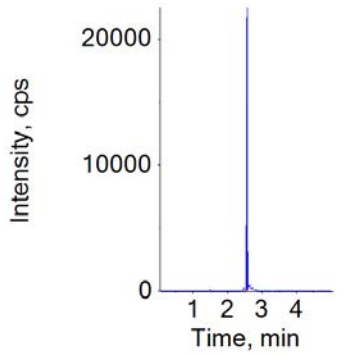


IS:
ST-247
IS Masses:
379.000/287.100 Da
IS Peak Area:
3.547585935e+004

Sample Name:	4 047 SIGA-246-022 085P842 9069 A Day 1 0h PLM-1 1			Plate Number:	7
Acquisition Date:	11/16/2019 2:02:59 PM	Sample Type:	Unknown	Vial Position:	47

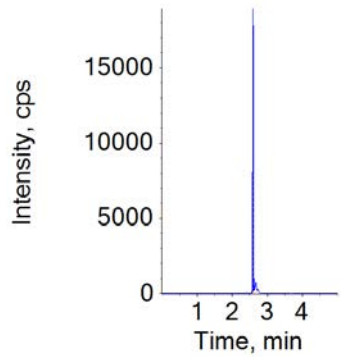


Analyte:
ST-246
Analyte Masses:
375.300/283.300 Da
Analyte Peak Area:
4.832833333e+001
Peak Area Ratio:
1.39e-003

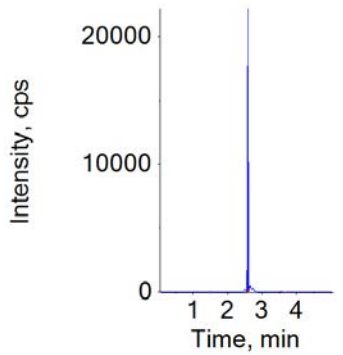


IS:
ST-247
IS Masses:
379.000/287.100 Da
IS Peak Area:
3.488228477e+004

Sample Name:	4 048 SIGA-246-022 085P843 9069 A Day 1 0.5h PLM-1 1			Plate Number:	7
Acquisition Date:	11/16/2019 2:08:33 PM	Sample Type:	Unknown	Vial Position:	48

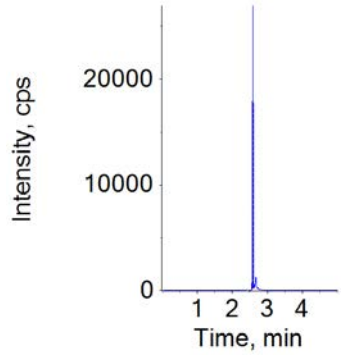


Analyte:
ST-246
Analyte Masses:
375.300/283.300 Da
Analyte Peak Area:
2.918731668e+004
Peak Area Ratio:
8.13e-001

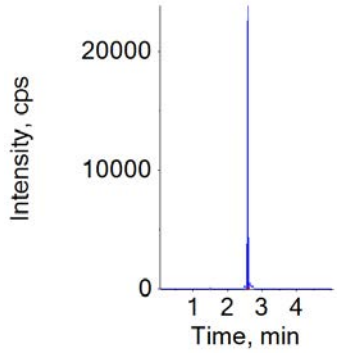


IS:
ST-247
IS Masses:
379.000/287.100 Da
IS Peak Area:
3.591772033e+004

Sample Name:	4 049 SIGA-246-022 085P844 9069 A Day 1 1h PLM-1 1			Plate Number:	7
Acquisition Date:	11/16/2019 2:14:07 PM	Sample Type:	Unknown	Vial Position:	49

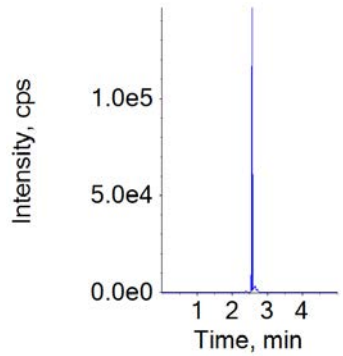


Analyte:
ST-246
Analyte Masses:
375.300/283.300 Da
Analyte Peak Area:
4.137511331e+004
Peak Area Ratio:
1.13e+000

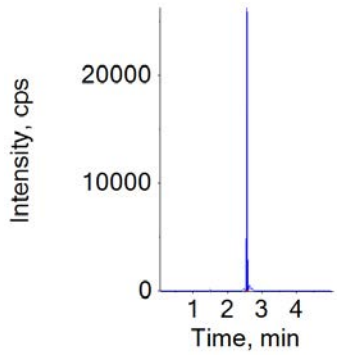


IS:
ST-247
IS Masses:
379.000/287.100 Da
IS Peak Area:
3.652477776e+004

Sample Name:	4 050 SIGA-246-022 085P845 9069 A Day 1 2h PLM-1 1			Plate Number:	7
Acquisition Date:	11/16/2019 2:19:43 PM	Sample Type:	Unknown	Vial Position:	50

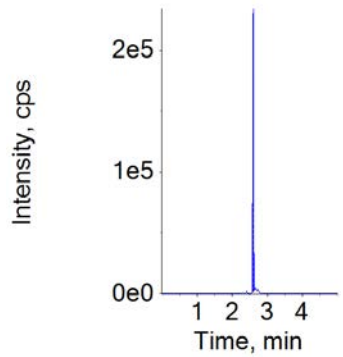


Analyte:
ST-246
Analyte Masses:
375.300/283.300 Da
Analyte Peak Area:
2.296332667e+005
Peak Area Ratio:
5.95e+000

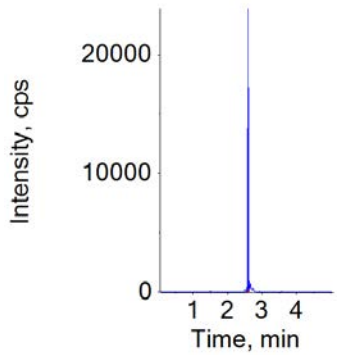


IS:
ST-247
IS Masses:
379.000/287.100 Da
IS Peak Area:
3.861520049e+004

Sample Name:	4 051 SIGA-246-022 085P846 9069 A Day 1 4h PLM-1 1			Plate Number:	7
Acquisition Date:	11/16/2019 2:25:19 PM	Sample Type:	Unknown	Vial Position:	51

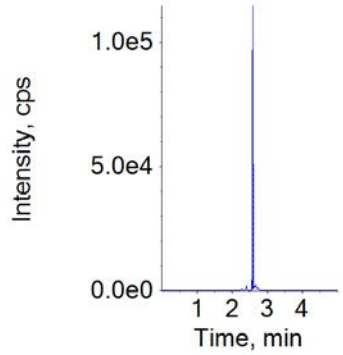


Analyte:
ST-246
Analyte Masses:
375.300/283.300 Da
Analyte Peak Area:
3.977427667e+005
Peak Area Ratio:
1.06e+001

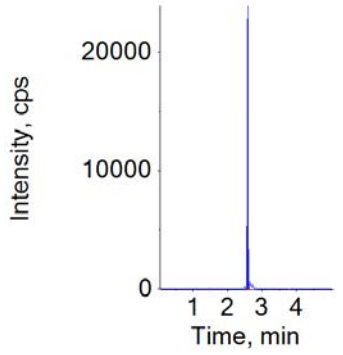


IS:
ST-247
IS Masses:
379.000/287.100 Da
IS Peak Area:
3.752370236e+004

Sample Name:	4 052 SIGA-246-022 085P847 9069 A Day 1 6h PLM-1 1			Plate Number:	7
Acquisition Date:	11/16/2019 2:30:54 PM	Sample Type:	Unknown	Vial Position:	52

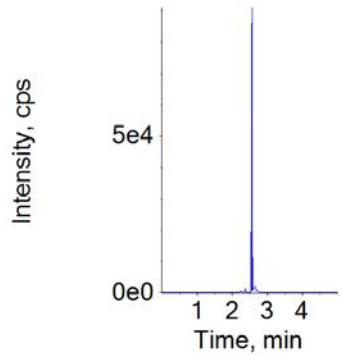


Analyte:
ST-246
Analyte Masses:
375.300/283.300 Da
Analyte Peak Area:
1.686776399e+005
Peak Area Ratio:
4.45e+000

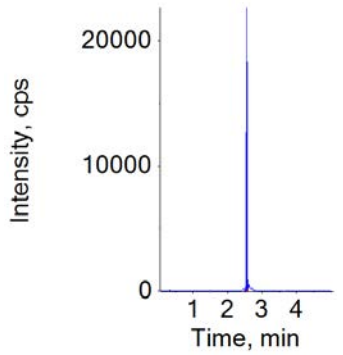


IS:
ST-247
IS Masses:
379.000/287.100 Da
IS Peak Area:
3.790002763e+004

Sample Name:	4 053 SIGA-246-022 085P848 9069 A Day 1 8h PLM-1 1			Plate Number:	7
Acquisition Date:	11/16/2019 2:36:28 PM	Sample Type:	Unknown	Vial Position:	53

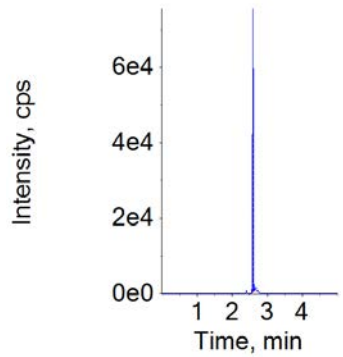


Analyte:
ST-246
Analyte Masses:
375.300/283.300 Da
Analyte Peak Area:
1.340991849e+005
Peak Area Ratio:
3.67e+000

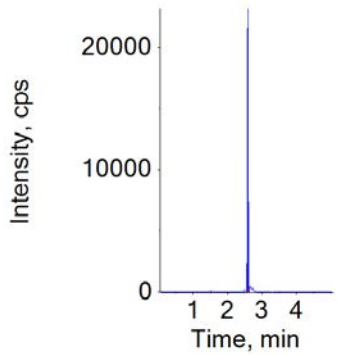


IS:
ST-247
IS Masses:
379.000/287.100 Da
IS Peak Area:
3.656885932e+004

Sample Name:	4 054 SIGA-246-022 085P849 9069 A Day 1 12h PLM-1 1			Plate Number:	7
Acquisition Date:	11/16/2019 2:42:02 PM	Sample Type:	Unknown	Vial Position:	54

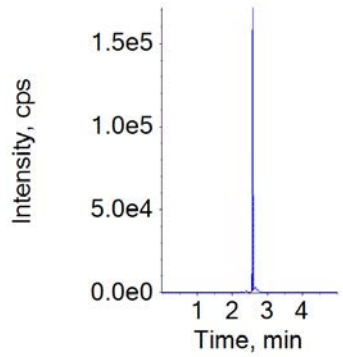


Analyte:
ST-246
Analyte Masses:
375.300/283.300 Da
Analyte Peak Area:
1.179335049e+005
Peak Area Ratio:
3.14e+000

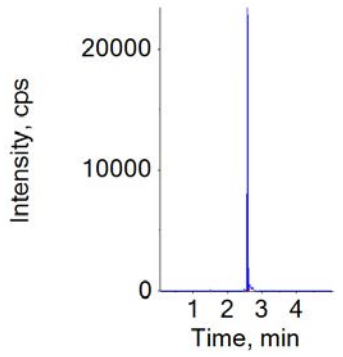


IS:
ST-247
IS Masses:
379.000/287.100 Da
IS Peak Area:
3.757019363e+004

Sample Name:	4 055 SIGA-246-022 085P850 9069 A Day 1 14h PLM-1 1			Plate Number:	7
Acquisition Date:	11/16/2019 2:47:37 PM	Sample Type:	Unknown	Vial Position:	55

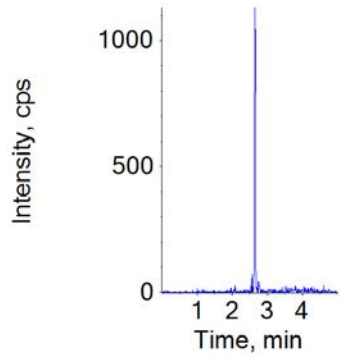


Analyte:
ST-246
Analyte Masses:
375.300/283.300 Da
Analyte Peak Area:
2.591802699e+005
Peak Area Ratio:
6.97e+000

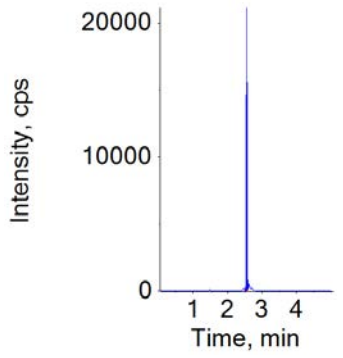


IS:
ST-247
IS Masses:
379.000/287.100 Da
IS Peak Area:
3.721035231e+004

Sample Name:	4 056 SIGA-246-022 085P1074 9073 A Day 1 0h PLM-1 1			Plate Number:	7
Acquisition Date:	11/16/2019 2:53:11 PM	Sample Type:	Unknown	Vial Position:	56

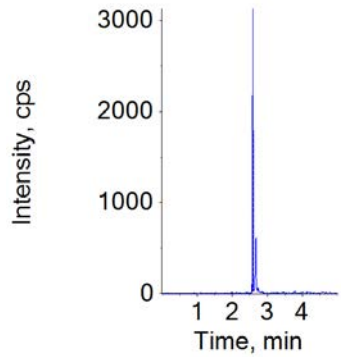


Analyte:
ST-246
Analyte Masses:
375.300/283.300 Da
Analyte Peak Area:
1.134216667e+002
Peak Area Ratio:
3.21e-003

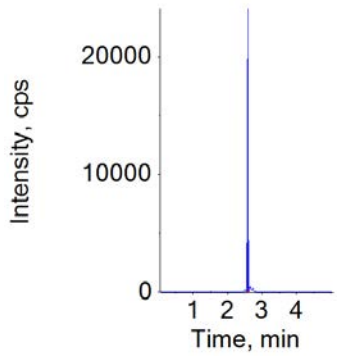


IS:
ST-247
IS Masses:
379.000/287.100 Da
IS Peak Area:
3.537143364e+004

Sample Name:	4 057 SIGA-246-022 085P1075 9073 A Day 1 0.5h PLM-1 1			Plate Number:	7
Acquisition Date:	11/16/2019 2:58:45 PM	Sample Type:	Unknown	Vial Position:	57

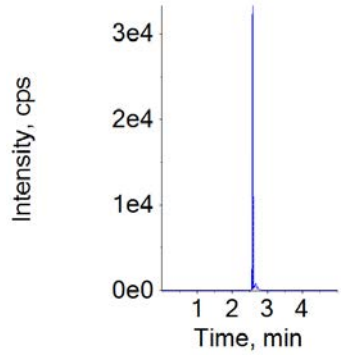


Analyte:
ST-246
Analyte Masses:
375.300/283.300 Da
Analyte Peak Area:
4.724604997e+003
Peak Area Ratio:
1.24e-001

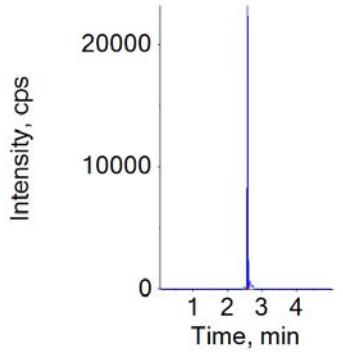


IS:
ST-247
IS Masses:
379.000/287.100 Da
IS Peak Area:
3.803520460e+004

Sample Name:	4 058 SIGA-246-022 085P1076 9073 A Day 1 1h PLM-1 1			Plate Number:	7
Acquisition Date:	11/16/2019 3:04:21 PM	Sample Type:	Unknown	Vial Position:	58

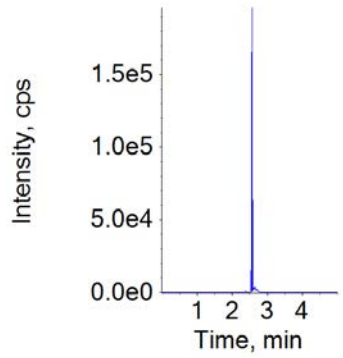


Analyte:
ST-246
Analyte Masses:
375.300/283.300 Da
Analyte Peak Area:
5.117486667e+004
Peak Area Ratio:
1.40e+000

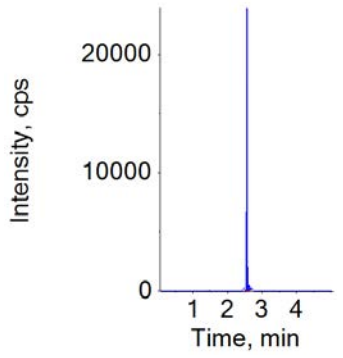


IS:
ST-247
IS Masses:
379.000/287.100 Da
IS Peak Area:
3.643881337e+004

Sample Name:	4 059 SIGA-246-022 085P1077 9073 A Day 1 2h PLM-1 1			Plate Number:	7
Acquisition Date:	11/16/2019 3:09:55 PM	Sample Type:	Unknown	Vial Position:	59

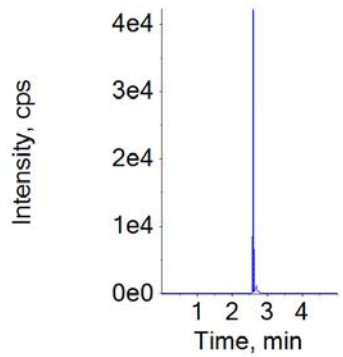


Analyte:
ST-246
Analyte Masses:
375.300/283.300 Da
Analyte Peak Area:
2.972803167e+005
Peak Area Ratio:
7.78e+000

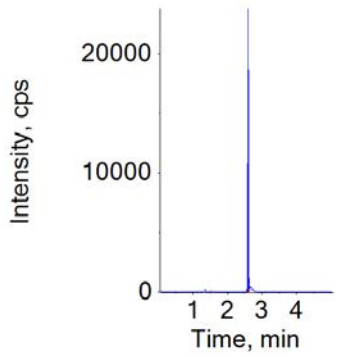


IS:
ST-247
IS Masses:
379.000/287.100 Da
IS Peak Area:
3.819240643e+004

Sample Name:	4 060 SIGA-246-022 MQC 2 1			Plate Number:	7
Acquisition Date:	11/16/2019 3:15:29 PM	Sample Type:	Quality Control	Vial Position:	60

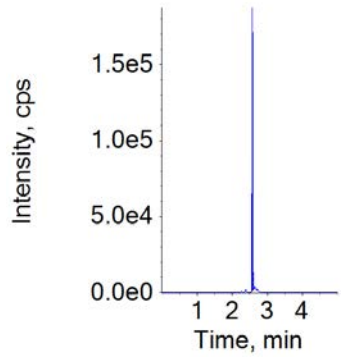


Analyte:
ST-246
Analyte Masses:
375.300/283.300 Da
Analyte Peak Area:
6.558146503e+004
Peak Area Ratio:
1.84e+000

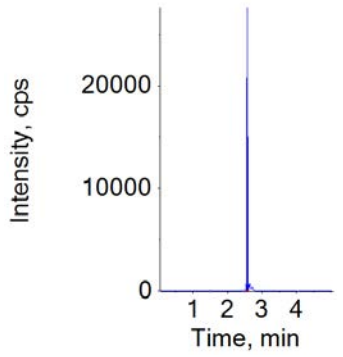


IS:
ST-247
IS Masses:
379.000/287.100 Da
IS Peak Area:
3.572575014e+004

Sample Name:	4 061 SIGA-246-022 085P1078 9073 A Day 1 4h PLM-1 1			Plate Number:	7
Acquisition Date:	11/16/2019 3:21:03 PM	Sample Type:	Unknown	Vial Position:	61

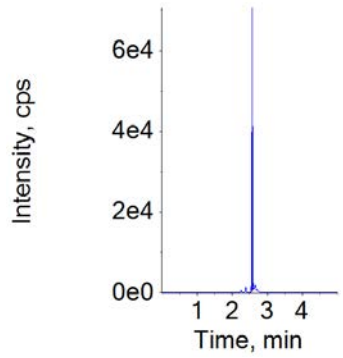


Analyte:
ST-246
Analyte Masses:
375.300/283.300 Da
Analyte Peak Area:
2.971708948e+005
Peak Area Ratio:
6.98e+000

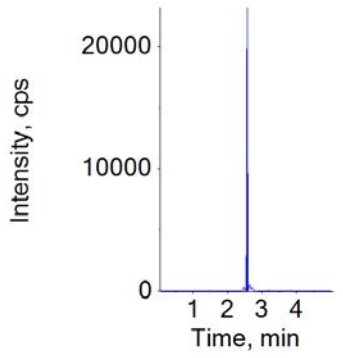


IS:
ST-247
IS Masses:
379.000/287.100 Da
IS Peak Area:
4.258752647e+004

Sample Name:	4 062 SIGA-246-022 085P1079 9073 A Day 1 6h PLM-1 1			Plate Number:	7
Acquisition Date:	11/16/2019 3:26:39 PM	Sample Type:	Unknown	Vial Position:	62

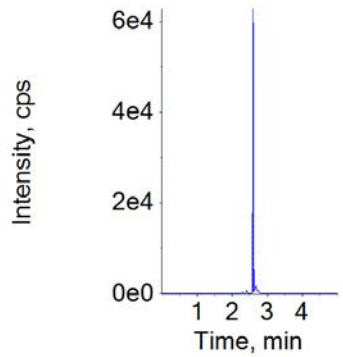


Analyte:
ST-246
Analyte Masses:
375.300/283.300 Da
Analyte Peak Area:
1.034520250e+005
Peak Area Ratio:
2.63e+000

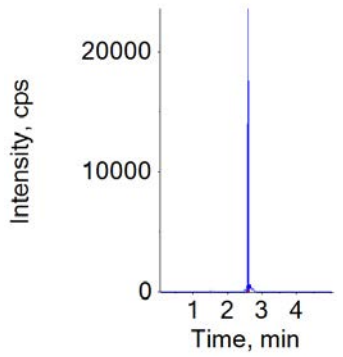


IS:
ST-247
IS Masses:
379.000/287.100 Da
IS Peak Area:
3.934318951e+004

Sample Name:	4 063 SIGA-246-022 085P1080 9073 A Day 1 8h PLM-1 1			Plate Number:	7
Acquisition Date:	11/16/2019 3:32:15 PM	Sample Type:	Unknown	Vial Position:	63

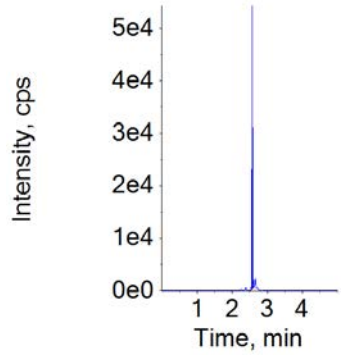


Analyte:
ST-246
Analyte Masses:
375.300/283.300 Da
Analyte Peak Area:
9.278530662e+004
Peak Area Ratio:
2.49e+000

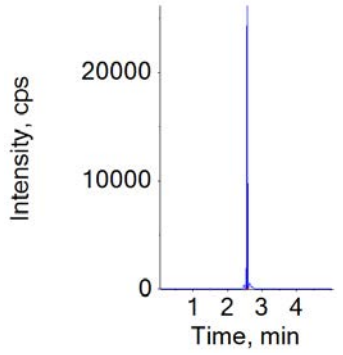


IS:
ST-247
IS Masses:
379.000/287.100 Da
IS Peak Area:
3.721049632e+004

Sample Name:	4 064 SIGA-246-022 085P1081 9073 A Day 1 12h PLM-1 1			Plate Number:	7
Acquisition Date:	11/16/2019 3:37:52 PM	Sample Type:	Unknown	Vial Position:	64

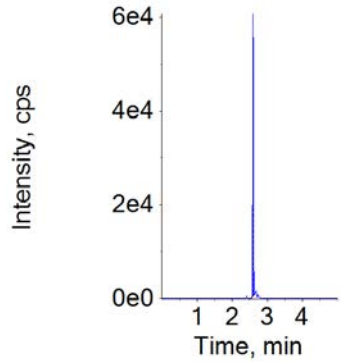


Analyte:	
ST-246	
Analyte Masses:	
375.300/283.300 Da	
Analyte Peak Area:	
7.400845000e+004	
Peak Area Ratio:	
1.81e+000	

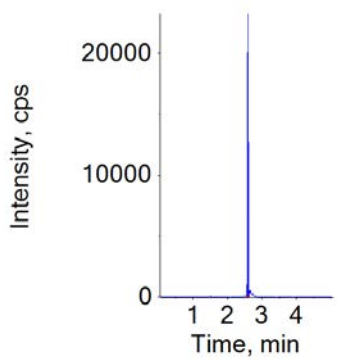


IS:	
ST-247	
IS Masses:	
379.000/287.100 Da	
IS Peak Area:	
4.079889549e+004	

Sample Name:	4 065 SIGA-246-022 085P1082 9073 A Day 1 14h PLM-1 1			Plate Number:	7
Acquisition Date:	11/16/2019 3:43:28 PM	Sample Type:	Unknown	Vial Position:	65

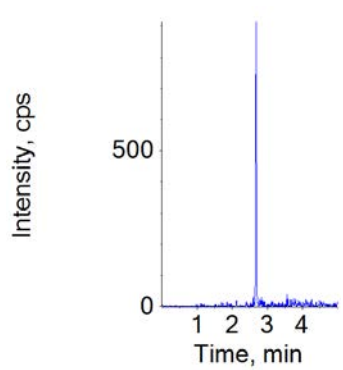


Analyte:	
ST-246	
Analyte Masses:	
375.300/283.300 Da	
Analyte Peak Area:	
9.113383995e+004	
Peak Area Ratio:	
2.30e+000	

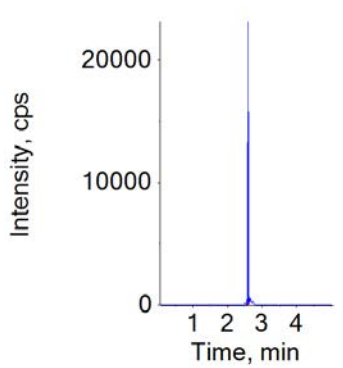


IS:	
ST-247	
IS Masses:	
379.000/287.100 Da	
IS Peak Area:	
3.959656240e+004	

Sample Name:	4 066 SIGA-246-022 085P900 9077 A Day 1 0h PLM-1 1			Plate Number:	7
Acquisition Date:	11/16/2019 3:49:03 PM	Sample Type:	Unknown	Vial Position:	66

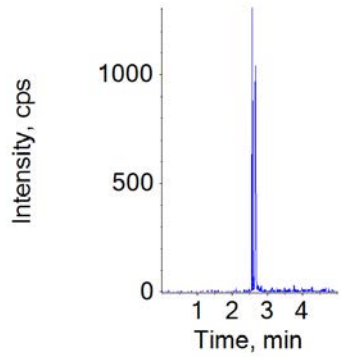


Analyte:	
ST-246	
Analyte Masses:	
375.300/283.300 Da	
Analyte Peak Area:	
2.940000000e+001	
Peak Area Ratio:	
8.09e-004	

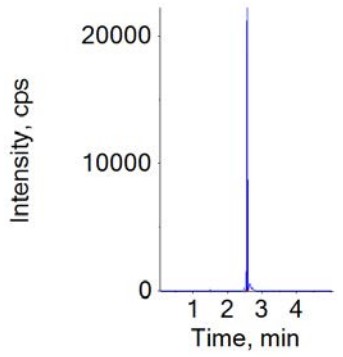


IS:	
ST-247	
IS Masses:	
379.000/287.100 Da	
IS Peak Area:	
3.636300060e+004	

Sample Name:	4 067 SIGA-246-022 085P901 9077 A Day 1 0.5h PLM-1 1			Plate Number:	7
Acquisition Date:	11/16/2019 3:54:39 PM	Sample Type:	Unknown	Vial Position:	67

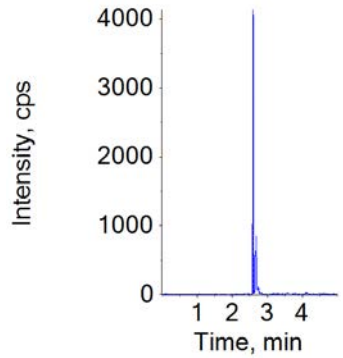


Analyte:	
ST-246	
Analyte Masses:	
375.300/283.300 Da	
Analyte Peak Area:	
1.894755001e+003	
Peak Area Ratio:	
5.44e-002	

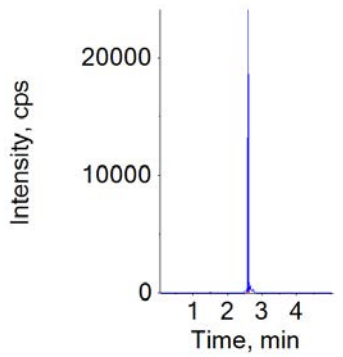


IS:	
ST-247	
IS Masses:	
379.000/287.100 Da	
IS Peak Area:	
3.483029373e+004	

Sample Name:	4 068 SIGA-246-022 085P902 9077 A Day 1 1h PLM-1 1			Plate Number:	7
Acquisition Date:	11/16/2019 4:00:14 PM	Sample Type:	Unknown	Vial Position:	68

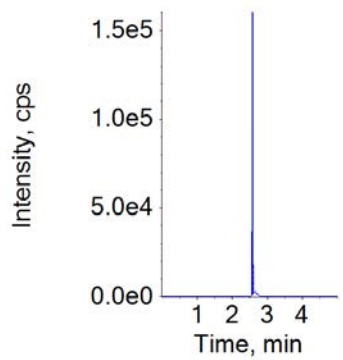


Analyte:	
ST-246	
Analyte Masses:	
375.300/283.300 Da	
Analyte Peak Area:	
6.503456667e+003	
Peak Area Ratio:	
1.69e-001	

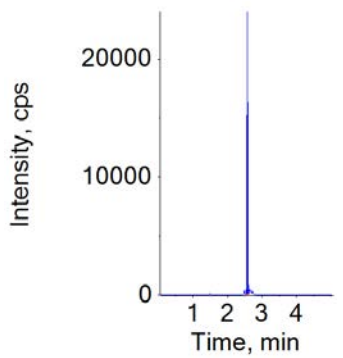


IS:	
ST-247	
IS Masses:	
379.000/287.100 Da	
IS Peak Area:	
3.842387262e+004	

Sample Name:	4 069 SIGA-246-022 085P903 9077 A Day 1 2h PLM-1 1			Plate Number:	7
Acquisition Date:	11/16/2019 4:05:49 PM	Sample Type:	Unknown	Vial Position:	69

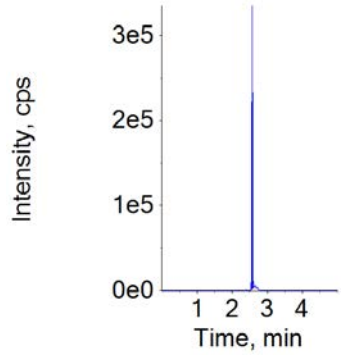


Analyte:	
ST-246	
Analyte Masses:	
375.300/283.300 Da	
Analyte Peak Area:	
2.458644166e+005	
Peak Area Ratio:	
6.50e+000	

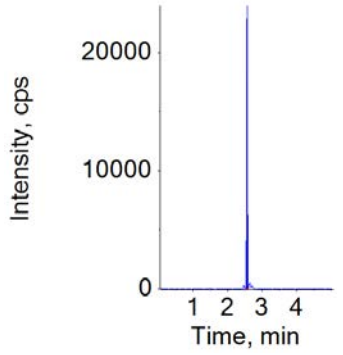


IS:	
ST-247	
IS Masses:	
379.000/287.100 Da	
IS Peak Area:	
3.784173399e+004	

Sample Name:	4 070 SIGA-246-022 085P904 9077 A Day 1 4h PLM-1 1			Plate Number:	7
Acquisition Date:	11/16/2019 4:11:25 PM	Sample Type:	Unknown	Vial Position:	70

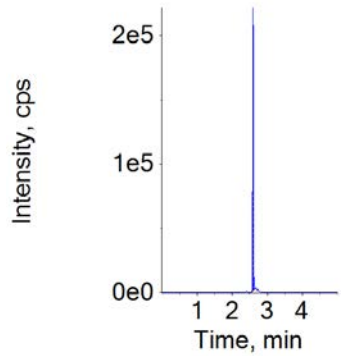


Analyte:
ST-246
Analyte Masses:
375.300/283.300 Da
Analyte Peak Area:
5.516544900e+005
Peak Area Ratio:
1.46e+001

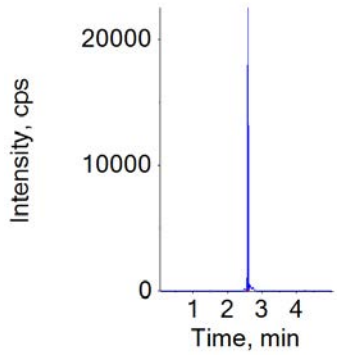


IS:
ST-247
IS Masses:
379.000/287.100 Da
IS Peak Area:
3.787288527e+004

Sample Name:	4 071 SIGA-246-022 085P905 9077 A Day 1 6h PLM-1 1			Plate Number:	7
Acquisition Date:	11/16/2019 4:16:59 PM	Sample Type:	Unknown	Vial Position:	71

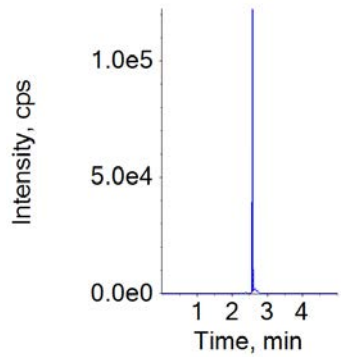


Analyte:
ST-246
Analyte Masses:
375.300/283.300 Da
Analyte Peak Area:
3.415605450e+005
Peak Area Ratio:
8.97e+000

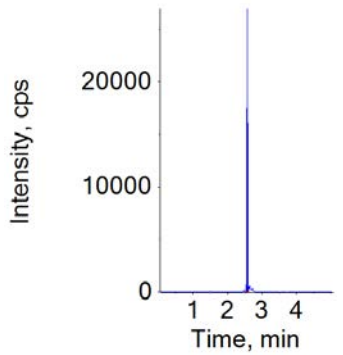


IS:
ST-247
IS Masses:
379.000/287.100 Da
IS Peak Area:
3.806382614e+004

Sample Name:	4 072 SIGA-246-022 085P906 9077 A Day 1 8h PLM-1 1			Plate Number:	7
Acquisition Date:	11/16/2019 4:22:35 PM	Sample Type:	Unknown	Vial Position:	72

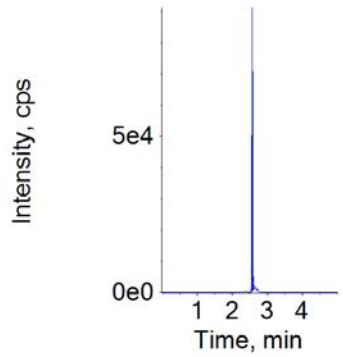


Analyte:
ST-246
Analyte Masses:
375.300/283.300 Da
Analyte Peak Area:
1.957541650e+005
Peak Area Ratio:
4.83e+000

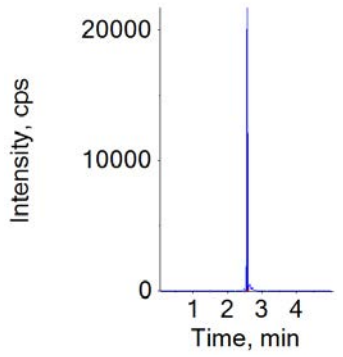


IS:
ST-247
IS Masses:
379.000/287.100 Da
IS Peak Area:
4.055055676e+004

Sample Name:	4 073 SIGA-246-022 085P907 9077 A Day 1 12h PLM-1 1			Plate Number:	7
Acquisition Date:	11/16/2019 4:28:08 PM	Sample Type:	Unknown	Vial Position:	73

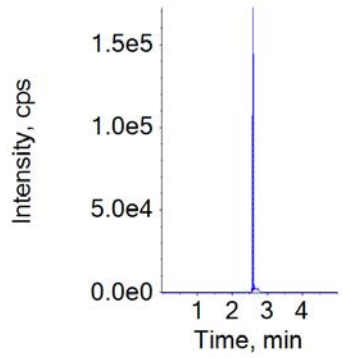


Analyte:
ST-246
Analyte Masses:
375.300/283.300 Da
Analyte Peak Area:
1.471745749e+005
Peak Area Ratio:
3.80e+000

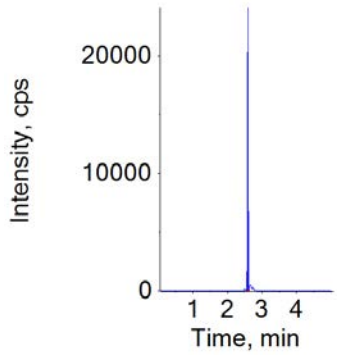


IS:
ST-247
IS Masses:
379.000/287.100 Da
IS Peak Area:
3.876759627e+004

Sample Name:	4 074 SIGA-246-022 085P908 9077 A Day 1 14h PLM-1 1			Plate Number:	7
Acquisition Date:	11/16/2019 4:33:44 PM	Sample Type:	Unknown	Vial Position:	74

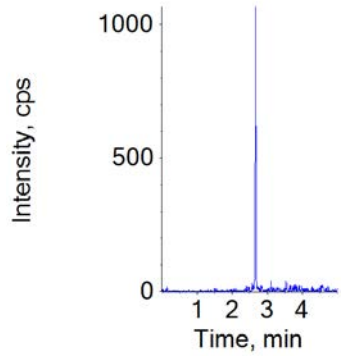


Analyte:
ST-246
Analyte Masses:
375.300/283.300 Da
Analyte Peak Area:
2.775353701e+005
Peak Area Ratio:
7.69e+000

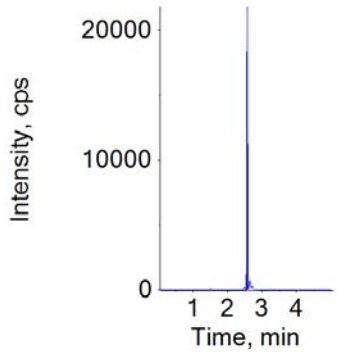


IS:
ST-247
IS Masses:
379.000/287.100 Da
IS Peak Area:
3.611305380e+004

Sample Name:	4 075 SIGA-246-022 085P987 9080 A Day 1 0h PLM-1 1			Plate Number:	7
Acquisition Date:	11/16/2019 4:39:19 PM	Sample Type:	Unknown	Vial Position:	75

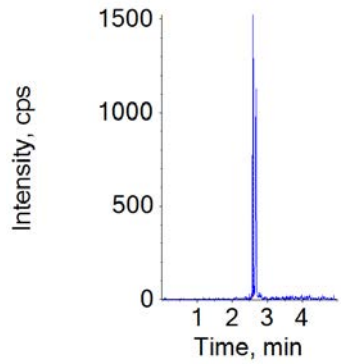


Analyte:
ST-246
Analyte Masses:
375.300/283.300 Da
Analyte Peak Area:
2.312333340e+001
Peak Area Ratio:
6.69e-004

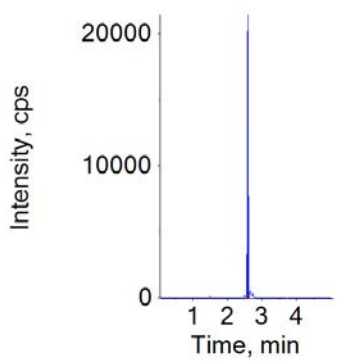


IS:
ST-247
IS Masses:
379.000/287.100 Da
IS Peak Area:
3.457199217e+004

Sample Name:	4 076 SIGA-246-022 085P988 9080 A Day 1 0.5h PLM-1 1			Plate Number:	7
Acquisition Date:	11/16/2019 4:44:54 PM	Sample Type:	Unknown	Vial Position:	76

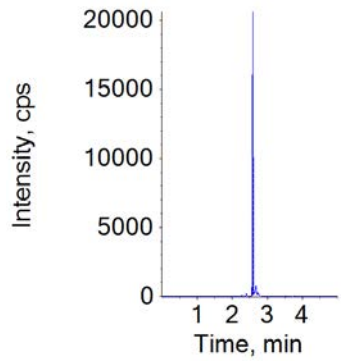


Analyte:
ST-246
Analyte Masses:
375.300/283.300 Da
Analyte Peak Area:
2.251326668e+003
Peak Area Ratio:
6.00e-002

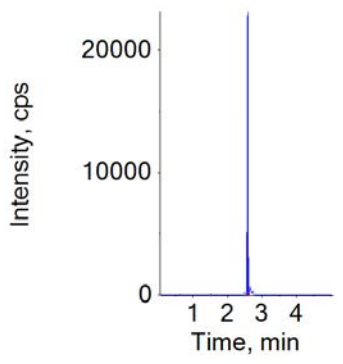


IS:
ST-247
IS Masses:
379.000/287.100 Da
IS Peak Area:
3.752265723e+004

Sample Name:	4 077 SIGA-246-022 085P989 9080 A Day 1 1h PLM-1 1			Plate Number:	7
Acquisition Date:	11/16/2019 4:50:29 PM	Sample Type:	Unknown	Vial Position:	77

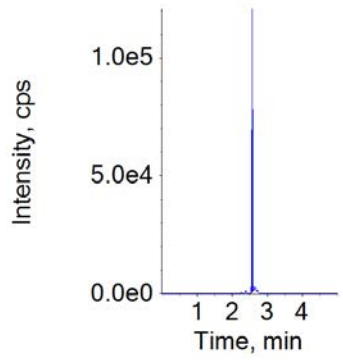


Analyte:
ST-246
Analyte Masses:
375.300/283.300 Da
Analyte Peak Area:
3.148960668e+004
Peak Area Ratio:
8.34e-001

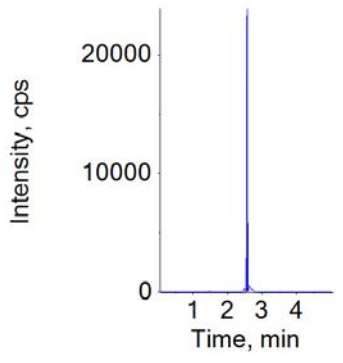


IS:
ST-247
IS Masses:
379.000/287.100 Da
IS Peak Area:
3.777033985e+004

Sample Name:	4 078 SIGA-246-022 085P990 9080 A Day 1 2h PLM-1 1			Plate Number:	7
Acquisition Date:	11/16/2019 4:56:05 PM	Sample Type:	Unknown	Vial Position:	78

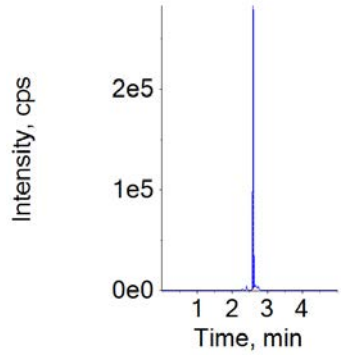


Analyte:
ST-246
Analyte Masses:
375.300/283.300 Da
Analyte Peak Area:
1.823766151e+005
Peak Area Ratio:
5.03e+000

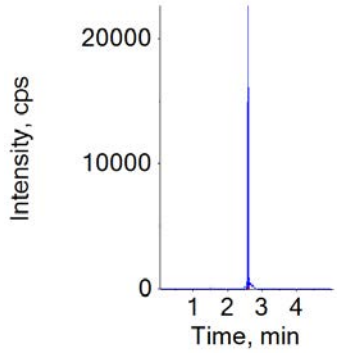


IS:
ST-247
IS Masses:
379.000/287.100 Da
IS Peak Area:
3.628993765e+004

Sample Name:	4 079 SIGA-246-022 085P991 9080 A Day 1 4h PLM-1 1			Plate Number:	7
Acquisition Date:	11/16/2019 5:01:41 PM	Sample Type:	Unknown	Vial Position:	79

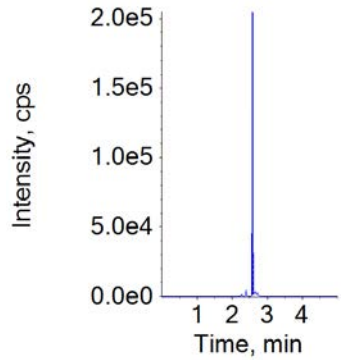


Analyte:
ST-246
Analyte Masses:
375.300/283.300 Da
Analyte Peak Area:
4.745769752e+005
Peak Area Ratio:
1.26e+001

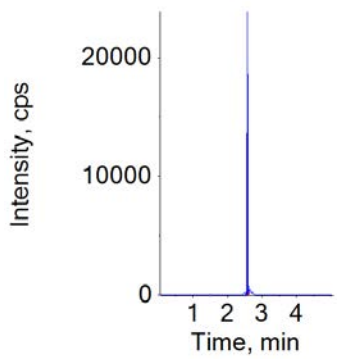


IS:
ST-247
IS Masses:
379.000/287.100 Da
IS Peak Area:
3.775839848e+004

Sample Name:	4 080 SIGA-246-022 085P992 9080 A Day 1 6h PLM-1 1			Plate Number:	7
Acquisition Date:	11/16/2019 5:07:16 PM	Sample Type:	Unknown	Vial Position:	80

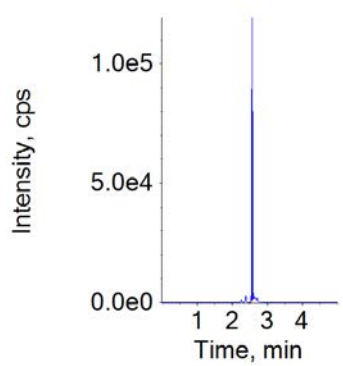


Analyte:
ST-246
Analyte Masses:
375.300/283.300 Da
Analyte Peak Area:
3.266823899e+005
Peak Area Ratio:
8.54e+000

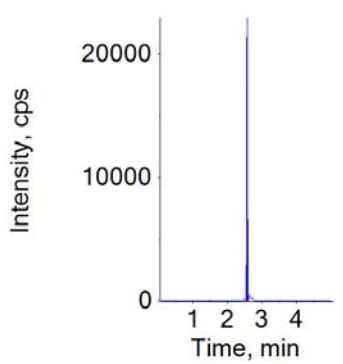


IS:
ST-247
IS Masses:
379.000/287.100 Da
IS Peak Area:
3.826602633e+004

Sample Name:	4 081 SIGA-246-022 085P993 9080 A Day 1 8h PLM-1 1			Plate Number:	7
Acquisition Date:	11/16/2019 5:12:51 PM	Sample Type:	Unknown	Vial Position:	81

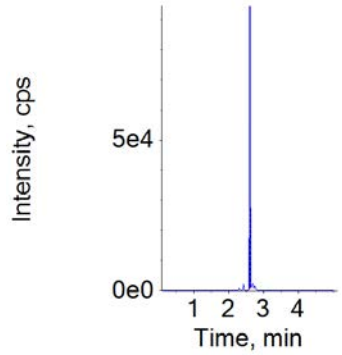


Analyte:
ST-246
Analyte Masses:
375.300/283.300 Da
Analyte Peak Area:
1.998243618e+005
Peak Area Ratio:
5.47e+000

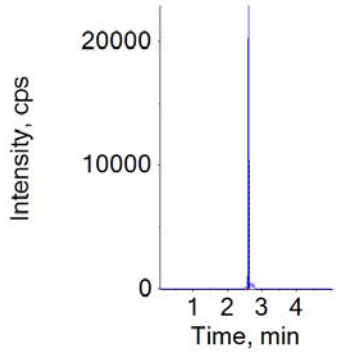


IS:
ST-247
IS Masses:
379.000/287.100 Da
IS Peak Area:
3.653195906e+004

Sample Name:	4 082 SIGA-246-022 085P994 9080 A Day 1 12h PLM-1 1			Plate Number:	7
Acquisition Date:	11/16/2019 5:18:26 PM	Sample Type:	Unknown	Vial Position:	82

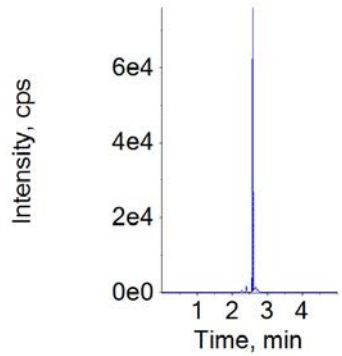


Analyte:
ST-246
Analyte Masses:
375.300/283.300 Da
Analyte Peak Area:
1.626782367e+005
Peak Area Ratio:
4.51e+000

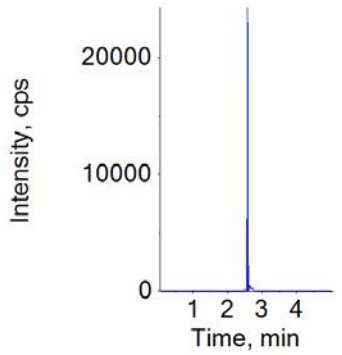


IS:
ST-247
IS Masses:
379.000/287.100 Da
IS Peak Area:
3.604838926e+004

Sample Name:	4 083 SIGA-246-022 085P995 9080 A Day 1 14h PLM-1 1			Plate Number:	7
Acquisition Date:	11/16/2019 5:24:01 PM	Sample Type:	Unknown	Vial Position:	83

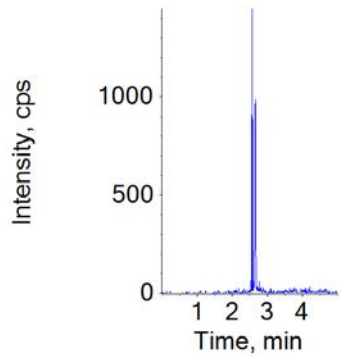


Analyte:
ST-246
Analyte Masses:
375.300/283.300 Da
Analyte Peak Area:
1.116766083e+005
Peak Area Ratio:
2.98e+000

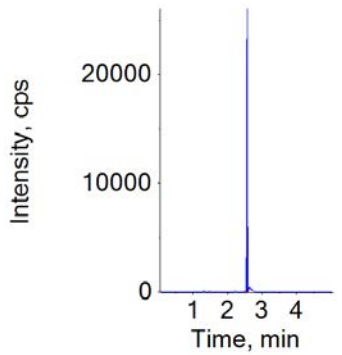


IS:
ST-247
IS Masses:
379.000/287.100 Da
IS Peak Area:
3.746519073e+004

Sample Name:	4 084 SIGA-246-022 STD 1 2 1			Plate Number:	7
Acquisition Date:	11/16/2019 5:29:36 PM	Sample Type:	Standard	Vial Position:	84

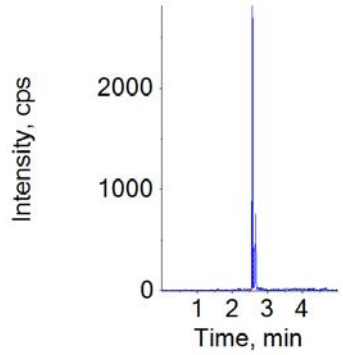


Analyte:
ST-246
Analyte Masses:
375.300/283.300 Da
Analyte Peak Area:
2.217508335e+003
Peak Area Ratio:
5.71e-002

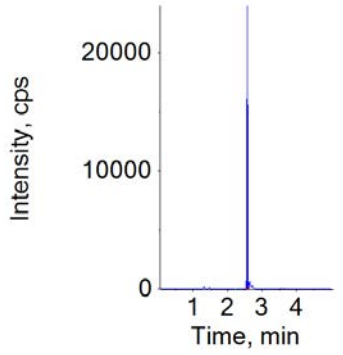


IS:
ST-247
IS Masses:
379.000/287.100 Da
IS Peak Area:
3.884335182e+004

Sample Name:	4 085 SIGA-246-022 STD 2 2 1			Plate Number:	7
Acquisition Date:	11/16/2019 5:35:12 PM	Sample Type:	Standard	Vial Position:	85

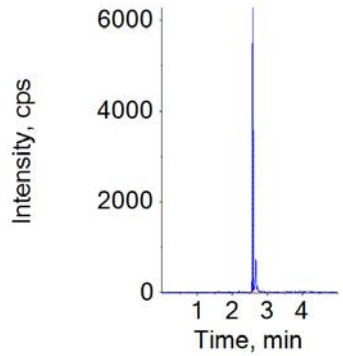


Analyte:
ST-246
Analyte Masses:
375.300/283.300 Da
Analyte Peak Area:
4.573671667e+003
Peak Area Ratio:
1.19e-001

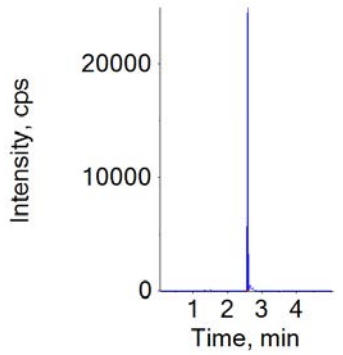


IS:
ST-247
IS Masses:
379.000/287.100 Da
IS Peak Area:
3.845554726e+004

Sample Name:	4 086 SIGA-246-022 STD 3 2 1			Plate Number:	7
Acquisition Date:	11/16/2019 5:40:48 PM	Sample Type:	Standard	Vial Position:	86

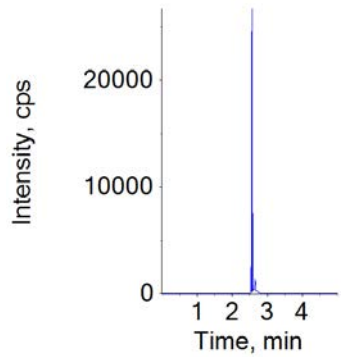


Analyte:
ST-246
Analyte Masses:
375.300/283.300 Da
Analyte Peak Area:
1.042824833e+004
Peak Area Ratio:
2.72e-001

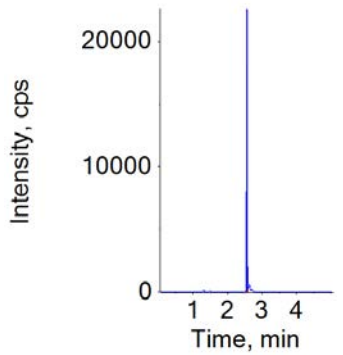


IS:
ST-247
IS Masses:
379.000/287.100 Da
IS Peak Area:
3.835186891e+004

Sample Name:	4 087 SIGA-246-022 STD 4 2 1			Plate Number:	7
Acquisition Date:	11/16/2019 5:46:23 PM	Sample Type:	Standard	Vial Position:	87

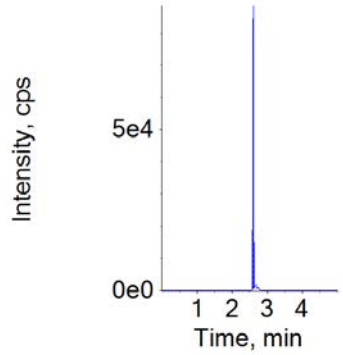


Analyte:
ST-246
Analyte Masses:
375.300/283.300 Da
Analyte Peak Area:
4.189984000e+004
Peak Area Ratio:
1.12e+000

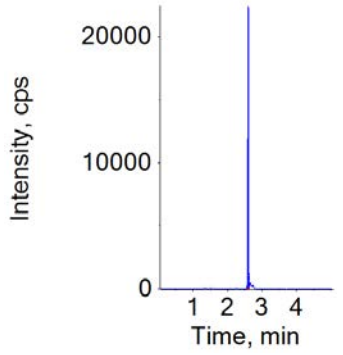


IS:
ST-247
IS Masses:
379.000/287.100 Da
IS Peak Area:
3.742295120e+004

Sample Name:	4 088 SIGA-246-022 STD 5 2 1			Plate Number:	7
Acquisition Date:	11/16/2019 5:51:59 PM	Sample Type:	Standard	Vial Position:	88

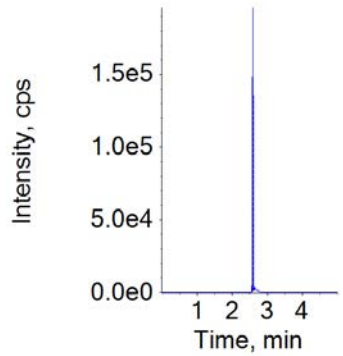


Analyte:
ST-246
Analyte Masses:
375.300/283.300 Da
Analyte Peak Area:
1.458986568e+005
Peak Area Ratio:
3.77e+000

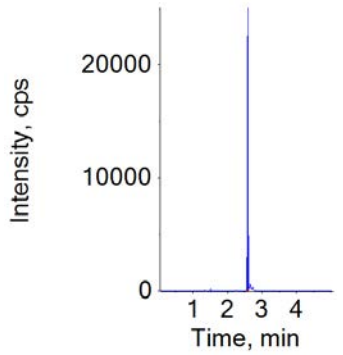


IS:
ST-247
IS Masses:
379.000/287.100 Da
IS Peak Area:
3.873508647e+004

Sample Name:	4 089 SIGA-246-022 STD 6 2 1			Plate Number:	7
Acquisition Date:	11/16/2019 5:57:35 PM	Sample Type:	Standard	Vial Position:	89

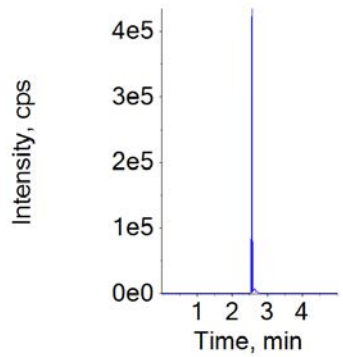


Analyte:
ST-246
Analyte Masses:
375.300/283.300 Da
Analyte Peak Area:
3.167247083e+005
Peak Area Ratio:
8.63e+000

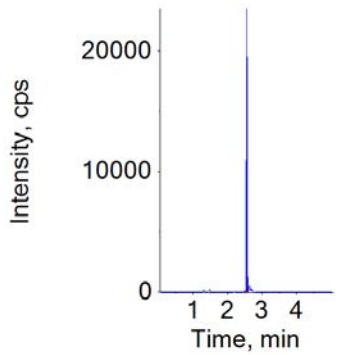


IS:
ST-247
IS Masses:
379.000/287.100 Da
IS Peak Area:
3.670101155e+004

Sample Name:	4 090 SIGA-246-022 HQC 2 1			Plate Number:	7
Acquisition Date:	11/16/2019 6:03:10 PM	Sample Type:	Quality Control	Vial Position:	90

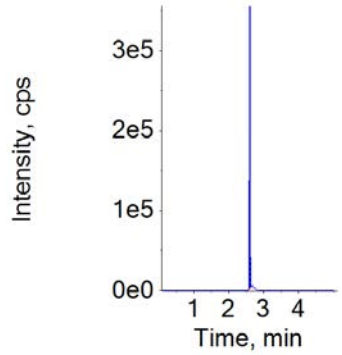


Analyte:
ST-246
Analyte Masses:
375.300/283.300 Da
Analyte Peak Area:
6.723723519e+005
Peak Area Ratio:
1.83e+001

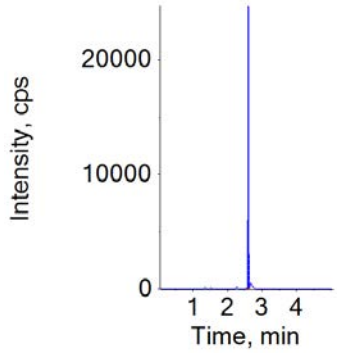


IS:
ST-247
IS Masses:
379.000/287.100 Da
IS Peak Area:
3.673728653e+004

Sample Name:	4 091 SIGA-246-022 STD 7 2 1			Plate Number:	7
Acquisition Date:	11/16/2019 6:08:46 PM	Sample Type:	Standard	Vial Position:	96

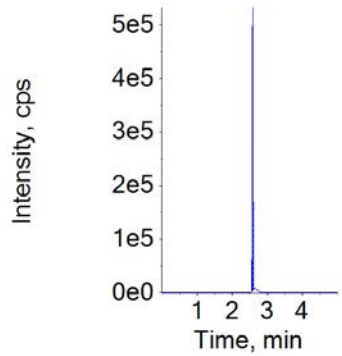


Analyte:
ST-246
Analyte Masses:
375.300/283.300 Da
Analyte Peak Area:
6.040107321e+005
Peak Area Ratio:
1.57e+001

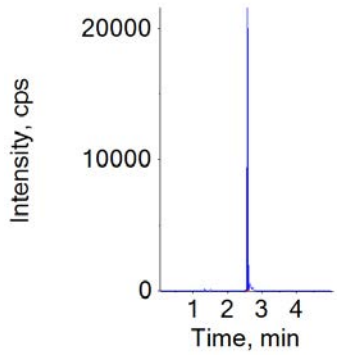


IS:
ST-247
IS Masses:
379.000/287.100 Da
IS Peak Area:
3.844461207e+004

Sample Name:	4 092 SIGA-246-022 STD 8 2 1			Plate Number:	7
Acquisition Date:	11/16/2019 6:14:20 PM	Sample Type:	Standard	Vial Position:	92

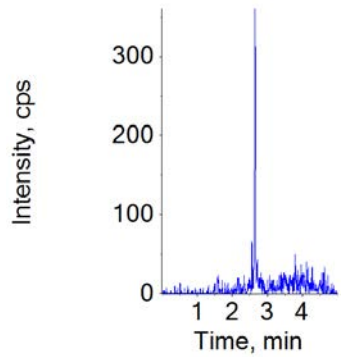


Analyte:
ST-246
Analyte Masses:
375.300/283.300 Da
Analyte Peak Area:
8.259638162e+005
Peak Area Ratio:
2.39e+001

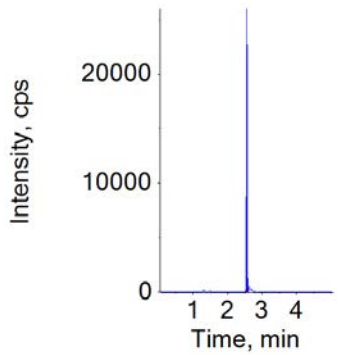


IS:
ST-247
IS Masses:
379.000/287.100 Da
IS Peak Area:
3.459333597e+004

Sample Name:	4 093 SIGA-246-022 CO IS 1 1			Plate Number:	7
Acquisition Date:	11/16/2019 6:19:56 PM	Sample Type:	Quality Control	Vial Position:	93

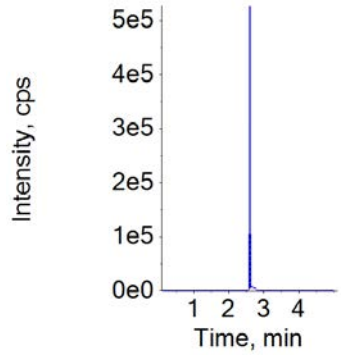


Analyte:
ST-246
Analyte Masses:
375.300/283.300 Da
Analyte Peak Area:
8.683666699e+001
Peak Area Ratio:
2.28e-003

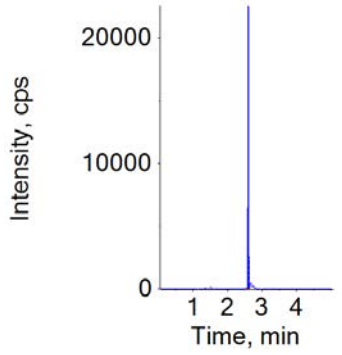


IS:
ST-247
IS Masses:
379.000/287.100 Da
IS Peak Area:
3.800304029e+004

Sample Name:	4 094 SIGA-246-022 CO ULOQ 1 1			Plate Number:	7
Acquisition Date:	11/16/2019 6:25:31 PM	Sample Type:	Quality Control	Vial Position:	94

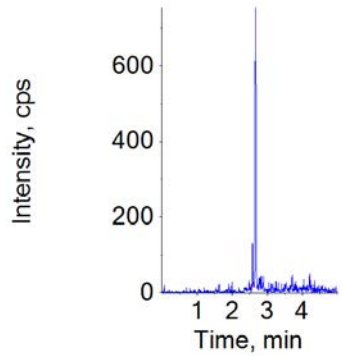


Analyte:
ST-246
Analyte Masses:
375.300/283.300 Da
Analyte Peak Area:
8.251205287e+005
Peak Area Ratio:
2.20e+001

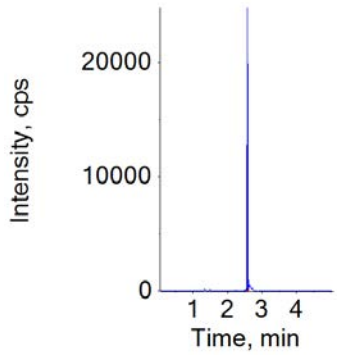


IS:
ST-247
IS Masses:
379.000/287.100 Da
IS Peak Area:
3.743170918e+004

Sample Name:	4 095 SIGA-246-022 CO IS 2 1			Plate Number:	7
Acquisition Date:	11/16/2019 6:31:07 PM	Sample Type:	Quality Control	Vial Position:	95

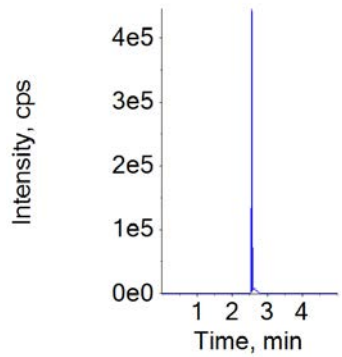


Analyte:
ST-246
Analyte Masses:
375.300/283.300 Da
Analyte Peak Area:
1.295850009e+002
Peak Area Ratio:
3.34e-003

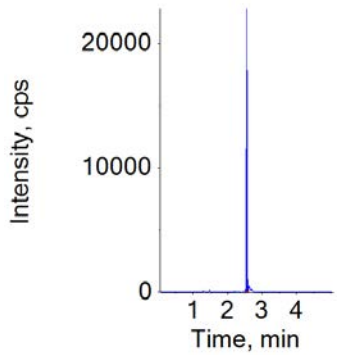


IS:
ST-247
IS Masses:
379.000/287.100 Da
IS Peak Area:
3.885117241e+004

Sample Name:	4 096 SIGA-246-022 CO ULOQ 2 1			Plate Number:	7
Acquisition Date:	11/16/2019 6:36:44 PM	Sample Type:	Quality Control	Vial Position:	94

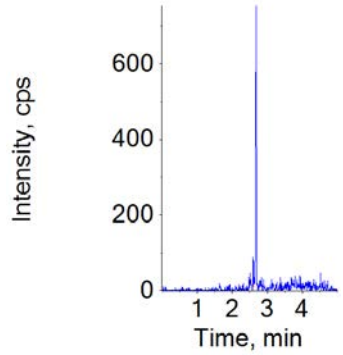


Analyte:
ST-246
Analyte Masses:
375.300/283.300 Da
Analyte Peak Area:
7.508229683e+005
Peak Area Ratio:
2.08e+001

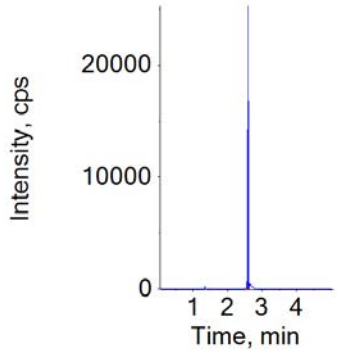


IS:
ST-247
IS Masses:
379.000/287.100 Da
IS Peak Area:
3.612323521e+004

Sample Name:	4 097 SIGA-246-022 CO IS 3 1			Plate Number:	7
Acquisition Date:	11/16/2019 6:42:18 PM	Sample Type:	Quality Control	Vial Position:	95



Analyte:
ST-246
Analyte Masses:
375.300/283.300 Da
Analyte Peak Area:
1.137500008e+002
Peak Area Ratio:
2.94e-003



IS:
ST-247
IS Masses:
379.000/287.100 Da
IS Peak Area:
3.864026632e+004

10.3 TEST METHOD

HPLC/MS/MS Test Method

Determination of Tecovirimat from Human K_3EDTA Plasma

Test Method Number: TM19-535

1. METHOD SUMMARY

This procedure describes a method for the quantitative analysis of Tecovirimat (previously known as ST-246) extracted from human K_3EDTA plasma by HPLC/MS/MS. The dynamic range of this assay is 5.00 to 2000 ng/mL for ST-246; concentrations higher than the ULOQ may be accommodated by dilution with blank matrix. Acetonitrile precipitation and HPLC/MS/MS will be used to determine the concentration of the analyte present in the matrix. An aliquot of the extract will be injected onto an HPLC/MS/MS triple quadrupole mass spectrometer. The peak area of the product ion of the analyte will be measured against the peak area of the product ion of the stable label internal standard (ST-247). A calibration curve spanning the curve range and containing at least six concentrations in duplicate will be used to quantify the analyte concentration. The retention times for the analyte and the IS are approximately 2.2 minutes. For more information regarding this assay, refer to the assay validation report AV15-ST246-03 Add. 2.

Table 1-1 Equipment List

Equipment	Manufacturer	Model
Mass Spectrometer	Applied Biosystems	API-4000
HPLC pump controller	Shimadzu	CBM
HPLC pump	Shimadzu	LC-20AD
HPLC pump	Shimadzu	LC-20AD
HPLC autosampler	Shimadzu	SIL 20 AC
Column Heater	Analytical Sales & Service	Hotsleeve 10L
HPLC Column	Supelco	Discovery HS-C18, 2.1x50mm, 3µm
Centrifuge	Beckman Coulter	Allegra 6R
Personal Pipettor	Apricot Designs	PP-550MS-XH

Equipment can be substituted with devices shown to perform similar procedures per SOP AA-308.

Table 1-2 Reagent List

Reagent	Vendor	Catalog #
Methanol (MeOH)	Fisher	A452-4
Acetonitrile (ACN)	Fisher	A998-4
Formic Acid (FA)	Sigma	F-0507
Dimethyl Sulfoxide (DMSO)	Fisher	D159-4
Water (H_2O)	In-House Millipore System	In-House

Note: Equivalent quality products may be substituted per SOP AA-308.

Table 1-3 Control Matrix

Vendor	Description	Species
BioIVT	K_3EDTA	Human

All matrices stored at nominal -20 °C.

1.1 MOBILE PHASE PREPARATION

The aqueous mobile phase is a water with 0.1% formic acid solution (v/v), and the organic mobile phase is an acetonitrile with 0.1% formic acid solution (v/v). The rinse solvent is 1:1 methanol:water or 1:1 acetonitrile:water with 1% formic acid. See SOP AA-214 for details on the preparation of mobile phases and rinse solvent.

1.2 ANALYTE AND INTERNAL STANDARD STOCK SOLUTIONS

Prepare a 1.00 mg/mL solution of Tecovirimat (ST-246) in DMSO, and a 1.00 mg/mL solution of the internal standard (ST-247) in methanol in 15 mL polypropylene tubes, being sure to adequately mix the solutions upon preparation. Label the tubes properly and store at nominal -20°C. Details of stock solution preparation will be recorded in CIMS.

1.3 INTERNAL STANDARD WORKING SOLUTION

Prepare approximately 1000 mL of internal standard at 5.00 ng/mL being sure to adequately mix the solution upon preparation. Label the solution properly and store at nominal -20°C. A recommended procedure is to take 5.00 µL of the 1.00 mg/mL stock solution and bring to a final volume of 1000 mL with acetonitrile using a volumetric flask. Other methods of internal standard preparation are acceptable as long as the final concentration is 5.00 ng/mL. Details of the preparation will be recorded in CIMS.

1.4 ANALYTE WORKING SOLUTIONS

Working solutions for standards and QCs should be prepared using the following template. These working solutions should be aliquoted into single-use aliquots and stored at -20°C. Details of the preparation will be recorded in CIMS.

Standard Curve Working Solution Preparation

Working Solution ID	Final Concentration [ng/mL]	Final Volume (µL)	Initial [ng/mL]	Initial Volume (µL)	Volume of DMSO (µL)
STD8 WS	40000	625	1000000	**25.0**	**600**
STD7 WS	30000	1667	1000000	**50.0**	**1617**
STD6 WS	14000	1500	30000	**700**	**800**
STD5 WS	7000	1400	14000	**700**	**700**
STD4 WS	2000	1750	7000	**500**	**1250**
STD3 WS	500	2000	2000	**500**	**1500**
STD2 WS	200	1250	500	**500**	**750**
STD1 WS	100	1000	200	**500**	**500**

QC Working Solution Preparation

Working Solution ID	Final Concentration [ng/mL]	Final Volume (µL)	Initial [ng/mL]	Initial Volume (µL)	Volume of DMSO (µL)
ULOQ WS	40000	625	1000000	**25.0**	**600**
HQC WS	32000	1563	1000000	**50.0**	**1513**
MQC WS	3000	1333	32000	**125**	**1208**
LQC WS	300	1250	3000	**125**	**1125**
LLOQ WS	100	375	300	**125**	**250**

1.5 STANDARD CURVE IN PLASMA PREPARATION

Standard curves will be prepared fresh on each day of preparation. The preparation volumes can be adjusted as long as the final concentrations remain the same. Any remaining volume will be discarded. Details of the preparation will be documented on the extraction procedure printout.

Standard Curve in Plasma Preparation

Standard ID	Final Plasma Conc. [ng/mL]	Final Volume (µL)	Initial WS Conc. [ng/mL]	Initial Volume of WS (µL)	Volume of Plasma (µL)
2000 or STD8	2000	500	40000	**25.0**	**475**
1500 or STD7	1500	500	30000	**25.0**	**475**
700 or STD6	700	500	14000	**25.0**	**475**
350 or STD5	350	500	7000	**25.0**	**475**
100 or STD4	100	500	2000	**25.0**	**475**
25.0 or STD3	25.0	500	500	**25.0**	**475**
10.0 or STD2	10.0	500	200	**25.0**	**475**
5.00 or STD1	5.00	500	100	**25.0**	**475**

1.6 QC IN PLASMA PREPARATION

Prepare QC samples in matrix at each level using the following template. Aliquot appropriate volume for single use aliquots into properly labeled cryovials and store at -70°C. The preparation volumes can be adjusted as long as the final concentrations remain the same. Details of the preparation will be documented on the extraction procedure printout.

QC in Plasma Preparation

QC ID	Final Plasma Conc. [ng/mL]	Final Volume (µL)	Initial WS Conc. [ng/mL]	Initial Volume of WS (µL)	Volume of Plasma (µL)
DQC	50000	1000	1000000	**50.0**	**950**
ULOQ	2000	3000	40000	**150**	**2850**
HQC	1600	3000	32000	**150**	**2850**
MQC	150	3000	3000	**150**	**2850**
LQC	15.0	3000	300	**150**	**2850**
LLOQ	5.00	3000	100	**150**	**2850**

2. ASSAY PERFORMANCE

2.1 SYSTEM SUITABILITY CHECK

System suitability (SYS) samples should be acquired prior to the injection of any batch samples. These samples should be included in the quantitation file for the batch. If multiple batches are prepared and analyzed without any time gaps in the acquisition, only one set of SYS samples may be acquired prior to the acquisition of the first batch, in which case any subsequent batch paperwork should reference the initial system suitability evaluation.

SYS samples are extracted samples that include internal standard as well as analyte at or near the LLOQ. At least five SYS samples must be injected. Prior to the start of sample analysis batches, the precision (%CV) of the internal standard signal or the area ratio for three consecutive SYS injections should be calculated. The signal to noise ratio (S/N) should be determined for at least one SYS sample. The retention time should be checked to be sure that it is within test method specifications. The data from these calculations (precision and S/N) should be maintained with the batch paperwork. Retention time information for the SYS will be maintained electronically within Analyst for LC-MS.

2.2 INTERNAL STANDARD VARIATION

The IS response for a given injection is considered acceptable if the response is within a specific range when taken as a percentage of the average IS response for the entire run. The data that results from any incurred sample that fails to meet IS response criteria will be considered invalid and the sample will be reanalyzed if possible.

2.3 ASSAY PERFORMANCE SPECIFICATIONS

The specific requirements for the precision of the system suitability as well as the accuracy of the IS response are maintained in a database found at the location shown below.

M:\AlturasTestMethods\TMCriteria_SYS_ISDev\TMCriteria_SYS_ISDev.mdb

3. INSTRUMENT CONDITIONS

HPLC Conditions

Mobile Phase A: Water with 0.1% formic acid solution
Mobile Phase B: Acetonitrile with 0.1% formic acid solution
Rinse Solvent: 1:1 Methanol:water OR 1:1 acetonitrile:water with 1% formic acid
Flow Rate: 0.7 mL/min
Pump B Starting Concentration: 5%
Injection Volume: 1-40 µL as needed
Column Heater Temperature: 50°C
Autosampler Temperature: 10°C
HPLC Column Type: C18

Time	Module	Events	Parameter
0.50	System Controller	Event*	1
2.60	System Controller	Event*	0
3.00	Pumps	Pump B Conc.	95
3.70	Pumps	Pump B Conc.	95
4.50	Pumps	Pump B Conc.	5
4.90	System Controller	Stop	

*Note-a switching valve is used to divert waste.

Negaitve MS Conditions – ESI MODE

CAD gas	12	DP	-80
CUR gas	20	EP	-15
GAS 1	50	CE	-50
GAS 2	50	CXP	-5
ESI Voltage, V	-4500	Analyte Transition, m/z	375.3 → 283.3
ESI Temperature, °C	600	IS Transition, m/z	379.0 → 287.1
		Dwell Time, ms	100

Analysis conditions may change according to SOP AA-308. Although it is recommended that conditions remain constant, there are times where conditions may need to vary to obtain optimal results.

Initial Integration Parameter Settings

Min Peak Height	0.000 cps	RT Window	30.000 sec
Min Peak Width	0.000 sec	Smoothing Width	3 points
Integration Algorithm	Automatic – IQA II		

Integration parameters may change based upon chromatography for the batch. Global changes to the integration parameters are preferable; however, it is permissible to change the integration parameters on a single sample if necessary. Any non-global changes to integration parameters must be approved by a Senior Scientist or the Laboratory Manager; this approval should be documented in the Analyst audit trail.

4. EXTRACTION PROCEDURE

Study Number _____ Batch Number _____

Extraction Procedure Start Time (step 2.) _____

1. Thaw matrix and samples at ambient temperature.
2. For each standard concentration, add 25 µL of the designated working solution to 475 µL of plasma. Vortex for approximately 5 minutes.

   Pipette ID 25 µL _____ Pipette ID 475 µL _____
3. For each QC concentration, follow the template in section 1.6 Record volumes and pipettes below. For freshly prepared bulk QCs, enter info into CIMS.

   ☐ N/A; bulk QCs used
   Volume working solution (µL)_____ Pipette ID working solution _____
   Volume plasma (µL)_____ Pipette ID plasma _____

   Vortex for approximately 5 minutes.

Sample Aliquot Time (step 4.) _____

4. Aliquot 50 µL of the standard, QC or unknown sample into a clean well of a 96 well plate.

   Pipette ID 50 µL _____ Pipette ID 50 µL (blanks) _____
5. Precipitate proteins of all samples except double blanks and matrix blanks with 500 µL of the internal standard working solution (5.00 ng/mL ST-247 in acetonitrile). Add 500 µL of blank acetonitrile to double blanks and matrix blanks. Vortex briefly and centrifuge at approximately 3000 rpm for approximately 5 minutes.

   Pipette ID 500 µL _____
6. Transfer approximately 300 µL of the supernatant to a clean 96 well plate. See attached automatic pipettor program printout.
7. Evaporate under nitrogen at 40°C.

   Evaporator ID _____
8. Reconstitute with 100 µL of 1:1 ACN:H_2O with 1% formic acid. Vortex briefly and centrifuge at approximately 3000 rpm for approximately 5 minutes.

   Pipette ID 100 µL _____ ☐ Column heater set to 50°C

Extraction Procedure End Time _____

Signature _____ Date _____

Effective Date: 12/2/2019

Revision: 002

5. SPECIAL SAMPLE HANDLING

To be added later if necessary.

6. STATISTICAL CALCULATIONS

Watson and Excel are used for all calculations. Quantitation will be performed using a linear $1/x^2$ regression.

7. CARRYOVER

In each sample analysis batch, a double blank sample will be injected after a ULOQ point. If the double blank sample has an analyte peak area response ≤20% of the passing LLOQ curve point(s), carryover will not be considered a factor in that day's analysis and carryover factor (COF) COF will not be evaluated.

If the double blank sample has an analyte peak area response >20% of the LLOQ curve point(s), COF will be evaluated to determine the extent of carryover. The carryover factor (COF) will be established by injecting a ULOQ point followed by a blank sample containing internal standard (blank IS), in triplicate. The COF will be calculated by dividing the peak area ratio of the blank IS sample by the peak area ratio of the ULOQ point. The COF value of each replicate will be averaged to determine the overall COF.

Carryover from one sample (Sample A) to the following sample (Sample B) will be evaluated by applying the COF using the equation:

$$\% \text{ carryover} = \frac{100(\text{COF})(\text{A})}{\text{B}}$$

Where A is the area ratio of Sample A and B is the area ratio of Sample B.

If the calculated carryover from Sample A is greater than 5.0% of Sample B, then Sample B will be reanalyzed.

Signatures

Jennifer Zimmer

Document ID: TM19-535
Revision: 002
Electronically signed by Jennifer Zimmer
Title: Laboratory Director
Date: 12/2/2019 10:24:20 AM
Reason: Approval of Document

Timberly Maddox

Document ID: TM19-535
Revision: 002
Electronically signed by Timberly Maddox
Title: Quality Control Associate
Date: 12/2/2019 10:38:14 AM
Reason: Approval of Document

Ashley Davie

Document ID: TM19-535
Revision: 002
Electronically signed by Ashley Davie
Title: Scientist
Date: 12/2/2019 12:04:29 PM
Reason: Approval of Document

Alturas Analytics, Inc.
Document History

Record Count: 3
Document Count: 1

Location:	Test Method		
Document ID:	TM19-535		**Title:** Determination of ST-246 from Human K3EDTA Plasma
Current Revision:	**Current Effective Date:**	**Current New Review Date:**	**Reason for Change:**
002	02-Dec-2019	02-Dec-2019	Add cross reference for tecovirimat and ST-246.
Prior Revisions	**Prior Effective Dates**	**Prior Next Review Dates**	**Reason for Change**
001	01-Oct-2019	01-Oct-2019	Remove "WS" from QC ID in section 1.6.
000	15-Jul-2019	15-Jul-2019	Original document
	11-Jul-2019	11-Jul-2019	

Quality Systems Integrators

10.4 BIOANALYTICAL SAMPLE ANALYSIS PLAN

Alturas Analytics, Inc.
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Bioanalytical Sample Analysis Plan

Study Title:	A POST MARKETING STUDY OF THE SAFETY, TOLERABILITY, AND PHARMACOKINETICS OF TPOXX® IN ADULT SUBJECTS WEIGHING MORE THAN 120 KG
Bioanalytical Principal Investigator:	Jennifer Zimmer, PhD
Bioanalytical Test Site:	Alturas Analytics, Inc. 1324 Alturas Dr. Moscow, ID 83843
Sponsor:	SIGA Technologies, Inc. 4575 SW Research Way, Suite 110 Corvallis, Oregon 97333
Sponsor Contact:	Biswajit Maiti Telephone No.: (541) 753-2000 E-mail: BMaiti@siga.com
Study Number:	SIGA-246-022

1. REVISION HISTORY:

SAP Version	Version Date	Changes
Original	23 JUL 2019	Original

2. STUDY OVERVIEW:

Objective	Bioanalytical sample analysis for the determination of ST-246 in Human Plasma by HPLC/MS/MS
Bioanalytical Method	TM19-535
Matrix	Human K3EDTA Plasma
Analyte	ST-246
Internal Standard	ST-247
Limits of Quantitation	• LLOQ: 5.00 ng/mL • ULOQ: 2000 ng/mL
Sample Storage	-70°C
Summary of Expected Timepoints	Day 1 Predose, and at 0.5, 1, 2, 4, 6, 8, 12, 14, 16, 18, 20, and 24 hours post AM dose Day 6 Predose and 4 hours post AM dose Day 7 Predose and at 0.5, 1, 2, 4, 6, 8, 12, 14, 16, 18, 20, 24 and 48 hours post AM dose
Special Sample Handling Requirements	No special handling required
Biosafety Assessment	BSL-2; SOP AA-016 should be consulted for proper sample handling procedures.
Conditions of Blinding	Data will not be blinded

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3. SAMPLE ANALYSIS

Projected Analytical Start Date	August, 2019
Projected Analytical End Date	October, 2019
Sample Analysis Details	All samples analyzed in singlet
Sample Batching Requirements	Recommended to place all samples from a single subject in the same batch
Assay Criteria	• Acceptance criteria will be based upon Alturas Analytics' SOP AA-301 – The calibration curve will be prepared in duplicate, with one replicate analyzed at the beginning of the batch and the other replicate analyzed at the end of the batch. – No more than ¼ of the curve points may deviate from nominal by more than 15% (20% at the LLOQ) in order for the sample concentrations from that batch to be reported. – QC samples will be interspersed throughout the batch. The number of QCs analyzed with the batch must be ≥ 5% of the number of samples in that batch. There must be at least 6 QC samples (n=2 at each QC level) analyzed with any batch. – No more than ½ of the QC samples at any level or ⅓ of the QC samples overall may deviate from nominal by more than 15% in order for the sample concentrations from that batch to be reported. – Dilution QCs (in triplicate) will be included in each batch in which samples require dilution. These QCs will be prepared at the highest dilution scheme required by the samples. No more than ⅓ of the dilution QC samples may deviate from nominal by more than 15% (20% if the dilution QCs are ≥ 200X dilution QCs) – Double blank and blank with internal standard samples will be analyzed in each batch. Both samples must have an analyte response ≤ 20.0% of the valid LLOQ curve points for the batch. In addition, the double blank sample must have an internal standard response ≤ 5.0 % of the valid LLOQ curve points for the batch. • Reassays will be determined based upon Alturas Analytics' SOP AA-304
Analytical System(s)	• API-4000
Pre-dilution of Samples	Pre-dilutions will be determined based on estimated analyte concentrations from historical data

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4. INCURRED SAMPLE REANALYSIS

Sample Selection	• Ten percent (10%) of the total number of study samples (with a minimum of twenty (20) samples) must be selected for ISR for studies with up to 1000 samples. • For studies with greater than 1000 samples, a minimum of 10% of samples will be chosen for the first 1000 samples and a minimum of 5% of samples will be chosen from the remaining samples. • If less than 20 samples in a given study have concentrations >LQC, the study is exempted from this requirement. • When possible, samples should be chosen to cover the concentration range from C_{max} to LQC.
Assay Criteria	• Acceptance criteria will be based upon Alturas Analytics' SOP AA-312 – At least ⅔ of the ISR samples should be < 20% different from the original results.
Reporting	ISR results will be reported in the final report.

5. DATA & REPORT INFORMATION

Data Reporting	The sponsor will be provided with data in Microsoft Excel format unless data format otherwise specified in an approved data transfer plan.
Sample Analysis Report	Following the completion of sample analysis, a draft report will be provided to the sponsor for comment. The report will be finalized following the incorporation of any comments.

6. REGULATORY, QA INVOLVEMENT & ARCHIVE STATEMENT

Regulatory Requirements	The bioanalytical portion of this study is intended for the support of a clinical study, and as such, is not required to be subject to Good Laboratory Practice regulation. However, all work will be conducted within a facility operating in compliance with US FDA Good Laboratory Practice Regulations, and laboratory procedures will satisfy the requirements of those regulations.
QA Involvement	Audits will include, at a minimum: • In-process audit • Data audit • Report audit
Archive Statement	All electronic or hard copy data will be archived according to Alturas Analytics' SOP AA-012 and SOP AA-507. • All hard copy and electronic data will be archived the day of the completion of the study. • All study data will be logged into the archives and maintained in accordance with 21 CFR Part 58.195 or five years, whichever is longer.

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7. DELIVERABLES:

At the conclusion of sample analysis, Alturas Analytics will provide one copy of the final audited draft report to the Sponsor. Audited drafts will be available for Sponsor review prior to finalization of the report. The report will include the following information:

QA Statement	
PI Statement	
Assay Procedure	• Brief description of method sample preparation and analysis • Copy of Test Method
Standard Preparation	• Batch/Lot number, purity, manufacturer • Known stability at time of use • Copy of Certificate of Analysis
Sample Tracking	• Dates of receipt of shipments, condition and contents • Storage location and condition and statement comparing storage time to validation storage length
Sample Analysis	• Table of batches (including failed batches), instrument ID and analysis dates • Range of standard curve, including standard curve and QC values • Standard curve regression, equation and r^2 value • Table of standard results of all passing runs with accuracy and precision • Tables of interbatch QC results for all passing runs (accuracy and precision) • Table of the samples and calculated concentrations • Chromatograms (curve and QC samples from one day of analysis) and ≥ 5% of all samples
Deviations from SOPs, Methods and Protocols	• Description of deviation(s) • Impact on study results • Description and supporting data of significant investigations
Incurred Sample Reanalysis	• An assessment of ISR results
Communication	• Any communication that impacts the outcome of the study, or alters the protocol

8. APPROVAL:

[redacted]

Jennifer Zimmer, PhD — Date
Laboratory Director
Alturas Analytics, Inc.

[redacted]

Biswajit Maiti — Date
Director, Drug Metabolism & Pharmacokinetics
SIGA Technologies, Inc.

9. REVIEW:

[redacted]

David Schumacher, RQAP-GLP — Date
Quality Assurance Unit
Alturas Analytics, Inc.