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An Open Label, Balanced, Randomized, Two-Treatment, Four-Period, Two-Sequence, Single Oral Dose, Full Replicate Crossover, Bioequivalence Study of Albendazole Tablets IP 400 mg of Biddle Sawyer Limited (GSK group company) with Albendazole Tablets 400 mg of Glaxo SmithKline Consumer Healthcare, South Africa (PTY) Ltd in Healthy, Adult Participants under Fed Condition.

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ABBREVIATIONS AND DEFINITIONS

λz	:	First order rate constant associated with the terminal (log-linear) portion of the curve
Abs	:	Absolute
ACE	:	Angiotensin converting enzyme
AE	:	Adverse event
ALT	:	Alanine aminotransferase
ANC	:	Absolute neutrophil count
ANOVA	:	Analysis of variance
AST	:	Aspartate aminotransferase
AUC	:	Area under the curve
AUC_%Extrap_obs	:	% Residual area
AUC0-∞	:	Area under the plasma concentration versus time curve from time zero to infinity
AUC(0-t)	:	Area under the plasma concentration-time curve up to the last measured time point
BE	:	Bioequivalence
BMI	:	Body mass index
BSA	:	Body surface area
Cmax	:	Maximal (peak) plasma concentration
cm	:	Centimeter
CFB	:	Change from baseline
CI	:	Confidence interval
COVID	:	Corona virus disease
CV	:	Coefficient of variation
CRO	:	Contract research organization
ECG	:	Electrocardiogram
GMR	:	Geometric mean ratio
Hb	:	Hemoglobin
HBsAg	:	Hepatitis B surface antigen
HCV	:	Hepatitis C virus
HCT	:	Hematocrit
HIV	:	Human immunodeficiency virus
h/hr/hrs	:	Hours
ICH	:	The international council for harmonisation of technical requirements for pharmaceuticals for human use

IP	:	Investigational product
kg	:	Kilograms
ln	:	Logarithmic value to the base 'e'
m^2	:	Meter square
MCH	:	Mean cell hemoglobin
MCHC	:	Mean corpuscular hemoglobin concentration
MCV	:	Mean corpuscular volume
MedDRA	:	Medical dictionary for regulatory activities
mg	:	Milligram
min	:	Minimum
mL	:	Milliliter
NQ	:	Non-quantifiable
OTC	:	Over the counter medicine
PK	:	Pharmacokinetic(s)
PT	:	Preferred term
RBC	:	Red blood cell
RDW-CV	:	Red cell distribution width - coefficient of variation
R^2	:	Goodness of fit statistic for the terminal phase, adjusted for the number of points used in the estimation of λz
SAE	:	Serious adverse event
SAP	:	Statistical analysis plan
SAS	:	Statistical analysis system
SD	:	Standard deviation
SGOT	:	Serum glutamic-oxaloacetic transaminase
SGPT	:	Serum glutamic pyruvic transaminase
SCABE	:	Scaled average bioequivalence
SOC	:	System organ class
SWR	:	Within-subject standard deviation of the reference study intervention
t1/2	:	Terminal half-life
TOST	:	Two one-sided t-test
Tmax	:	Time of the maximum measured plasma concentration
WBC	:	White blood cell
WHO	:	World health organization

1 Introduction

This statistical analysis plan provides the framework for the analysis and summarization of the data generated from the study conducted to assess the bioequivalence Albendazole Tablets IP 400 mg (Test) of Biddle Sawyer Limited (GSK group company) compared with Albendazole Tablets 400 mg (Reference) of Glaxo SmithKline Consumer Healthcare, South Africa (PTY) Ltd in Healthy, Adult Participants under Fed Condition.

2 Objective, Endpoints and Estimands

Objectives	Endpoints
Primary	
• To evaluate if Test Study Intervention (T): Albendazole tablets IP 400 mg, manufactured by Biddle Sawyer Limited is bioequivalent to Reference Study Intervention (R): Albendazole Tablets 400 mg, manufactured by GSK Consumer Healthcare, South Africa (PTY)	• Albendazole Cmax and AUC(0-t)
Secondary	
• To assess secondary pharmacokinetic parameters of Test Study Intervention (T): Albendazole tablets IP 400 mg relative to Reference Study Intervention (R): Albendazole tablets 400 mg.	• Albendazole AUC0-∞, Tmax, t1/2, lambda-z (λz) and AUC_%Extrap_obs. • Albendazole sulfoxide Cmax, AUC(0-t), AUC0-∞, Tmax, t1/2, lambda-z (λz) and AUC_%Extrap_obs.
• To assess the safety and tolerability of a single oral dose of the test versus the reference study intervention.	• Incidence of AE. • Absolute and change from baseline in vital signs parameters at each timepoint.

Primary estimand/coprimary estimands:

The primary clinical question of interest is:
To evaluate if Test Study Intervention (T): Albendazole tablets IP 400 mg is bioequivalent to Reference Study Intervention (R) Albendazole tablets 400 mg in healthy adult participants under fed conditions.
The estimand is described by the following attributes:

- **Population**: Healthy adult participants between 18 to 45 years of age.
- **Treatment condition**: Single dose of Albendazole tablets IP 400 or Albendazole tablets 400 mg, each treatment period given under fed conditions to healthy participants.
- **Variable/endpoint**: Cmax and AUC(0-t)
- **Summary measure**:
  - Treatment ratios of geometric least square means with 90% CI, and within-subject coefficient of variation of reference study intervention (intra-subject CV in %).
- **Intercurrent events**:
  - Permanent Treatment discontinuation due to any reason (includes COVID-19 positive, AE related withdrawal etc.) - While-on treatment strategy that is, all available data up until the withdrawal of the consent will be reported.
  - Use of prohibited or rescue medication which could affect PK parameters (Cmax and AUC(0-t)) during the study - Hypothetical strategy
  - Experiences emesis/vomiting before 2 times of median Tmax (i.e. 2 x 2hour = 4hour) after dose administration - Hypothetical strategy.
- **Rationale for estimand**:
  - The rationale of the while on treatment strategy is to estimate the PK parameters when participants have taken the dose/treatment condition.
  - The rationale of hypothetical strategy for prohibited/rescue medication is to minimize the potential confounding of PK data (Cmax and AUC(0-t)). It attempts to estimate treatment effects had the intercurrent event not occurred. In this scenario, if the intercurrent event occurred before 2 times median Tmax (i.e. 2 x 2hour = 4hour) after study drug administration, PK parameters (Cmax and AUC (0- t)) data would be set to be missing for that period.
  - Hypothetical strategy would be considered if emesis/vomits occur before 2 times the median Tmax (i.e., 2 x 2hour = 4hour) after study drug administration in particular period, this is because the drug would not have been absorbed into the body. In this situation, PK parameters (Cmax and AUC(0-t)) data would set to be missing for that period.

Secondary estimand(s) - PK endpoint

The secondary clinical question of interest is:
To assess secondary pharmacokinetic parameters of Test Study Investigation (T): Albendazole tablets IP 400 mg relative to Reference Study Investigation (R): Albendazole tablets 400 mg.

The estimand is described by the following attributes:

- **Population**: Healthy adult participants between 18 to 45 years of age.

- **Treatment condition**: Single dose of Albendazole tablets IP 400 mg or Albendazole tablets 400 mg, each treatment period given under fed conditions to healthy participants.

Variable/endpoint:

- **Albendazole** AUC0-∞, Tmax, t1/2, λz and AUC_%Extrap_obs.

- **Albendazole sulfoxide** Cmax, AUC(0-t), AUC0-∞, Tmax, t1/2, λz and AUC_%Extrap_obs.

Summary measure:

Descriptive statistics (N, n, arithmetic mean, 95% CI of arithmetic mean, SD, median, minimum, maximum, and geometric mean) will be presented for untransformed secondary PK parameters (AUC0-∞, AUC(0-t), Tmax, t1/2, λz and AUC_%Extrap_obs).

- **Intercurrent events**:
  - Same as primary endpoint

- **Rationale for estimand**:
  - The rationale of hypothetical strategy which is impacted to secondary PK parameters (AUC0-∞, AUC(0-t), Tmax, t1/2, λz and AUC_%Extrap_obs) during the study is same as primary estimands.

Secondary estimand(s) - 2(Safety)

The secondary clinical question of interest is:

To assess the safety and tolerability of a single oral dose of Test Study Intervention (T): Albendazole tablets IP 400 mg relative to Reference Study Intervention (R): Albendazole tablets 400 mg.

The estimand is described by the following attributes:

- **Population**: Healthy adult participants between 18 to 45 years of age.

- **Treatment condition**: Single dose of Albendazole tablets IP 400 mg or Albendazole tablets 400 mg, each treatment period given under fed conditions for healthy participants.

- **Variable/endpoint**: Incidence of AE and Absolute and change from baseline in vital signs parameters at each timepoint.

- **Summary measure**:
  - Number and percentage will be presented for incidence of AE.
  - Descriptive statistics (N, n, mean, SD, median, minimum, and maximum) will be presented for absolute and change from baseline values of vital signs parameters at each timepoint.

- **Intercurrent events**:

  Permanent Treatment discontinuation due to any reason (includes COVID-19 positive, AE related withdrawal etc.) - Treatment policy strategy.

- **Rationale for estimand**:

  Permanent Treatment discontinuation due to any reason will be handled with a treatment policy strategy as occurrence of AE until participant are on study will be collected and reported.

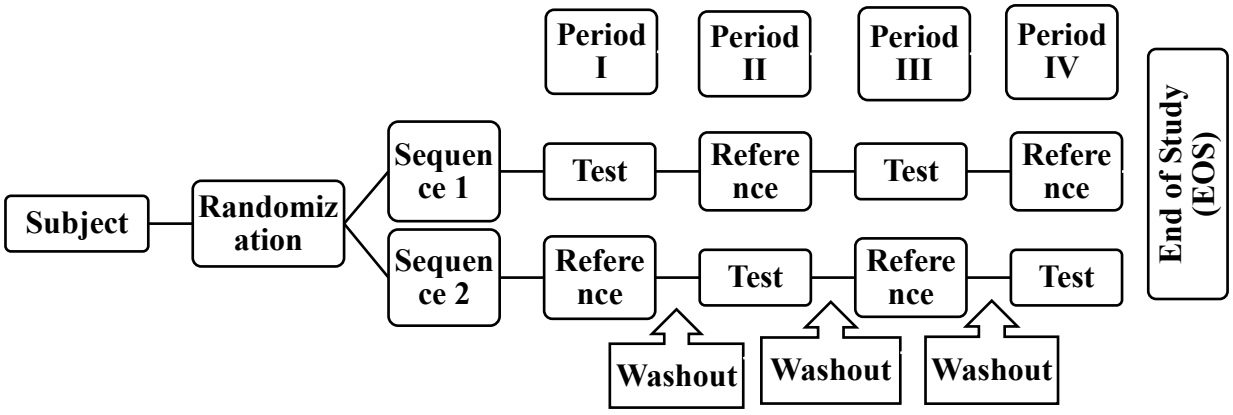
3 Overall Study Design

3.1 Study Design

An Open Label, Balanced, Randomized, Two-Treatment, Four-Period, Two-Sequence, Single Oral Dose, Full Replicate Crossover, Bioequivalence Study of Albendazole Tablets IP 400 mg of Biddle Sawyer Limited (GSK group company) with Albendazole Tablets 400 mg of GSK Consumer Healthcare, South Africa (PTY) Ltd in Healthy, Adult Participants under Fed Condition.

Based on **Error! Reference source not found.**, this study will employ 2 sequences in a 4-period cross-over design, i.e. T-R-T-R and R-T-R-T (T=test study intervention, R=reference study intervention).

Study design overview



3.2 Study Intervention(s) Administered

Intervention Label	Test (T)	Reference (R)
Intervention Name	Albendazole tablets IP 400 mg	Albendazole 400 mg tablets
Intervention Description	Solid dosage form	Solid dosage form
Type	Drug	Drug
Dose Formulation	Tablet	Tablet
Unit Dose Strength(s)	400 mg	400 mg
Dosage Level(s)	single oral dose of 400 mg	single oral dose of 400 mg
Route of Administration	oral	oral
Use	active comparator	active comparator
IMP and NIMP/AxMP.	Study intervention	Study intervention
Sourcing	Provided by the sponsor	Provided by the sponsor
Packaging and Labeling	Study intervention will be provided in container. Each container will be labeled as required per country requirement.	Study intervention will be provided in container. Each container will be labeled as required per country requirement.

3.3 Sample Size

Based on the WHO guideline for albendazole, the maximum intra-subject variability observed for primary pharmacokinetic parameters Cmax and AUC(0-t) could be up to ~ 68% and 62% respectively. For this sample size calculation, a product difference of up to 10% (i.e. T/R ratio as 90.0-111.1%) has been assumed.

The sample size was determined using R software considering the following assumptions:

a. T/R ratio = 90.0-111.1%
b. Intra-Subject CV (%) ~ 68% (Cmax) and 62% (AUC(0-t)), or 48% (both)
c. Significance Level = 5%

Correlation between Cmax and AUC(0-t) was calculated to be very high, based on an in-house albendazole study (GSK study O7921353). The exact Cmax and AUC(0-t) covariance matrix was calculated from this historical study as per below table and used to simulate realistic Cmax and AUC(0-t) values based on multivariate normal distributions. These values were then used to perform joint power calculation on the basis of inclusion of 70 participants with varying levels of missing data. To determine the power, success rates were based on 1000 replicates of the study design.

Table 1 Covariance matrix used for Cmax and AUC(0-t) in power calculations

	AUC(0-t)	Cmax
AUC_{0-t}	0.814	0.685
Cmax	0.685	0.747

Table 2 Joint power calculation results (N=1000) across various scenarios of missing data

Scenario	Joint Power (CV% = 48% for both Cmax and AUC(0-t))	Joint Power (CV% = 68% and 62% for AUC(0-t) and Cmax respectively)
48 participants have complete data for Cmax and AUC(0-t) for all 4 periods and 22 Participants data is completely missing	90.3%	93.7%
48 participants have complete data for Cmax and AUC(0-t) for all 4 periods, 10 participants have 2 period data and 12 participants data is completely missing	93.4%	95.8%
48 participants have complete data for Cmax and AUC(0-t) for all 4 periods, 6 participants have data for 2 periods and 16 remaining participants have no data at all	91.5%	94.9%

Based on these results, and the aforementioned covariance matrix, at least 48 participants would be required to power a study to 90% to establish bioequivalence under the assumptions

highlighted above. Based on experience, ~30% dropouts and/or withdrawals (due to unavoidable reasons like medical ground, adverse events, own accord, etc.) should be considered, requiring a target inclusion of 70 participants for this study. In-house data showed the variance of Cmax and AUC to be closer to 48%, implying that the above sample size calculation takes into account the worst-case scenario, and may in fact provide a power of > 95%.
Sufficient number of volunteers will be asked to report on the day of check-in of period I in order to ensure that at least **70 participants** will be enrolled in the beginning of the study. Subsequent dropouts after dosing in period I will not be replaced.

Note: Additional participants if available, may be checked-in on the day of check in of period I to compensate for any dropout prior to dosing of period I. These participants will be dosed if there are dropouts prior to dosing in period I. If there are no dropouts, these participants will be checked-out without being dosed after completion of dosing in period I.

3.4 Randomization

Participants will be assigned either of the two sequence 'TRTR' or 'RTRT' based on the randomization schedule by Lambda generated using SAS® Version 9.4 or higher (SAS Institute Inc., USA). Equal allocation of participants in each sequence is planned.

The personnel involved in dispensing of study intervention and verification of dispensed study interventions will be accountable for ensuring compliance to randomization schedule.

3.5 PK Sampling Schedule

A total of 22 blood samples each of 3 mL, will be collected from each participant in each period.

The venous blood samples will be withdrawn at the following times. All actual sample times will be recorded in addition to their planned time.

Day	Time points (Hours)	Proposed clock time	Analytes to measure	
			Albendazole	Albendazole Sulfoxide
1	Pre-dose (0.00)	Within 60 minutes prior to dosing	√	√
	0.33	0h20min	√	√
	0.67	0h40min	√	√
	1.00	1h00min	√	√
	1.33	1h20min	√	√
	1.67	1h40min	√	√
	2.00	2h00min	√	√
	2.33	2h20min	√	√
	2.67	2h40min	√	√
	3.00	3h00min	√	√
	3.33	3h20min	√	√
	3.67	3h40min	√	√
	4.00	4h00min	√	√

Day	Time points (Hours)	Proposed clock time	Analytes to measure	
			Albendazole	Albendazole Sulfoxide
	4.50	4h30min	√	√
	5.00	5h00min	√	√
	6.00	6h00min	√	√
	8.00	8h00min	√	√
	10.00	10h00min	√	√
	12.00	12h00min	√	√
	14.00	14h00min	√	√
2	18.00	18h00min	√	√
	24.00	24h00min	√	√

Day 1: Day of study intervention administration in each period.
Day 2: Subsequent day after study intervention administration in each period.

4 Analysis sets

The analysis set will be defined as follows:

Analysis Sets	Description	Analysis Evaluate
Randomized	All participants assigned to study treatment	Study Population
Safety set	The safety set will include all randomized participants who receive at least 1 dose of study medication. The safety population will be used for all analyses of safety data.	Safety
PK set	All participants in the Safety set who had at least 1 measurable PK assessment (for the purpose of the PK analysis, only those participants in this dataset who have evaluable data for one test and one reference period will be used).	PK

5 Assessment of Pharmacokinetic Parameters

5.1 Pharmacokinetic analysis

Pharmacokinetic analysis will be performed on the available concentration data of all the participants.

Criteria for exclusion of pharmacokinetic parameters of particular participants from statistical analysis will be as below:

Participants who were discontinued/withdrawn and do not have evaluable data for at least 1 treatment and 1 reference drug period will be excluded.

Three consecutive missing (M) / Non-Reportable (NR) samples in elimination phase may significantly influence the AUC(0-t) and elimination phase dependent parameters (AUC0-∞, AUC0-t, t1/2, λz, AUC_%Extrap_obs). Inclusion of such parameters in the statistical analysis may mislead the final outcome. Hence, AUC(0-t) and elimination phase dependent parameters (AUC0-∞, AUC(0-t), t1/2, λz, AUC_%Extrap_obs) will be excluded.

The concentration–time profiles of subjects who exhibit pre-dose concentrations higher than 5% of the corresponding Cmax of that period will be excluded from the statistical analysis [Note: a statistical sensitivity analysis including the same will be provided for information purpose].

Participants without measurable concentrations or who have only very low plasma concentrations relative to that of the product in question, will be excluded from the pharmacokinetic and statistical analyses. A participant is considered to have very low plasma concentrations if their AUC is less than 5% of the geometric mean AUC of the product in question, calculated without inclusion of data from the outlying participant [Note: statistical analysis with including the same will be provided for information purpose].

Note: This exclusion will be period specific.

5.2 Pharmacokinetic Parameters

The following pharmacokinetic parameters will be computed for albendazole and albendazole sulfoxide using non-compartmental model of Phoenix® WinNonlin® Version 8.3 or higher (Certara L.P.) for each period:

- Primary Pharmacokinetic Parameters: Cmax, AUC_{0-t}
- Secondary Pharmacokinetic Parameters: $AUC_{0-\infty}$, Tmax, λz, t1/2, AUC_%Extrap_obs

Primary PK Parameters:		
Cmax	:	Maximum measured plasma concentration.
AUC(0-t)	:	Area under the plasma concentration versus time curve from time zero to the last measurable concentration as calculated by linear trapezoidal method.
Secondary PK Parameters		
AUC0-∞	:	Area under the plasma concentration versus time curve from time zero to time infinity. Where AUC0-∞ = AUC(0-t) + Ct/λz, Ct is the last measurable concentration and λz is the terminal rate constant.
Tmax	:	Time of the maximum measured plasma concentration.
λz	:	First order rate constant associated with the terminal (log-linear) portion of the curve. This is estimated via linear regression of time vs. log concentration. This parameter will be calculated by linear least squares regression analysis using at least last 3 non-zero plasma concentration values.
t1/2	:	The terminal half-life will be calculated as 0.693/λz.
AUC_%Extrap_obs	:	The residual area in percentage will be determined by the formula, [(AUC0-∞ - AUC0-t)/AUC0-∞] x 100.

For all the above computations, actual time points of the sample collection will be used.

Non-quantifiable (NQ) data, such as concentrations below the quantification limit may be excluded or omitted, depending on where they are located in time, see Section 6.3.2.6.

No value of λ_z, $AUC_{0-\infty}$, AUC_%Extrap_obs and $t_{1/2}$ will be reported for cases that do not exhibit a terminal log-linear phase in the concentration versus time profile.

6 Statistical Considerations

6.1 Statistical Hypotheses

According to WHO product specific guidance (Notes on the Design of Bioequivalence Study: Albendazole; 29 March 2021), albendazole pharmacokinetics in the fed state is highly variable (up to 68% for Cmax and 62% for AUC). Therefore, this study was designed as a replicate cross-over study, to estimate variability more accurately and, if indicated, to widen the acceptance range for Cmax and AUC(0-t) (**Error! Reference source not found.**, 2021). Considering the same, full replicate study has been planned in line with WHO product specific guidance document and reference-scaled average bioequivalence approach will be used for hypothesis testing.

The null hypothesis to be tested is:

$$H_0: \frac{(\mu_T - \mu_R)^2}{\sigma_{WR}^2} \geq \theta$$

Versus alternative hypothesis

$$H_1: \frac{(\mu_T - \mu_R)^2}{\sigma_{WR}^2} < \theta$$

Where: μ_T and μ_R are the means of ln-transformed PK parameters (Cmax and/or AUC) obtained from the BE study for the test and reference products, respectively.

σ_{WR} is the within-subject standard deviation of the ln-transformed values of PK parameter of the reference study intervention.

Testing will be performed at a level of 0.05 and θ is the scaled average BE limit.

The test drug must pass for primary endpoint PK parameters (Cmax and AUC(0-t)) to demonstrate BE to the reference drug. Let σ_{W0} be the regulatory constant (based on 0.80-1.25 geometric mean ratio restriction criteria) and assumed to be 0.294.

a. The 90% confidence interval of GMR of T/R must be contained within [U, L] = exp [$\pm k \cdot s_{WR}$], which is scale acceptance limit based on k(θS),

Where k = ln(1.25)/σ_{W0} which is approx. 0.760

U is the upper limit of the acceptance range, L is the lower limit of the acceptance range,

s_{WR} is the within-subject standard deviation of the ln-transformed values of PK parameter of the reference study intervention.

b. Point estimate of GMR of T/R should be between 80.00 –125.00%.

For the parameters Cmax and AUC(0-t), if the intra-subject CV_W of for the reference study intervention is less than or equal to 0.30 upon trial completion for any of these treatment group, conventional average BE approach with TOST procedure with α=0.05 for each one-sided test will

be used to test $0.8 \leq GMR \leq 1.25$. This is equivalent to requiring that a 90% interval for the true ratio of test to reference geometric means falls entirely within the range of 80.00 to 125.00%. If the intra-subject coefficient of variation (CV_W) of for the reference study intervention is greater than 0.30 upon trial completion, a reference-scaled average bioequivalence approach will be used[3].

If the intra-subject variability for Cmax and AUC(0-t) following replicate administrations of the comparator product is > 30%, the acceptance criteria for Cmax and AUC(0-t) will be widened to a maximum of 69.84–143.19%.

6.2 Multiplicity Adjustment

No multiplicity adjustment is required for this bioequivalence study.

6.3 Statistical Analysis

6.3.1 General considerations

The pharmacokinetic parameters will be analyzed to evaluate the differences between the test and reference study interventions by applying referenced scaled average bioequivalence approach. This approach will be assessed based on GMR and 90% confidence interval for ln-transformed PK parameters Cmax and AUCt using RSABE.

All the statistical analysis will be performed using SAS® Version 9.4 or higher (SAS Institute Inc., USA).

The participants having pharmacokinetic parameters available for 2 reference treatments will be included for calculation of intra-subject variability of reference study intervention.

Descriptive statistics & average bioequivalence analysis will be performed on the participants having pharmacokinetic parameters available for at least 1 test and 1 reference arm.

6.3.2 Primary Endpoint(s)/Estimand(s) Analysis

6.3.2.1 Descriptive statistics

Statistical analysis for primary endpoints will include descriptive statistics for the following pharmacokinetic parameters:

Cmax and AUC(0-t)

Descriptive statistics (N, n, arithmetic mean, 95% CI of arithmetic mean, geometric mean, 95% CI of geometric mean, SD, median, minimum and maximum) will be presented for primary PK parameters.

Average values of Test Study Intervention-T and Reference Study Intervention-R for PK parameters for each participant will be calculated and reported. Descriptive statistics will be calculated and reported for the same data.

Individual values of PK parameters for Test Study Intervention-T (first administration), Test Study Intervention-T (second administration), Reference Study Intervention-R (first administration) and Reference Study Intervention-R (second administration) for each participant will be calculated and reported. Descriptive statistics will be calculated and reported for the same data.

PK parameters will be analyzed to evaluate the differences between the test and reference products by applying SCABE following EMA guidelines in investigation of bioequivalence regarding highly variable drug product (% of CVw >30), otherwise ABE will be applied.

6.3.2.2 Analysis of Variance (ANOVA)

Analysis of Variance (ANOVA) will be used on ln-transformed pharmacokinetic parameters Cmax and AUC(0-t) for albendazole or albendazole sulfoxide. The ANOVA model will include sequence, participant(sequence), period and formulation as fixed effects.

Each analysis of variance will include calculation of ratio of geometric least-squares means and the standard error associated with these ratios.

The above statistical analyses will be done using PROC GLM of SAS® procedure. A significance level of 5% (alpha =0.05) will be used for the model.

6.3.2.3 90% Confidence Interval

90% confidence intervals for the ratio of geometric least squares means between drug formulations will be calculated for ln-transformed data of Cmax and AUC(0-t) for albendazole and albendazole sulfoxide.

6.3.2.4 Ratio analysis

Ratio of geometric least squares means of test and reference formulations will be computed and reported for ln-transformed pharmacokinetic parameters Cmax and AUC(0-t) for albendazole and albendazole sulfoxide.

6.3.2.5 Intra-subject variability

Intra-subject variability of reference study intervention-R will be computed and reported for ln-transformed pharmacokinetic parameters Cmax and AUC(0-t) for albendazole and albendazole sulfoxide.

The existence of outlier subjects that inflate the intra-subject variability will be assessed. In case of such outliers, results will be reported with and without those outliers.

6.3.2.6 Missing and non-reportable values

If 1 or more NQ values occur in a profile before the first measurable concentration, they will be assigned a value of zero concentration.

If a single NQ value occurs between measurable concentrations in a profile, the NQ should be omitted (set to missing) in the derivation of pharmacokinetic parameters and statistical analysis.

If 2 or more NQ values occur in succession between measurable concentrations, the values in question will be set to missing. For the derivation of pharmacokinetic parameters, these NQs will be omitted. The NQ values will be set to 0 and the trapezoidal rule will be applied to all the observed data.

NQs which occur after the last measurable concentration will be omitted (set to missing) in the derivation of pharmacokinetic parameters and statistical analysis. Any missing samples (M) concentration value will be disregarded in pharmacokinetic and statistical analysis.

6.3.2.7 Intercurrent event and handling of missing data

The data will be affected by occurrence of the intercurrent event and only data available while the participant is receiving the treatment will be used under while-on treatment policy strategy. Participant level missing data will not be imputed, and available data will be used in the analysis.

In the case of emesis/vomiting or use of prohibited/rescue medication, the data for that period will not be used for the analysis of PK parameters relating to the primary endpoint using hypothetical strategy.

6.3.2.8 Bioequivalence criteria

Based on the statistical results of 90% confidence interval for the ratio of the geometric least square means for both ln-transformed pharmacokinetic parameters Cmax and AUC(0-t), conclusion will be drawn for Test Study Intervention-T vs. Reference Study Intervention-R for albendazole with following considerations.

For Cmax and AUC(0-t):

1. If within-reference intra-subject CV of ln-transformed Cmax and/or AUC(0-t) ≤ 30% then bioequivalence of the test study intervention with that of the reference study intervention will be concluded, if the 90% confidence interval falls within the acceptance range of 80.00–125.00% for ln-transformed pharmacokinetic parameter Cmax and AUC(0-t).

2. If within-reference intra-subject CV of ln-transformed Cmax and/or AUC(0-t) > 30% then Cmax and/or AUC(0-t) limit will be widened using scaled-average-bioequivalence. Under scaled-average-bioequivalence, [U,L] = exp [±k· S_{WR}] where U is the upper limit of the acceptance range, L is the lower limit of the acceptance range, k is the regulatory constant set to 0.760 and S_{WR} is the within-subject standard deviation of the ln transformed values of Cmax and/or AUC(0-t) of the reference study intervention.

3. If within-reference intra-subject CV of ln-transformed Cmax and/or AUC(0-t) ≥ 50% then Cmax and/or AUC(0-t) bioequivalence limits will be widened to a maximum of 69.84 – 143.19%.

Bioequivalence of the test study intervention with that of the reference study intervention will be concluded for Cmax and AUC(0-t), if both of the following conditions are satisfied:

- The 90% confidence interval for ln-transformed data of Cmax and AUC(0-t) falls within the respective newly widen range [U, L] = exp [±k· S_{WR}], which is based upon the within-subject variability observed for respective pharmacokinetic parameter.
- The geometric least square mean ratio (GMR) of test to reference for Cmax and AUC(0-t) falls within the acceptance range of 80.00– 125.00%.

Data of metabolite albendazole sulfoxide will be provided as supportive information only.

6.3.3 Secondary Endpoint(s)/Estimand(s) Analysis

Statistical analysis for secondary endpoints will include descriptive statistics for the following pharmacokinetic parameters:

Albendazole: AUC0-∞, Tmax, t1/2, λz and AUC_%Extrap_obs

Albendazole sulfoxide: AUC0-∞, AUC0-t, Cmax, Tmax, t1/2, λz and AUC_%Extrap_obs.

Descriptive statistics (N, n, arithmetic mean, 95% CI of arithmetic mean, SD, median, minimum, maximum and geometric mean with 95% CI) will be presented for untransformed secondary PK parameters.

Average values of Test Study Intervention-T and Reference Study Intervention-R for PK parameters for each participant will be calculated and reported. Descriptive statistics will be calculated and reported for the same data.

Individual values of PK parameters for Test Study Intervention-T (first administration), Test Study Intervention-T (second administration), Reference Study Intervention-R (first administration) and Reference Study Intervention-R (second administration) for each participant will be calculated and reported. Descriptive statistics will be calculated and reported for the same data.

In case of treatment discontinuation due to any reason, only the data available before the occurrence of intercurrent event will be used to estimate secondary PK parameters using while-on-treatment policy strategy.

If any participant experience emesis/vomiting or if a prohibited/rescue medication is used by any participant, the participant's data for that period will not be used for the analysis of secondary endpoints related to PK using hypothetical strategy.

Treatment policy strategy will be used to analyze the secondary endpoints related to safety to make use of all available data for a participant.

7 Safety Assessment and Analysis

7.1 Safety Assessment

Demographic data
Demographic data such as date of birth, sex, race, age, and ethnicity will be assessed on screening visit.

Body Measurement
Body measurement data such as height, weight and BMI will be assessed on screening visit.

Medication history
Current medication (prescribed medication & OTC medication, herbal remedies, cimetidine, praziquantel, dexamethasone, ritonavir, phenytoin, carbamazepine, phenobarbital) and usage of any concomitant therapy or any ingestion of medicine in the previous 14 days prior to dosing of period I and any vaccine (including COVID-19 vaccine) from 14 days prior to dosing of period I. Medication history will be recorded on PERIOD 1 (Day 1)

Physical examination
Physical examination will be assessed on screening visit, check in (Day 1) and check-out (Day 2) of each period.

Urine drug scan and breath alcohol test
Drug abuse in urine and Breath alcohol test will be performed on check-in of each period.

Chest X-ray
Chest X-ray (within the last 6 months) (postero-anterior view) will be carried out at the time of screening.

Vital signs
Vitals (sitting blood pressure and radial pulse) will be recorded at pre-dose (within 60 minutes before the dosing) and at 2, 4, 6, 12 and 24 hours post-dose in each period.
Note: All post-dose vitals will be performed within ± 40 minutes of the scheduled time.

Recording of vital signs (blood pressure, respiratory rate and radial pulse and body temperature) will be done at screening, after check-in, before check-out in each period.

Note: Vital signs before checkout may be started 120 minutes prior to the scheduled time of check-out of each participant.

12-lead ECG

12-lead ECG will be carried out at the time of screening (up to 28 days before Dosing in period I).

Clinical safety laboratory tests

Serology tests (HIV AB (1 & 2), Anti HCV and HBsAg) will be performed at the time of screening.
Urine parameters will be performed at the time of screening.
Urine parameters: Specific Gravity, Leucocytes, Bilirubin, Urobilinogen, Erythrocytes, pH, Protein, Ketones, Glucose, Nitrite, Microscopic examination (As applicable).

Laboratory assessment for hematology and biochemistry will be performed at the time of screening. Laboratory assessment for hematology and biochemistry (except random glucose, sodium, potassium, chloride, alkaline phosphatase) will be performed at the end of the study (at the time of check-out of period IV).
Laboratory assessment for liver function test (SGPT, SGOP and total bilirubin) will be performed prior to check-in of period II, III and IV.
Hematology: Hemoglobin [Hb], RBC count, HCT, MCV, MCH, MCHC, RDW CV, Platelet count, WBC (total), Neutrophils %, Lymphocytes %, Eosinophils %, Monocytes %, Basophils %, Neutrophils abs, Eosinophils abs
Biochemistry: Random Glucose, Bilirubin Total, Total Protein, Albumin, Serum Globulin, A/G ratio, SGOT (AST), SGPT (ALT), Creatinine, Blood Urea Nitrogen, Sodium, Potassium, Chloride, Alkaline phosphatase.

Pregnancy testing

Serum Pregnancy test for female participants will be done at the time of screening, prior to check-in of each period and at the end of the study (at the time of check-out of period IV). Pregnancy testing must be done even if the participant is menstruating at the time of the study visit. The study intervention may only be administered if the pregnancy test is negative.

7.2 Safety Analysis

Safety analysis will be done on the safety set. Safety variables include AEs, clinical laboratory parameters, vital signs, physical examinations. Safety variables will be listed and summarized with descriptive statistics as appropriate.

Continuous variables will be Summarized by treatment/sequence group using summary statistics (number of observations, mean, standard deviation, median, minimum and maximum etc.) as applicable. Categorical values will be summarized by the treatment group using frequencies and percentages.

Result obtained when evaluating safety (adverse events, vital signs, clinical laboratory tests etc.) will be listed and evaluated descriptively.

Adverse events

All AEs reported during the study must be included in the safety analysis. AEs will be classified by system organ class, by preferred term from the MedDRA version 25.0 or higher. They will be presented in individual listings and summary tables, and evaluated descriptively and in terms of

frequencies, by treatment. As will be summarized for all subjects in Safety set across two treatment groups by System Organ Class (SOC) and Preferred Term (PT). p-value using chi-square test or fisher exact test will be provided for the AE data.

Intensity refers to the severity of the AE.: Mild, Moderate, Severe.

Clinical laboratory values

Clinical laboratory values will be compared to their reference ranges. Values outside the normal ranges will be highlighted. The Investigator has to comment, whether the abnormality is clinically relevant.

Other safety parameters

All results of vital sign measurements will be presented in individual listings. Where appropriate, results and possible changes in parameters will be evaluated descriptively or by descriptive statistics (mean, SD, median, range). Descriptive statistics (N, n, mean, SD, median, minimum and maximum) will be presented for absolute and change from baseline values of vital signs parameters at each timepoint.

Demographic data will be shown in tables as mean values, SD and ranges (min, max).

Clinical laboratory data will be shown in tables as mean values, SD and ranges (min, max) as applicable.

Physical examination, 12 lead ECG, Chest X-Ray performance and concomitant medication will be presented in data listings.

Protocol deviations

A list of all protocol deviations and an assessment of their impact will be included in listing. The deviations will include dosing related, IMP related, lab related, early, late or missed safety assessments, etc.

A number of participants with minor and major deviations will be provided.

8 Change from the protocol

"*The ANOVA model will include sequence, participant(sequence), period and formulation as fixed effects*" as per the WHO requirements.

9 Interim analysis

No interim analysis has been planned in this study.

10 Software Information for Analysis

SAS® Version 9.4 or higher (SAS Institute Inc., USA) will be used for statistical and safety analysis.
Phoenix® WinNonlin® Version 8.3 or higher (Certara L.P.) will be used for pharmacokinetic analysis.

11 Format Specifications for outputs

1. Output files of SAS procedures/Phoenix WinNonlin (statistical analyses, summary tables, individual data listings, etc.) will be produced as PDF files.

2. Each individual PDF file will contain the statistical analysis output, i.e. a summary table, or data listing grouped by treatment or/and visit, for one analysis population, and for a single type of analysis.
3. The rules for grouping may vary according to the type of data (study outcome, safety), individual data listings, listings of derived variables, etc. and the type of output file which is produced (statistical analyses, summary tables, graphs).
4. Page format will be "A4".
5. Each listing will be numbered in the format Page X of Y (where Y denotes total number of pages in that particular listing). Page number will appear in the bottom right part of the listing.
6. For each output, 'Lambda Therapeutic Research Ltd.' Will appear in the Top left corner of the Header, 'Confidential' and 'Title' of the output will appear in the Centre of the Header and towards the Top right corner the 'project number' will be presented.
7. The font and font size for header/footer and body of the output will be Courier New size 9 pt which will be generated from SAS. The font and font size for header/footer and body of the output will be Times New Roman 12 pt which will be generated from Phoenix WinNonlin.

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16.1.9.5 Statistical Analysis Plan

Note: Numbering in outputs may change depending on the inclusion/exclusion of the subjects considered for statistical analysis.

17 References

1. ICH Harmonized Tripartite Guideline – Statistical Principles for Clinical Trials (E9). Step 5 September 1998.
2. ICH Harmonized Tripartite Guideline – Structure and Content of Clinical Study Reports (E3). Step 5 July 1996.
3. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-fifth report (TR1033), annex 6: Multisource (generic) pharmaceutical products: guidelines on registeration requirements to establish interchangeability. World Health Organisation. 25 March 2021

18 Tables and Listings shells

14.1 Demographic Data

14.1.1 Demographic data and baseline characteristics (Randomized set)

Lambda Therapeutic Research Ltd. Confidential Project No. 0110-23

Table No. 14.1.1

Demographic data and baseline characteristics (Randomized set)

	Statistics	TRTR (N=xx)	RTRT (N=xx)	Total (N=xx)	p-value
Age (years)	n	xx	xx	xx	x.xxxx
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	
	Median	xx.x	xx.x	xx.x	
	Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	
Gender					-
Male	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
Female	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
Race					
Asian	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	-
American Indian or Alaska Native	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
…					
Other	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
Ethnicity					
Not Hispanic or Latino	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	-
Hispanic or Latino	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
Not Reported	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
Unknown	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	
Height (cm)	n	xx	xx	xx	x.xxxx
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	
	Median	xx.x	xx.x	xx.x	
	Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	

Lambda Therapeutic Research Ltd. Confidential Project No. 0110-23

Table No. 14.1.1

Demographic data and baseline characteristics (Randomized set)

	Statistics	TRTR (N=xx)	RTRT (N=xx)	Total (N=xx)	p-value
Weight (kg)	n	xx	xx	xx	x.xxxx
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	
	Median	xx.x	xx.x	xx.x	
	Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	
BMI (kg/m²)	n	xx	xx	xx	x.xxxx
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	
	Median	xx.x	xx.x	xx.x	
	Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	

N = Number of subjects in safety set, n = Number of subjects in respective categories
Note: Percentages are calculated based on the total number of subjects in each category.
Treatment specification -> T = Test Product and R = Reference Product.
p-value is calculated using an independent t-test.
Reference Listings: 16.2.1.3, 16.2.4.1, 16.2.9.3

Output Generated on: DDMMMYYYY hh:mm

<Note: Repeat the same table as 14.1.2 for Safety set and 14.1.3 for PK set >

14.1.4 Visit wise distribution of subjects (Randomized set)

Lambda Therapeutic Research Ltd. Confidential Project No. 0110-23

Table 14.1.4

Visit wise distribution of subjects (Randomized set)

Visits	TRTR (N=xx) n (%)	RTRT (N=xx) n (%)	Total (N=xx) n (%)
PERIOD 1 (Day-1)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PERIOD 2 (Day-1)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PERIOD 3 (Day-1)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PERIOD 4 (Day-1)	xx (xx.x)	xx (xx.x)	xx (xx.x)

N = Number of subjects in safety set, n = Number of subjects in respective categories
Note: Percentages are calculated based on the total number of subjects in each category.
Treatment specification -> T = Test Product and R = Reference Product.
Reference Listing: 16.2.1.3, 16.2.9.7

Output Generated on: DDMMMYYYY hh:mm

<Note: Repeat the same table as 14.1.5 for Safety set and 14.1.6 for PK set.>

14.1.7 Summary of protocol deviations

Lambda Therapeutic Research Ltd. Confidential Project No. 0110-23

Table No. 14.1.7
Summary of protocol deviations

Protocol deviation	Type of Protocol Deviation		Total
	Major	Minor	
Subjects with protocol deviations	xx	xx	xx
At least one protocol deviation	xx	xx	xx
Dosing Related	xx	xx	xx
IMP Related	xx	xx	xx
Lab Related	xx	xx	xx
Others	xx	xx	xx
.			
.			
.			

Reference Listing: 16.2.2

Output Generated on: DDMMMYYYY hh:mm

14.2 Pharmacokinetic Data

14.2.1 Plasma Albendazole Data

14.2.1.1 Summary statistics of pharmacokinetic parameters for albendazole

Lambda Therapeutic Research Ltd. Confidential Project No. 0110-23
The SAS System Version 9.4 Table No. 14.2.1.1 Sponsor: GSK Research & Development

Summary statistics of pharmacokinetic parameters for albendazole
Albendazole Tablets IP 400 mg
Dosing: Single Oral Dose; Condition: Fed; Population: Healthy, Adult Participants

Measures		Tmax (unit)	Cmax (unit)	AUC0-t (unit)
Test Treatment-T				
N		xx	xx	xx
Mean		xx.xx	xx.xxx	xx.xxx
SD		xx.xxx	xx.xxxx	xx.xxxx
CV(%)		xx.x	xx.x	xx.x
Geometric Mean		xx.xx	xx.xxx	xx.xxx
Reference Treatment-R				
N		xx	xx	xx
Mean		xx.xx	xx.xxx	xx.xxx
SD		xx.xxx	xx.xxxx	xx.xxxx
CV(%)		xx.x	xx.x	xx.x
Geometric Mean		xx.xx	xx.xxx	xx.xxx
ANOVA p-value				
ln-transformed	Sequence	-	x.xxxx	x.xxxx
	Period	-	x.xxxx	x.xxxx
	Formulation	-	x.xxxx	x.xxxx
	Participant(Sequence)	-	x.xxxx	x.xxxx
Geometric Least Squares Means				
ln-transformed	Test-T	-	xxxx.xxx	xxxx.xxx
	Reference-R	-	xxxx.xxx	xxxx.xxx
Ratio of Geometric Least Squares Means(%)(T/R)				
ln-transformed		-	xxx.x	xxx.x
Intra subject Variability of Reference Formulation-R(%)				
ln-transformed		-	xx.x	xx.x
Within subject standard deviation of Reference Formulation-R (SWR)				
ln-transformed		-	xx.x	xx.x
90% Confidence Interval (T Vs. R)				
ln-transformed	Lower	-	xxx.xx	xxx.xx
	Upper	-	xxx.xx	xxx.xx
	Power(%)	-	xxx.x	xxx.x
	Bioequivalence	-	YES/NO	YES/NO

Output Generated on: DDMMMYYYY hh:mm

<Note: Repeat the same table as 14.2.2.1 for albendazole sulfoxide >

14.2.1.2 Pharmacokinetic parameters (untransformed) of albendazole for Test Product-T and Reference Product-R

Lambda Therapeutic Research Ltd. Confidential Project No. 0110-23

Table No. 14.2.1.2

Pharmacokinetic parameters (untransformed) of albendazole for Test Product-T and Reference Product-R												
Participants	Sequence	Tmax (unit)		Cmax (unit)			AUC0-t (unit)			AUC0-inf (unit)		
		Formulation		Formulation			Formulation			Formulation		
		T	R	T	R	(T/R)%	T	R	(T/R)%	T	R	(T/R)%
1001		xx.xx	xx.xx	xx.xxx	xx.xxx	xx.x	xx.xxx	xx.xxx	xx.x	xx.xxx	xx.xxx	xx.x
1002		xx.xx	xx.xx	xx.xxx	xx.xxx	xx.x	xx.xxx	xx.xxx	xx.x	xx.xxx	xx.xxx	xx.x
.		.	.	.	.	.	.	.	.	.	.	.
.		.	.	.	.	.	.	.	.	.	.	.
.		.	.	.	.	.	.	.	.	.	.	.
n		xx.xx	xx.xx	xx.xxx	xx.xxx	xx.x	xx.xxx	xx.xxx	xx.x	xx.xxx	xx.xxx	xx.x
N		xx	xx	xx	xx	-	xx	xx	-	xx	xx	-
Mean		xx.xx	xx.xx	xx.xxx	xx.xxx	-	xx.xxx	xx.xxx	-	xx.xxx	xx.xxx	-
95% CI of arithmetic mean		x.xx-x.xx	x.xx-x.xx	x.xxx-x.xxx	x.xxx-x.xxx	-	x.xxx-x.xxx	x.xxx-x.xxx	-	x.xxx-x.xxx	x.xxx-x.xxx	-
SD		xx.xxx	xx.xxx	xx.xxxx	xx.xxxx	-	xx.xxxx	xx.xxxx	-	xx.xxxx	xx.xxxx	-
Min		xx.xx	xx.xx	xx.xxx	xx.xxx	-	xx.xxx	xx.xxx	-	xx.xxx	xx.xxx	-
Median		xx.xx	xx.xxx	xx.xxx	xx.xxx	-	xx.xxx	xx.xxx	-	xx.xxx	xx.xxx	-
Max		xx.xx	xx.xx	xx.xxx	xx.xxx	-	xx.xxx	xx.xxx	-	xx.xxx	xx.xxx	-
CV%		xx.x	xx.x	xx.x	xx.x	-	xx.x	xx.x	-	xx.x	xx.x	-
Geometric Mean		xx.xx	xx.xx	xx.xxx	xx.xxx	-	xx.xxx	xx.xxx	-	xx.xxx	xx.xxx	-
95% CI of geometric mean		x.xx-x.xx	x.xx-x.xx	x.xxx-x.xxx	x.xxx-x.xxx	-	x.xxx-x.xxx	x.xxx-x.xxx	-	x.xxx-x.xxx	x.xxx-x.xxx	-

<Note: Repeat the same table as 14.2.2.2 for albendazole sulfoxide.>

14.2.1.2 Contd 1. Pharmacokinetic parameters (untransformed) of albendazole for Test Product-T and Reference Product-R

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Table No. 14.2.1.2 Contd.

Pharmacokinetic parameters (untransformed) of albendazole for Test Product-T and Reference Product-R

Participants	Sequence	AUC_%Extrap_obs (%)		Lambda_z (unit)		t1/2 (unit)	
		Formulation		Formulation		Formulation	
		T	R	T	R	T	R
1001		xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx
1002		xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx
.		.	.	.	.	.	.
.		.	.	.	.	.	.
.		.	.	.	.	.	.
n		xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx
N		xx	xx	xx	xx	xx	xx
Mean		xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx
95% CI of arithmetic mean		x.xxx-x.xxx	x.xxx-x.xxx	x.xxx-x.xxx	x.xxx-x.xxx	x.xxx-x.xxx	x.xxx-x.xxx
SD		xx.xxxx	xx.xxxx	xx.xxxx	xx.xxxx	xx.xxxx	xx.xxxx
Min		xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx
Median		xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx
Max		xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx
CV%		xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Geometric Mean		xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx
95% CI of geometric mean		x.xxx-x.xxx	x.xxx-x.xxx	x.xxx-x.xxx	x.xxx-x.xxx	x.xxx-x.xxx	x.xxx-x.xxx

<Note: Repeat the same table as 14.2.2.2 for albendazole sulfoxide.>

14.2.1.3 Individual Pharmacokinetic parameter (untransformed) of albendazole for Test Product-T1 (first administration), Test Product-T2 (second administration), Reference Product-R1 (first administration) and Reference Product-R2 (second administration)

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Table No. 14.2.1.3

Individual pharmacokinetic parameters (untransformed) of albendazole for Test Product-T1 (first administration), Test Product-T2 (second administration), Reference Product-R1 (first administration) and Reference Product-R2 (second administration)

Participants	Sequence	Tmax (unit)				Cmax (unit)				AUC0-t (unit)			
		Formulation				Formulation				Formulation			
		T1	T2	R1	R2	T1	T2	R1	R2	T1	T2	R1	R2
1001		xx.xx	xx.xx	xx.xx	xx.xx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx
1002		xx.xx	xx.xx	xx.xx	xx.xx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx
.		.	.	.	.	.	.	.	.	.	.	.	.
.		.	.	.	.	.	.	.	.	.	.	.	.
.		.	.	.	.	.	.	.	.	.	.	.	.
n		xx.xx	xx.xx	xx.xx	xx.xx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx
N		xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
Mean		xx.xx	xx.xxx	xx.xx	xx.xx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx
95% CI of arithmetic mean		x.xx-x.xx	x.xxx-x.xxx	x.xx-x.xx	x.xx-x.xx	x.xxx-x.xxx	x.xxx-x.xxx	x.xxx-x.xxx	x.xxx-x.xxx	x.xxx-x.xxx	x.xxx-x.xxx	x.xxx-x.xxx	x.xxx-x.xxx
SD		xx.xxx	xx.xxxx	xx.xxx	xx.xxx	xx.xxxx	xx.xxxx	xx.xxxx	xx.xxxx	xx.xxxx	xx.xxxx	xx.xxxx	xx.xxxx
Min		xx.xx	xx.xxx	xx.xx	xx.xx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx
Median		xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx
Max		xx.xx	xx.xxx	xx.xx	xx.xx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx
CV%		xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Geometric Mean		xx.xx	xx.xxx	xx.xx	xx.xx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx
95% CI of geometric mean		x.xx-x.xx	x.xxx-x.xxx	x.xx-x.xx	x.xx-x.xx	x.xxx-x.xxx	x.xxx-x.xxx	x.xxx-x.xxx	x.xxx-x.xxx	x.xxx-x.xxx	x.xxx-x.xxx	x.xxx-x.xxx	x.xxx-x.xxx

<Note: Repeat the same table as 14.2.2.3 for albendazole sulfoxide >

14.2.1.3 Contd. Individual pharmacokinetic parameter (untransformed) of albendazole for Test Product-T1 (first administration), Test Product-T2 (second administration), Reference Product-R1 (first administration) and Reference Product-R2 (second administration)

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Table No. 14.2.1.3 Contd.

Individual pharmacokinetic parameters (untransformed) of albendazole for Test Product-T1 (first administration), Test Product-T2 (second administration), Reference Product-R1 (first administration) and Reference Product-R2 (second administration)

Participants	Sequence	AUC0-inf (unit)				AUC_%Extrap_obs (%)			
		Formulation				Formulation			
		T1	T2	R1	R2	T1	T2	R1	R2
1001		xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx
1002		xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx
.		.	.	.	.	.	.	.	.
n		xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx
N		xx	xx	xx	xx	xx	xx	xx	xx
Mean		xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx
95% CI of arithmetic mean		x.xxx-x.xxx	x.xxx-x.xxx	x.xxx-x.xxx	x.xxx-x.xxx	x.xxx-x.xxx	x.xxx-x.xxx	x.xxx-x.xxx	x.xxx-x.xxx
SD		xx.xxxx	xx.xxxx	xx.xxxx	xx.xxxx	xx.xxxx	xx.xxxx	xx.xxxx	xx.xxxx
Min		xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx
Median		xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx
Max		xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx
CV%		xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Geometric Mean		xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx
95% CI of geometric mean		x.xxx-x.xxx	x.xxx-x.xxx	x.xxx-x.xxx	x.xxx-x.xxx	x.xxx-x.xxx	x.xxx-x.xxx	x.xxx-x.xxx	x.xxx-x.xxx

<Note: Repeat the same table as 14.2.2.3 for albendazole sulfoxide >

14.2.1.3 Contd. Individual pharmacokinetic parameter (untransformed) of albendazole for Test Product-T1 (first administration), Test Product-T2 (second administration), Reference Product-R1 (first administration) and Reference Product-R2 (second administration)

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Table No. 14.2.1.3 Contd.

Individual pharmacokinetic parameters (untransformed) of albendazole for Test Product-T1 (first administration), Test Product-T2 (second administration), Reference Product-R1 (first administration) and Reference Product-R2 (second administration)

Participants	Sequence	Lambda_z (unit)				t1/2 (unit)			
		Formulation				Formulation			
		T1	T2	R1	R2	T1	T2	R1	R2
1001		xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx
1002		xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx
.		.	.	.	.	.	.	.	.
.		.	.	.	.	.	.	.	.
n		xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx
N		xx	xx	xx	xx	xx	xx	xx	xx
Mean		xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx
95% CI of arithmetic mean		x.xxx-x.xxx	x.xxx-x.xxx	x.xxx-x.xxx	x.xxx-x.xxx	x.xxx-x.xxx	x.xxx-x.xxx	x.xxx-x.xxx	x.xxx-x.xxx
SD		xx.xxxx	xx.xxxx	xx.xxxx	xx.xxxx	xx.xxxx	xx.xxxx	xx.xxxx	xx.xxxx
Min		xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx
Median		xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx
Max		xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx
CV%		xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Geometric Mean		xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx
95% CI of geometric mean		x.xxx-x.xxx	x.xxx-x.xxx	x.xxx-x.xxx	x.xxx-x.xxx	x.xxx-x.xxx	x.xxx-x.xxx	x.xxx-x.xxx	x.xxx-x.xxx

<Note: Repeat the same table as 14.2.2.3 for albendazole sulfoxide >

14.2.1.4 Pharmacokinetic parameters (untransformed) of data excluded from statistical analysis for albendazole (if applicable)

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Table No. 14.2.1.4

Pharmacokinetic parameters (untransformed) of data excluded from statistical analysis for albendazole

Participants	Period	Sequence	Formulation	Tmax (unit)	Cmax (unit)	AUC0-t (unit)	AUC0-inf (unit)	AUC_%Extrap_obs (%)	Lambda_z (unit)	t1/2 (unit)
1001				xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xx
1002				xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xx
.				.	.	.	.	.	.	.
.				.	.	.	.	.	.	.
.				.	.	.	.	.	.	.
.				.	.	.	.	.	.	.
n				xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xx

<Note: Repeat the same table as 14.2.2.4 for albendazole sulfoxide.>

14.2.1.5 Pharmacokinetic parameters (ln-transformed) of albendazole for Test Product-T and Reference Product-R

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Table No. 14.2.1.5

Pharmacokinetic parameters (ln-transformed) of albendazole for Test Product-T and Reference Product-R

Participants	Sequence	Cmax		AUC0-t	
		Formulation		Formulation	
		T	R	T	R
1001		xx.xxx	xx.xxx	xx.xxx	xx.xxx
1002		xx.xxx	xx.xxx	xx.xxx	xx.xxx
.		.	.	.	.
.		.	.	.	.
.		.	.	.	.
n		xx.xxx	xx.xxx	xx.xxx	xx.xxx
N		xx	xx	xx	xx
Mean		xx.xxx	xx.xxx	xx.xxx	xx.xxx
95% CI of arithmetic mean		x.xxx-x.xxx	x.xxx-x.xxx	x.xxx-x.xxx	x.xxx-x.xxx
SD		xx.xxxx	xx.xxxx	xx.xxxx	xx.xxxx
Min		xx.xxx	xx.xxx	xx.xxx	xx.xxx
Median		xx.xxx	xx.xxx	xx.xxx	xx.xxx
Max		xx.xxx	xx.xxx	xx.xxx	xx.xxx
CV%		xx.x	xx.x	xx.x	xx.x
Geometric Mean		xx.xxx	xx.xxx	xx.xxx	xx.xxx
95% CI of geometric mean		x.xxx-x.xxx	x.xxx-x.xxx	x.xxx-x.xxx	x.xxx-x.xxx

<Note: Repeat the same table as 14.2.2.5 for albendazole sulfoxide.>

14.2.1.6 Individual Pharmacokinetic parameter (ln-transformed) of albendazole for Test Product-T1 (first administration), Test Product-T2 (second administration), Reference Product-R1 (first administration) and Reference Product-R2 (second administration)

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Table No. 14.2.1.6

Individual pharmacokinetic parameters (ln-transformed) of albendazole for Test Product-T1 (first administration), Test Product-T2 (second administration), Reference Product-R1 (first administration) and Reference Product-R2 (second administration)

Participants	Sequence	Cmax (unit)				AUC0-t (unit)			
		Formulation				Formulation			
		T1	T2	R1	R2	T1	T2	R1	R2
1001		xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx
1002		xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx
.		.	.	.	.	.	.	.	.
.		.	.	.	.	.	.	.	.
.		.	.	.	.	.	.	.	.
n		xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx
N		xx	xx	xx	xx	xx	xx	xx	xx
Mean		xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx
95% CI of arithmetic mean		x.xxx-x.xxx	x.xxx-x.xxx	x.xxx-x.xxx	x.xxx-x.xxx	x.xxx-x.xxx	x.xxx-x.xxx	x.xxx-x.xxx	x.xxx-x.xxx
SD		xx.xxxx	xx.xxxx	xx.xxxx	xx.xxxx	xx.xxxx	xx.xxxx	xx.xxxx	xx.xxxx
Min		xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx
Median		xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx
Max		xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx
CV%		xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Geometric Mean		xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx	xx.xxx
95% CI of geometric mean		x.xxx-x.xxx	x.xxx-x.xxx	x.xxx-x.xxx	x.xxx-x.xxx	x.xxx-x.xxx	x.xxx-x.xxx	x.xxx-x.xxx	x.xxx-x.xxx

<Note: Repeat the same table as 14.2.2.6 for albendazole sulfoxide.>

14.2.1.7 Plasma concentration of albendazole for Test Product-T1 (first administration)

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Table 14.2.1.7

Time (unit)	Plasma concentration of albendazole for Test Product-T1 (first administration)				N	Mean	SD	Min	Median	Max	CV%	Geometric Mean
	Participants											
	Concentration (unit)											
	1001	1002	.	n								
T_1	xx.xxx	xx.xxx	.	xx.xxx	xx	x.xxx	x.xxxx	x.xxx	x.xxx	x.xxx	x.x	x.xxx
T_2	xx.xxx	xx.xxx	.	xx.xxx	xx	x.xxx	x.xxxx	x.xxx	x.xxx	x.xxx	x.x	x.xxx
.	.	.	.	.	.	.	.	.	.	.	.	.
.	.	.	.	.	.	.	.	.	.	.	.	.
.	.	.	.	.	.	.	.	.	.	.	.	.
.	.	.	.	.	.	.	.	.	.	.	.	.
.	.	.	.	.	.	.	.	.	.	.	.	.
.	.	.	.	.	.	.	.	.	.	.	.	.
T_i	xx.xxx	xx.xxx	.	xx.xxx	xx	x.xxx	x.xxxx	x.xxx	x.xxx	x.xxx	x.x	x.xxx

Note: Here T_i (i = 1, 2……. n) denotes the time points at which blood sample has been taken

<Note 1: Repeat the same table as 14.2.1.8 for Test Product-T2 (second administration), 14.2.1.9 for Reference Product-R1 (first administration) and 14.2.1.10 for Reference Product-R2 (second administration) of albendazole.>

<Note 2: Repeat the same table as 14.2.2.7 for Test Product-T1 (first administration), 14.2.2.8 for Test Product-T2 (second administration), 14.2.2.9 for Reference Product-R1 (first administration) and 14.2.2.10 for Reference Product-R2 (second administration) of albendazole sulfoxide.>

14.2.1.11 Plasma concentration of data excluded from statistical analysis for albendazole (if applicable)

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Table 14.2.1.11

Time (h)	Plasma concentration of data excluded from statistical analysis for albendazole			
	Participants			
	Concentration (unit)			
	1001	1002	.	n
	Period	Period	.	Period
	Formulation	Formulation		Formulation
T_1	xx.xxx	xx.xxx	.	xx.xxx
T_2	xx.xxx	xx.xxx	.	xx.xxx
.	.	.	.	.
.	.	.	.	.
.	.	.	.	.
.	.	.	.	.
.	.	.	.	.
.	.	.	.	.
T_i	xx.xxx	xx.xxx	.	xx.xxx

Note: Here T_i (i = 1, 2……. n) denotes the time points at which blood sample has been taken.

<Note: Repeat the same table as 14.2.2.12 for albendazole sulfoxide.>

14.2.3 Actual time points used for pharmacokinetic evaluation

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Table 14.2.3
Actual time points used for pharmacokinetic evaluation

Participants	Period	Time Point (unit)	Difference in Minutes	Difference in Hour	Actual Time of Collection (unit)
1001		x.xxx		x.xxx	x.xxx
1002		x.xxx		x.xxx	x.xxx
.		.		.	.
.		.		.	.
.		.		.	.
.		.		.	.
.		.		.	.
.		.		.	.
.		.		.	.
.		.		.	.
n		x.xxx		x.xxx	x.xxx

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14.3 Safety Data

14.3.1 Overall summary of treatment emergent adverse events (Safety set)

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Table 14.3.1

Overall summary of treatment emergent adverse events (Safety set)

	Test Treatment-T (N=xx) n (%) e	Reference Treatment-R (N=xx) n (%) e	Total (N=xx) n (%) e	p-value
At least one TEAE	xx (xx.x) xx	xx (xx.x) xx	xx (xx.x) xx	x.xxxx
At least one TEAE leading to discontinuation	xx (xx.x) xx	xx (xx.x) xx	xx (xx.x) xx	x.xxxx
At least one TESAE	xx (xx.x) xx	xx (xx.x) xx	xx (xx.x) xx	-
Assessment of intensity				-
Mild	xx (xx.x) xx	xx (xx.x) xx	xx (xx.x) xx	
Moderate	xx (xx.x) xx	xx (xx.x) xx	xx (xx.x) xx	
Severe	xx (xx.x) xx	xx (xx.x) xx	xx (xx.x) xx	
Seriousness criteria				-
Congenital Anomaly/Birth Defect	xx (xx.x) xx	xx (xx.x) xx	xx (xx.x) xx	
Hospitalization or prolongation of existing hospitalization	xx (xx.x) xx	xx (xx.x) xx	xx (xx.x) xx	
Result in persistent or Significant Disability/incapacity	xx (xx.x) xx	xx (xx.x) xx	xx (xx.x) xx	
Life threatening	xx (xx.x) xx	xx (xx.x) xx	xx (xx.x) xx	
Abnormal pregnancy outcomes	xx (xx.x) xx	xx (xx.x) xx	xx (xx.x) xx	
Death	xx (xx.x) xx	xx (xx.x) xx	xx (xx.x) xx	
Other Medically Important Event	xx (xx.x) xx	xx (xx.x) xx	xx (xx.x) xx	
Relationship to Study Treatment				-
Related				
Certain	xx (xx.x) xx	xx (xx.x) xx	xx (xx.x) xx	
Probable/Likely	xx (xx.x) xx	xx (xx.x) xx	xx (xx.x) xx	
Possible	xx (xx.x) xx	xx (xx.x) xx	xx (xx.x) xx	
Not Related				
Unlikely	xx (xx.x) xx	xx (xx.x) xx	xx (xx.x) xx	
Conditional/Unclassified	xx (xx.x) xx	xx (xx.x) xx	xx (xx.x) xx	

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Table 14.3.1

Overall summary of treatment emergent adverse events (Safety set)

	Test Treatment-T (N=xx) n (%) e	Reference Treatment-R (N=xx) n (%) e	Total (N=xx) n (%) e	p-value
Unassessable/Unclassifiable	xx (xx.x) xx	xx (xx.x) xx	xx (xx.x) xx	
Unrelated	xx (xx.x) xx	xx (xx.x) xx	xx (xx.x) xx	
Action Taken with Study Treatment				-
Dose Increased	xx (xx.x) xx	xx (xx.x) xx	xx (xx.x) xx	
Dose Not Changed	xx (xx.x) xx	xx (xx.x) xx	xx (xx.x) xx	
Dose Reduced	xx (xx.x) xx	xx (xx.x) xx	xx (xx.x) xx	
Drug Interrupted	xx (xx.x) xx	xx (xx.x) xx	xx (xx.x) xx	
Drug Withdrawn	xx (xx.x) xx	xx (xx.x) xx	xx (xx.x) xx	
Not Applicable	xx (xx.x) xx	xx (xx.x) xx	xx (xx.x) xx	
Unknown	xx (xx.x) xx	xx (xx.x) xx	xx (xx.x) xx	
Outcome				-
Not Recovered/Not Resolved	xx (xx.x) xx	xx (xx.x) xx	xx (xx.x) xx	
Recovering/resolving	xx (xx.x) xx	xx (xx.x) xx	xx (xx.x) xx	
Recovered/Resolved	xx (xx.x) xx	xx (xx.x) xx	xx (xx.x) xx	
Recovered/Resolved With Sequelae	xx (xx.x) xx	xx (xx.x) xx	xx (xx.x) xx	
Stable	xx (xx.x) xx	xx (xx.x) xx	xx (xx.x) xx	
Change in severity	xx (xx.x) xx	xx (xx.x) xx	xx (xx.x) xx	
Fatal	xx (xx.x) xx	xx (xx.x) xx	xx (xx.x) xx	
Converted to SAE	xx (xx.x) xx	xx (xx.x) xx	xx (xx.x) xx	
Unknown	xx (xx.x) xx	xx (xx.x) xx	xx (xx.x) xx	
Death	xx (xx.x) xx	xx (xx.x) xx	xx (xx.x) xx	

N = Number of subjects in respective treatment population.
n = Number of subjects in respective categories; e = Number of events.
Percentages are based on the number of subjects allocated to each category.
P-value is calculated based on a chi-square test. If any cell has expected counts less than 5, then the Fisher's exact test is used instead.
Reference Listing: 16.2.7.1

Output Generated on: DDMMMYYYY hh:mm

14.3.2 Summary of treatment emergent adverse events by system organ class and preferred term (Safety set)

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Table 14.3.2

Summary of treatment emergent adverse events by system organ class and preferred term (Safety set)

System Organ Class Preferred Term	Test Treatment-T (N=xx) n (%) e	Reference Treatment-R (N=xx) n (%) e	Total (N=xx) n (%) e
Subjects with At least one TEAE	xx (xx.x) xx	xx (xx.x) xx	xx (xx.x) xx
System Organ Class 1	xx (xx.x) xx	xx (xx.x) xx	xx (xx.x) xx
Preferred Term 1	xx (xx.x) xx	xx (xx.x) xx	xx (xx.x) xx
Preferred Term 2	xx (xx.x) xx	xx (xx.x) xx	xx (xx.x) xx
.			
.			
.			
System Organ Class 2	xx (xx.x) xx	xx (xx.x) xx	xx (xx.x) xx
Preferred Term 1	xx (xx.x) xx	xx (xx.x) xx	xx (xx.x) xx
Preferred Term 2	xx (xx.x) xx	xx (xx.x) xx	xx (xx.x) xx
Etc.			

N = Number of subjects in respective treatment population.
n = Number of subjects in respective categories; e = Number of events.
Percentages are based on the number of subjects allocated to each category.
Each subjects is counted at the most once within each PT.
Adverse Events are coded using Medical Dictionary for Regulatory Activities (MedDRA) version xx
Reference Listing: 16.2.7.1

Output Generated on: DDMMMYYYY hh:mm

14.3.3 Summary of treatment emergent adverse events by relationship to study drug and system organ class and preferred term (Safety set)

Lambda Therapeutic Research Ltd. Confidential Project No. 0110-23

Table 14.3.3

Summary of treatment emergent adverse events by relationship to study drug and system organ class and preferred term (Safety set)

System Organ Class Preferred Term	Test Treatment-T (N=xx) n (%) e		Reference Treatment-R (N=xx) n (%) e		Total (N=xx) n (%) e	
	Related	Not-Related	Related	Not-Related	Related	Not-Related
Subjects with At least one TEAE	xx (xx.x) xx	xx (xx.x) xx	xx (xx.x) xx	xx (xx.x) xx	xx (xx.x) xx	xx (xx.x) xx
System Organ Class 1	xx (xx.x) xx	xx (xx.x) xx	xx (xx.x) xx	xx (xx.x) xx	xx (xx.x) xx	xx (xx.x) xx
Preferred Term 1	xx (xx.x) xx	xx (xx.x) xx	xx (xx.x) xx	xx (xx.x) xx	xx (xx.x) xx	xx (xx.x) xx
Preferred Term 2	xx (xx.x) xx	xx (xx.x) xx	xx (xx.x) xx	xx (xx.x) xx	xx (xx.x) xx	xx (xx.x) xx
.						
.						
.						
System Organ Class 2	xx (xx.x) xx	xx (xx.x) xx	xx (xx.x) xx	xx (xx.x) xx	xx (xx.x) xx	xx (xx.x) xx
Preferred Term 1	xx (xx.x) xx	xx (xx.x) xx	xx (xx.x) xx	xx (xx.x) xx	xx (xx.x) xx	xx (xx.x) xx
Preferred Term 2	xx (xx.x) xx	xx (xx.x) xx	xx (xx.x) xx	xx (xx.x) xx	xx (xx.x) xx	xx (xx.x) xx
Etc.						

N = Number of subjects in respective treatment population.
n = Number of subjects in respective categories; e = Number of events.
Percentages are based on the number of subjects allocated to each category.
Each subject is counted at most once within each PT.
Adverse Events are coded using Medical Dictionary for Regulatory Activities (MedDRA) version xx
Reference Listing: 16.2.7.1

Output Generated on: DDMMMYYYY hh:mm

14.3.4 Summary of treatment emergent adverse events by severity grade and system organ class and preferred term (Safety set)

Lambda Therapeutic Research Ltd. Confidential Project No. 0110-23

Table 14.3.4

Summary of treatment emergent adverse events by severity grade and system organ class and preferred term (Safety set)

System Organ Class Preferred Term	Test Treatment-T (N=xx) n (%) e	Reference Treatment-R (N=xx) n (%) e	Total (N=xx) n (%) e
Subjects with At least one TEAE	xx (xx.x) xx	xx (xx.x) xx	xx (xx.x) xx
Mild			
System Organ Class 1	xx (xx.x) xx	xx (xx.x) xx	xx (xx.x) xx
Preferred Term 1	xx (xx.x) xx	xx (xx.x) xx	xx (xx.x) xx
Preferred Term 2	xx (xx.x) xx	xx (xx.x) xx	xx (xx.x) xx
.			
.			
.			
System Organ Class 2	xx (xx.x) xx	xx (xx.x) xx	xx (xx.x) xx
Preferred Term 1	xx (xx.x) xx	xx (xx.x) xx	xx (xx.x) xx
Preferred Term 2	xx (xx.x) xx	xx (xx.x) xx	xx (xx.x) xx
Etc.			

N = Number of subjects in respective treatment population.
n = Number of subjects in respective categories; e = Number of events.
Percentages are based on the number of subjects allocated to each category.
Each subject is counted at most once within each PT.
Adverse Events are coded using Medical Dictionary for Regulatory Activities (MedDRA) version xx
Reference Listing: 16.2.7.1

Output Generated on: DDMMMYYYY hh:mm

14.3.5 Summary of subject disposition

Lambda Therapeutic Research Ltd. Confidential Project No. 0110-23

Table 14.3.5

Summary of subject disposition

	TRTR (N=xx) n (%)	RTRT (N=xx) n (%)	Total (N=xx) n (%)
Subjects Randomized	xx (xx.x)	xx (xx.x)	xx (xx.x)
Subjects included in Safety set	xx (xx.x)	xx (xx.x)	xx (xx.x)
Subjects included in PK set	xx (xx.x)	xx (xx.x)	xx (xx.x)
Subjects who completed study	xx (xx.x)	xx (xx.x)	xx (xx.x)
Subjects who discontinued study	xx (xx.x)	xx (xx.x)	xx (xx.x)
Reason for discontinuing study			
Reason 1	xx (xx.x)	xx (xx.x)	xx (xx.x)
Reason 2	xx (xx.x)	xx (xx.x)	xx (xx.x)
Reason 3	xx (xx.x)	xx (xx.x)	xx (xx.x)
Etc.	xx (xx.x)	xx (xx.x)	xx (xx.x)

N = Number of subjects in safety set, n = Number of subjects in respective categories
Note: Percentages are calculated based on the total number of subjects in each category.
Treatment specification -> T = Test Product and R = Reference Product.
Reference Listing: 16.2.1.2

Output Generated on: DDMMMYYYY hh:mm

<Note for programmers: Reason for discontinued should be in descending order i.e., highest reported reasons should come first.>

14.3.6 Summary of vital signs (Safety set)

Lambda Therapeutic Research Ltd. Confidential Project No. 0110-23

Table 14.3.6
Summary of vital signs (Safety set)

Parameters (Unit)	Visit (Day)	Time Point	Statistics	TRTR (N=xx)	RTRT (N=xx)	Total (N=xx)	p-value
Pulse rate (beats/min)	Screening		n	xx	xx	xx	x.xxxx
			Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	
			Median	xx.x	xx.x	xx.x	
			Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	
	Assessment Visit X	Time Point 1	n	xx	xx	xx	x.xxxx
			Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	
			Median	xx.x	xx.x	xx.x	
			Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	
		Time Point 2	n	xx	xx	xx	x.xxxx
			Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	
			Median	xx.x	xx.x	xx.x	
			Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	
	Assessment Visit Y	Time Point 1	n	xx	xx	xx	x.xxxx
			Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	
			Median	xx.x	xx.x	xx.x	
			Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	
Etc.	Etc.	Etc.					

N = Number of subjects in safety set, n = Number of subjects in respective categories
P-value is calculated using an independent t-test.
Treatment specification -> T = Test Product and R = Reference Product.
Reference Listing: 16.2.9.4

Output Generated on: DDMMMYYYY hh:mm

<Note for programmers: This table will continue for vital parameters like Systolic Blood Pressure (mmHg), Diastolic Blood Pressure (mmHg), Oral Body Temperature (°F), etc.>

14.3.7 Summary of change from baseline for vital signs (Safety set)

Lambda Therapeutic Research Ltd. Confidential Project No. 0110-23

Table 14.3.7

Summary of change from baseline for vital signs (Safety set)

Parameters (Unit)	Visit (Day)	Time Point	Statistics	TRTR (N=xx)	RTRT (N=xx)	Total (N=xx)
Diastolic Blood Pressure (mmHg)	Assessment Visit X	Time Point 1	n	xx	xx	xx
			Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
			Median	xx.x	xx.x	xx.x
			Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
		Time Point 2	n	xx	xx	xx
			Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
			Median	xx.x	xx.x	xx.x
			Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
	Assessment Visit Y	Time Point 1	n	xx	xx	xx
			Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
			Median	xx.x	xx.x	xx.x
			Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Etc.	Etc.	Etc.				

N = Number of subjects in safety set, n = Number of subjects in respective categories
Change from Baseline (CFB) = Post Baseline assessment – Baseline assessment (0.00 Hrs Pre-Dose).
Treatment specification -> T = Test Product and R = Reference Product.
Reference Listing: 16.2.9.4

Output Generated on: DDMMMYYYY hh:mm

14.3.8 Summary of quantitative safety laboratory variables (Safety set)

Lambda Therapeutic Research Ltd. Confidential Project No. 0110-23

Table 14.3.8

Summary of quantitative safety laboratory variables (Safety set)

Parameters (Unit)	Visit	Statistics	TRTR (N=xx)	RTRT (N=xx)	Total (N=xx)
Hemoglobin (g/dL)	Screening	n	xx	xx	xx
		Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
		Median	xx.x	xx.x	xx.x
		Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
	Assessment Visit X	n	xx	xx	xx
		Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
		Median	xx.x	xx.x	xx.x
		Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
	Assessment Visit Y	n	xx	xx	xx
		Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
		Median	xx.x	xx.x	xx.x
		Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Etc.	Etc.				

N = Number of subjects in safety set, n = Number of subjects in respective categories
Treatment specification -> T = Test Product and R = Reference Product.
Quantitative data values observed out of limit of quantification are adjusted to quantification limits for descriptive statistics.
In case of repeat sample collection latest result has been considered for the analysis.
Reference Listings: 16.2.8.1

Output Generated on: DDMMMYYYY hh:mm

<Note to Programmer: This table will continue for all other Laboratory parameters and some additional test.>

14.3.9 Summary of qualitative safety laboratory variables (Safety set)

Lambda Therapeutic Research Ltd. Confidential Project No. 0110-23

Table 14.3.9

Summary of qualitative safety laboratory variables (Safety set)

Parameters (Unit)	Visit	Result	Statistics	TRTR (N=xx)	RTRT (N=xx)	Total (N=xx)
HBsAg	Screening	xxx	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		xxx	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		xxx	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Assessment Visit X	xxx	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		xxx	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		xxx	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Assessment Visit Y	xxx	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		xxx	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		xxx	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Etc.	Etc.					

N = Number of subjects in safety set, n = Number of subjects in respective categories
Note: Percentages are calculated based on the total number of subjects in each category.
Treatment specification -> T = Test Product and R = Reference Product.
In case of repeat sample collection latest result has been considered for the analysis.
Reference Listing: 16.2.8.1

Output Generated on: DDMMMYYYY hh:mm

<Note to Programmer: This table will continue for all other Laboratory parameters and some additional test.>

14.3.10 Summary of concomitant medication (Safety set)

Lambda Therapeutic Research Ltd. Confidential Project No. 0110-23

Table 14.3.10

Summary of concomitant medication (Safety set)

	TRTR (N=xx) n (%)	RTRT (N=xx) n (%)	Total (N=xx) n (%)
At least one concomitant medication	xx (xx.x)	xx (xx.x)	xx (xx.x)
Medication 1	xx (xx.x)	xx (xx.x)	xx (xx.x)
Medication 2	xx (xx.x)	xx (xx.x)	xx (xx.x)
Medication 3	xx (xx.x)	xx (xx.x)	xx (xx.x)
Etc.	xx (xx.x)	xx (xx.x)	xx (xx.x)

N = Number of subjects in safety set, n = Number of subjects in respective categories
Note: Percentages are calculated based on the total number of subjects in each category.
Treatment specification -> T = Test Product and R = Reference Product.
Reference Listing: 16.2.10

Output Generated on: DDMMMYYYY hh:mm

In-text tables

Table 1: Summary of Adverse events

Adverse events (as per MedDRA PT - Version xxx)	Albendazole tablets IP 400 mg Test (T)	Albendazole 400 mg tablets Reference (R)	Total
XXXXXXXXX	x	x	x
XXXXXXXXX	x	x	x
XXXXXXXXX	x	x	x
XXXXXXXXX	x	x	x
XXXXXXXXX	x	x	x
XXXXXXXXX	x	x	x
XXXXXXXXX	x	x	x
XXXXXXXXX	x	x	x
XXXXXXXXX	x	x	x
XXXXXXXXX	x	x	x
XXXXXXXXX	x	x	x
Total	x	x	x

Table 2: Summary of Adverse Events with System Organ Class

System Organ Class	MedDRA (PT) (Version xxx)	Albendazole tablets IP 400 mg Test (T)	Albendazole 400 mg tablets Reference (R)	No. of events
XXXXXXXXX	XXXXXXXXX	x	x	x
XXXXXXXXX	XXXXXXXXX	x	x	x
XXXXXXXXX	XXXXXXXXX	x	x	x
XXXXXXXXX	XXXXXXXXX	x	x	x
XXXXXXXXX	XXXXXXXXX	x	x	x
XXXXXXXXX	XXXXXXXXX	x	x	x
XXXXXXXXX	XXXXXXXXX	x	x	x
XXXXXXXXX	XXXXXXXXX	x	x	x
XXXXXXXXX	XXXXXXXXX	x	x	x
XXXXXXXXX	XXXXXXXXX	x	x	x
XXXXXXXXX	XXXXXXXXX	x	x	x
Total		x	x	x

Listings

16.2.1 Subject disposition

16.2.1.1 Screen failure subjects

Screening No.	Date of screening	Subject Study Completion Status	Reason for Screen Failure	If 'Other', 'Physician decision', 'Withdrawal by subject', please specify

Screening No.	Date of screening	If Non-fulfillment of inclusion/exclusion criteria or Protocol Violation, please specify	If 'Death', Date of Death

16.2.1.2 Study completion status

Subject no.	Sequence	Subject Study Completion Status	Date of Completion or Premature Discontinuation	Date of last dose of study drug administration	Reason for Discontinuation

Subject no.	Sequence	If 'Other', 'Physician decision', 'Withdrawal by subject', 'Adverse event', specify	If Non-fulfilment of inclusion/exclusion criteria or Protocol Violation, specify	If 'Death', Date of Death

16.2.1.3 Subject distribution in analysis population

Subject no.	Sequence	Subjects included in Randomized set	Subjects included in Safety set	Subjects included in PK set

16.2.1.4 Inclusion - Exclusion criteria

Subject no.	Sequence	Does the subject meet all inclusion criteria?	If No, Mark the INCLUSION criterion number(s) not met	Does the subject meet any exclusion criteria?	If Yes, Mark the EXCLUSION criterion number(s) met

16.2.1.5 Inclusion criteria description

Code	Inclusion criteria description

16.2.1.6 Exclusion criteria description

Code	Exclusion criteria description

16.2.2 Protocol deviations

Subject no.	Sequence	Visit No.	Date of deviation Occurrence	Protocol Section	Protocol requirement

Subject no.	Sequence	Visit No.	Type (Major/Minor)	Reason for deviation	Description of the Deviation	Corrective Action	Preventive Action	Impact Assessment

<Note: Listing will be displayed as per available data from the source.>

16.2.3 Subjects excluded from the analysis

16.2.3.1 Subjects excluded from the analysis (PK set)

Subject No.	Period	Reason

16.2.4 Demographic data

16.2.4.1 Demographic data and baseline characteristics

Screening no.	Subject no.	Sequence	Date of Informed consent form signed (Screening)	Date of Informed consent form signed (Study Specific)	Date of Birth	Age (Years)	Gender	Ethnicity	Race	If Other, please specify

< Note for programmers: This listing will be created on Randomized set.>

16.2.4.2 Personal history

Subject no.	Sequence	Personal history assessment done for female subject?	Reproductive status

16.2.4.3 Medical and surgical history details

Subject no.	Sequence	Visit	Nature of condition	Medical/Surgical history term	Medical/Surgical history code

Subject no.	Sequence	Visit	Start date	End date	Ongoing

16.2.4.4 Physical examination

Subject no.	Sequence	Visit	Date of assessment	Body System	Result	Specify if Abnormal CS/Not Done	Any New clinically significant abnormality finding or worsening of condition since last assessment?

Subject no.	Sequence	Visit	If yes, please select body System	If yes, please specify abnormality

16.2.4.5 Medication history

Subject no.	Sequence	Subject taken any medication from 14 days prior to dosing of period I?

16.2.5 Compliance and drug concentration data

16.2.5.1 Study drug administration

Subject no.	Sequence	Visit	Study drug administration performed?	Date of study drug administration	Time of Study drug administration	Mouth check done after dosing?	If 'No', then specify	Any deviation during dosing?	If 'Yes', please specify

16.2.5.2 Compliance assessment

Subject no.	Sequence	Visit	Has the subject been compliant to all pre dose compliance criteria?:	If 'No', then specify	Has the subject been compliant to all post dose compliance criteria?	If No, then specify

16.2.5.3 PK sample collection

Subject no.	Sequence	Visit	Time point	Actual Date of PK sample collection	Actual Time of PK sample collection	Any Deviation?	If 'Yes', please specify

16.2.5.4 Concentration-time data for albendazole

Participant	Sequence	Period	Formulation	Form	Schedule Time (h)	Actual Time (h)	Concentration (unit)

Programming note: Similar listing will be generated for albendazole sulfoxide as 16.2.5.6.

16.2.5.5 Pharmacokinetic data for albendazole

Participant	Sequence	Period	Formulation	Form	Tmax (h)	Cmax (unit)	AUC0-t (unit)	AUC0-inf (unit)	AUC_%Extrap_obs (%)	Lambda_z (unit)	t1/2 (unit)

Programming note: Similar listing will be generated for albendazole sulfoxide as 16.2.5.7.

16.2.7 Adverse events (each subject)

16.2.7.1 Adverse events by severity, relationship to the study drug and by MedDRA term

Subject no.	Treatment	Adverse event term	Adverse Event Code	Start date	Start Time	End date	End time

Subject no.	Treatment	Assessment of intensity	Is this adverse event serious?	If Serious, Please specify seriousness criteria	Relationship to Study Treatment	Action Taken with Study Treatment	Outcome	Concomitant treatment/Therapy given

Subject no.	Treatment	Preferred Term	Preferred Term code	System Organ Class	Lowest Level Term	Lowest Level Term Code	High Level Term	High Level Term Code	High Level Group Term	High Level Group Term Code

Note: Only subjects having an adverse event are included in this listing.

16.2.7.2 Serious adverse events (if applicable)

Subject no.	Treatment	Adverse event term	Adverse Event Code	Start date	Start Time	End date	End time

Subject no.	Treatment	Preferred Term	Preferred Term code	System Organ Class	Lowest Level Term	Lowest Level Term Code	High Level Term	High Level Term Code	High Level Group Term	High Level Group Term Code

Note: Only subjects having serious adverse events are included in this listing.

16.2.8 Listing of individual laboratory measurements (by Subject)

16.2.8.1 Central laboratory tests

					Laboratory Test group					
Subject no.	Sequence	Visit	Date of sample collection	Time of sample collection	Laboratory Test	Unit	Laboratory range - Minimum	Laboratory range - Maximum	Laboratory Results	Flagging (L/H/A/N)

16.2.8.2 Safety Laboratory analysis

Subject no.	Sequence	Visit	Date of sample collection	Time of sample collection	Specimen Type

Subject no.	Sequence	Visit	Panel Name	Overall Interpretation	If Abnormal CS, specify	Repeat sample status	If 'Other', then specify

16.2.9 Individual subject data listings

16.2.9.1 12 Lead electrocardiogram

Subject no.	Sequence	Date of Assessment	Interpretation	If Interpretation is "Abnormal CS", please specify

16.2.9.2 Chest x-ray

Subject no.	Sequence	Visit	Date of assessment	Interpretation	If Abnormal CS, please specify

16.2.9.3 Body measurements

Subject no.	Sequence	Height(cm)	Weight (Kgs)	BMI(kg/m^2)

< Note for programmers: This listing will be created on Randomized set.>

16.2.9.4 Vital signs

Subject no.	Sequence	Visit	Time Point	Date of measurement	Time of measurement	Systolic blood pressure	Diastolic blood pressure

Subject no.	Sequence	Visit	Radial pulse	Respiratory rate	Body temperature	Interpretation	If Abnormal CS, please specify	CFB

Change from Baseline (CFB) = Post Baseline assessment – Baseline assessment (0.00 Hrs Pre-Dose)

16.2.9.5 Urine drug scan and breath alcohol test

Subject no.	Sequence	Visit	Date of assessment	Urine drug scan result	Breath alcohol test result

16.2.9.6 Lifestyle compliance assessment

Subject no.	Sequence	Visit	Subject followed all the instruction of lifestyle restriction as per protocol?	If "No" then specify

16.2.9.7 Subjects date of visit

Subject no.	Sequence	Visit	Date of Visit

< Note for programmers: This listing will be created on Randomized set.>

16.2.9.8 Unscheduled visit (if applicable)

Subject no.	Sequence	Reason for unscheduled visit	Date of unscheduled visit	Activity Name	If Other, please specify	If any abnormal clinically significant findings, then provide details

16.2.10 Prior - Concomitant medication

Subject no.	Sequence	Medication Name or Therapy	Medication Code	Indication code	Indication	Dose per administration	Unit	If 'Other' (Unit), please specify

Subject no.	Sequence	Frequency	If 'Other' (Frequency), please specify	Route	If 'Other' (Route), please specify	Start date	End date	Ongoing