CROSS ALLIANCE
Contract Research Organisation for Scientific Services

HELSINN

STATISTICAL ANALYSIS PLAN

Study CRO-PK-22-363 - Sponsor code PNET-22-08

A phase I, open label, single dose, two parts study in male and female healthy subjects to assess the safety and pharmacokinetics of Fosnetupitant 235 mg administered as IV bolus and of derived Netupitant and Netupitant metabolites

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Open label, single dose, two parts (part A and part B), safety and pharmacokinetics phase I study. Study Part B will be conducted according to a randomized cross-over design

Investigational product:	IV fosnetupitant 235 mg free base 20 mL ready to use solution for intravenous administration, Patheon Italia S.p.A., Italy
Reference product:	IV Akynzeo (235 mg fosnetupitant/0.25 mg palonosetron) in 20 mL injectable solution, Baxter Oncology GmbH, Germany
Placebo:	0.9% sodium chloride injection solution ready to use solution for intravenous administration (placebo), purchased from the market
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Development phase:	Phase I
Version and date:	Final version 1.0, 18JUN2024

This study will be conducted in compliance with the protocol and the principles of Good Clinical Practice (GCP) [ICH topic E6 (R2)] and with the local regulatory requirements

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This document comprises 31 pages plus appendices

VERSIONS' HISTORY

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Draft version 0.2	10JUN2024	[redacted] issued the draft version 0.2 after Sponsor's revision
Final version 1.0	18JUN2024	[redacted] issued the final version after MW's revision

APPROVAL AND ACKNOWLEDGEMENT

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Head of Data Science, Technical Operations

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Coordination (for acknowledgement only)

[redacted]

STUDY SCHEDULE

Study procedures of Part A

ACTIVITIES	Screening	Admission	Active treatment administration	Observation and release	Final visit or ETV[8]
Visit	**V1**	**V2**	**V3**		**V4 or ETV[8]**
Day	**-21 to -2**	**-1**	**1**	**2**	**7**
Informed consent	x				
Inclusion/Exclusion criteria	x	x			
Full physical examination	x				x
Short physical examination		x[1]		x	
Demographics	x				
Medical and surgical history	x				
Previous and concomitant treatments	x	x	x	x	x
Height and body mass index (BMI)	x				
Body weight	x	x			x
Safety laboratory (hematology, blood chemistry, urinalysis)	x				x
Virology (HBs Ag, HCV Ab, HIV)	x				
Pregnancy test	x[2]	x[3]			x[3]
Urine drug screen	x	x			
Salivary alcohol test		x			
Triplicate 12-lead ECGs	x		x[4]	x[6]	x
Vital signs	x	x	x[5]	x[6]	x
Enrolment		x			
Confinement		x	x		
Active Treatment administration			x		
PK blood sampling[7]			x ---------- x		
Discharge				x	
AE recording[9]	x	x	x	x	x

1. *Only if screening full physical examination performed more than 7 days before Day -1*
2. *Women only - serum b-HCG test*
3. *Women only - urine test*
4. *At pre-dose, at the end of injection, then at 1, 2, 4 and 24 h after end of administration; to be measured after 5 min at rest in supine position before recording.*
5. *At pre-dose, at the end of the injection, then at 1, 2, 4 and 24 h after the end of the injection; to be measured after 5 min at rest in sitting position before measurement.*
6. *Upon discharge at 24 h after the end of active treatment injection.*
7. *See schedule in tabular format at next page.*
8. *Early termination visit (ETV) upon discontinuation in case of premature termination*
9. *AEs monitored starting at the screening visit, immediately after informed consent, up to the final visit or ETV*

Schedule of PK blood sampling

	Blood sampling times after the start of T or R treatment									
	T injection of								Reference product infusion of	
	2 min		5 min		15 min		30 min		30 min	30 min
	Part A	Part B	Part A	Part B	Part A	Part B	Part A	Part B	Part A (Rα)	Part B (R)
Pre-dose	X	X	X	X	X	X	X	X	X	X
2 min	X	X								
5 min	X	X	X	X						
10 min	X	X	X	X						
15 min	X	X	X	X	X	X				
20 min	X	X	X	X	X	X				
30 min	X	X	X	X	X	X	X	X	X	X
45 min	X	X	X	X	X	X	X	X	X	X
1 h	X	X	X	X	X	X	X	X	X	X
1.5 h	X	X	X	X	X	X	X	X	X	X
2 h	X	X	X	X	X	X	X	X	X	X
3 h	X	X	X	X	X	X	X	X	X	X
4 h	X	X	X	X	X	X	X	X	X	X
8 h	X	X	X	X	X	X	X	X	X	X
12 h	X	X	X	X	X	X	X	X	X	X
24 h	X	X	X	X	X	X	X	X	X	X
48 h		X		X		X		X		X
72 h		X		X		X		X		X
96 h		X		X		X		X		X
120 h		X		X		X		X		X
144 h		X		X		X		X		X
168 h		X		X		X		X		X
192 h		X		X		X		X		X
216 h		X		X		X		X		X
240 h		X		X		X		X		X

TABLES OF CONTENTS

ABBREVIATIONS

β-HCG	human chorionic gonadotropin β
AE	Adverse Event
AUC_{0-t}	Area under the concentration-time curve from time zero to time t
AUC∞	Area under the concentration versus time curve up to infinity
$\%AUC_{extra}$	Percentage of the residual area extrapolated to infinity in relation to the AUC∞
BLQL	Below Lower Quantification Limit
BP	Blood Pressure
CDISC	Clinical Data Interchange Standards Consortium
CI	Confidence Interval
C_{max}	Peak drug concentration
CPL	Clinical Project Leader
CRF	Case Report Form
CRO	Contract Research Organisation
CV	Coefficient of Variation
DIABP	Diastolic Blood Pressure
ECG	Electrocardiogram
ETV	Early Termination Visit
FSFV	First Subject First Visit
GCP	Good Clinical Practice
GLP	Good Laboratory Practice
HBs Ag	Hepatitis B virus surface antigen
HCV Ab	Hepatitis C virus antibodies
HIV	Human Immunodeficiency Virus
HR	Heart Rate
ICH	International Conference on Harmonisation
IGA	Investigator Global Assessment
IMP	Investigational Medicinal Product
LSLV	Last Subject Last Visit
MedDRA	Medical Dictionary for Regulatory Activities
N	Normal
NA	Not Applicable
NC	Not calculated
NCS	Not clinically significant
NSAIDs	Non-Steroidal Anti-Inflammatory Drugs
OTC	Over The Counter
PD	Pharmacodynamics
PK	Pharmacokinetics
PT	Preferred Term
PTAE	Pre-Treatment Adverse Event
QOL	Quality of Life
SYSBP	Systolic Blood Pressure
SD	Standard Deviation
SOC	System Organ Class
SDTM	Study Data Tabulation Model
T	Test
TEAE	Treatment-Emergent Adverse Event
$t_{1/2}$	Half-life

T_{max}	Time to achieve Cmax
USDA	United States Department of Agriculture
WHODDE	World Health Organisation Drug Dictionary Enhanced

1 INTRODUCTION

Statistical analysis is performed by the CROSS Research Biometry Unit. The end-points and methods of analysis specified in this SAP are consistent with ICH E6 (R2) and E9 guidelines (1, 2). The present SAP has been compiled for part A of the study by the CRO Biometry Unit based on the final version 3.0 of the clinical study protocol (3), reviewed by the Sponsor and finalized before the database lock.

1.1 Changes with respect to the study protocol

No change with respect to the study protocol (3) was introduced in this SAP.

2 STUDY OBJECTIVES

The primary objective is to define the shortest safe and tolerable duration of IV injection of fosnetupitant 235 mg among 4 durations tested in decreasing order: 30, 15, 5 and 2 min, respectively.

The secondary objectives are:

- to characterize the pharmacokinetic (PK) profile in plasma of fosnetupitant, netupitant and netupitant metabolites M1, M2 and M3 after injection of T administered at the relevant injection duration and after injection of undiluted R (defined as Rα)
- to determine the safety and tolerability of T administered at the relevant injection duration

2.1 Primary end-points

- Type, number and frequency of TEAEs collected up to 24 h post-dose.

2.2 Secondary safety end-points

- Vital signs (blood pressure, pulse rate), 12-lead ECG, clinical laboratory tests (blood chemistry, hematology and urinalysis), body weight and physical examination

2.3 Secondary PK end-points

For plasma fosnetupitant, netupitant and its main metabolites M1, M2 and M3, when applicable the following parameters will be measured/calculated:

- C0, Cmax, tmax, Clast, tlast, AUC0-t (for all analytes), AUC0-24, λz, t½, CL, V_Z, MRT

3 INVESTIGATIONAL PLAN

3.1 Overall study design

Open label, single dose, safety and PK phase I study.

3.2 Discussion of design

The study design is in compliance with the relevant FDA guidance document for industry on bioavailability studies (4).

The study design is based upon that of a previous study of CINVANTI® (aprepitant injectable emulsion) published by Ottoboni et al. (5) where it is described that, due to a shortage of small volume parental solutions, the American Society of Health-System Pharmacists recommended switching the delivery of treatments from infusion to IV push.

The selected dose for the fosnetupitant component is 235 mg, corresponding to 260 mg of fosnetupitant chloride hydrochloride, previously shown to be equivalent in exposure (Netupitant AUC) to the netupitant dose present in the oral NEPA FDC (300 mg of netupitant).

See paragraph 11.2 of the study protocol (3) for further details.

4 STUDY POPULATION

4.1 Target population

Male and female adult healthy volunteers aged between 18 and 55 years old.

4.2 Inclusion criteria

To be enrolled in this study, subjects must fulfil all these criteria:

1. *Informed consent*: signed written informed consent before inclusion in the study
2. *Sex and Age*: healthy men/women volunteers, 18-55 years old (inclusive)
3. *Body Mass Index (BMI)*: 18.5-30 kg/m^2 inclusive
4. *Vital signs*: systolic blood pressure 100-139 mmHg, diastolic blood pressure 50-89 mmHg, pulse rate 50-99 bpm, measured after 5 min at rest in the sitting position
5. *Full comprehension*: ability to comprehend the full nature and purpose of the study, including possible risks and side effects; ability to co-operate with the investigator and to comply with the requirements of the entire study
6. *Contraception and fertility (women only):* women of childbearing potential defined as a non-menopausal woman who has not had a bilateral oophorectomy or medically documented ovarian failure and/or at risk for pregnancy must agree, signing the informed consent form, to use a highly effective method of contraception throughout the study and to continue for 14 days after the last dose of the study treatment. Highly effective contraceptive measures include:
    a. Hormonal oral, implantable, transdermal, or injectable contraceptives for at least 2 months before the screening visit.
    b. A non-hormonal intrauterine device [IUD] for at least 2 months before the screening visit
    c. A sterile or vasectomized sexual partner
    d. True (long-term) heterosexual abstinence, defined as refraining from heterosexual intercourse when this is in line with the preferred and usual lifestyle of the subject, while periodic abstinence (e.g., calendar, ovulation, symptothermal, post-ovulation methods), lactational amenorrhea and withdrawal are not acceptable.

    Women of non-child-bearing potential or in post-menopausal status defined as such when there is either:

    a. 12 months of spontaneous amenorrhea or
    b. 6 months of spontaneous amenorrhea with serum FSH levels > 40 mIU/mL or
    c. 6 weeks documented postsurgical bilateral oophorectomy with or without hysterectomy

    will be admitted.
    For all women, pregnancy test result must be negative at screening and admission (Day -1).

7. *Contraception (men only)*: men will either be sterile or agree to use one of the following approved methods of contraception from the first study drug administration until at least 14 days after the last administration, also in case their partner is currently pregnant:
    a. A male condom with spermicide
    b. A sterile sexual partner or a partner in post-menopausal status for at least one year
    c. Use by the female sexual partner of an IUD, a female condom with spermicide, a contraceptive sponge with spermicide, a diaphragm with spermicide, a cervical cap with spermicide, or hormonal oral, implantable, transdermal, or injectable contraceptives for at least 2 months before the screening visit

    Men must accept to inform their partners of the participation in the clinical study. Furthermore, they will not donate sperm from the date of the informed consent form's signature, throughout the study, and for at least 14 days after the last dose of the study treatment. These requirements are based upon the availability and results of reproductive toxicity data.

4.3 Exclusion criteria

Subjects meeting any of these criteria will not be enrolled in the study:

1. *12-leads Electrocardiogram (ECG) (supine position)*: clinically significant abnormalities at screening. With regards to QTc, the following will be considered as exclusion criterion: mean corrected QT (QTcF) > 450 ms. HR < 50 or > 99 bpm. PR < 100 or >220 ms. QRS > 120 ms. Relevantly abnormal T-wave patterns
2. *Physical examination findings*: clinically significant abnormal physical findings which could interfere with the objectives of the study
3. *Laboratory analyses*: clinically significant abnormal laboratory values at screening, indicative of physical illness or suggesting the subject's exclusion, in his/her best interest
4. *Allergy*: ascertained or presumptive hypersensitivity to the active principle and/or formulations' ingredients; history of anaphylaxis to drugs or allergic reactions in general, which the investigator considers may affect the outcome of the study
5. *Diseases*: significant history, in the opinion of the Investigator, of renal, hepatic, gastrointestinal, cardiovascular (in particular, heart failure, hypokalemia, family history of Long QT Syndrome, history of superficial thrombophlebitis or deep vein thrombosis), respiratory, skin, hematological, endocrine or neurological diseases that may interfere with the aim of the study
6. *Medications*: medications, including over the counter (OTC) medications and herbal remedies in the 2 weeks before the first visit of the study. Hormonal contraceptives for women are allowed
7. *CYP3A4 inducers and inhibitors:* use of any inducer or inhibitor of CYP3A4 enzymes (drugs, food, herbal remedies) in the 28 days or in the 7 days, respectively, before the planned first study drug administration and during the whole study
8. *Investigative drug studies*: participation in the evaluation of any investigational product for 3 months before this study. The 3-month interval is calculated as the time between the first calendar day of the month that follows the last visit of the previous study and the first day of the present study

9. *Blood donation or significant blood loss*: blood donations or significant blood loss in the 3 months before the first visit of this study
10. *Drug, alcohol, caffeine, tobacco*: history of drug, alcohol [>1 drink/day for women and >2 drinks/day for men, defined according to the USDA Dietary Guidelines 2020-2025 (317)], caffeine (>5 cups coffee/tea/day) or tobacco abuse (≥10 cigarettes/day)
11. *Drug test*: positive result at the urine drug screening test at screening or Day -1
12. *Alcohol test*: positive salivary alcohol test at Day -1
13. *Diet*: abnormal diets (<1600 or >3500 kcal/day) or substantial changes in eating habits in the 4 weeks before screening; vegetarians
14. *Pregnancy (women only)*: positive or missing pregnancy test at screening or Day -1, pregnant or lactating women
15. *Netupitant studies*: enrolment in a previous study of netupitant or fosnetupitant (alone or in combination with palonosetron)

4.3.1 Not allowed treatments

No medication, including OTC and herbal remedies, will be allowed in the 2 weeks before the first visit of the study (Screening - Visit 1) and during the whole study duration. In particular, the use of CYP3A4 inducers or CYP3A4 inhibitors (drugs, food, herbs) in the 28 days or in the 7 days, respectively, before the 1st study treatment intake on Day 1 will not be allowed.

Paracetamol will be allowed as therapeutic countermeasure for certain types of AEs according to the Investigator's opinion. Hormonal contraceptives will be allowed.

The intake of any other medication will be reported as a protocol deviation. However, it will lead to subject's discontinuation from the study only if the Investigator, together with the Sponsor, considers the medication as being able to affect the study assessments or outcome.

4.4 Use of contraceptive methods

In case of men or women of childbearing potential, the Investigator, in consultation with the subject, will select the appropriate method/methods of contraception for the individual according to the list of contraception methods of inclusion criteria 6 and 7, and instruct the subject or a screened man referring to his partner in their consistent and correct use. Highly effective contraceptive measures include those listed in inclusion criteria 6 and 7.
Moreover, men will not donate sperm from the date of the informed consent form's signature, throughout the study, and for at least 14 days after the last dose of the study treatment.
At screening and at each study visit, the Investigator will instruct subjects on the need to use contraception throughout the study and to continue for 14 days after the last dose of assigned treatment. In addition, the Investigator will instruct the subjects to call immediately if a selected birth control method is discontinued or if pregnancy is known or suspected.

5 STUDY SCHEDULE

The schedule of the study is summarised at page 6.

5.1 Study visits and procedures

Each subject will undergo 4 visits.

Study foresees, after the screening process, a confinement of approximately one and a half days at the Phase I Unit and one ambulatory visit (V4) 7 days post-dose. The maximum study duration for study will be 28 days, including the screening period.

The first subject first visit (FSFV) is defined as the 1st screening visit performed at the Phase I Unit for study by the 1st screened subject. The last subject last visit (LSLV) is defined as the last visit performed at the Phase I Unit by the last subject in study, i.e., the last visit foreseen by the study protocol, independently of the fact that the subject is a completer or a withdrawn subject.

The following phases, visits and procedures are performed:

- **Screening phase**
  - Screening – visit 1: between Day -21 and Day -2
  - Visit 2: Day -1

- **Interventional phase**
  - Visit 3: Days 1-2

- **Final phase**
  - Visit 4: Day 7: Final visit or Early termination visit (ETV). In case of early discontinuation, discontinued subjects will undergo an ETV.

	Day	Procedures/Assessments	Notes
Screening – visit 1	*From Day -21 to Day -2*	➢ Explanation to the subject of study aims, procedures and possible risks ➢ Informed consent signature ➢ Screening number assignment (as S001, S002, etc.) ➢ Demographic data and lifestyle recording ➢ Medical/surgical history ➢ Previous/concomitant medications ➢ Full physical examination (body weight, height, body mass index, vital signs, physical abnormalities) ➢ Triplicate 12-lead ECG recording ➢ Laboratory analyses: hematology, blood chemistry, urinalysis and virology ➢ Serum pregnancy test (women only) ➢ Urine multi-drug screening test ➢ AE recording ➢ Inclusion/exclusion criteria evaluation	*Note:* The first two letters of the surname followed by the first two letters of the first name will be used in the Phase I Unit source document only and will not be transferred to the Sponsor
Visit 2	*Day -1*	➢ Short physical examination (only if screening physical examination performed more than 7 days before Day -1) ➢ Recording of concomitant medications ➢ Salivary alcohol test ➢ Urine pregnancy test (women only) ➢ Urine multi-drug screening test ➢ Body weight ➢ Vital signs measurement ➢ AE recording ➢ Inclusion/exclusion criteria evaluation ➢ Eligibility evaluation ➢ Enrolment ➢ Subject study number assignment (as 001, 002, etc.)	Arrival at the Phase I Unit in the evening Confinement until the morning of Day 2 Standardized low-fat dinner Fasting for 10 h (overnight)
Visit 3	*Day 1*	➢ T or Rα treatment ➢ Vital signs measurement ➢ Triplicate 12-lead ECG recording ➢ Blood sample collection for PK analysis ➢ Recording of concomitant medications ➢ AE recording	Standardized lunch at about 13:00 (5 h post-dose) Standardized dinner at about 20:00 (12 h post-dose)
	Day 2	➢ Vital signs measurement ➢ Triplicate 12-lead ECG recording ➢ Blood sample collection for PK analysis ➢ Recording of concomitant medications ➢ Short physical examination upon discharge ➢ AE recording	Discharge from the Phase I Unit in the morning after the 24-h post-dose blood sample collection, ECG recording and vital signs check

	Day	Procedures/Assessments	Notes
Visit 4 - Final Visit/ETV	*Day 7 / at ETV in case of discontinuation*	➢ Full physical examination (body weight and physical abnormalities) ➢ Recording of concomitant medications ➢ Vital signs measurement ➢ Triplicate 12-lead ECG recording ➢ Urine pregnancy test (women only) ➢ Laboratory analyses as at screening, except for virology ➢ AE recording In case of clinically significant results at the final visit, the subjects will be followed-up by the Investigator until the normalization of the concerned clinical parameter(s)	Upon leaving, the subjects will be instructed to contact immediately the Investigator in case of occurrence of any adverse reactions

5.2 Decisional process for escalation to next administration duration

All TEAEs will be recorded in the CRF. TEAEs will be assessed by the Investigator with focus on general safety and local tolerability (i.e., any TEAEs appearing after start of injection and interesting the injection arm).

Following all planned subject's safety assessments and before subject's discharge, the Investigator will evaluate the reported TEAEs.

5.2.1 Decisional process for treatment of subjects within the cohorts

Subjects belonging to cohort 2, 3 and 4 will be sequentially treated as 3 subgroups of 3, 3 and 4 subjects respectively, in each cohort.
Following the treatment of the first 3 subjects in the cohort, the collected safety parameters will be carefully assessed by the Investigator. In particular, the local tolerability will be evaluated in view of confirming the treatment of the next subgroup of 3 subjects in the same cohort.
If deemed necessary, the study Investigator will contact the Sponsor Medical Expert and seek advice.
The same process will be repeated following the second subgroup of 3 subjects for confirming the treatment of the last 4 subjects of the cohort.

5.2.2 Decisional process for escalation to next administration duration

Following the completion of each cohort, the Sponsor Medical Expert will be provided with a summary of the observed tolerability, detailing each TEAE reported up to 60 min after the end of infusion of T and up to subject's discharge on Day 2. The Investigator will provide his assessments on severity and relationship to T. The Investigator will also provide a conclusion on the systemic and local tolerability related to the administration duration of T tested in the cohort, including his suggestion whether to consider safe to proceed with treating the next cohort of subjects with the next predefined infusion duration of T.

If the safety data obtained from a T treated cohort are considered as not sufficient for taking a decision on the infusion duration de-escalation process, and if additional safety data are deemed necessary to allow such decision to be taken, the study Investigator and the Sponsor Medical Expert may decide to add additional subjects (up to a maximum of 4 subjects per cohort) to the 10 subjects of the treated cohort.

The Sponsor Medical Expert will confirm the Sponsor's agreement to proceed or not with the treatment of the next planned subjects' cohort / injection duration.

Study will be stopped if any of the following criteria is met:

1. Any serious adverse event (SAE) assessed as at least possibly related to T experienced within 60 min after the end of T injection by at least one subject in a cohort.
2. Any AE coded with the same preferred term (PT) occurring to 2 subjects of the same cohort with both AEs judged at least as possibly related to T and of severe intensity, within 60 min after the end of T injection.

3. Any AE coded with the same PT occurring to 3 (or more) subjects of the same cohort with the AEs judged at least as possibly related to T and of moderate intensity, within 60 min after the end of T injection.

5.3 Diet and lifestyle

During the subjects' confinement at the Phase I Unit, they will not take any food or drinks (except water) for about 10 h (i.e., overnight) before P, T or R. Water will be allowed as desired, except for 1 h before and 1 h after P, T or R administration start. In order to maintain an adequate hydration, the subjects will be encouraged to drink at least 180 mL of still mineral water every 2 h for 5 h post-dose, starting at 1 h post-dose.

On Day 1 the subjects will remain fasted until 5 h after the start of injection/infusion. Standardized lunch and dinner will be served at approximately 5 h and 12 h after the start of injection/infusion.

On Day -1 a standardized low-fat dinner will be served. One cup of coffee or tea will be allowed after each meal only; any other coffee, tea or food containing xanthines (i.e., coke, energy drinks, chocolate, etc.), alcohol and grapefruit will be forbidden during confinement. In particular, grapefruit and any other food or beverage known to interfere with cytochrome P450 will be forbidden for 7 days (168 h) before the first study treatment administration until the end of the study.

During confinements, smoking will be forbidden.
During confinement, routine ambulant daily activities will be strongly recommended.

5.4 Restrictions

The subjects will be confined from the evening preceding T or Rα (undiluted R) treatment (study Day -1) until the morning of Day 2. All other study visits will be ambulatory.
During confinement, hazardous, strenuous or athletic activities will not be permitted.

6 STUDY SUBJECT IDENTIFICATION METHOD AND TREATMENT ASSIGNMENT METHOD

6.1 Unique subject identifier

All the subjects who sign the informed consent form for each part of the present study will be coded with "unique subject identifiers" when data are extracted from the study database into the domains of the CDISC SDTM model.
The unique subject identifier consists of the sponsor study code (i.e., PNET-22-08), the 3-digit site number (i.e., 001), the 4-digit screening number (e.g., S001, S002, etc.) and, if applicable, the 3-digit subject study number (e.g., 001, 002, etc.). Study code, site number, screening number and subject study or randomization number are separated by slashes ("/").

6.2 Subject identifier for the study

The last 8 digits of the unique subject identifier (enrolled subjects), corresponding to the subject screening and subject study numbers separated by a slash, or the last 4 digits of the unique subject identifier (not enrolled subjects), corresponding to the subject screening number, will appear as subject identifier in the individual listings and figures of the clinical study report and will be used to identify the subjects in in-text tables or wording (if applicable).

6.3 Randomisation

Cohorts are not randomized.

6.4 Treatment allocation

In cohort 1, the subjects will be assigned to one parallel treatment (T or Rα) according to their admittance to the Phase I Unit, i.e., the first 10 subjects will receive Rα and the next ten T.

6.5 Blinding

This is an open-label study. No masking procedure will be applied.

7 STUDY EVALUATION PARAMETERS

7.1 Study variables

7.1.1 Primary safety variables

- Type, number and frequency of TEAEs collected up to 24 h post-dose.

7.1.2 Secondary safety variables

The assessment of safety and tolerability of the IMP is based on treatment-emergent adverse events, vital signs (blood pressure and pulse rate), 12-lead ECG, clinical laboratory tests (blood chemistry, hematology and urinalysis), body weight and physical examination.

7.2 PK parameters

For plasma fosnetupitant, netupitant and its main metabolites M1, M2 and M3, when applicable, the following parameters will be measured/calculated:

- C_0: Plasma concentration at the end of the injection or infusion
- C_{max}: Maximum concentration
- t_{max}: Time to achieve C_{max}
- C_{last}: Last measurable plasma concentration above the lower limit of quantification of the bioanalytical method
- t_{last}: Time of last measurable plasma concentration above the lower limit of quantification of the bioanalytical method
- AUC_{0-t}: Area under the concentration-time curve from administration to the last observed concentration time t, calculated with the linear trapezoidal method
- AUC_{0-24}: Area Under the concentration-time Curve from time zero to 24h
- λ_z: Terminal elimination rate constant, calculated, if feasible, by log-linear regression using at least 3 points, C_0 and C_{max} excluded
- $t_{1/2}$: Apparent terminal half-life, calculated, if feasible, as $\ln 2/\lambda_z$
- CL: Systemic clearance
- V_z: Apparent volume of distribution in the post-distribution phase
- MRT: Mean residence time

The quality of log-linear regression (and, consequently, the reliability of the extrapolated PK parameters) should be demonstrated by a determination coefficient $R_2 \geq 0.8$. Individual extrapolated parameters, when considered unreliable, will be reported as NC (not calculated).

8 STATISTICAL METHOD

The data documented in this study and the parameters measured will be evaluated and compared using classic descriptive statistics, i.e., geometric mean (PK data only), arithmetic mean, SD, CV (%), minimum, median and maximum values for quantitative variables, and frequencies for qualitative variables.

Not available data are evaluated as “missing values”. The statistical analysis of demographic and safety data is performed using SAS® version 9.3 (TS1M1) (8) or higher (the actual version is stated in the final report).
The statistical analysis of PK parameters is performed using Phoenix WinNonlin® version 8.3.5 (9) or higher and SAS® version 9.3 (TS1M1) or higher.

Demographic, safety, and PK analyses will be performed by the Biometry Unit of the CRO, while ECG statistical analysis will be performed by the provider of continuous ECG.

8.1 Tables, listings and figures layout

Tables, listings and figures are provided according to the following settings:

- Background: White
- Foreground: Black
- Font face: Times
- Font style: Roman
- Font size: 10 pt
- Font weight: Medium (data, footers and notes), Bold (titles and headers)
- Font width: Normal
- Layout: Landscape
- Top Margin: 2.5 cm
- Bottom Margin: 2.5 cm
- Left Margin: 0.8 cm
- Right Margin: 0.8 cm
- Test label: T
- Reference label: Rα
- Cohort label: Cohort 1 30 min (Rα), Cohort 1 30 min (T), Cohort 2 15 min (T), Cohort 3 5 min (T), Cohort 4 2 min (T)
- Date format: ddMMMyyyy
- Means, standard deviations, percent coefficient of variations, medians, lower confidence limits and upper confidence limits are rounded to one digit more than the original data
- Minima and maxima keep the same number of decimal digits as the source values
- p-values are rounded to the fourth decimal digit and are flagged by an asterisk (*) in case of statistical significance (i.e. p-value < 0.05 or, in case of centre by treatment interaction, p-value < 0.10)
- p-values lower than 0.0001 are reported as "<.0001 *".

Data and results will be presented by cohort to which the subject belongs. For Cohort 1 data will be presented separately for subjects who received reference or test product.

8.2 Analysis sets

8.2.1 Definitions

A subject will be defined as screened after the signature of the informed consent, regardless of the completion of all the screening procedures.

A subject will be defined as eligible if he/she meets all the inclusion/exclusion criteria. Otherwise, he/she will be defined as a screen failure.

A subject will be defined as enrolled in the study if he/she is included in the interventional phase of the study. The enrolment will be performed through a non-randomized inclusion in the study.

An eligible but not enrolled subject will be defined as a reserve.

The following analysis sets are defined:

- *Enrolled set*: all enrolled subjects. This analysis set will be used for demographic, baseline and background characteristics
- *Safety set*: all subjects who receive at least one dose of the IMPs, including partial administration. This analysis set will be used for the safety analyses
- *PK set*: all enrolled subjects who fulfil the study protocol requirements in terms of T or Rα administration and have evaluable PK data readouts, with no major deviations that may affect the PK results. This analysis set will be used for the statistical analysis of the PK results.

Each subject will be coded by the CRO Biometry Unit as valid or not valid for the Safety set, PK set. Subjects will be evaluated according to the treatment they actually receive.

8.2.2 Reasons for exclusion from the PK Set

Reasons for the exclusion of subjects from one period in the PK set are the following:

- intake of concomitant medications or food / beverages which could render the plasma concentration-time profile unreliable
- AEs which could render the plasma concentration-time profile unreliable
- administration errors which could render the plasma concentration-time profile unreliable
- other events which could render the plasma concentration-time profile unreliable

If one of these events occurs, it will be noted in the CRF as the study is being conducted.

8.3 Sample size and power considerations

The planned number of 20 healthy subjects to be included in cohort 1 and of 10 healthy subjects to be included in each following cohort (cohorts 2, 3 and 4) of the study was not computed by statistical assumptions.

8.4 Demographic, baseline and background characteristics

Critical demographic characteristics will be examined according to qualitative or quantitative data. Qualitative data will be summarized in contingency tables. Quantitative data will be summarized using classic descriptive statistics.

8.4.1 Subjects' disposition

The disposition of all subjects enrolled in the study will be listed (Listing 16.2.4.1) and summarised by cohort and overall (Table 14.1.1.1). The number and proportion of subjects enrolled, treated and completing the study, the number and proportion of withdrawals and the reasons for withdrawal will be presented.

8.4.2 Analysis sets

The subjects included in each analysis sets will be summarised by cohort and overall (Table 14.1.1.2).

8.4.3 Subjects excluded from PK and/or safety analysis

All subjects excluded from the PK and/or safety analysis will be listed and the reasons for exclusion will be reported (Listing 16.2.3.1).

8.4.4 Discontinued subjects

All subjects who discontinued the clinical trial (if any) will be listed (Listing 16.2.1.1). Last IMP administered before discontinuation, gender, age, last visit performed before discontinuation, time elapsed from last IMP administration (hours), date of premature discontinuation and primary reason for subject premature discontinuation will be reported.

8.4.5 Protocol deviations

All the protocol deviations reported during the clinical trial will be listed (Listing 16.2.2.1) and summarised by cohort and overall classified as minor and major (Table 14.1.1.5). The number and proportion of subjects for each deviation will be reported.

8.4.6 Demography

Demographic data will be listed (Listing 16.2.4.2) and summarised by cohort and overall (Table 14.1.1.3). The number and proportion of subjects in each category for categorical variables (sex and race) and descriptive statistics (mean, SD, CV%, minimum, median and maximum) for continuous variables (age, body weight, height, BMI) will be presented.

8.4.7 Physical examination

Date of the physical examination at screening, overall Investigator’s interpretation (as normal or abnormal and, if abnormal, clinically significant or not clinically significant) and clinically significant abnormalities (if any) will be listed (Listing 16.2.4.4).

8.4.8 Fertility status and contraceptive method

The fertility status and the contraceptive method used by the female subjects will be listed (Listing 16.2.10.6).

8.4.9 Reproductive status and contraception

The reproductive status and the contraceptive method used by the male subjects will be listed (Listing 16.2.10.7).

8.4.10 Salivary alcohol test, pregnancy test and urine drug test

The date/time of the result of salivary alcohol test, pregnancy test and urine drug test will be listed (Listing 16.2.8.1).

8.4.11 Inclusion/exclusion criteria not met

All the unmet inclusion/exclusion criteria will be listed (Listing 16.2.4.3) and summarised by cohort and overall (Table 14.1.1.4).

8.4.12 Medical and surgical history

All the diseases of medical history and the surgeries of all subjects enrolled in the study will be coded using the Medical Dictionary for Regulatory Activities (MedDRA) version 27.0. and listed (Listing 16.2.10.1) .

8.4.13 Prior and concomitant medication

All prior and concomitant medications will be coded using the World Health Organization Drug Dictionary Enhanced (WHODDE) version March 1, 2024 and listed (Listing 16.2.10.3).

8.4.14 Tobacco, alcohol and caffeine consumption

Individual tobacco, alcohol and caffeine consumption habits history collected at screening will be listed (Listing 16.2.10.4).

8.4.15 Subjects' study visits

The dates of all subjects study visits will be listed (Listing 16.2.10.5).

8.4.16 Meals

The date/time of the standardised meals will be listed (Listing 16.2.10.8).

8.5 IMP administration

8.5.1 IMP administration (date/time)

The date and time of all IMP administrations and the details of the study drug interruption will be listed (Listing 16.2.5.1).

8.5.2 Fasting condition

The start date/time of fasting conditions and its duration will be listed (Listing 16.2.5.2).

8.5.3 Dose per body weight

The dose per body weight of IMP will be listed (Listing 16.2.5.3) and summarised using descriptive statistics (Table 14.3.5.6). The body weight collected at the screening visit will be used for the calculation.

8.6 PK analysis

The PK analysis will be performed on the subjects included into the PK Set.

8.6.1 PK blood samples collection

The actual date/time of PK blood samples collection will be listed (Listing 16.2.5.4).

8.6.2 Descriptive pharmacokinetics

A descriptive PK will be presented. Individual subject concentrations of fosnetupitant, netupitant and its main metabolites M1, M2 and M3, when applicable, will be presented in data listings and summarized at each time-point.
The calculated PK parameters will be listed, displayed and summarised in tables and figures. Individual and mean curves (+SD at sampling times), indicating inter-subject variability, will be plotted. Data below the lower quantification limit (BLQL) will be considered as 0 in the calculations and presented as BLQL in listings and tables. As a consequence of BLQL (i.e. 0) values, calculated geometric means (if requested) could be null. For this reason, in the presence of any null value, the geometric mean will be reported as not calculated (NC).

For plasma concentration of each analyte, descriptive statistics (N, mean, geometric mean, SD, CV%, median, minimum and maximum) will be tabulated at each time point (Table 14.2.1.1, Table 14.2.1.2, Table 14.2.1.3, Table 14.2.1.4, Table 14.2.1.5). Individual subject concentrations will be presented in data listings (Listing 16.2.5.5, Listing 16.2.5.6, Listing 16.2.5.7, Listing 16.2.5.8. Listing 16.2.5.9). All derived PK parameters will be listed (Listing 16.2.6.1, Listing 16.2.6.2, Listing 16.2.6.3, Listing 16.2.6.4, Listing 16.2.6.5) and their descriptive statistics (N, mean, geometric mean, SD, CV%, median, minimum and maximum) summarised (Table 14.2.2.1, Table 14.2.2.2, Table 14.2.2.3, Table 14.2.2.4, Table 14.2.2.5).

8.7 Safety and tolerability analysis

The safety and tolerability analysis will be performed on the subjects included into the Safety Set.

8.7.1 Adverse events

Adverse events (AEs) will be coded by System Organ Class (SOC) and Preferred Term (PT), using the Medical Dictionary for Regulatory Activities (MedDRA) version 27.0.
AEs will be classified as pre-treatment AEs (PTAEs) and treatment-emergent AEs (TEAEs), according to the period of occurrence, as follows:

- PTAEs: all AEs occurring before the dose of IMP and not worsening after the dose of IMP
- TEAEs: all AEs occurring or worsening after the dose of IMP

Individual PTAEs and TEAEs will be listed in subject data listings (Listing 16.2.7.1, Listing 16.2.7.2).
No summary table will be provided for PTAEs.

TEAEs will be summarized by cohort and overall.
The number and percentage of subjects with any TEAE and the number of TEAEs will be presented. (Table 14.3.1.1).
The number and percentage of subjects with any TEAE and the number of TEAEs will be presented by SOC and PT (Table 14.3.1.2).
The number and percentage of subjects with any TEAE by severity and the number of TEAEs by intensity will be presented by SOC and PT (Table 14.3.1.3).
The number and percentage of subjects with any TEAE related to the IMP and the number of TEAEs related to the IMP will be presented by SOC and PT (Table 14.3.1.4).

If applicable, serious TEAE will be summarized by SOC and PT (Table 14.3.1.5) and by relationship to IMP (Table 14.3.1.6).

All TEAEs leading to death, Serious TEAEs and all TEAEs leading to discontinuation will be listed (Table 14.3.2.1).

8.7.2 Vital signs

The date/time of vital signs and body weight assessments and the values of vital signs and body weight will be listed (Listing 16.2.9.1).
A table of all the abnormal vital signs' values (Table 14.3.5.1) and a table with descriptive statistics by cohort and overall will be presented (Table 14.3.5.2).

8.7.3 Body weight

The date/time of body weight assessments and the values of body weight will be listed (Listing 16.2.9.1) and summarized by cohort and overall with descriptive statistics (Table 14.3.5.3).

8.7.4 ECG

The date/time of 12-lead ECG recording and the values of ECG parameters will be listed, as well as the overall investigator's interpretation (as normal or abnormal and, if abnormal, clinically significant or not clinically significant) and clinically significant abnormalities (if any) (Listing 16.2.9.2, Listing 16.2.9.3).

A table of all the abnormal ECG parameters' values by cohort and overall will be presented (Table 14.3.5.4) and the overall Investigator's interpretation will be summarized by cohort and overall using tables of frequency (Table 14.3.5.5).

8.7.5 Laboratory data

The date/time of samples collection and the values of laboratory parameters will be listed, as well as the overall investigator's interpretation (as normal or abnormal and, if abnormal, clinically significant or not clinically significant) and clinically significant findings (if any) (Listing 16.2.8.1, Listing 16.2.8.2).
A table of all the abnormal values by cohort and overall will be presented (Table 14.3.4.1) and the overall Investigator's interpretation will be summarized by cohort and overall using tables of frequency (Table 14.3.4.2).

8.7.6 Physical examination

Date of the physical examination at Day -1, if applicable, and end of the study, overall Investigator's interpretation (as normal or abnormal and, if abnormal, clinically significant or not clinically significant) and clinically significant abnormalities (if any) will be listed (Listing 16.2.10.2).

8.8 Analysis datasets

Analysis datasets will be created according to the version 2.1 of the ADaM model of CDISC (10).

9 REFERENCES

1 ICH Topic E6 (R2): Good clinical practice.

2 ICH Topic E9: Statistical principles for clinical trials.

3 Study Protocol CRO-PK-23-363. " A phase I, open label, single dose, two parts study in male and female healthy subjects to assess the safety and pharmacokinetics of Fosnetupitant 235 mg administered as IV bolus and of derived Netupitant and Netupitant metabolites". Final version 3.0, 24MAY2023

4 Guidance for Industry. Bioavailability Studies Submitted in NDAs or INDs — General Considerations. U.S. Department of Health and Human Services. Food and Drug Administration, Center for Drug Evaluation and Research (CDER), Apr 2022

5 Ottoboni T, Lauw M, K MR, Cravets M, Manhard K, Clendeninn N and B Quart. HTX-019 via 2-min injection or 30-min infusion in healthy subjects. Future Oncol. 2019;15(8):865-874

6 ICH Topic E 8, General Considerations for Clinical Trials, CPMP/ICH/291/95, March 1998

7 U.S. Department of Health and Human Services and U.S. Department of Agriculture, Nutrition and your health: 2020-2025 Dietary Guidelines

8 SAS/STAT® User's Guide

9 WinNonLin Getting Started Guide, Pharsight Corporation

10 CDISC Analysis Data Model Version 2.1

10 APPENDICES

1. Section 14 - Tables Shells
2. Section 16.2 - Individual Subject Data Listings Shells

Section 14 - Tables Shells

Table 14.1.1.1 - Subjects' disposition - Enrolled set

	Cohort 1 30 min (Rα) n (%)	**Cohort 1 30 min (T) n (%)**	**Cohort 2 15 min (T) n (%)**	**Cohort 3 5 min (T) n (%)**	**Cohort 4 2 min (T) n (%)**	**Overall n (%)**
Enrolled	nn	nn	nn	nn	nn	nn
Discontinued before treatment [1]	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
Treated [1]	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
Completed [2]	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
Discontinued [2]	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
Adverse event [2]	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
Withdrawal by subject [2]	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
...	...	...	...	...	...	...

Note: The number and the proportion of subjects of each disposition event are reported
Note 1:The denominator for calculating the proportions is the number of enrolled subjects overall and in each cohort
Note 2: The denominator for calculating the proportions is the number of treated subjects overall and in each cohort
Source: Listing 16.2.4.1 - Subjects' disposition
Program: Tables\k363-ds-tbl.sas

Table 14.1.1.2 - Analysis sets - Enrolled set

	Cohort 1 **30 min (Rα)** **n (%)**	**Cohort 1** **30 min (T)** **n (%)**	**Cohort 2** **15 min (T)** **n (%)**	**Cohort 3** **5 min (T)** **n (%)**	**Cohort 4** **2 min (T)** **n (%)**	**Overall** **n (%)**
Safety Set	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
PK Set	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)

Note: The number and the proportion of subjects included in each analysis set are reported
The denominator for calculating the proportions is the number of subjects in the enrolled set overall and in each cohort
Source: Listing 16.2.3.1 - Subjects excluded from safety and/or PK analysis
Program: Tables\k363-ds-tbl.sas

Table 14.1.1.3 - Demography - Enrolled set, Safety set and PK set

Cohort 1: 30 min (Rα)

		Statistics	**Enrolled Set N=XX**	**Safety Set N=XX**	**PK Set N=XX**
Sex	Female	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	Male	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
Ethnicity	Hispanic or Latino	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	Not Hispanic or Latino	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	Not reported	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	Unknown	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
Race	White	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	Asian	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	American Indian or Alaska Native	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	African American	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	Native Hawaiian or Other Pacific Islander	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	Other	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
Age [years]		N	nn	nn	nn

Note: Subjects are summarised according to the cohort they belong to
Note 1: The number and the proportion of subjects of each sex and race are reported
Note 2: The denominator for calculating the proportions is the number of subjects in each analysis set and cohort
Source: Listing 16.2.4.3 - Demography
Program: Tables\k363-dm-tbl.sas

Table 14.1.1.3 - Demography - Enrolled set, Safety set and PK set

Cohort 1: 30 min (Rα)

	Statistics	Enrolled Set N=XX	Safety Set N=XX	PK Set N=XX
Age [years]	Mean	xx.x	xx.x	xx.x
	SD	xx.x	xx.x	xx.x
	CV%	xx.x	xx.x	xx.x
	Min	xx	xx	xx
	Median	xx.x	xx.x	xx.x
	Max	xx	xx	xx
Height [cm]	N	nn	nn	nn
	Mean	xx.x	xx.x	xx.x
	SD	xx.x	xx.x	xx.x
	CV%	xx.x	xx.x	xx.x
	Min	xx	xx	xx
	Median	xx.x	xx.x	xx.x
	Max	xx	xx	xx
Body Weight [kg]	N	nn	nn	nn
	Mean	xx.xx	xx.xx	xx.xx

Note: Subjects are summarised according to the cohort they belong to
Note 1: The number and the proportion of subjects of each sex and race are reported
Note 2: The denominator for calculating the proportions is the number of subjects in each analysis set and cohort
Source: Listing 16.2.4.3 - Demography
Program: Tables\k363-dm-tbl.sas

Table 14.1.1.3 - Demography - Enrolled set, Safety set and PK set

Cohort 1: 30 min (Rα)

	Statistics	**Enrolled Set N=XX**	**Safety Set N=XX**	**PK Set N=XX**
Body Weight [kg]	SD	xx.xx	xx.xx	xx.xx
	CV%	xx.xx	xx.xx	xx.xx
	Min	xx.x	xx.x	xx.x
	Median	xx.xx	xx.xx	xx.xx
	Max	xx.x	xx.x	xx.x
Body Mass Index [kg/m^2]	N	nn	nn	nn
	Mean	xx.xx	xx.xx	xx.xx
	SD	xx.xx	xx.xx	xx.xx
	CV%	xx.xx	xx.xx	xx.xx
	Min	xx.x	xx.x	xx.x
	Median	xx.xx	xx.xx	xx.xx
	Max	xx.x	xx.x	xx.x

Note: Subjects are summarised according to the cohort they belong to
Note 1: The number and the proportion of subjects of each sex and race are reported
Note 2: The denominator for calculating the proportions is the number of subjects in each analysis set and cohort
Source: Listing 16.2.4.3 - Demography
Program: Tables\k363-dm-tbl.sas

Table 14.1.1.3 - Demography - Enrolled set, Safety set and PK set

Cohort 1: 30 min (T)

		Statistics	Enrolled Set N=XX	Safety Set N=XX	PK Set N=XX
Sex	Female	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	Male	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
Ethnicity	Hispanic or Latino	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	Not Hispanic or Latino	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	Not reported	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	Unknown	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
Race	White	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	Asian	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	American Indian or Alaska Native	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	African American	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	Native Hawaiian or Other Pacific Islander	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	Other	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
Age [years]		N	nn	nn	nn

Note: Subjects are summarised according to the cohort they belong to
Note 1: The number and the proportion of subjects of each sex and race are reported
Note 2: The denominator for calculating the proportions is the number of subjects in each analysis set and cohort
Source: Listing 16.2.4.3 - Demography
Program: Tables\k363-dm-tbl.sas

Table 14.1.1.3 - Demography - Enrolled set, Safety set and PK set

Cohort 1: 30 min (T)

	Statistics	**Enrolled Set N=XX**	**Safety Set N=XX**	**PK Set N=XX**
Age [years]	Mean	xx.x	xx.x	xx.x
	SD	xx.x	xx.x	xx.x
	CV%	xx.x	xx.x	xx.x
	Min	xx	xx	xx
	Median	xx.x	xx.x	xx.x
	Max	xx	xx	xx
Height [cm]	N	nn	nn	nn
	Mean	xx.x	xx.x	xx.x
	SD	xx.x	xx.x	xx.x
	CV%	xx.x	xx.x	xx.x
	Min	xx	xx	xx
	Median	xx.x	xx.x	xx.x
	Max	xx	xx	xx
Body Weight [kg]	N	nn	nn	nn
	Mean	xx.xx	xx.xx	xx.xx

Note: Subjects are summarised according to the cohort they belong to
Note 1: The number and the proportion of subjects of each sex and race are reported
Note 2: The denominator for calculating the proportions is the number of subjects in each analysis set and cohort
Source: Listing 16.2.4.3 - Demography
Program: Tables\k363-dm-tbl.sas

Table 14.1.1.3 - Demography - Enrolled set, Safety set and PK set

Cohort 1: 30 min (T)

	Statistics	**Enrolled Set N=XX**	**Safety Set N=XX**	**PK Set N=XX**
Body Weight [kg]	SD	xx.xx	xx.xx	xx.xx
	CV%	xx.xx	xx.xx	xx.xx
	Min	xx.x	xx.x	xx.x
	Median	xx.xx	xx.xx	xx.xx
	Max	xx.x	xx.x	xx.x
Body Mass Index [kg/m^2]	N	nn	nn	nn
	Mean	xx.xx	xx.xx	xx.xx
	SD	xx.xx	xx.xx	xx.xx
	CV%	xx.xx	xx.xx	xx.xx
	Min	xx.x	xx.x	xx.x
	Median	xx.xx	xx.xx	xx.xx
	Max	xx.x	xx.x	xx.x

Note: Subjects are summarised according to the cohort they belong to
Note 1: The number and the proportion of subjects of each sex and race are reported
Note 2: The denominator for calculating the proportions is the number of subjects in each analysis set and cohort
Source: Listing 16.2.4.3 - Demography
Program: Tables\k363-dm-tbl.sas

Table 14.1.1.3 - Demography - Enrolled set, Safety set and PK set

Cohort 2: 15 min (T)

		Statistics	**Enrolled Set N=XX**	**Safety Set N=XX**	**PK Set N=XX**
Sex	Female	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	Male	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
Ethnicity	Hispanic or Latino	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	Not Hispanic or Latino	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	Not reported	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	Unknown	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
Race	White	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	Asian	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	American Indian or Alaska Native	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	African American	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	Native Hawaiian or Other Pacific Islander	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	Other	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
Age [years]		N	nn	nn	nn

Note: Subjects are summarised according to the cohort they belong to
Note 1: The number and the proportion of subjects of each sex and race are reported
Note 2: The denominator for calculating the proportions is the number of subjects in each analysis set and cohort
Source: Listing 16.2.4.3 - Demography
Program: Tables\k363-dm-tbl.sas

Table 14.1.1.3 - Demography - Enrolled set, Safety set and PK set

Cohort 2: 15 min (T)

	Statistics	**Enrolled Set N=XX**	**Safety Set N=XX**	**PK Set N=XX**
Age [years]	Mean	xx.x	xx.x	xx.x
	SD	xx.x	xx.x	xx.x
	CV%	xx.x	xx.x	xx.x
	Min	xx	xx	xx
	Median	xx.x	xx.x	xx.x
	Max	xx	xx	xx
Height [cm]	N	nn	nn	nn
	Mean	xx.x	xx.x	xx.x
	SD	xx.x	xx.x	xx.x
	CV%	xx.x	xx.x	xx.x
	Min	xx	xx	xx
	Median	xx.x	xx.x	xx.x
	Max	xx	xx	xx
Body Weight [kg]	N	nn	nn	nn
	Mean	xx.xx	xx.xx	xx.xx

Note: Subjects are summarised according to the cohort they belong to
Note 1: The number and the proportion of subjects of each sex and race are reported
Note 2: The denominator for calculating the proportions is the number of subjects in each analysis set and cohort
Source: Listing 16.2.4.3 - Demography
Program: Tables\k363-dm-tbl.sas

Table 14.1.1.3 - Demography - Enrolled set, Safety set and PK set

Cohort 2: 15 min (T)

	Statistics	**Enrolled Set N=XX**	**Safety Set N=XX**	**PK Set N=XX**
Body Weight [kg]	SD	xx.xx	xx.xx	xx.xx
	CV%	xx.xx	xx.xx	xx.xx
	Min	xx.x	xx.x	xx.x
	Median	xx.xx	xx.xx	xx.xx
	Max	xx.x	xx.x	xx.x
Body Mass Index [kg/m^2]	N	nn	nn	nn
	Mean	xx.xx	xx.xx	xx.xx
	SD	xx.xx	xx.xx	xx.xx
	CV%	xx.xx	xx.xx	xx.xx
	Min	xx.x	xx.x	xx.x
	Median	xx.xx	xx.xx	xx.xx
	Max	xx.x	xx.x	xx.x

Note: Subjects are summarised according to the cohort they belong to
Note 1: The number and the proportion of subjects of each sex and race are reported
Note 2: The denominator for calculating the proportions is the number of subjects in each analysis set and cohort
Source: Listing 16.2.4.3 - Demography
Program: Tables\k363-dm-tbl.sas

Table 14.1.1.3 - Demography - Enrolled set, Safety set and PK set

Cohort 3: 5 min (T)

		Statistics	**Enrolled Set N=XX**	**Safety Set N=XX**	**PK Set N=XX**
Sex	Female	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	Male	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
Ethnicity	Hispanic or Latino	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	Not Hispanic or Latino	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	Not reported	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	Unknown	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
Race	White	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	Asian	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	American Indian or Alaska Native	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	African American	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	Native Hawaiian or Other Pacific Islander	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	Other	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
Age [years]		N	nn	nn	nn

Note: Subjects are summarised according to the cohort they belong to
Note 1: The number and the proportion of subjects of each sex and race are reported
Note 2: The denominator for calculating the proportions is the number of subjects in each analysis set and cohort
Source: Listing 16.2.4.3 - Demography
Program: Tables\k363-dm-tbl.sas

Table 14.1.1.3 - Demography - Enrolled set, Safety set and PK set

Cohort 3: 5 min (T)

	Statistics	**Enrolled Set N=XX**	**Safety Set N=XX**	**PK Set N=XX**
Age [years]	Mean	xx.x	xx.x	xx.x
	SD	xx.x	xx.x	xx.x
	CV%	xx.x	xx.x	xx.x
	Min	xx	xx	xx
	Median	xx.x	xx.x	xx.x
	Max	xx	xx	xx
Height [cm]	N	nn	nn	nn
	Mean	xx.x	xx.x	xx.x
	SD	xx.x	xx.x	xx.x
	CV%	xx.x	xx.x	xx.x
	Min	xx	xx	xx
	Median	xx.x	xx.x	xx.x
	Max	xx	xx	xx
Body Weight [kg]	N	nn	nn	nn
	Mean	xx.xx	xx.xx	xx.xx

Note: Subjects are summarised according to the cohort they belong to
Note 1: The number and the proportion of subjects of each sex and race are reported
Note 2: The denominator for calculating the proportions is the number of subjects in each analysis set and cohort
Source: Listing 16.2.4.3 - Demography
Program: Tables\k363-dm-tbl.sas

Table 14.1.1.3 - Demography - Enrolled set, Safety set and PK set

Cohort 3: 5 min (T)

	Statistics	**Enrolled Set N=XX**	**Safety Set N=XX**	**PK Set N=XX**
Body Weight [kg]	SD	xx.xx	xx.xx	xx.xx
	CV%	xx.xx	xx.xx	xx.xx
	Min	xx.x	xx.x	xx.x
	Median	xx.xx	xx.xx	xx.xx
	Max	xx.x	xx.x	xx.x
Body Mass Index [kg/m^2]	N	nn	nn	nn
	Mean	xx.xx	xx.xx	xx.xx
	SD	xx.xx	xx.xx	xx.xx
	CV%	xx.xx	xx.xx	xx.xx
	Min	xx.x	xx.x	xx.x
	Median	xx.xx	xx.xx	xx.xx
	Max	xx.x	xx.x	xx.x

Note: Subjects are summarised according to the cohort they belong to
Note 1: The number and the proportion of subjects of each sex and race are reported
Note 2: The denominator for calculating the proportions is the number of subjects in each analysis set and cohort
Source: Listing 16.2.4.3 - Demography
Program: Tables\k363-dm-tbl.sas

Table 14.1.1.3 - Demography - Enrolled set, Safety set and PK set

Cohort 4: 2 min (T)

		Statistics	**Enrolled Set N=XX**	**Safety Set N=XX**	**PK Set N=XX**
Sex	Female	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	Male	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
Ethnicity	Hispanic or Latino	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	Not Hispanic or Latino	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	Not reported	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	Unknown	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
Race	White	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	Asian	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	American Indian or Alaska Native	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	African American	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	Native Hawaiian or Other Pacific Islander	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	Other	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
Age [years]		N	nn	nn	nn

Note: Subjects are summarised according to the cohort they belong to
Note 1: The number and the proportion of subjects of each sex and race are reported
Note 2: The denominator for calculating the proportions is the number of subjects in each analysis set and cohort
Source: Listing 16.2.4.3 - Demography
Program: Tables\k363-dm-tbl.sas

Table 14.1.1.3 - Demography - Enrolled set, Safety set and PK set

Cohort 4: 2 min (T)

	Statistics	**Enrolled Set N=XX**	**Safety Set N=XX**	**PK Set N=XX**
Age [years]	Mean	xx.x	xx.x	xx.x
	SD	xx.x	xx.x	xx.x
	CV%	xx.x	xx.x	xx.x
	Min	xx	xx	xx
	Median	xx.x	xx.x	xx.x
	Max	xx	xx	xx
Height [cm]	N	nn	nn	nn
	Mean	xx.x	xx.x	xx.x
	SD	xx.x	xx.x	xx.x
	CV%	xx.x	xx.x	xx.x
	Min	xx	xx	xx
	Median	xx.x	xx.x	xx.x
	Max	xx	xx	xx
Body Weight [kg]	N	nn	nn	nn
	Mean	xx.xx	xx.xx	xx.xx

Note: Subjects are summarised according to the cohort they belong to
Note 1: The number and the proportion of subjects of each sex and race are reported
Note 2: The denominator for calculating the proportions is the number of subjects in each analysis set and cohort
Source: Listing 16.2.4.3 - Demography
Program: Tables\k363-dm-tbl.sas

Table 14.1.1.3 - Demography - Enrolled set, Safety set and PK set

Cohort 4: 2 min (T)

	Statistics	**Enrolled Set N=XX**	**Safety Set N=XX**	**PK Set N=XX**
Body Weight [kg]	SD	xx.xx	xx.xx	xx.xx
	CV%	xx.xx	xx.xx	xx.xx
	Min	xx.x	xx.x	xx.x
	Median	xx.xx	xx.xx	xx.xx
	Max	xx.x	xx.x	xx.x
Body Mass Index [kg/m^2]	N	nn	nn	nn
	Mean	xx.xx	xx.xx	xx.xx
	SD	xx.xx	xx.xx	xx.xx
	CV%	xx.xx	xx.xx	xx.xx
	Min	xx.x	xx.x	xx.x
	Median	xx.xx	xx.xx	xx.xx
	Max	xx.x	xx.x	xx.x

Note: Subjects are summarised according to the cohort they belong to
Note 1: The number and the proportion of subjects of each sex and race are reported
Note 2: The denominator for calculating the proportions is the number of subjects in each analysis set and cohort
Source: Listing 16.2.4.3 - Demography
Program: Tables\k363-dm-tbl.sas

Table 14.1.1.3 - Demography - Enrolled set, Safety set and PK set

Overall

		Statistics	Enrolled Set N=XX	Safety Set N=XX	PK Set N=XX
Sex	Female	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	Male	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
Ethnicity	Hispanic or Latino	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	Not Hispanic or Latino	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	Not reported	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	Unknown	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
Race	White	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	Asian	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	American Indian or Alaska Native	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	African American	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	Native Hawaiian or Other Pacific Islander	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	Other	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
Age [years]		N	nn	nn	nn

Note: Subjects are summarised according to the cohort they belong to
Note 1: The number and the proportion of subjects of each sex and race are reported
Note 2: The denominator for calculating the proportions is the number of subjects in each analysis set and cohort
Source: Listing 16.2.4.3 - Demography
Program: Tables\k363-dm-tbl.sas

Table 14.1.1.3 - Demography - Enrolled set, Safety set and PK set

Overall

	Statistics	**Enrolled Set N=XX**	**Safety Set N=XX**	**PK Set N=XX**
Age [years]	Mean	xx.x	xx.x	xx.x
	SD	xx.x	xx.x	xx.x
	CV%	xx.x	xx.x	xx.x
	Min	xx	xx	xx
	Median	xx.x	xx.x	xx.x
	Max	xx	xx	xx
Height [cm]	N	nn	nn	nn
	Mean	xx.x	xx.x	xx.x
	SD	xx.x	xx.x	xx.x
	CV%	xx.x	xx.x	xx.x
	Min	xx	xx	xx
	Median	xx.x	xx.x	xx.x
	Max	xx	xx	xx
Body Weight [kg]	N	nn	nn	nn
	Mean	xx.xx	xx.xx	xx.xx

Note: Subjects are summarised according to the cohort they belong to
Note 1: The number and the proportion of subjects of each sex and race are reported
Note 2: The denominator for calculating the proportions is the number of subjects in each analysis set and cohort
Source: Listing 16.2.4.3 - Demography
Program: Tables\k363-dm-tbl.sas

Table 14.1.1.3 - Demography - Enrolled set, Safety set and PK set

Overall

	Statistics	**Enrolled Set N=XX**	**Safety Set N=XX**	**PK Set N=XX**
Body Weight [kg]	SD	xx.xx	xx.xx	xx.xx
	CV%	xx.xx	xx.xx	xx.xx
	Min	xx.x	xx.x	xx.x
	Median	xx.xx	xx.xx	xx.xx
	Max	xx.x	xx.x	xx.x
Body Mass Index [kg/m^2]	N	nn	nn	nn
	Mean	xx.xx	xx.xx	xx.xx
	SD	xx.xx	xx.xx	xx.xx
	CV%	xx.xx	xx.xx	xx.xx
	Min	xx.x	xx.x	xx.x
	Median	xx.xx	xx.xx	xx.xx
	Max	xx.x	xx.x	xx.x

Note: Subjects are summarised according to the cohort they belong to
Note 1: The number and the proportion of subjects of each sex and race are reported
Note 2: The denominator for calculating the proportions is the number of subjects in each analysis set and cohort
Source: Listing 16.2.4.3 - Demography
Program: Tables\k363-dm-tbl.sas

Table 14.1.1.4 - Inclusion/exclusion criteria not met - Enrolled set, Safety set and PK set

Cohort 1: 30 min (Rα)

	Enrolled Set N=XX	**Safety Set N=XX**	**PK Set N=XX**
Number of subjects with any inclusion/exclusion criteria not met	nn (xx.x)	nn (xx.x)	nn (xx.x)
Inclusion	nn (xx.x)	nn (xx.x)	nn (xx.x)
Inclusion criterion 1 [Informed consent]	nn (xx.x)	nn (xx.x)	nn (xx.x)
Inclusion criterion 2 [Sex and Age]	nn (xx.x)	nn (xx.x)	nn (xx.x)
...	nn (xx.x)	nn (xx.x)	nn (xx.x)
Exclusion	nn (xx.x)	nn (xx.x)	nn (xx.x)
Exclusion criterion 1 [ECG (12-leads, supine position)]	nn (xx.x)	nn (xx.x)	nn (xx.x)
Exclusion criterion 2 [Physical findings]	nn (xx.x)	nn (xx.x)	nn (xx.x)
...	nn (xx.x)	nn (xx.x)	nn (xx.x)

Note: Subjects are summarised according to the cohort they belong to
The number and the proportion of subjects for any criterion not met are reported
The denominator for calculating the proportions is the number of subjects in each analysis set and cohort
Source: Listing 16.2.4.4 - Inclusion/Exclusion criteria not met
Program:Tables\k363-ie-tbl.sas

Table 14.1.1.4 - Inclusion/exclusion criteria not met - Enrolled set, Safety set and PK set

Cohort 1: 30 min (T)

	Enrolled Set N=XX	**Safety Set N=XX**	**PK Set N=XX**
Number of subjects with any inclusion/exclusion criteria not met	nn (xx.x)	nn (xx.x)	nn (xx.x)
Inclusion	nn (xx.x)	nn (xx.x)	nn (xx.x)
Inclusion criterion 1 [Informed consent]	nn (xx.x)	nn (xx.x)	nn (xx.x)
Inclusion criterion 2 [Sex and Age]	nn (xx.x)	nn (xx.x)	nn (xx.x)
...	nn (xx.x)	nn (xx.x)	nn (xx.x)
Exclusion	nn (xx.x)	nn (xx.x)	nn (xx.x)
Exclusion criterion 1 [ECG (12-leads, supine position)]	nn (xx.x)	nn (xx.x)	nn (xx.x)
Exclusion criterion 2 [Physical findings]	nn (xx.x)	nn (xx.x)	nn (xx.x)
...	nn (xx.x)	nn (xx.x)	nn (xx.x)

Note: Subjects are summarised according to the cohort they belong to
The number and the proportion of subjects for any criterion not met are reported
The denominator for calculating the proportions is the number of subjects in each analysis set and cohort
Source: Listing 16.2.4.4 - Inclusion/Exclusion criteria not met
Program:Tables\k363-ie-tbl.sas

Table 14.1.1.4 - Inclusion/exclusion criteria not met - Enrolled set, Safety set and PK set

Cohort 2: 15 min (T)

	Enrolled Set N=XX	**Safety Set N=XX**	**PK Set N=XX**
Number of subjects with any inclusion/exclusion criteria not met	nn (xx.x)	nn (xx.x)	nn (xx.x)
Inclusion	nn (xx.x)	nn (xx.x)	nn (xx.x)
Inclusion criterion 1 [Informed consent]	nn (xx.x)	nn (xx.x)	nn (xx.x)
Inclusion criterion 2 [Sex and Age]	nn (xx.x)	nn (xx.x)	nn (xx.x)
...	nn (xx.x)	nn (xx.x)	nn (xx.x)
Exclusion	nn (xx.x)	nn (xx.x)	nn (xx.x)
Exclusion criterion 1 [ECG (12-leads, supine position)]	nn (xx.x)	nn (xx.x)	nn (xx.x)
Exclusion criterion 2 [Physical findings]	nn (xx.x)	nn (xx.x)	nn (xx.x)
...	nn (xx.x)	nn (xx.x)	nn (xx.x)

Note: Subjects are summarised according to the cohort they belong to
The number and the proportion of subjects for any criterion not met are reported
The denominator for calculating the proportions is the number of subjects in each analysis set and cohort
Source: Listing 16.2.4.4 - Inclusion/Exclusion criteria not met
Program:Tables\k363-ie-tbl.sas

Table 14.1.1.4 - Inclusion/exclusion criteria not met - Enrolled set, Safety set and PK set

Cohort 3: 5 min (T)

	Enrolled Set N=XX	**Safety Set N=XX**	**PK Set N=XX**
Number of subjects with any inclusion/exclusion criteria not met	nn (xx.x)	nn (xx.x)	nn (xx.x)
Inclusion	nn (xx.x)	nn (xx.x)	nn (xx.x)
Inclusion criterion 1 [Informed consent]	nn (xx.x)	nn (xx.x)	nn (xx.x)
Inclusion criterion 2 [Sex and Age]	nn (xx.x)	nn (xx.x)	nn (xx.x)
...	nn (xx.x)	nn (xx.x)	nn (xx.x)
Exclusion	nn (xx.x)	nn (xx.x)	nn (xx.x)
Exclusion criterion 1 [ECG (12-leads, supine position)]	nn (xx.x)	nn (xx.x)	nn (xx.x)
Exclusion criterion 2 [Physical findings]	nn (xx.x)	nn (xx.x)	nn (xx.x)
...	nn (xx.x)	nn (xx.x)	nn (xx.x)

Note: Subjects are summarised according to the cohort they belong to
The number and the proportion of subjects for any criterion not met are reported
The denominator for calculating the proportions is the number of subjects in each analysis set and cohort _
Source: Listing 16.2.4.4 - Inclusion/Exclusion criteria not met
Program:Tables\k363-ie-tbl.sas

Table 14.1.1.4 - Inclusion/exclusion criteria not met - Enrolled set, Safety set and PK set

Cohort 4: 2 min (T)

	Enrolled Set N=XX	**Safety Set N=XX**	**PK Set N=XX**
Number of subjects with any inclusion/exclusion criteria not met	nn (xx.x)	nn (xx.x)	nn (xx.x)
Inclusion	nn (xx.x)	nn (xx.x)	nn (xx.x)
Inclusion criterion 1 [Informed consent]	nn (xx.x)	nn (xx.x)	nn (xx.x)
Inclusion criterion 2 [Sex and Age]	nn (xx.x)	nn (xx.x)	nn (xx.x)
...	nn (xx.x)	nn (xx.x)	nn (xx.x)
Exclusion	nn (xx.x)	nn (xx.x)	nn (xx.x)
Exclusion criterion 1 [ECG (12-leads, supine position)]	nn (xx.x)	nn (xx.x)	nn (xx.x)
Exclusion criterion 2 [Physical findings]	nn (xx.x)	nn (xx.x)	nn (xx.x)
...	nn (xx.x)	nn (xx.x)	nn (xx.x)

Note: Subjects are summarised according to the cohort they belong to
The number and the proportion of subjects for any criterion not met are reported
The denominator for calculating the proportions is the number of subjects in each analysis set and cohort _
Source: Listing 16.2.4.4 - Inclusion/Exclusion criteria not met
Program:Tables\k363-ie-tbl.sas

Table 14.1.1.4 - Inclusion/exclusion criteria not met - Enrolled set, Safety set and PK set

Overall

	Enrolled Set N=XX	**Safety Set N=XX**	**PK Set N=XX**
Number of subjects with any inclusion/exclusion criteria not met	nn (xx.x)	nn (xx.x)	nn (xx.x)
Inclusion	nn (xx.x)	nn (xx.x)	nn (xx.x)
Inclusion criterion 1 [Informed consent]	nn (xx.x)	nn (xx.x)	nn (xx.x)
Inclusion criterion 2 [Sex and Age]	nn (xx.x)	nn (xx.x)	nn (xx.x)
...	nn (xx.x)	nn (xx.x)	nn (xx.x)
Exclusion	nn (xx.x)	nn (xx.x)	nn (xx.x)
Exclusion criterion 1 [ECG (12-leads, supine position)]	nn (xx.x)	nn (xx.x)	nn (xx.x)
Exclusion criterion 2 [Physical findings]	nn (xx.x)	nn (xx.x)	nn (xx.x)
...	nn (xx.x)	nn (xx.x)	nn (xx.x)

Note: Subjects are summarised according to the cohort they belong to
The number and the proportion of subjects for any criterion not met are reported
The denominator for calculating the proportions is the number of subjects in each analysis set and cohort
Source: Listing 16.2.4.4 - Inclusion/Exclusion criteria not met
Program:Tables\k363-ie-tbl.sas

Table 14.1.1.5 - Protocol deviations - Enrolled set, Safety set and PK set

Cohort 1: 30 min (Rα)

	Enrolled Set N=XX	**Safety Set N=XX**	**PK Set N=XX**
Number of subjects with any protocol deviation	nn (xx.x)	nn (xx.x)	nn (xx.x)
Major	nn (xx.x)	nn (xx.x)	nn (xx.x)
Treatment deviation	nn (xx.x)	nn (xx.x)	nn (xx.x)
Inclusion criteria violation	nn (xx.x)	nn (xx.x)	nn (xx.x)
Exclusion criteria violation	nn (xx.x)	nn (xx.x)	nn (xx.x)
Medication not admitted	nn (xx.x)	nn (xx.x)	nn (xx.x)
...	nn (xx.x)	nn (xx.x)	nn (xx.x)
Minor	nn (xx.x)	nn (xx.x)	nn (xx.x)
Deviation from scheduled sampling time	nn (xx.x)	nn (xx.x)	nn (xx.x)
Deviation from scheduled assessment time	nn (xx.x)	nn (xx.x)	nn (xx.x)
...	nn (xx.x)	nn (xx.x)	nn (xx.x)

Note: Subjects are summarised according to the cohort they belong to
The number and the proportion of subjects for any protocol violation are reported
The denominator for calculating the proportions is the number of subjects in each analysis set and cohort
Source: Listing 16.2.2.1 - Protocol deviations
Program: Tables\k363-dv-tbl.sas

Table 14.1.1.5 - Protocol deviations - Enrolled set, Safety set and PK set

Cohort 1: 30 min (T)

	Enrolled Set N=XX	**Safety Set N=XX**	**PK Set N=XX**
Number of subjects with any protocol deviation	nn (xx.x)	nn (xx.x)	nn (xx.x)
Major	nn (xx.x)	nn (xx.x)	nn (xx.x)
Treatment deviation	nn (xx.x)	nn (xx.x)	nn (xx.x)
Inclusion criteria violation	nn (xx.x)	nn (xx.x)	nn (xx.x)
Exclusion criteria violation	nn (xx.x)	nn (xx.x)	nn (xx.x)
Medication not admitted	nn (xx.x)	nn (xx.x)	nn (xx.x)
...	nn (xx.x)	nn (xx.x)	nn (xx.x)
Minor	nn (xx.x)	nn (xx.x)	nn (xx.x)
Deviation from scheduled sampling time	nn (xx.x)	nn (xx.x)	nn (xx.x)
Deviation from scheduled assessment time	nn (xx.x)	nn (xx.x)	nn (xx.x)
...	nn (xx.x)	nn (xx.x)	nn (xx.x)

Note: Subjects are summarised according to the cohort they belong to
The number and the proportion of subjects for any protocol violation are reported
The denominator for calculating the proportions is the number of subjects in each analysis set and cohort
Source: Listing 16.2.2.1 - Protocol deviations
Program: Tables\k363-dv-tbl.sas

Table 14.1.1.5 - Protocol deviations - Enrolled set, Safety set and PK set

Cohort 2: 15 min (T)

	Enrolled Set N=XX	**Safety Set N=XX**	**PK Set N=XX**
Number of subjects with any protocol deviation	nn (xx.x)	nn (xx.x)	nn (xx.x)
Major	nn (xx.x)	nn (xx.x)	nn (xx.x)
Treatment deviation	nn (xx.x)	nn (xx.x)	nn (xx.x)
Inclusion criteria violation	nn (xx.x)	nn (xx.x)	nn (xx.x)
Exclusion criteria violation	nn (xx.x)	nn (xx.x)	nn (xx.x)
Medication not admitted	nn (xx.x)	nn (xx.x)	nn (xx.x)
...	nn (xx.x)	nn (xx.x)	nn (xx.x)
Minor	nn (xx.x)	nn (xx.x)	nn (xx.x)
Deviation from scheduled sampling time	nn (xx.x)	nn (xx.x)	nn (xx.x)
Deviation from scheduled assessment time	nn (xx.x)	nn (xx.x)	nn (xx.x)
...	nn (xx.x)	nn (xx.x)	nn (xx.x)

Note: Subjects are summarised according to the cohort they belong to
The number and the proportion of subjects for any protocol violation are reported
The denominator for calculating the proportions is the number of subjects in each analysis set and cohort
Source: Listing 16.2.2.1 - Protocol deviations
Program: Tables\k363-dv-tbl.sas

Table 14.1.1.5 - Protocol deviations - Enrolled set, Safety set and PK set

Cohort 3: 5 min (T)

	Enrolled Set N=XX	**Safety Set N=XX**	**PK Set N=XX**
Number of subjects with any protocol deviation	nn (xx.x)	nn (xx.x)	nn (xx.x)
Major	nn (xx.x)	nn (xx.x)	nn (xx.x)
Treatment deviation	nn (xx.x)	nn (xx.x)	nn (xx.x)
Inclusion criteria violation	nn (xx.x)	nn (xx.x)	nn (xx.x)
Exclusion criteria violation	nn (xx.x)	nn (xx.x)	nn (xx.x)
Medication not admitted	nn (xx.x)	nn (xx.x)	nn (xx.x)
...	nn (xx.x)	nn (xx.x)	nn (xx.x)
Minor	nn (xx.x)	nn (xx.x)	nn (xx.x)
Deviation from scheduled sampling time	nn (xx.x)	nn (xx.x)	nn (xx.x)
Deviation from scheduled assessment time	nn (xx.x)	nn (xx.x)	nn (xx.x)
...	nn (xx.x)	nn (xx.x)	nn (xx.x)

Note: Subjects are summarised according to the cohort they belong to
The number and the proportion of subjects for any protocol violation are reported
The denominator for calculating the proportions is the number of subjects in each analysis set and cohort
Source: Listing 16.2.2.1 - Protocol deviations
Program: Tables\k363-dv-tbl.sas

Table 14.1.1.5 - Protocol deviations - Enrolled set, Safety set and PK set

Cohort 4: 2 min (T)

	Enrolled Set N=XX	**Safety Set N=XX**	**PK Set N=XX**
Number of subjects with any protocol deviation	nn (xx.x)	nn (xx.x)	nn (xx.x)
Major	nn (xx.x)	nn (xx.x)	nn (xx.x)
Treatment deviation	nn (xx.x)	nn (xx.x)	nn (xx.x)
Inclusion criteria violation	nn (xx.x)	nn (xx.x)	nn (xx.x)
Exclusion criteria violation	nn (xx.x)	nn (xx.x)	nn (xx.x)
Medication not admitted	nn (xx.x)	nn (xx.x)	nn (xx.x)
...	nn (xx.x)	nn (xx.x)	nn (xx.x)
Minor	nn (xx.x)	nn (xx.x)	nn (xx.x)
Deviation from scheduled sampling time	nn (xx.x)	nn (xx.x)	nn (xx.x)
Deviation from scheduled assessment time	nn (xx.x)	nn (xx.x)	nn (xx.x)
...	nn (xx.x)	nn (xx.x)	nn (xx.x)

Note: Subjects are summarised according to the cohort they belong to
The number and the proportion of subjects for any protocol violation are reported
The denominator for calculating the proportions is the number of subjects in each analysis set and cohort
Source: Listing 16.2.2.1 - Protocol deviations
Program: Tables\k363-dv-tbl.sas

Table 14.1.1.5 - Protocol deviations - Enrolled set, Safety set and PK set

Overall

	Enrolled Set N=XX	Safety Set N=XX	PK Set N=XX
Number of subjects with any protocol deviation	nn (xx.x)	nn (xx.x)	nn (xx.x)
Major	nn (xx.x)	nn (xx.x)	nn (xx.x)
Treatment deviation	nn (xx.x)	nn (xx.x)	nn (xx.x)
Inclusion criteria violation	nn (xx.x)	nn (xx.x)	nn (xx.x)
Exclusion criteria violation	nn (xx.x)	nn (xx.x)	nn (xx.x)
Medication not admitted	nn (xx.x)	nn (xx.x)	nn (xx.x)
...	nn (xx.x)	nn (xx.x)	nn (xx.x)
Minor	nn (xx.x)	nn (xx.x)	nn (xx.x)
Deviation from scheduled sampling time	nn (xx.x)	nn (xx.x)	nn (xx.x)
Deviation from scheduled assessment time	nn (xx.x)	nn (xx.x)	nn (xx.x)
...	nn (xx.x)	nn (xx.x)	nn (xx.x)

Note: Subjects are summarised according to the cohort they belong to
The number and the proportion of subjects for any protocol violation are reported
The denominator for calculating the proportions is the number of subjects in each analysis set and cohort
Source: Listing 16.2.2.1 - Protocol deviations
Program: Tables\k363-dv-tbl.sas

Table 14.2.1.1 - Fosnetupitant Concentrations (ng/mL) Summary - PK set

Cohort 1: 30 min (Rα)

Statistics	Pre dose	2 min	5 min	10 min	15 min	20 min	30 min	45 min	1 hour	1.5 hour	2 h	3 h	4 h	8 h	12 h	24 h
N	xx.xx	---	---	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Geo.Mean	xx.xx	---	---	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Mean	xx.xx	---	---	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
SD	xx.xx	---	---	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
CV%	xx.xx	---	---	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Min	xx.xx	---	---	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.xx	---	---	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Max	xx.xx	---	---	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx

Note: Subjects are listed according to the cohort they belong to
Sampling times are counted from the start of the injection/infusion
Source: Listing 16.2.5.5 - Fosnetupitant Concentrations (ng/mL) measured in plasma
Program: pk-analysis\k363-pc-tbl.sas

Table 14.2.1.1 - Fosnetupitant Concentrations (ng/mL) Summary - PK set

Cohort 1: 30 min (T)

Statistics	Pre dose	2 min	5 min	10 min	15 min	20 min	30 min	45 min	1 hour	1.5 hour	2 h	3 h	4 h	8 h	12 h	24 h
N	xx.xx	---	---	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Geo.Mean	xx.xx	---	---	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Mean	xx.xx	---	---	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
SD	xx.xx	---	---	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
CV%	xx.xx	---	---	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Min	xx.xx	---	---	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.xx	---	---	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Max	xx.xx	---	---	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx

Note: Subjects are listed according to the cohort they belong to
Sampling times are counted from the start of the injection/infusion
Source: Listing 16.2.5.5 - Fosnetupitant Concentrations (ng/mL) measured in plasma
Program: pk-analysis\k363-pc-tbl.sas

Table 14.2.1.1 - Fosnetupitant Concentrations (ng/mL) Summary - PK set

Cohort 2: 15 min (T)

Statistics	Pre dose	2 min	5 min	10 min	15 min	20 min	30 min	45 min	1 hour	1.5 hour	2 h	3 h	4 h	8 h	12 h	24 h
N	xx.xx	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Geo.Mean	xx.xx	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Mean	xx.xx	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
SD	xx.xx	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
CV%	xx.xx	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Min	xx.xx	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.xx	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Max	xx.xx	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx

Note: Subjects are listed according to the cohort they belong to
Sampling times are counted from the start of the injection/infusion
Source: Listing 16.2.5.5 - Fosnetupitant Concentrations (ng/mL) measured in plasma
Program: pk-analysis\k363-pc-tbl.sas

Table 14.2.1.1 - Fosnetupitant Concentrations (ng/mL) Summary - PK set

Cohort 3: 5 min (T)

Statistics	Pre dose	2 min	5 min	10 min	15 min	20 min	30 min	45 min	1 hour	1.5 hour	2 h	3 h	4 h	8 h	12 h	24 h
N	xx.xx	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Geo.Mean	xx.xx	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Mean	xx.xx	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
SD	xx.xx	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
CV%	xx.xx	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Min	xx.xx	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.xx	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Max	xx.xx	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx

Note: Subjects are listed according to the cohort they belong to
Sampling times are counted from the start of the injection/infusion
Source: Listing 16.2.5.5 - Fosnetupitant Concentrations (ng/mL) measured in plasma
Program: pk-analysis\k363-pc-tbl.sas

Table 14.2.1.1 - Fosnetupitant Concentrations (ng/mL) Summary - PK set

Cohort 4: 2 min (T)

Statistics	Pre dose	2 min	5 min	10 min	15 min	20 min	30 min	45 min	1 hour	1.5 hour	2 h	3 h	4 h	8 h	12 h	24 h
N	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Geo.Mean	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Mean	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
CV%	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Min	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Max	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx

Note: Subjects are listed according to the cohort they belong to
Sampling times are counted from the start of the injection/infusion
Source: Listing 16.2.5.5 - Fosnetupitant Concentrations (ng/mL) measured in plasma
Program: pk-analysis\k363-pc-tbl.sas

Table 14.2.1.2 - Netupitant Concentrations (ng/mL) Summary - PK set

Cohort 1: 30 min (Rα)

Statistics	Pre dose	2 min	5 min	10 min	15 min	20 min	30 min	45 min	1 hour	1.5 hour	2 h	3 h	4 h	8 h	12 h	24 h
N	xx.xx	---	---	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Geo.Mean	xx.xx	---	---	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Mean	xx.xx	---	---	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
SD	xx.xx	---	---	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
CV%	xx.xx	---	---	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Min	xx.xx	---	---	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.xx	---	---	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Max	xx.xx	---	---	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx

Note: Subjects are listed according to the cohort they belong to
Sampling times are counted from the start of the injection/infusion
Source: Listing 16.2.5.6 - Netupitant Concentrations (ng/mL) measured in plasma
Program: pk-analysis\k363-pc-tbl.sas

Table 14.2.1.2 - Netupitant Concentrations (ng/mL) Summary - PK set

Cohort 1: 30 min (T)

Statistics	Pre dose	2 min	5 min	10 min	15 min	20 min	30 min	45 min	1 hour	1.5 hour	2 h	3 h	4 h	8 h	12 h	24 h
N	xx.xx	---	---	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Geo.Mean	xx.xx	---	---	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Mean	xx.xx	---	---	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
SD	xx.xx	---	---	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
CV%	xx.xx	---	---	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Min	xx.xx	---	---	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.xx	---	---	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Max	xx.xx	---	---	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx

Note: Subjects are listed according to the cohort they belong to
Sampling times are counted from the start of the injection/infusion
Source: Listing 16.2.5.6 - Netupitant Concentrations (ng/mL) measured in plasma
Program: pk-analysis\k363-pc-tbl.sas

Table 14.2.1.2 - Netupitant Concentrations (ng/mL) Summary - PK set

Cohort 2: 15 min (T)

Statistics	Pre dose	2 min	5 min	10 min	15 min	20 min	30 min	45 min	1 hour	1.5 hour	2 h	3 h	4 h	8 h	12 h	24 h
N	xx.xx	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Geo.Mean	xx.xx	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Mean	xx.xx	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
SD	xx.xx	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
CV%	xx.xx	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Min	xx.xx	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.xx	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Max	xx.xx	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx

Note: Subjects are listed according to the cohort they belong to
Sampling times are counted from the start of the injection/infusion
Source: Listing 16.2.5.6 - Netupitant Concentrations (ng/mL) measured in plasma
Program: pk-analysis\k363-pc-tbl.sas

Table 14.2.1.2 - Netupitant Concentrations (ng/mL) Summary - PK set

Cohort 3: 5 min (T)

Statistics	Pre dose	2 min	5 min	10 min	15 min	20 min	30 min	45 min	1 hour	1.5 hour	2 h	3 h	4 h	8 h	12 h	24 h
N	xx.xx	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Geo.Mean	xx.xx	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Mean	xx.xx	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
SD	xx.xx	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
CV%	xx.xx	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Min	xx.xx	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.xx	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Max	xx.xx	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx

Note: Subjects are listed according to the cohort they belong to
Sampling times are counted from the start of the injection/infusion
Source: Listing 16.2.5.6 - Netupitant Concentrations (ng/mL) measured in plasma
Program: pk-analysis\k363-pc-tbl.sas

Table 14.2.1.2 - Netupitant Concentrations (ng/mL) Summary - PK set

Cohort 4: 2 min (T)

Statistics	Pre dose	2 min	5 min	10 min	15 min	20 min	30 min	45 min	1 hour	1.5 hour	2 h	3 h	4 h	8 h	12 h	24 h
N	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Geo.Mean	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Mean	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
CV%	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Min	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Max	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx

Note: Subjects are listed according to the cohort they belong to
Sampling times are counted from the start of the injection/infusion
Source: Listing 16.2.5.6 - Netupitant Concentrations (ng/mL) measured in plasma
Program: pk-analysis\k363-pc-tbl.sas

Table 14.2.1.3 - Netupitant metabolite M1 Concentrations (ng/mL) Summary - PK set

Cohort 1: 30 min (Rα)

Statistics	Pre dose	2 min	5 min	10 min	15 min	20 min	30 min	45 min	1 hour	1.5 hour	2 h	3 h	4 h	8 h	12 h	24 h
N	xx.xx	---	---	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Geo.Mean	xx.xx	---	---	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Mean	xx.xx	---	---	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
SD	xx.xx	---	---	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
CV%	xx.xx	---	---	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Min	xx.xx	---	---	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.xx	---	---	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Max	xx.xx	---	---	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx

Note: Subjects are listed according to the cohort they belong to
Sampling times are counted from the start of the injection/infusion
Source: Listing 16.2.5.7 - Netupitant metabolite M1 Concentrations (ng/mL) measured in plasma
Program: pk-analysis\k363-pc-tbl.sas

Table 14.2.1.3 - Netupitant metabolite M1 Concentrations (ng/mL) Summary - PK set

Cohort 1: 30 min (T)

Statistics	Pre dose	2 min	5 min	10 min	15 min	20 min	30 min	45 min	1 hour	1.5 hour	2 h	3 h	4 h	8 h	12 h	24 h
N	xx.xx	---	---	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Geo.Mean	xx.xx	---	---	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Mean	xx.xx	---	---	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
SD	xx.xx	---	---	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
CV%	xx.xx	---	---	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Min	xx.xx	---	---	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.xx	---	---	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Max	xx.xx	---	---	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx

Note: Subjects are listed according to the cohort they belong to
Sampling times are counted from the start of the injection/infusion
Source: Listing 16.2.5.7 - Netupitant metabolite M1 Concentrations (ng/mL) measured in plasma
Program: pk-analysis\k363-pc-tbl.sas

Table 14.2.1.3 - Netupitant metabolite M1 Concentrations (ng/mL) Summary - PK set

Cohort 2: 15 min (T)

Statistics	Pre dose	2 min	5 min	10 min	15 min	20 min	30 min	45 min	1 hour	1.5 hour	2 h	3 h	4 h	8 h	12 h	24 h
N	xx.xx	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Geo.Mean	xx.xx	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Mean	xx.xx	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
SD	xx.xx	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
CV%	xx.xx	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Min	xx.xx	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.xx	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Max	xx.xx	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx

Note: Subjects are listed according to the cohort they belong to
Sampling times are counted from the start of the injection/infusion
Source: Listing 16.2.5.7 - Netupitant metabolite M1 Concentrations (ng/mL) measured in plasma
Program: pk-analysis\k363-pc-tbl.sas

Table 14.2.1.3 - Netupitant metabolite M1 Concentrations (ng/mL) Summary - PK set

Cohort 3: 5 min (T)

Statistics	Pre dose	2 min	5 min	10 min	15 min	20 min	30 min	45 min	1 hour	1.5 hour	2 h	3 h	4 h	8 h	12 h	24 h
N	xx.xx	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Geo.Mean	xx.xx	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Mean	xx.xx	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
SD	xx.xx	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
CV%	xx.xx	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Min	xx.xx	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.xx	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Max	xx.xx	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx

Note: Subjects are listed according to the cohort they belong to
Sampling times are counted from the start of the injection/infusion
Source: Listing 16.2.5.7 - Netupitant metabolite M1 Concentrations (ng/mL) measured in plasma
Program: pk-analysis\k363-pc-tbl.sas

Table 14.2.1.3 - Netupitant metabolite M1 Concentrations (ng/mL) Summary - PK set

Cohort 4: 2 min (T)

Statistics	Pre dose	2 min	5 min	10 min	15 min	20 min	30 min	45 min	1 hour	1.5 hour	2 h	3 h	4 h	8 h	12 h	24 h
N	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Geo.Mean	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Mean	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
CV%	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Min	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Max	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx

Note: Subjects are listed according to the cohort they belong to
Sampling times are counted from the start of the injection/infusion
Source: Listing 16.2.5.7 - Netupitant metabolite M1 Concentrations (ng/mL) measured in plasma
Program: pk-analysis\k363-pc-tbl.sas

Table 14.2.1.4 - Netupitant metabolite M2 Concentrations (ng/mL) Summary - PK set

Cohort 1: 30 min (Rα)

Statistics	Pre dose	2 min	5 min	10 min	15 min	20 min	30 min	45 min	1 hour	1.5 hour	2 h	3 h	4 h	8 h	12 h	24 h
N	xx.xx	---	---	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Geo.Mean	xx.xx	---	---	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Mean	xx.xx	---	---	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
SD	xx.xx	---	---	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
CV%	xx.xx	---	---	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Min	xx.xx	---	---	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.xx	---	---	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Max	xx.xx	---	---	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx

Note: Subjects are listed according to the cohort they belong to
Sampling times are counted from the start of the injection/infusion
Source: Listing 16.2.5.8 - Netupitant metabolite M2 Concentrations (ng/mL) measured in plasma
Program: pk-analysis\k363-pc-tbl.sas

Table 14.2.1.4 - Netupitant metabolite M2 Concentrations (ng/mL) Summary - PK set

Cohort 1: 30 min (T)

Statistics	Pre dose	2 min	5 min	10 min	15 min	20 min	30 min	45 min	1 hour	1.5 hour	2 h	3 h	4 h	8 h	12 h	24 h
N	xx.xx	---	---	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Geo.Mean	xx.xx	---	---	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Mean	xx.xx	---	---	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
SD	xx.xx	---	---	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
CV%	xx.xx	---	---	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Min	xx.xx	---	---	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.xx	---	---	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Max	xx.xx	---	---	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx

Note: Subjects are listed according to the cohort they belong to
Sampling times are counted from the start of the injection/infusion
Source: Listing 16.2.5.8 - Netupitant metabolite M2 Concentrations (ng/mL) measured in plasma
Program: pk-analysis\k363-pc-tbl.sas

Table 14.2.1.4 - Netupitant metabolite M2 Concentrations (ng/mL) Summary - PK set

Cohort 2: 15 min (T)

Statistics	Pre dose	2 min	5 min	10 min	15 min	20 min	30 min	45 min	1 hour	1.5 hour	2 h	3 h	4 h	8 h	12 h	24 h
N	xx.xx	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Geo.Mean	xx.xx	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Mean	xx.xx	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
SD	xx.xx	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
CV%	xx.xx	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Min	xx.xx	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.xx	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Max	xx.xx	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx

Note: Subjects are listed according to the cohort they belong to
Sampling times are counted from the start of the injection/infusion
Source: Listing 16.2.5.8 - Netupitant metabolite M2 Concentrations (ng/mL) measured in plasma
Program: pk-analysis\k363-pc-tbl.sas

Table 14.2.1.4 - Netupitant metabolite M2 Concentrations (ng/mL) Summary - PK set

Cohort 3: 5 min (T)

Statistics	Pre dose	2 min	5 min	10 min	15 min	20 min	30 min	45 min	1 hour	1.5 hour	2 h	3 h	4 h	8 h	12 h	24 h
N	xx.xx	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Geo.Mean	xx.xx	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Mean	xx.xx	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
SD	xx.xx	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
CV%	xx.xx	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Min	xx.xx	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.xx	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Max	xx.xx	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx

Note: Subjects are listed according to the cohort they belong to
Sampling times are counted from the start of the injection/infusion
Source: Listing 16.2.5.8 - Netupitant metabolite M2 Concentrations (ng/mL) measured in plasma
Program: pk-analysis\k363-pc-tbl.sas

Table 14.2.1.4 - Netupitant metabolite M2 Concentrations (ng/mL) Summary - PK set

Cohort 4: 2 min (T)

Statistics	Pre dose	2 min	5 min	10 min	15 min	20 min	30 min	45 min	1 hour	1.5 hour	2 h	3 h	4 h	8 h	12 h	24 h
N	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Geo.Mean	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Mean	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
CV%	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Min	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Max	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx

Note: Subjects are listed according to the cohort they belong to
Sampling times are counted from the start of the injection/infusion
Source: Listing 16.2.5.8 - Netupitant metabolite M2 Concentrations (ng/mL) measured in plasma
Program: pk-analysis\k363-pc-tbl.sas

Table 14.2.1.5 - Netupitant metabolite M3 Concentrations (ng/mL) Summary - PK set

Cohort 1: 30 min (Rα)

Statistics	Pre dose	2 min	5 min	10 min	15 min	20 min	30 min	45 min	1 hour	1.5 hour	2 h	3 h	4 h	8 h	12 h	24 h
N	xx.xx	---	---	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Geo.Mean	xx.xx	---	---	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Mean	xx.xx	---	---	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
SD	xx.xx	---	---	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
CV%	xx.xx	---	---	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Min	xx.xx	---	---	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.xx	---	---	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Max	xx.xx	---	---	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx

Note: Subjects are listed according to the cohort they belong to
Sampling times are counted from the start of the injection/infusion
Source: Listing 16.2.5.9 - Netupitant metabolite M3 Concentrations (ng/mL) measured in plasma
Program: pk-analysis\k363-pc-tbl.sas

Table 14.2.1.5 - Netupitant metabolite M3 Concentrations (ng/mL) Summary - PK set

Cohort 1: 30 min (T)

Statistics	Pre dose	2 min	5 min	10 min	15 min	20 min	30 min	45 min	1 hour	1.5 hour	2 h	3 h	4 h	8 h	12 h	24 h
N	xx.xx	---	---	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Geo.Mean	xx.xx	---	---	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Mean	xx.xx	---	---	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
SD	xx.xx	---	---	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
CV%	xx.xx	---	---	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Min	xx.xx	---	---	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.xx	---	---	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Max	xx.xx	---	---	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx

Note: Subjects are listed according to the cohort they belong to
Sampling times are counted from the start of the injection/infusion
Source: Listing 16.2.5.9 - Netupitant metabolite M3 Concentrations (ng/mL) measured in plasma
Program: pk-analysis\k363-pc-tbl.sas

Table 14.2.1.5 - Netupitant metabolite M3 Concentrations (ng/mL) Summary - PK set

Cohort 2: 15 min (T)

Statistics	Pre dose	2 min	5 min	10 min	15 min	20 min	30 min	45 min	1 hour	1.5 hour	2 h	3 h	4 h	8 h	12 h	24 h
N	xx.xx	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Geo.Mean	xx.xx	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Mean	xx.xx	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
SD	xx.xx	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
CV%	xx.xx	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Min	xx.xx	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.xx	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Max	xx.xx	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx

Note: Subjects are listed according to the cohort they belong to
Sampling times are counted from the start of the injection/infusion
Source: Listing 16.2.5.9 - Netupitant metabolite M3 Concentrations (ng/mL) measured in plasma
Program: pk-analysis\k363-pc-tbl.sas

Table 14.2.1.5 - Netupitant metabolite M3 Concentrations (ng/mL) Summary - PK set

Cohort 3: 5 min (T)

Statistics	Pre dose	2 min	5 min	10 min	15 min	20 min	30 min	45 min	1 hour	1.5 hour	2 h	3 h	4 h	8 h	12 h	24 h
N	xx.xx	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Geo.Mean	xx.xx	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Mean	xx.xx	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
SD	xx.xx	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
CV%	xx.xx	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Min	xx.xx	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.xx	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Max	xx.xx	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx

Note: Subjects are listed according to the cohort they belong to
Sampling times are counted from the start of the injection/infusion
Source: Listing 16.2.5.9 - Netupitant metabolite M3 Concentrations (ng/mL) measured in plasma
Program: pk-analysis\k363-pc-tbl.sas

Table 14.2.1.5 - Netupitant metabolite M3 Concentrations (ng/mL) Summary - PK set

Cohort 4: 2 min (T)

Statistics	Pre dose	2 min	5 min	10 min	15 min	20 min	30 min	45 min	1 hour	1.5 hour	2 h	3 h	4 h	8 h	12 h	24 h
N	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Geo.Mean	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Mean	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
CV%	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Min	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Max	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx

Note: Subjects are listed according to the cohort they belong to
Sampling times are counted from the start of the injection/infusion
Source: Listing 16.2.5.9 - Netupitant metabolite M3 Concentrations (ng/mL) measured in plasma
Program: pk-analysis\k363-pc-tbl.sas

Table 14.2.2.1 - Plasma PK parameters - Fosnetupitant - PK set

Cohort 1: 30 min (Rα)

Statistics	**C_{max} (ng/mL)**	**C_0 (ng/mL)**	**C_{last} (ng/mL)**	**t_{last} (h)**	**t_{max} (h)**	**AUC_{0-t} (h*ng/mL)**	**AUC_{0-24} (h*ng/mL)**	**λ_z (1/h)**	**$t_{½}$ (h)**	**CL (mL/h)**	**V_z (mL)**	**MRT (h)**
N	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Geo.Mean	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Mean	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
SD	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
CV%	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Min	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Median	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Max	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx

Note: Subjects are summarised according to the cohort they belong to
Source: Listing 16.2.6.1 - Plasma PK parameters - Fosnetupitant
Program: pk-analysis\k363-pp-tbl.sas

Table 14.2.2.1 - Plasma PK parameters - Fosnetupitant - PK set

Cohort 1: 30 min (T)

Statistics	**C_{max} (ng/mL)**	**C_0 (ng/mL)**	**C_{last} (ng/mL)**	**t_{last} (h)**	**t_{max} (h)**	**AUC_{0-t} (h*ng/mL)**	**AUC_{0-24} (h*ng/mL)**	**λ_z (1/h)**	**$t_{½}$ (h)**	**CL (mL/h)**	**V_z (mL)**	**MRT (h)**
N	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Geo.Mean	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Mean	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
SD	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
CV%	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Min	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Median	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Max	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx

Note: Subjects are summarised according to the cohort they belong to
Source: Listing 16.2.6.1 - Plasma PK parameters - Fosnetupitant
Program: pk-analysis\k363-pp-tbl.sas

Table 14.2.2.1 - Plasma PK parameters - Fosnetupitant - PK set

Cohort 2: 15 min (T)

Statistics	**C_{max} (ng/mL)**	**C_0 (ng/mL)**	**C_{last} (ng/mL)**	**t_{last} (h)**	**t_{max} (h)**	**AUC_{0-t} (h*ng/mL)**	**AUC_{0-24} (h*ng/mL)**	**λ_z (1/h)**	**$t_{½}$ (h)**	**CL (mL/h)**	**V_z (mL)**	**MRT (h)**
N	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Geo.Mean	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Mean	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
SD	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
CV%	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Min	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Median	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Max	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx

Note: Subjects are summarised according to the cohort they belong to
Source: Listing 16.2.6.1 - Plasma PK parameters - Fosnetupitant
Program: pk-analysis\k363-pp-tbl.sas

Table 14.2.2.1 - Plasma PK parameters - Fosnetupitant - PK set

Cohort 3: 5 min (T)

Statistics	**C_{max} (ng/mL)**	**C_0 (ng/mL)**	**C_{last} (ng/mL)**	**t_{last} (h)**	**t_{max} (h)**	**AUC_{0-t} (h*ng/mL)**	**AUC_{0-24} (h*ng/mL)**	**λ_z (1/h)**	**$t_{½}$ (h)**	**CL (mL/h)**	**V_z (mL)**	**MRT (h)**
N	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Geo.Mean	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Mean	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
SD	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
CV%	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Min	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Median	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Max	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx

Note: Subjects are summarised according to the cohort they belong to
Source: Listing 16.2.6.1 - Plasma PK parameters - Fosnetupitant
Program: pk-analysis\k363-pp-tbl.sas

Table 14.2.2.1 - Plasma PK parameters - Fosnetupitant - PK set

Cohort 4: 2 min (T)

Statistics	**C_{max} (ng/mL)**	**C_0 (ng/mL)**	**C_{last} (ng/mL)**	**t_{last} (h)**	**t_{max} (h)**	**AUC_{0-t} (h*ng/mL)**	**AUC_{0-24} (h*ng/mL)**	**λ_z (1/h)**	**$t_{½}$ (h)**	**CL (mL/h)**	**V_z (mL)**	**MRT (h)**
N	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Geo.Mean	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Mean	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
SD	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
CV%	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Min	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Median	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Max	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx

Note: Subjects are summarised according to the cohort they belong to
Source: Listing 16.2.6.1 - Plasma PK parameters - Fosnetupitant
Program: pk-analysis\k363-pp-tbl.sas

Table 14.2.2.2 - Plasma PK parameters - Netupitant - PK set

Cohort 1: 30 min (Rα)

Statistics	**C_{max} (ng/mL)**	**C_0 (ng/mL)**	**C_{last} (ng/mL)**	**t_{last} (h)**	**t_{max} (h)**	**AUC_{0-t} (h*ng/mL)**	**AUC_{0-24} (h*ng/mL)**	**λ_z (1/h)**	**$t_{½}$ (h)**	**CL (mL/h)**	**V_z (mL)**	**MRT (h)**
N	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Geo.Mean	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Mean	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
SD	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
CV%	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Min	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Median	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Max	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx

Note: Subjects are summarised according to the cohort they belong to
Source: Listing 16.2.6.2 - Plasma PK parameters - Netupitant
Program: pk-analysis\k363-pp-tbl.sas

Table 14.2.2.2 - Plasma PK parameters - Netupitant - PK set

Cohort 1: 30 min (T)

Statistics	**C_{max} (ng/mL)**	**C_0 (ng/mL)**	**C_{last} (ng/mL)**	**t_{last} (h)**	**t_{max} (h)**	**AUC_{0-t} (h*ng/mL)**	**AUC_{0-24} (h*ng/mL)**	**λ_z (1/h)**	**$t_{½}$ (h)**	**CL (mL/h)**	**V_z (mL)**	**MRT (h)**
N	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Geo.Mean	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Mean	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
SD	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
CV%	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Min	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Median	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Max	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx

Note: Subjects are summarised according to the cohort they belong to
Source: Listing 16.2.6.2 - Plasma PK parameters - Netupitant
Program: pk-analysis\k363-pp-tbl.sas

Table 14.2.2.2 - Plasma PK parameters - Netupitant - PK set

Cohort 2: 15 min (T)

Statistics	**C_{max} (ng/mL)**	**C_0 (ng/mL)**	**C_{last} (ng/mL)**	**t_{last} (h)**	**t_{max} (h)**	**AUC_{0-t} (h*ng/mL)**	**AUC_{0-24} (h*ng/mL)**	**λ_z (1/h)**	**$t_{½}$ (h)**	**CL (mL/h)**	**V_z (mL)**	**MRT (h)**
N	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Geo.Mean	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Mean	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
SD	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
CV%	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Min	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Median	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Max	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx

Note: Subjects are summarised according to the cohort they belong to
Source: Listing 16.2.6.2 - Plasma PK parameters - Netupitant
Program: pk-analysis\k363-pp-tbl.sas

Table 14.2.2.2 - Plasma PK parameters - Netupitant - PK set

Cohort 3: 5 min (T)

Statistics	**C_{max} (ng/mL)**	**C_0 (ng/mL)**	**C_{last} (ng/mL)**	**t_{last} (h)**	**t_{max} (h)**	**AUC_{0-t} (h*ng/mL)**	**AUC_{0-24} (h*ng/mL)**	**λ_z (1/h)**	**$t_{½}$ (h)**	**CL (mL/h)**	**V_z (mL)**	**MRT (h)**
N	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Geo.Mean	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Mean	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
SD	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
CV%	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Min	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Median	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Max	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx

Note: Subjects are summarised according to the cohort they belong to
Source: Listing 16.2.6.2 - Plasma PK parameters - Netupitant
Program: pk-analysis\k363-pp-tbl.sas

Table 14.2.2.2 - Plasma PK parameters - Netupitant - PK set

Cohort 4: 2 min (T)

Statistics	**C_{max} (ng/mL)**	**C_0 (ng/mL)**	**C_{last} (ng/mL)**	**t_{last} (h)**	**t_{max} (h)**	**AUC_{0-t} (h*ng/mL)**	**AUC_{0-24} (h*ng/mL)**	**λ_z (1/h)**	**$t_{½}$ (h)**	**CL (mL/h)**	**V_z (mL)**	**MRT (h)**
N	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Geo.Mean	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Mean	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
SD	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
CV%	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Min	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Median	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Max	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx

Note: Subjects are summarised according to the cohort they belong to
Source: Listing 16.2.6.2 - Plasma PK parameters - Netupitant
Program: pk-analysis\k363-pp-tbl.sas

Table 14.2.2.3 - Plasma PK parameters - Netupitant metabolite M1 - PK set

Cohort 1: 30 min (Rα)

Statistics	**C_{max} (ng/mL)**	**C_0 (ng/mL)**	**C_{last} (ng/mL)**	**t_{last} (h)**	**t_{max} (h)**	**AUC_{0-t} (h*ng/mL)**	**AUC_{0-24} (h*ng/mL)**	**λ_z (1/h)**	**$t_{½}$ (h)**	**CL (mL/h)**	**V_z (mL)**	**MRT (h)**
N	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Geo.Mean	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Mean	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
SD	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
CV%	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Min	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Median	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Max	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx

Note: Subjects are summarised according to the cohort they belong to
Source: Listing 16.2.6.3 - Plasma PK parameters - Netupitant metabolite M1
Program: pk-analysis\k363-pp-tbl.sas

Table 14.2.2.3 - Plasma PK parameters - Netupitant metabolite M1 - PK set

Cohort 1: 30 min (T)

Statistics	**C_{max} (ng/mL)**	**C_0 (ng/mL)**	**C_{last} (ng/mL)**	**t_{last} (h)**	**t_{max} (h)**	**AUC_{0-t} (h*ng/mL)**	**AUC_{0-24} (h*ng/mL)**	**λ_z (1/h)**	**$t_{½}$ (h)**	**CL (mL/h)**	**V_z (mL)**	**MRT (h)**
N	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Geo.Mean	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Mean	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
SD	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
CV%	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Min	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Median	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Max	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx

Note: Subjects are summarised according to the cohort they belong to
Source: Listing 16.2.6.3 - Plasma PK parameters - Netupitant metabolite M1
Program: pk-analysis\k363-pp-tbl.sas

Table 14.2.2.3 - Plasma PK parameters - Netupitant metabolite M1 - PK set

Cohort 2: 15 min (T)

Statistics	**C_{max} (ng/mL)**	**C_0 (ng/mL)**	**C_{last} (ng/mL)**	**t_{last} (h)**	**t_{max} (h)**	**AUC_{0-t} (h*ng/mL)**	**AUC_{0-24} (h*ng/mL)**	**λ_z (1/h)**	**$t_{½}$ (h)**	**CL (mL/h)**	**V_z (mL)**	**MRT (h)**
N	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Geo.Mean	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Mean	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
SD	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
CV%	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Min	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Median	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Max	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx

Note: Subjects are summarised according to the cohort they belong to
Source: Listing 16.2.6.3 - Plasma PK parameters - Netupitant metabolite M1
Program: pk-analysis\k363-pp-tbl.sas

Table 14.2.2.3 - Plasma PK parameters - Netupitant metabolite M1 - PK set

Cohort 3: 5 min (T)

Statistics	**C_{max} (ng/mL)**	**C_0 (ng/mL)**	**C_{last} (ng/mL)**	**t_{last} (h)**	**t_{max} (h)**	**AUC_{0-t} (h*ng/mL)**	**AUC_{0-24} (h*ng/mL)**	**λ_z (1/h)**	**$t_{½}$ (h)**	**CL (mL/h)**	**V_z (mL)**	**MRT (h)**
N	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Geo.Mean	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Mean	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
SD	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
CV%	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Min	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Median	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Max	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx

Note: Subjects are summarised according to the cohort they belong to
Source: Listing 16.2.6.3 - Plasma PK parameters - Netupitant metabolite M1
Program: pk-analysis\k363-pp-tbl.sas

Table 14.2.2.3 - Plasma PK parameters - Netupitant metabolite M1 - PK set

Cohort 4: 2 min (T)

Statistics	**C_{max} (ng/mL)**	**C_0 (ng/mL)**	**C_{last} (ng/mL)**	**t_{last} (h)**	**t_{max} (h)**	**AUC_{0-t} (h*ng/mL)**	**AUC_{0-24} (h*ng/mL)**	**λ_z (1/h)**	**$t_{½}$ (h)**	**CL (mL/h)**	**V_z (mL)**	**MRT (h)**
N	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Geo.Mean	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Mean	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
SD	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
CV%	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Min	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Median	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Max	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx

Note: Subjects are summarised according to the cohort they belong to
Source: Listing 16.2.6.3 - Plasma PK parameters - Netupitant metabolite M1
Program: pk-analysis\k363-pp-tbl.sas

Table 14.2.2.4 - Plasma PK parameters - Netupitant metabolite M2 - PK set

Cohort 1: 30 min (Rα)

Statistics	**C_{max} (ng/mL)**	**C_0 (ng/mL)**	**C_{last} (ng/mL)**	**t_{last} (h)**	**t_{max} (h)**	**AUC_{0-t} (h*ng/mL)**	**AUC_{0-24} (h*ng/mL)**	**λ_z (1/h)**	**$t_{½}$ (h)**	**CL (mL/h)**	**V_z (mL)**	**MRT (h)**
N	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Geo.Mean	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Mean	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
SD	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
CV%	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Min	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Median	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Max	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx

Note: Subjects are summarised according to the cohort they belong to
Source: Listing 16.2.6.4 - Plasma PK parameters - Netupitant metabolite M2
Program: pk-analysis\k363-pp-tbl.sas

Table 14.2.2.4 - Plasma PK parameters - Netupitant metabolite M2 - PK set

Cohort 1: 30 min (T)

Statistics	**C_{max} (ng/mL)**	**C_0 (ng/mL)**	**C_{last} (ng/mL)**	**t_{last} (h)**	**t_{max} (h)**	**AUC_{0-t} (h*ng/mL)**	**AUC_{0-24} (h*ng/mL)**	**λ_z (1/h)**	**$t_{½}$ (h)**	**CL (mL/h)**	**V_z (mL)**	**MRT (h)**
N	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Geo.Mean	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Mean	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
SD	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
CV%	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Min	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Median	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Max	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx

Note: Subjects are summarised according to the cohort they belong to
Source: Listing 16.2.6.4 - Plasma PK parameters - Netupitant metabolite M2
Program: pk-analysis\k363-pp-tbl.sas

Table 14.2.2.4 - Plasma PK parameters - Netupitant metabolite M2 - PK set

Cohort 2: 15 min (T)

Statistics	**C_{max} (ng/mL)**	**C_0 (ng/mL)**	**C_{last} (ng/mL)**	**t_{last} (h)**	**t_{max} (h)**	**AUC_{0-t} (h*ng/mL)**	**AUC_{0-24} (h*ng/mL)**	**λ_z (1/h)**	**$t_{½}$ (h)**	**CL (mL/h)**	**V_z (mL)**	**MRT (h)**
N	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Geo.Mean	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Mean	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
SD	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
CV%	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Min	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Median	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Max	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx

Note: Subjects are summarised according to the cohort they belong to
Source: Listing 16.2.6.4 - Plasma PK parameters - Netupitant metabolite M2
Program: pk-analysis\k363-pp-tbl.sas

Table 14.2.2.4 - Plasma PK parameters - Netupitant metabolite M2 - PK set

Cohort 3: 5 min (T)

Statistics	**C_{max} (ng/mL)**	**C_0 (ng/mL)**	**C_{last} (ng/mL)**	**t_{last} (h)**	**t_{max} (h)**	**AUC_{0-t} (h*ng/mL)**	**AUC_{0-24} (h*ng/mL)**	**λ_z (1/h)**	**$t_{½}$ (h)**	**CL (mL/h)**	**V_z (mL)**	**MRT (h)**
N	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Geo.Mean	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Mean	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
SD	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
CV%	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Min	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Median	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Max	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx

Note: Subjects are summarised according to the cohort they belong to
Source: Listing 16.2.6.4 - Plasma PK parameters - Netupitant metabolite M2
Program: pk-analysis\k363-pp-tbl.sas

Table 14.2.2.4 - Plasma PK parameters - Netupitant metabolite M2 - PK set

Cohort 4: 2 min (T)

Statistics	**C_{max} (ng/mL)**	**C_0 (ng/mL)**	**C_{last} (ng/mL)**	**t_{last} (h)**	**t_{max} (h)**	**AUC_{0-t} (h*ng/mL)**	**AUC_{0-24} (h*ng/mL)**	**λ_z (1/h)**	**$t_{½}$ (h)**	**CL (mL/h)**	**V_z (mL)**	**MRT (h)**
N	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Geo.Mean	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Mean	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
SD	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
CV%	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Min	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Median	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Max	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx

Note: Subjects are summarised according to the cohort they belong to
Source: Listing 16.2.6.4 - Plasma PK parameters - Netupitant metabolite M2
Program: pk-analysis\k363-pp-tbl.sas

Table 14.2.2.5 - Plasma PK parameters - Netupitant metabolite M3 - PK set

Cohort 1: 30 min (Rα)

Statistics	**C_{max} (ng/mL)**	**C_0 (ng/mL)**	**C_{last} (ng/mL)**	**t_{last} (h)**	**t_{max} (h)**	**AUC_{0-t} (h*ng/mL)**	**AUC_{0-24} (h*ng/mL)**	**λ_z (1/h)**	**$t_{½}$ (h)**	**CL (mL/h)**	**V_z (mL)**	**MRT (h)**
N	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Geo.Mean	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Mean	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
SD	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
CV%	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Min	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Median	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Max	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx

Note: Subjects are summarised according to the cohort they belong to
Source: Listing 16.2.6.5 - Plasma PK parameters - Netupitant metabolite M3
Program: pk-analysis\k363-pp-tbl.sas

Table 14.2.2.5 - Plasma PK parameters - Netupitant metabolite M3 - PK set

Cohort 1: 30 min (T)

Statistics	**C_{max} (ng/mL)**	**C_0 (ng/mL)**	**C_{last} (ng/mL)**	**t_{last} (h)**	**t_{max} (h)**	**AUC_{0-t} (h*ng/mL)**	**AUC_{0-24} (h*ng/mL)**	**λ_z (1/h)**	**$t_{½}$ (h)**	**CL (mL/h)**	**V_z (mL)**	**MRT (h)**
N	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Geo.Mean	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Mean	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
SD	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
CV%	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Min	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Median	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Max	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx

Note: Subjects are summarised according to the cohort they belong to
Source: Listing 16.2.6.5 - Plasma PK parameters - Netupitant metabolite M3
Program: pk-analysis\k363-pp-tbl.sas

Table 14.2.2.5 - Plasma PK parameters - Netupitant metabolite M3 - PK set

Cohort 2: 15 min (T)

Statistics	**C_{max} (ng/mL)**	**C_0 (ng/mL)**	**C_{last} (ng/mL)**	**t_{last} (h)**	**t_{max} (h)**	**AUC_{0-t} (h*ng/mL)**	**AUC_{0-24} (h*ng/mL)**	**λ_z (1/h)**	**$t_{½}$ (h)**	**CL (mL/h)**	**V_z (mL)**	**MRT (h)**
N	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Geo.Mean	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Mean	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
SD	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
CV%	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Min	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Median	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Max	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx

Note: Subjects are summarised according to the cohort they belong to
Source: Listing 16.2.6.5 - Plasma PK parameters - Netupitant metabolite M3
Program: pk-analysis\k363-pp-tbl.sas

Table 14.2.2.5 - Plasma PK parameters - Netupitant metabolite M3 - PK set

Cohort 3: 5 min (T)

Statistics	**C_{max} (ng/mL)**	**C_0 (ng/mL)**	**C_{last} (ng/mL)**	**t_{last} (h)**	**t_{max} (h)**	**AUC_{0-t} (h*ng/mL)**	**AUC_{0-24} (h*ng/mL)**	**λ_z (1/h)**	**$t_{½}$ (h)**	**CL (mL/h)**	**V_z (mL)**	**MRT (h)**
N	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Geo.Mean	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Mean	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
SD	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
CV%	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Min	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Median	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Max	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx

Note: Subjects are summarised according to the cohort they belong to
Source: Listing 16.2.6.5 - Plasma PK parameters - Netupitant metabolite M3
Program: pk-analysis\k363-pp-tbl.sas

Table 14.2.2.5 - Plasma PK parameters - Netupitant metabolite M3 - PK set

Cohort 4: 2 min (T)

Statistics	**C_{max} (ng/mL)**	**C_0 (ng/mL)**	**C_{last} (ng/mL)**	**t_{last} (h)**	**t_{max} (h)**	**AUC_{0-t} (h*ng/mL)**	**AUC_{0-24} (h*ng/mL)**	**λ_z (1/h)**	**$t_{½}$ (h)**	**CL (mL/h)**	**V_z (mL)**	**MRT (h)**
N	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Geo.Mean	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Mean	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
SD	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
CV%	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Min	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Median	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Max	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx

Note: Subjects are summarised according to the cohort they belong to
Source: Listing 16.2.6.5 - Plasma PK parameters - Netupitant metabolite M3
Program: pk-analysis\k363-pp-tbl.sas

Table 14.3.1.1 - Global frequency of subjects with treatment-emergent adverse events - Safety set

Cohort 1: 30 min (Rα)

	Safety Set N=XX n (%) [n AE]
Treatment-emergent Adverse Events	nn (xx.x) [kk]
Relationship	nn (xx.x) [kk]
Related	nn (xx.x) [kk]
Not related	nn (xx.x) [kk]
Severity	nn (xx.x) [kk]
Mild	nn (xx.x) [kk]
Moderate	nn (xx.x) [kk]
Severe	nn (xx.x) [kk]
Leading to discontinuation	nn (xx.x) [kk]

Note:Subjects are summarised according to the relationship and severity reported
The number and the proportion of subjects with any adverse event and the number of adverse events for each classification level are reported
The denominator for calculating the proportions is the number of subjects in the safety set
Source: Listing 16.2.7.1 - Treatment-emergent adverse events
Program: Tables\k363-ae-01-tbl.sas

Table 14.3.1.1 - Global frequency of subjects with treatment-emergent adverse events - Safety set

Cohort 1: 30 min (Rα)

	Safety Set N=XX n (%) [n AE]
Serious Treatment-emergent Adverse Events	nn (xx.x) [kk]
Relationship	nn (xx.x) [kk]
Related	nn (xx.x) [kk]
Not related	nn (xx.x) [kk]
Severity	nn (xx.x) [kk]
Mild	nn (xx.x) [kk]
Moderate	nn (xx.x) [kk]
Severe	nn (xx.x) [kk]
Leading to discontinuation	nn (xx.x) [kk]

Note:Subjects are summarised according to the relationship and severity reported
The number and the proportion of subjects with any adverse event and the number of adverse events for each classification level are reported
The denominator for calculating the proportions is the number of subjects in the safety set
Source: Listing 16.2.7.1 - Treatment-emergent adverse events
Program: Tables\k363-ae-01-tbl.sas

Table 14.3.1.1 - Global frequency of subjects with treatment-emergent adverse events - Safety set

Cohort 1: 30 min (T)

	Safety Set N=XX n (%) [n AE]
Treatment-emergent Adverse Events	nn (xx.x) [kk]
Relationship	nn (xx.x) [kk]
Related	nn (xx.x) [kk]
Not related	nn (xx.x) [kk]
Severity	nn (xx.x) [kk]
Mild	nn (xx.x) [kk]
Moderate	nn (xx.x) [kk]
Severe	nn (xx.x) [kk]
Leading to discontinuation	nn (xx.x) [kk]

Note:Subjects are summarised according to the relationship and severity reported
The number and the proportion of subjects with any adverse event and the number of adverse events for each classification level are reported
The denominator for calculating the proportions is the number of subjects in the safety set
Source: Listing 16.2.7.1 - Treatment-emergent adverse events
Program: Tables\k363-ae-01-tbl.sas

Table 14.3.1.1 - Global frequency of subjects with treatment-emergent adverse events - Safety set

Cohort 1: 30 min (T)

	Safety Set N=XX n (%) [n AE]
Serious Treatment-emergent Adverse Events	nn (xx.x) [kk]
Relationship	nn (xx.x) [kk]
Related	nn (xx.x) [kk]
Not related	nn (xx.x) [kk]
Severity	nn (xx.x) [kk]
Mild	nn (xx.x) [kk]
Moderate	nn (xx.x) [kk]
Severe	nn (xx.x) [kk]
Leading to discontinuation	nn (xx.x) [kk]

Note:Subjects are summarised according to the relationship and severity reported
The number and the proportion of subjects with any adverse event and the number of adverse events for each classification level are reported
The denominator for calculating the proportions is the number of subjects in the safety set
Source: Listing 16.2.7.1 - Treatment-emergent adverse events
Program: Tables\k363-ae-01-tbl.sas

Table 14.3.1.1 - Global frequency of subjects with treatment-emergent adverse events - Safety set

Cohort 2: 15 min (T)

	Safety Set N=XX n (%) [n AE]
Treatment-emergent Adverse Events	nn (xx.x) [kk]
Relationship	nn (xx.x) [kk]
Related	nn (xx.x) [kk]
Not related	nn (xx.x) [kk]
Severity	nn (xx.x) [kk]
Mild	nn (xx.x) [kk]
Moderate	nn (xx.x) [kk]
Severe	nn (xx.x) [kk]
Leading to discontinuation	nn (xx.x) [kk]

Note:Subjects are summarised according to the relationship and severity reported
The number and the proportion of subjects with any adverse event and the number of adverse events for each classification level are reported
The denominator for calculating the proportions is the number of subjects in the safety set
Source: Listing 16.2.7.1 - Treatment-emergent adverse events
Program: Tables\k363-ae-01-tbl.sas

Table 14.3.1.1 - Global frequency of subjects with treatment-emergent adverse events - Safety set

Cohort 2: 15 min (T)

	Safety Set N=XX n (%) [n AE]
Serious Treatment-emergent Adverse Events	nn (xx.x) [kk]
Relationship	nn (xx.x) [kk]
Related	nn (xx.x) [kk]
Not related	nn (xx.x) [kk]
Severity	nn (xx.x) [kk]
Mild	nn (xx.x) [kk]
Moderate	nn (xx.x) [kk]
Severe	nn (xx.x) [kk]
Leading to discontinuation	nn (xx.x) [kk]

Note:Subjects are summarised according to the relationship and severity reported
The number and the proportion of subjects with any adverse event and the number of adverse events for each classification level are reported
The denominator for calculating the proportions is the number of subjects in the safety set
Source: Listing 16.2.7.1 - Treatment-emergent adverse events
Program: Tables\k363-ae-01-tbl.sas

Table 14.3.1.1 - Global frequency of subjects with treatment-emergent adverse events - Safety set

Cohort 3: 5 min (T)

	Safety Set N=XX n (%) [n AE]
Treatment-emergent Adverse Events	nn (xx.x) [kk]
Relationship	nn (xx.x) [kk]
Related	nn (xx.x) [kk]
Not related	nn (xx.x) [kk]
Severity	nn (xx.x) [kk]
Mild	nn (xx.x) [kk]
Moderate	nn (xx.x) [kk]
Severe	nn (xx.x) [kk]
Leading to discontinuation	nn (xx.x) [kk]

Note:Subjects are summarised according to the relationship and severity reported
The number and the proportion of subjects with any adverse event and the number of adverse events for each classification level are reported
The denominator for calculating the proportions is the number of subjects in the safety set
Source: Listing 16.2.7.1 - Treatment-emergent adverse events
Program: Tables\k363-ae-01-tbl.sas

Table 14.3.1.1 - Global frequency of subjects with treatment-emergent adverse events - Safety set

Cohort 3: 5 min (T)

	Safety Set N=XX n (%) [n AE]
Serious Treatment-emergent Adverse Events	nn (xx.x) [kk]
Relationship	nn (xx.x) [kk]
Related	nn (xx.x) [kk]
Not related	nn (xx.x) [kk]
Severity	nn (xx.x) [kk]
Mild	nn (xx.x) [kk]
Moderate	nn (xx.x) [kk]
Severe	nn (xx.x) [kk]
Leading to discontinuation	nn (xx.x) [kk]

Note:Subjects are summarised according to the relationship and severity reported
The number and the proportion of subjects with any adverse event and the number of adverse events for each classification level are reported
The denominator for calculating the proportions is the number of subjects in the safety set
Source: Listing 16.2.7.1 - Treatment-emergent adverse events
Program: Tables\k363-ae-01-tbl.sas

Table 14.3.1.1 - Global frequency of subjects with treatment-emergent adverse events - Safety set

Cohort 4: 2 min (T)

	Safety Set N=XX n (%) [n AE]
Treatment-emergent Adverse Events	nn (xx.x) [kk]
Relationship	nn (xx.x) [kk]
Related	nn (xx.x) [kk]
Not related	nn (xx.x) [kk]
Severity	nn (xx.x) [kk]
Mild	nn (xx.x) [kk]
Moderate	nn (xx.x) [kk]
Severe	nn (xx.x) [kk]
Leading to discontinuation	nn (xx.x) [kk]

Note:Subjects are summarised according to the relationship and severity reported
The number and the proportion of subjects with any adverse event and the number of adverse events for each classification level are reported
The denominator for calculating the proportions is the number of subjects in the safety set
Source: Listing 16.2.7.1 - Treatment-emergent adverse events
Program: Tables\k363-ae-01-tbl.sas

Table 14.3.1.1 - Global frequency of subjects with treatment-emergent adverse events - Safety set

Cohort 4: 2 min (T)

	Safety Set N=XX n (%) [n AE]
Serious Treatment-emergent Adverse Events	nn (xx.x) [kk]
Relationship	nn (xx.x) [kk]
Related	nn (xx.x) [kk]
Not related	nn (xx.x) [kk]
Severity	nn (xx.x) [kk]
Mild	nn (xx.x) [kk]
Moderate	nn (xx.x) [kk]
Severe	nn (xx.x) [kk]
Leading to discontinuation	nn (xx.x) [kk]

Note:Subjects are summarised according to the relationship and severity reported
The number and the proportion of subjects with any adverse event and the number of adverse events for each classification level are reported
The denominator for calculating the proportions is the number of subjects in the safety set
Source: Listing 16.2.7.1 - Treatment-emergent adverse events
Program: Tables\k363-ae-01-tbl.sas

Table 14.3.1.1 - Global frequency of subjects with treatment-emergent adverse events - Safety set

Overall

	Safety Set N=XX n (%) [n AE]
Treatment-emergent Adverse Events	nn (xx.x) [kk]
Relationship	nn (xx.x) [kk]
Related	nn (xx.x) [kk]
Not related	nn (xx.x) [kk]
Severity	nn (xx.x) [kk]
Mild	nn (xx.x) [kk]
Moderate	nn (xx.x) [kk]
Severe	nn (xx.x) [kk]
Leading to discontinuation	nn (xx.x) [kk]

Note:Subjects are summarised according to the relationship and severity reported
The number and the proportion of subjects with any adverse event and the number of adverse events for each classification level are reported
The denominator for calculating the proportions is the number of subjects in the safety set
Source: Listing 16.2.7.1 - Treatment-emergent adverse events
Program: Tables\k363-ae-01-tbl.sas

Table 14.3.1.1 - Global frequency of subjects with treatment-emergent adverse events - Safety set

Overall

	Safety Set N=XX n (%) [n AE]
Serious Treatment-emergent Adverse Events	nn (xx.x) [kk]
Relationship	nn (xx.x) [kk]
Related	nn (xx.x) [kk]
Not related	nn (xx.x) [kk]
Severity	nn (xx.x) [kk]
Mild	nn (xx.x) [kk]
Moderate	nn (xx.x) [kk]
Severe	nn (xx.x) [kk]
Leading to discontinuation	nn (xx.x) [kk]

Note:Subjects are summarised according to the relationship and severity reported
The number and the proportion of subjects with any adverse event and the number of adverse events for each classification level are reported
The denominator for calculating the proportions is the number of subjects in the safety set
Source: Listing 16.2.7.1 - Treatment-emergent adverse events
Program: Tables\k363-ae-01-tbl.sas

Table 14.3.1.2 - Subjects with treatment-emergent adverse events by system organ class and preferred term - Safety set

Cohort 1: 30 min (Rα)

System Organ Class [1] **Preferred Term** [1]	**Safety Set** **N=XX** **n (%) [n AE]**
Treatment-emergent Adverse Events	nn (xx.x) [kk]
Nervous system disorders	nn (xx.x) [kk]
Headache	nn (xx.x) [kk]
...	...
Gastrointestinal disorders	nn (xx.x) [kk]
Abdominal pain upper	nn (xx.x) [kk]
Diarrhoea	nn (xx.x) [kk]
...	...

Note: The number and the proportion of subjects with any adverse event and the number of adverse events for each classification level are reported
The denominator for calculating the proportions is the number of subjects in the safety set
Note 1: MedDRA version 27.0
Source: Listing 16.2.7.1 - Treatment-emergent adverse events
Program: Tables\k363-ae-02-tbl.sas

Table 14.3.1.2 - Subjects with treatment-emergent adverse events by system organ class and preferred term - Safety set

Cohort 1: 30 min (T)

System Organ Class [1] **Preferred Term** [1]	**Safety Set** **N=XX** **n (%) [n AE]**
Treatment-emergent Adverse Events	nn (xx.x) [kk]
Nervous system disorders	nn (xx.x) [kk]
Headache	nn (xx.x) [kk]
...	...
Gastrointestinal disorders	nn (xx.x) [kk]
Abdominal pain upper	nn (xx.x) [kk]
Diarrhoea	nn (xx.x) [kk]
...	...

Note: The number and the proportion of subjects with any adverse event and the number of adverse events for each classification level are reported
The denominator for calculating the proportions is the number of subjects in the safety set
Note 1: MedDRA version 27.0
Source: Listing 16.2.7.1 - Treatment-emergent adverse events
Program: Tables\k363-ae-02-tbl.sas

Table 14.3.1.2 - Subjects with treatment-emergent adverse events by system organ class and preferred term - Safety set

Cohort 2: 15 min (T)

System Organ Class [1] **Preferred Term** [1]	**Safety Set** **N=XX** **n (%) [n AE]**
Treatment-emergent Adverse Events	nn (xx.x) [kk]
Nervous system disorders	nn (xx.x) [kk]
Headache	nn (xx.x) [kk]
...	...
Gastrointestinal disorders	nn (xx.x) [kk]
Abdominal pain upper	nn (xx.x) [kk]
Diarrhoea	nn (xx.x) [kk]
...	...

Note: The number and the proportion of subjects with any adverse event and the number of adverse events for each classification level are reported
The denominator for calculating the proportions is the number of subjects in the safety set
Note 1: MedDRA version 27.0
Source: Listing 16.2.7.1 - Treatment-emergent adverse events
Program: Tables\k363-ae-02-tbl.sas

Table 14.3.1.2 - Subjects with treatment-emergent adverse events by system organ class and preferred term - Safety set

Cohort 3: 5 min (T)

System Organ Class [1] **Preferred Term** [1]	**Safety Set** **N=XX** **n (%) [n AE]**
Treatment-emergent Adverse Events	nn (xx.x) [kk]
Nervous system disorders	nn (xx.x) [kk]
Headache	nn (xx.x) [kk]
...	...
Gastrointestinal disorders	nn (xx.x) [kk]
Abdominal pain upper	nn (xx.x) [kk]
Diarrhoea	nn (xx.x) [kk]
...	...

Note: The number and the proportion of subjects with any adverse event and the number of adverse events for each classification level are reported
The denominator for calculating the proportions is the number of subjects in the safety set
Note 1: MedDRA version 27.0
Source: Listing 16.2.7.1 - Treatment-emergent adverse events
Program: Tables\k363-ae-02-tbl.sas

Table 14.3.1.2 - Subjects with treatment-emergent adverse events by system organ class and preferred term - Safety set

Cohort 4: 2 min (T)

System Organ Class [1] **Preferred Term** [1]	**Safety Set** **N=XX** **n (%) [n AE]**
Treatment-emergent Adverse Events	nn (xx.x) [kk]
Nervous system disorders	nn (xx.x) [kk]
Headache	nn (xx.x) [kk]
...	...
Gastrointestinal disorders	nn (xx.x) [kk]
Abdominal pain upper	nn (xx.x) [kk]
Diarrhoea	nn (xx.x) [kk]
...	...

Note: The number and the proportion of subjects with any adverse event and the number of adverse events for each classification level are reported
The denominator for calculating the proportions is the number of subjects in the safety set
Note 1: MedDRA version 27.0
Source: Listing 16.2.7.1 - Treatment-emergent adverse events
Program: Tables\k363-ae-02-tbl.sas

Table 14.3.1.2 - Subjects with treatment-emergent adverse events by system organ class and preferred term - Safety set

Overall

System Organ Class [1] **Preferred Term** [1]	**Safety Set** **N=XX** **n (%) [n AE]**
Treatment-emergent Adverse Events	nn (xx.x) [kk]
Nervous system disorders	nn (xx.x) [kk]
Headache	nn (xx.x) [kk]
...	...
Gastrointestinal disorders	nn (xx.x) [kk]
Abdominal pain upper	nn (xx.x) [kk]
Diarrhoea	nn (xx.x) [kk]
...	...

Note: The number and the proportion of subjects with any adverse event and the number of adverse events for each classification level are reported
The denominator for calculating the proportions is the number of subjects in the safety set
Note 1: MedDRA version 27.0
Source: Listing 16.2.7.1 - Treatment-emergent adverse events
Program: Tables\k363-ae-02-tbl.sas

Table 14.3.1.3 - Subjects with treatment-emergent adverse events by severity, system organ class and preferred term - Safety set

Cohort 1: 30 min (Rα)

	Safety Set		
System Organ Class [1] **Preferred Term [1]**	**Mild** **n (%) [n AE]**	**Moderate** **n (%) [n AE]**	**Severe** **n (%) [n AE]**
Treatment-emergent Adverse Events	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]
Nervous system disorders	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]
Headache	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]
...	...	...	...
Gastrointestinal disorders	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]
Abdominal pain upper	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]
Diarrhoea	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]
...	...	...	...

Note: The number and the proportion of subjects with any adverse event and the number of adverse events for each classification level are reported
The denominator for calculating the proportions is the number of subjects in the safety set
Note 1: MedDRA version 27.0
Source: Listing 16.2.7.1 - Treatment-emergent adverse events
Program: Tables\k363-ae-02-tbl.sas

Table 14.3.1.3 - Subjects with treatment-emergent adverse events by severity, system organ class and preferred term - Safety set

Cohort 1: 30 min (T)

	Safety Set		
System Organ Class [1] **Preferred Term [1]**	**Mild** **n (%) [n AE]**	**Moderate** **n (%) [n AE]**	**Severe** **n (%) [n AE]**
Treatment-emergent Adverse Events	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]
Nervous system disorders	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]
Headache	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]
...	...	...	...
Gastrointestinal disorders	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]
Abdominal pain upper	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]
Diarrhoea	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]
...	...	...	...

Note: The number and the proportion of subjects with any adverse event and the number of adverse events for each classification level are reported
The denominator for calculating the proportions is the number of subjects in the safety set
Note 1: MedDRA version 27.0
Source: Listing 16.2.7.1 - Treatment-emergent adverse events
Program: Tables\k363-ae-02-tbl.sas

Table 14.3.1.3 - Subjects with treatment-emergent adverse events by severity, system organ class and preferred term - Safety set

Cohort 2: 15 min (T)

	Safety Set		
System Organ Class [1] **Preferred Term [1]**	**Mild** **n (%) [n AE]**	**Moderate** **n (%) [n AE]**	**Severe** **n (%) [n AE]**
Treatment-emergent Adverse Events	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]
Nervous system disorders	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]
Headache	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]
...	...	...	...
Gastrointestinal disorders	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]
Abdominal pain upper	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]
Diarrhoea	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]
...	...	...	...

Note: The number and the proportion of subjects with any adverse event and the number of adverse events for each classification level are reported
The denominator for calculating the proportions is the number of subjects in the safety set
Note 1: MedDRA version 27.0
Source: Listing 16.2.7.1 - Treatment-emergent adverse events
Program: Tables\k363-ae-02-tbl.sas

Table 14.3.1.3 - Subjects with treatment-emergent adverse events by severity, system organ class and preferred term - Safety set

Cohort 3: 5 min (T)

	Safety Set		
System Organ Class [1] **Preferred Term [1]**	**Mild** **n (%) [n AE]**	**Moderate** **n (%) [n AE]**	**Severe** **n (%) [n AE]**
Treatment-emergent Adverse Events	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]
Nervous system disorders	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]
Headache	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]
...	...	...	...
Gastrointestinal disorders	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]
Abdominal pain upper	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]
Diarrhoea	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]
...	...	...	...

Note: The number and the proportion of subjects with any adverse event and the number of adverse events for each classification level are reported
The denominator for calculating the proportions is the number of subjects in the safety set
Note 1: MedDRA version 27.0
Source: Listing 16.2.7.1 - Treatment-emergent adverse events
Program: Tables\k363-ae-02-tbl.sas

Table 14.3.1.3 - Subjects with treatment-emergent adverse events by severity, system organ class and preferred term - Safety set

Cohort 4: 2 min (T)

	Safety Set		
System Organ Class [1] **Preferred Term [1]**	**Mild** **n (%) [n AE]**	**Moderate** **n (%) [n AE]**	**Severe** **n (%) [n AE]**
Treatment-emergent Adverse Events	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]
Nervous system disorders	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]
Headache	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]
...	...	...	...
Gastrointestinal disorders	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]
Abdominal pain upper	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]
Diarrhoea	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]
...	...	...	...

Note: The number and the proportion of subjects with any adverse event and the number of adverse events for each classification level are reported
The denominator for calculating the proportions is the number of subjects in the safety set
Note 1: MedDRA version 27.0
Source: Listing 16.2.7.1 - Treatment-emergent adverse events
Program: Tables\k363-ae-02-tbl.sas

Table 14.3.1.3 - Subjects with treatment-emergent adverse events by severity, system organ class and preferred term - Safety set

Overall

	Safety Set		
System Organ Class [1] **Preferred Term [1]**	**Mild** **n (%) [n AE]**	**Moderate** **n (%) [n AE]**	**Severe** **n (%) [n AE]**
Treatment-emergent Adverse Events	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]
Nervous system disorders	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]
Headache	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]
...	...	...	...
Gastrointestinal disorders	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]
Abdominal pain upper	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]
Diarrhoea	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]
...	...	...	...

Note: The number and the proportion of subjects with any adverse event and the number of adverse events for each classification level are reported
The denominator for calculating the proportions is the number of subjects in the safety set
Note 1: MedDRA version 27.0
Source: Listing 16.2.7.1 - Treatment-emergent adverse events
Program: Tables\k363-ae-02-tbl.sas

Table 14.3.1.4 - Subjects with treatment-emergent adverse events related to the IMP by system organ class and preferred term - Safety set

Cohort 1: 30 min (Rα)

System Organ Class [1] **Preferred Term** [1]	**Safety Set** **N=XX** **n (%) [n AE]**
Treatment-emergent Adverse Events related to the IMP	nn (xx.x) [kk]
Nervous system disorders	nn (xx.x) [kk]
Headache	nn (xx.x) [kk]
...	...
Gastrointestinal disorders	nn (xx.x) [kk]
Abdominal pain upper	nn (xx.x) [kk]
Diarrhoea	nn (xx.x) [kk]
...	...

Note: The number and the proportion of subjects with any related adverse event and the number of related adverse events for each classification level are reported
The denominator for calculating the proportions is the number of subjects in the safety set
Note 1: MedDRA version 27.0
Source: Listing 16.2.7.1 - Treatment-emergent adverse events
Program: Tables\k363-ae-02-tbl.sas

Table 14.3.1.4 - Subjects with treatment-emergent adverse events related to the IMP by system organ class and preferred term - Safety set

Cohort 1: 30 min (T)

System Organ Class [1] **Preferred Term** [1]	**Safety Set** **N=XX** **n (%) [n AE]**
Treatment-emergent Adverse Events related to the IMP	nn (xx.x) [kk]
Nervous system disorders	nn (xx.x) [kk]
Headache	nn (xx.x) [kk]
...	...
Gastrointestinal disorders	nn (xx.x) [kk]
Abdominal pain upper	nn (xx.x) [kk]
Diarrhoea	nn (xx.x) [kk]
...	...

Note: The number and the proportion of subjects with any related adverse event and the number of related adverse events for each classification level are reported
The denominator for calculating the proportions is the number of subjects in the safety set
Note 1: MedDRA version 27.0
Source: Listing 16.2.7.1 - Treatment-emergent adverse events
Program: Tables\k363-ae-02-tbl.sas

Table 14.3.1.4 - Subjects with treatment-emergent adverse events related to the IMP by system organ class and preferred term - Safety set

Cohort 2: 15 min (T)

System Organ Class [1] **Preferred Term** [1]	**Safety Set** **N=XX** **n (%) [n AE]**
Treatment-emergent Adverse Events related to the IMP	nn (xx.x) [kk]
Nervous system disorders	nn (xx.x) [kk]
Headache	nn (xx.x) [kk]
...	...
Gastrointestinal disorders	nn (xx.x) [kk]
Abdominal pain upper	nn (xx.x) [kk]
Diarrhoea	nn (xx.x) [kk]
...	...

Note: The number and the proportion of subjects with any related adverse event and the number of related adverse events for each classification level are reported
The denominator for calculating the proportions is the number of subjects in the safety set
Note 1: MedDRA version 27.0
Source: Listing 16.2.7.1 - Treatment-emergent adverse events
Program: Tables\k363-ae-02-tbl.sas

Table 14.3.1.4 - Subjects with treatment-emergent adverse events related to the IMP by system organ class and preferred term - Safety set

Cohort 3: 5 min (T)

System Organ Class [1] **Preferred Term** [1]	**Safety Set** **N=XX** **n (%) [n AE]**
Treatment-emergent Adverse Events related to the IMP	nn (xx.x) [kk]
Nervous system disorders	nn (xx.x) [kk]
Headache	nn (xx.x) [kk]
...	...
Gastrointestinal disorders	nn (xx.x) [kk]
Abdominal pain upper	nn (xx.x) [kk]
Diarrhoea	nn (xx.x) [kk]
...	...

Note: The number and the proportion of subjects with any related adverse event and the number of related adverse events for each classification level are reported
The denominator for calculating the proportions is the number of subjects in the safety set
Note 1: MedDRA version 27.0
Source: Listing 16.2.7.1 - Treatment-emergent adverse events
Program: Tables\k363-ae-02-tbl.sas

Table 14.3.1.4 - Subjects with treatment-emergent adverse events related to the IMP by system organ class and preferred term - Safety set

Cohort 4: 2 min (T)

System Organ Class [1] **Preferred Term** [1]	**Safety Set** **N=XX** **n (%) [n AE]**
Treatment-emergent Adverse Events related to the IMP	nn (xx.x) [kk]
Nervous system disorders	nn (xx.x) [kk]
Headache	nn (xx.x) [kk]
...	...
Gastrointestinal disorders	nn (xx.x) [kk]
Abdominal pain upper	nn (xx.x) [kk]
Diarrhoea	nn (xx.x) [kk]
...	...

Note: The number and the proportion of subjects with any related adverse event and the number of related adverse events for each classification level are reported
The denominator for calculating the proportions is the number of subjects in the safety set
Note 1: MedDRA version 27.0
Source: Listing 16.2.7.1 - Treatment-emergent adverse events
Program: Tables\k363-ae-02-tbl.sas

Table 14.3.1.4 - Subjects with treatment-emergent adverse events related to the IMP by system organ class and preferred term - Safety set

Overall

System Organ Class [1] **Preferred Term** [1]	**Safety Set** **N=XX** **n (%) [n AE]**
Treatment-emergent Adverse Events related to the IMP	nn (xx.x) [kk]
Nervous system disorders	nn (xx.x) [kk]
Headache	nn (xx.x) [kk]
...	...
Gastrointestinal disorders	nn (xx.x) [kk]
Abdominal pain upper	nn (xx.x) [kk]
Diarrhoea	nn (xx.x) [kk]
...	...

Note: The number and the proportion of subjects with any related adverse event and the number of related adverse events for each classification level are reported
The denominator for calculating the proportions is the number of subjects in the safety set _
Note 1: MedDRA version 27.0
Source: Listing 16.2.7.1 - Treatment-emergent adverse events
Program: Tables\k363-ae-02-tbl.sas

Table 14.3.1.5 - Subjects with serious treatment-emergent adverse events by system organ class and preferred term - Safety set

Cohort 1: 30 min (Rα)

System Organ Class [1] **Preferred Term** [1]	**Safety Set** **N=XX** **n (%) [n AE]**
Serious Treatment-emergent Adverse Events	nn (xx.x) [kk]
Nervous system disorders	nn (xx.x) [kk]
Headache	nn (xx.x) [kk]
...	...
Gastrointestinal disorders	nn (xx.x) [kk]
Abdominal pain upper	nn (xx.x) [kk]
Diarrhoea	nn (xx.x) [kk]
...	...

Note: The number and the proportion of subjects with any serious adverse event and the number of serious adverse events for each classification level are reported
The denominator for calculating the proportions is the number of subjects in the safety set
Note 1: MedDRA version 27.0
Source: Listing 16.2.7.1 - Treatment-emergent adverse events
Program: Tables\k363-ae-02-tbl.sas

Table 14.3.1.5 - Subjects with serious treatment-emergent adverse events by system organ class and preferred term - Safety set

Cohort 1: 30 min (T)

System Organ Class [1] **Preferred Term** [1]	**Safety Set** **N=XX** **n (%) [n AE]**
Serious Treatment-emergent Adverse Events	nn (xx.x) [kk]
Nervous system disorders	nn (xx.x) [kk]
Headache	nn (xx.x) [kk]
...	...
Gastrointestinal disorders	nn (xx.x) [kk]
Abdominal pain upper	nn (xx.x) [kk]
Diarrhoea	nn (xx.x) [kk]
...	...

Note: The number and the proportion of subjects with any serious adverse event and the number of serious adverse events for each classification level are reported
The denominator for calculating the proportions is the number of subjects in the safety set
Note 1: MedDRA version 27.0
Source: Listing 16.2.7.1 - Treatment-emergent adverse events
Program: Tables\k363-ae-02-tbl.sas

Table 14.3.1.5 - Subjects with serious treatment-emergent adverse events by system organ class and preferred term - Safety set

Cohort 2: 15 min (T)

System Organ Class [1] **Preferred Term** [1]	**Safety Set** **N=XX** **n (%) [n AE]**
Serious Treatment-emergent Adverse Events	nn (xx.x) [kk]
Nervous system disorders	nn (xx.x) [kk]
Headache	nn (xx.x) [kk]
...	...
Gastrointestinal disorders	nn (xx.x) [kk]
Abdominal pain upper	nn (xx.x) [kk]
Diarrhoea	nn (xx.x) [kk]
...	...

Note: The number and the proportion of subjects with any serious adverse event and the number of serious adverse events for each classification level are reported
The denominator for calculating the proportions is the number of subjects in the safety set
Note 1: MedDRA version 27.0
Source: Listing 16.2.7.1 - Treatment-emergent adverse events
Program: Tables\k363-ae-02-tbl.sas

Table 14.3.1.5 - Subjects with serious treatment-emergent adverse events by system organ class and preferred term - Safety set

Cohort 3: 5 min (T)

System Organ Class [1] **Preferred Term** [1]	**Safety Set** **N=XX** **n (%) [n AE]**
Serious Treatment-emergent Adverse Events	nn (xx.x) [kk]
Nervous system disorders	nn (xx.x) [kk]
Headache	nn (xx.x) [kk]
...	...
Gastrointestinal disorders	nn (xx.x) [kk]
Abdominal pain upper	nn (xx.x) [kk]
Diarrhoea	nn (xx.x) [kk]
...	...

Note: The number and the proportion of subjects with any serious adverse event and the number of serious adverse events for each classification level are reported
The denominator for calculating the proportions is the number of subjects in the safety set
Note 1: MedDRA version 27.0
Source: Listing 16.2.7.1 - Treatment-emergent adverse events
Program: Tables\k363-ae-02-tbl.sas

Table 14.3.1.5 - Subjects with serious treatment-emergent adverse events by system organ class and preferred term - Safety set

Cohort 4: 2 min (T)

System Organ Class [1] **Preferred Term [1]**	**Safety Set** **N=XX** **n (%) [n AE]**
Serious Treatment-emergent Adverse Events	nn (xx.x) [kk]
Nervous system disorders	nn (xx.x) [kk]
Headache	nn (xx.x) [kk]
...	...
Gastrointestinal disorders	nn (xx.x) [kk]
Abdominal pain upper	nn (xx.x) [kk]
Diarrhoea	nn (xx.x) [kk]
...	...

Note: The number and the proportion of subjects with any serious adverse event and the number of serious adverse events for each classification level are reported
The denominator for calculating the proportions is the number of subjects in the safety set
Note 1: MedDRA version 27.0
Source: Listing 16.2.7.1 - Treatment-emergent adverse events
Program: Tables\k363-ae-02-tbl.sas

Table 14.3.1.5 - Subjects with serious treatment-emergent adverse events by system organ class and preferred term - Safety set

Overall

System Organ Class [1] **Preferred Term** [1]	**Safety Set** **N=XX** **n (%) [n AE]**
Serious Treatment-emergent Adverse Events	nn (xx.x) [kk]
Nervous system disorders	nn (xx.x) [kk]
Headache	nn (xx.x) [kk]
...	...
Gastrointestinal disorders	nn (xx.x) [kk]
Abdominal pain upper	nn (xx.x) [kk]
Diarrhoea	nn (xx.x) [kk]
...	...

Note: The number and the proportion of subjects with any serious adverse event and the number of serious adverse events for each classification level are reported
The denominator for calculating the proportions is the number of subjects in the safety set _
Note 1: MedDRA version 27.0
Source: Listing 16.2.7.1 - Treatment-emergent adverse events
Program: Tables\k363-ae-02-tbl.sas

Table 14.3.1.6 - Subjects with serious treatment-emergent adverse events related to the IMP by system organ class and preferred term - Safety set

Cohort 1: 30 min (Rα)

System Organ Class [1] **Preferred Term** [1]	**Safety Set** **N=XX** **n (%) [n AE]**
Serious Treatment-emergent Adverse Events related to the IMP	nn (xx.x) [kk]
Nervous system disorders	nn (xx.x) [kk]
Headache	nn (xx.x) [kk]
...	...
Gastrointestinal disorders	nn (xx.x) [kk]
Abdominal pain upper	nn (xx.x) [kk]
Diarrhoea	nn (xx.x) [kk]
...	...

Note: The number and the proportion of subjects with any serious related adverse event and the number of serious related adverse events for each classification level are reported
The denominator for calculating the proportions is the number of subjects in the safety set
Note 1: MedDRA version 27.0
Source: Listing 16.2.7.1 - Treatment-emergent adverse events
Program: Tables\k363-ae-02-tbl.sas

Table 14.3.1.6 - Subjects with serious treatment-emergent adverse events related to the IMP by system organ class and preferred term - Safety set

Cohort 1: 30 min (T)

System Organ Class [1] **Preferred Term** [1]	**Safety Set** **N=XX** **n (%) [n AE]**
Serious Treatment-emergent Adverse Events related to the IMP	nn (xx.x) [kk]
Nervous system disorders	nn (xx.x) [kk]
Headache	nn (xx.x) [kk]
...	...
Gastrointestinal disorders	nn (xx.x) [kk]
Abdominal pain upper	nn (xx.x) [kk]
Diarrhoea	nn (xx.x) [kk]
...	...

Note: The number and the proportion of subjects with any serious related adverse event and the number of serious related adverse events for each classification level are reported
The denominator for calculating the proportions is the number of subjects in the safety set
Note 1: MedDRA version 27.0
Source: Listing 16.2.7.1 - Treatment-emergent adverse events
Program: Tables\k363-ae-02-tbl.sas

Table 14.3.1.6 - Subjects with serious treatment-emergent adverse events related to the IMP by system organ class and preferred term - Safety set

Cohort 2: 15 min (T)

System Organ Class [1] **Preferred Term** [1]	**Safety Set** **N=XX** **n (%) [n AE]**
Serious Treatment-emergent Adverse Events related to the IMP	nn (xx.x) [kk]
Nervous system disorders	nn (xx.x) [kk]
Headache	nn (xx.x) [kk]
...	...
Gastrointestinal disorders	nn (xx.x) [kk]
Abdominal pain upper	nn (xx.x) [kk]
Diarrhoea	nn (xx.x) [kk]
...	...

Note: The number and the proportion of subjects with any serious related adverse event and the number of serious related adverse events for each classification level are reported
The denominator for calculating the proportions is the number of subjects in the safety set
Note 1: MedDRA version 27.0
Source: Listing 16.2.7.1 - Treatment-emergent adverse events
Program: Tables\k363-ae-02-tbl.sas

Table 14.3.1.6 - Subjects with serious treatment-emergent adverse events related to the IMP by system organ class and preferred term - Safety set

Cohort 3: 5 min (T)

System Organ Class [1] **Preferred Term** [1]	**Safety Set** **N=XX** **n (%) [n AE]**
Serious Treatment-emergent Adverse Events related to the IMP	nn (xx.x) [kk]
Nervous system disorders	nn (xx.x) [kk]
Headache	nn (xx.x) [kk]
...	...
Gastrointestinal disorders	nn (xx.x) [kk]
Abdominal pain upper	nn (xx.x) [kk]
Diarrhoea	nn (xx.x) [kk]
...	...

Note: The number and the proportion of subjects with any serious related adverse event and the number of serious related adverse events for each classification level are reported
The denominator for calculating the proportions is the number of subjects in the safety set
Note 1: MedDRA version 27.0
Source: Listing 16.2.7.1 - Treatment-emergent adverse events
Program: Tables\k363-ae-02-tbl.sas

Table 14.3.1.6 - Subjects with serious treatment-emergent adverse events related to the IMP by system organ class and preferred term - Safety set

Cohort 4: 2 min (T)

System Organ Class [1] **Preferred Term** [1]	**Safety Set** **N=XX** **n (%) [n AE]**
Serious Treatment-emergent Adverse Events related to the IMP	nn (xx.x) [kk]
Nervous system disorders	nn (xx.x) [kk]
Headache	nn (xx.x) [kk]
...	...
Gastrointestinal disorders	nn (xx.x) [kk]
Abdominal pain upper	nn (xx.x) [kk]
Diarrhoea	nn (xx.x) [kk]
...	...

Note: The number and the proportion of subjects with any serious related adverse event and the number of serious related adverse events for each classification level are reported
The denominator for calculating the proportions is the number of subjects in the safety set _
Note 1: MedDRA version 27.0
Source: Listing 16.2.7.1 - Treatment-emergent adverse events
Program: Tables\k363-ae-02-tbl.sas

Table 14.3.1.6 - Subjects with serious treatment-emergent adverse events related to the IMP by system organ class and preferred term - Safety set

Overall

System Organ Class [1] **Preferred Term** [1]	**Safety Set** **N=XX** **n (%) [n AE]**
Serious Treatment-emergent Adverse Events related to the IMP	nn (xx.x) [kk]
Nervous system disorders	nn (xx.x) [kk]
Headache	nn (xx.x) [kk]
...	...
Gastrointestinal disorders	nn (xx.x) [kk]
Abdominal pain upper	nn (xx.x) [kk]
Diarrhoea	nn (xx.x) [kk]
...	...

Note: The number and the proportion of subjects with any serious related adverse event and the number of serious related adverse events for each classification level are reported
The denominator for calculating the proportions is the number of subjects in the safety set
Note 1: MedDRA version 27.0
Source: Listing 16.2.7.1 - Treatment-emergent adverse events
Program: Tables\k363-ae-02-tbl.sas

Table 14.3.2.1 - Treatment-emergent adverse events leading to death, serious adverse events or treatment-emergent adverse events leading to discontinuation - Safety set

Cohort 1: 30 min (Rα)

Subject ID	Adverse Event ID		
S001/001	1	Description:	Headache
		Preferred Term [1]:	Headache
		System Organ Class [1]:	Nervous system disorders
		Start Date/Time - End Date/Time (Day):	ddMMMyyyy hh:mm (k) - ddMMMyyyy (j)
		Last Study Drug Administration Date/Time Before Onset:	ddMMMyyyy hh:mm
		Relation to the Study Drug	Not related
		Severity:	Mild
		Serious Adverse Event?	N
		Seriousness criteria:	---
		Action Taken with Study Drug:	None
		Other Action Taken:	None
		Outcome:	Recovered/Resolved
...	...	...	...

Note 1: MedDRA version 27.0
Source: Listing 16.2.7.1 - Treatment-emergent adverse events
Program: Tables\k363-ae-03-tbl.sas

Table 14.3.2.1 - Treatment-emergent adverse events leading to death, serious adverse events or treatment-emergent adverse events leading to discontinuation - Safety set

Cohort 1: 30 min (T)

Subject ID	Adverse Event ID		
S001/001	1	Description:	Headache
		Preferred Term [1]:	Headache
		System Organ Class [1]:	Nervous system disorders
		Start Date/Time - End Date/Time (Day):	ddMMMyyyy hh:mm (k) - ddMMMyyyy (j)
		Last Study Drug Administration Date/Time Before Onset:	ddMMMyyyy hh:mm
		Relation to the Study Drug	Not related
		Severity:	Mild
		Serious Adverse Event?	N
		Seriousness criteria:	---
		Action Taken with Study Drug:	None
		Other Action Taken:	None
		Outcome:	Recovered/Resolved
...	...	...	...

Note 1: MedDRA version 27.0
Source: Listing 16.2.7.1 - Treatment-emergent adverse events
Program: Tables\k363-ae-03-tbl.sas

Table 14.3.2.1 - Treatment-emergent adverse events leading to death, serious adverse events or treatment-emergent adverse events leading to discontinuation - Safety set

Cohort 2: 15 min (T)

Subject ID	Adverse Event ID		
S001/001	1	Description:	Headache
		Preferred Term [1]:	Headache
		System Organ Class [1]:	Nervous system disorders
		Start Date/Time - End Date/Time (Day):	ddMMMyyyy hh:mm (k) - ddMMMyyyy (j)
		Last Study Drug Administration Date/Time Before Onset:	ddMMMyyyy hh:mm
		Relation to the Study Drug	Not related
		Severity:	Mild
		Serious Adverse Event?	N
		Seriousness criteria:	---
		Action Taken with Study Drug:	None
		Other Action Taken:	None
		Outcome:	Recovered/Resolved
...	...	...	...

Note 1: MedDRA version 27.0
Source: Listing 16.2.7.1 - Treatment-emergent adverse events
Program: Tables\k363-ae-03-tbl.sas

Table 14.3.2.1 - Treatment-emergent adverse events leading to death, serious adverse events or treatment-emergent adverse events leading to discontinuation - Safety set

Cohort 3: 5 min (T)

Subject ID	Adverse Event ID		
S001/001	1	Description:	Headache
		Preferred Term [1]:	Headache
		System Organ Class [1]:	Nervous system disorders
		Start Date/Time - End Date/Time (Day):	ddMMMyyyy hh:mm (k) - ddMMMyyyy (j)
		Last Study Drug Administration Date/Time Before Onset:	ddMMMyyyy hh:mm
		Relation to the Study Drug	Not related
		Severity:	Mild
		Serious Adverse Event?	N
		Seriousness criteria:	---
		Action Taken with Study Drug:	None
		Other Action Taken:	None
		Outcome:	Recovered/Resolved
...	...	...	...

Note 1: MedDRA version 27.0
Source: Listing 16.2.7.1 - Treatment-emergent adverse events
Program: Tables\k363-ae-03-tbl.sas

Table 14.3.2.1 - Treatment-emergent adverse events leading to death, serious adverse events or treatment-emergent adverse events leading to discontinuation - Safety set

Cohort 4: 2 min (T)

Subject ID	Adverse Event ID		
S001/001	1	Description:	Headache
		Preferred Term [1]:	Headache
		System Organ Class [1]:	Nervous system disorders
		Start Date/Time - End Date/Time (Day):	ddMMMyyyy hh:mm (k) - ddMMMyyyy (j)
		Last Study Drug Administration Date/Time Before Onset:	ddMMMyyyy hh:mm
		Relation to the Study Drug	Not related
		Severity:	Mild
		Serious Adverse Event?	N
		Seriousness criteria:	---
		Action Taken with Study Drug:	None
		Other Action Taken:	None
		Outcome:	Recovered/Resolved
...	...	...	...

Note 1: MedDRA version 27.0
Source: Listing 16.2.7.1 - Treatment-emergent adverse events
Program: Tables\k363-ae-03-tbl.sas

Table 14.3.4.1 - Abnormal laboratory values - Safety set

Cohort 1: 30 min (Rα)

Category of Laboratory Parameters: BLOOD CHEMISTRY

Subject ID	Time Point	Collection Date/time	Parameter	Value and Abnormality [1]	Normal Range or Reference Value	Clinically Significant? [2]
S001/001	Screening	ddMMMyyyy hh:mm	Phosphate [mmol/L]	0.84 [A]	0.87 - 1.45	NCS
...	...	...	...	...	...	...
S001/001	End of Study	ddMMMyyyy hh:mm	Phosphate [mmol/L]	0.84 [A]	0.87 - 1.45	NCS
...	...	...	...	...	...	...

Note: Subjects are summarised according to the cohort they belong to
Note 1: A=Abnormal
Note 2: NCS=Not clinically significant, CS= Clinically Significant
Source: Listing 16.2.8.1 - Individual laboratory measurements
Program: Tables\k363-lb-tbl.sas

Table 14.3.4.1 - Abnormal laboratory values - Safety set

Cohort 1: 30 min (Rα)

Category of Laboratory Parameters: HAEMATOLOGY

Subject ID	Time Point	Collection Date/time	Parameter	Value and Abnormality [1]	Normal Range or Reference Value	Clinically Significant? [2]
S001/001	Screening	ddMMMyyyy hh:mm	Leukocytes [10^9/L]	10.02 [A]	4.00 - 10.00	NCS
...	...	...	...	...	...	...
S001/001	End of Study	ddMMMyyyy hh:mm	Leukocytes [10^9/L]	10.02 [A]	4.00 - 10.00	NCS
...	...	...	...	...	...	...

Note: Subjects are summarised according to the group they belong to
Note 1: A=Abnormal
Note 2: NCS=Not clinically significant, CS= Clinically Significant
Source: Listing 16.2.8.1 - Individual laboratory measurements
Program: Tables\k363-lb-tbl.sas

Table 14.3.4.1 - Abnormal laboratory values - Safety set

Cohort 1: 30 min (Rα)

Category of Laboratory Parameters: URINE ANALYSIS

Subject ID	Time Point	Collection Date/time	Parameter	Value and Abnormality [1]	Normal Range or Reference Value	Clinically Significant? [2]
S001/001	Screening	ddMMMyyyy hh:mm	Urinary Hemoglobin	+++ [A]	Absent	NCS
...	...	...	...	...	...	...
S001/001	End of Study	ddMMMyyyy hh:mm	Urinary Hemoglobin	+++ [A]	Absent	NCS
...	...	...	...	...	...	...

Note: Subjects are summarised according to the group they belong to
Note 1: A=Different from reference value
Note 2: NCS=Not clinically significant, CS= Clinically Significant
Source: Listing 16.2.8.1 - Individual laboratory measurements
Program: Tables\k363-lb-tbl.sas

Table 14.3.4.1 - Abnormal laboratory values - Safety set

Cohort 1: 30 min (T)
Category of Laboratory Parameters: BLOOD CHEMISTRY

Subject ID	Time Point	Collection Date/time	Parameter	Value and Abnormality [1]	Normal Range or Reference Value	Clinically Significant? [2]
S012/011	Screening	ddMMMyyyy hh:mm	Phosphate [mmol/L]	0.84 [A]	0.87 - 1.45	NCS
...	...	...	...	...	...	...
S012/011	End of Study	ddMMMyyyy hh:mm	Phosphate [mmol/L]	0.84 [A]	0.87 - 1.45	NCS
...	...	...	...	...	...	...

Note: Subjects are summarised according to the group they belong to
Note 1: A=Abnormal
Note 2: NCS=Not clinically significant, CS= Clinically Significant
Source: Listing 16.2.8.1 - Individual laboratory measurements
Program: Tables\k363-lb-tbl.sas

Table 14.3.4.1 - Abnormal laboratory values - Safety set

Cohort 1: 30 min (T)
Category of Laboratory Parameters: HAEMATOLOGY

Subject ID	Time Point	Collection Date/time	Parameter	Value and Abnormality [1]	Normal Range or Reference Value	Clinically Significant? [2]
S012/011	Screening	ddMMMyyyy hh:mm	Leukocytes [10^9/L]	10.02 [A]	4.00 - 10.00	NCS
...	...	...	...	...	...	...
S012/011	End of Study	ddMMMyyyy hh:mm	Leukocytes [10^9/L]	10.02 [A]	4.00 - 10.00	NCS
...	...	...	...	...	...	...

Note: Subjects are summarised according to the group they belong to
Note 1: A=Abnormal
Note 2: NCS=Not clinically significant, CS= Clinically Significant
Source: Listing 16.2.8.1 - Individual laboratory measurements
Program: Tables\k363-lb-tbl.sas

Table 14.3.4.1 - Abnormal laboratory values - Safety set

Cohort 1: 30 min (T)
Category of Laboratory Parameters: URINE ANALYSIS

Subject ID	Time Point	Collection Date/time	Parameter	Value and Abnormality [1]	Normal Range or Reference Value	Clinically Significant? [2]
S012/011	Screening	ddMMMyyyy hh:mm	Urinary Hemoglobin	+++ [A]	Absent	NCS
...	...	...	...	...	...	...
S012/011	End of Study	ddMMMyyyy hh:mm	Urinary Hemoglobin	+++ [A]	Absent	NCS
...	...	...	...	...	...	...

Note: Subjects are summarised according to the group they belong to
Note 1: A=Different from reference value
Note 2: NCS=Not clinically significant, CS= Clinically Significant
Source: Listing 16.2.8.1 - Individual laboratory measurements
Program: Tables\k363-lb-tbl.sas

Table 14.3.4.1 - Abnormal laboratory values - Safety set

Cohort 2: 15 min (T)
Category of Laboratory Parameters: BLOOD CHEMISTRY

Subject ID	Time Point	Collection Date/time	Parameter	Value and Abnormality [1]	Normal Range or Reference Value	Clinically Significant? [2]
S025/023	Screening	ddMMMyyyy hh:mm	Phosphate [mmol/L]	0.84 [A]	0.87 - 1.45	NCS
...	...	...	...	...	...	...
S025/023	End of Study	ddMMMyyyy hh:mm	Phosphate [mmol/L]	0.84 [A]	0.87 - 1.45	NCS
...	...	...	...	...	...	...

Note: Subjects are summarised according to the group they belong to
Note 1: A=Abnormal
Note 2: NCS=Not clinically significant, CS= Clinically Significant
Source: Listing 16.2.8.1 - Individual laboratory measurements
Program: Tables\k363-lb-tbl.sas

Table 14.3.4.1 - Abnormal laboratory values - Safety set

Cohort 2: 15 min (T)
Category of Laboratory Parameters: HAEMATOLOGY

Subject ID	Time Point	Collection Date/time	Parameter	Value and Abnormality [1]	Normal Range or Reference Value	Clinically Significant? [2]
S025/023	Screening	ddMMMyyyy hh:mm	Leukocytes [10^9/L]	10.02 [A]	4.00 - 10.00	NCS
...	...	...	...	...	...	...
S025/023	End of Study	ddMMMyyyy hh:mm	Leukocytes [10^9/L]	10.02 [A]	4.00 - 10.00	NCS
...	...	...	...	...	...	...

Note: Subjects are summarised according to the group they belong to
Note 1: A=Abnormal
Note 2: NCS=Not clinically significant, CS= Clinically Significant
Source: Listing 16.2.8.1 - Individual laboratory measurements
Program: Tables\k363-lb-tbl.sas

Table 14.3.4.1 - Abnormal laboratory values - Safety set

Cohort 2: 15 min (T)
Category of Laboratory Parameters: URINE ANALYSIS

Subject ID	Time Point	Collection Date/time	Parameter	Value and Abnormality [1]	Normal Range or Reference Value	Clinically Significant? [2]
S025/023	Screening	ddMMMyyyy hh:mm	Urinary Hemoglobin	+++ [A]	Absent	NCS
...	...	...	...	...	...	...
S025/023	End of Study	ddMMMyyyy hh:mm	Urinary Hemoglobin	+++ [A]	Absent	NCS
...	...	...	...	...	...	...

Note: Subjects are summarised according to the group they belong to
Note 1: A=Different from reference value
Note 2: NCS=Not clinically significant, CS= Clinically Significant
Source: Listing 16.2.8.1 - Individual laboratory measurements
Program: Tables\k363-lb-tbl.sas

Table 14.3.4.1 - Abnormal laboratory values - Safety set

Cohort 3: 5 min (T)
Category of Laboratory Parameters: BLOOD CHEMISTRY

Subject ID	Time Point	Collection Date/time	Parameter	Value and Abnormality [1]	Normal Range or Reference Value	Clinically Significant? [2]
S036/032	Screening	ddMMMyyyy hh:mm	Phosphate [mmol/L]	0.84 [A]	0.87 - 1.45	NCS
...	...	...	...	...	...	...
S036/032	End of Study	ddMMMyyyy hh:mm	Phosphate [mmol/L]	0.84 [A]	0.87 - 1.45	NCS
...	...	...	...	...	...	...

Note: Subjects are summarised according to the group they belong to
Note 1: A=Abnormal
Note 2: NCS=Not clinically significant, CS= Clinically Significant
Source: Listing 16.2.8.1 - Individual laboratory measurements
Program: Tables\k363-lb-tbl.sas

Table 14.3.4.1 - Abnormal laboratory values - Safety set

Cohort 3: 5 min (T)
Category of Laboratory Parameters: HAEMATOLOGY

Subject ID	Time Point	Collection Date/time	Parameter	Value and Abnormality [1]	Normal Range or Reference Value	Clinically Significant? [2]
S036/032	Screening	ddMMMyyyy hh:mm	Leukocytes [10^9/L]	10.02 [A]	4.00 - 10.00	NCS
...	...	...	...	...	...	...
S036/032	End of Study	ddMMMyyyy hh:mm	Leukocytes [10^9/L]	10.02 [A]	4.00 - 10.00	NCS
...	...	...	...	...	...	...

Note: Subjects are summarised according to the group they belong to
Note 1: A=Abnormal
Note 2: NCS=Not clinically significant, CS= Clinically Significant
Source: Listing 16.2.8.1 - Individual laboratory measurements
Program: Tables\k363-lb-tbl.sas

Table 14.3.4.1 - Abnormal laboratory values - Safety set

Cohort 3: 5 min (T)
Category of Laboratory Parameters: URINE ANALYSIS

Subject ID	Time Point	Collection Date/time	Parameter	Value and Abnormality [1]	Normal Range or Reference Value	Clinically Significant? [2]
S036/032	Screening	ddMMMyyyy hh:mm	Urinary Hemoglobin	+++ [A]	Absent	NCS
...	...	...	...	...	...	...
S036/032	End of Study	ddMMMyyyy hh:mm	Urinary Hemoglobin	+++ [A]	Absent	NCS
...	...	...	...	...	...	...

Note: Subjects are summarised according to the group they belong to
Note 1: A=Different from reference value
Note 2: NCS=Not clinically significant, CS= Clinically Significant _
Source: Listing 16.2.8.1 - Individual laboratory measurements
Program: Tables\k363-lb-tbl.sas

Table 14.3.4.1 - Abnormal laboratory values - Safety set

Cohort 4: 2 min (T)
Category of Laboratory Parameters: BLOOD CHEMISTRY

Subject ID	Time Point	Collection Date/time	Parameter	Value and Abnormality [1]	Normal Range or Reference Value	Clinically Significant? [2]
S044/040	Screening	ddMMMyyyy hh:mm	Phosphate [mmol/L]	0.84 [A]	0.87 - 1.45	NCS
...	...	...	...	...	...	...
S044/040	End of Study	ddMMMyyyy hh:mm	Phosphate [mmol/L]	0.84 [A]	0.87 - 1.45	NCS
...	...	...	...	...	...	...

Note: Subjects are summarised according to the group they belong to
Note 1: A=Abnormal
Note 2: NCS=Not clinically significant, CS= Clinically Significant
Source: Listing 16.2.8.1 - Individual laboratory measurements
Program: Tables\k363-lb-tbl.sas

Table 14.3.4.1 - Abnormal laboratory values - Safety set

Cohort 4: 2 min (T)
Category of Laboratory Parameters: HAEMATOLOGY

Subject ID	Time Point	Collection Date/time	Parameter	Value and Abnormality [1]	Normal Range or Reference Value	Clinically Significant? [2]
S044/040	Screening	ddMMMyyyy hh:mm	Leukocytes [10^9/L]	10.02 [A]	4.00 - 10.00	NCS
...	...	...	...	...	...	...
S044/040	End of Study	ddMMMyyyy hh:mm	Leukocytes [10^9/L]	10.02 [A]	4.00 - 10.00	NCS
...	...	...	...	...	...	...

Note: Subjects are summarised according to the group they belong to
Note 1: A=Abnormal
Note 2: NCS=Not clinically significant, CS= Clinically Significant
Source: Listing 16.2.8.1 - Individual laboratory measurements
Program: Tables\k363-lb-tbl.sas

Table 14.3.4.1 - Abnormal laboratory values - Safety set

Cohort 4: 2 min (T)
Category of Laboratory Parameters: URINE ANALYSIS

Subject ID	Time Point	Collection Date/time	Parameter	Value and Abnormality [1]	Normal Range or Reference Value	Clinically Significant? [2]
S044/040	Screening	ddMMMyyyy hh:mm	Urinary Hemoglobin	+++ [A]	Absent	NCS
...	...	...	...	...	...	...
S044/040	End of Study	ddMMMyyyy hh:mm	Urinary Hemoglobin	+++ [A]	Absent	NCS
...	...	...	...	...	...	...

Note: Subjects are summarised according to the group they belong to
Note 1: A=Different from reference value
Note 2: NCS=Not clinically significant, CS= Clinically Significant
Source: Listing 16.2.8.1 - Individual laboratory measurements
Program: Tables\k363-lb-tbl.sas

Table 14.3.4.2 - Contingency tables of investigator's interpretation of laboratory test results - Safety set

Cohort 1: 30 min (Rα)

Time Point	Investigator's interpretation	Safety Set N=XX
Screening	Normal	nn (xx.x)
	Abnormal, Not Clinically Significant	nn (xx.x)
	Abnormal, Clinically Significant	nn (xx.x)
End of Study	Normal	nn (xx.x)
	Abnormal, Not Clinically Significant	nn (xx.x)
	Abnormal, Clinically Significant	nn (xx.x)

Note: Subjects are summarised according to the group they belong to
The number and the proportion of subjects for each classification level are reported
The denominator for calculating the proportions is the number of subjects in each cohort in the safety set
Source: Listing 16.2.8.2 - Investigator's interpretation of laboratory test results
Program: Tables\k363-lb-tbl.sas

Table 14.3.4.2 - Contingency tables of investigator's interpretation of laboratory test results - Safety set

Cohort 1: 30 min (T)

Time Point	Investigator's interpretation	Safety Set N=XX
Screening	Normal	nn (xx.x)
	Abnormal, Not Clinically Significant	nn (xx.x)
	Abnormal, Clinically Significant	nn (xx.x)
End of Study	Normal	nn (xx.x)
	Abnormal, Not Clinically Significant	nn (xx.x)
	Abnormal, Clinically Significant	nn (xx.x)

Note: Subjects are summarised according to the group they belong to
The number and the proportion of subjects for each classification level are reported
The denominator for calculating the proportions is the number of subjects in each cohort in the safety set
Source: Listing 16.2.8.2 - Investigator's interpretation of laboratory test results
Program: Tables\k363-lb-tbl.sas

Table 14.3.4.2 - Contingency tables of investigator's interpretation of laboratory test results - Safety set

Cohort 2: 15 min (T)

Time Point	Investigator's interpretation	Safety Set N=XX
Screening	Normal	nn (xx.x)
	Abnormal, Not Clinically Significant	nn (xx.x)
	Abnormal, Clinically Significant	nn (xx.x)
End of Study	Normal	nn (xx.x)
	Abnormal, Not Clinically Significant	nn (xx.x)
	Abnormal, Clinically Significant	nn (xx.x)

Note: Subjects are summarised according to the group they belong to _
The number and the proportion of subjects for each classification level are reported
The denominator for calculating the proportions is the number of subjects in each cohort in the safety set
Source: Listing 16.2.8.2 - Investigator's interpretation of laboratory test results
Program: Tables\k363-lb-tbl.sas

Table 14.3.4.2 - Contingency tables of investigator's interpretation of laboratory test results - Safety set

Cohort 3: 5 min (T)

Time Point	Investigator's interpretation	Safety Set N=XX
Screening	Normal	nn (xx.x)
	Abnormal, Not Clinically Significant	nn (xx.x)
	Abnormal, Clinically Significant	nn (xx.x)
End of Study	Normal	nn (xx.x)
	Abnormal, Not Clinically Significant	nn (xx.x)
	Abnormal, Clinically Significant	nn (xx.x)

Note: Subjects are summarised according to the group they belong to _
The number and the proportion of subjects for each classification level are reported
The denominator for calculating the proportions is the number of subjects in each cohort in the safety set
Source: Listing 16.2.8.2 - Investigator's interpretation of laboratory test results
Program: Tables\k363-lb-tbl.sas

Table 14.3.4.2 - Contingency tables of investigator's interpretation of laboratory test results - Safety set

Cohort 4: 2 min (T)

Time Point	Investigator's interpretation	Safety Set N=XX
Screening	Normal	nn (xx.x)
	Abnormal, Not Clinically Significant	nn (xx.x)
	Abnormal, Clinically Significant	nn (xx.x)
End of Study	Normal	nn (xx.x)
	Abnormal, Not Clinically Significant	nn (xx.x)
	Abnormal, Clinically Significant	nn (xx.x)

Note: Subjects are summarised according to the group they belong to _
The number and the proportion of subjects for each classification level are reported
The denominator for calculating the proportions is the number of subjects in each cohort in the safety set
Source: Listing 16.2.8.2 - Investigator's interpretation of laboratory test results
Program: Tables\k363-lb-tbl.sas

Table 14.3.4.2 - Contingency tables of investigator's interpretation of laboratory test results - Safety set

Overall

Time Point	Investigator's interpretation	Safety Set N=XX
Screening	Normal	nn (xx.x)
	Abnormal, Not Clinically Significant	nn (xx.x)
	Abnormal, Clinically Significant	nn (xx.x)
End of Study	Normal	nn (xx.x)
	Abnormal, Not Clinically Significant	nn (xx.x)
	Abnormal, Clinically Significant	nn (xx.x)

Note: Subjects are summarised according to the group they belong to
The number and the proportion of subjects for each classification level are reported
The denominator for calculating the proportions is the number of subjects in each cohort in the safety set
Source: Listing 16.2.8.2 - Investigator's interpretation of laboratory test results
Program: Tables\k363-lb-tbl.sas

Table 14.3.5.1 - Abnormal vital signs - Safety set

Cohort 1: 30 min (Rα)

Subject ID	Time Point	Assessment Date/Time	Parameter	Value and Abnormality [1]	Normal Range	Clinically Significant? [2]
S001/001	Screening	ddMMMyyyy hh:mm	Systolic Blood Pressure [mmHg]	96 [L]	100-139	NCS
S001/001	Visit 2	ddMMMyyyy hh:mm	Systolic Blood Pressure [mmHg]	89 [L]	100-139	NCS
...	...	...	...	...	...	...

Note: Subjects are summarised according to the cohort they belong to
Note 1: H=Higher than upper normal limit, L=Lower than lower normal limit
Note 2: NCS=Not clinically significant, CS= Clinically Significant
Source: Listing 16.2.9.1 - Vital signs and body weight
Program: Tables\k363-vs-tbl.sas

Table 14.3.5.1 - Abnormal vital signs - Safety set

Cohort 1: 30 min (T)

Subject ID	Time Point	Assessment Date/Time	Parameter	Value and Abnormality [1]	Normal Range	Clinically Significant? [2]
S012/011	Screening	ddMMMyyyy hh:mm	Systolic Blood Pressure [mmHg]	96 [L]	100-139	NCS
S012/011	Visit 2	ddMMMyyyy hh:mm	Systolic Blood Pressure [mmHg]	89 [L]	100-139	NCS
...	...	...	...	...	...	...

Note: Subjects are summarised according to the cohort they belong to
Note 1: H=Higher than upper normal limit, L=Lower than lower normal limit
Note 2: NCS=Not clinically significant, CS= Clinically Significant
Source: Listing 16.2.9.1 - Vital signs and body weight
Program: Tables\k363-vs-tbl.sas

Table 14.3.5.1 - Abnormal vital signs - Safety set

Cohort 2: 15 min (T)

Subject ID	Time Point	Assessment Date/Time	Parameter	Value and Abnormality [1]	Normal Range	Clinically Significant? [2]
S025/023	Screening	ddMMMyyyy hh:mm	Systolic Blood Pressure [mmHg]	96 [L]	100-139	NCS
S025/023	Visit 2	ddMMMyyyy hh:mm	Systolic Blood Pressure [mmHg]	89 [L]	100-139	NCS
...	...	...	...	...	...	...

Note: Subjects are summarised according to the cohort they belong to
Note 1: H=Higher than upper normal limit, L=Lower than lower normal limit
Note 2: NCS=Not clinically significant, CS= Clinically Significant
Source: Listing 16.2.9.1 - Vital signs and body weight
Program: Tables\k363-vs-tbl.sas

Table 14.3.5.1 - Abnormal vital signs - Safety set

Cohort 3: 5 min (T)

Subject ID	Time Point	Assessment Date/Time	Parameter	Value and Abnormality [1]	Normal Range	Clinically Significant? [2]
S036/032	Screening	ddMMMyyyy hh:mm	Systolic Blood Pressure [mmHg]	96 [L]	100-139	NCS
S036/032	Visit 2	ddMMMyyyy hh:mm	Systolic Blood Pressure [mmHg]	89 [L]	100-139	NCS
...	...	...	...	...	...	...

Note: Subjects are summarised according to the cohort they belong to
Note 1: H=Higher than upper normal limit, L=Lower than lower normal limit
Note 2: NCS=Not clinically significant, CS= Clinically Significant
Source: Listing 16.2.9.1 - Vital signs and body weight
Program: Tables\k363-vs-tbl.sas

Table 14.3.5.1 - Abnormal vital signs - Safety set

Cohort 4: 2 min (T)

Subject ID	Time Point	Assessment Date/Time	Parameter	Value and Abnormality [1]	Normal Range	Clinically Significant? [2]
S044/040	Screening	ddMMMyyyy hh:mm	Systolic Blood Pressure [mmHg]	96 [L]	100-139	NCS
S044/040	Visit 2	ddMMMyyyy hh:mm	Systolic Blood Pressure [mmHg]	89 [L]	100-139	NCS
...	...	...	...	...	...	...

Note: Subjects are summarised according to the cohort they belong to
Note 1: H=Higher than upper normal limit, L=Lower than lower normal limit
Note 2: NCS=Not clinically significant, CS= Clinically Significant
Source: Listing 16.2.9.1 - Vital signs and body weight
Program: Tables\k363-vs-tbl.sas

Table 14.3.5.2 - Descriptive statistics of vital signs - Safety set

Cohort 1: 30 min (Rα)

Parameter	Time Point	Statistics	Safety Set N=XX
Systolic Blood Pressure [mmHg]	Screening	N	nn
		Mean	xxx.x
		SD	xxx.x
		CV%	xxx.x
		Min	xxx
		Median	xxx.x
		Max	xxx
Systolic Blood Pressure [mmHg]	Visit 2	N	nn
		Mean	xxx.x
		SD	xxx.x
		CV%	xxx.x
		Min	xxx
		Median	xxx.x
		Max	xxx
Systolic Blood Pressure [mmHg]	...	N	nn
		Mean	xxx.x
		SD	xxx.x
		CV%	xxx.x

Subjects are summarised according to the cohort they belong to
Source: Listing 16.2.9.1 - Vital signs and Body weight
Program:Tables\k363-vs-tbl.sas

Table 14.3.5.2 - Descriptive statistics of vital signs - Safety set

Cohort 1: 30 min (Rα)

Parameter	Time Point	Statistics	Safety Set N=XX
Systolic Blood Pressure [mmHg]	...	Min	xxx
		Median	xxx.x
		Max	xxx
Systolic Blood Pressure [mmHg]	Visit 4 - Final Visit	N	nn
		Mean	xxx.x
		SD	xxx.x
		CV%	xxx.x
		Min	xxx
		Median	xxx.x
		Max	xxx
Diastolic Blood Pressure [mmHg]	Screening	N	nn
		Mean	xxx.x
		SD	xxx.x
		CV%	xxx.x
		Min	xxx
		Median	xxx.x
		Max	xxx
Diastolic Blood Pressure [mmHg]	Visit 2	N	nn

Subjects are summarised according to the cohort they belong to
Source: Listing 16.2.9.1 - Vital signs and Body weight
Program:Tables\k363-vs-tbl.sas

Table 14.3.5.2 - Descriptive statistics of vital signs - Safety set

Cohort 1: 30 min (Rα)

Parameter	Time Point	Statistics	Safety Set N=XX
Diastolic Blood Pressure [mmHg]	Visit 2	Mean	xxx.x
		SD	xxx.x
		CV%	xxx.x
		Min	xxx
		Median	xxx.x
		Max	xxx
Diastolic Blood Pressure [mmHg]	...	N	nn
		Mean	xxx.x
		SD	xxx.x
		CV%	xxx.x
		Min	xxx
		Median	xxx.x
		Max	xxx
Diastolic Blood Pressure [mmHg]	Visit 4 - Final Visit	N	nn
		Mean	xxx.x
		SD	xxx.x
		CV%	xxx.x
		Min	xxx
		Median	xxx.x

Subjects are summarised according to the cohort they belong to
Source: Listing 16.2.9.1 - Vital signs and Body weight
Program:Tables\k363-vs-tbl.sas

Table 14.3.5.2 - Descriptive statistics of vital signs - Safety set

Cohort 1: 30 min (Rα)

Parameter	Time Point	Statistics	Safety Set N=XX
Diastolic Blood Pressure [mmHg]	Visit 4 - Final Visit	Max	xxx
Heart Rate [beats/min]	Screening	N	nn
		Mean	xxx.x
		SD	xxx.x
		CV%	xxx.x
		Min	xxx
		Median	xxx.x
		Max	xxx
Heart Rate [beats/min]	Visit 2	N	nn
		Mean	xxx.x
		SD	xxx.x
		CV%	xxx.x
		Min	xxx
		Median	xxx.x
		Max	xxx
Heart Rate [beats/min]	...	N	nn
		Mean	xxx.x
		SD	xxx.x

Subjects are summarised according to the cohort they belong to
Source: Listing 16.2.9.1 - Vital signs and Body weight
Program:Tables\k363-vs-tbl.sas

Table 14.3.5.2 - Descriptive statistics of vital signs - Safety set

Cohort 1: 30 min (Rα)

Parameter	Time Point	Statistics	Safety Set N=XX
Heart Rate [beats/min]	...	CV%	xxx.x
		Min	xxx
		Median	xxx.x
		Max	xxx
Heart Rate [beats/min]	Visit 4 - Final Visit	N	nn
		Mean	xxx.x
		SD	xxx.x
		CV%	xxx.x
		Min	xxx
		Median	xxx.x
		Max	xxx

Subjects are summarised according to the cohort they belong to
Source: Listing 16.2.9.1 - Vital signs and Body weight
Program:Tables\k363-vs-tbl.sas

Table 14.3.5.2 - Descriptive statistics of vital signs - Safety set

Cohort 1: 30 min (T)

Parameter	Time Point	Statistics	Safety Set N=XX
Systolic Blood Pressure [mmHg]	Screening	N	nn
		Mean	xxx.x
		SD	xxx.x
		CV%	xxx.x
		Min	xxx
		Median	xxx.x
		Max	xxx
Systolic Blood Pressure [mmHg]	Visit 2	N	nn
		Mean	xxx.x
		SD	xxx.x
		CV%	xxx.x
		Min	xxx
		Median	xxx.x
		Max	xxx
Systolic Blood Pressure [mmHg]	...	N	nn
		Mean	xxx.x
		SD	xxx.x
		CV%	xxx.x
		Min	xxx

Subjects are summarised according to the cohort they belong to
Source: Listing 16.2.9.1 - Vital signs and Body weight
Program:Tables\k363-vs-tbl.sas

Table 14.3.5.2 - Descriptive statistics of vital signs - Safety set

Cohort 1: 30 min (T)

Parameter	Time Point	Statistics	Safety Set N=XX
Systolic Blood Pressure [mmHg]	...	Median	xxx.x
		Max	xxx
Systolic Blood Pressure [mmHg]	Visit 4 - Final Visit	N	nn
		Mean	xxx.x
		SD	xxx.x
		CV%	xxx.x
		Min	xxx
		Median	xxx.x
		Max	xxx
Diastolic Blood Pressure [mmHg]	Screening	N	nn
		Mean	xxx.x
		SD	xxx.x
		CV%	xxx.x
		Min	xxx
		Median	xxx.x
		Max	xxx
Diastolic Blood Pressure [mmHg]	Visit 2	N	nn
		Mean	xxx.x
		SD	xxx.x

Subjects are summarised according to the cohort they belong to
Source: Listing 16.2.9.1 - Vital signs and Body weight
Program:Tables\k363-vs-tbl.sas

Table 14.3.5.2 - Descriptive statistics of vital signs - Safety set

Cohort 1: 30 min (T)

Parameter	Time Point	Statistics	Safety Set N=XX
Diastolic Blood Pressure [mmHg]	Visit 2	CV%	xxx.x
		Min	xxx
		Median	xxx.x
		Max	xxx
Diastolic Blood Pressure [mmHg]	...	N	nn
		Mean	xxx.x
		SD	xxx.x
		CV%	xxx.x
		Min	xxx
		Median	xxx.x
		Max	xxx
Diastolic Blood Pressure [mmHg]	Visit 4 - Final Visit	N	nn
		Mean	xxx.x
		SD	xxx.x
		CV%	xxx.x
		Min	xxx
		Median	xxx.x
		Max	xxx
Heart Rate [beats/min]	Screening	N	nn

Subjects are summarised according to the cohort they belong to
Source: Listing 16.2.9.1 - Vital signs and Body weight
Program:Tables\k363-vs-tbl.sas

Table 14.3.5.2 - Descriptive statistics of vital signs - Safety set

Cohort 1: 30 min (T)

Parameter	Time Point	Statistics	Safety Set N=XX
Heart Rate [beats/min]	Screening	Mean	xxx.x
		SD	xxx.x
		CV%	xxx.x
		Min	xxx
		Median	xxx.x
		Max	xxx
Heart Rate [beats/min]	Visit 2	N	nn
		Mean	xxx.x
		SD	xxx.x
		CV%	xxx.x
		Min	xxx
		Median	xxx.x
		Max	xxx
Heart Rate [beats/min]	...	N	nn
		Mean	xxx.x
		SD	xxx.x
		CV%	xxx.x
		Min	xxx
		Median	xxx.x
		Max	xxx

Subjects are summarised according to the cohort they belong to
Source: Listing 16.2.9.1 - Vital signs and Body weight
Program:Tables\k363-vs-tbl.sas

Table 14.3.5.2 - Descriptive statistics of vital signs - Safety set

Cohort 1: 30 min (T)

Parameter	Time Point	Statistics	Safety Set N=XX
Heart Rate [beats/min]	Visit 4 - Final Visit	N	nn
		Mean	xxx.x
		SD	xxx.x
		CV%	xxx.x
		Min	xxx
		Median	xxx.x
		Max	xxx

Subjects are summarised according to the cohort they belong to
Source: Listing 16.2.9.1 - Vital signs and Body weight
Program:Tables\k363-vs-tbl.sas

Table 14.3.5.2 - Descriptive statistics of vital signs - Safety set

Cohort 2: 15 min (T)

Parameter	Time Point	Statistics	Safety Set N=XX
Systolic Blood Pressure [mmHg]	Screening	N	nn
		Mean	xxx.x
		SD	xxx.x
		CV%	xxx.x
		Min	xxx
		Median	xxx.x
		Max	xxx
Systolic Blood Pressure [mmHg]	Visit 2	N	nn
		Mean	xxx.x
		SD	xxx.x
		CV%	xxx.x
		Min	xxx
		Median	xxx.x
		Max	xxx
Systolic Blood Pressure [mmHg]	...	N	nn
		Mean	xxx.x
		SD	xxx.x
		CV%	xxx.x
		Min	xxx

Subjects are summarised according to the cohort they belong to
Source: Listing 16.2.9.1 - Vital signs and Body weight
Program:Tables\k363-vs-tbl.sas

Table 14.3.5.2 - Descriptive statistics of vital signs - Safety set

Cohort 2: 15 min (T)

Parameter	Time Point	Statistics	Safety Set N=XX
Systolic Blood Pressure [mmHg]	...	Median	xxx.x
		Max	xxx
Systolic Blood Pressure [mmHg]	Visit 4 - Final Visit	N	nn
		Mean	xxx.x
		SD	xxx.x
		CV%	xxx.x
		Min	xxx
		Median	xxx.x
		Max	xxx
Diastolic Blood Pressure [mmHg]	Screening	N	nn
		Mean	xxx.x
		SD	xxx.x
		CV%	xxx.x
		Min	xxx
		Median	xxx.x
		Max	xxx
Diastolic Blood Pressure [mmHg]	Visit 2	N	nn
		Mean	xxx.x
		SD	xxx.x

Subjects are summarised according to the cohort they belong to
Source: Listing 16.2.9.1 - Vital signs and Body weight
Program:Tables\k363-vs-tbl.sas

Table 14.3.5.2 - Descriptive statistics of vital signs - Safety set

Cohort 2: 15 min (T)

Parameter	Time Point	Statistics	Safety Set N=XX
Diastolic Blood Pressure [mmHg]	Visit 2	CV%	xxx.x
		Min	xxx
		Median	xxx.x
		Max	xxx
Diastolic Blood Pressure [mmHg]	...	N	nn
		Mean	xxx.x
		SD	xxx.x
		CV%	xxx.x
		Min	xxx
		Median	xxx.x
		Max	xxx
Diastolic Blood Pressure [mmHg]	Visit 4 - Final Visit	N	nn
		Mean	xxx.x
		SD	xxx.x
		CV%	xxx.x
		Min	xxx
		Median	xxx.x
		Max	xxx
Heart Rate [beats/min]	Screening	N	nn

Subjects are summarised according to the cohort they belong to
Source: Listing 16.2.9.1 - Vital signs and Body weight
Program:Tables\k363-vs-tbl.sas

Table 14.3.5.2 - Descriptive statistics of vital signs - Safety set

Cohort 2: 15 min (T)

Parameter	Time Point	Statistics	Safety Set N=XX
Heart Rate [beats/min]	Screening	Mean	xxx.x
		SD	xxx.x
		CV%	xxx.x
		Min	xxx
		Median	xxx.x
		Max	xxx
Heart Rate [beats/min]	Visit 2	N	nn
		Mean	xxx.x
		SD	xxx.x
		CV%	xxx.x
		Min	xxx
		Median	xxx.x
		Max	xxx
Heart Rate [beats/min]	...	N	nn
		Mean	xxx.x
		SD	xxx.x
		CV%	xxx.x
		Min	xxx
		Median	xxx.x
		Max	xxx

Subjects are summarised according to the cohort they belong to
Source: Listing 16.2.9.1 - Vital signs and Body weight
Program:Tables\k363-vs-tbl.sas

Table 14.3.5.2 - Descriptive statistics of vital signs - Safety set

Cohort 2: 15 min (T)

Parameter	Time Point	Statistics	Safety Set N=XX
Heart Rate [beats/min]	Visit 4 - Final Visit	N	nn
		Mean	xxx.x
		SD	xxx.x
		CV%	xxx.x
		Min	xxx
		Median	xxx.x
		Max	xxx

Subjects are summarised according to the cohort they belong to
Source: Listing 16.2.9.1 - Vital signs and Body weight
Program:Tables\k363-vs-tbl.sas

Table 14.3.5.2 - Descriptive statistics of vital signs - Safety set

Cohort 3: 5 min (T)

Parameter	Time Point	Statistics	Safety Set N=XX
Systolic Blood Pressure [mmHg]	Screening	N	nn
		Mean	xxx.x
		SD	xxx.x
		CV%	xxx.x
		Min	xxx
		Median	xxx.x
		Max	xxx
Systolic Blood Pressure [mmHg]	Visit 2	N	nn
		Mean	xxx.x
		SD	xxx.x
		CV%	xxx.x
		Min	xxx
		Median	xxx.x
		Max	xxx
Systolic Blood Pressure [mmHg]	...	N	nn
		Mean	xxx.x
		SD	xxx.x
		CV%	xxx.x
		Min	xxx

Subjects are summarised according to the cohort they belong to
Source: Listing 16.2.9.1 - Vital signs and Body weight
Program:Tables\k363-vs-tbl.sas

Table 14.3.5.2 - Descriptive statistics of vital signs - Safety set

Cohort 3: 5 min (T)

Parameter	Time Point	Statistics	Safety Set N=XX
Systolic Blood Pressure [mmHg]	...	Median	xxx.x
		Max	xxx
Systolic Blood Pressure [mmHg]	Visit 4 - Final Visit	N	nn
		Mean	xxx.x
		SD	xxx.x
		CV%	xxx.x
		Min	xxx
		Median	xxx.x
		Max	xxx
Diastolic Blood Pressure [mmHg]	Screening	N	nn
		Mean	xxx.x
		SD	xxx.x
		CV%	xxx.x
		Min	xxx
		Median	xxx.x
		Max	xxx
Diastolic Blood Pressure [mmHg]	Visit 2	N	nn
		Mean	xxx.x
		SD	xxx.x

Subjects are summarised according to the cohort they belong to
Source: Listing 16.2.9.1 - Vital signs and Body weight
Program:Tables\k363-vs-tbl.sas

Table 14.3.5.2 - Descriptive statistics of vital signs - Safety set

Cohort 3: 5 min (T)

Parameter	Time Point	Statistics	Safety Set N=XX
Diastolic Blood Pressure [mmHg]	Visit 2	CV%	xxx.x
		Min	xxx
		Median	xxx.x
		Max	xxx
Diastolic Blood Pressure [mmHg]	...	N	nn
		Mean	xxx.x
		SD	xxx.x
		CV%	xxx.x
		Min	xxx
		Median	xxx.x
		Max	xxx
Diastolic Blood Pressure [mmHg]	Visit 4 - Final Visit	N	nn
		Mean	xxx.x
		SD	xxx.x
		CV%	xxx.x
		Min	xxx
		Median	xxx.x
		Max	xxx
Heart Rate [beats/min]	Screening	N	nn

Subjects are summarised according to the cohort they belong to
Source: Listing 16.2.9.1 - Vital signs and Body weight
Program:Tables\k363-vs-tbl.sas

Table 14.3.5.2 - Descriptive statistics of vital signs - Safety set

Cohort 3: 5 min (T)

Parameter	Time Point	Statistics	Safety Set N=XX
Heart Rate [beats/min]	Screening	Mean	xxx.x
		SD	xxx.x
		CV%	xxx.x
		Min	xxx
		Median	xxx.x
		Max	xxx
Heart Rate [beats/min]	Visit 2	N	nn
		Mean	xxx.x
		SD	xxx.x
		CV%	xxx.x
		Min	xxx
		Median	xxx.x
		Max	xxx
Heart Rate [beats/min]	...	N	nn
		Mean	xxx.x
		SD	xxx.x
		CV%	xxx.x
		Min	xxx
		Median	xxx.x
		Max	xxx

Subjects are summarised according to the cohort they belong to
Source: Listing 16.2.9.1 - Vital signs and Body weight
Program:Tables\k363-vs-tbl.sas

Table 14.3.5.2 - Descriptive statistics of vital signs - Safety set

Cohort 3: 5 min (T)

Parameter	Time Point	Statistics	Safety Set N=XX
Heart Rate [beats/min]	Visit 4 - Final Visit	N	nn
		Mean	xxx.x
		SD	xxx.x
		CV%	xxx.x
		Min	xxx
		Median	xxx.x
		Max	xxx

Subjects are summarised according to the cohort they belong to
Source: Listing 16.2.9.1 - Vital signs and Body weight
Program:Tables\k363-vs-tbl.sas

Table 14.3.5.2 - Descriptive statistics of vital signs - Safety set

Cohort 4: 2 min (T)

Parameter	Time Point	Statistics	Safety Set N=XX
Systolic Blood Pressure [mmHg]	Screening	N	nn
		Mean	xxx.x
		SD	xxx.x
		CV%	xxx.x
		Min	xxx
		Median	xxx.x
		Max	xxx
Systolic Blood Pressure [mmHg]	Visit 2	N	nn
		Mean	xxx.x
		SD	xxx.x
		CV%	xxx.x
		Min	xxx
		Median	xxx.x
		Max	xxx
Systolic Blood Pressure [mmHg]	...	N	nn
		Mean	xxx.x
		SD	xxx.x
		CV%	xxx.x
		Min	xxx

Subjects are summarised according to the cohort they belong to
Source: Listing 16.2.9.1 - Vital signs and Body weight
Program:Tables\k363-vs-tbl.sas

Table 14.3.5.2 - Descriptive statistics of vital signs - Safety set

Cohort 4: 2 min (T)

Parameter	Time Point	Statistics	Safety Set N=XX
Systolic Blood Pressure [mmHg]	...	Median	xxx.x
		Max	xxx
Systolic Blood Pressure [mmHg]	Visit 4 - Final Visit	N	nn
		Mean	xxx.x
		SD	xxx.x
		CV%	xxx.x
		Min	xxx
		Median	xxx.x
		Max	xxx
Diastolic Blood Pressure [mmHg]	Screening	N	nn
		Mean	xxx.x
		SD	xxx.x
		CV%	xxx.x
		Min	xxx
		Median	xxx.x
		Max	xxx
Diastolic Blood Pressure [mmHg]	Visit 2	N	nn
		Mean	xxx.x
		SD	xxx.x

Subjects are summarised according to the cohort they belong to
Source: Listing 16.2.9.1 - Vital signs and Body weight
Program:Tables\k363-vs-tbl.sas

Table 14.3.5.2 - Descriptive statistics of vital signs - Safety set

Cohort 4: 2 min (T)

Parameter	Time Point	Statistics	Safety Set N=XX
Diastolic Blood Pressure [mmHg]	Visit 2	CV%	xxx.x
		Min	xxx
		Median	xxx.x
		Max	xxx
Diastolic Blood Pressure [mmHg]	...	N	nn
		Mean	xxx.x
		SD	xxx.x
		CV%	xxx.x
		Min	xxx
		Median	xxx.x
		Max	xxx
Diastolic Blood Pressure [mmHg]	Visit 4 - Final Visit	N	nn
		Mean	xxx.x
		SD	xxx.x
		CV%	xxx.x
		Min	xxx
		Median	xxx.x
		Max	xxx
Heart Rate [beats/min]	Screening	N	nn

Subjects are summarised according to the cohort they belong to
Source: Listing 16.2.9.1 - Vital signs and Body weight
Program:Tables\k363-vs-tbl.sas

Table 14.3.5.2 - Descriptive statistics of vital signs - Safety set

Cohort 4: 2 min (T)

Parameter	Time Point	Statistics	Safety Set N=XX
Heart Rate [beats/min]	Screening	Mean	xxx.x
		SD	xxx.x
		CV%	xxx.x
		Min	xxx
		Median	xxx.x
		Max	xxx
Heart Rate [beats/min]	Visit 2	N	nn
		Mean	xxx.x
		SD	xxx.x
		CV%	xxx.x
		Min	xxx
		Median	xxx.x
		Max	xxx
Heart Rate [beats/min]	...	N	nn
		Mean	xxx.x
		SD	xxx.x
		CV%	xxx.x
		Min	xxx
		Median	xxx.x
		Max	xxx

Subjects are summarised according to the cohort they belong to
Source: Listing 16.2.9.1 - Vital signs and Body weight
Program:Tables\k363-vs-tbl.sas

Table 14.3.5.2 - Descriptive statistics of vital signs - Safety set

Cohort 4: 2 min (T)

Parameter	Time Point	Statistics	Safety Set N=XX
Heart Rate [beats/min]	Visit 4 - Final Visit	N	nn
		Mean	xxx.x
		SD	xxx.x
		CV%	xxx.x
		Min	xxx
		Median	xxx.x
		Max	xxx

Subjects are summarised according to the cohort they belong to
Source: Listing 16.2.9.1 - Vital signs and Body weight
Program:Tables\k363-vs-tbl.sas

Table 14.3.5.2 - Descriptive statistics of vital signs - Safety set

Overall

Parameter	Time Point	Statistics	Safety Set N=XX
Systolic Blood Pressure [mmHg]	Screening	N	nn
		Mean	xxx.x
		SD	xxx.x
		CV%	xxx.x
		Min	xxx
		Median	xxx.x
		Max	xxx
Systolic Blood Pressure [mmHg]	Visit 2	N	nn
		Mean	xxx.x
		SD	xxx.x
		CV%	xxx.x
		Min	xxx
		Median	xxx.x
		Max	xxx
Systolic Blood Pressure [mmHg]	...	N	nn
		Mean	xxx.x
		SD	xxx.x
		CV%	xxx.x
		Min	xxx

Subjects are summarised according to the cohort they belong to
Source: Listing 16.2.9.1 - Vital signs and Body weight
Program:Tables\k363-vs-tbl.sas

Table 14.3.5.2 - Descriptive statistics of vital signs - Safety set

Overall

Parameter	Time Point	Statistics	Safety Set N=XX
Systolic Blood Pressure [mmHg]	...	Median	xxx.x
		Max	xxx
Systolic Blood Pressure [mmHg]	Visit 4 - Final Visit	N	nn
		Mean	xxx.x
		SD	xxx.x
		CV%	xxx.x
		Min	xxx
		Median	xxx.x
		Max	xxx
Diastolic Blood Pressure [mmHg]	Screening	N	nn
		Mean	xxx.x
		SD	xxx.x
		CV%	xxx.x
		Min	xxx
		Median	xxx.x
		Max	xxx
Diastolic Blood Pressure [mmHg]	Visit 2	N	nn
		Mean	xxx.x
		SD	xxx.x

Subjects are summarised according to the cohort they belong to
Source: Listing 16.2.9.1 - Vital signs and Body weight
Program:Tables\k363-vs-tbl.sas

Table 14.3.5.2 - Descriptive statistics of vital signs - Safety set

Overall

Parameter	Time Point	Statistics	Safety Set N=XX
Diastolic Blood Pressure [mmHg]	Visit 2	CV%	xxx.x
		Min	xxx
		Median	xxx.x
		Max	xxx
Diastolic Blood Pressure [mmHg]	...	N	nn
		Mean	xxx.x
		SD	xxx.x
		CV%	xxx.x
		Min	xxx
		Median	xxx.x
		Max	xxx
Diastolic Blood Pressure [mmHg]	Visit 4 - Final Visit	N	nn
		Mean	xxx.x
		SD	xxx.x
		CV%	xxx.x
		Min	xxx
		Median	xxx.x
		Max	xxx
Heart Rate [beats/min]	Screening	N	nn

Subjects are summarised according to the cohort they belong to
Source: Listing 16.2.9.1 - Vital signs and Body weight
Program:Tables\k363-vs-tbl.sas

Table 14.3.5.2 - Descriptive statistics of vital signs - Safety set

Overall

Parameter	Time Point	Statistics	Safety Set N=XX
Heart Rate [beats/min]	Screening	Mean	xxx.x
		SD	xxx.x
		CV%	xxx.x
		Min	xxx
		Median	xxx.x
		Max	xxx
Heart Rate [beats/min]	Visit 2	N	nn
		Mean	xxx.x
		SD	xxx.x
		CV%	xxx.x
		Min	xxx
		Median	xxx.x
		Max	xxx
Heart Rate [beats/min]	...	N	nn
		Mean	xxx.x
		SD	xxx.x
		CV%	xxx.x
		Min	xxx
		Median	xxx.x
		Max	xxx

Subjects are summarised according to the cohort they belong to
Source: Listing 16.2.9.1 - Vital signs and Body weight
Program:Tables\k363-vs-tbl.sas

Table 14.3.5.2 - Descriptive statistics of vital signs - Safety set

Overall

Parameter	Time Point	Statistics	Safety Set N=XX
Heart Rate [beats/min]	Visit 4 - Final Visit	N	nn
		Mean	xxx.x
		SD	xxx.x
		CV%	xxx.x
		Min	xxx
		Median	xxx.x
		Max	xxx

Subjects are summarised according to the cohort they belong to
Source: Listing 16.2.9.1 - Vital signs and Body weight
Program:Tables\k363-vs-tbl.sas

Table 14.3.5.3 - Descriptive statistics of body weight - Safety set

Cohort 1: 30 min (Rα)

Parameter	Time Point	Statistics	Safety Set N=XX
Weight [kg]	Screening	N	nn
		Mean	xxx.xx
		SD	xxx.xx
		CV%	xxx.xx
		Min	xxx.x
		Median	xxx.xx
		Max	xxx.x
Weight [kg]	End of Study	N	nn
		Mean	xxx.xx
		SD	xxx.xx
		CV%	xxx.xx
		Min	xxx.x
		Median	xxx.xx
		Max	xxx.x

Note:Subjects are summarised according to the cohort they belong to
End of Study = Final visit or early termination visit
Source: Listing 16.2.9.1 - Vital signs and Body weight
Program: Tables\k363-vs-tbl.sas

Table 14.3.5.3 - Descriptive statistics of body weight - Safety set

Cohort 1: 30 min (T)

Parameter	Time Point	Statistics	Safety Set N=XX
Weight [kg]	Screening	N	nn
		Mean	xxx.xx
		SD	xxx.xx
		CV%	xxx.xx
		Min	xxx.x
		Median	xxx.xx
		Max	xxx.x
Weight [kg]	End of Study	N	nn
		Mean	xxx.xx
		SD	xxx.xx
		CV%	xxx.xx
		Min	xxx.x
		Median	xxx.xx
		Max	xxx.x

Note:Subjects are summarised according to the cohort they belong to
End of Study = Final visit or early termination visit
Source: Listing 16.2.9.1 - Vital signs and Body weight
Program: Tables\k363-vs-tbl.sas

Table 14.3.5.3 - Descriptive statistics of body weight - Safety set

Cohort 2: 15 min (T)

Parameter	Time Point	Statistics	Safety Set N=XX
Weight [kg]	Screening	N	nn
		Mean	xxx.xx
		SD	xxx.xx
		CV%	xxx.xx
		Min	xxx.x
		Median	xxx.xx
		Max	xxx.x
Weight [kg]	End of Study	N	nn
		Mean	xxx.xx
		SD	xxx.xx
		CV%	xxx.xx
		Min	xxx.x
		Median	xxx.xx
		Max	xxx.x

Note:Subjects are summarised according to the cohort they belong to
End of Study = Final visit or early termination visit
Source: Listing 16.2.9.1 - Vital signs and Body weight
Program: Tables\k363-vs-tbl.sas

Table 14.3.5.3 - Descriptive statistics of body weight - Safety set

Cohort 3: 5 min (T)

Parameter	Time Point	Statistics	Safety Set N=XX
Weight [kg]	Screening	N	nn
		Mean	xxx.xx
		SD	xxx.xx
		CV%	xxx.xx
		Min	xxx.x
		Median	xxx.xx
		Max	xxx.x
Weight [kg]	End of Study	N	nn
		Mean	xxx.xx
		SD	xxx.xx
		CV%	xxx.xx
		Min	xxx.x
		Median	xxx.xx
		Max	xxx.x

Note:Subjects are summarised according to the cohort they belong to
End of Study = Final visit or early termination visit
Source: Listing 16.2.9.1 - Vital signs and Body weight
Program: Tables\k363-vs-tbl.sas

Table 14.3.5.3 - Descriptive statistics of body weight - Safety set

Cohort 4: 2 min (T)

Parameter	Time Point	Statistics	Safety Set N=XX
Weight [kg]	Screening	N	nn
		Mean	xxx.xx
		SD	xxx.xx
		CV%	xxx.xx
		Min	xxx.x
		Median	xxx.xx
		Max	xxx.x
Weight [kg]	End of Study	N	nn
		Mean	xxx.xx
		SD	xxx.xx
		CV%	xxx.xx
		Min	xxx.x
		Median	xxx.xx
		Max	xxx.x

Note:Subjects are summarised according to the cohort they belong to
End of Study = Final visit or early termination visit
Source: Listing 16.2.9.1 - Vital signs and Body weight
Program: Tables\k363-vs-tbl.sas

Table 14.3.5.3 - Descriptive statistics of body weight - Safety set

Overall

Parameter	Time Point	Statistics	Safety Set N=XX
Weight [kg]	Screening	N	nn
		Mean	xxx.xx
		SD	xxx.xx
		CV%	xxx.xx
		Min	xxx.x
		Median	xxx.xx
		Max	xxx.x
Weight [kg]	End of Study	N	nn
		Mean	xxx.xx
		SD	xxx.xx
		CV%	xxx.xx
		Min	xxx.x
		Median	xxx.xx
		Max	xxx.x

Note:Subjects are summarised according to the cohort they belong to
End of Study = Final visit or early termination visit
Source: Listing 16.2.9.1 - Vital signs and Body weight
Program: Tables\k363-vs-tbl.sas

Table 14.3.5.4 - Abnormal recorded values of ECG - Safety set

Cohort 1: 30 min (Rα)

Subject ID	Time Point	Replicate	Assessment Date/Time	Parameter	Value	Clinically Significant? [1]
S001/001	Screening	1st	ddMMMyyyy hh:mm	Heart Rate [beats/min]	96	NCS
S001/001	Screening	2nd	ddMMMyyyy hh:mm	Heart Rate [beats/min]	94	NCS
S001/001	Screening	3rd	ddMMMyyyy hh:mm	Heart Rate [beats/min]	98	NCS
S001/001	Visit 3 - Pre dose	1st	ddMMMyyyy hh:mm	Heart Rate [beats/min]	96	NCS
...	...	...	...	...	...	...

Note: Note: Subjects are summarised according to the cohort they belong to
Note 1: NCS=Not clinically significant, CS= Clinically Significant
Source: Listing 16.2.9.2 - Recorded parameters of ECG, Listing 16.2.9.3 - Investigator's interpretation of ECG
Program:Tables\k363-eg-tbl.sas

Table 14.3.5.4 - Abnormal recorded values of ECG - Safety set

Cohort 1: 30 min (T)

Subject ID	Time Point	Replicate	Assessment Date/Time	Parameter	Value	Clinically Significant? [1]
S012/011	Screening	1st	ddMMMyyyy hh:mm	Heart Rate [beats/min]	96	NCS
S012/011	Screening	2nd	ddMMMyyyy hh:mm	Heart Rate [beats/min]	94	NCS
S012/011	Screening	3rd	ddMMMyyyy hh:mm	Heart Rate [beats/min]	98	NCS
S012/011	Visit 3 - Pre dose	1st	ddMMMyyyy hh:mm	Heart Rate [beats/min]	96	NCS
...	...	...	...	...	...	...

Note: Note: Subjects are summarised according to the cohort they belong to
Note 1: NCS=Not clinically significant, CS= Clinically Significant
Source: Listing 16.2.9.2 - Recorded parameters of ECG, Listing 16.2.9.3 - Investigator's interpretation of ECG
Program:Tables\k363-eg-tbl.sas

Table 14.3.5.4 - Abnormal recorded values of ECG - Safety set

Cohort 2: 15 min (T)

Subject ID	Time Point	Replicate	Assessment Date/Time	Parameter	Value	Clinically Significant? [1]
S025/023	Screening	1st	ddMMMyyyy hh:mm	Heart Rate [beats/min]	96	NCS
S025/023	Screening	2nd	ddMMMyyyy hh:mm	Heart Rate [beats/min]	94	NCS
S025/023	Screening	3rd	ddMMMyyyy hh:mm	Heart Rate [beats/min]	98	NCS
S025/023	Visit 3 - Pre dose	1st	ddMMMyyyy hh:mm	Heart Rate [beats/min]	96	NCS
...	...	...	...	...	...	...

Note: Note: Subjects are summarised according to the cohort they belong to
Note 1: NCS=Not clinically significant, CS= Clinically Significant
Source: Listing 16.2.9.2 - Recorded parameters of ECG, Listing 16.2.9.3 - Investigator's interpretation of ECG
Program:Tables\k363-eg-tbl.sas

Table 14.3.5.4 - Abnormal recorded values of ECG - Safety set

Cohort 3: 5 min (T)

Subject ID	Time Point	Replicate	Assessment Date/Time	Parameter	Value	Clinically Significant? [1]
S036/032	Screening	1st	ddMMMyyyy hh:mm	Heart Rate [beats/min]	96	NCS
S036/032	Screening	2nd	ddMMMyyyy hh:mm	Heart Rate [beats/min]	94	NCS
S036/032	Screening	3rd	ddMMMyyyy hh:mm	Heart Rate [beats/min]	98	NCS
S036/032	Visit 3 - Pre dose	1st	ddMMMyyyy hh:mm	Heart Rate [beats/min]	96	NCS
...	...	...	...	...	...	...

Note: Note: Subjects are summarised according to the cohort they belong to
Note 1: NCS=Not clinically significant, CS= Clinically Significant
Source: Listing 16.2.9.2 - Recorded parameters of ECG, Listing 16.2.9.3 - Investigator's interpretation of ECG
Program:Tables\k363-eg-tbl.sas

Table 14.3.5.4 - Abnormal recorded values of ECG - Safety set

Cohort 4: 2 min (T)

Subject ID	Time Point	Replicate	Assessment Date/Time	Parameter	Value	Clinically Significant? [1]
S044/040	Screening	1st	ddMMMyyyy hh:mm	Heart Rate [beats/min]	96	NCS
S044/040	Screening	2nd	ddMMMyyyy hh:mm	Heart Rate [beats/min]	94	NCS
S044/040	Screening	3rd	ddMMMyyyy hh:mm	Heart Rate [beats/min]	98	NCS
S044/040	Visit 3 - Pre dose	1st	ddMMMyyyy hh:mm	Heart Rate [beats/min]	96	NCS
...	...	...	...	...	...	...

Note: Note: Subjects are summarised according to the cohort they belong to
Note 1: NCS=Not clinically significant, CS= Clinically Significant
Source: Listing 16.2.9.2 - Recorded parameters of ECG, Listing 16.2.9.3 - Investigator's interpretation of ECG
Program:Tables\k363-eg-tbl.sas

Table 14.3.5.5 - Contingency tables of investigator's interpretation of ECG results - Safety set

Cohort 1: 30 min (Rα)

Time Point	Replicate	Investigator's interpretation	Safety Set N=XX
Screening	1st	Normal	nn (xx.x)
		Abnormal, Not Clinically Significant	nn (xx.x)
		Abnormal, Clinically Significant	nn (xx.x)
Screening	2nd	Normal	nn (xx.x)
		Abnormal, Not Clinically Significant	nn (xx.x)
		Abnormal, Clinically Significant	nn (xx.x)
Screening	3rd	Normal	nn (xx.x)
		Abnormal, Not Clinically Significant	nn (xx.x)
		Abnormal, Clinically Significant	nn (xx.x)
...	...	...	...
End of Study	1st	Normal	nn (xx.x)
		Abnormal, Not Clinically Significant	nn (xx.x)
		Abnormal, Clinically Significant	nn (xx.x)
End of Study	2nd	Normal	nn (xx.x)
		Abnormal, Not Clinically Significant	nn (xx.x)
		Abnormal, Clinically Significant	nn (xx.x)

Note: Subjects are summarised according to the cohort they belong to
The number and the proportion of subjects for each classification level are reported
The denominator for calculating the proportions is the number of subjects in each cohort in the safety set
Source: Listing 16.2.9.3 - Investigator's interpretation of ECG
Program: Tables\k363-eg-tbl.sas

Table 14.3.5.5 - Contingency tables of investigator's interpretation of ECG results - Safety set

Cohort 1: 30 min (Rα)

Time Point	Replicate	Investigator's interpretation	Safety Set N=XX
End of Study	3rd	Normal	nn (xx.x)
		Abnormal, Not Clinically Significant	nn (xx.x)
		Abnormal, Clinically Significant	nn (xx.x)

Note: Subjects are summarised according to the cohort they belong to
The number and the proportion of subjects for each classification level are reported
The denominator for calculating the proportions is the number of subjects in each cohort in the safety set
Source: Listing 16.2.9.3 - Investigator's interpretation of ECG
Program: Tables\k363-eg-tbl.sas

Table 14.3.5.5 - Contingency tables of investigator's interpretation of ECG results - Safety set

Cohort 1: 30 min (T)

Time Point	Replicate	Investigator's interpretation	Safety Set N=XX
Screening	1st	Normal	nn (xx.x)
		Abnormal, Not Clinically Significant	nn (xx.x)
		Abnormal, Clinically Significant	nn (xx.x)
Screening	2nd	Normal	nn (xx.x)
		Abnormal, Not Clinically Significant	nn (xx.x)
		Abnormal, Clinically Significant	nn (xx.x)
Screening	3rd	Normal	nn (xx.x)
		Abnormal, Not Clinically Significant	nn (xx.x)
		Abnormal, Clinically Significant	nn (xx.x)
...	...	...	...
End of Study	1st	Normal	nn (xx.x)
		Abnormal, Not Clinically Significant	nn (xx.x)
		Abnormal, Clinically Significant	nn (xx.x)
End of Study	2nd	Normal	nn (xx.x)
		Abnormal, Not Clinically Significant	nn (xx.x)
		Abnormal, Clinically Significant	nn (xx.x)

Note: Subjects are summarised according to the cohort they belong to
The number and the proportion of subjects for each classification level are reported
The denominator for calculating the proportions is the number of subjects in each cohort in the safety set
Source: Listing 16.2.9.3 - Investigator's interpretation of ECG
Program: Tables\k363-eg-tbl.sas

Table 14.3.5.5 - Contingency tables of investigator's interpretation of ECG results - Safety set

Cohort 1: 30 min (T)

Time Point	Replicate	Investigator's interpretation	Safety Set N=XX
End of Study	3rd	Normal	nn (xx.x)
		Abnormal, Not Clinically Significant	nn (xx.x)
		Abnormal, Clinically Significant	nn (xx.x)

Note: Subjects are summarised according to the cohort they belong to
The number and the proportion of subjects for each classification level are reported
The denominator for calculating the proportions is the number of subjects in each cohort in the safety set
Source: Listing 16.2.9.3 - Investigator's interpretation of ECG
Program: Tables\k363-eg-tbl.sas

Table 14.3.5.5 - Contingency tables of investigator's interpretation of ECG results - Safety set

Cohort 2: 15 min (T)

Time Point	Replicate	Investigator's interpretation	Safety Set N=XX
Screening	1st	Normal	nn (xx.x)
		Abnormal, Not Clinically Significant	nn (xx.x)
		Abnormal, Clinically Significant	nn (xx.x)
Screening	2nd	Normal	nn (xx.x)
		Abnormal, Not Clinically Significant	nn (xx.x)
		Abnormal, Clinically Significant	nn (xx.x)
Screening	3rd	Normal	nn (xx.x)
		Abnormal, Not Clinically Significant	nn (xx.x)
		Abnormal, Clinically Significant	nn (xx.x)
...	...	...	...
End of Study	1st	Normal	nn (xx.x)
		Abnormal, Not Clinically Significant	nn (xx.x)
		Abnormal, Clinically Significant	nn (xx.x)
End of Study	2nd	Normal	nn (xx.x)
		Abnormal, Not Clinically Significant	nn (xx.x)
		Abnormal, Clinically Significant	nn (xx.x)

Note: Subjects are summarised according to the cohort they belong to
The number and the proportion of subjects for each classification level are reported
The denominator for calculating the proportions is the number of subjects in each cohort in the safety set
Source: Listing 16.2.9.3 - Investigator's interpretation of ECG
Program: Tables\k363-eg-tbl.sas

Table 14.3.5.5 - Contingency tables of investigator's interpretation of ECG results - Safety set

Cohort 2: 15 min (T)

Time Point	Replicate	Investigator's interpretation	Safety Set N=XX
End of Study	3rd	Normal	nn (xx.x)
		Abnormal, Not Clinically Significant	nn (xx.x)
		Abnormal, Clinically Significant	nn (xx.x)

Note: Subjects are summarised according to the cohort they belong to
The number and the proportion of subjects for each classification level are reported
The denominator for calculating the proportions is the number of subjects in each cohort in the safety set
Source: Listing 16.2.9.3 - Investigator's interpretation of ECG
Program: Tables\k363-eg-tbl.sas

Table 14.3.5.5 - Contingency tables of investigator's interpretation of ECG results - Safety set

Cohort 3: 5 min (T)

Time Point	Replicate	Investigator's interpretation	Safety Set N=XX
Screening	1st	Normal	nn (xx.x)
		Abnormal, Not Clinically Significant	nn (xx.x)
		Abnormal, Clinically Significant	nn (xx.x)
Screening	2nd	Normal	nn (xx.x)
		Abnormal, Not Clinically Significant	nn (xx.x)
		Abnormal, Clinically Significant	nn (xx.x)
Screening	3rd	Normal	nn (xx.x)
		Abnormal, Not Clinically Significant	nn (xx.x)
		Abnormal, Clinically Significant	nn (xx.x)
...	...	...	...
End of Study	1st	Normal	nn (xx.x)
		Abnormal, Not Clinically Significant	nn (xx.x)
		Abnormal, Clinically Significant	nn (xx.x)
End of Study	2nd	Normal	nn (xx.x)
		Abnormal, Not Clinically Significant	nn (xx.x)
		Abnormal, Clinically Significant	nn (xx.x)

Note: Subjects are summarised according to the cohort they belong to
The number and the proportion of subjects for each classification level are reported
The denominator for calculating the proportions is the number of subjects in each cohort in the safety set
Source: Listing 16.2.9.3 - Investigator's interpretation of ECG
Program: Tables\k363-eg-tbl.sas

Table 14.3.5.5 - Contingency tables of investigator's interpretation of ECG results - Safety set

Cohort 3: 5 min (T)

Time Point	Replicate	Investigator's interpretation	Safety Set N=XX
End of Study	3rd	Normal	nn (xx.x)
		Abnormal, Not Clinically Significant	nn (xx.x)
		Abnormal, Clinically Significant	nn (xx.x)

Note: Subjects are summarised according to the cohort they belong to
The number and the proportion of subjects for each classification level are reported
The denominator for calculating the proportions is the number of subjects in each cohort in the safety set
Source: Listing 16.2.9.3 - Investigator's interpretation of ECG
Program: Tables\k363-eg-tbl.sas

Table 14.3.5.5 - Contingency tables of investigator's interpretation of ECG results - Safety set

Cohort 4: 2 min (T)

Time Point	Replicate	Investigator's interpretation	Safety Set N=XX
Screening	1st	Normal	nn (xx.x)
		Abnormal, Not Clinically Significant	nn (xx.x)
		Abnormal, Clinically Significant	nn (xx.x)
Screening	2nd	Normal	nn (xx.x)
		Abnormal, Not Clinically Significant	nn (xx.x)
		Abnormal, Clinically Significant	nn (xx.x)
Screening	3rd	Normal	nn (xx.x)
		Abnormal, Not Clinically Significant	nn (xx.x)
		Abnormal, Clinically Significant	nn (xx.x)
...	...	...	...
End of Study	1st	Normal	nn (xx.x)
		Abnormal, Not Clinically Significant	nn (xx.x)
		Abnormal, Clinically Significant	nn (xx.x)
End of Study	2nd	Normal	nn (xx.x)
		Abnormal, Not Clinically Significant	nn (xx.x)
		Abnormal, Clinically Significant	nn (xx.x)

Note: Subjects are summarised according to the cohort they belong to
The number and the proportion of subjects for each classification level are reported
The denominator for calculating the proportions is the number of subjects in each cohort in the safety set
Source: Listing 16.2.9.3 - Investigator's interpretation of ECG
Program: Tables\k363-eg-tbl.sas

Table 14.3.5.5 - Contingency tables of investigator's interpretation of ECG results - Safety set

Cohort 4: 2 min (T)

Time Point	Replicate	Investigator's interpretation	Safety Set N=XX
End of Study	3rd	Normal	nn (xx.x)
		Abnormal, Not Clinically Significant	nn (xx.x)
		Abnormal, Clinically Significant	nn (xx.x)

Note: Subjects are summarised according to the cohort they belong to
The number and the proportion of subjects for each classification level are reported
The denominator for calculating the proportions is the number of subjects in each cohort in the safety set
Source: Listing 16.2.9.3 - Investigator's interpretation of ECG
Program: Tables\k363-eg-tbl.sas

Table 14.3.5.5 - Contingency tables of investigator's interpretation of ECG results - Safety set

Overall

Time Point	Replicate	Investigator's interpretation	Safety Set N=XX
Screening	1st	Normal	nn (xx.x)
		Abnormal, Not Clinically Significant	nn (xx.x)
		Abnormal, Clinically Significant	nn (xx.x)
Screening	2nd	Normal	nn (xx.x)
		Abnormal, Not Clinically Significant	nn (xx.x)
		Abnormal, Clinically Significant	nn (xx.x)
Screening	3rd	Normal	nn (xx.x)
		Abnormal, Not Clinically Significant	nn (xx.x)
		Abnormal, Clinically Significant	nn (xx.x)
...	...	...	...
End of Study	1st	Normal	nn (xx.x)
		Abnormal, Not Clinically Significant	nn (xx.x)
		Abnormal, Clinically Significant	nn (xx.x)
End of Study	2nd	Normal	nn (xx.x)
		Abnormal, Not Clinically Significant	nn (xx.x)
		Abnormal, Clinically Significant	nn (xx.x)

Note: Subjects are summarised according to the cohort they belong to
The number and the proportion of subjects for each classification level are reported
The denominator for calculating the proportions is the number of subjects in each cohort in the safety set
Source: Listing 16.2.9.3 - Investigator's interpretation of ECG
Program: Tables\k363-eg-tbl.sas

Table 14.3.5.5 - Contingency tables of investigator's interpretation of ECG results - Safety set

Overall

Time Point	Replicate	Investigator's interpretation	Safety Set N=XX
End of Study	3rd	Normal	nn (xx.x)
		Abnormal, Not Clinically Significant	nn (xx.x)
		Abnormal, Clinically Significant	nn (xx.x)

Note: Subjects are summarised according to the cohort they belong to
The number and the proportion of subjects for each classification level are reported
The denominator for calculating the proportions is the number of subjects in each cohort in the safety set
Source: Listing 16.2.9.3 - Investigator's interpretation of ECG
Program: Tables\k363-eg-tbl.sas

Table 14.3.5.6 - Descriptive statistics of dose per body weight - Safety set

Cohort 1: 30 min (Rα)

Parameter	**Statistics**	**Safety Set N=XX**
Dose per body weight [mg/kg]	N	nn
	Mean	xx.x
	SD	xx.x
	CV%	xx.x
	Median	xx.x
	Min	xx
	Max	xx

Note: Subjects are summarised according to the cohort they belong to
Note: The dose per body weight was calculated using the screening body weight
Source: Listing 16.2.5.3 - Dose per body weight
Program: Tables\k363-ex-tbl.sas

Table 14.3.5.6 - Descriptive statistics of dose per body weight - Safety set

Cohort 1: 30 min (T)

Parameter	**Statistics**	**Safety Set N=XX**
Dose per body weight [mg/kg]	N	nn
	Mean	xx.x
	SD	xx.x
	CV%	xx.x
	Median	xx.x
	Min	xx
	Max	xx

Note: Subjects are summarised according to the cohort they belong to
Note: The dose per body weight was calculated using the screening body weight
Source: Listing 16.2.5.3 - Dose per body weight
Program: Tables\k363-ex-tbl.sas

Table 14.3.5.6 - Descriptive statistics of dose per body weight - Safety set

Cohort 2: 15 min (T)

Parameter	**Statistics**	**Safety Set N=XX**
Dose per body weight [mg/kg]	N	nn
	Mean	xx.x
	SD	xx.x
	CV%	xx.x
	Median	xx.x
	Min	xx
	Max	xx

Note: Subjects are summarised according to the cohort they belong to
Note: The dose per body weight was calculated using the screening body weight
Source: Listing 16.2.5.3 - Dose per body weight
Program: Tables\k363-ex-tbl.sas

Table 14.3.5.6 - Descriptive statistics of dose per body weight - Safety set

Cohort 3: 5 min (T)

Parameter	**Statistics**	**Safety Set N=XX**
Dose per body weight [mg/kg]	N	nn
	Mean	xx.x
	SD	xx.x
	CV%	xx.x
	Median	xx.x
	Min	xx
	Max	xx

Note: Subjects are summarised according to the cohort they belong to
Note: The dose per body weight was calculated using the screening body weight
Source: Listing 16.2.5.3 - Dose per body weight
Program: Tables\k363-ex-tbl.sas

Table 14.3.5.6 - Descriptive statistics of dose per body weight - Safety set

Cohort 4: 2 min (T)

Parameter	**Statistics**	**Safety Set N=XX**
Dose per body weight [mg/kg]	N	nn
	Mean	xx.x
	SD	xx.x
	CV%	xx.x
	Median	xx.x
	Min	xx
	Max	xx

Note: Subjects are summarised according to the cohort they belong to
Note: The dose per body weight was calculated using the screening body weight
Source: Listing 16.2.5.3 - Dose per body weight
Program: Tables\k363-ex-tbl.sas

Table 14.3.5.6 - Descriptive statistics of dose per body weight - Safety set

Overall

Parameter	**Statistics**	**Safety Set N=XX**
Dose per body weight [mg/kg]	N	nn
	Mean	xx.x
	SD	xx.x
	CV%	xx.x
	Median	xx.x
	Min	xx
	Max	xx

Note: Subjects are summarised according to the cohort they belong to
Note: The dose per body weight was calculated using the screening body weight
Source: Listing 16.2.5.3 - Dose per body weight
Program: Tables\k363-ex-tbl.sas

Section 16.2 - Individual Subject Data Listings Shells

Section 16.2 - Individual Subject Data Listings Shells

Listing 16.2.1.1 - Discontinued subjects

Subject ID	Cohort	Sex	Age (years)	Last visit	Date/time of last IMP administration	Date of premature Study termination	Time elapsed from last IMP administration (days)	Primary reason for subject premature study termination
S001/001	1: 30 min (Rα)	F	22	Visit 3 - Days 1-2	ddMMMyyyy hh:mm	ddMMMyyyy	1	Withdrawal by subject
S012/011	2: 30 min (T)	M	40	Visit 3 - Days 1-2	ddMMMyyyy hh:mm	ddMMMyyyy	1	Adverse event
...	...	...		...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Program: Listings\k363-ds-lst.sas

Listing 16.2.2.1 - Protocol deviations

Subject ID	Cohort	Deviation Number	Deviation Category	Deviation Coded Term	Deviation Description
S001/001	1: 30 min (Rα)	1	Minor	Deviation from scheduled sampling time	Sample number 2 was collected outside the window of 30 min pre-dose
S019/016	1: 30 min (T)	1	Major	Inclusion criteria violation	Inclusion criteria violation
S026/022	2: 15 min (T)	1	Major	Inclusion criteria violation	Inclusion criteria violation
S039/033	3: 5 min (T)	1	Minor	Deviation in EGC recording	Deviation occurred during collection of EGC recording
S047/041	4: 2 min (T)	1	Minor	Deviation from scheduled sampling time	Sample number 2 was collected outside the window of 30 min pre-dose
...	...		...	...	...

Program: Listings\k363-dv-lst.sas

Listing 16.2.3.1 - Subjects excluded from safety and/or PK analysis

Subject ID	Cohort	Sex	Age (years)	Enrolled Set	Safety Set	PK Set	Reason for the exclusion
S14/012	1: 30 min (T)	F	23	Y	N	N	Lack of IMP intake (Safety set); No PK data available (PK set)
S37/032	3: 5 min (T)	F	52	Y	Y	N	No PK data available (PK set)
...	...	...		...	...	...	...

Program: Listings\k363-ds-lst.sas

Listing 16.2.4.1 - Subjects' disposition

Cohort 1: 30 min (Rα)

Subject ID	Date of Informed Consent	Date of Screening	Date of Enrolment	Date of Administration	Completed or Discontinued	Date of End of Study	Reason for discontinuation
S001/001	ddMMMyyyy	ddMMMyyyy	ddMMMyyyy	ddMMMyyyy	Discontinued	ddMMMyyyy	Withdrawal by subject
...	...	...	...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Program: Listings\k363-ds-lst.sas

Listing 16.2.4.1 - Subjects' disposition

Cohort 1: 30 min (T)

Subject ID	Date of Informed Consent	Date of Screening	Date of Enrolment	Date of Administration	Completed or Discontinued	Date of End of Study	Reason for discontinuation
S013/011	ddMMMyyyy	ddMMMyyyy	ddMMMyyyy	ddMMMyyyy	Completed	ddMMMyyyy	
...	...	...	...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Program: Listings\k363-ds-lst.sas

Listing 16.2.4.1 - Subjects' disposition

Cohort 2: 15 min (T)

Subject ID	Date of Informed Consent	Date of Screening	Date of Enrolment	Date of Administration	Completed or Discontinued	Date of End of Study	Reason for discontinuation
S024/021	ddMMMyyyy	ddMMMyyyy	ddMMMyyyy	ddMMMyyyy	Discontinued	ddMMMyyyy	Adverse event
...	...	...	...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Program: Listings\k363-ds-lst.sas

Listing 16.2.4.1 - Subjects' disposition

Cohort 3: 5 min (T)

Subject ID	Date of Informed Consent	Date of Screening	Date of Enrolment	Date of Administration	Completed or Discontinued	Date of End of Study	Reason for discontinuation
S038/031	ddMMMyyyy	ddMMMyyyy	ddMMMyyyy	ddMMMyyyy	Discontinued	ddMMMyyyy	Withdrawal by subject
...	...	...	...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Program: Listings\k363-ds-lst.sas

Listing 16.2.4.1 - Subjects' disposition

Cohort 4: 2 min (T)

Subject ID	Date of Informed Consent	Date of Screening	Date of Enrolment	Date of Administration	Completed or Discontinued	Date of End of Study	Reason for discontinuation
S049/041	ddMMMyyyy	ddMMMyyyy	ddMMMyyyy	ddMMMyyyy	Completed	ddMMMyyyy	
...	...	...	...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Program: Listings\k363-ds-lst.sas

Listing 16.2.4.2 - Demography

Cohort 1: 30 min (Rα)

Subject ID	Sex	Birth Year	Ethnicity	Race	Age (years)	Height (cm)	Body Weight (kg)	Body Mass Index (kg/m^2)
S001/001	F	1983	Not Hispanic or Latino	White	40	170	55.0	18.0
...	...	...	...	...		...	...	...

Note: Subjects are listed according to the cohort they belong to _
Program:Listings\k363-dm-lst.sas

Listing 16.2.4.2 - Demography

Cohort 1: 30 min (T)

Subject ID	Sex	Birth Year	Ethnicity	Race	Age (years)	Height (cm)	Body Weight (kg)	Body Mass Index (kg/m^2)
S002/002	F	1990	Hispanic or Latino	Other	33	165	65.0	23.9
...	...	...	...	...		...	...	...

Note: Subjects are listed according to the cohort they belong to _
Program:Listings\k363-dm-lst.sas

Listing 16.2.4.2 - Demography

Cohort 2: 15 min (T)

Subject ID	Sex	Birth Year	Ethnicity	Race	Age (years)	Height (cm)	Body Weight (kg)	Body Mass Index (kg/m^2)
S024/021	M	1978	Not Hispanic or Latino	White	45	180	85.0	26.2
...	...	...	...	...		...	...	...

Note: Subjects are listed according to the cohort they belong to _
Program:Listings\k363-dm-lst.sas

Listing 16.2.4.2 - Demography

Cohort 3: 5 min (T)

Subject ID	Sex	Birth Year	Ethnicity	Race	Age (years)	Height (cm)	Body Weight (kg)	Body Mass Index (kg/m^2)
S035/031	M	1992	Not Hispanic or Latino	White	29	177	75.0	23.9
...	...	...	...	...		...	...	...

Note: Subjects are listed according to the cohort they belong to _
Program:Listings\k363-dm-lst.sas

Listing 16.2.4.2 - Demography

Cohort 4: 2 min (T)

Subject ID	Sex	Birth Year	Ethnicity	Race	Age (years)	Height (cm)	Body Weight (kg)	Body Mass Index (kg/m^2)
S048/041	F	1975	Not Hispanic or Latino	White	48	163	59.0	22.2
...	...	...	...	...		...	...	...

Note: Subjects are listed according to the cohort they belong to _
Program:Listings\k363-dm-lst.sas

Listing 16.2.4.3 - Inclusion/Exclusion criteria not met

Subject ID	Cohort	Criterion	Verbatim
S001/001	1: 30 min (Rα)	Exclusion criterion 3	Laboratory analyses: laboratory values clinically significant abnormal at screening, indicative of physical illness or suggesting the subject's exclusion, in his/her best interest
015/012	1: 30 min (T)	Exclusion criterion 9	Blood donation or significant blood loss: blood donations or significant blood loss in the 3 months before the first visit of this study
028/023	2: 15 min (T)	Exclusion criterion 14	Positive or missing pregnancy test at screening or Day -1, pregnant or lactating women
037/032	3: 5 min (T)	Exclusion criterion 3	Clinically significant abnormal laboratory values at screening, indicative of physical illness or suggesting the subject's exclusion, in his/her best interest
049/043	4: 2 min (T)	Exclusion criterion 2	Clinically significant abnormal physical findings which could interfere with the objectives of the study
...	...	...	...

Program: Listings\k363-ie-lst.sas

Listing 16.2.4.4 - Physical examination at screening

Cohort 1: 30 min (Rα)

Subject ID	Time Point	Physical Examination Date	Body System	Interpretation	Findings
S001/001	Screening	ddMMMyyyy	General Appearance	Normal	
			Head, Eyes, Ears, Nose and Throat	Normal	
			Skin	Abnormal, not Clinical significant	Left wrist cicatrix
...	...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Program: Listings\k363-pe-lst.sas

Listing 16.2.4.4 - Physical examination at screening

Cohort 1: 30 min (T)

Subject ID	Time Point	Physical Examination Date	Body System	Interpretation	Findings
S013/011	Screening	ddMMMyyyy	General Appearance	Normal	
			Head, Eyes, Ears, Nose and Throat	Normal	
...	...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Program: Listings\k363-pe-lst.sas

Listing 16.2.4.4 - Physical examination at screening

Cohort 2: 15 min (T)

Subject ID	Time Point	Physical Examination Date	Body System	Interpretation	Findings
S24/021	Screening	ddMMMyyyy	General Appearance	Normal	
			Head, Eyes, Ears, Nose and Throat	Normal	
...	...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Program: Listings\k363-pe-lst.sas

Listing 16.2.4.4 - Physical examination at screening

Cohort 3: 5 min (T)

Subject ID	Time Point	Physical Examination Date	Body System	Interpretation	Findings
S35/031	Screening	ddMMMyyyy	General Appearance	Normal	
			Head, Eyes, Ears, Nose and Throat	Normal	
...	...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Program: Listings\k363-pe-lst.sas

Listing 16.2.4.4 - Physical examination at screening

Cohort 4: 2 min (T)

Subject ID	Time Point	Physical Examination Date	Body System	Interpretation	Findings
S46/041	Screening	ddMMMyyyy	General Appearance	Normal	
			Head, Eyes, Ears, Nose and Throat	Normal	
...	...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Program: Listings\k363-pe-lst.sas

Listing 16.2.5.1 - Investigational medicinal products administration

Cohort 1: 30 min (Rα)

Subject ID	Time Point	Date/Time of Start of Administration	Date/Time of End of Administration	Volume Administered (mL)	Has there been at least one interruption?	Interruption Nr.	Was the interruption due to AE?	Time of Start of Interruption	Time of End of Interruption
S001/001	Visit 3	ddMMMyyyy hh:mm	ddMMMyyyy hh:mm	20	Y	1	N	hh:mm	hh:mm
...	...	...	...	...	...	---	---	---	---

Note: Subjects are listed according to the cohort they belong to
Program: Listings\k363-ex-lst.sas

Listing 16.2.5.1 - Investigational medicinal products administration

Cohort 1: 30 min (T)

Subject ID	Time Point	Date/Time of Start of Administration	Date/Time of End of Administration	Volume Administered (mL)	Has there been at least one interruption?	Interruption Nr.	Was the interruption due to AE?	Time of Start of Interruption	Time of End of Interruption
S012/011	Visit 3	ddMMMyyyy hh:mm	ddMMMyyyy hh:mm	20	Y	1	N	hh:mm	hh:mm
...	...	...	...	...	...	---	---	---	---

Note: Subjects are listed according to the cohort they belong to
Program: Listings\k363-ex-lst.sas

Listing 16.2.5.1 - Investigational medicinal products administration

Cohort 2: 15 min (T)

Subject ID	Time Point	Date/Time of Start of Administration	Date/Time of End of Administration	Volume Administered (mL)	Has there been at least one interruption?	Interruption Nr.	Was the interruption due to AE?	Time of Start of Interruption	Time of End of Interruption
S024/021	Visit 3	ddMMMyyyy hh:mm	ddMMMyyyy hh:mm	20	N	NA	NA	---	---
...	...	...	...	...	...	---	---	---	---

Note: Subjects are listed according to the cohort they belong to
Program: Listings\k363-ex-lst.sas

Listing 16.2.5.1 - Investigational medicinal products administration

Cohort 3: 5 min (T)

Subject ID	Time Point	Date/Time of Start of Administration	Date/Time of End of Administration	Volume Administered (mL)	Has there been at least one interruption?	Interruption Nr.	Was the interruption due to AE?	Time of Start of Interruption	Time of End of Interruption
S035/031	Visit 3	ddMMMyyyy hh:mm	ddMMMyyyy hh:mm	20	N	NA	NA	---	---
...	...	...	...	...	...	---	---	---	---

Note: Subjects are listed according to the cohort they belong to
Program: Listings\k363-ex-lst.sas

Listing 16.2.5.1 - Investigational medicinal products administration

Cohort 4: 2 min (T)

Subject ID	Time Point	Date/Time of Start of Administration	Date/Time of End of Administration	Volume Administered (mL)	Has there been at least one interruption?	Interruption Nr.	Was the interruption due to AE?	Time of Start of Interruption	Time of End of Interruption
S046/041	Visit 3	ddMMMyyyy hh:mm	ddMMMyyyy hh:mm	20	N	NA	NA	---	---
...	...	...	...	...	...	---	---	---	---

Note: Subjects are listed according to the cohort they belong to
Program: Listings\k363-ex-lst.sas

Listing 16.2.5.2 - Fasting conditions

Cohort 1: 30 min (Rα)

Subject ID	Time Point	Date/Time of Start of Administration	Fasting Conditions From 10 h before IMP Administration?	Fasting Conditions Start Date/time	Duration between Start of Fasting Conditions and Start of IMP administration
S001/001	Visit 3	ddMMMyyyy hh:mm	Y	ddMMMyyyy hh:mm	xx h xx min
...	...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Program: Listings\k363-ex-lst.sas

Listing 16.2.5.2 - Fasting conditions

Cohort 1: 30 min (T)

Subject ID	Time Point	Date/Time of Start of Administration	Fasting Conditions From 10 h before IMP Administration?	Fasting Conditions Start Date/time	Duration between Start of Fasting Conditions and Start of IMP administration
S012/011	Visit 3	ddMMMyyyy hh:mm	Y	ddMMMyyyy hh:mm	xx h xx min
...	...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Program: Listings\k363-ex-lst.sas

Listing 16.2.5.2 - Fasting conditions

Cohort 2: 15 min (T)

Subject ID	Time Point	Date/Time of Start of Administration	Fasting Conditions From 10 h before IMP Administration?	Fasting Conditions Start Date/time	Duration between Start of Fasting Conditions and Start of IMP administration
S024/021	Visit 3	ddMMMyyyy hh:mm	Y	ddMMMyyyy hh:mm	xx h xx min
...	...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Program: Listings\k363-ex-lst.sas

Listing 16.2.5.2 - Fasting conditions

Cohort 3: 5 min (T)

Subject ID	Time Point	Date/Time of Start of Administration	Fasting Conditions From 10 h before IMP Administration?	Fasting Conditions Start Date/time	Duration between Start of Fasting Conditions and Start of IMP administration
S035/031	Visit 3	ddMMMyyyy hh:mm	Y	ddMMMyyyy hh:mm	xx h xx min
...	...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Program: Listings\k363-ex-lst.sas

Listing 16.2.5.2 - Fasting conditions

Cohort 4: 2 min (T)

Subject ID	Time Point	Date/Time of Start of Administration	Fasting Conditions From 10 h before IMP Administration?	Fasting Conditions Start Date/time	Duration between Start of Fasting Conditions and Start of IMP administration
S046/041	Visit 3	ddMMMyyyy hh:mm	Y	ddMMMyyyy hh:mm	xx h xx min
...	...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Program: Listings\k363-ex-lst.sas

Listing 16.2.5.3 - Dose per body weight

Cohort 1: 30 min (Rα)

Subject ID	Active Ingredient	Dose per Administration (mg)	Body Weight (kg)	Dose per Body Weight (mg/kg)
S001/001	Fosnetupitant	235	55.0	4.27
S001/001	Palonosetron	0.25	55.0	0.005
...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
The dose per body weight is calculated using the screening body weight and the actual dose administered
Program: Listings\k363-ex-lst.sas

Listing 16.2.5.3 - Dose per body weight

Cohort 1: 30 min (T)

Subject ID	Active Ingredient	Dose per Administration (mg)	Body Weight (kg)	Dose per Body Weight (mg/kg)
S012/011	Fosnetupitant	235	70.0	3.36
...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
The dose per body weight is calculated using the screening body weight and the actual dose administered
Program: Listings\k363-ex-lst.sas

Listing 16.2.5.3 - Dose per body weight

Cohort 1: 15 min (T)

Subject ID	Active Ingredient	Dose per Administration (mg)	Body Weight (kg)	Dose per Body Weight (mg/kg)
S024/021	Fosnetupitant	235	70.0	3.36
...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
The dose per body weight is calculated using the screening body weight and the actual dose administered
Program: Listings\k363-ex-lst.sas

Listing 16.2.5.3 - Dose per body weight

Cohort 1: 5 min (T)

Subject ID	Active Ingredient	Dose per Administration (mg)	Body Weight (kg)	Dose per Body Weight (mg/kg)
S036/031	Fosnetupitant	235	64.0	3.67
...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
The dose per body weight is calculated using the screening body weight and the actual dose administered
Program: Listings\k363-ex-lst.sas

Listing 16.2.5.3 - Dose per body weight

Cohort 1: 2 min (T)

Subject ID	Active Ingredient	Dose per Administration (mg)	Body Weight (kg)	Dose per Body Weight (mg/kg)
S048/041	Fosnetupitant	235	57.0	4.12
...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
The dose per body weight is calculated using the screening body weight and the actual dose administered
Program: Listings\k363-ex-lst.sas

Listing 16.2.5.4 - PK samples collection dates and times

Cohort 1: 30 min (Rα)

Subject ID	IMP Administration Start Date/Time	Sample Number	Nominal Time Point	Collection Date/time	Time from the start of IMP infusion/injection	Sampling collection time as per protocol?
S001/001	ddMMMyyyy hh:mm	1	Pre-dose - Within 30 min before start of infusion	ddMMMyyyy hh:mm	-xx min	Yes
S001/001	ddMMMyyyy hh:mm	2	30 min after start of infusion	ddMMMyyyy hh:mm	xx min	Yes
S001/001	ddMMMyyyy hh:mm	3	45 min ± 2 min after start of infusion	ddMMMyyyy hh:mm	xx min	No
S001/001	ddMMMyyyy hh:mm	4	1 h ± 2 min after start of infusion	ddMMMyyyy hh:mm	xx min	No
S001/001	ddMMMyyyy hh:mm	5	1.5h ± 2 min after start of infusion	ddMMMyyyy hh:mm	xx min	Yes
...	...	...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Program: Listings\k363-pc-lst.sas

Listing 16.2.5.4 - PK samples collection dates and times

Cohort 1: 30 min (T)

Subject ID	IMP Administration Start Date/Time	Sample Number	Nominal Time Point	Collection Date/time	Time from the start of IMP infusion/injection	Sampling collection time as per protocol?
S012/011	ddMMMyyyy hh:mm	1	Pre-dose - Within 30 min before start of infusion	ddMMMyyyy hh:mm	-xx min	Yes
S012/011	ddMMMyyyy hh:mm	2	30 min after start of infusion	ddMMMyyyy hh:mm	xx min	Yes
S012/011	ddMMMyyyy hh:mm	3	45 min ± 2 min after start of infusion	ddMMMyyyy hh:mm	xx min	No
S012/011	ddMMMyyyy hh:mm	4	1 h ± 2 min after start of infusion	ddMMMyyyy hh:mm	xx min	No
S012/011	ddMMMyyyy hh:mm	5	1.5h ± 2 min after start of infusion	ddMMMyyyy hh:mm	xx min	No
...	...	...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Program: Listings\k363-pc-lst.sas

Listing 16.2.5.4 - PK samples collection dates and times

Cohort 2: 15 min (T)

Subject ID	IMP Administration Start Date/Time	Sample Number	Nominal Time Point	Collection Date/time	Time from the start of IMP infusion/injection	Sampling collection time as per protocol?
S024/021	ddMMMyyyy hh:mm	1	Pre-dose - Within 30 min before start of infusion	ddMMMyyyy hh:mm	-xx min	Yes
S024/021	ddMMMyyyy hh:mm	2	15 min after start of infusion	ddMMMyyyy hh:mm	xx min	Yes
S024/021	ddMMMyyyy hh:mm	3	20 min after start of infusion	ddMMMyyyy hh:mm	xx min	Yes
S024/021	ddMMMyyyy hh:mm	4	30 min after start of infusion	ddMMMyyyy hh:mm	xx min	Yes
S024/021	ddMMMyyyy hh:mm	5	45 min ± 2 min after start of infusion	ddMMMyyyy hh:mm	xx min	Yes
...	...	...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Program: Listings\k363-pc-lst.sas

Listing 16.2.5.4 - PK samples collection dates and times

Cohort 3: 5 min (T)

Subject ID	IMP Administration Start Date/Time	Sample Number	Nominal Time Point	Collection Date/time	Time from the start of IMP infusion/injection	Sampling collection time as per protocol?
S036/031	ddMMMyyyy hh:mm	1	Pre-dose - Within 30 min before start of infusion	ddMMMyyyy hh:mm	-xx min	No
S036/031	ddMMMyyyy hh:mm	2	5 min after start of infusion	ddMMMyyyy hh:mm	xx min	No
S036/031	ddMMMyyyy hh:mm	3	10 min after start of infusion	ddMMMyyyy hh:mm	xx min	Yes
S036/031	ddMMMyyyy hh:mm	4	15 min after start of infusion	ddMMMyyyy hh:mm	xx min	Yes
S036/031	ddMMMyyyy hh:mm	5	20 min after start of infusion	ddMMMyyyy hh:mm	xx min	Yes
...	...	...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Program: Listings\k363-pc-lst.sas

Listing 16.2.5.4 - PK samples collection dates and times

Cohort 4: 2 min (T)

Subject ID	IMP Administration Start Date/Time	Sample Number	Nominal Time Point	Collection Date/time	Time from the start of IMP infusion/injection	Sampling collection time as per protocol?
S048/041	ddMMMyyyy hh:mm	1	Pre-dose - Within 30 min before start of infusion	ddMMMyyyy hh:mm	-xx min	Yes
S048/041	ddMMMyyyy hh:mm	2	2 min after start of infusion	ddMMMyyyy hh:mm	xx min	Yes
S048/041	ddMMMyyyy hh:mm	3	5 min after start of infusion	ddMMMyyyy hh:mm	xx min	Yes
S048/041	ddMMMyyyy hh:mm	4	10 min after start of infusion	ddMMMyyyy hh:mm	xx min	Yes
S048/041	ddMMMyyyy hh:mm	5	15 min after start of infusion	ddMMMyyyy hh:mm	xx min	No
...	...	...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Program: Listings\k363-pc-lst.sas

Listing 16.2.5.5 - Fosnetupitant Concentrations (ng/mL) measured in plasma

Cohort 1: 30 min (Rα)

Subject ID	Pre dose	2 min	5 min	10 min	15 min	20 min	30 min	45 min	1 hour	1.5 hour	2 h	3 h	4 h	8 h	12 h	24 h
S001/001	xx.xx	---	---	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Sampling times are counted from the start of the injection/infusion
BQL: Below Lower Quantification Limit (20.00 ng/mL)
Program: Listings\k363-pc-lst.sas

Listing 16.2.5.5 - Fosnetupitant Concentrations (ng/mL) measured in plasma

Cohort 1: 30 min (T)

Subject ID	Pre dose	2 min	5 min	10 min	15 min	20 min	30 min	45 min	1 hour	1.5 hour	2 h	3 h	4 h	8 h	12 h	24 h
S012/011	xx.xx	---	---	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Sampling times are counted from the start of the injection/infusion
BQL: Below Lower Quantification Limit (20.00 ng/mL)
Program: Listings\k363-pc-lst.sas

Listing 16.2.5.5 - Fosnetupitant Concentrations (ng/mL) measured in plasma

Cohort 2: 15 min (T)

Subject ID	Pre dose	2 min	5 min	10 min	15 min	20 min	30 min	45 min	1 hour	1.5 hour	2 h	3 h	4 h	8 h	12 h	24 h
S024/021	xx.xx	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Sampling times are counted from the start of the injection/infusion
BQL: Below Lower Quantification Limit (20.00 ng/mL)
Program: Listings\k363-pc-lst.sas

Listing 16.2.5.5 - Fosnetupitant Concentrations (ng/mL) measured in plasma

Cohort 3: 5 min (T)

Subject ID	Pre dose	2 min	5 min	10 min	15 min	20 min	30 min	45 min	1 hour	1.5 hour	2 h	3 h	4 h	8 h	12 h	24 h
S036/031	xx.xx	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Sampling times are counted from the start of the injection/infusion
BQL: Below Lower Quantification Limit (20.00 ng/mL)
Program: Listings\k363-pc-lst.sas

Listing 16.2.5.5 - Fosnetupitant Concentrations (ng/mL) measured in plasma

Cohort 4: 2 min (T)

Subject ID	Pre dose	2 min	5 min	10 min	15 min	20 min	30 min	45 min	1 hour	1.5 hour	2 h	3 h	4 h	8 h	12 h	24 h
S048/041	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Sampling times are counted from the start of the injection/infusion
BQL: Below Lower Quantification Limit (20.00 ng/mL)
Program: Listings\k363-pc-lst.sas

Listing 16.2.5.6 - Netupitant Concentrations (ng/mL) measured in plasma

Cohort 1: 30 min (Rα)

Subject ID	Pre dose	2 min	5 min	10 min	15 min	20 min	30 min	45 min	1 hour	1.5 hour	2 h	3 h	4 h	8 h	12 h	24 h
S001/001	xx.xx	---	---	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Sampling times are counted from the start of the injection/infusion
BQL: Below Lower Quantification Limit (20.00 ng/mL)
Program: Listings\k363-pc-lst.sas

Listing 16.2.5.6 - Netupitant Concentrations (ng/mL) measured in plasma

Cohort 1: 30 min (T)

Subject ID	Pre dose	2 min	5 min	10 min	15 min	20 min	30 min	45 min	1 hour	1.5 hour	2 h	3 h	4 h	8 h	12 h	24 h
S012/011	xx.xx	---	---	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Sampling times are counted from the start of the injection/infusion
BQL: Below Lower Quantification Limit (20.00 ng/mL)
Program: Listings\k363-pc-lst.sas

Listing 16.2.5.6 - Netupitant Concentrations (ng/mL) measured in plasma

Cohort 2: 15 min (T)

Subject ID	Pre dose	2 min	5 min	10 min	15 min	20 min	30 min	45 min	1 hour	1.5 hour	2 h	3 h	4 h	8 h	12 h	24 h
S024/021	xx.xx	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Sampling times are counted from the start of the injection/infusion
BQL: Below Lower Quantification Limit (20.00 ng/mL)
Program: Listings\k363-pc-lst.sas

Listing 16.2.5.6 - Netupitant Concentrations (ng/mL) measured in plasma

Cohort 3: 5 min (T)

Subject ID	Pre dose	2 min	5 min	10 min	15 min	20 min	30 min	45 min	1 hour	1.5 hour	2 h	3 h	4 h	8 h	12 h	24 h
S036/031	xx.xx	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Sampling times are counted from the start of the injection/infusion
BQL: Below Lower Quantification Limit (20.00 ng/mL)
Program: Listings\k363-pc-lst.sas

Listing 16.2.5.6 - Netupitant Concentrations (ng/mL) measured in plasma

Cohort 4: 2 min (T)

Subject ID	Pre dose	2 min	5 min	10 min	15 min	20 min	30 min	45 min	1 hour	1.5 hour	2 h	3 h	4 h	8 h	12 h	24 h
S048/041	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Sampling times are counted from the start of the injection/infusion
BQL: Below Lower Quantification Limit (20.00 ng/mL)
Program: Listings\k363-pc-lst.sas

Listing 16.2.5.7 - Netupitant metabolite M1 Concentrations (ng/mL) measured in plasma

Cohort 1: 30 min (Rα)

Subject ID	Pre dose	2 min	5 min	10 min	15 min	20 min	30 min	45 min	1 hour	1.5 hour	2 h	3 h	4 h	8 h	12 h	24 h
S001/001	xx.xx	---	---	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Sampling times are counted from the start of the injection/infusion
BQL: Below Lower Quantification Limit (20.00 ng/mL)
Program: Listings\k363-pc-lst.sas

Listing 16.2.5.7 - Netupitant metabolite M1 Concentrations (ng/mL) measured in plasma

Cohort 1: 30 min (T)

Subject ID	Pre dose	2 min	5 min	10 min	15 min	20 min	30 min	45 min	1 hour	1.5 hour	2 h	3 h	4 h	8 h	12 h	24 h
S012/011	xx.xx	---	---	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Sampling times are counted from the start of the injection/infusion
BQL: Below Lower Quantification Limit (20.00 ng/mL)
Program: Listings\k363-pc-lst.sas

Listing 16.2.5.7 - Netupitant metabolite M1 Concentrations (ng/mL) measured in plasma

Cohort 2: 15 min (T)

Subject ID	Pre dose	2 min	5 min	10 min	15 min	20 min	30 min	45 min	1 hour	1.5 hour	2 h	3 h	4 h	8 h	12 h	24 h
S024/021	xx.xx	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Sampling times are counted from the start of the injection/infusion
BQL: Below Lower Quantification Limit (20.00 ng/mL)
Program: Listings\k363-pc-lst.sas

Listing 16.2.5.7 - Netupitant metabolite M1 Concentrations (ng/mL) measured in plasma

Cohort 3: 5 min (T)

Subject ID	Pre dose	2 min	5 min	10 min	15 min	20 min	30 min	45 min	1 hour	1.5 hour	2 h	3 h	4 h	8 h	12 h	24 h
S036/031	xx.xx	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Sampling times are counted from the start of the injection/infusion
BQL: Below Lower Quantification Limit (20.00 ng/mL)
Program: Listings\k363-pc-lst.sas

Listing 16.2.5.7 - Netupitant metabolite M1 Concentrations (ng/mL) measured in plasma

Cohort 4: 2 min (T)

Subject ID	Pre dose	2 min	5 min	10 min	15 min	20 min	30 min	45 min	1 hour	1.5 hour	2 h	3 h	4 h	8 h	12 h	24 h
S048/041	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Sampling times are counted from the start of the injection/infusion
BQL: Below Lower Quantification Limit (20.00 ng/mL)
Program: Listings\k363-pc-lst.sas

Listing 16.2.5.8 - Netupitant metabolite M2 Concentrations (ng/mL) measured in plasma

Cohort 1: 30 min (Rα)

Subject ID	Pre dose	2 min	5 min	10 min	15 min	20 min	30 min	45 min	1 hour	1.5 hour	2 h	3 h	4 h	8 h	12 h	24 h
S001/001	xx.xx	---	---	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Sampling times are counted from the start of the injection/infusion
BQL: Below Lower Quantification Limit (20.00 ng/mL)
Program: Listings\k363-pc-lst.sas

Listing 16.2.5.8 - Netupitant metabolite M2 Concentrations (ng/mL) measured in plasma

Cohort 1: 30 min (T)

Subject ID	Pre dose	2 min	5 min	10 min	15 min	20 min	30 min	45 min	1 hour	1.5 hour	2 h	3 h	4 h	8 h	12 h	24 h
S012/011	xx.xx	---	---	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Sampling times are counted from the start of the injection/infusion
BQL: Below Lower Quantification Limit (20.00 ng/mL)
Program: Listings\k363-pc-lst.sas

Listing 16.2.5.8 - Netupitant metabolite M2 Concentrations (ng/mL) measured in plasma

Cohort 2: 15 min (T)

Subject ID	Pre dose	2 min	5 min	10 min	15 min	20 min	30 min	45 min	1 hour	1.5 hour	2 h	3 h	4 h	8 h	12 h	24 h
S024/021	xx.xx	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Sampling times are counted from the start of the injection/infusion
BQL: Below Lower Quantification Limit (20.00 ng/mL)
Program: Listings\k363-pc-lst.sas

Listing 16.2.5.8 - Netupitant metabolite M2 Concentrations (ng/mL) measured in plasma

Cohort 3: 5 min (T)

Subject ID	Pre dose	2 min	5 min	10 min	15 min	20 min	30 min	45 min	1 hour	1.5 hour	2 h	3 h	4 h	8 h	12 h	24 h
S036/031	xx.xx	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Sampling times are counted from the start of the injection/infusion
BQL: Below Lower Quantification Limit (20.00 ng/mL)
Program: Listings\k363-pc-lst.sas

Listing 16.2.5.8 - Netupitant metabolite M2 Concentrations (ng/mL) measured in plasma

Cohort 4: 2 min (T)

Subject ID	Pre dose	2 min	5 min	10 min	15 min	20 min	30 min	45 min	1 hour	1.5 hour	2 h	3 h	4 h	8 h	12 h	24 h
S048/041	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Sampling times are counted from the start of the injection/infusion
BQL: Below Lower Quantification Limit (20.00 ng/mL)
Program: Listings\k363-pc-lst.sas

Listing 16.2.5.9 - Netupitant metabolite M3 Concentrations (ng/mL) measured in plasma

Cohort 1: 30 min (Rα)

Subject ID	Pre dose	2 min	5 min	10 min	15 min	20 min	30 min	45 min	1 hour	1.5 hour	2 h	3 h	4 h	8 h	12 h	24 h
S001/001	xx.xx	---	---	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Sampling times are counted from the start of the injection/infusion
BQL: Below Lower Quantification Limit (20.00 ng/mL)
Program: Listings\k363-pc-lst.sas

Listing 16.2.5.9 - Netupitant metabolite M3 Concentrations (ng/mL) measured in plasma

Cohort 1: 30 min (T)

Subject ID	Pre dose	2 min	5 min	10 min	15 min	20 min	30 min	45 min	1 hour	1.5 hour	2 h	3 h	4 h	8 h	12 h	24 h
S012/011	xx.xx	---	---	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Sampling times are counted from the start of the injection/infusion
BQL: Below Lower Quantification Limit (20.00 ng/mL)
Program: Listings\k363-pc-lst.sas

Listing 16.2.5.9 - Netupitant metabolite M3 Concentrations (ng/mL) measured in plasma

Cohort 2: 15 min (T)

Subject ID	Pre dose	2 min	5 min	10 min	15 min	20 min	30 min	45 min	1 hour	1.5 hour	2 h	3 h	4 h	8 h	12 h	24 h
S024/021	xx.xx	---	---	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Sampling times are counted from the start of the injection/infusion
BQL: Below Lower Quantification Limit (20.00 ng/mL)
Program: Listings\k363-pc-lst.sas

Listing 16.2.5.9 - Netupitant metabolite M3 Concentrations (ng/mL) measured in plasma

Cohort 3: 5 min (T)

Subject ID	Pre dose	2 min	5 min	10 min	15 min	20 min	30 min	45 min	1 hour	1.5 hour	2 h	3 h	4 h	8 h	12 h	24 h
S036/031	xx.xx	---	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Sampling times are counted from the start of the injection/infusion
BQL: Below Lower Quantification Limit (20.00 ng/mL)
Program: Listings\k363-pc-lst.sas

Listing 16.2.5.9 - Netupitant metabolite M3 Concentrations (ng/mL) measured in plasma

Cohort 4: 2 min (T)

Subject ID	Pre dose	2 min	5 min	10 min	15 min	20 min	30 min	45 min	1 hour	1.5 hour	2 h	3 h	4 h	8 h	12 h	24 h
S048/041	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Sampling times are counted from the start of the injection/infusion
BQL: Below Lower Quantification Limit (20.00 ng/mL)
Program: Listings\k363-pc-lst.sas

Listing 16.2.6.1 - Plasma PK parameters - Fosnetupitant

Cohort 1: 30 min (Rα)

Subject ID	C_{max} (ng/mL)	C_0 (ng/mL)	C_{last} (ng/mL)	t_{last} (h)	t_{max} (h)	AUC_{last} (h*ng/mL)	AUC_{0-24} (h*ng/mL)	λ_z (1/h)	$t_{½}$ (h)	CL (mL/h)	V_z (mL)	MRT (h)
S001/001	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
...	...	...	...	...	...	...	...	...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Program: pk-analysis\k363-pp-lst.sas

Listing 16.2.6.1 - Plasma PK parameters - Fosnetupitant

Cohort 1: 30 min (T)

Subject ID	C_{max} (ng/mL)	C_0 (ng/mL)	C_{last} (ng/mL)	t_{last} (h)	t_{max} (h)	AUC_{last} (h*ng/mL)	AUC_{0-24} (h*ng/mL)	λ_z (1/h)	$t_{½}$ (h)	CL (mL/h)	V_z (mL)	MRT (h)
S012/011	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
...	...	...	...	...	...	...	...	...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Program: pk-analysis\k363-pp-lst.sas

Listing 16.2.6.1 - Plasma PK parameters - Fosnetupitant

Cohort 2: 15 min (T)

Subject ID	C_{max} (ng/mL)	C_0 (ng/mL)	C_{last} (ng/mL)	t_{last} (h)	t_{max} (h)	AUC_{last} (h*ng/mL)	AUC_{0-24} (h*ng/mL)	λ_z (1/h)	$t_{½}$ (h)	CL (mL/h)	V_z (mL)	MRT (h)
S024/021	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
...	...	...	...	...	...	...	...	...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Program: pk-analysis\k363-pp-lst.sas

Listing 16.2.6.1 - Plasma PK parameters - Fosnetupitant

Cohort 3: 5 min (T)

Subject ID	C_{max} (ng/mL)	C_0 (ng/mL)	C_{last} (ng/mL)	t_{last} (h)	t_{max} (h)	AUC_{last} (h*ng/mL)	AUC_{0-24} (h*ng/mL)	λ_z (1/h)	$t_{½}$ (h)	CL (mL/h)	V_z (mL)	MRT (h)
S036/031	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
...	...	...	...	...	...	...	...	...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Program: pk-analysis\k363-pp-lst.sas

Listing 16.2.6.1 - Plasma PK parameters - Fosnetupitant

Cohort 4: 2 min (T)

Subject ID	C_{max} (ng/mL)	C_0 (ng/mL)	C_{last} (ng/mL)	t_{last} (h)	t_{max} (h)	AUC_{last} (h*ng/mL)	AUC_{0-24} (h*ng/mL)	λ_z (1/h)	$t_{½}$ (h)	CL (mL/h)	V_z (mL)	MRT (h)
S048/041	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
...	...	...	...	...	...	...	...	...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Program: pk-analysis\k363-pp-lst.sas

Listing 16.2.6.2 - Plasma PK parameters - Netupitant

Cohort 1: 30 min (Rα)

Subject ID	C_{max} (ng/mL)	C_0 (ng/mL)	C_{last} (ng/mL)	t_{last} (h)	t_{max} (h)	AUC_{last} (h*ng/mL)	AUC_{0-24} (h*ng/mL)	λ_z (1/h)	$t_{½}$ (h)	CL (mL/h)	V_z (mL)	MRT (h)
S001/001	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
...	...	...	...	...	...	...	...	...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Program: pk-analysis\k363-pp-lst.sas

Listing 16.2.6.2 - Plasma PK parameters - Netupitant

Cohort 1: 30 min (T)

Subject ID	C_{max} (ng/mL)	C_0 (ng/mL)	C_{last} (ng/mL)	t_{last} (h)	t_{max} (h)	AUC_{last} (h*ng/mL)	AUC_{0-24} (h*ng/mL)	λ_z (1/h)	$t_{½}$ (h)	CL (mL/h)	V_z (mL)	MRT (h)
S012/011	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
...	...	...	...	...	...	...	...	...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Program: pk-analysis\k363-pp-lst.sas

Listing 16.2.6.2 - Plasma PK parameters - Netupitant

Cohort 2: 15 min (T)

Subject ID	C_{max} (ng/mL)	C_0 (ng/mL)	C_{last} (ng/mL)	t_{last} (h)	t_{max} (h)	AUC_{last} (h*ng/mL)	AUC_{0-24} (h*ng/mL)	λ_z (1/h)	$t_{½}$ (h)	CL (mL/h)	V_z (mL)	MRT (h)
S024/021	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
...	...	...	...	...	...	...	...	...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Program: pk-analysis\k363-pp-lst.sas

Listing 16.2.6.2 - Plasma PK parameters - Netupitant

Cohort 3: 5 min (T)

Subject ID	C_{max} (ng/mL)	C_0 (ng/mL)	C_{last} (ng/mL)	t_{last} (h)	t_{max} (h)	AUC_{last} (h*ng/mL)	AUC_{0-24} (h*ng/mL)	λ_z (1/h)	$t_{½}$ (h)	CL (mL/h)	V_z (mL)	MRT (h)
S036/031	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
...	...	...	...	...	...	...	...	...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Program: pk-analysis\k363-pp-lst.sas

Listing 16.2.6.2 - Plasma PK parameters - Netupitant

Cohort 4: 2 min (T)

Subject ID	C_{max} (ng/mL)	C_0 (ng/mL)	C_{last} (ng/mL)	t_{last} (h)	t_{max} (h)	AUC_{last} (h*ng/mL)	AUC_{0-24} (h*ng/mL)	λ_z (1/h)	$t_{½}$ (h)	CL (mL/h)	V_z (mL)	MRT (h)
S048/041	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
...	...	...	...	...	...	...	...	...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Program: pk-analysis\k363-pp-lst.sas

Listing 16.2.6.3 - Plasma PK parameters - Netupitant metabolite M1

Cohort 1: 30 min (Rα)

Subject ID	C_{max} (ng/mL)	C_0 (ng/mL)	C_{last} (ng/mL)	t_{last} (h)	t_{max} (h)	AUC_{last} (h*ng/mL)	AUC_{0-24} (h*ng/mL)	λ_z (1/h)	$t_{½}$ (h)	CL (mL/h)	V_z (mL)	MRT (h)
S001/001	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
...	...	...	...	...	...	...	...	...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Program: pk-analysis\k363-pp-lst.sas

Listing 16.2.6.3 - Plasma PK parameters - Netupitant metabolite M1

Cohort 1: 30 min (T)

Subject ID	C_{max} (ng/mL)	C_0 (ng/mL)	C_{last} (ng/mL)	t_{last} (h)	t_{max} (h)	AUC_{last} (h*ng/mL)	AUC_{0-24} (h*ng/mL)	λ_z (1/h)	$t_{½}$ (h)	CL (mL/h)	V_z (mL)	MRT (h)
S012/011	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
...	...	...	...	...	...	...	...	...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Program: pk-analysis\k363-pp-lst.sas

Listing 16.2.6.3 - Plasma PK parameters - Netupitant metabolite M1

Cohort 2: 15 min (T)

Subject ID	C_{max} (ng/mL)	C_0 (ng/mL)	C_{last} (ng/mL)	t_{last} (h)	t_{max} (h)	AUC_{last} (h*ng/mL)	AUC_{0-24} (h*ng/mL)	λ_z (1/h)	$t_{½}$ (h)	CL (mL/h)	V_z (mL)	MRT (h)
S024/021	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
...	...	...	...	...	...	...	...	...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Program: pk-analysis\k363-pp-lst.sas

Listing 16.2.6.3 - Plasma PK parameters - Netupitant metabolite M1

Cohort 3: 5 min (T)

Subject ID	C_{max} (ng/mL)	C_0 (ng/mL)	C_{last} (ng/mL)	t_{last} (h)	t_{max} (h)	AUC_{last} (h*ng/mL)	AUC_{0-24} (h*ng/mL)	λ_z (1/h)	$t_{½}$ (h)	CL (mL/h)	V_z (mL)	MRT (h)
S036/031	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
...	...	...	...	...	...	...	...	...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Program: pk-analysis\k363-pp-lst.sas

Listing 16.2.6.3 - Plasma PK parameters - Netupitant metabolite M1

Cohort 4: 2 min (T)

Subject ID	C_{max} (ng/mL)	C_0 (ng/mL)	C_{last} (ng/mL)	t_{last} (h)	t_{max} (h)	AUC_{last} (h*ng/mL)	AUC_{0-24} (h*ng/mL)	λ_z (1/h)	$t_{½}$ (h)	CL (mL/h)	V_z (mL)	MRT (h)
S048/041	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
...	...	...	...	...	...	...	...	...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Program: pk-analysis\k363-pp-lst.sas

Listing 16.2.6.4 - Plasma PK parameters - Netupitant metabolite M2

Cohort 1: 30 min (Rα)

Subject ID	C_{max} (ng/mL)	C_0 (ng/mL)	C_{last} (ng/mL)	t_{last} (h)	t_{max} (h)	AUC_{last} (h*ng/mL)	AUC_{0-24} (h*ng/mL)	λ_z (1/h)	$t_{½}$ (h)	CL (mL/h)	V_z (mL)	MRT (h)
S001/001	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
...	...	...	...	...	...	...	...	...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Program: pk-analysis\k363-pp-lst.sas

Listing 16.2.6.4 - Plasma PK parameters - Netupitant metabolite M2

Cohort 1: 30 min (T)

Subject ID	C_{max} (ng/mL)	C_0 (ng/mL)	C_{last} (ng/mL)	t_{last} (h)	t_{max} (h)	AUC_{last} (h*ng/mL)	AUC_{0-24} (h*ng/mL)	λ_z (1/h)	$t_{½}$ (h)	CL (mL/h)	V_z (mL)	MRT (h)
S012/011	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
...	...	...	...	...	...	...	...	...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Program: pk-analysis\k363-pp-lst.sas

Listing 16.2.6.4 - Plasma PK parameters - Netupitant metabolite M2

Cohort 2: 15 min (T)

Subject ID	C_{max} (ng/mL)	C_0 (ng/mL)	C_{last} (ng/mL)	t_{last} (h)	t_{max} (h)	AUC_{last} (h*ng/mL)	AUC_{0-24} (h*ng/mL)	λ_z (1/h)	$t_{½}$ (h)	CL (mL/h)	V_z (mL)	MRT (h)
S024/021	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
...	...	...	...	...	...	...	...	...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Program: pk-analysis\k363-pp-lst.sas

Listing 16.2.6.4 - Plasma PK parameters - Netupitant metabolite M2

Cohort 3: 5 min (T)

Subject ID	C_{max} (ng/mL)	C_0 (ng/mL)	C_{last} (ng/mL)	t_{last} (h)	t_{max} (h)	AUC_{last} (h*ng/mL)	AUC_{0-24} (h*ng/mL)	λ_z (1/h)	$t_{½}$ (h)	CL (mL/h)	V_z (mL)	MRT (h)
S036/031	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
...	...	...	...	...	...	...	...	...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Program: pk-analysis\k363-pp-lst.sas

Listing 16.2.6.4 - Plasma PK parameters - Netupitant metabolite M2

Cohort 4: 2 min (T)

Subject ID	C_{max} (ng/mL)	C_0 (ng/mL)	C_{last} (ng/mL)	t_{last} (h)	t_{max} (h)	AUC_{last} (h*ng/mL)	AUC_{0-24} (h*ng/mL)	λ_z (1/h)	$t_{½}$ (h)	CL (mL/h)	V_z (mL)	MRT (h)
S048/041	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
...	...	...	...	...	...	...	...	...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Program: pk-analysis\k363-pp-lst.sas

Listing 16.2.6.5 - Plasma PK parameters - Netupitant metabolite M3

Cohort 1: 30 min (Rα)

Subject ID	C_{max} (ng/mL)	C_0 (ng/mL)	C_{last} (ng/mL)	t_{last} (h)	t_{max} (h)	AUC_{last} (h*ng/mL)	AUC_{0-24} (h*ng/mL)	λ_z (1/h)	$t_{½}$ (h)	CL (mL/h)	V_z (mL)	MRT (h)
S001/001	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
...	...	...	...	...	...	...	...	...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Program: pk-analysis\k363-pp-lst.sas

Listing 16.2.6.5 - Plasma PK parameters - Netupitant metabolite M3

Cohort 1: 30 min (T)

Subject ID	C_{max} (ng/mL)	C_0 (ng/mL)	C_{last} (ng/mL)	t_{last} (h)	t_{max} (h)	AUC_{last} (h*ng/mL)	AUC_{0-24} (h*ng/mL)	λ_z (1/h)	$t_{½}$ (h)	CL (mL/h)	V_z (mL)	MRT (h)
S012/011	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
...	...	...	...	...	...	...	...	...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Program: pk-analysis\k363-pp-lst.sas

Listing 16.2.6.5 - Plasma PK parameters - Netupitant metabolite M3

Cohort 2: 15 min (T)

Subject ID	C_{max} (ng/mL)	C_0 (ng/mL)	C_{last} (ng/mL)	t_{last} (h)	t_{max} (h)	AUC_{last} (h*ng/mL)	AUC_{0-24} (h*ng/mL)	λ_z (1/h)	$t_{½}$ (h)	CL (mL/h)	V_z (mL)	MRT (h)
S024/021	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
...	...	...	...	...	...	...	...	...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Program: pk-analysis\k363-pp-lst.sas

Listing 16.2.6.5 - Plasma PK parameters - Netupitant metabolite M3

Cohort 3: 5 min (T)

Subject ID	C_{max} (ng/mL)	C_0 (ng/mL)	C_{last} (ng/mL)	t_{last} (h)	t_{max} (h)	AUC_{last} (h*ng/mL)	AUC_{0-24} (h*ng/mL)	λ_z (1/h)	$t_{½}$ (h)	CL (mL/h)	V_z (mL)	MRT (h)
S036/031	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
...	...	...	...	...	...	...	...	...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Program: pk-analysis\k363-pp-lst.sas

Listing 16.2.6.5 - Plasma PK parameters - Netupitant metabolite M3

Cohort 4: 2 min (T)

Subject ID	C_{max} (ng/mL)	C_0 (ng/mL)	C_{last} (ng/mL)	t_{last} (h)	t_{max} (h)	AUC_{last} (h*ng/mL)	AUC_{0-24} (h*ng/mL)	λ_z (1/h)	$t_{½}$ (h)	CL (mL/h)	V_z (mL)	MRT (h)
S048/041	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
...	...	...	...	...	...	...	...	...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Program: pk-analysis\k363-pp-lst.sas

Listing 16.2.7.1 - Treatment-emergent adverse events

Cohort 1: 30 min (Rα)

Subject ID	Adverse Event ID		
S001/001	1	Description:	Headache
		Preferred Term [1]:	Headache
		System Organ Class [1]:	Nervous system disorders
		Start Date/Time - End Date/Time (Day):	ddMMMyyyy hh:mm (k) - ddMMMyyyy (j)
		Last Study Drug Administration Date/Time Before Onset:	ddMMMyyyy hh:mm
		Relation to the Study Drug	Not related
		Severity:	Mild
		Serious Adverse Event?	N
		Seriousness criteria:	---
		Action Taken with Study Drug:	None
		Other Action Taken:	None
		Outcome:	Recovered/Resolved
...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Note 1: MedDRA version 27.0
Program: Listings\k363-ae-lst.sas

Listing 16.2.7.1 - Treatment-emergent adverse events

Cohort 1: 30 min (T)

Subject ID	Adverse Event ID		
S012/011	1	Description:	Headache
		Preferred Term [1]:	Headache
		System Organ Class [1]:	Nervous system disorders
		Start Date/Time - End Date/Time (Day):	ddMMMyyyy hh:mm (k) - ddMMMyyyy (j)
		Last Study Drug Administration Date/Time Before Onset:	ddMMMyyyy hh:mm
		Relation to the Study Drug	Not related
		Severity:	Mild
		Serious Adverse Event?	N
		Seriousness criteria:	---
		Action Taken with Study Drug:	None
		Other Action Taken:	None
		Outcome:	Recovered/Resolved
...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Note 1: MedDRA version 27.0
Program: Listings\k363-ae-lst.sas

Listing 16.2.7.1 - Treatment-emergent adverse events

Cohort 2: 15 min (T)

Subject ID	Adverse Event ID		
S024/021	1	Description:	Headache
		Preferred Term [1]:	Headache
		System Organ Class [1]:	Nervous system disorders
		Start Date/Time - End Date/Time (Day):	ddMMMyyyy hh:mm (k) - ddMMMyyyy (j)
		Last Study Drug Administration Date/Time Before Onset:	ddMMMyyyy hh:mm
		Relation to the Study Drug	Not related
		Severity:	Mild
		Serious Adverse Event?	N
		Seriousness criteria:	---
		Action Taken with Study Drug:	None
		Other Action Taken:	None
		Outcome:	Recovered/Resolved
...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Note 1: MedDRA version 27.0
Program: Listings\k363-ae-lst.sas

Listing 16.2.7.1 - Treatment-emergent adverse events

Cohort 3: 5 min (T)

Subject ID	Adverse Event ID		
S036/031	1	Description:	Headache
		Preferred Term [1]:	Headache
		System Organ Class [1]:	Nervous system disorders
		Start Date/Time - End Date/Time (Day):	ddMMMyyyy hh:mm (k) - ddMMMyyyy (j)
		Last Study Drug Administration Date/Time Before Onset:	ddMMMyyyy hh:mm
		Relation to the Study Drug	Not related
		Severity:	Mild
		Serious Adverse Event?	N
		Seriousness criteria:	---
		Action Taken with Study Drug:	None
		Other Action Taken:	None
		Outcome:	Recovered/Resolved
...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Note 1: MedDRA version 27.0
Program: Listings\k363-ae-lst.sas

Listing 16.2.7.1 - Treatment-emergent adverse events

Cohort 4: 2 min (T)

Subject ID	Adverse Event ID		
S048/041	1	Description:	Headache
		Preferred Term [1]:	Headache
		System Organ Class [1]:	Nervous system disorders
		Start Date/Time - End Date/Time (Day):	ddMMMyyyy hh:mm (k) - ddMMMyyyy (j)
		Last Study Drug Administration Date/Time Before Onset:	ddMMMyyyy hh:mm
		Relation to the Study Drug	Not related
		Severity:	Mild
		Serious Adverse Event?	N
		Seriousness criteria:	---
		Action Taken with Study Drug:	None
		Other Action Taken:	None
		Outcome:	Recovered/Resolved
...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Note 1: MedDRA version 27.0
Program: Listings\k363-ae-lst.sas

Listing 16.2.7.2 - Pre-treatment adverse events

Cohort 1: 30 min (Rα)

Subject ID	Adverse Event ID		
S001/001	1	Description:	Headache
		Preferred Term [1]:	Headache
		System Organ Class [1]:	Nervous system disorders
		Start Date/Time - End Date/Time (Day):	ddMMMyyyy hh:mm (k) - ddMMMyyyy (j)
		Relation to the Study Drug	Not related
		Severity:	Mild
		Serious Adverse Event?	N
		Seriousness criteria:	---
		Action Taken with Study Drug:	---
		Other Action Taken:	None
		Outcome:	Recovered/Resolved
...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Note 1: MedDRA version 27.0
Program: Listings\k363-ae-lst.sas

Listing 16.2.7.2 - Pre-treatment adverse events

Cohort 1: 30 min (T)

Subject ID	Adverse Event ID		
S012/011	1	Description:	Headache
		Preferred Term [1]:	Headache
		System Organ Class [1]:	Nervous system disorders
		Start Date/Time - End Date/Time (Day):	ddMMMyyyy hh:mm (k) - ddMMMyyyy (j)
		Relation to the Study Drug	Not related
		Severity:	Mild
		Serious Adverse Event?	N
		Seriousness criteria:	---
		Action Taken with Study Drug:	---
		Other Action Taken:	None
		Outcome:	Recovered/Resolved
...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Note 1: MedDRA version 27.0
Program: Listings\k363-ae-lst.sas

Listing 16.2.7.2 - Pre-treatment adverse events

Cohort 2: 15 min (T)

Subject ID	Adverse Event ID		
S024/021	1	Description:	Headache
		Preferred Term [1]:	Headache
		System Organ Class [1]:	Nervous system disorders
		Start Date/Time - End Date/Time (Day):	ddMMMyyyy hh:mm (k) - ddMMMyyyy (j)
		Relation to the Study Drug	Not related
		Severity:	Mild
		Serious Adverse Event?	N
		Seriousness criteria:	---
		Action Taken with Study Drug:	---
		Other Action Taken:	None
		Outcome:	Recovered/Resolved
...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Note 1: MedDRA version 27.0
Program: Listings\k363-ae-lst.sas

Listing 16.2.7.2 - Pre-treatment adverse events

Cohort 3: 5 min (T)

Subject ID	Adverse Event ID		
S036/031	1	Description:	Headache
		Preferred Term [1]:	Headache
		System Organ Class [1]:	Nervous system disorders
		Start Date/Time - End Date/Time (Day):	ddMMMyyyy hh:mm (k) - ddMMMyyyy (j)
		Relation to the Study Drug	Not related
		Severity:	Mild
		Serious Adverse Event?	N
		Seriousness criteria:	---
		Action Taken with Study Drug:	---
		Other Action Taken:	None
		Outcome:	Recovered/Resolved
...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Note 1: MedDRA version 27.0
Program: Listings\k363-ae-lst.sas

Listing 16.2.7.2 - Pre-treatment adverse events

Cohort 4: 2 min (T)

Subject ID	Adverse Event ID		
S048/041	1	Description:	Headache
		Preferred Term [1]:	Headache
		System Organ Class [1]:	Nervous system disorders
		Start Date/Time - End Date/Time (Day):	ddMMMyyyy hh:mm (k) - ddMMMyyyy (j)
		Relation to the Study Drug	Not related
		Severity:	Mild
		Serious Adverse Event?	N
		Seriousness criteria:	---
		Action Taken with Study Drug:	---
		Other Action Taken:	None
		Outcome:	Recovered/Resolved
...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Note 1: MedDRA version 27.0
Program: Listings\k363-ae-lst.sas

Listing 16.2.8.1 - Individual laboratory measurements

Cohort 1: 30 min (Rα)

Category of Laboratory Parameters: BLOOD CHEMISTRY

Subject ID	Time Point	Collection Date/time	Parameter	Value and Abnormality [1]	Normal Range or Reference Value	Clinically Significant? [2]
S001/001	Screening	ddMMMyyyy hh:mm	Sodium [mmol/L]	138	136 - 145	NCS
S001/001	Screening	ddMMMyyyy hh:mm	Potassium [mmol/L]	4.4	3.5 - 5.1	NCS
S001/001	Screening	ddMMMyyyy hh:mm	Calcium [mmol/L]	2.27	2.10 - 2.55	NCS
S001/001	Screening	ddMMMyyyy hh:mm	Chloride [mmol/L]	103	96 - 110	NCS
S001/001	Screening	ddMMMyyyy hh:mm	Phosphate [mmol/L]	0.84 [A]	0.87 - 1.45	NCS
S001/001	Screening	ddMMMyyyy hh:mm	Alkaline Phosphatase [U/L]	95	<= 104	NCS
S001/001	Screening	ddMMMyyyy hh:mm	Gamma Glutamyl Transferase [U/L]	17	<= 39	NCS
S001/001	Screening	ddMMMyyyy hh:mm	Aspartate Aminotransferase [U/L]	24	<= 35	NCS
S001/001	Screening	ddMMMyyyy hh:mm	Alanine Aminotransferase [U/L]	30	<= 35	NCS
...	...	...	...	...	...	...
S001/001	End of Study	ddMMMyyyy hh:mm	Sodium [mmol/L]	138	136 - 145	NCS
S001/001	End of Study	ddMMMyyyy hh:mm	Potassium [mmol/L]	4.4	3.5 - 5.1	NCS
S001/001	End of Study	ddMMMyyyy hh:mm	Calcium [mmol/L]	2.27	2.10 - 2.55	NCS
S001/001	End of Study	ddMMMyyyy hh:mm	Chloride [mmol/L]	103	96 - 110	NCS
S001/001	End of Study	ddMMMyyyy hh:mm	Phosphate [mmol/L]	0.84 [A]	0.87 - 1.45	NCS
S001/001	End of Study	ddMMMyyyy hh:mm	Alkaline Phosphatase [U/L]	95	<= 104	NCS
S001/001	End of Study	ddMMMyyyy hh:mm	Gamma Glutamyl Transferase [U/L]	17	<= 39	NCS
S001/001	End of Study	ddMMMyyyy hh:mm	Aspartate Aminotransferase [U/L]	24	<= 35	NCS
S001/001	End of Study	ddMMMyyyy hh:mm	Alanine Aminotransferase [U/L]	30	<= 35	NCS
...	...	...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Note 1: A=Abnormal
Note 2: CS= Clinically Significant, NCS= Not Clinically Significant
Program: Listings\k363-lb-lst.sas

Listing 16.2.8.1 - Individual laboratory measurements

Cohort 1: 30 min (Rα)

Category of Laboratory Parameters: HAEMATOLOGY

Subject ID	Time Point	Collection Date/time	Parameter	Value and Abnormality [1]	Normal Range or Reference Value	Clinically Significant? [2]
S001/001	Screening	ddMMMyyyy hh:mm	Leukocytes [10^9/L]	10.02 [A]	4.00 - 10.00	NCS
S001/001	Screening	ddMMMyyyy hh:mm	Erythrocytes [10^12/L]	5.19	3.90 - 5.30	NCS
S001/001	Screening	ddMMMyyyy hh:mm	Hemoglobin [g/dL]	15.4	12.0 - 16.0	NCS
S001/001	Screening	ddMMMyyyy hh:mm	Hemoglobin [mmol/L]	9.6	7.5 - 9.9	NCS
S001/001	Screening	ddMMMyyyy hh:mm	Hematocrit [%]	44	37 - 47	NCS
S001/001	Screening	ddMMMyyyy hh:mm	Ery. Mean Corpuscular Volume [fL]	84	83 - 100	NCS
S001/001	Screening	ddMMMyyyy hh:mm	Ery. Mean Corpuscular Hemoglobin [pg]	30	27 - 34	NCS
S001/001	Screening	ddMMMyyyy hh:mm	Ery. Mean Corpuscular HGB Concentration [g/dL]	35	32 - 36	NCS
...	...	...	...	...	...	...
S001/001	End of Study	ddMMMyyyy hh:mm	Leukocytes [10^9/L]	10.02 [A]	4.00 - 10.00	NCS
S001/001	End of Study	ddMMMyyyy hh:mm	Erythrocytes [10^12/L]	5.19	3.90 - 5.30	NCS
S001/001	End of Study	ddMMMyyyy hh:mm	Hemoglobin [g/dL]	15.4	12.0 - 16.0	NCS
S001/001	End of Study	ddMMMyyyy hh:mm	Hemoglobin [mmol/L]	9.6	7.5 - 9.9	NCS
S001/001	End of Study	ddMMMyyyy hh:mm	Hematocrit [%]	44	37 - 47	NCS
S001/001	End of Study	ddMMMyyyy hh:mm	Ery. Mean Corpuscular Volume [fL]	84	83 - 100	NCS
S001/001	End of Study	ddMMMyyyy hh:mm	Ery. Mean Corpuscular Hemoglobin [pg]	30	27 - 34	NCS
S001/001	End of Study	ddMMMyyyy hh:mm	Ery. Mean Corpuscular HGB Concentration [g/dL]	35	32 - 36	NCS
...	...	...	...	...	...	...

Note 1: A=Abnormal
Note 2: CS= Clinically Significant, NCS= Not Clinically Significant
Program: Listings\k363-lb-lst.sas

Listing 16.2.8.1 - Individual laboratory measurements

Cohort 1: 30 min (Rα)

Category of Laboratory Parameters: URINE ANALYSIS

Subject ID	Time Point	Collection Date/time	Parameter	Value and Abnormality [1]	Normal Range or Reference Value	Clinically Significant? [2]
S001/001	Screening	ddMMMyyyy hh:mm	Urobilinogen	Normal	Normal	NCS
S001/001	Screening	ddMMMyyyy hh:mm	Urinary Bilirubin	Absent	Absent	NCS
S001/001	Screening	ddMMMyyyy hh:mm	Ketones	Absent	Absent	NCS
S001/001	Screening	ddMMMyyyy hh:mm	Urinary Hemoglobin	+++ [A]	Absent	NCS
S001/001	Screening	ddMMMyyyy hh:mm	Urinary Leukocytes	Absent	Absent	NCS
S001/001	Screening	ddMMMyyyy hh:mm	Sediment Examination	Checked		
S001/001	Screening	ddMMMyyyy hh:mm	Urinary Sediment Leukocytes	Absent	Absent or 0-2 per field	NCS
S001/001	Screening	ddMMMyyyy hh:mm	Urinary Sediment Erythrocytes	0-2 per field	Absent or 0-2 per field	NCS
...	...	...	...	...	...	...
S001/001	End of Study	ddMMMyyyy hh:mm	Urobilinogen	Normal	Normal	NCS
S001/001	End of Study	ddMMMyyyy hh:mm	Urinary Bilirubin	Absent	Absent	NCS
S001/001	End of Study	ddMMMyyyy hh:mm	Ketones	Absent	Absent	NCS
S001/001	End of Study	ddMMMyyyy hh:mm	Urinary Hemoglobin	+++ [A]	Absent	NCS
S001/001	End of Study	ddMMMyyyy hh:mm	Urinary Leukocytes	Absent	Absent	NCS
S001/001	End of Study	ddMMMyyyy hh:mm	Sediment Examination	Checked		
S001/001	End of Study	ddMMMyyyy hh:mm	Urinary Sediment Leukocytes	Absent	Absent or 0-2 per field	NCS
S001/001	End of Study	ddMMMyyyy hh:mm	Urinary Sediment Erythrocytes	0-2 per field	Absent or 0-2 per field	NCS
...	...	...	...	...	...	...

Note 1: A=Different from reference value
Note 2: CS= Clinically Significant, NCS= Not Clinically Significant
Program: Listings\k363-lb-lst.sas

Listing 16.2.8.1 - Individual laboratory measurements

Cohort 1: 30 min (Rα)

Category of Laboratory Parameters: URINE DRUG SCREENING

Subject ID	Time Point	Collection Date/time	Parameter	Value and Abnormality [1]	Normal Range or Reference Value	Clinically Significant? [2]
S001/001	Screening	ddMMMyyyy hh:mm	Amphetamine	Negative	Negative	---
S001/001	Screening	ddMMMyyyy hh:mm	Cannabinoids	Negative	Negative	---
S001/001	Screening	ddMMMyyyy hh:mm	Cocaine	Negative	Negative	---
S001/001	Screening	ddMMMyyyy hh:mm	Ecstasy	Negative	Negative	---
S001/001	Screening	ddMMMyyyy hh:mm	Methamphetamine	Negative	Negative	---
S001/001	Screening	ddMMMyyyy hh:mm	Opiate	Negative	Negative	---
S001/001	Visit 2 - Day -1	ddMMMyyyy hh:mm	Amphetamine	Negative	Negative	---
S001/001	Visit 2 - Day -1	ddMMMyyyy hh:mm	Cannabinoids	Negative	Negative	---
S001/001	Visit 2 - Day -1	ddMMMyyyy hh:mm	Cocaine	Negative	Negative	---
S001/001	Visit 2 - Day -1	ddMMMyyyy hh:mm	Ecstasy	Negative	Negative	---
S001/001	Visit 2 - Day -1	ddMMMyyyy hh:mm	Methamphetamine	Negative	Negative	---
S001/001	Visit 2 - Day -1	ddMMMyyyy hh:mm	Opiate	Negative	Negative	---
...	...	...	...	...	...	...

Note 1: A=Different from reference value
Note 2: Clinical Significance is not collected for Urine Drug Screening
Program: Listings\k363-lb-lst.sas

Listing 16.2.8.1 - Individual laboratory measurements

Cohort 1: 30 min (Rα)

Category of Laboratory Parameters: VIROLOGY

Subject ID	Time Point	Collection Date/time	Parameter	Value and Abnormality [1]	Normal Range or Reference Value	Clinically Significant? [2]
S001/001	Screening	ddMMMyyyy hh:mm	Hepatitis B Virus Surface Antigen	Negative	Negative	NCS
S001/001	Screening	ddMMMyyyy hh:mm	Hepatitis C Virus Antibody	Negative	Negative	NCS
S001/001	Screening	ddMMMyyyy hh:mm	HIV Ag/Ab Combo	Negative	Negative	NCS
...	...	...	...	...	...	...

Note 1: A=Different from reference value
Note 2: CS= Clinically Significant, NCS= Not Clinically Significant
Program: Listings\k363-lb-lst.sas

Listing 16.2.8.1 - Individual laboratory measurements

Cohort 1: 30 min (Rα)

Category of Laboratory Parameters: SALIVARY BREATH TEST AND PREGNANCY TEST

Subject ID	Time Point	Collection Date/time	Parameter	Value and Abnormality [1]	Normal Range or Reference Value	Clinically Significant? [2]
S001/001	Screening	ddMMMyyyy hh:mm	Pregnancy Test (Serum)	Negative	Negative	NCS
S001/001	Visit 2 - Day -1	ddMMMyyyy hh:mm	Pregnancy Test (Urine)	Negative	Negative	---
S001/001	Visit 2 - Day -1	ddMMMyyyy hh:mm	Salivary Alcohol Test	Negative	Negative	---
...	...	...	...	...	...	...

Note 1: A=Different from reference value

Note 2: Clinical Significance is reported for serum pregnancy test only. CS= Clinically Significant, NCS= Not Clinically Significant

Program: Listings\k363-lb-lst.sas

Listing 16.2.8.1 - Individual laboratory measurements

Cohort 1: 30 min (T)
Category of Laboratory Parameters: BLOOD CHEMISTRY

Subject ID	Time Point	Collection Date/time	Parameter	Value and Abnormality [1]	Normal Range or Reference Value	Clinically Significant? [2]
S012/011	Screening	ddMMMyyyy hh:mm	Sodium [mmol/L]	138	136 - 145	NCS
S012/011	Screening	ddMMMyyyy hh:mm	Potassium [mmol/L]	4.4	3.5 - 5.1	NCS
S012/011	Screening	ddMMMyyyy hh:mm	Calcium [mmol/L]	2.27	2.10 - 2.55	NCS
S012/011	Screening	ddMMMyyyy hh:mm	Chloride [mmol/L]	103	96 - 110	NCS
S012/011	Screening	ddMMMyyyy hh:mm	Phosphate [mmol/L]	0.84 [A]	0.87 - 1.45	NCS
S012/011	Screening	ddMMMyyyy hh:mm	Alkaline Phosphatase [U/L]	95	<= 104	NCS
S012/011	Screening	ddMMMyyyy hh:mm	Gamma Glutamyl Transferase [U/L]	17	<= 39	NCS
S012/011	Screening	ddMMMyyyy hh:mm	Aspartate Aminotransferase [U/L]	24	<= 35	NCS
S012/011	Screening	ddMMMyyyy hh:mm	Alanine Aminotransferase [U/L]	30	<= 35	NCS
...	...	...	...	...	...	...
S012/011	End of Study	ddMMMyyyy hh:mm	Sodium [mmol/L]	138	136 - 145	NCS
S012/011	End of Study	ddMMMyyyy hh:mm	Potassium [mmol/L]	4.4	3.5 - 5.1	NCS
S012/011	End of Study	ddMMMyyyy hh:mm	Calcium [mmol/L]	2.27	2.10 - 2.55	NCS
S012/011	End of Study	ddMMMyyyy hh:mm	Chloride [mmol/L]	103	96 - 110	NCS
S012/011	End of Study	ddMMMyyyy hh:mm	Phosphate [mmol/L]	0.84 [A]	0.87 - 1.45	NCS
S012/011	End of Study	ddMMMyyyy hh:mm	Alkaline Phosphatase [U/L]	95	<= 104	NCS
S012/011	End of Study	ddMMMyyyy hh:mm	Gamma Glutamyl Transferase [U/L]	17	<= 39	NCS
S012/011	End of Study	ddMMMyyyy hh:mm	Aspartate Aminotransferase [U/L]	24	<= 35	NCS
S012/011	End of Study	ddMMMyyyy hh:mm	Alanine Aminotransferase [U/L]	30	<= 35	NCS
...	...	...	...	...	...	...

Note 1: A=Abnormal
Note 2: CS= Clinically Significant, NCS= Not Clinically Significant
Program: Listings\k363-lb-lst.sas

Listing 16.2.8.1 - Individual laboratory measurements

Cohort 1: 30 min (T)
Category of Laboratory Parameters: HAEMATOLOGY

Subject ID	Time Point	Collection Date/time	Parameter	Value and Abnormality [1]	Normal Range or Reference Value	Clinically Significant? [2]
S012/011	Screening	ddMMMyyyy hh:mm	Leukocytes [10^9/L]	10.02 [A]	4.00 - 10.00	NCS
S012/011	Screening	ddMMMyyyy hh:mm	Erythrocytes [10^12/L]	5.19	3.90 - 5.30	NCS
S012/011	Screening	ddMMMyyyy hh:mm	Hemoglobin [g/dL]	15.4	12.0 - 16.0	NCS
S012/011	Screening	ddMMMyyyy hh:mm	Hemoglobin [mmol/L]	9.6	7.5 - 9.9	NCS
S012/011	Screening	ddMMMyyyy hh:mm	Hematocrit [%]	44	37 - 47	NCS
S012/011	Screening	ddMMMyyyy hh:mm	Ery. Mean Corpuscular Volume [fL]	84	83 - 100	NCS
S012/011	Screening	ddMMMyyyy hh:mm	Ery. Mean Corpuscular Hemoglobin [pg]	30	27 - 34	NCS
S012/011	Screening	ddMMMyyyy hh:mm	Ery. Mean Corpuscular HGB Concentration [g/dL]	35	32 - 36	NCS
...	...	...	...	...	...	...
S012/011	End of Study	ddMMMyyyy hh:mm	Leukocytes [10^9/L]	10.02 [A]	4.00 - 10.00	NCS
S012/011	End of Study	ddMMMyyyy hh:mm	Erythrocytes [10^12/L]	5.19	3.90 - 5.30	NCS
S012/011	End of Study	ddMMMyyyy hh:mm	Hemoglobin [g/dL]	15.4	12.0 - 16.0	NCS
S012/011	End of Study	ddMMMyyyy hh:mm	Hemoglobin [mmol/L]	9.6	7.5 - 9.9	NCS
S012/011	End of Study	ddMMMyyyy hh:mm	Hematocrit [%]	44	37 - 47	NCS
S012/011	End of Study	ddMMMyyyy hh:mm	Ery. Mean Corpuscular Volume [fL]	84	83 - 100	NCS
S012/011	End of Study	ddMMMyyyy hh:mm	Ery. Mean Corpuscular Hemoglobin [pg]	30	27 - 34	NCS
S012/011	End of Study	ddMMMyyyy hh:mm	Ery. Mean Corpuscular HGB Concentration [g/dL]	35	32 - 36	NCS
...	...	...	...	...	...	...

Note 1: A=Different from reference value
Note 2: CS= Clinically Significant, NCS= Not Clinically Significant
Program: Listings\k363-lb-lst.sas

Listing 16.2.8.1 - Individual laboratory measurements

Cohort 1: 30 min (T)
Category of Laboratory Parameters: URINE ANALYSIS

Subject ID	Time Point	Collection Date/time	Parameter	Value and Abnormality [1]	Normal Range or Reference Value	Clinically Significant? [2]
S012/011	Screening	ddMMMyyyy hh:mm	Urobilinogen	Normal	Normal	NCS
S012/011	Screening	ddMMMyyyy hh:mm	Urinary Bilirubin	Absent	Absent	NCS
S012/011	Screening	ddMMMyyyy hh:mm	Ketones	Absent	Absent	NCS
S012/011	Screening	ddMMMyyyy hh:mm	Urinary Hemoglobin	+++ [A]	Absent	NCS
S012/011	Screening	ddMMMyyyy hh:mm	Urinary Leukocytes	Absent	Absent	NCS
S012/011	Screening	ddMMMyyyy hh:mm	Sediment Examination	Checked		
S012/011	Screening	ddMMMyyyy hh:mm	Urinary Sediment Leukocytes	Absent	Absent or 0-2 per field	NCS
S012/011	Screening	ddMMMyyyy hh:mm	Urinary Sediment Erythrocytes	0-2 per field	Absent or 0-2 per field	NCS
...	...	...	...	...	...	...
S012/011	End of Study	ddMMMyyyy hh:mm	Urobilinogen	Normal	Normal	NCS
S012/011	End of Study	ddMMMyyyy hh:mm	Urinary Bilirubin	Absent	Absent	NCS
S012/011	End of Study	ddMMMyyyy hh:mm	Ketones	Absent	Absent	NCS
S012/011	End of Study	ddMMMyyyy hh:mm	Urinary Hemoglobin	+++ [A]	Absent	NCS
S012/011	End of Study	ddMMMyyyy hh:mm	Urinary Leukocytes	Absent	Absent	NCS
S012/011	End of Study	ddMMMyyyy hh:mm	Sediment Examination	Checked		
S012/011	End of Study	ddMMMyyyy hh:mm	Urinary Sediment Leukocytes	Absent	Absent or 0-2 per field	NCS
S012/011	End of Study	ddMMMyyyy hh:mm	Urinary Sediment Erythrocytes	0-2 per field	Absent or 0-2 per field	NCS
...	...	...	...	...	...	...

Note 1: A=Different from reference value
Note 2: Clinical Significance is not collected for Urine Drug Screening
Program: Listings\k363-lb-lst.sas

Listing 16.2.8.1 - Individual laboratory measurements

Cohort 1: 30 min (T)
Category of Laboratory Parameters: URINE DRUG SCREENING

Subject ID	Time Point	Collection Date/time	Parameter	Value and Abnormality [1]	Normal Range or Reference Value	Clinically Significant? [2]
S012/011	Screening	ddMMMyyyy hh:mm	Amphetamine	Negative	Negative	---
S012/011	Screening	ddMMMyyyy hh:mm	Cannabinoids	Negative	Negative	---
S012/011	Screening	ddMMMyyyy hh:mm	Cocaine	Negative	Negative	---
S012/011	Screening	ddMMMyyyy hh:mm	Ecstasy	Negative	Negative	---
S012/011	Screening	ddMMMyyyy hh:mm	Methamphetamine	Negative	Negative	---
S012/011	Screening	ddMMMyyyy hh:mm	Opiate	Negative	Negative	---
S012/011	Visit 2 - Day -1	ddMMMyyyy hh:mm	Amphetamine	Negative	Negative	---
S012/011	Visit 2 - Day -1	ddMMMyyyy hh:mm	Cannabinoids	Negative	Negative	---
S012/011	Visit 2 - Day -1	ddMMMyyyy hh:mm	Cocaine	Negative	Negative	---
S012/011	Visit 2 - Day -1	ddMMMyyyy hh:mm	Ecstasy	Negative	Negative	---
S012/011	Visit 2 - Day -1	ddMMMyyyy hh:mm	Methamphetamine	Negative	Negative	---
S012/011	Visit 2 - Day -1	ddMMMyyyy hh:mm	Opiate	Negative	Negative	---
...	...	...	...	...	...	...

Note 1: A=Different from reference value
Note 2: CS= Clinically Significant, NCS= Not Clinically Significant
Program: Listings\k363-lb-lst.sas

Listing 16.2.8.1 - Individual laboratory measurements

Cohort 1: 30 min (T)
Category of Laboratory Parameters: VIROLOGY

Subject ID	Time Point	Collection Date/time	Parameter	Value and Abnormality [1]	Normal Range or Reference Value	Clinically Significant? [2]
S012/011	Screening	ddMMMyyyy hh:mm	Hepatitis B Virus Surface Antigen	Negative	Negative	NCS
S012/011	Screening	ddMMMyyyy hh:mm	Hepatitis C Virus Antibody	Negative	Negative	NCS
S012/011	Screening	ddMMMyyyy hh:mm	HIV Ag/Ab Combo	Negative	Negative	NCS
...	...	...	...	...	...	...

Note 1: A=Different from reference value
Note 2: Clinical Significance is reported for serum pregnancy test only. CS= Clinically Significant, NCS= Not Clinically Significant
Program: Listings\k363-lb-lst.sas

Listing 16.2.8.1 - Individual laboratory measurements

Cohort 1: 30 min (T)
Category of Laboratory Parameters: SALIVARY BREATH TEST AND PREGNANCY TEST

Subject ID	Time Point	Collection Date/time	Parameter	Value and Abnormality [1]	Normal Range or Reference Value	Clinically Significant? [2]
S012/011	Screening	ddMMMyyyy hh:mm	Pregnancy Test (Serum)	Negative	Negative	NCS
S012/011	Visit 2 - Day -1	ddMMMyyyy hh:mm	Pregnancy Test (Urine)	Negative	Negative	---
S012/011	Visit 2 - Day -1	ddMMMyyyy hh:mm	Salivary Alcohol Test	Negative	Negative	---
...	...	...	...	...	...	...

Note 1: A=Abnormal
Note 2: CS= Clinically Significant, NCS= Not Clinically Significant
Program: Listings\k363-lb-lst.sas

Listing 16.2.8.1 - Individual laboratory measurements

Cohort 2: 15 min (T)
Category of Laboratory Parameters: BLOOD CHEMISTRY

Subject ID	Time Point	Collection Date/time	Parameter	Value and Abnormality [1]	Normal Range or Reference Value	Clinically Significant? [2]
S024/021	Screening	ddMMMyyyy hh:mm	Sodium [mmol/L]	138	136 - 145	NCS
S024/021	Screening	ddMMMyyyy hh:mm	Potassium [mmol/L]	4.4	3.5 - 5.1	NCS
S024/021	Screening	ddMMMyyyy hh:mm	Calcium [mmol/L]	2.27	2.10 - 2.55	NCS
S024/021	Screening	ddMMMyyyy hh:mm	Chloride [mmol/L]	103	96 - 110	NCS
S024/021	Screening	ddMMMyyyy hh:mm	Phosphate [mmol/L]	0.84 [A]	0.87 - 1.45	NCS
S024/021	Screening	ddMMMyyyy hh:mm	Alkaline Phosphatase [U/L]	95	<= 104	NCS
S024/021	Screening	ddMMMyyyy hh:mm	Gamma Glutamyl Transferase [U/L]	17	<= 39	NCS
S024/021	Screening	ddMMMyyyy hh:mm	Aspartate Aminotransferase [U/L]	24	<= 35	NCS
S024/021	Screening	ddMMMyyyy hh:mm	Alanine Aminotransferase [U/L]	30	<= 35	NCS
...	...	...	...	...	...	...
S024/021	End of Study	ddMMMyyyy hh:mm	Sodium [mmol/L]	138	136 - 145	NCS
S024/021	End of Study	ddMMMyyyy hh:mm	Potassium [mmol/L]	4.4	3.5 - 5.1	NCS
S024/021	End of Study	ddMMMyyyy hh:mm	Calcium [mmol/L]	2.27	2.10 - 2.55	NCS
S024/021	End of Study	ddMMMyyyy hh:mm	Chloride [mmol/L]	103	96 - 110	NCS
S024/021	End of Study	ddMMMyyyy hh:mm	Phosphate [mmol/L]	0.84 [A]	0.87 - 1.45	NCS
S024/021	End of Study	ddMMMyyyy hh:mm	Alkaline Phosphatase [U/L]	95	<= 104	NCS
S024/021	End of Study	ddMMMyyyy hh:mm	Gamma Glutamyl Transferase [U/L]	17	<= 39	NCS
S024/021	End of Study	ddMMMyyyy hh:mm	Aspartate Aminotransferase [U/L]	24	<= 35	NCS
S024/021	End of Study	ddMMMyyyy hh:mm	Alanine Aminotransferase [U/L]	30	<= 35	NCS
...	...	...	...	...	...	...

Note 1: A=Different from reference value
Note 2: CS= Clinically Significant, NCS= Not Clinically Significant
Program: Listings\k363-lb-lst.sas

Listing 16.2.8.1 - Individual laboratory measurements

Cohort 2: 15 min (T)
Category of Laboratory Parameters: HAEMATOLOGY

Subject ID	Time Point	Collection Date/time	Parameter	Value and Abnormality [1]	Normal Range or Reference Value	Clinically Significant? [2]
S024/021	Screening	ddMMMyyyy hh:mm	Leukocytes [10^9/L]	10.02 [A]	4.00 - 10.00	NCS
S024/021	Screening	ddMMMyyyy hh:mm	Erythrocytes [10^12/L]	5.19	3.90 - 5.30	NCS
S024/021	Screening	ddMMMyyyy hh:mm	Hemoglobin [g/dL]	15.4	12.0 - 16.0	NCS
S024/021	Screening	ddMMMyyyy hh:mm	Hemoglobin [mmol/L]	9.6	7.5 - 9.9	NCS
S024/021	Screening	ddMMMyyyy hh:mm	Hematocrit [%]	44	37 - 47	NCS
S024/021	Screening	ddMMMyyyy hh:mm	Ery. Mean Corpuscular Volume [fL]	84	83 - 100	NCS
S024/021	Screening	ddMMMyyyy hh:mm	Ery. Mean Corpuscular Hemoglobin [pg]	30	27 - 34	NCS
S024/021	Screening	ddMMMyyyy hh:mm	Ery. Mean Corpuscular HGB Concentration [g/dL]	35	32 - 36	NCS
...	...	...	...	...	...	...
S024/021	End of Study	ddMMMyyyy hh:mm	Leukocytes [10^9/L]	10.02 [A]	4.00 - 10.00	NCS
S024/021	End of Study	ddMMMyyyy hh:mm	Erythrocytes [10^12/L]	5.19	3.90 - 5.30	NCS
S024/021	End of Study	ddMMMyyyy hh:mm	Hemoglobin [g/dL]	15.4	12.0 - 16.0	NCS
S024/021	End of Study	ddMMMyyyy hh:mm	Hemoglobin [mmol/L]	9.6	7.5 - 9.9	NCS
S024/021	End of Study	ddMMMyyyy hh:mm	Hematocrit [%]	44	37 - 47	NCS
S024/021	End of Study	ddMMMyyyy hh:mm	Ery. Mean Corpuscular Volume [fL]	84	83 - 100	NCS
S024/021	End of Study	ddMMMyyyy hh:mm	Ery. Mean Corpuscular Hemoglobin [pg]	30	27 - 34	NCS
S024/021	End of Study	ddMMMyyyy hh:mm	Ery. Mean Corpuscular HGB Concentration [g/dL]	35	32 - 36	NCS
...	...	...	...	...	...	...

Note 1: A=Different from reference value
Note 2: Clinical Significance is not collected for Urine Drug Screening
Program: Listings\k363-lb-lst.sas

Listing 16.2.8.1 - Individual laboratory measurements

Cohort 2: 15 min (T)
Category of Laboratory Parameters: URINE ANALYSIS

Subject ID	Time Point	Collection Date/time	Parameter	Value and Abnormality [1]	Normal Range or Reference Value	Clinically Significant? [2]
S024/021	Screening	ddMMMyyyy hh:mm	Urobilinogen	Normal	Normal	NCS
S024/021	Screening	ddMMMyyyy hh:mm	Urinary Bilirubin	Absent	Absent	NCS
S024/021	Screening	ddMMMyyyy hh:mm	Ketones	Absent	Absent	NCS
S024/021	Screening	ddMMMyyyy hh:mm	Urinary Hemoglobin	+++ [A]	Absent	NCS
S024/021	Screening	ddMMMyyyy hh:mm	Urinary Leukocytes	Absent	Absent	NCS
S024/021	Screening	ddMMMyyyy hh:mm	Sediment Examination	Checked		
S024/021	Screening	ddMMMyyyy hh:mm	Urinary Sediment Leukocytes	Absent	Absent or 0-2 per field	NCS
S024/021	Screening	ddMMMyyyy hh:mm	Urinary Sediment Erythrocytes	0-2 per field	Absent or 0-2 per field	NCS
...	...	...	...	...	...	...
S024/021	End of Study	ddMMMyyyy hh:mm	Urobilinogen	Normal	Normal	NCS
S024/021	End of Study	ddMMMyyyy hh:mm	Urinary Bilirubin	Absent	Absent	NCS
S024/021	End of Study	ddMMMyyyy hh:mm	Ketones	Absent	Absent	NCS
S024/021	End of Study	ddMMMyyyy hh:mm	Urinary Hemoglobin	+++ [A]	Absent	NCS
S024/021	End of Study	ddMMMyyyy hh:mm	Urinary Leukocytes	Absent	Absent	NCS
S024/021	End of Study	ddMMMyyyy hh:mm	Sediment Examination	Checked		
S024/021	End of Study	ddMMMyyyy hh:mm	Urinary Sediment Leukocytes	Absent	Absent or 0-2 per field	NCS
S024/021	End of Study	ddMMMyyyy hh:mm	Urinary Sediment Erythrocytes	0-2 per field	Absent or 0-2 per field	NCS
...	...	...	...	...	...	...

Note 1: A=Different from reference value
Note 2: CS= Clinically Significant, NCS= Not Clinically Significant
Program: Listings\k363-lb-lst.sas

Listing 16.2.8.1 - Individual laboratory measurements

Cohort 2: 15 min (T)
Category of Laboratory Parameters: URINE DRUG SCREENING

Subject ID	Time Point	Collection Date/time	Parameter	Value and Abnormality [1]	Normal Range or Reference Value	Clinically Significant? [2]
S024/021	Screening	ddMMMyyyy hh:mm	Amphetamine	Negative	Negative	---
S024/021	Screening	ddMMMyyyy hh:mm	Cannabinoids	Negative	Negative	---
S024/021	Screening	ddMMMyyyy hh:mm	Cocaine	Negative	Negative	---
S024/021	Screening	ddMMMyyyy hh:mm	Ecstasy	Negative	Negative	---
S024/021	Screening	ddMMMyyyy hh:mm	Methamphetamine	Negative	Negative	---
S024/021	Screening	ddMMMyyyy hh:mm	Opiate	Negative	Negative	---
S024/021	Visit 2 - Day -1	ddMMMyyyy hh:mm	Amphetamine	Negative	Negative	---
S024/021	Visit 2 - Day -1	ddMMMyyyy hh:mm	Cannabinoids	Negative	Negative	---
S024/021	Visit 2 - Day -1	ddMMMyyyy hh:mm	Cocaine	Negative	Negative	---
S024/021	Visit 2 - Day -1	ddMMMyyyy hh:mm	Ecstasy	Negative	Negative	---
S024/021	Visit 2 - Day -1	ddMMMyyyy hh:mm	Methamphetamine	Negative	Negative	---
S024/021	Visit 2 - Day -1	ddMMMyyyy hh:mm	Opiate	Negative	Negative	---
...	...	...	...	...	...	...

Note 1: A=Different from reference value
Note 2: Clinical Significance is reported for serum pregnancy test only. CS= Clinically Significant, NCS= Not Clinically Significant
Program: Listings\k363-lb-lst.sas

Listing 16.2.8.1 - Individual laboratory measurements

Cohort 2: 15 min (T)
Category of Laboratory Parameters: VIROLOGY

Subject ID	Time Point	Collection Date/time	Parameter	Value and Abnormality [1]	Normal Range or Reference Value	Clinically Significant? [2]
S024/021	Screening	ddMMMyyyy hh:mm	Hepatitis B Virus Surface Antigen	Negative	Negative	NCS
S024/021	Screening	ddMMMyyyy hh:mm	Hepatitis C Virus Antibody	Negative	Negative	NCS
S024/021	Screening	ddMMMyyyy hh:mm	HIV Ag/Ab Combo	Negative	Negative	NCS
...	...	...	...	...	...	...

Note 1: A=Abnormal
Note 2: CS= Clinically Significant, NCS= Not Clinically Significant
Program: Listings\k363-lb-lst.sas

Listing 16.2.8.1 - Individual laboratory measurements

Cohort 2: 15 min (T)
Category of Laboratory Parameters: SALIVARY BREATH TEST AND PREGNANCY TEST

Subject ID	Time Point	Collection Date/time	Parameter	Value and Abnormality [1]	Normal Range or Reference Value	Clinically Significant? [2]
S024/021	Screening	ddMMMyyyy hh:mm	Pregnancy Test (Serum)	Negative	Negative	NCS
S024/021	Visit 2 - Day -1	ddMMMyyyy hh:mm	Pregnancy Test (Urine)	Negative	Negative	---
S024/021	Visit 2 - Day -1	ddMMMyyyy hh:mm	Salivary Alcohol Test	Negative	Negative	---
...	...	...	...	...	...	...

Note 1: A=Different from reference value
Note 2: CS= Clinically Significant, NCS= Not Clinically Significant
Program: Listings\k363-lb-lst.sas

Listing 16.2.8.1 - Individual laboratory measurements

Cohort 3: 5 min (T)
Category of Laboratory Parameters: BLOOD CHEMISTRY

Subject ID	Time Point	Collection Date/time	Parameter	Value and Abnormality [1]	Normal Range or Reference Value	Clinically Significant? [2]
S036/031	Screening	ddMMMyyyy hh:mm	Sodium [mmol/L]	138	136 - 145	NCS
S036/031	Screening	ddMMMyyyy hh:mm	Potassium [mmol/L]	4.4	3.5 - 5.1	NCS
S036/031	Screening	ddMMMyyyy hh:mm	Calcium [mmol/L]	2.27	2.10 - 2.55	NCS
S036/031	Screening	ddMMMyyyy hh:mm	Chloride [mmol/L]	103	96 - 110	NCS
S036/031	Screening	ddMMMyyyy hh:mm	Phosphate [mmol/L]	0.84 [A]	0.87 - 1.45	NCS
S036/031	Screening	ddMMMyyyy hh:mm	Alkaline Phosphatase [U/L]	95	<= 104	NCS
S036/031	Screening	ddMMMyyyy hh:mm	Gamma Glutamyl Transferase [U/L]	17	<= 39	NCS
S036/031	Screening	ddMMMyyyy hh:mm	Aspartate Aminotransferase [U/L]	24	<= 35	NCS
S036/031	Screening	ddMMMyyyy hh:mm	Alanine Aminotransferase [U/L]	30	<= 35	NCS
...	...	...	...	...	...	...
S036/031	End of Study	ddMMMyyyy hh:mm	Sodium [mmol/L]	138	136 - 145	NCS
S036/031	End of Study	ddMMMyyyy hh:mm	Potassium [mmol/L]	4.4	3.5 - 5.1	NCS
S036/031	End of Study	ddMMMyyyy hh:mm	Calcium [mmol/L]	2.27	2.10 - 2.55	NCS
S036/031	End of Study	ddMMMyyyy hh:mm	Chloride [mmol/L]	103	96 - 110	NCS
S036/031	End of Study	ddMMMyyyy hh:mm	Phosphate [mmol/L]	0.84 [A]	0.87 - 1.45	NCS
S036/031	End of Study	ddMMMyyyy hh:mm	Alkaline Phosphatase [U/L]	95	<= 104	NCS
S036/031	End of Study	ddMMMyyyy hh:mm	Gamma Glutamyl Transferase [U/L]	17	<= 39	NCS
S036/031	End of Study	ddMMMyyyy hh:mm	Aspartate Aminotransferase [U/L]	24	<= 35	NCS
S036/031	End of Study	ddMMMyyyy hh:mm	Alanine Aminotransferase [U/L]	30	<= 35	NCS
...	...	...	...	...	...	...

Note 1: A=Different from reference value
Note 2: Clinical Significance is not collected for Urine Drug Screening
Program: Listings\k363-lb-lst.sas

Listing 16.2.8.1 - Individual laboratory measurements

Cohort 3: 5 min (T)
Category of Laboratory Parameters: HAEMATOLOGY

Subject ID	Time Point	Collection Date/time	Parameter	Value and Abnormality [1]	Normal Range or Reference Value	Clinically Significant? [2]
S036/031	Screening	ddMMMyyyy hh:mm	Leukocytes [10^9/L]	10.02 [A]	4.00 - 10.00	NCS
S036/031	Screening	ddMMMyyyy hh:mm	Erythrocytes [10^12/L]	5.19	3.90 - 5.30	NCS
S036/031	Screening	ddMMMyyyy hh:mm	Hemoglobin [g/dL]	15.4	12.0 - 16.0	NCS
S036/031	Screening	ddMMMyyyy hh:mm	Hemoglobin [mmol/L]	9.6	7.5 - 9.9	NCS
S036/031	Screening	ddMMMyyyy hh:mm	Hematocrit [%]	44	37 - 47	NCS
S036/031	Screening	ddMMMyyyy hh:mm	Ery. Mean Corpuscular Volume [fL]	84	83 - 100	NCS
S036/031	Screening	ddMMMyyyy hh:mm	Ery. Mean Corpuscular Hemoglobin [pg]	30	27 - 34	NCS
S036/031	Screening	ddMMMyyyy hh:mm	Ery. Mean Corpuscular HGB Concentration [g/dL]	35	32 - 36	NCS
...	...	...	...	...	...	...
S036/031	End of Study	ddMMMyyyy hh:mm	Leukocytes [10^9/L]	10.02 [A]	4.00 - 10.00	NCS
S036/031	End of Study	ddMMMyyyy hh:mm	Erythrocytes [10^12/L]	5.19	3.90 - 5.30	NCS
S036/031	End of Study	ddMMMyyyy hh:mm	Hemoglobin [g/dL]	15.4	12.0 - 16.0	NCS
S036/031	End of Study	ddMMMyyyy hh:mm	Hemoglobin [mmol/L]	9.6	7.5 - 9.9	NCS
S036/031	End of Study	ddMMMyyyy hh:mm	Hematocrit [%]	44	37 - 47	NCS
S036/031	End of Study	ddMMMyyyy hh:mm	Ery. Mean Corpuscular Volume [fL]	84	83 - 100	NCS
S036/031	End of Study	ddMMMyyyy hh:mm	Ery. Mean Corpuscular Hemoglobin [pg]	30	27 - 34	NCS
S036/031	End of Study	ddMMMyyyy hh:mm	Ery. Mean Corpuscular HGB Concentration [g/dL]	35	32 - 36	NCS
...	...	...	...	...	...	...

Note 1: A=Different from reference value
Note 2: CS= Clinically Significant, NCS= Not Clinically Significant
Program: Listings\k363-lb-lst.sas

Listing 16.2.8.1 - Individual laboratory measurements

Cohort 3: 5 min (T)
Category of Laboratory Parameters: URINE ANALYSIS

Subject ID	Time Point	Collection Date/time	Parameter	Value and Abnormality [1]	Normal Range or Reference Value	Clinically Significant? [2]
S036/031	Screening	ddMMMyyyy hh:mm	Urobilinogen	Normal	Normal	NCS
S036/031	Screening	ddMMMyyyy hh:mm	Urinary Bilirubin	Absent	Absent	NCS
S036/031	Screening	ddMMMyyyy hh:mm	Ketones	Absent	Absent	NCS
S036/031	Screening	ddMMMyyyy hh:mm	Urinary Hemoglobin	+++ [A]	Absent	NCS
S036/031	Screening	ddMMMyyyy hh:mm	Urinary Leukocytes	Absent	Absent	NCS
S036/031	Screening	ddMMMyyyy hh:mm	Sediment Examination	Checked		
S036/031	Screening	ddMMMyyyy hh:mm	Urinary Sediment Leukocytes	Absent	Absent or 0-2 per field	NCS
S036/031	Screening	ddMMMyyyy hh:mm	Urinary Sediment Erythrocytes	0-2 per field	Absent or 0-2 per field	NCS
...	...	...	...	...	...	...
S036/031	End of Study	ddMMMyyyy hh:mm	Urobilinogen	Normal	Normal	NCS
S036/031	End of Study	ddMMMyyyy hh:mm	Urinary Bilirubin	Absent	Absent	NCS
S036/031	End of Study	ddMMMyyyy hh:mm	Ketones	Absent	Absent	NCS
S036/031	End of Study	ddMMMyyyy hh:mm	Urinary Hemoglobin	+++ [A]	Absent	NCS
S036/031	End of Study	ddMMMyyyy hh:mm	Urinary Leukocytes	Absent	Absent	NCS
S036/031	End of Study	ddMMMyyyy hh:mm	Sediment Examination	Checked		
S036/031	End of Study	ddMMMyyyy hh:mm	Urinary Sediment Leukocytes	Absent	Absent or 0-2 per field	NCS
S036/031	End of Study	ddMMMyyyy hh:mm	Urinary Sediment Erythrocytes	0-2 per field	Absent or 0-2 per field	NCS
...	...	...	...	...	...	...

Note 1: A=Different from reference value
Note 2: Clinical Significance is reported for serum pregnancy test only. CS= Clinically Significant, NCS= Not Clinically Significant
Program: Listings\k363-lb-lst.sas

Listing 16.2.8.1 - Individual laboratory measurements

Cohort 3: 5 min (T)
Category of Laboratory Parameters: URINE DRUG SCREENING

Subject ID	Time Point	Collection Date/time	Parameter	Value and Abnormality [1]	Normal Range or Reference Value	Clinically Significant? [2]
S036/031	Screening	ddMMMyyyy hh:mm	Amphetamine	Negative	Negative	---
S036/031	Screening	ddMMMyyyy hh:mm	Cannabinoids	Negative	Negative	---
S036/031	Screening	ddMMMyyyy hh:mm	Cocaine	Negative	Negative	---
S036/031	Screening	ddMMMyyyy hh:mm	Ecstasy	Negative	Negative	---
S036/031	Screening	ddMMMyyyy hh:mm	Methamphetamine	Negative	Negative	---
S036/031	Screening	ddMMMyyyy hh:mm	Opiate	Negative	Negative	---
S036/031	Visit 2 - Day -1	ddMMMyyyy hh:mm	Amphetamine	Negative	Negative	---
S036/031	Visit 2 - Day -1	ddMMMyyyy hh:mm	Cannabinoids	Negative	Negative	---
S036/031	Visit 2 - Day -1	ddMMMyyyy hh:mm	Cocaine	Negative	Negative	---
S036/031	Visit 2 - Day -1	ddMMMyyyy hh:mm	Ecstasy	Negative	Negative	---
S036/031	Visit 2 - Day -1	ddMMMyyyy hh:mm	Methamphetamine	Negative	Negative	---
S036/031	Visit 2 - Day -1	ddMMMyyyy hh:mm	Opiate	Negative	Negative	---
...	...	...	...	...	...	...

Note 1: A=Abnormal
Note 2: CS= Clinically Significant, NCS= Not Clinically Significant
Program: Listings\k363-lb-lst.sas

Listing 16.2.8.1 - Individual laboratory measurements

Cohort 3: 5 min (T)
Category of Laboratory Parameters: VIROLOGY

Subject ID	Time Point	Collection Date/time	Parameter	Value and Abnormality [1]	Normal Range or Reference Value	Clinically Significant? [2]
S036/031	Screening	ddMMMyyyy hh:mm	Hepatitis B Virus Surface Antigen	Negative	Negative	NCS
S036/031	Screening	ddMMMyyyy hh:mm	Hepatitis C Virus Antibody	Negative	Negative	NCS
S036/031	Screening	ddMMMyyyy hh:mm	HIV Ag/Ab Combo	Negative	Negative	NCS
...	...	...	...	...	...	...

Note 1: A=Different from reference value
Note 2: CS= Clinically Significant, NCS= Not Clinically Significant
Program: Listings\k363-lb-lst.sas

Listing 16.2.8.1 - Individual laboratory measurements

Cohort 3: 5 min (T)
Category of Laboratory Parameters: SALIVARY BREATH TEST AND PREGNANCY TEST

Subject ID	Time Point	Collection Date/time	Parameter	Value and Abnormality [1]	Normal Range or Reference Value	Clinically Significant? [2]
S036/031	Screening	ddMMMyyyy hh:mm	Pregnancy Test (Serum)	Negative	Negative	NCS
S036/031	Visit 2 - Day -1	ddMMMyyyy hh:mm	Pregnancy Test (Urine)	Negative	Negative	---
S036/031	Visit 2 - Day -1	ddMMMyyyy hh:mm	Salivary Alcohol Test	Negative	Negative	---
...	...	...	...	...	...	...

Note 1: A=Different from reference value
Note 2: Clinical Significance is not collected for Urine Drug Screening
Program: Listings\k363-lb-lst.sas

Listing 16.2.8.1 - Individual laboratory measurements

Cohort 4: 2 min (T)
Category of Laboratory Parameters: BLOOD CHEMISTRY

Subject ID	Time Point	Collection Date/time	Parameter	Value and Abnormality [1]	Normal Range or Reference Value	Clinically Significant? [2]
S048/041	Screening	ddMMMyyyy hh:mm	Sodium [mmol/L]	138	136 - 145	NCS
S048/041	Screening	ddMMMyyyy hh:mm	Potassium [mmol/L]	4.4	3.5 - 5.1	NCS
S048/041	Screening	ddMMMyyyy hh:mm	Calcium [mmol/L]	2.27	2.10 - 2.55	NCS
S048/041	Screening	ddMMMyyyy hh:mm	Chloride [mmol/L]	103	96 - 110	NCS
S048/041	Screening	ddMMMyyyy hh:mm	Phosphate [mmol/L]	0.84 [A]	0.87 - 1.45	NCS
S048/041	Screening	ddMMMyyyy hh:mm	Alkaline Phosphatase [U/L]	95	<= 104	NCS
S048/041	Screening	ddMMMyyyy hh:mm	Gamma Glutamyl Transferase [U/L]	17	<= 39	NCS
S048/041	Screening	ddMMMyyyy hh:mm	Aspartate Aminotransferase [U/L]	24	<= 35	NCS
S048/041	Screening	ddMMMyyyy hh:mm	Alanine Aminotransferase [U/L]	30	<= 35	NCS
...	...	...	...	...	...	...
S048/041	End of Study	ddMMMyyyy hh:mm	Sodium [mmol/L]	138	136 - 145	NCS
S048/041	End of Study	ddMMMyyyy hh:mm	Potassium [mmol/L]	4.4	3.5 - 5.1	NCS
S048/041	End of Study	ddMMMyyyy hh:mm	Calcium [mmol/L]	2.27	2.10 - 2.55	NCS
S048/041	End of Study	ddMMMyyyy hh:mm	Chloride [mmol/L]	103	96 - 110	NCS
S048/041	End of Study	ddMMMyyyy hh:mm	Phosphate [mmol/L]	0.84 [A]	0.87 - 1.45	NCS
S048/041	End of Study	ddMMMyyyy hh:mm	Alkaline Phosphatase [U/L]	95	<= 104	NCS
S048/041	End of Study	ddMMMyyyy hh:mm	Gamma Glutamyl Transferase [U/L]	17	<= 39	NCS
S048/041	End of Study	ddMMMyyyy hh:mm	Aspartate Aminotransferase [U/L]	24	<= 35	NCS
S048/041	End of Study	ddMMMyyyy hh:mm	Alanine Aminotransferase [U/L]	30	<= 35	NCS
...	...	...	...	...	...	...

Note 1: A=Different from reference value
Note 2: CS= Clinically Significant, NCS= Not Clinically Significant
Program: Listings\k363-lb-lst.sas

Listing 16.2.8.1 - Individual laboratory measurements

Cohort 4: 2 min (T)
Category of Laboratory Parameters: HAEMATOLOGY

Subject ID	Time Point	Collection Date/time	Parameter	Value and Abnormality [1]	Normal Range or Reference Value	Clinically Significant? [2]
S048/041	Screening	ddMMMyyyy hh:mm	Leukocytes [10^9/L]	10.02 [A]	4.00 - 10.00	NCS
S048/041	Screening	ddMMMyyyy hh:mm	Erythrocytes [10^12/L]	5.19	3.90 - 5.30	NCS
S048/041	Screening	ddMMMyyyy hh:mm	Hemoglobin [g/dL]	15.4	12.0 - 16.0	NCS
S048/041	Screening	ddMMMyyyy hh:mm	Hemoglobin [mmol/L]	9.6	7.5 - 9.9	NCS
S048/041	Screening	ddMMMyyyy hh:mm	Hematocrit [%]	44	37 - 47	NCS
S048/041	Screening	ddMMMyyyy hh:mm	Ery. Mean Corpuscular Volume [fL]	84	83 - 100	NCS
S048/041	Screening	ddMMMyyyy hh:mm	Ery. Mean Corpuscular Hemoglobin [pg]	30	27 - 34	NCS
S048/041	Screening	ddMMMyyyy hh:mm	Ery. Mean Corpuscular HGB Concentration [g/dL]	35	32 - 36	NCS
...	...	...	...	...	...	...
S048/041	End of Study	ddMMMyyyy hh:mm	Leukocytes [10^9/L]	10.02 [A]	4.00 - 10.00	NCS
S048/041	End of Study	ddMMMyyyy hh:mm	Erythrocytes [10^12/L]	5.19	3.90 - 5.30	NCS
S048/041	End of Study	ddMMMyyyy hh:mm	Hemoglobin [g/dL]	15.4	12.0 - 16.0	NCS
S048/041	End of Study	ddMMMyyyy hh:mm	Hemoglobin [mmol/L]	9.6	7.5 - 9.9	NCS
S048/041	End of Study	ddMMMyyyy hh:mm	Hematocrit [%]	44	37 - 47	NCS
S048/041	End of Study	ddMMMyyyy hh:mm	Ery. Mean Corpuscular Volume [fL]	84	83 - 100	NCS
S048/041	End of Study	ddMMMyyyy hh:mm	Ery. Mean Corpuscular Hemoglobin [pg]	30	27 - 34	NCS
S048/041	End of Study	ddMMMyyyy hh:mm	Ery. Mean Corpuscular HGB Concentration [g/dL]	35	32 - 36	NCS
...	...	...	...	...	...	...

Note 1: A=Different from reference value
Note 2: Clinical Significance is reported for serum pregnancy test only. CS= Clinically Significant, NCS= Not Clinically Significant
Program: Listings\k363-lb-lst.sas

Listing 16.2.8.1 - Individual laboratory measurements

Cohort 4: 2 min (T)
Category of Laboratory Parameters: URINE ANALYSIS

Subject ID	Time Point	Collection Date/time	Parameter	Value and Abnormality [1]	Normal Range or Reference Value	Clinically Significant? [2]
S048/041	Screening	ddMMMyyyy hh:mm	Urobilinogen	Normal	Normal	NCS
S048/041	Screening	ddMMMyyyy hh:mm	Urinary Bilirubin	Absent	Absent	NCS
S048/041	Screening	ddMMMyyyy hh:mm	Ketones	Absent	Absent	NCS
S048/041	Screening	ddMMMyyyy hh:mm	Urinary Hemoglobin	+++ [A]	Absent	NCS
S048/041	Screening	ddMMMyyyy hh:mm	Urinary Leukocytes	Absent	Absent	NCS
S048/041	Screening	ddMMMyyyy hh:mm	Sediment Examination	Checked		
S048/041	Screening	ddMMMyyyy hh:mm	Urinary Sediment Leukocytes	Absent	Absent or 0-2 per field	NCS
S048/041	Screening	ddMMMyyyy hh:mm	Urinary Sediment Erythrocytes	0-2 per field	Absent or 0-2 per field	NCS
...	...	...	...	...	...	...
S048/041	End of Study	ddMMMyyyy hh:mm	Urobilinogen	Normal	Normal	NCS
S048/041	End of Study	ddMMMyyyy hh:mm	Urinary Bilirubin	Absent	Absent	NCS
S048/041	End of Study	ddMMMyyyy hh:mm	Ketones	Absent	Absent	NCS
S048/041	End of Study	ddMMMyyyy hh:mm	Urinary Hemoglobin	+++ [A]	Absent	NCS
S048/041	End of Study	ddMMMyyyy hh:mm	Urinary Leukocytes	Absent	Absent	NCS
S048/041	End of Study	ddMMMyyyy hh:mm	Sediment Examination	Checked		
S048/041	End of Study	ddMMMyyyy hh:mm	Urinary Sediment Leukocytes	Absent	Absent or 0-2 per field	NCS
S048/041	End of Study	ddMMMyyyy hh:mm	Urinary Sediment Erythrocytes	0-2 per field	Absent or 0-2 per field	NCS
...	...	...	...	...	...	...

Note 1: A=Abnormal
Note 2: CS= Clinically Significant, NCS= Not Clinically Significant
Program: Listings\k363-lb-lst.sas

Listing 16.2.8.1 - Individual laboratory measurements

Cohort 4: 2 min (T)
Category of Laboratory Parameters: URINE DRUG SCREENING

Subject ID	Time Point	Collection Date/time	Parameter	Value and Abnormality [1]	Normal Range or Reference Value	Clinically Significant? [2]
S048/041	Screening	ddMMMyyyy hh:mm	Amphetamine	Negative	Negative	---
S048/041	Screening	ddMMMyyyy hh:mm	Cannabinoids	Negative	Negative	---
S048/041	Screening	ddMMMyyyy hh:mm	Cocaine	Negative	Negative	---
S048/041	Screening	ddMMMyyyy hh:mm	Ecstasy	Negative	Negative	---
S048/041	Screening	ddMMMyyyy hh:mm	Methamphetamine	Negative	Negative	---
S048/041	Screening	ddMMMyyyy hh:mm	Opiate	Negative	Negative	---
S048/041	Visit 2 - Day -1	ddMMMyyyy hh:mm	Amphetamine	Negative	Negative	---
S048/041	Visit 2 - Day -1	ddMMMyyyy hh:mm	Cannabinoids	Negative	Negative	---
S048/041	Visit 2 - Day -1	ddMMMyyyy hh:mm	Cocaine	Negative	Negative	---
S048/041	Visit 2 - Day -1	ddMMMyyyy hh:mm	Ecstasy	Negative	Negative	---
S048/041	Visit 2 - Day -1	ddMMMyyyy hh:mm	Methamphetamine	Negative	Negative	---
S048/041	Visit 2 - Day -1	ddMMMyyyy hh:mm	Opiate	Negative	Negative	---
...	...	...	...	...	...	...

Note 1: A=Different from reference value
Note 2: CS= Clinically Significant, NCS= Not Clinically Significant
Program: Listings\k363-lb-lst.sas

Listing 16.2.8.1 - Individual laboratory measurements

Cohort 4: 2 min (T)
Category of Laboratory Parameters: VIROLOGY

Subject ID	Time Point	Collection Date/time	Parameter	Value and Abnormality [1]	Normal Range or Reference Value	Clinically Significant? [2]
S048/041	Screening	ddMMMyyyy hh:mm	Hepatitis B Virus Surface Antigen	Negative	Negative	NCS
S048/041	Screening	ddMMMyyyy hh:mm	Hepatitis C Virus Antibody	Negative	Negative	NCS
S048/041	Screening	ddMMMyyyy hh:mm	HIV Ag/Ab Combo	Negative	Negative	NCS
...	...	...	...	...	...	...

Note 1: A=Different from reference value
Note 2: Clinical Significance is not collected for Urine Drug Screening
Program: Listings\k363-lb-lst.sas

Listing 16.2.8.1 - Individual laboratory measurements

Cohort 4: 2 min (T)
Category of Laboratory Parameters: SALIVARY BREATH TEST AND PREGNANCY TEST

Subject ID	Time Point	Collection Date/time	Parameter	Value and Abnormality [1]	Normal Range or Reference Value	Clinically Significant? [2]
S048/041	Screening	ddMMMyyyy hh:mm	Pregnancy Test (Serum)	Negative	Negative	NCS
S048/041	Visit 2 - Day -1	ddMMMyyyy hh:mm	Pregnancy Test (Urine)	Negative	Negative	---
S048/041	Visit 2 - Day -1	ddMMMyyyy hh:mm	Salivary Alcohol Test	Negative	Negative	---
...	...	...	...	...	...	...

Note 1: A=Different from reference value
Note 2: CS= Clinically Significant, NCS= Not Clinically Significant
Program: Listings\k363-lb-lst.sas

Listing 16.2.8.2 - Investigator's interpretation of laboratory test results

Cohort 1: 30 min (Rα)

Subject ID	Time Point	Assessment Date	Specimen	Investigator's Interpretation	Which AE the Abnormality is related to?	Which MH the Abnormality is related to?
S001/001	Screening	ddMMMyyyy	Blood	Abnormal, Not Clinically Significant	---	---
S001/001	Screening	ddMMMyyyy	Urine	Abnormal, Not Clinically Significant	---	---
S001/001	End of Study	ddMMMyyyy	Blood	Normal	---	---
S001/001	End of Study	ddMMMyyyy	Urine	Normal	---	---
...	...	...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Note: End of Study = final visit or early termination visit
Program: Listings\k363-lb-lst.sas

Listing 16.2.8.2 - Investigator's interpretation of laboratory test results

Cohort 1: 30 min (T)

Subject ID	Time Point	Assessment Date	Specimen	Investigator's Interpretation	Which AE the Abnormality is related to?	Which MH the Abnormality is related to?
S012/011	Screening	ddMMMyyyy	Blood	Abnormal, Not Clinically Significant	---	---
S012/011	Screening	ddMMMyyyy	Urine	Abnormal, Not Clinically Significant	---	---
S012/011	End of Study	ddMMMyyyy	Blood	Normal	---	---
S012/011	End of Study	ddMMMyyyy	Urine	Normal	---	---
...	...	...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Note: End of Study = final visit or early termination visit
Program: Listings\k363-lb-lst.sas

Listing 16.2.8.2 - Investigator's interpretation of laboratory test results

Cohort 2: 15 min (T)

Subject ID	Time Point	Assessment Date	Specimen	Investigator's Interpretation	Which AE the Abnormality is related to?	Which MH the Abnormality is related to?
S024/021	Screening	ddMMMyyyy	Blood	Abnormal, Not Clinically Significant	---	---
S024/021	Screening	ddMMMyyyy	Urine	Abnormal, Not Clinically Significant	---	---
S024/021	End of Study	ddMMMyyyy	Blood	Normal	---	---
S024/021	End of Study	ddMMMyyyy	Urine	Normal	---	---
...	...	...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Note: End of Study = final visit or early termination visit
Program: Listings\k363-lb-lst.sas

Listing 16.2.8.2 - Investigator's interpretation of laboratory test results

Cohort 3: 5 min (T)

Subject ID	Time Point	Assessment Date	Specimen	Investigator's Interpretation	Which AE the Abnormality is related to?	Which MH the Abnormality is related to?
S036/031	Screening	ddMMMyyyy	Blood	Abnormal, Not Clinically Significant	---	---
S036/031	Screening	ddMMMyyyy	Urine	Abnormal, Not Clinically Significant	---	---
S036/031	End of Study	ddMMMyyyy	Blood	Normal	---	---
S036/031	End of Study	ddMMMyyyy	Urine	Normal	---	---
...	...	...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Note: End of Study = final visit or early termination visit
Program: Listings\k363-lb-lst.sas

Listing 16.2.8.2 - Investigator's interpretation of laboratory test results

Cohort 4: 2 min (T)

Subject ID	Time Point	Assessment Date	Specimen	Investigator's Interpretation	Which AE the Abnormality is related to?	Which MH the Abnormality is related to?
S048/041	Screening	ddMMMyyyy	Blood	Abnormal, Not Clinically Significant	---	---
S048/041	Screening	ddMMMyyyy	Urine	Abnormal, Not Clinically Significant	---	---
S048/041	End of Study	ddMMMyyyy	Blood	Normal	---	---
S048/041	End of Study	ddMMMyyyy	Urine	Normal	---	---
...	...	...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Note: End of Study = final visit or early termination visit
Program: Listings\k363-lb-lst.sas

Listing 16.2.9.1 - Vital signs and body weight

Cohort 1: 30 min (Rα)

Subject ID	Time Point	Assessment Date/Time	Parameter	Value and Abnormality [1]	Normal Range
S001/001	Screening	ddMMMyyyy hh:mm	Systolic Blood Pressure [mmHg]	96 [L]	100-139
S001/001	Screening	ddMMMyyyy hh:mm	Diastolic Blood Pressure [mmHg]	58	50-89
S001/001	Screening	ddMMMyyyy hh:mm	Heart Rate [beats/min]	88	50-90
S001/001	Screening	ddMMMyyyy hh:mm	Weight [kg]	55.5	NA
S001/001	Screening	ddMMMyyyy hh:mm	Height [cm]	166	NA
S001/001	Screening	ddMMMyyyy hh:mm	BMI [kg/m^2]	20.1	NA
S001/001	Visit 2	ddMMMyyyy hh:mm	Systolic Blood Pressure [mmHg]	96 [L]	100-139
S001/001	Visit 2	ddMMMyyyy hh:mm	Diastolic Blood Pressure [mmHg]	58	50-89
S001/001	Visit 2	ddMMMyyyy hh:mm	Heart Rate [beats/min]	88	50-90
S001/001	Visit 2	ddMMMyyyy hh:mm	Weight [kg]	55.5	NA
S001/001	Visit 3 - Pre dose	ddMMMyyyy hh:mm	Systolic Blood Pressure [mmHg]	96 [L]	100-139
S001/001	Visit 3 - Pre dose	ddMMMyyyy hh:mm	Diastolic Blood Pressure [mmHg]	58	50-89
S001/001	Visit 3 - Pre dose	ddMMMyyyy hh:mm	Heart Rate [beats/min]	88	50-90
S001/001	Visit 3 - at the end of injection	ddMMMyyyy hh:mm	Systolic Blood Pressure [mmHg]	96 [L]	100-139
S001/001	Visit 3 - at the end of injection	ddMMMyyyy hh:mm	Diastolic Blood Pressure [mmHg]	58	50-89
S001/001	Visit 3 - at the end of injection	ddMMMyyyy hh:mm	Heart Rate [beats/min]	88	50-90
S001/001	Visit 3 - 1 h after the end of injection	ddMMMyyyy hh:mm	Systolic Blood Pressure [mmHg]	96 [L]	100-139

Note: Subjects are listed according to the cohort they belong to _
End of Study = final visit or early termination visit
Note 1: H=Higher than upper normal limit, L=Lower than lower normal limit
Program: Listings\k363-vs-lst.sas

Listing 16.2.9.1 - Vital signs and body weight

Cohort 1: 30 min (Rα)

Subject ID	Time Point	Assessment Date/Time	Parameter	Value and Abnormality [1]	Normal Range
S001/001	Visit 3 - 1 h after the end of injection	ddMMMyyyy hh:mm	Diastolic Blood Pressure [mmHg]	58	50-89
S001/001	Visit 3 - 1 h after the end of injection	ddMMMyyyy hh:mm	Heart Rate [beats/min]	88	50-90
S001/001	Visit 3 - 2 h after the end of injection	ddMMMyyyy hh:mm	Systolic Blood Pressure [mmHg]	96 [L]	100-139
S001/001	Visit 3 - 2 h after the end of injection	ddMMMyyyy hh:mm	Diastolic Blood Pressure [mmHg]	58	50-89
S001/001	Visit 3 - 2 h after the end of injection	ddMMMyyyy hh:mm	Heart Rate [beats/min]	88	50-90
S001/001	Visit 3 - 4 h after the end of injection	ddMMMyyyy hh:mm	Systolic Blood Pressure [mmHg]	96 [L]	100-139
S001/001	Visit 3 - 4 h after the end of injection	ddMMMyyyy hh:mm	Diastolic Blood Pressure [mmHg]	58	50-89
S001/001	Visit 3 - 4 h after the end of injection	ddMMMyyyy hh:mm	Heart Rate [beats/min]	88	50-90
S001/001	Visit 3 - 24 h after the end of injection	ddMMMyyyy hh:mm	Systolic Blood Pressure [mmHg]	96 [L]	100-139
S001/001	Visit 3 - 24 h after the end of injection	ddMMMyyyy hh:mm	Diastolic Blood Pressure [mmHg]	58	50-89
S001/001	Visit 3 - 24 h after the end of injection	ddMMMyyyy hh:mm	Heart Rate [beats/min]	88	50-90
S001/001	Visit 3 - 24 h after the end of injection	ddMMMyyyy hh:mm	Weight [kg]	55.5	NA
S001/001	End of Study	ddMMMyyyy hh:mm	Systolic Blood Pressure [mmHg]	96 [L]	100-139
S001/001	End of Study	ddMMMyyyy hh:mm	Diastolic Blood Pressure [mmHg]	58	50-89
S001/001	End of Study	ddMMMyyyy hh:mm	Heart Rate [beats/min]	88	50-90
S001/001	End of Study	ddMMMyyyy hh:mm	Weight [kg]	55.5	NA
...	...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to _
End of Study = final visit or early termination visit
Note 1: H=Higher than upper normal limit, L=Lower than lower normal limit
Program: Listings\k363-vs-lst.sas

Listing 16.2.9.1 - Vital signs and body weight

Cohort 1: 30 min (T)

Subject ID	Time Point	Assessment Date/Time	Parameter	Value and Abnormality [1]	Normal Range
S012/011	Screening	ddMMMyyyy hh:mm	Systolic Blood Pressure [mmHg]	96 [L]	100-139
S012/011	Screening	ddMMMyyyy hh:mm	Diastolic Blood Pressure [mmHg]	58	50-89
S012/011	Screening	ddMMMyyyy hh:mm	Heart Rate [beats/min]	88	50-90
S012/011	Screening	ddMMMyyyy hh:mm	Weight [kg]	55.5	NA
S012/011	Screening	ddMMMyyyy hh:mm	Height [cm]	166	NA
S012/011	Screening	ddMMMyyyy hh:mm	BMI [kg/m^2]	20.1	NA
S012/011	Visit 2	ddMMMyyyy hh:mm	Systolic Blood Pressure [mmHg]	96 [L]	100-139
S012/011	Visit 2	ddMMMyyyy hh:mm	Diastolic Blood Pressure [mmHg]	58	50-89
S012/011	Visit 2	ddMMMyyyy hh:mm	Heart Rate [beats/min]	88	50-90
S012/011	Visit 2	ddMMMyyyy hh:mm	Weight [kg]	55.5	NA
S012/011	Visit 3 - Pre dose	ddMMMyyyy hh:mm	Systolic Blood Pressure [mmHg]	96 [L]	100-139
S012/011	Visit 3 - Pre dose	ddMMMyyyy hh:mm	Diastolic Blood Pressure [mmHg]	58	50-89
S012/011	Visit 3 - Pre dose	ddMMMyyyy hh:mm	Heart Rate [beats/min]	88	50-90
S012/011	Visit 3 - at the end of injection	ddMMMyyyy hh:mm	Systolic Blood Pressure [mmHg]	96 [L]	100-139
S012/011	Visit 3 - at the end of injection	ddMMMyyyy hh:mm	Diastolic Blood Pressure [mmHg]	58	50-89
S012/011	Visit 3 - at the end of injection	ddMMMyyyy hh:mm	Heart Rate [beats/min]	88	50-90
S012/011	Visit 3 - 1 h after the end of injection	ddMMMyyyy hh:mm	Systolic Blood Pressure [mmHg]	96 [L]	100-139

Note: Subjects are listed according to the cohort they belong to
End of Study = final visit or early termination visit
Note 1: H=Higher than upper normal limit, L=Lower than lower normal limit
Program: Listings\k363-vs-lst.sas

Listing 16.2.9.1 - Vital signs and body weight

Cohort 1: 30 min (T)

Subject ID	Time Point	Assessment Date/Time	Parameter	Value and Abnormality [1]	Normal Range
S012/011	Visit 3 - 1 h after the end of injection	ddMMMyyyy hh:mm	Diastolic Blood Pressure [mmHg]	58	50-89
S012/011	Visit 3 - 1 h after the end of injection	ddMMMyyyy hh:mm	Heart Rate [beats/min]	88	50-90
S012/011	Visit 3 - 2 h after the end of injection	ddMMMyyyy hh:mm	Systolic Blood Pressure [mmHg]	96 [L]	100-139
S012/011	Visit 3 - 2 h after the end of injection	ddMMMyyyy hh:mm	Diastolic Blood Pressure [mmHg]	58	50-89
S012/011	Visit 3 - 2 h after the end of injection	ddMMMyyyy hh:mm	Heart Rate [beats/min]	88	50-90
S012/011	Visit 3 - 4 h after the end of injection	ddMMMyyyy hh:mm	Systolic Blood Pressure [mmHg]	96 [L]	100-139
S012/011	Visit 3 - 4 h after the end of injection	ddMMMyyyy hh:mm	Diastolic Blood Pressure [mmHg]	58	50-89
S012/011	Visit 3 - 4 h after the end of injection	ddMMMyyyy hh:mm	Heart Rate [beats/min]	88	50-90
S012/011	Visit 3 - 24 h after the end of injection	ddMMMyyyy hh:mm	Systolic Blood Pressure [mmHg]	96 [L]	100-139
S012/011	Visit 3 - 24 h after the end of injection	ddMMMyyyy hh:mm	Diastolic Blood Pressure [mmHg]	58	50-89
S012/011	Visit 3 - 24 h after the end of injection	ddMMMyyyy hh:mm	Heart Rate [beats/min]	88	50-90
S012/011	Visit 3 - 24 h after the end of injection	ddMMMyyyy hh:mm	Weight [kg]	55.5	NA
S012/011	End of Study	ddMMMyyyy hh:mm	Systolic Blood Pressure [mmHg]	96 [L]	100-139
S012/011	End of Study	ddMMMyyyy hh:mm	Diastolic Blood Pressure [mmHg]	58	50-89
S012/011	End of Study	ddMMMyyyy hh:mm	Heart Rate [beats/min]	88	50-90
S012/011	End of Study	ddMMMyyyy hh:mm	Weight [kg]	55.5	NA
...	...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
End of Study = final visit or early termination visit
Note 1: H=Higher than upper normal limit, L=Lower than lower normal limit
Program: Listings\k363-vs-lst.sas

Listing 16.2.9.1 - Vital signs and body weight

Cohort 2: 15 min (T)

Subject ID	Time Point	Assessment Date/Time	Parameter	Value and Abnormality [1]	Normal Range
S024/021	Screening	ddMMMyyyy hh:mm	Systolic Blood Pressure [mmHg]	96 [L]	100-139
S024/021	Screening	ddMMMyyyy hh:mm	Diastolic Blood Pressure [mmHg]	58	50-89
S024/021	Screening	ddMMMyyyy hh:mm	Heart Rate [beats/min]	88	50-90
S024/021	Screening	ddMMMyyyy hh:mm	Weight [kg]	55.5	NA
S024/021	Screening	ddMMMyyyy hh:mm	Height [cm]	166	NA
S024/021	Screening	ddMMMyyyy hh:mm	BMI [kg/m^2]	20.1	NA
S024/021	Visit 2	ddMMMyyyy hh:mm	Systolic Blood Pressure [mmHg]	96 [L]	100-139
S024/021	Visit 2	ddMMMyyyy hh:mm	Diastolic Blood Pressure [mmHg]	58	50-89
S024/021	Visit 2	ddMMMyyyy hh:mm	Heart Rate [beats/min]	88	50-90
S024/021	Visit 2	ddMMMyyyy hh:mm	Weight [kg]	55.5	NA
S024/021	Visit 3 - Pre dose	ddMMMyyyy hh:mm	Systolic Blood Pressure [mmHg]	96 [L]	100-139
S024/021	Visit 3 - Pre dose	ddMMMyyyy hh:mm	Diastolic Blood Pressure [mmHg]	58	50-89
S024/021	Visit 3 - Pre dose	ddMMMyyyy hh:mm	Heart Rate [beats/min]	88	50-90
S024/021	Visit 3 - at the end of injection	ddMMMyyyy hh:mm	Systolic Blood Pressure [mmHg]	96 [L]	100-139
S024/021	Visit 3 - at the end of injection	ddMMMyyyy hh:mm	Diastolic Blood Pressure [mmHg]	58	50-89
S024/021	Visit 3 - at the end of injection	ddMMMyyyy hh:mm	Heart Rate [beats/min]	88	50-90
S024/021	Visit 3 - 1 h after the end of injection	ddMMMyyyy hh:mm	Systolic Blood Pressure [mmHg]	96 [L]	100-139

Note: Subjects are listed according to the cohort they belong to
End of Study = final visit or early termination visit
Note 1: H=Higher than upper normal limit, L=Lower than lower normal limit
Program: Listings\k363-vs-lst.sas

Listing 16.2.9.1 - Vital signs and body weight

Cohort 2: 15 min (T)

Subject ID	Time Point	Assessment Date/Time	Parameter	Value and Abnormality [1]	Normal Range
S024/021	Visit 3 - 1 h after the end of injection	ddMMMyyyy hh:mm	Diastolic Blood Pressure [mmHg]	58	50-89
S024/021	Visit 3 - 1 h after the end of injection	ddMMMyyyy hh:mm	Heart Rate [beats/min]	88	50-90
S024/021	Visit 3 - 2 h after the end of injection	ddMMMyyyy hh:mm	Systolic Blood Pressure [mmHg]	96 [L]	100-139
S024/021	Visit 3 - 2 h after the end of injection	ddMMMyyyy hh:mm	Diastolic Blood Pressure [mmHg]	58	50-89
S024/021	Visit 3 - 2 h after the end of injection	ddMMMyyyy hh:mm	Heart Rate [beats/min]	88	50-90
S024/021	Visit 3 - 4 h after the end of injection	ddMMMyyyy hh:mm	Systolic Blood Pressure [mmHg]	96 [L]	100-139
S024/021	Visit 3 - 4 h after the end of injection	ddMMMyyyy hh:mm	Diastolic Blood Pressure [mmHg]	58	50-89
S024/021	Visit 3 - 4 h after the end of injection	ddMMMyyyy hh:mm	Heart Rate [beats/min]	88	50-90
S024/021	Visit 3 - 24 h after the end of injection	ddMMMyyyy hh:mm	Systolic Blood Pressure [mmHg]	96 [L]	100-139
S024/021	Visit 3 - 24 h after the end of injection	ddMMMyyyy hh:mm	Diastolic Blood Pressure [mmHg]	58	50-89
S024/021	Visit 3 - 24 h after the end of injection	ddMMMyyyy hh:mm	Heart Rate [beats/min]	88	50-90
S024/021	Visit 3 - 24 h after the end of injection	ddMMMyyyy hh:mm	Weight [kg]	55.5	NA
S024/021	End of Study	ddMMMyyyy hh:mm	Systolic Blood Pressure [mmHg]	96 [L]	100-139
S024/021	End of Study	ddMMMyyyy hh:mm	Diastolic Blood Pressure [mmHg]	58	50-89
S024/021	End of Study	ddMMMyyyy hh:mm	Heart Rate [beats/min]	88	50-90
S024/021	End of Study	ddMMMyyyy hh:mm	Weight [kg]	55.5	NA
...	...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
End of Study = final visit or early termination visit
Note 1: H=Higher than upper normal limit, L=Lower than lower normal limit
Program: Listings\k363-vs-lst.sas

Listing 16.2.9.1 - Vital signs and body weight

Cohort 3: 5 min (T)

Subject ID	Time Point	Assessment Date/Time	Parameter	Value and Abnormality [1]	Normal Range
S036/031	Screening	ddMMMyyyy hh:mm	Systolic Blood Pressure [mmHg]	96 [L]	100-139
S036/031	Screening	ddMMMyyyy hh:mm	Diastolic Blood Pressure [mmHg]	58	50-89
S036/031	Screening	ddMMMyyyy hh:mm	Heart Rate [beats/min]	88	50-90
S036/031	Screening	ddMMMyyyy hh:mm	Weight [kg]	55.5	NA
S036/031	Screening	ddMMMyyyy hh:mm	Height [cm]	166	NA
S036/031	Screening	ddMMMyyyy hh:mm	BMI [kg/m^2]	20.1	NA
S036/031	Visit 2	ddMMMyyyy hh:mm	Systolic Blood Pressure [mmHg]	96 [L]	100-139
S036/031	Visit 2	ddMMMyyyy hh:mm	Diastolic Blood Pressure [mmHg]	58	50-89
S036/031	Visit 2	ddMMMyyyy hh:mm	Heart Rate [beats/min]	88	50-90
S036/031	Visit 2	ddMMMyyyy hh:mm	Weight [kg]	55.5	NA
S036/031	Visit 3 - Pre dose	ddMMMyyyy hh:mm	Systolic Blood Pressure [mmHg]	96 [L]	100-139
S036/031	Visit 3 - Pre dose	ddMMMyyyy hh:mm	Diastolic Blood Pressure [mmHg]	58	50-89
S036/031	Visit 3 - Pre dose	ddMMMyyyy hh:mm	Heart Rate [beats/min]	88	50-90
S036/031	Visit 3 - at the end of injection	ddMMMyyyy hh:mm	Systolic Blood Pressure [mmHg]	96 [L]	100-139
S036/031	Visit 3 - at the end of injection	ddMMMyyyy hh:mm	Diastolic Blood Pressure [mmHg]	58	50-89
S036/031	Visit 3 - at the end of injection	ddMMMyyyy hh:mm	Heart Rate [beats/min]	88	50-90
S036/031	Visit 3 - 1 h after the end of injection	ddMMMyyyy hh:mm	Systolic Blood Pressure [mmHg]	96 [L]	100-139

Note: Subjects are listed according to the cohort they belong to
End of Study = final visit or early termination visit
Note 1: H=Higher than upper normal limit, L=Lower than lower normal limit
Program: Listings\k363-vs-lst.sas

Listing 16.2.9.1 - Vital signs and body weight

Cohort 3: 5 min (T)

Subject ID	Time Point	Assessment Date/Time	Parameter	Value and Abnormality [1]	Normal Range
S036/031	Visit 3 - 1 h after the end of injection	ddMMMyyyy hh:mm	Diastolic Blood Pressure [mmHg]	58	50-89
S036/031	Visit 3 - 1 h after the end of injection	ddMMMyyyy hh:mm	Heart Rate [beats/min]	88	50-90
S036/031	Visit 3 - 2 h after the end of injection	ddMMMyyyy hh:mm	Systolic Blood Pressure [mmHg]	96 [L]	100-139
S036/031	Visit 3 - 2 h after the end of injection	ddMMMyyyy hh:mm	Diastolic Blood Pressure [mmHg]	58	50-89
S036/031	Visit 3 - 2 h after the end of injection	ddMMMyyyy hh:mm	Heart Rate [beats/min]	88	50-90
S036/031	Visit 3 - 4 h after the end of injection	ddMMMyyyy hh:mm	Systolic Blood Pressure [mmHg]	96 [L]	100-139
S036/031	Visit 3 - 4 h after the end of injection	ddMMMyyyy hh:mm	Diastolic Blood Pressure [mmHg]	58	50-89
S036/031	Visit 3 - 4 h after the end of injection	ddMMMyyyy hh:mm	Heart Rate [beats/min]	88	50-90
S036/031	Visit 3 - 24 h after the end of injection	ddMMMyyyy hh:mm	Systolic Blood Pressure [mmHg]	96 [L]	100-139
S036/031	Visit 3 - 24 h after the end of injection	ddMMMyyyy hh:mm	Diastolic Blood Pressure [mmHg]	58	50-89
S036/031	Visit 3 - 24 h after the end of injection	ddMMMyyyy hh:mm	Heart Rate [beats/min]	88	50-90
S036/031	Visit 3 - 24 h after the end of injection	ddMMMyyyy hh:mm	Weight [kg]	55.5	NA
S036/031	End of Study	ddMMMyyyy hh:mm	Systolic Blood Pressure [mmHg]	96 [L]	100-139
S036/031	End of Study	ddMMMyyyy hh:mm	Diastolic Blood Pressure [mmHg]	58	50-89
S036/031	End of Study	ddMMMyyyy hh:mm	Heart Rate [beats/min]	88	50-90
S036/031	End of Study	ddMMMyyyy hh:mm	Weight [kg]	55.5	NA
...	...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
End of Study = final visit or early termination visit
Note 1: H=Higher than upper normal limit, L=Lower than lower normal limit
Program: Listings\k363-vs-lst.sas

Listing 16.2.9.1 - Vital signs and body weight

Cohort 4: 2 min (T)

Subject ID	Time Point	Assessment Date/Time	Parameter	Value and Abnormality [1]	Normal Range
S048/041	Screening	ddMMMyyyy hh:mm	Systolic Blood Pressure [mmHg]	96 [L]	100-139
S048/041	Screening	ddMMMyyyy hh:mm	Diastolic Blood Pressure [mmHg]	58	50-89
S048/041	Screening	ddMMMyyyy hh:mm	Heart Rate [beats/min]	88	50-90
S048/041	Screening	ddMMMyyyy hh:mm	Weight [kg]	55.5	NA
S048/041	Screening	ddMMMyyyy hh:mm	Height [cm]	166	NA
S048/041	Screening	ddMMMyyyy hh:mm	BMI [kg/m^2]	20.1	NA
S048/041	Visit 2	ddMMMyyyy hh:mm	Systolic Blood Pressure [mmHg]	96 [L]	100-139
S048/041	Visit 2	ddMMMyyyy hh:mm	Diastolic Blood Pressure [mmHg]	58	50-89
S048/041	Visit 2	ddMMMyyyy hh:mm	Heart Rate [beats/min]	88	50-90
S048/041	Visit 2	ddMMMyyyy hh:mm	Weight [kg]	55.5	NA
S048/041	Visit 3 - Pre dose	ddMMMyyyy hh:mm	Systolic Blood Pressure [mmHg]	96 [L]	100-139
S048/041	Visit 3 - Pre dose	ddMMMyyyy hh:mm	Diastolic Blood Pressure [mmHg]	58	50-89
S048/041	Visit 3 - Pre dose	ddMMMyyyy hh:mm	Heart Rate [beats/min]	88	50-90
S048/041	Visit 3 - at the end of injection	ddMMMyyyy hh:mm	Systolic Blood Pressure [mmHg]	96 [L]	100-139
S048/041	Visit 3 - at the end of injection	ddMMMyyyy hh:mm	Diastolic Blood Pressure [mmHg]	58	50-89
S048/041	Visit 3 - at the end of injection	ddMMMyyyy hh:mm	Heart Rate [beats/min]	88	50-90
S048/041	Visit 3 - 1 h after the end of injection	ddMMMyyyy hh:mm	Systolic Blood Pressure [mmHg]	96 [L]	100-139

Note: Subjects are listed according to the cohort they belong to
End of Study = final visit or early termination visit
Note 1: H=Higher than upper normal limit, L=Lower than lower normal limit
Program: Listings\k363-vs-lst.sas

Listing 16.2.9.1 - Vital signs and body weight

Cohort 4: 2 min (T)

Subject ID	Time Point	Assessment Date/Time	Parameter	Value and Abnormality [1]	Normal Range
S048/041	Visit 3 - 1 h after the end of injection	ddMMMyyyy hh:mm	Diastolic Blood Pressure [mmHg]	58	50-89
S048/041	Visit 3 - 1 h after the end of injection	ddMMMyyyy hh:mm	Heart Rate [beats/min]	88	50-90
S048/041	Visit 3 - 2 h after the end of injection	ddMMMyyyy hh:mm	Systolic Blood Pressure [mmHg]	96 [L]	100-139
S048/041	Visit 3 - 2 h after the end of injection	ddMMMyyyy hh:mm	Diastolic Blood Pressure [mmHg]	58	50-89
S048/041	Visit 3 - 2 h after the end of injection	ddMMMyyyy hh:mm	Heart Rate [beats/min]	88	50-90
S048/041	Visit 3 - 4 h after the end of injection	ddMMMyyyy hh:mm	Systolic Blood Pressure [mmHg]	96 [L]	100-139
S048/041	Visit 3 - 4 h after the end of injection	ddMMMyyyy hh:mm	Diastolic Blood Pressure [mmHg]	58	50-89
S048/041	Visit 3 - 4 h after the end of injection	ddMMMyyyy hh:mm	Heart Rate [beats/min]	88	50-90
S048/041	Visit 3 - 24 h after the end of injection	ddMMMyyyy hh:mm	Systolic Blood Pressure [mmHg]	96 [L]	100-139
S048/041	Visit 3 - 24 h after the end of injection	ddMMMyyyy hh:mm	Diastolic Blood Pressure [mmHg]	58	50-89
S048/041	Visit 3 - 24 h after the end of injection	ddMMMyyyy hh:mm	Heart Rate [beats/min]	88	50-90
S048/041	Visit 3 - 24 h after the end of injection	ddMMMyyyy hh:mm	Weight [kg]	55.5	NA
S048/041	End of Study	ddMMMyyyy hh:mm	Systolic Blood Pressure [mmHg]	96 [L]	100-139
S048/041	End of Study	ddMMMyyyy hh:mm	Diastolic Blood Pressure [mmHg]	58	50-89
S048/041	End of Study	ddMMMyyyy hh:mm	Heart Rate [beats/min]	88	50-90
S048/041	End of Study	ddMMMyyyy hh:mm	Weight [kg]	55.5	NA
...	...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
End of Study = final visit or early termination visit
Note 1: H=Higher than upper normal limit, L=Lower than lower normal limit
Program: Listings\k363-vs-lst.sas

Listing 16.2.9.2 - Recorded parameters of ECG

Cohort 1: 30 min (Rα)

Subject ID	Time Point	Replicate	Assessment Date/Time	Parameter	Value
S001/001	Screening	1st	ddMMMyyyy hh:mm	Heart Rate [beats/min]	xxx
S001/001	Screening	1st	ddMMMyyyy hh:mm	RR Interval [msec]	xxx
S001/001	Screening	1st	ddMMMyyyy hh:mm	PR Interval [msec]	xxx
S001/001	Screening	1st	ddMMMyyyy hh:mm	QRS Duration [msec]	xxx
S001/001	Screening	1st	ddMMMyyyy hh:mm	QT Interval [msec]	xxx
S001/001	Screening	1st	ddMMMyyyy hh:mm	QTcB Interval [msec]	xxx
S001/001	Screening	1st	ddMMMyyyy hh:mm	QTcF Interval [msec]	xxx
S001/001	Screening	2nd	ddMMMyyyy hh:mm	Heart Rate [beats/min]	xxx
S001/001	Screening	2nd	ddMMMyyyy hh:mm	RR Interval [msec]	xxx
S001/001	Screening	2nd	ddMMMyyyy hh:mm	PR Interval [msec]	xxx
S001/001	Screening	2nd	ddMMMyyyy hh:mm	QRS Duration [msec]	xxx
S001/001	Screening	2nd	ddMMMyyyy hh:mm	QT Interval [msec]	xxx
S001/001	Screening	2nd	ddMMMyyyy hh:mm	QTcB Interval [msec]	xxx
S001/001	Screening	2nd	ddMMMyyyy hh:mm	QTcF Interval [msec]	xxx
S001/001	Screening	3rd	ddMMMyyyy hh:mm	Heart Rate [beats/min]	xxx
S001/001	Screening	3rd	ddMMMyyyy hh:mm	RR Interval [msec]	xxx
S001/001	Screening	3rd	ddMMMyyyy hh:mm	PR Interval [msec]	xxx
S001/001	Screening	3rd	ddMMMyyyy hh:mm	QRS Duration [msec]	xxx

Note: Subjects are listed according to the cohort they belong to
Program: Listings\k363-eg-lst.sas

Listing 16.2.9.2 - Recorded parameters of ECG

Cohort 1: 30 min (Rα)

Subject ID	Time Point	Replicate	Assessment Date/Time	Parameter	Value
S001/001	Screening	3rd	ddMMMyyyy hh:mm	QT Interval [msec]	xxx
S001/001	Screening	3rd	ddMMMyyyy hh:mm	QTcB Interval [msec]	xxx
S001/001	Screening	3rd	ddMMMyyyy hh:mm	QTcF Interval [msec]	xxx
S001/001	Visit 3 - Pre dose	1st	ddMMMyyyy hh:mm	Heart Rate [beats/min]	xxx
S001/001	Visit 3 - Pre dose	1st	ddMMMyyyy hh:mm	RR Interval [msec]	xxx
S001/001	Visit 3 - Pre dose	1st	ddMMMyyyy hh:mm	PR Interval [msec]	xxx
S001/001	Visit 3 - Pre dose	1st	ddMMMyyyy hh:mm	QRS Duration [msec]	xxx
S001/001	Visit 3 - Pre dose	1st	ddMMMyyyy hh:mm	QT Interval [msec]	xxx
S001/001	Visit 3 - Pre dose	1st	ddMMMyyyy hh:mm	QTcB Interval [msec]	xxx
S001/001	Visit 3 - Pre dose	1st	ddMMMyyyy hh:mm	QTcF Interval [msec]	xxx
S001/001	Visit 3 - Pre dose	2nd	ddMMMyyyy hh:mm	Heart Rate [beats/min]	xxx
S001/001	Visit 3 - Pre dose	2nd	ddMMMyyyy hh:mm	RR Interval [msec]	xxx
S001/001	Visit 3 - Pre dose	2nd	ddMMMyyyy hh:mm	PR Interval [msec]	xxx
S001/001	Visit 3 - Pre dose	2nd	ddMMMyyyy hh:mm	QRS Duration [msec]	xxx
S001/001	Visit 3 - Pre dose	2nd	ddMMMyyyy hh:mm	QT Interval [msec]	xxx
S001/001	Visit 3 - Pre dose	2nd	ddMMMyyyy hh:mm	QTcB Interval [msec]	xxx
S001/001	Visit 3 - Pre dose	2nd	ddMMMyyyy hh:mm	QTcF Interval [msec]	xxx
S001/001	Visit 3 - Pre dose	3rd	ddMMMyyyy hh:mm	Heart Rate [beats/min]	xxx

Note: Subjects are listed according to the cohort they belong to
Program: Listings\k363-eg-lst.sas

Listing 16.2.9.2 - Recorded parameters of ECG

Cohort 1: 30 min (Rα)

Subject ID	Time Point	Replicate	Assessment Date/Time	Parameter	Value
S001/001	Visit 3 - Pre dose	3rd	ddMMMyyyy hh:mm	RR Interval [msec]	xxx
S001/001	Visit 3 - Pre dose	3rd	ddMMMyyyy hh:mm	PR Interval [msec]	xxx
S001/001	Visit 3 - Pre dose	3rd	ddMMMyyyy hh:mm	QRS Duration [msec]	xxx
S001/001	Visit 3 - Pre dose	3rd	ddMMMyyyy hh:mm	QT Interval [msec]	xxx
S001/001	Visit 3 - Pre dose	3rd	ddMMMyyyy hh:mm	QTcB Interval [msec]	xxx
S001/001	Visit 3 - Pre dose	3rd	ddMMMyyyy hh:mm	QTcF Interval [msec]	xxx
...	...	...	...	...	...
S001/001	End of Study	1st	ddMMMyyyy hh:mm	Heart Rate [beats/min]	xxx
S001/001	End of Study	1st	ddMMMyyyy hh:mm	RR Interval [msec]	xxx
S001/001	End of Study	1st	ddMMMyyyy hh:mm	PR Interval [msec]	xxx
S001/001	End of Study	1st	ddMMMyyyy hh:mm	QRS Duration [msec]	xxx
S001/001	End of Study	1st	ddMMMyyyy hh:mm	QT Interval [msec]	xxx
S001/001	End of Study	1st	ddMMMyyyy hh:mm	QTcB Interval [msec]	xxx
S001/001	End of Study	1st	ddMMMyyyy hh:mm	QTcF Interval [msec]	xxx
S001/001	End of Study	2nd	ddMMMyyyy hh:mm	Heart Rate [beats/min]	xxx
S001/001	End of Study	2nd	ddMMMyyyy hh:mm	RR Interval [msec]	xxx
S001/001	End of Study	2nd	ddMMMyyyy hh:mm	PR Interval [msec]	xxx
S001/001	End of Study	2nd	ddMMMyyyy hh:mm	QRS Duration [msec]	xxx

Note: Subjects are listed according to the cohort they belong to
Program: Listings\k363-eg-lst.sas

Listing 16.2.9.2 - Recorded parameters of ECG

Cohort 1: 30 min (Rα)

Subject ID	Time Point	Replicate	Assessment Date/Time	Parameter	Value
S001/001	End of Study	2nd	ddMMMyyyy hh:mm	QT Interval [msec]	xxx
S001/001	End of Study	2nd	ddMMMyyyy hh:mm	QTcB Interval [msec]	xxx
S001/001	End of Study	2nd	ddMMMyyyy hh:mm	QTcF Interval [msec]	xxx
S001/001	End of Study	3rd	ddMMMyyyy hh:mm	Heart Rate [beats/min]	xxx
S001/001	End of Study	3rd	ddMMMyyyy hh:mm	RR Interval [msec]	xxx
S001/001	End of Study	3rd	ddMMMyyyy hh:mm	PR Interval [msec]	xxx
S001/001	End of Study	3rd	ddMMMyyyy hh:mm	QRS Duration [msec]	xxx
S001/001	End of Study	3rd	ddMMMyyyy hh:mm	QT Interval [msec]	xxx
S001/001	End of Study	3rd	ddMMMyyyy hh:mm	QTcB Interval [msec]	xxx
S001/001	End of Study	3rd	ddMMMyyyy hh:mm	QTcF Interval [msec]	xxx

Note: Subjects are listed according to the cohort they belong to
Program: Listings\k363-eg-lst.sas

Listing 16.2.9.2 - Recorded parameters of ECG

Cohort 1: 30 min (T)

Subject ID	Time Point	Replicate	Assessment Date/Time	Parameter	Value
S001/001	Screening	1st	ddMMMyyyy hh:mm	Heart Rate [beats/min]	xxx
S001/001	Screening	1st	ddMMMyyyy hh:mm	RR Interval [msec]	xxx
S001/001	Screening	1st	ddMMMyyyy hh:mm	PR Interval [msec]	xxx
S001/001	Screening	1st	ddMMMyyyy hh:mm	QRS Duration [msec]	xxx
S001/001	Screening	1st	ddMMMyyyy hh:mm	QT Interval [msec]	xxx
S001/001	Screening	1st	ddMMMyyyy hh:mm	QTcB Interval [msec]	xxx
S001/001	Screening	1st	ddMMMyyyy hh:mm	QTcF Interval [msec]	xxx
S001/001	Screening	2nd	ddMMMyyyy hh:mm	Heart Rate [beats/min]	xxx
S001/001	Screening	2nd	ddMMMyyyy hh:mm	RR Interval [msec]	xxx
S001/001	Screening	2nd	ddMMMyyyy hh:mm	PR Interval [msec]	xxx
S001/001	Screening	2nd	ddMMMyyyy hh:mm	QRS Duration [msec]	xxx
S001/001	Screening	2nd	ddMMMyyyy hh:mm	QT Interval [msec]	xxx
S001/001	Screening	2nd	ddMMMyyyy hh:mm	QTcB Interval [msec]	xxx
S001/001	Screening	2nd	ddMMMyyyy hh:mm	QTcF Interval [msec]	xxx
S001/001	Screening	3rd	ddMMMyyyy hh:mm	Heart Rate [beats/min]	xxx
S001/001	Screening	3rd	ddMMMyyyy hh:mm	RR Interval [msec]	xxx
S001/001	Screening	3rd	ddMMMyyyy hh:mm	PR Interval [msec]	xxx
S001/001	Screening	3rd	ddMMMyyyy hh:mm	QRS Duration [msec]	xxx

Note: Subjects are listed according to the cohort they belong to
Program: Listings\k363-eg-lst.sas

Listing 16.2.9.2 - Recorded parameters of ECG

Cohort 1: 30 min (T)

Subject ID	Time Point	Replicate	Assessment Date/Time	Parameter	Value
S001/001	Screening	3rd	ddMMMyyyy hh:mm	QT Interval [msec]	xxx
S001/001	Screening	3rd	ddMMMyyyy hh:mm	QTcB Interval [msec]	xxx
S001/001	Screening	3rd	ddMMMyyyy hh:mm	QTcF Interval [msec]	xxx
S001/001	Visit 3 - Pre dose	1st	ddMMMyyyy hh:mm	Heart Rate [beats/min]	xxx
S001/001	Visit 3 - Pre dose	1st	ddMMMyyyy hh:mm	RR Interval [msec]	xxx
S001/001	Visit 3 - Pre dose	1st	ddMMMyyyy hh:mm	PR Interval [msec]	xxx
S001/001	Visit 3 - Pre dose	1st	ddMMMyyyy hh:mm	QRS Duration [msec]	xxx
S001/001	Visit 3 - Pre dose	1st	ddMMMyyyy hh:mm	QT Interval [msec]	xxx
S001/001	Visit 3 - Pre dose	1st	ddMMMyyyy hh:mm	QTcB Interval [msec]	xxx
S001/001	Visit 3 - Pre dose	1st	ddMMMyyyy hh:mm	QTcF Interval [msec]	xxx
S001/001	Visit 3 - Pre dose	2nd	ddMMMyyyy hh:mm	Heart Rate [beats/min]	xxx
S001/001	Visit 3 - Pre dose	2nd	ddMMMyyyy hh:mm	RR Interval [msec]	xxx
S001/001	Visit 3 - Pre dose	2nd	ddMMMyyyy hh:mm	PR Interval [msec]	xxx
S001/001	Visit 3 - Pre dose	2nd	ddMMMyyyy hh:mm	QRS Duration [msec]	xxx
S001/001	Visit 3 - Pre dose	2nd	ddMMMyyyy hh:mm	QT Interval [msec]	xxx
S001/001	Visit 3 - Pre dose	2nd	ddMMMyyyy hh:mm	QTcB Interval [msec]	xxx
S001/001	Visit 3 - Pre dose	2nd	ddMMMyyyy hh:mm	QTcF Interval [msec]	xxx
S001/001	Visit 3 - Pre dose	3rd	ddMMMyyyy hh:mm	Heart Rate [beats/min]	xxx

Note: Subjects are listed according to the cohort they belong to
Program: Listings\k363-eg-lst.sas

Listing 16.2.9.2 - Recorded parameters of ECG

Cohort 1: 30 min (T)

Subject ID	Time Point	Replicate	Assessment Date/Time	Parameter	Value
S001/001	Visit 3 - Pre dose	3rd	ddMMMyyyy hh:mm	RR Interval [msec]	xxx
S001/001	Visit 3 - Pre dose	3rd	ddMMMyyyy hh:mm	PR Interval [msec]	xxx
S001/001	Visit 3 - Pre dose	3rd	ddMMMyyyy hh:mm	QRS Duration [msec]	xxx
S001/001	Visit 3 - Pre dose	3rd	ddMMMyyyy hh:mm	QT Interval [msec]	xxx
S001/001	Visit 3 - Pre dose	3rd	ddMMMyyyy hh:mm	QTcB Interval [msec]	xxx
S001/001	Visit 3 - Pre dose	3rd	ddMMMyyyy hh:mm	QTcF Interval [msec]	xxx
...	...	...	...	...	...
S001/001	End of Study	1st	ddMMMyyyy hh:mm	Heart Rate [beats/min]	xxx
S001/001	End of Study	1st	ddMMMyyyy hh:mm	RR Interval [msec]	xxx
S001/001	End of Study	1st	ddMMMyyyy hh:mm	PR Interval [msec]	xxx
S001/001	End of Study	1st	ddMMMyyyy hh:mm	QRS Duration [msec]	xxx
S001/001	End of Study	1st	ddMMMyyyy hh:mm	QT Interval [msec]	xxx
S001/001	End of Study	1st	ddMMMyyyy hh:mm	QTcB Interval [msec]	xxx
S001/001	End of Study	1st	ddMMMyyyy hh:mm	QTcF Interval [msec]	xxx
S001/001	End of Study	2nd	ddMMMyyyy hh:mm	Heart Rate [beats/min]	xxx
S001/001	End of Study	2nd	ddMMMyyyy hh:mm	RR Interval [msec]	xxx
S001/001	End of Study	2nd	ddMMMyyyy hh:mm	PR Interval [msec]	xxx
S001/001	End of Study	2nd	ddMMMyyyy hh:mm	QRS Duration [msec]	xxx

Note: Subjects are listed according to the cohort they belong to
Program: Listings\k363-eg-lst.sas

Listing 16.2.9.2 - Recorded parameters of ECG

Cohort 1: 30 min (T)

Subject ID	Time Point	Replicate	Assessment Date/Time	Parameter	Value
S001/001	End of Study	2nd	ddMMMyyyy hh:mm	QT Interval [msec]	xxx
S001/001	End of Study	2nd	ddMMMyyyy hh:mm	QTcB Interval [msec]	xxx
S001/001	End of Study	2nd	ddMMMyyyy hh:mm	QTcF Interval [msec]	xxx
S001/001	End of Study	3rd	ddMMMyyyy hh:mm	Heart Rate [beats/min]	xxx
S001/001	End of Study	3rd	ddMMMyyyy hh:mm	RR Interval [msec]	xxx
S001/001	End of Study	3rd	ddMMMyyyy hh:mm	PR Interval [msec]	xxx
S001/001	End of Study	3rd	ddMMMyyyy hh:mm	QRS Duration [msec]	xxx
S001/001	End of Study	3rd	ddMMMyyyy hh:mm	QT Interval [msec]	xxx
S001/001	End of Study	3rd	ddMMMyyyy hh:mm	QTcB Interval [msec]	xxx
S001/001	End of Study	3rd	ddMMMyyyy hh:mm	QTcF Interval [msec]	xxx

Note: Subjects are listed according to the cohort they belong to
Program: Listings\k363-eg-lst.sas

Listing 16.2.9.2 - Recorded parameters of ECG

Cohort 2: 15 min (T)

Subject ID	Time Point	Replicate	Assessment Date/Time	Parameter	Value
S001/001	Screening	1st	ddMMMyyyy hh:mm	Heart Rate [beats/min]	xxx
S001/001	Screening	1st	ddMMMyyyy hh:mm	RR Interval [msec]	xxx
S001/001	Screening	1st	ddMMMyyyy hh:mm	PR Interval [msec]	xxx
S001/001	Screening	1st	ddMMMyyyy hh:mm	QRS Duration [msec]	xxx
S001/001	Screening	1st	ddMMMyyyy hh:mm	QT Interval [msec]	xxx
S001/001	Screening	1st	ddMMMyyyy hh:mm	QTcB Interval [msec]	xxx
S001/001	Screening	1st	ddMMMyyyy hh:mm	QTcF Interval [msec]	xxx
S001/001	Screening	2nd	ddMMMyyyy hh:mm	Heart Rate [beats/min]	xxx
S001/001	Screening	2nd	ddMMMyyyy hh:mm	RR Interval [msec]	xxx
S001/001	Screening	2nd	ddMMMyyyy hh:mm	PR Interval [msec]	xxx
S001/001	Screening	2nd	ddMMMyyyy hh:mm	QRS Duration [msec]	xxx
S001/001	Screening	2nd	ddMMMyyyy hh:mm	QT Interval [msec]	xxx
S001/001	Screening	2nd	ddMMMyyyy hh:mm	QTcB Interval [msec]	xxx
S001/001	Screening	2nd	ddMMMyyyy hh:mm	QTcF Interval [msec]	xxx
S001/001	Screening	3rd	ddMMMyyyy hh:mm	Heart Rate [beats/min]	xxx
S001/001	Screening	3rd	ddMMMyyyy hh:mm	RR Interval [msec]	xxx
S001/001	Screening	3rd	ddMMMyyyy hh:mm	PR Interval [msec]	xxx
S001/001	Screening	3rd	ddMMMyyyy hh:mm	QRS Duration [msec]	xxx

Note: Subjects are listed according to the cohort they belong to
Program: Listings\k363-eg-lst.sas

Listing 16.2.9.2 - Recorded parameters of ECG

Cohort 2: 15 min (T)

Subject ID	Time Point	Replicate	Assessment Date/Time	Parameter	Value
S001/001	Screening	3rd	ddMMMyyyy hh:mm	QT Interval [msec]	xxx
S001/001	Screening	3rd	ddMMMyyyy hh:mm	QTcB Interval [msec]	xxx
S001/001	Screening	3rd	ddMMMyyyy hh:mm	QTcF Interval [msec]	xxx
S001/001	Visit 3 - Pre dose	1st	ddMMMyyyy hh:mm	Heart Rate [beats/min]	xxx
S001/001	Visit 3 - Pre dose	1st	ddMMMyyyy hh:mm	RR Interval [msec]	xxx
S001/001	Visit 3 - Pre dose	1st	ddMMMyyyy hh:mm	PR Interval [msec]	xxx
S001/001	Visit 3 - Pre dose	1st	ddMMMyyyy hh:mm	QRS Duration [msec]	xxx
S001/001	Visit 3 - Pre dose	1st	ddMMMyyyy hh:mm	QT Interval [msec]	xxx
S001/001	Visit 3 - Pre dose	1st	ddMMMyyyy hh:mm	QTcB Interval [msec]	xxx
S001/001	Visit 3 - Pre dose	1st	ddMMMyyyy hh:mm	QTcF Interval [msec]	xxx
S001/001	Visit 3 - Pre dose	2nd	ddMMMyyyy hh:mm	Heart Rate [beats/min]	xxx
S001/001	Visit 3 - Pre dose	2nd	ddMMMyyyy hh:mm	RR Interval [msec]	xxx
S001/001	Visit 3 - Pre dose	2nd	ddMMMyyyy hh:mm	PR Interval [msec]	xxx
S001/001	Visit 3 - Pre dose	2nd	ddMMMyyyy hh:mm	QRS Duration [msec]	xxx
S001/001	Visit 3 - Pre dose	2nd	ddMMMyyyy hh:mm	QT Interval [msec]	xxx
S001/001	Visit 3 - Pre dose	2nd	ddMMMyyyy hh:mm	QTcB Interval [msec]	xxx
S001/001	Visit 3 - Pre dose	2nd	ddMMMyyyy hh:mm	QTcF Interval [msec]	xxx
S001/001	Visit 3 - Pre dose	3rd	ddMMMyyyy hh:mm	Heart Rate [beats/min]	xxx

Note: Subjects are listed according to the cohort they belong to
Program: Listings\k363-eg-lst.sas

Listing 16.2.9.2 - Recorded parameters of ECG

Cohort 2: 15 min (T)

Subject ID	Time Point	Replicate	Assessment Date/Time	Parameter	Value
S001/001	Visit 3 - Pre dose	3rd	ddMMMyyyy hh:mm	RR Interval [msec]	xxx
S001/001	Visit 3 - Pre dose	3rd	ddMMMyyyy hh:mm	PR Interval [msec]	xxx
S001/001	Visit 3 - Pre dose	3rd	ddMMMyyyy hh:mm	QRS Duration [msec]	xxx
S001/001	Visit 3 - Pre dose	3rd	ddMMMyyyy hh:mm	QT Interval [msec]	xxx
S001/001	Visit 3 - Pre dose	3rd	ddMMMyyyy hh:mm	QTcB Interval [msec]	xxx
S001/001	Visit 3 - Pre dose	3rd	ddMMMyyyy hh:mm	QTcF Interval [msec]	xxx
...	...	...	...	...	...
S001/001	End of Study	1st	ddMMMyyyy hh:mm	Heart Rate [beats/min]	xxx
S001/001	End of Study	1st	ddMMMyyyy hh:mm	RR Interval [msec]	xxx
S001/001	End of Study	1st	ddMMMyyyy hh:mm	PR Interval [msec]	xxx
S001/001	End of Study	1st	ddMMMyyyy hh:mm	QRS Duration [msec]	xxx
S001/001	End of Study	1st	ddMMMyyyy hh:mm	QT Interval [msec]	xxx
S001/001	End of Study	1st	ddMMMyyyy hh:mm	QTcB Interval [msec]	xxx
S001/001	End of Study	1st	ddMMMyyyy hh:mm	QTcF Interval [msec]	xxx
S001/001	End of Study	2nd	ddMMMyyyy hh:mm	Heart Rate [beats/min]	xxx
S001/001	End of Study	2nd	ddMMMyyyy hh:mm	RR Interval [msec]	xxx
S001/001	End of Study	2nd	ddMMMyyyy hh:mm	PR Interval [msec]	xxx
S001/001	End of Study	2nd	ddMMMyyyy hh:mm	QRS Duration [msec]	xxx

Note: Subjects are listed according to the cohort they belong to
Program: Listings\k363-eg-lst.sas

Listing 16.2.9.2 - Recorded parameters of ECG

Cohort 2: 15 min (T)

Subject ID	Time Point	Replicate	Assessment Date/Time	Parameter	Value
S001/001	End of Study	2nd	ddMMMyyyy hh:mm	QT Interval [msec]	xxx
S001/001	End of Study	2nd	ddMMMyyyy hh:mm	QTcB Interval [msec]	xxx
S001/001	End of Study	2nd	ddMMMyyyy hh:mm	QTcF Interval [msec]	xxx
S001/001	End of Study	3rd	ddMMMyyyy hh:mm	Heart Rate [beats/min]	xxx
S001/001	End of Study	3rd	ddMMMyyyy hh:mm	RR Interval [msec]	xxx
S001/001	End of Study	3rd	ddMMMyyyy hh:mm	PR Interval [msec]	xxx
S001/001	End of Study	3rd	ddMMMyyyy hh:mm	QRS Duration [msec]	xxx
S001/001	End of Study	3rd	ddMMMyyyy hh:mm	QT Interval [msec]	xxx
S001/001	End of Study	3rd	ddMMMyyyy hh:mm	QTcB Interval [msec]	xxx
S001/001	End of Study	3rd	ddMMMyyyy hh:mm	QTcF Interval [msec]	xxx

Note: Subjects are listed according to the cohort they belong to
Program: Listings\k363-eg-lst.sas

Listing 16.2.9.2 - Recorded parameters of ECG

Cohort 3: 5 min (T)

Subject ID	Time Point	Replicate	Assessment Date/Time	Parameter	Value
S001/001	Screening	1st	ddMMMyyyy hh:mm	Heart Rate [beats/min]	xxx
S001/001	Screening	1st	ddMMMyyyy hh:mm	RR Interval [msec]	xxx
S001/001	Screening	1st	ddMMMyyyy hh:mm	PR Interval [msec]	xxx
S001/001	Screening	1st	ddMMMyyyy hh:mm	QRS Duration [msec]	xxx
S001/001	Screening	1st	ddMMMyyyy hh:mm	QT Interval [msec]	xxx
S001/001	Screening	1st	ddMMMyyyy hh:mm	QTcB Interval [msec]	xxx
S001/001	Screening	1st	ddMMMyyyy hh:mm	QTcF Interval [msec]	xxx
S001/001	Screening	2nd	ddMMMyyyy hh:mm	Heart Rate [beats/min]	xxx
S001/001	Screening	2nd	ddMMMyyyy hh:mm	RR Interval [msec]	xxx
S001/001	Screening	2nd	ddMMMyyyy hh:mm	PR Interval [msec]	xxx
S001/001	Screening	2nd	ddMMMyyyy hh:mm	QRS Duration [msec]	xxx
S001/001	Screening	2nd	ddMMMyyyy hh:mm	QT Interval [msec]	xxx
S001/001	Screening	2nd	ddMMMyyyy hh:mm	QTcB Interval [msec]	xxx
S001/001	Screening	2nd	ddMMMyyyy hh:mm	QTcF Interval [msec]	xxx
S001/001	Screening	3rd	ddMMMyyyy hh:mm	Heart Rate [beats/min]	xxx
S001/001	Screening	3rd	ddMMMyyyy hh:mm	RR Interval [msec]	xxx
S001/001	Screening	3rd	ddMMMyyyy hh:mm	PR Interval [msec]	xxx
S001/001	Screening	3rd	ddMMMyyyy hh:mm	QRS Duration [msec]	xxx

Note: Subjects are listed according to the cohort they belong to
Program: Listings\k363-eg-lst.sas

Listing 16.2.9.2 - Recorded parameters of ECG

Cohort 3: 5 min (T)

Subject ID	Time Point	Replicate	Assessment Date/Time	Parameter	Value
S001/001	Screening	3rd	ddMMMyyyy hh:mm	QT Interval [msec]	xxx
S001/001	Screening	3rd	ddMMMyyyy hh:mm	QTcB Interval [msec]	xxx
S001/001	Screening	3rd	ddMMMyyyy hh:mm	QTcF Interval [msec]	xxx
S001/001	Visit 3 - Pre dose	1st	ddMMMyyyy hh:mm	Heart Rate [beats/min]	xxx
S001/001	Visit 3 - Pre dose	1st	ddMMMyyyy hh:mm	RR Interval [msec]	xxx
S001/001	Visit 3 - Pre dose	1st	ddMMMyyyy hh:mm	PR Interval [msec]	xxx
S001/001	Visit 3 - Pre dose	1st	ddMMMyyyy hh:mm	QRS Duration [msec]	xxx
S001/001	Visit 3 - Pre dose	1st	ddMMMyyyy hh:mm	QT Interval [msec]	xxx
S001/001	Visit 3 - Pre dose	1st	ddMMMyyyy hh:mm	QTcB Interval [msec]	xxx
S001/001	Visit 3 - Pre dose	1st	ddMMMyyyy hh:mm	QTcF Interval [msec]	xxx
S001/001	Visit 3 - Pre dose	2nd	ddMMMyyyy hh:mm	Heart Rate [beats/min]	xxx
S001/001	Visit 3 - Pre dose	2nd	ddMMMyyyy hh:mm	RR Interval [msec]	xxx
S001/001	Visit 3 - Pre dose	2nd	ddMMMyyyy hh:mm	PR Interval [msec]	xxx
S001/001	Visit 3 - Pre dose	2nd	ddMMMyyyy hh:mm	QRS Duration [msec]	xxx
S001/001	Visit 3 - Pre dose	2nd	ddMMMyyyy hh:mm	QT Interval [msec]	xxx
S001/001	Visit 3 - Pre dose	2nd	ddMMMyyyy hh:mm	QTcB Interval [msec]	xxx
S001/001	Visit 3 - Pre dose	2nd	ddMMMyyyy hh:mm	QTcF Interval [msec]	xxx
S001/001	Visit 3 - Pre dose	3rd	ddMMMyyyy hh:mm	Heart Rate [beats/min]	xxx

Note: Subjects are listed according to the cohort they belong to
Program: Listings\k363-eg-lst.sas

Listing 16.2.9.2 - Recorded parameters of ECG

Cohort 3: 5 min (T)

Subject ID	Time Point	Replicate	Assessment Date/Time	Parameter	Value
S001/001	Visit 3 - Pre dose	3rd	ddMMMyyyy hh:mm	RR Interval [msec]	xxx
S001/001	Visit 3 - Pre dose	3rd	ddMMMyyyy hh:mm	PR Interval [msec]	xxx
S001/001	Visit 3 - Pre dose	3rd	ddMMMyyyy hh:mm	QRS Duration [msec]	xxx
S001/001	Visit 3 - Pre dose	3rd	ddMMMyyyy hh:mm	QT Interval [msec]	xxx
S001/001	Visit 3 - Pre dose	3rd	ddMMMyyyy hh:mm	QTcB Interval [msec]	xxx
S001/001	Visit 3 - Pre dose	3rd	ddMMMyyyy hh:mm	QTcF Interval [msec]	xxx
...	...	...	...	...	...
S001/001	End of Study	1st	ddMMMyyyy hh:mm	Heart Rate [beats/min]	xxx
S001/001	End of Study	1st	ddMMMyyyy hh:mm	RR Interval [msec]	xxx
S001/001	End of Study	1st	ddMMMyyyy hh:mm	PR Interval [msec]	xxx
S001/001	End of Study	1st	ddMMMyyyy hh:mm	QRS Duration [msec]	xxx
S001/001	End of Study	1st	ddMMMyyyy hh:mm	QT Interval [msec]	xxx
S001/001	End of Study	1st	ddMMMyyyy hh:mm	QTcB Interval [msec]	xxx
S001/001	End of Study	1st	ddMMMyyyy hh:mm	QTcF Interval [msec]	xxx
S001/001	End of Study	2nd	ddMMMyyyy hh:mm	Heart Rate [beats/min]	xxx
S001/001	End of Study	2nd	ddMMMyyyy hh:mm	RR Interval [msec]	xxx
S001/001	End of Study	2nd	ddMMMyyyy hh:mm	PR Interval [msec]	xxx
S001/001	End of Study	2nd	ddMMMyyyy hh:mm	QRS Duration [msec]	xxx

Note: Subjects are listed according to the cohort they belong to
Program: Listings\k363-eg-lst.sas

Listing 16.2.9.2 - Recorded parameters of ECG

Cohort 3: 5 min (T)

Subject ID	Time Point	Replicate	Assessment Date/Time	Parameter	Value
S001/001	End of Study	2nd	ddMMMyyyy hh:mm	QT Interval [msec]	xxx
S001/001	End of Study	2nd	ddMMMyyyy hh:mm	QTcB Interval [msec]	xxx
S001/001	End of Study	2nd	ddMMMyyyy hh:mm	QTcF Interval [msec]	xxx
S001/001	End of Study	3rd	ddMMMyyyy hh:mm	Heart Rate [beats/min]	xxx
S001/001	End of Study	3rd	ddMMMyyyy hh:mm	RR Interval [msec]	xxx
S001/001	End of Study	3rd	ddMMMyyyy hh:mm	PR Interval [msec]	xxx
S001/001	End of Study	3rd	ddMMMyyyy hh:mm	QRS Duration [msec]	xxx
S001/001	End of Study	3rd	ddMMMyyyy hh:mm	QT Interval [msec]	xxx
S001/001	End of Study	3rd	ddMMMyyyy hh:mm	QTcB Interval [msec]	xxx
S001/001	End of Study	3rd	ddMMMyyyy hh:mm	QTcF Interval [msec]	xxx

Note: Subjects are listed according to the cohort they belong to
Program: Listings\k363-eg-lst.sas

Listing 16.2.9.2 - Recorded parameters of ECG

Cohort 4: 2 min (T)

Subject ID	Time Point	Replicate	Assessment Date/Time	Parameter	Value
S001/001	Screening	1st	ddMMMyyyy hh:mm	Heart Rate [beats/min]	xxx
S001/001	Screening	1st	ddMMMyyyy hh:mm	RR Interval [msec]	xxx
S001/001	Screening	1st	ddMMMyyyy hh:mm	PR Interval [msec]	xxx
S001/001	Screening	1st	ddMMMyyyy hh:mm	QRS Duration [msec]	xxx
S001/001	Screening	1st	ddMMMyyyy hh:mm	QT Interval [msec]	xxx
S001/001	Screening	1st	ddMMMyyyy hh:mm	QTcB Interval [msec]	xxx
S001/001	Screening	1st	ddMMMyyyy hh:mm	QTcF Interval [msec]	xxx
S001/001	Screening	2nd	ddMMMyyyy hh:mm	Heart Rate [beats/min]	xxx
S001/001	Screening	2nd	ddMMMyyyy hh:mm	RR Interval [msec]	xxx
S001/001	Screening	2nd	ddMMMyyyy hh:mm	PR Interval [msec]	xxx
S001/001	Screening	2nd	ddMMMyyyy hh:mm	QRS Duration [msec]	xxx
S001/001	Screening	2nd	ddMMMyyyy hh:mm	QT Interval [msec]	xxx
S001/001	Screening	2nd	ddMMMyyyy hh:mm	QTcB Interval [msec]	xxx
S001/001	Screening	2nd	ddMMMyyyy hh:mm	QTcF Interval [msec]	xxx
S001/001	Screening	3rd	ddMMMyyyy hh:mm	Heart Rate [beats/min]	xxx
S001/001	Screening	3rd	ddMMMyyyy hh:mm	RR Interval [msec]	xxx
S001/001	Screening	3rd	ddMMMyyyy hh:mm	PR Interval [msec]	xxx
S001/001	Screening	3rd	ddMMMyyyy hh:mm	QRS Duration [msec]	xxx

Note: Subjects are listed according to the cohort they belong to
Program: Listings\k363-eg-lst.sas

Listing 16.2.9.2 - Recorded parameters of ECG

Cohort 4: 2 min (T)

Subject ID	Time Point	Replicate	Assessment Date/Time	Parameter	Value
S001/001	Screening	3rd	ddMMMyyyy hh:mm	QT Interval [msec]	xxx
S001/001	Screening	3rd	ddMMMyyyy hh:mm	QTcB Interval [msec]	xxx
S001/001	Screening	3rd	ddMMMyyyy hh:mm	QTcF Interval [msec]	xxx
S001/001	Visit 3 - Pre dose	1st	ddMMMyyyy hh:mm	Heart Rate [beats/min]	xxx
S001/001	Visit 3 - Pre dose	1st	ddMMMyyyy hh:mm	RR Interval [msec]	xxx
S001/001	Visit 3 - Pre dose	1st	ddMMMyyyy hh:mm	PR Interval [msec]	xxx
S001/001	Visit 3 - Pre dose	1st	ddMMMyyyy hh:mm	QRS Duration [msec]	xxx
S001/001	Visit 3 - Pre dose	1st	ddMMMyyyy hh:mm	QT Interval [msec]	xxx
S001/001	Visit 3 - Pre dose	1st	ddMMMyyyy hh:mm	QTcB Interval [msec]	xxx
S001/001	Visit 3 - Pre dose	1st	ddMMMyyyy hh:mm	QTcF Interval [msec]	xxx
S001/001	Visit 3 - Pre dose	2nd	ddMMMyyyy hh:mm	Heart Rate [beats/min]	xxx
S001/001	Visit 3 - Pre dose	2nd	ddMMMyyyy hh:mm	RR Interval [msec]	xxx
S001/001	Visit 3 - Pre dose	2nd	ddMMMyyyy hh:mm	PR Interval [msec]	xxx
S001/001	Visit 3 - Pre dose	2nd	ddMMMyyyy hh:mm	QRS Duration [msec]	xxx
S001/001	Visit 3 - Pre dose	2nd	ddMMMyyyy hh:mm	QT Interval [msec]	xxx
S001/001	Visit 3 - Pre dose	2nd	ddMMMyyyy hh:mm	QTcB Interval [msec]	xxx
S001/001	Visit 3 - Pre dose	2nd	ddMMMyyyy hh:mm	QTcF Interval [msec]	xxx
S001/001	Visit 3 - Pre dose	3rd	ddMMMyyyy hh:mm	Heart Rate [beats/min]	xxx

Note: Subjects are listed according to the cohort they belong to
Program: Listings\k363-eg-lst.sas

Listing 16.2.9.2 - Recorded parameters of ECG

Cohort 4: 2 min (T)

Subject ID	Time Point	Replicate	Assessment Date/Time	Parameter	Value
S001/001	Visit 3 - Pre dose	3rd	ddMMMyyyy hh:mm	RR Interval [msec]	xxx
S001/001	Visit 3 - Pre dose	3rd	ddMMMyyyy hh:mm	PR Interval [msec]	xxx
S001/001	Visit 3 - Pre dose	3rd	ddMMMyyyy hh:mm	QRS Duration [msec]	xxx
S001/001	Visit 3 - Pre dose	3rd	ddMMMyyyy hh:mm	QT Interval [msec]	xxx
S001/001	Visit 3 - Pre dose	3rd	ddMMMyyyy hh:mm	QTcB Interval [msec]	xxx
S001/001	Visit 3 - Pre dose	3rd	ddMMMyyyy hh:mm	QTcF Interval [msec]	xxx
...	...	...	...	...	...
S001/001	End of Study	1st	ddMMMyyyy hh:mm	Heart Rate [beats/min]	xxx
S001/001	End of Study	1st	ddMMMyyyy hh:mm	RR Interval [msec]	xxx
S001/001	End of Study	1st	ddMMMyyyy hh:mm	PR Interval [msec]	xxx
S001/001	End of Study	1st	ddMMMyyyy hh:mm	QRS Duration [msec]	xxx
S001/001	End of Study	1st	ddMMMyyyy hh:mm	QT Interval [msec]	xxx
S001/001	End of Study	1st	ddMMMyyyy hh:mm	QTcB Interval [msec]	xxx
S001/001	End of Study	1st	ddMMMyyyy hh:mm	QTcF Interval [msec]	xxx
S001/001	End of Study	2nd	ddMMMyyyy hh:mm	Heart Rate [beats/min]	xxx
S001/001	End of Study	2nd	ddMMMyyyy hh:mm	RR Interval [msec]	xxx
S001/001	End of Study	2nd	ddMMMyyyy hh:mm	PR Interval [msec]	xxx
S001/001	End of Study	2nd	ddMMMyyyy hh:mm	QRS Duration [msec]	xxx

Note: Subjects are listed according to the cohort they belong to
Program: Listings\k363-eg-lst.sas

Listing 16.2.9.2 - Recorded parameters of ECG

Cohort 4: 2 min (T)

Subject ID	Time Point	Replicate	Assessment Date/Time	Parameter	Value
S001/001	End of Study	2nd	ddMMMyyyy hh:mm	QT Interval [msec]	xxx
S001/001	End of Study	2nd	ddMMMyyyy hh:mm	QTcB Interval [msec]	xxx
S001/001	End of Study	2nd	ddMMMyyyy hh:mm	QTcF Interval [msec]	xxx
S001/001	End of Study	3rd	ddMMMyyyy hh:mm	Heart Rate [beats/min]	xxx
S001/001	End of Study	3rd	ddMMMyyyy hh:mm	RR Interval [msec]	xxx
S001/001	End of Study	3rd	ddMMMyyyy hh:mm	PR Interval [msec]	xxx
S001/001	End of Study	3rd	ddMMMyyyy hh:mm	QRS Duration [msec]	xxx
S001/001	End of Study	3rd	ddMMMyyyy hh:mm	QT Interval [msec]	xxx
S001/001	End of Study	3rd	ddMMMyyyy hh:mm	QTcB Interval [msec]	xxx
S001/001	End of Study	3rd	ddMMMyyyy hh:mm	QTcF Interval [msec]	xxx

Note: Subjects are listed according to the cohort they belong to
Program: Listings\k363-eg-lst.sas

Listing 16.2.9.3 - Investigator's interpretation of ECG

Cohort 1: 30 min (Rα)

Subject ID	Time Point	Replicate	Assessment Date/Time	Investigator's Interpretation	Investigator's Comment	Which AE the Abnormality is related to?	Which MH the Abnormality is related to?
S001/001	Screening	1st	ddMMMyyyy hh:mm	Abnormal, NCS	Irregularity in the heart rhythm	---	---
S001/001	Screening	2nd	ddMMMyyyy hh:mm	Abnormal, NCS	Irregularity in the heart rhythm	---	---
S001/001	Screening	3rd	ddMMMyyyy hh:mm	Abnormal, NCS	Irregularity in the heart rhythm	---	---
S001/001	Visit 3 - Pre dose	1st	ddMMMyyyy hh:mm	Normal	---	---	---
S001/001	Visit 3 - Pre dose	2nd	ddMMMyyyy hh:mm	Normal	---	---	---
S001/001	Visit 3 - Pre dose	3rd	ddMMMyyyy hh:mm	Normal	---	---	---
...	...	...	...	...	...	...	---
S001/001	End of study	1st	ddMMMyyyy hh:mm	Normal	---	---	---
S001/001	End of study	2nd	ddMMMyyyy hh:mm	Normal	---	---	---
S001/001	End of study	3rd	ddMMMyyyy hh:mm	Normal	---	---	---

Note: Subjects are listed according to the cohort they belong to
NCS: Not Clinically Significant
Program: Listings\k363-eg-lst.sas

Listing 16.2.9.3 - Investigator's interpretation of ECG

Cohort 1: 30 min (T)

Subject ID	Time Point	Replicate	Assessment Date/Time	Investigator's Interpretation	Investigator's Comment	Which AE the Abnormality is related to?	Which MH the Abnormality is related to?
S012/011	Screening	1st	ddMMMyyyy hh:mm	Abnormal, NCS	Irregularity in the heart rhythm	---	---
S012/011	Screening	2nd	ddMMMyyyy hh:mm	Abnormal, NCS	Irregularity in the heart rhythm	---	---
S012/011	Screening	3rd	ddMMMyyyy hh:mm	Abnormal, NCS	Irregularity in the heart rhythm	---	---
S012/011	Visit 3 - Pre dose	1st	ddMMMyyyy hh:mm	Normal	---	---	---
S012/011	Visit 3 - Pre dose	2nd	ddMMMyyyy hh:mm	Normal	---	---	---
S012/011	Visit 3 - Pre dose	3rd	ddMMMyyyy hh:mm	Normal	---	---	---
...	...	...	...	...	...	...	---
S012/011	End of study	1st	ddMMMyyyy hh:mm	Normal	---	---	---
S012/011	End of study	2nd	ddMMMyyyy hh:mm	Normal	---	---	---
S012/011	End of study	3rd	ddMMMyyyy hh:mm	Normal	---	---	---

Note: Subjects are listed according to the cohort they belong to
NCS: Not Clinically Significant
Program: Listings\k363-eg-lst.sas

Listing 16.2.9.3 - Investigator's interpretation of ECG

Cohort 2: 15 min (T)

Subject ID	Time Point	Replicate	Assessment Date/Time	Investigator's Interpretation	Investigator's Comment	Which AE the Abnormality is related to?	Which MH the Abnormality is related to?
S024/021	Screening	1st	ddMMMyyyy hh:mm	Abnormal, NCS	Irregularity in the heart rhythm	---	---
S024/021	Screening	2nd	ddMMMyyyy hh:mm	Abnormal, NCS	Irregularity in the heart rhythm	---	---
S024/021	Screening	3rd	ddMMMyyyy hh:mm	Abnormal, NCS	Irregularity in the heart rhythm	---	---
S024/021	Visit 3 - Pre dose	1st	ddMMMyyyy hh:mm	Normal	---	---	---
S024/021	Visit 3 - Pre dose	2nd	ddMMMyyyy hh:mm	Normal	---	---	---
S024/021	Visit 3 - Pre dose	3rd	ddMMMyyyy hh:mm	Normal	---	---	---
...	...	...	...	...	...	...	---
S024/021	End of study	1st	ddMMMyyyy hh:mm	Normal	---	---	---
S024/021	End of study	2nd	ddMMMyyyy hh:mm	Normal	---	---	---
S024/021	End of study	3rd	ddMMMyyyy hh:mm	Normal	---	---	---

Note: Subjects are listed according to the cohort they belong to
NCS: Not Clinically Significant
Program: Listings\k363-eg-lst.sas

Listing 16.2.9.3 - Investigator's interpretation of ECG

Cohort 3: 5 min (T)

Subject ID	Time Point	Replicate	Assessment Date/Time	Investigator's Interpretation	Investigator's Comment	Which AE the Abnormality is related to?	Which MH the Abnormality is related to?
S036/031	Screening	1st	ddMMMyyyy hh:mm	Abnormal, NCS	Irregularity in the heart rhythm	---	---
S036/031	Screening	2nd	ddMMMyyyy hh:mm	Abnormal, NCS	Irregularity in the heart rhythm	---	---
S036/031	Screening	3rd	ddMMMyyyy hh:mm	Abnormal, NCS	Irregularity in the heart rhythm	---	---
S036/031	Visit 3 - Pre dose	1st	ddMMMyyyy hh:mm	Normal	---	---	---
S036/031	Visit 3 - Pre dose	2nd	ddMMMyyyy hh:mm	Normal	---	---	---
S036/031	Visit 3 - Pre dose	3rd	ddMMMyyyy hh:mm	Normal	---	---	---
...	...	...	...	...	...	...	---
S036/031	End of study	1st	ddMMMyyyy hh:mm	Normal	---	---	---
S036/031	End of study	2nd	ddMMMyyyy hh:mm	Normal	---	---	---
S036/031	End of study	3rd	ddMMMyyyy hh:mm	Normal	---	---	---

Note: Subjects are listed according to the cohort they belong to
NCS: Not Clinically Significant
Program: Listings\k363-eg-lst.sas

Listing 16.2.9.3 - Investigator's interpretation of ECG

Cohort 4: 2 min (T)

Subject ID	Time Point	Replicate	Assessment Date/Time	Investigator's Interpretation	Investigator's Comment	Which AE the Abnormality is related to?	Which MH the Abnormality is related to?
S048/041	Screening	1st	ddMMMyyyy hh:mm	Abnormal, NCS	Irregularity in the heart rhythm	---	---
S048/041	Screening	2nd	ddMMMyyyy hh:mm	Abnormal, NCS	Irregularity in the heart rhythm	---	---
S048/041	Screening	3rd	ddMMMyyyy hh:mm	Abnormal, NCS	Irregularity in the heart rhythm	---	---
S048/041	Visit 3 - Pre dose	1st	ddMMMyyyy hh:mm	Normal	---	---	---
S048/041	Visit 3 - Pre dose	2nd	ddMMMyyyy hh:mm	Normal	---	---	---
S048/041	Visit 3 - Pre dose	3rd	ddMMMyyyy hh:mm	Normal	---	---	---
...	...	...	...	...	...	...	---
S048/041	End of study	1st	ddMMMyyyy hh:mm	Normal	---	---	---
S048/041	End of study	2nd	ddMMMyyyy hh:mm	Normal	---	---	---
S048/041	End of study	3rd	ddMMMyyyy hh:mm	Normal	---	---	---

Note: Subjects are listed according to the cohort they belong to
NCS: Not Clinically Significant
Program: Listings\k363-eg-lst.sas

Listing 16.2.10.1 - Medical and surgical history

Cohort 1: 30 min (Rα)

Subject ID	Category	Disease/Surgery ID		
S001/001	Medical History	M1	Verbatim:	Left shoulder luxation
			Preferred Term [1]:	Joint dislocation
			System Organ Class [1]:	Injury, poisoning and procedural complications
			Date of Diagnosis:	JUL2019
			Ongoing:	N
	Surgery	S1	Verbatim:	Right knee meniscectomy
			Preferred Term [1]:	Meniscus removal
			System Organ Class [1]:	Surgical and medical procedures
			Date of Surgery:	NOV1980
	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Note 1: MedDRA version 27.0
Program: Listings\k363-mh-lst.sas

Listing 16.2.10.1 - Medical and surgical history

Cohort 1: 30 min (T)

Subject ID	Category	Disease/Surgery ID		
S012/011	Medical History	M1	Verbatim:	Left shoulder luxation
			Preferred Term [1]:	Joint dislocation
			System Organ Class [1]:	Injury, poisoning and procedural complications
			Date of Diagnosis:	JUL2019
			Ongoing:	N
	Surgery	S1	Verbatim:	Right knee meniscectomy
			Preferred Term [1]:	Meniscus removal
			System Organ Class [1]:	Surgical and medical procedures
			Date of Surgery:	NOV1980
	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Note 1: MedDRA version 27.0
Program: Listings\k363-mh-lst.sas

Listing 16.2.10.1 - Medical and surgical history

Cohort 2: 15 min (T)

Subject ID	Category	Disease/Surgery ID		
S024/021	Medical History	M1	Verbatim:	Left shoulder luxation
			Preferred Term [1]:	Joint dislocation
			System Organ Class [1]:	Injury, poisoning and procedural complications
			Date of Diagnosis:	JUL2019
			Ongoing:	N
	Surgery	S1	Verbatim:	Right knee meniscectomy
			Preferred Term [1]:	Meniscus removal
			System Organ Class [1]:	Surgical and medical procedures
			Date of Surgery:	NOV1980
	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Note 1: MedDRA version 27.0
Program: Listings\k363-mh-lst.sas

Listing 16.2.10.1 - Medical and surgical history

Cohort 3: 5 min (T)

Subject ID	Category	Disease/Surgery ID		
S036/031	Medical History	M1	Verbatim:	Left shoulder luxation
			Preferred Term [1]:	Joint dislocation
			System Organ Class [1]:	Injury, poisoning and procedural complications
			Date of Diagnosis:	JUL2019
			Ongoing:	N
	Surgery	S1	Verbatim:	Right knee meniscectomy
			Preferred Term [1]:	Meniscus removal
			System Organ Class [1]:	Surgical and medical procedures
			Date of Surgery:	NOV1980
	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Note 1: MedDRA version 27.0
Program: Listings\k363-mh-lst.sas

Listing 16.2.10.1 - Medical and surgical history

Cohort 4: 2 min (T)

Subject ID	Category	Disease/Surgery ID		
S048/041	Medical History	M1	Verbatim:	Left shoulder luxation
			Preferred Term [1]:	Joint dislocation
			System Organ Class [1]:	Injury, poisoning and procedural complications
			Date of Diagnosis:	JUL2019
			Ongoing:	N
	Surgery	S1	Verbatim:	Right knee meniscectomy
			Preferred Term [1]:	Meniscus removal
			System Organ Class [1]:	Surgical and medical procedures
			Date of Surgery:	NOV1980
	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Note 1: MedDRA version 27.0
Program: Listings\k363-mh-lst.sas

Listing 16.2.10.2 - Physical examination

Cohort 1: 30 min (Rα)

Subject ID	Time Point	Physical Examination Date		
S001/001	Day -1	ddMMMyyyy	Investigator's Interpretation	Normal
	...	...	...	...
	End of Study	ddMMMyyyy	Investigator's Interpretation:	Abnormal, Clinically Significant
			Which AE (number) the Abnormality is related to?	1
			Which MH (number) the Abnormality is related to?	---
...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Note 1: MedDRA version 27.0
Program: Listings\k363-pe-lst.sas

Listing 16.2.10.2 - Physical examination

Cohort 1: 30 min (T)

Subject ID	Time Point	Physical Examination Date		
S012/011	Day -1	ddMMMyyyy	Investigator's Interpretation	Normal
	...	...	...	...
	End of Study	ddMMMyyyy	Investigator's Interpretation:	Abnormal, Clinically Significant
			Which AE (number) the Abnormality is related to?	1
			Which MH (number) the Abnormality is related to?	---
...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Note 1: MedDRA version 27.0
Program: Listings\k363-pe-lst.sas

Listing 16.2.10.2 - Physical examination

Cohort 2: 15 min (T)

Subject ID	Time Point	Physical Examination Date		
S024/021	Day -1	ddMMMyyyy	Investigator's Interpretation	Normal
	...	...	...	...
	End of Study	ddMMMyyyy	Investigator's Interpretation:	Abnormal, Clinically Significant
			Which AE (number) the Abnormality is related to?	1
			Which MH (number) the Abnormality is related to?	---
...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Note 1: MedDRA version 27.0
Program: Listings\k363-pe-lst.sas

Listing 16.2.10.2 - Physical examination

Cohort 3: 5 min (T)

Subject ID	Time Point	Physical Examination Date		
S036/031	Day -1	ddMMMyyyy	Investigator's Interpretation	Normal
	...	...	...	...
	End of Study	ddMMMyyyy	Investigator's Interpretation:	Abnormal, Clinically Significant
			Which AE (number) the Abnormality is related to?	1
			Which MH (number) the Abnormality is related to?	---
...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Note 1: MedDRA version 27.0
Program: Listings\k363-pe-lst.sas

Listing 16.2.10.2 - Physical examination

Cohort 4: 2 min (T)

Subject ID	Time Point	Physical Examination Date		
S048/041	Day -1	ddMMMyyyy	Investigator's Interpretation	Normal
	...	...	...	...
	End of Study	ddMMMyyyy	Investigator's Interpretation:	Abnormal, Clinically Significant
			Which AE (number) the Abnormality is related to?	1
			Which MH (number) the Abnormality is related to?	---
...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Note 1: MedDRA version 27.0
Program: Listings\k363-pe-lst.sas

Listing 16.2.10.3 - Prior and concomitant medications

Cohort 1: 30 min (Rα)

Subject ID	Category	Medication ID		
S001/001	Prior	1	Verbatim:	Alerid
			Standardised Medication Name [1]:	Alerid
			Active Ingredients [1]:	Cetirizine hydrochloride
			Medication Class [1, 2]:	Piperazine derivatives (R06AE)
			Indication:	Pollinosis
			Dose per Administration:	10 mg
			Start - End Date/Time:	2013 - Ongoing
			Frequency - Route:	1 time per day - Oral
	Concomitant	2	Verbatim:	Paracen
			Standardised Medication Name [1]:	Paracen
			Active Ingredients [1]:	Paracetamol
			Medication Class [1, 2]:	Anilides (N02BE)
			Indication:	Headache
			Dose:	500 mg
			Start - End Date/Time:	15JUN2019 19:08 - 15JUN2019 19:08
			Frequency - Route:	Once - Oral
	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Note 1: WHO Drug Dictionary Enhanced March 1, 2024
Note 2: Anatomical Therapeutic Chemical classification, 4th level term
Program: Listings\k363-cm-lst.sas

Listing 16.2.10.3 - Prior and concomitant medications

Cohort 1: 30 min (T)

Subject ID	Category	Medication ID		
S012/011	Prior	1	Verbatim:	Alerid
			Standardised Medication Name [1]:	Alerid
			Active Ingredients [1]:	Cetirizine hydrochloride
			Medication Class [1, 2]:	Piperazine derivatives (R06AE)
			Indication:	Pollinosis
			Dose per Administration:	10 mg
			Start - End Date/Time:	2013 - Ongoing
			Frequency - Route:	1 time per day - Oral
	Concomitant	2	Verbatim:	Paracen
			Standardised Medication Name [1]:	Paracen
			Active Ingredients [1]:	Paracetamol
			Medication Class [1, 2]:	Anilides (N02BE)
			Indication:	Headache
			Dose:	500 mg
			Start - End Date/Time:	15JUN2019 19:08 - 15JUN2019 19:08
			Frequency - Route:	Once - Oral
	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Note 1: WHO Drug Dictionary Enhanced March 1, 2024
Note 2: Anatomical Therapeutic Chemical classification, 4th level term
Program: Listings\k363-cm-lst.sas

Listing 16.2.10.3 - Prior and concomitant medications

Cohort 2: 15 min (T)

Subject ID	Category	Medication ID		
S024/021	Prior	1	Verbatim:	Alerid
			Standardised Medication Name [1]:	Alerid
			Active Ingredients [1]:	Cetirizine hydrochloride
			Medication Class [1, 2]:	Piperazine derivatives (R06AE)
			Indication:	Pollinosis
			Dose per Administration:	10 mg
			Start - End Date/Time:	2013 - Ongoing
			Frequency - Route:	1 time per day - Oral
	Concomitant	2	Verbatim:	Paracen
			Standardised Medication Name [1]:	Paracen
			Active Ingredients [1]:	Paracetamol
			Medication Class [1, 2]:	Anilides (N02BE)
			Indication:	Headache
			Dose:	500 mg
			Start - End Date/Time:	15JUN2019 19:08 - 15JUN2019 19:08
			Frequency - Route:	Once - Oral
	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Note 1: WHO Drug Dictionary Enhanced March 1, 2024
Note 2: Anatomical Therapeutic Chemical classification, 4th level term
Program: Listings\k363-cm-lst.sas

Listing 16.2.10.3 - Prior and concomitant medications

Cohort 3: 5 min (T)

Subject ID	Category	Medication ID		
S036/031	Prior	1	Verbatim:	Alerid
			Standardised Medication Name [1]:	Alerid
			Active Ingredients [1]:	Cetirizine hydrochloride
			Medication Class [1, 2]:	Piperazine derivatives (R06AE)
			Indication:	Pollinosis
			Dose per Administration:	10 mg
			Start - End Date/Time:	2013 - Ongoing
			Frequency - Route:	1 time per day - Oral
	Concomitant	2	Verbatim:	Paracen
			Standardised Medication Name [1]:	Paracen
			Active Ingredients [1]:	Paracetamol
			Medication Class [1, 2]:	Anilides (N02BE)
			Indication:	Headache
			Dose:	500 mg
			Start - End Date/Time:	15JUN2019 19:08 - 15JUN2019 19:08
			Frequency - Route:	Once - Oral
	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Note 1: WHO Drug Dictionary Enhanced March 1, 2024
Note 2: Anatomical Therapeutic Chemical classification, 4th level term
Program: Listings\k363-cm-lst.sas

Listing 16.2.10.3 - Prior and concomitant medications

Cohort 4: 2 min (T)

Subject ID	Category	Medication ID		
S048/041	Prior	1	Verbatim:	Alerid
			Standardised Medication Name [1]:	Alerid
			Active Ingredients [1]:	Cetirizine hydrochloride
			Medication Class [1, 2]:	Piperazine derivatives (R06AE)
			Indication:	Pollinosis
			Dose per Administration:	10 mg
			Start - End Date/Time:	2013 - Ongoing
			Frequency - Route:	1 time per day - Oral
	Concomitant	2	Verbatim:	Paracen
			Standardised Medication Name [1]:	Paracen
			Active Ingredients [1]:	Paracetamol
			Medication Class [1, 2]:	Anilides (N02BE)
			Indication:	Headache
			Dose:	500 mg
			Start - End Date/Time:	15JUN2019 19:08 - 15JUN2019 19:08
			Frequency - Route:	Once - Oral
	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Note 1: WHO Drug Dictionary Enhanced March 1, 2024
Note 2: Anatomical Therapeutic Chemical classification, 4th level term
Program: Listings\k363-cm-lst.sas

Listing 16.2.10.4 - Substance use

Cohort 1: 30 min (Rα)

Subject ID	Category	Consumption level	Consumption per Day	End of consumption Date
S001/001	Tobacco	Non smoker	---	---
	Alcohol	Occasionally	---	---
	Caffeine	No consumption	---	---
...	...	...	---	---

Note: Subjects are listed according to the cohort they belong to
Program: Listings\k363-su-lst.sas

Listing 16.2.10.4 - Substance use

Cohort 1: 30 min (T)

Subject ID	Category	Consumption level	Consumption per Day	End of consumption Date
S012/011	Tobacco	Ex smoker	---	JUL2018
	Alcohol	Regularly	4 drinks per day	---
	Caffeine	Consumption	3 cups coffee/tea per day	---
...	...	...	---	---

Note: Subjects are listed according to the cohort they belong to
Program: Listings\k363-su-lst.sas

Listing 16.2.10.4 - Substance use

Cohort 2: 15 min (T)

Subject ID	Category	Consumption level	Consumption per Day	End of consumption Date
S024/021	Tobacco	Smoker	10 cigarettes per day	---
	Alcohol	Occasionally	---	---
	Caffeine	Consumption	5 cups coffee/tea per day	---
...	...	...	---	---

Note: Subjects are listed according to the cohort they belong to
Program: Listings\k363-su-lst.sas

Listing 16.2.10.4 - Substance use

Cohort 3: 5 min (T)

Subject ID	Category	Consumption level	Consumption per Day	End of consumption Date
S036/031	Tobacco	Smoker	5 cigarettes per day	---
	Alcohol	No	---	---
	Caffeine	No consumption	---	---
...	...	...	---	---

Note: Subjects are listed according to the cohort they belong to
Program: Listings\k363-su-lst.sas

Listing 16.2.10.4 - Substance use

Cohort 4: 2 min (T)

Subject ID	Category	Consumption level	Consumption per Day	End of consumption Date
S048/041	Tobacco	Non smoker	---	---
	Alcohol	No	---	---
	Caffeine	Consumption	5 cups coffee/tea per day	---
...	...	...	---	---

Note: Subjects are listed according to the cohort they belong to
Program: Listings\k363-su-lst.sas

Listing 16.2.10.5 - Subjects study visits

Cohort 1: 30 min (Rα)

Subject ID	Screening Visit 1 Day -14/-2 Date (Day)	Visit 2 Day -1 Date (Day)	Visit 3 Day 1 Start Date (Day)	Visit 3 Day 2 End Date (Day)	Final Visit Visit 4 Date (Day)	Early Termination Visit Date (Day)
S001/001	ddMMMyyyy (-j)	ddMMMyyyy (-1)	ddMMMyyyy (1)	ddMMMyyyy (1)	ddMMMyyyy (6)	ddMMMyyyy (x)
...	...	...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Program: Listings\k363-sv-lst.sas

Listing 16.2.10.5 - Subjects study visits

Cohort 1: 30 min (T)

Subject ID	Screening Visit 1 Day -14/-2 Date (Day)	Visit 2 Day -1 Date (Day)	Visit 3 Day 1 Start Date (Day)	Visit 3 Day 2 End Date (Day)	Final Visit Visit 4 Date (Day)	Early Termination Visit Date (Day)
S012/011	ddMMMyyyy (-j)	ddMMMyyyy (-1)	ddMMMyyyy (1)	ddMMMyyyy (1)	ddMMMyyyy (6)	ddMMMyyyy (x)
...	...	...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Program: Listings\k363-sv-lst.sas

Listing 16.2.10.5 - Subjects study visits

Cohort 2: 15 min (T)

Subject ID	Screening Visit 1 Day -14/-2 Date (Day)	Visit 2 Day -1 Date (Day)	Visit 3 Day 1 Start Date (Day)	Visit 3 Day 2 End Date (Day)	Final Visit Visit 4 Date (Day)	Early Termination Visit Date (Day)
S024/021	ddMMMyyyy (-j)	ddMMMyyyy (-1)	ddMMMyyyy (1)	ddMMMyyyy (1)	ddMMMyyyy (6)	ddMMMyyyy (x)
...	...	...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Program: Listings\k363-sv-lst.sas

Listing 16.2.10.5 - Subjects study visits

Cohort 3: 5 min (T)

Subject ID	Screening Visit 1 Day -14/-2 Date (Day)	Visit 2 Day -1 Date (Day)	Visit 3 Day 1 Start Date (Day)	Visit 3 Day 2 End Date (Day)	Final Visit Visit 4 Date (Day)	Early Termination Visit Date (Day)
S036/031	ddMMMyyyy (-j)	ddMMMyyyy (-1)	ddMMMyyyy (1)	ddMMMyyyy (1)	ddMMMyyyy (6)	ddMMMyyyy (x)
...	...	...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Program: Listings\k363-sv-lst.sas

Listing 16.2.10.5 - Subjects study visits

Cohort 4: 2 min (T)

Subject ID	Screening Visit 1 Day -14/-2 Date (Day)	Visit 2 Day -1 Date (Day)	Visit 3 Day 1 Start Date (Day)	Visit 3 Day 2 End Date (Day)	Final Visit Visit 4 Date (Day)	Early Termination Visit Date (Day)
S048/041	ddMMMyyyy (-j)	ddMMMyyyy (-1)	ddMMMyyyy (1)	ddMMMyyyy (1)	ddMMMyyyy (6)	ddMMMyyyy (x)
...	...	...	...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Program: Listings\k363-sv-lst.sas

Listing 16.2.10.6 - Fertility status and contraception

Cohort 1: 30 min (Rα)

Subject ID	Chilbearing Potential?	Reason for not childbearing potential?	Reliable Contraceptive Method Used?
S002/001	Yes	---	Yes
...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Only female subjects are listed
Program: Listings\k363-rp-lst.sas

Listing 16.2.10.6 - Fertility status and contraception

Cohort 1: 30 min (T)

Subject ID	Chilbearing Potential?	Reason for not childbearing potential?	Reliable Contraceptive Method Used?
S013/012	Yes	---	Yes
...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Only female subjects are listed
Program: Listings\k363-rp-lst.sas

Listing 16.2.10.6 - Fertility status and contraception

Cohort 2: 15 min (T)

Subject ID	Chilbearing Potential?	Reason for not childbearing potential?	Reliable Contraceptive Method Used?
S025/022	No	Surgical Sterilisation	---
...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Only female subjects are listed
Program: Listings\k363-rp-lst.sas

Listing 16.2.10.6 - Fertility status and contraception

Cohort 3: 5 min (T)

Subject ID	Chilbearing Potential?	Reason for not childbearing potential?	Reliable Contraceptive Method Used?
S036/031	Yes	---	Yes
...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Only female subjects are listed
Program: Listings\k363-rp-lst.sas

Listing 16.2.10.6 - Fertility status and contraception

Cohort 4: 2 min (T)

Subject ID	Chilbearing Potential?	Reason for not childbearing potential?	Reliable Contraceptive Method Used?
S049/042	No	12 months of spontaneous amenorrhea	---
...	...	...	...

Note: Subjects are listed according to the cohort they belong to
Only female subjects are listed
Program: Listings\k363-rp-lst.sas

Listing 16.2.10.7 - Reproductive status and contraception

Cohort 1: 30 min (Rα)

Subject ID	Is he Sterile?	Approved Contraceptive Method Used?
S002/001	No	Yes
...	..	...

Note: Subjects are listed according to the cohort they belong to
Only male subjects are listed
Program: Listings\k363-rp-lst.sas

Listing 16.2.10.7 - Reproductive status and contraception

Cohort 1: 30 min (T)

Subject ID	Is he Sterile?	Approved Contraceptive Method Used?
S012/011	Ye	---
...	..	...

Note: Subjects are listed according to the cohort they belong to
Only male subjects are listed
Program: Listings\k363-rp-lst.sas

Listing 16.2.10.7 - Reproductive status and contraception

Cohort 2: 15 min (T)

Subject ID	Is he Sterile?	Approved Contraceptive Method Used?
S024/021	No	Yes
...	..	...

Note: Subjects are listed according to the cohort they belong to
Only male subjects are listed
Program: Listings\k363-rp-lst.sas

Listing 16.2.10.7 - Reproductive status and contraception

Cohort 3: 5 min (T)

Subject ID	Is he Sterile?	Approved Contraceptive Method Used?
S036/031	Ye	---
...	..	...

Note: Subjects are listed according to the cohort they belong to
Only male subjects are listed
Program: Listings\k363-rp-lst.sas

Listing 16.2.10.7 - Reproductive status and contraception

Cohort 4: 2 min (T)

Subject ID	Is he Sterile?	Approved Contraceptive Method Used?
S049/042	No	Yes
...	..	...

Note: Subjects are listed according to the cohort they belong to
Only male subjects are listed
Program: Listings\k363-rp-lst.sas

Listing 16.2.10.8 - Meals

Cohort 1: 30 min (Rα)

Subject ID	IMP Administration Date/Time	Meal Number	Standardised Meal	Time Point	Meal Served?	Meal Start Date/Time
S001/001	ddMMMyyyy hh:mm	1	Dinner	Visit 2 - Day -1	Y	ddMMMyyyy hh:mm
S001/001	ddMMMyyyy hh:mm	2	Lunch	Day 1 - 5 hours post-dose	Y	ddMMMyyyy hh:mm
S001/001	ddMMMyyyy hh:mm	3	Dinner	Day 1 - 12 hours post-dose	Y	ddMMMyyyy hh:mm
...	...	...	...	...	.	...

Note: Subjects are listed according to the cohort they belong to
Program: Listings\k363-ml-lst.sas

Listing 16.2.10.8 - Meals

Cohort 1: 30 min (T)

Subject ID	IMP Administration Date/Time	Meal Number	Standardised Meal	Time Point	Meal Served?	Meal Start Date/Time
S012/011	ddMMMyyyy hh:mm	1	Dinner	Visit 2 - Day -1	Y	ddMMMyyyy hh:mm
S012/011	ddMMMyyyy hh:mm	2	Lunch	Day 1 - 5 hours post-dose	Y	ddMMMyyyy hh:mm
S012/011	ddMMMyyyy hh:mm	3	Dinner	Day 1 - 12 hours post-dose	Y	ddMMMyyyy hh:mm
...	...	...	...	...	.	...

Note: Subjects are listed according to the cohort they belong to
Program: Listings\k363-ml-lst.sas

Listing 16.2.10.8 - Meals

Cohort 2: 15 min (T)

Subject ID	IMP Administration Date/Time	Meal Number	Standardised Meal	Time Point	Meal Served?	Meal Start Date/Time
S024/021	ddMMMyyyy hh:mm	1	Dinner	Visit 2 - Day -1	Y	ddMMMyyyy hh:mm
S024/021	ddMMMyyyy hh:mm	2	Lunch	Day 1 - 5 hours post-dose	Y	ddMMMyyyy hh:mm
S024/021	ddMMMyyyy hh:mm	3	Dinner	Day 1 - 12 hours post-dose	Y	ddMMMyyyy hh:mm
...	...	...	...	...	.	...

Note: Subjects are listed according to the cohort they belong to
Program: Listings\k363-ml-lst.sas

Listing 16.2.10.8 - Meals

Cohort 3: 5 min (T)

Subject ID	IMP Administration Date/Time	Meal Number	Standardised Meal	Time Point	Meal Served?	Meal Start Date/Time
S036/031	ddMMMyyyy hh:mm	1	Dinner	Visit 2 - Day -1	Y	ddMMMyyyy hh:mm
S036/031	ddMMMyyyy hh:mm	2	Lunch	Day 1 - 5 hours post-dose	Y	ddMMMyyyy hh:mm
S036/031	ddMMMyyyy hh:mm	3	Dinner	Day 1 - 12 hours post-dose	Y	ddMMMyyyy hh:mm
...	...	...	...	...	.	...

Note: Subjects are listed according to the cohort they belong to
Program: Listings\k363-ml-lst.sas

Listing 16.2.10.8 - Meals

Cohort 4: 2 min (T)

Subject ID	IMP Administration Date/Time	Meal Number	Standardised Meal	Time Point	Meal Served?	Meal Start Date/Time
S048/041	ddMMMyyyy hh:mm	1	Dinner	Visit 2 - Day -1	Y	ddMMMyyyy hh:mm
S048/041	ddMMMyyyy hh:mm	2	Lunch	Day 1 - 5 hours post-dose	Y	ddMMMyyyy hh:mm
S048/041	ddMMMyyyy hh:mm	3	Dinner	Day 1 - 12 hours post-dose	Y	ddMMMyyyy hh:mm
...	...	...	...	...	.	...

Note: Subjects are listed according to the cohort they belong to
Program: Listings\k363-ml-lst.sas