Division	:	Worldwide Development
Information Type	:	Reporting and Analysis Plan (RAP)

Title	:	Reporting and Analysis Plan for 204706: A single centre, single dose, open-label, randomized, 2-part, 2-way crossover study to determine the bioequivalence of levocetirizine oral disintegrating tablet given with water and without water compared to levocetirizine immediate release tablet in healthy Japanese male subjects
Compound Number	:	GSK2074687 (Levocetirizine)
Effective Date	:	15-MAY-2018

Description:

- The purpose of this RAP is to describe the planned analyses and output to be included in the Clinical Pharmacology Study Report for Protocol 204706.
- This RAP is intended to describe the safety and pharmacokinetics analyses required for the study.
- This RAP will be provided to the study team members to convey the content of the Statistical Analysis Complete (SAC) deliverable.

RAP Author(s):

Approver	Date	Approval Method
PPD Study statistician (Manager, Biostatistics Group 1, Biomedical Data Sciences Department, Japan)		
PPD Pharmacokineticist (Staff, Clinical Pharmacology Office, Japan)	14-MAY-2018	eSignature

RAP Team Approvals:

Approver	Date	Approval Method
PPD CIL and OSL (Manager, Clinical Pharmacology Office, Medicines Development, Japan	14-MAY-2018	eSignature
PPD DQL (Staff, Data Practice Group, Biomedical Data Sciences Department, Japan)	15-MAY-2018	eSignature
PPD Clinical programmer (Manager, Statistical Programming & Reporting Group, Biomedical Data Sciences Department, Japan)	15-MAY-2018	eSignature

Clinical Statistics and Clinical Programming Line Approvals:

Approver	Date	Approval Method
PPD Clinical Statistics Line approver (Associate Manager, Biostatistics Group 1, Biomedical Data Sciences Department, Japan)	14-MAY-2018	eSignature
PPD Clinical Programming Line approver (Department Manager, Biomedical Data Sciences Department, Japan)	14-MAY-2018	eSignature

TABLE OF CONTENTS

PAGE

1. INTRODUCTION

The purpose of this reporting and analysis plan (RAP) is to describe the analyses to be included in the Clinical Pharmacology Study Report for Protocol.

Revision Chronology:		
Version 00	15-MAY-2018	Original

2. SUMMARY OF KEY PROTOCOL INFORMATION

2.1. Changes to the Protocol Defined Statistical Analysis Plan

There were no changes or deviations to the originally planned statistical analysis specified in the protocol (Dated: 20/Apr/2018).

2.2. Study Objective(s) and Endpoint(s)

Objectives	Endpoints
Primary Objectives	**Primary Endpoints**
• To evaluate the bioequivalence between levocetirizine ODT (Orally Disintegrating Tablet) 5 mg (Test product) and levocetirizine IRT (Immediate Release Tablet) 5 mg (Reference product) in healthy Japanese male subjects	• Plasma PK parameters of levocetirizine: AUC(0-t) and Cmax
Secondary Objectives	**Secondary Endpoints**
• To assess the safety and tolerability following a single dose of levocetirizine 5 mg when given as levocetirizine ODT and levocetirizine IRT in healthy Japanese male subjects.	• Adverse events (AEs), changes from baseline in clinical laboratory tests, vital signs (blood pressure, pulse rate and body temperature), and 12-lead electrocardiogram (ECG). • Plasma PK parameters of levocetirizine: AUC(0-inf), tmax, t1/2, %AUCex, CL/F, Vz/F, kel and MRT.
Exploratory Objectives	**Exploratory Endpoints**
• To assess the palatability questionnaire	• The palatability questionnaire

2.3. Study Design

Overview of Study Design and Key Features

Part 1 (Dosing of levocetirizine ODT with water)

- Single dose of levocetirizine ODT 5 mg x 1 with 150 mL of water in the fasted state
- Single dose of levocetirizine IRT 5 mg x 1 with 150 mL of water in the fasted state

Group	n	Period 1	Period 2
A	12	Levocetirizine IRT 5 mg (with water)	Levocetirizine ODT 5 mg (with water)
B	12	Levocetirizine ODT 5 mg (with water)	Levocetirizine IRT 5 mg (with water)

Part 2 (Dosing of levocetirizine ODT without water)

- Single dose of levocetirizine ODT 5 mg x 1 without water in the fasted state
- Single dose of levocetirizine IRT 5 mg x 1 with 150 mL of water in the fasted state

Group	n	Period 1	Period 2
C	12	Levocetirizine IRT 5 mg (with water)	Levocetirizine ODT 5 mg (without water)
D	12	Levocetirizine ODT 5 mg (without water)	Levocetirizine IRT 5 mg (with water)

Design Features	• This is a single centre, open-label, single dose, randomized, 2-way crossover study in healthy Japanese male subjects. • This study consists of two parts: Part 1 compares dosing of levocetirizine ODT and levocetirizine IRT taken with 150 mL water in the fasted state, Part 2 compares dosing of levocetirizine ODT without water and levocetirizine IRT with 150 mL water in the fasted state. • If subjects prematurely discontinue the study, additional replacement subjects may be recruited and assigned to the same treatment sequence at the discretion of the Sponsor in consultation with the investigator. • If bioequivalence cannot be demonstrated in Part 1 and/or Part 2 because of an insufficient number of subjects, an add-on subject study will be performed using 12 (6 subjects in each group) or more subjects in each part.
Dosing	• All subjects will receive a single dose of levocetirizine 5 mg after an overnight fast (at least 10 hours) during the intervention period
Time & Events	• Refer to Appendix 2: Schedule of Activities.
Treatment Assignment	• In both parts (Part 1 and Part 2), total number of 24 subjects will be equally divided into two groups (12 subjects in each group) and will be randomized in a 1:1 ratio to one of two groups in each part. • Subjects will participate either in Part 1 or Part 2 without overlapping.
Interim Analysis	• No formal interim analyses are planned.

2.4. Statistical Hypotheses / Statistical Analyses

This study is designed to test the bioequivalence of levocetirizine ODT 5 mg (with water or without water) relative to levocetirizine IRT 5 mg.

The null hypothesis is that the true ratio of the geometric mean of the levocetirizine ODT 5mg (μ_{test}) to the geometric mean of the levocetirizine IRT 5mg (μ_{ref}), μ_{test}/μ_{ref}, for each primary PK endpoint (AUC(0-t) and Cmax of levocetirizine), is either less than or equal to 0.80 or greater than or equal to 1.25. The alternative hypothesis is that the true ratio of the test treatment geometric mean to the reference treatment geometric mean is greater than 0.80 and less than 1.25.

Symbolically, this is expressed as follows:

H_0: $\mu_{test}/\mu_{ref} \leq 0.80$ or $\mu_{test}/\mu_{ref} \geq 1.25$,

i.e., treatments are not bioequivalent.

Versus

H_1: $0.80 < \mu_{test}/\mu_{ref} < 1.25$,

i.e., treatments are bioequivalent.

These hypotheses will be considered for levocetirizine ODT 5 mg with water or without water separately, relative to levocetirizine IRT 5 mg.

For each PK parameter designated as a primary endpoint (AUC(0-t) and Cmax), a two one-sided t-test (TOST) procedure [Schuirmann, 1987] with α=0.05 for each one-sided test will be used to test this set of hypotheses. This is equivalent to requiring that a 90% interval for the true ratio of levocetirizine ODT 5 mg to levocetirizine IRT 5 mg geometric means (μ_{test}/μ_{ref}) falls entirely within the range of 0.80 to 1.25. A judgment by 90% CI will be conducted in this study.

If the bioequivalence will not be shown above, ODT 5 mg will be accepted as bioequivalent where the point estimate for true ratio of levocetirizine ODT 5 mg to levocetirizine IRT 5 mg geometric mean (μ_{test}/μ_{ref}) of AUC(0-t) and Cmax are within 0.90 - 1.11, according to the criteria described in the Japanese Guideline for Bioequivalence Studies of Generic Products (Japanese BE guideline) [Pharmaceutical and Food Safety Bureau, Evaluation and Licensing Division, Ministry of Health, Labour, 2012].

3. PLANNED ANALYSES

3.1. Interim Analyses

No formal interim analyses are planned.

3.2. Final Analyses

The final analyses will be performed after the completion of the following sequential steps in each part respectively:

1. All participants have completed the study as defined in the protocol.
2. All required database cleaning activities have been completed and final database release (DBR) and database freeze (DBF) has been declared by Data Management.
3. Randomization codes have been distributed according to RandAll NG procedures.

As for an add-on subject study, the same sequential step above will be conducted.

4. ANALYSIS POPULATIONS

Population	Definition / Criteria	Analyses Evaluated
Screened	• Consisting of all participants screened in the study.	• Study Population
Screening Failure	• Participants who sign the ICF in the study but are never subsequently randomized. All participants who sign the ICF have the screening test in the study.	• Study Population
Safety	• All randomized participants who take at least one dose of study treatment. • Participants will be analyzed according to the treatment they actually received.	• Study Population • Safety • Palatability Questionnaire
Pharmacokinetic	• This population is defined as all participants administered at least one dose of study treatment and who have blood for plasma drug concentration sample taken and analyzed. • Participants will be analyzed according to the treatment they actually received.	• PK

Refer to Appendix 10: List of Data Displays which details the population used for each display.

4.1. Protocol Deviations

Important protocol deviations (including deviations related to study inclusion/exclusion criteria, conduct of the trial, patient management or patient assessment) will be summarised and listed.

Protocol deviations will be tracked by the study team throughout the conduct of the study in accordance with the Protocol Deviation Management Plan.

- Data will be reviewed prior to freezing the database to ensure all important deviations and deviations which may lead to exclusion from the analysis are captured and categorised on the protocol deviations dataset.
- This dataset will be the basis for the summaries and listings of protocol deviations.

A separate listing of all inclusion/exclusion criteria deviations will also be provided. This summary will be based on data as recorded on the inclusion/exclusion page of the eCRF.

5. CONSIDERATIONS FOR DATA ANALYSES AND DATA HANDLING CONVENTIONS

5.1. Study Treatment & Sub-group Display Descriptors

Treatment			
RandAll NG		Data Displays for Reporting	
Code	Description	Description	Order in TLF
A	Levocetirizine ODT 5 mg	Levocetirizine ODT 5 mg	1
A	Levocetirizine IRT 5 mg	Levocetirizine IRT 5 mg	2
B	Levocetirizine IRT 5 mg	Levocetirizine IRT 5 mg	2
B	Levocetirizine ODT 5 mg	Levocetirizine ODT 5 mg	1

Randomized group (sequence) will be displayed as A or B for Part 1, and C (= A in RandAll NG) or D (= B in RandAll NG) for Part 2 according to the protocol.

5.2. Baseline Definitions

Baseline to be used in analysis is pre-dose in each period. For all endpoints, the baseline value will be the latest pre-dose assessment with a non-missing value, including those from unscheduled visits.

Parameter	Study Assessments Considered as Baseline			Baseline Used in Data Display
	Screening	Day -1	Day 1 (Pre-Dose)	
Safety				
Clinical Laboratory Test (Hematology, Clinical chemistry, and Urinalysis)	X		X	Day 1 (Pre Dose)
12 Lead ECG & Vital Signs	X		X	Day 1 (Pre Dose)

Data of height, weight and BMI for demographic characteristics will be from screening visit.

Unless otherwise stated, if baseline data is missing, no derivation will be performed and baseline will be set to missing.

5.3. Other Considerations for Data Analyses and Data Handling Conventions

Other considerations for data analyses and data handling conventions are outlined in the appendices:

Section	Component
11.3	Appendix 3: Assessment Windows
11.4	Appendix 4: Study Phases and Treatment Emergent Adverse Events
11.5	Appendix 5: Data Display Standards & Handling Conventions
11.6	Appendix 6: Derived and Transformed Data
11.7	Appendix 7: Reporting Standards for Missing Data
11.8	Appendix 8: Values of Potential Clinical Importance

6. STUDY POPULATION ANALYSES

Study population analyses including analyses of subject's disposition, protocol deviations, demographic characteristics, prior and concomitant medications, and exposure will be based on GSK Core Data Standards. Details of the planned displays are presented in Appendix 10: List of Data Displays.

7. SAFETY ANALYSES

The safety analyses will be based on the Safety population, unless otherwise specified.

7.1. Adverse Events Analyses

Adverse events analyses including the analysis of adverse events (AEs), Serious (SAEs) and other significant AEs will be based on GSK Core Data Standards. The details of the planned displays are provided in Appendix 10: List of Data Displays.

7.2. Clinical Laboratory Analyses

Laboratory evaluations including the analyses of Chemistry laboratory tests, Hematology laboratory tests, Urinalysis, and liver function tests will be based on GSK Core Data Standards. The details of the planned displays are in Appendix 10: List of Data Displays.

7.3. Other Safety Analyses

The analyses of non-laboratory safety test results including ECGs and vital signs will be based on GSK Core Data Standards, unless otherwise specified. The details of the planned displays are presented in Appendix 10: List of Data Displays.

8. PHARMACOKINETIC ANALYSES

The PK analyses will be based on the Pharmacokinetic population, unless otherwise specified.

8.1. Primary Pharmacokinetic Analyses

8.1.1. Endpoint / Variables

8.1.1.1. Drug Concentration Measures

Refer to Appendix 5: Data Display Standards & Handling Conventions (Section 11.5.3 Reporting Standards for Pharmacokinetic)

8.1.1.2. Derived Pharmacokinetic Parameters

Pharmacokinetic parameters will be calculated by standard non-compartmental analysis according to current working practices and using the currently supported version of WinNonlin (version 6.3 or higher). All calculations of non-compartmental parameters will be based on actual sampling times. Pharmacokinetic parameters listed will be determined from the plasma concentration-time data, as data permits.

Parameter	Parameter Description
AUC (0-t) (hr*ng/mL)	Area under the concentration-time curve from time zero time (pre-dose) to the time of last quantifiable concentration (AUC(0-t)) will be calculated by the linear trapezoidal method (i.e., Linear Trapezoidal Linear Interpolation calculation method in Phoenix WinNonlin).
Cmax (ng/mL)	Maximum observed concentration will be obtained directly from the concentration-time data.

8.1.2. Summary Measure

PK parameters of AUC(0-t) and Cmax are summary measures.

8.1.3. Population of Interest

The primary pharmacokinetic analyses will be based on the PK population, unless otherwise specified.

8.1.4. Strategy for Intercurrent (Post-Randomization) Events

This section is not applicable, however, where a missing data for PK parameters will occur in a subject on period 1 or period 2, the subject data will be analyzed using the mixed effect model to evaluate the bioequivalence of PK parameter.

8.1.5. Statistical Analyses / Methods

Details of the planned displays are provided in Appendix 10: List of Data Displays and will be based on GSK Data Standards and statistical principles.

Unless otherwise specified, endpoints / variables defined in Section 8.1.1 will be summarised using descriptive statistics, graphically presented (where appropriate) and listed.

8.1.5.1. Statistical Methodology Specification

The following pharmacokinetic statistical analyses will only be performed if sufficient data is available (i.e. if participants have well defined plasma profiles).

Endpoint / Variables
• AUC(0-t) and Cmax
Model Specification
• Evaluation of BE will be performed for each part (Part 1 and Part 2) according to the criteria described in the Japanese BE Guideline. • After $\log_e$-transformation, primary PK parameter(s) of levocetirizine given as levocetirizine ODT 5 mg or when given as levocetirizine IRT 5 mg will be analyzed using a mixed effects model fitting terms for treatment and period as fixed effects, also subjects as a random effect. • The Kenward & Roger (KR) degrees of freedom approach will be used. • Point estimates for the adjusted means on the $\log_e$ scale, the mean difference between treatments and associated 90% confidence interval for the contrast (test-reference) will be constructed using the residual variance. • The point estimate and confidence interval will then be exponentially back-transformed to obtain adjusted (least square) geometric means for each treatment, and point estimates and associated 90% confidence interval for the ratio test/reference. • Two treatment are considered to be bioequivalent, if the 90% confidence intervals of the geometric mean ratio (μ_{test}/μ_{ref}) of AUC(0-t) and Cmax are within the acceptable range of 0.80 – 1.25. • Estimates of within-subject variability (%CVw) for AUC (0-t) and Cmax of levocetirizine will also be provided. • The within-subject coefficients of variation (%CVw) for AUC(0-t) and Cmax will be calculated based on the $\log_e$-normal distribution where: %CVw= SQRT(exp(MSE)-1) * 100 MSE is the residual mean squared error from the model • If the bioequivalence will not be shown above, ODT 5 mg will be accepted as bioequivalent to IRT 5mg where the following condition is satisfied. ○ Point estimate for geometric mean ratio (μ_{test}/μ_{ref}) of AUC(0-t) and Cmax are within 0.90 - 1.11.
Add-on subject study

Endpoint / Variables

• When an add-on subject study will be conducted, the data of two studies in each part would be combined for analysis.
• ODT 5 mg will be accepted as bioequivalent if the following condition is satisfied under the total pooled sample size of the main and add-on subject according to the criteria described in the Japanese BE Guideline.
  ○ The 90% confidence intervals of the geometric mean ratio (μ_{test}/μ_{ref}) of AUC(0-t) and Cmax are within the acceptable range of 0.80 – 1.25.
  ○ If the bioequivalence will not be shown above, point estimate for geometric mean ratio (μ_{test}/μ_{ref}) of AUC(0-t) and Cmax are within 0.90 - 1.11.
• After $\log_e$-transformation, primary PK parameter(s) of levocetirizine given as levocetirizine ODT 5 mg or when given as levocetirizine IRT 5 mg will be analyzed using a mixed effects model fitting terms for treatment, period and study (main or add-on subject study) as fixed effects, also subjects as a random effect.

8.2. Secondary Pharmacokinetic Analyses

8.2.1. Endpoint / Variables

8.2.1.1. Drug Concentration Measures

Refer to Appendix 5: Data Display Standards & Handling Conventions (Section 11.5.3 Reporting Standards for Pharmacokinetic)

8.2.1.2. Derived Pharmacokinetic Parameters

Pharmacokinetic parameters will be calculated by standard non-compartmental analysis according to current working practices and using the currently supported version of WinNonlin (version 6.3 or higher). All calculations of non-compartmental parameters will be based on actual sampling times. Pharmacokinetic parameters listed will be determined from the plasma concentration-time data, as data permits.

Parameter	Parameter Description
AUC (0-inf) (hr*ng/mL)	Area under the concentration-time curve from zero time (pre-dose) extrapolated to infinite time (AUC(0-inf)) will be calculated as follows: **AUC(0-inf) = AUC(0-t) + C(t) / kel**
%AUCex (%)	The percentage of AUC (0-inf) obtained by extrapolation (%AUCex) will be calculated as: **%AUCex = [AUC(0-inf) – AUC(0-t)] / AUC(0-inf) x 100**
tmax (hr)	Time to first occurrence of Cmax will be obtained directly from the concentration-time data.
t1/2 (hr)	Apparent terminal phase half-life will be calculated as: **t½ = ln2 / kel**
tlast (hr)	The time of the last measurable (positive) concentration.
kel (lambda_z) (1/hr)	The first order rate constant associated with the terminal (log-linear) portion of the curve.
lambda_z	The lower limit on time for values to be included in the calculation of kel.

Parameter	Parameter Description
lower (hr)	
lambda_z upper (hr)	The upper limit on time for values to be included in the calculation of kel.
#pts	The number of time points used in computing kel.
R-square	Square of the correlation coefficient.
CL/F (L/hr)	Apparent clearance following oral dosing will be calculated as: **CL/F = Dose / AUC (0-inf)**
Vz/F (L)	Apparent volume of distribution following oral dosing will be calculated as: **Vz/F = Dose / kel * AUC(0-inf)**
MRT (hr)	Mean residence time will be calculated as follows: **MRT = AUMC(0-inf) / AUC(0-inf)**

NOTES:

- Additional parameters may be included as required.
- kel is the terminal phase rate constant.
- C(t) is the last observed quantifiable concentration.
- AUMC is area under the moment curve.

8.2.2. Summary Measure

Derived PK parameters are shown in Section 8.2.1.2." Derived Pharmacokinetic Parameters" are summary measures.

8.2.3. Population of Interest

The secondary pharmacokinetic analyses will be based on the PK population, unless otherwise specified.

8.2.4. Strategy for Intercurrent (Post-Randomization) Events

This section is not applicable, however, where a missing data for PK parameters will occur in a subject on period 1 or period 2, the subject data will be analyzed using the mixed effect model to evaluate the bioequivalence of PK parameter.

8.2.5. Statistical Analyses / Methods

Details of the planned displays are provided in Appendix 10: List of Data Displays and will be based on GSK Data Standards and statistical principles.

Unless otherwise specified, endpoints / variables defined in Section 8.2.1 will be summarised using descriptive statistics, graphically presented (where appropriate) and listed.

8.2.5.1. Statistical Methodology Specification

Endpoint / Variables
• AUC(0-inf), tmax, kel, MRT
Model Specification
• Same manner as Section 8.1.5.1. "Statistical Methodology Specification" for AUC(0-inf), kel, MRT. • tmax will be analyzed with the non-parametric Wilcoxon Matched Pairs Method (Signed Rank Method) to compute point estimate and associated 90% confidence interval for the median difference, Levocetirizine ODT 5 mg – Levocetirizine IRT 5 mg, using normal approximation. Paired data of Levocetirizine ODT 5 mg and Levocetirizine IRT 5 mg will be used only and period effect will not be considered.
Add-on subject study
• Same manner as Section 8.1.5.1. "Statistical Methodology Specification" for AUC(0-inf), kel, MRT. • tmax will be analyzed with the non-parametric Wilcoxon Matched Pairs Method (Signed Rank Method) to compute point estimate and associated 90% confidence interval for the median difference, Levocetirizine ODT 5 mg – Levocetirizine IRT 5 mg, using normal approximation. Paired data of Levocetirizine ODT 5 mg and Levocetirizine IRT 5 mg will be used only and period effect and study effect (main or add-on subject study) will not be considered.

9. EXPLORATORY ANALYSES

The analysis of the palatability questionnaire will be based on the Safety population. The data will be summarized using descriptive statistics. All categorical responses will be summarized with counts and percentages. All ordinal data, e.g. ratings, will be summarized with mean, median, standard deviation, minimum, and maximum as well as counts and percentages of each rating. Palatability questionnaire data will also be listed.

10. REFERENCES

GlaxoSmithKline Document Numbers 2018N360906_00 Study Protocol of 204678. A single centre, single dose, 2 part, open-label, randomized, 2-way crossover study to determine the bioequivalence of levocetirizine oral disintegrating tablet given with water and without water compared to levocetirizine immediate release tablet in healthy Japanese male subjects (Effective date: 20-Apr-2018)

Pharmaceutical and Food Safety Bureau, Evaluation and Licensing Division, Ministry of Health, Labour, and Welfare. Guideline for Bioequivalence Studies of Generic Products. Notification 0229 No.10. Feb-2012.

Schuirmann DJ. 1987. A comparison of the two one-sided tests procedure and the power approach for assessing the equivalence of average bioavailability. *J Pharmacokinet and Biopharm*, 15, 657-680.

11. APPENDICES

11.1. Appendix 1: Protocol Deviation Management

Details will be referred latest Protocol Deviation Management Plan and data handling will be decided prior to final data base release.

11.2. Appendix 2: Schedule of Activities

11.2.1. Protocol Defined Schedule of Events

Procedure	Screening[2]	Part 1 and Part 2 Intervention period (Period 1 and Period 2)																	Follow-up[3]
		Day -1	Day 1													Day 2		Day 3	
			Pre dose	0 h	0.25 h	0.5 h	1 h	1.5 h	2 h	3 h	4 h	6 h	9 h	12 h	16 h	24 h	36 h	48 h	
Informed consent	X																		
Admission to unit		X																	
Height, Weight, Body mass index (BMI)	X																		
Physical examination	X	X	X				X									X		X	X
Serology test	X																		
Clinical laboratory test[1]	X		X															X	X
Urine drug screen	X																		
12-lead ECG	X		X				X											X	X
Vital signs	X		X				X									X		X	X
PK blood sampling			X		X	X	X	X	X	X	X	X	X	X	X	X	X	X	
Study intervention				X															
Palatability Questionnaire[4]																			
Adverse events				←														→	
Discharge from unit																		X	

1. Clinical laboratory test: haematology, clinical chemistry, and urinalysis
2. Screening: up to 30 days prior to Day 1 of Period 1
3. Follow-up: 5-7 days post dose of Period 2
4. Palatability questionnaire will be administered to each subject within 10 minutes following dosing of ODT treatments only

11.3. Appendix 3: Assessment Windows

Not applicable

11.4. Appendix 4: Study Phases and Treatment Emergent Adverse Events

11.4.1. Study Phases

Assessments and events will be classified according to the time of occurrence relative to dosing by period.

Study Phase	Definition
Pre-Treatment	Date <= Day -1 in Period 1
On-Treatment	Period 1: From Day 1 of Period 1 to Day 3 in Period 1. Period 2: From Day 1 of Period 2 to Day 3 in Period 2.
Follow-Up	After Day 3 in Period 2.

11.4.2. Treatment Emergent Flag for Adverse Events

Adverse events will be classified according to the time of occurrence relative to start and/or stop date of the study treatment by period.

Flag (Treatment State)	Definition
Pre-Treatment	• AE Start Date < Study Treatment Start Date and Time in Period 1
On treatment (Period 1)	• Dosing Start Date and Time in Period 1 ≤ AE Start Date and Time < Study Treatment Start Date and Time in Period 2
On treatment (Period 2)	• Dosing Start Date and Time in Period 2 ≤ AE Start Date and Time < Follow-Up
Onset Time Since First Dose (Minute)	• AE Onset Date and Time – Dosing Start Date and Time (if Dosing Start Date and Time > AE Onset Date and Time) • AE Onset Date and Time - Dosing Start Date and Time +1 (if dosing Start Date and Time ≤ AE Onset Date and Time) • Missing otherwise
Onset Time Since Last Dose (Minute)	• AE Start Date and Time – Most Recent Treatment Start Date and Time + 1
Duration (Minute)	• AE Resolution Date and Time – AE Onset Date and Time + 1

NOTES:

- If the study treatment stop date is missing, then the AE will be considered to be On-Treatment.
- Time of study treatment dosing and start/stop time of AEs should be considered, if collected.
- If AE onset time is missing, the duration will be calculated in days.

11.5. Appendix 5: Data Display Standards & Handling Conventions

11.5.1. Reporting Process

Software	
• The currently supported versions of SAS software will be used.	
Reporting Area	
HARP Server	: N/A
HARP Compound	: N/A
Analysis Datasets	
• Analysis datasets will be created according to Legacy GSK A&R dataset standards.	
Generation of RTF Files	
• RTF files will be generated.	

11.5.2. Reporting Standards

General

• The current GSK Integrated Data Standards Library (IDSL) will be applied for reporting, unless otherwise stated (IDSL Standards Location: https://spope.gsk.com/sites/IDSLLibrary/SitePages/Home.aspx):
  • 4.03 to 4.23: General Principles
  • 5.01 to 5.08: Principles Related to Data Listings
  • 6.01 to 6.11: Principles Related to Summary Tables
  • 7.01 to 7.13: Principles Related to Graphics

Formats
• GSK IDSL Statistical Principles (5.03 & 6.06.3) for decimal places (DP's) will be adopted for reporting of data based on the raw data collected, unless otherwise stated. • Numeric data will be reported at the precision collected on the eCRF. • The reported precision from non eCRF sources will follow the IDSL statistical principles but may be adjusted to a clinically interpretable number of DP's.
Planned and Actual Time

• Reporting for tables, figures and formal statistical analyses:
  • Planned time relative to dosing will be used in figures, summaries, statistical analyses and calculation of any derived parameters, unless otherwise stated.
  • The impact of any major deviation from the planned assessment times and/or scheduled visit days on the analyses and interpretation of the results will be assessed as appropriate.
• Reporting for Data Listings:
  • Planned and actual time relative to study drug dosing will be shown in listings (Refer to IDSL Statistical Principle 5.05.1).
  • Unscheduled or unplanned readings will be presented within the subject's listings.

Unscheduled Visits
• Unscheduled visits will not be included in summary tables and/or figures. • All unscheduled visits will be included in listings.

Descriptive Summary Statistics	
Continuous Data	Refer to IDSL Statistical Principle 6.06.1
Categorical Data	N, n, frequency, %
Graphical Displays	
• Refer to IDSL Statistical Principals 7.01 to 7.13.	

11.5.3. Reporting Standards for Pharmacokinetic

Pharmacokinetic Concentration Data	
PC Windows Non-Linear (WNL) File	PC WNL file (CSV format) for the non-compartmental analysis by Clinical Pharmacology Office will be created according to GUI_51487. Note: Concentration values will be imputed as per GUI_51487.
Descriptive Summary Statistics, Graphical Displays and Listings	Refer to IDSL PK Display Standards. Refer to IDSL Statistical Principle 6.06.1. Note: Concentration values will be imputed as per GUI_51487 for descriptive summary statistics/analysis and summarized graphical displays only.
Pharmacokinetic Parameter Derivation	
PK Parameter to be Derived by Programmer	No PK parameters derived by programmer are planned.
Pharmacokinetic Parameter Data	
Is NQ impacted PK Parameters Rule Being Followed	Yes, refer to Standards for Handling NQ Impacted PK Parameters in GUI_51487.
Descriptive Summary Statistics, Graphical Displays and Listings	Refer to IDSL PK Display Standards. tmax will not be $\log_e$-transformed for summary statistics.

11.6. Appendix 6: Derived and Transformed Data

11.6.1. General

Multiple Measurements at One Analysis Time Point
• Mean of the measurements will be calculated and used in any derivation of summary statistics but if listed, all data will be presented. • If there are two values within a time window the value closest to the target day for that window will be used. If values are the same distance from the target, then the mean will be taken. • Participants having both High and Low values for Normal Ranges at any post-baseline visit for safety parameters will be counted in both the High and Low categories of "Any visit post-baseline" row of related summary tables. This will also be applicable to relevant Potential Clinical Importance summary tables.
Study Day

• Calculated as the number of days from First Dose Date:
  • Ref Date = Missing → Study Day = Missing
  • Ref Date < (Dosing Start Date) → Study Day = Ref Date – (Dosing Start Date)
  • Ref Data ≥ (Dosing Start Date) → Study Day = Ref Date – (Dosing Start Date) + 1

11.6.2. Study Population

Demographics
Age

• GSK standard IDSL algorithms will be used for calculating age where birth date will be imputed as follows:
  o Any subject with a missing day will have this imputed as day '15'.
  o Any subject with a missing date and month will have this imputed as '30th June'.
• Birth date will be presented in listings as 'YYYY'.
• Reference date for age calculation will be from dosing start day.
• Reference date for calculation of age at screening will be from informed consent date.
• Analysis age group will be categorized (Years):
  <=18, 19-64, 65-74, >=75
• Age will be categorized for EudraCT:
  Adults (18-64 years)

11.6.3. Safety

Adverse Events
AE'S OF Special Interest
N/A

Laboratory Assessments
Haematology
Platelet Count, RBC Count, Haemoglobin, Hematocrit, RBC Indices (MCV, MCH, MCH, %Reticulocytes), WBC count with Differential (Neutrophils, Lymphocytes, Monocytes, Eosinophils, Basophils)
Clinical Chemistry
BUN, Creatinine, Glucose (fasting), Potassium, Sodium, Calcium, Aspartate Aminotransferase (AST), Alanine Aminotransferase (ALT), Alkaline phosphatise, Total and direct bilirubin, Total Protein

Laboratory Assessments
Routine Urinalysis
• Specific gravity, pH (assessed by dipstick) • Glucose, Protein, Blood, Ketones, Bilirubin, Urobilinogen by dipstick
ECG (12-lead ECG)
ECG findings, ECG values (Heart rate, PR interval, QRS duration, QT interval, and QTcF intervals)
Vital Signs
Pulse rate (Heart rate), Blood pressure (Systolic, Diastolic), Temperature

11.6.4. Pharmacokinetic

PK parameters
Primary parameters
AUC(0-t), Cmax
Secondary parameters
AUC(0-inf), tmax, t1/2, %AUCex, CL/F, Vz/F, kel, MRT (tlast, lambda_z lower, lambda_z upper, #pts, R-square will be listed only)
NQ, NC and ND
• If one or more non-quantifiable (NQ) values occur in a profile before the first measurable concentration, they will be assigned a value of zero concentration. For linear plots, zero concentration value(s) before the first measurable concentration will be included in the plot. For log-linear plots, zero concentration value(s) before the first measurable concentration will be assigned a missing value. • If a single NQ value occurs between measurable concentrations in a profile, the NQ should generally be set to missing in the derivation of pharmacokinetic parameters, statistical analysis, and the individual subject plots. • If two or more NQ values occur in succession between measurable concentrations, the profile will be deemed to have terminated at the last measurable concentration prior to these NQs. For the purpose of individual subject plots, these NQs will be set to 0, and the subsequent measurable concentrations will be retained. For the derivation of pharmacokinetic parameters, these NQs and any subsequent measurable concentrations will be set to missing. • NQs which occur after the last measurable concentration will be omitted (set to missing) in the derivation of pharmacokinetic parameters and from the individual subject plots. • Individual's PK parameters reported as 'NC' (Not Calculable) or 'ND' (Not Determined) will be included in listings but omitted (set to missing) from figures, summaries and statistical analyses.

11.6.5. Exploratory

Palatability Questionnaire
• Q1: to describe the taste of the product in subject's own words briefly • Q2: to rate the palatability (acceptability of taste) • Q3: to check all the descriptors (Sweet, Sour/tart, Bitter, Fruity, Nutty, Chalky, Medicinal) • Q4: to rate the mouth feel • Q5: to circle the number that best describes (5 score: Sweetness, Sour/tartness, Bitter)

11.7. Appendix 7: Reporting Standards for Missing Data

11.7.1. Premature Withdrawals

Element	Reporting Detail
General	• Subject study completion (i.e. as specified in the protocol) was defined as a subject has completed all phases of the study including the last follow-up visit as described in the protocol. • Withdrawn subjects may be replaced in the study. • All available data from participants who were withdrawn from the study will be listed and all available planned data will be included in summary tables and figures, unless otherwise specified.

11.7.2. Handling of Missing Data

Element	Reporting Detail
General	• Missing data occurs when any requested data is not provided, leading to blank fields on the collection instrument: ○ These data will be indicated by the use of a "blank" in subject listing displays. Unless all data for a specific visit are missing in which case the data is excluded from the table. ○ Answers such as "Not applicable" and "Not evaluable" are not considered to be missing data and should be displayed as such.
Outliers	• Any participants excluded from the summaries and/or statistical analyses will be documented along with the reason for exclusion in the clinical study report.

11.7.2.1. Handling of Missing and Partial Dates

Element	Reporting Detail
General	• Partial dates will be displayed as captured in subject listing displays.
Adverse Events	• The eCRF allows for the possibility of partial dates (i.e., only month and year) to be recorded for AE start and end dates; that is, the day of the month may be missing. In such a case, the following conventions will be applied for calculating the time to onset and the duration of the event: ○ Missing Start Day: First of the month will be used unless this is before the start date of study treatment; in this case the study treatment start date will be used and hence the event is considered On-treatment as per Appendix 4: Study Phases and Treatment Emergent Adverse Events. ○ Missing Stop Day: Last day of the month will be used, unless this is after the stop date of study treatment; in this case the study treatment stop date will be used. • Completely missing start or end dates will remain missing, with no imputation applied. Consequently, time to onset and duration of such events will be missing.
Concomitant Medications	• Partial dates for any concomitant medications recorded in the CRF will be imputed using the following convention: ○ If the partial date is a start date, a '01' will be used for the day and 'Jan' will be used for the month ○ If the partial date is a stop date, a '28/29/30/31' will be used for the day (dependent on the month and year) and 'Dec' will be used for the month. • The recorded partial date will be displayed in listings.

11.7.2.2. Handling of Missing for Statistical Analysis of BE

Element	Reporting Detail
Imputation	• No imputation will be performed for missing data. • Where a missing data for PK parameters (except for tmax) will occur in a subject on period 1 or period 2, the subject data will be analyzed using the mixed effect model to evaluate the bioequivalence of PK parameter

11.8. Appendix 8: Values of Potential Clinical Importance

11.8.1. Laboratory Values

Haematology				
Laboratory Parameter	**Units**	**Category**	**Clinical Concern Range**	
			Low Flag (< x)	**High Flag (>x)**
Hematocrit	Ratio of 1	Male		0.54
		Female		0.54
		Δ from BL	↓0.075	
Hemoglobin	g/L	Male		180
		Female		180
		Δ from BL	↓25	
Lymphocytes	$x10^9$/ L		0.8	
Neutrophil Count	$x10^9$/ L		1.5	
Platelet Count	$x10^9$/ L		100	550
While Blood Cell Count (WBC)	$x10^9$/ L		3	20

Note: ↓ indicates a negative direction of the change from baseline.

Clinical Chemistry				
Laboratory Parameter	**Units**	**Category**	**Clinical Concern Range**	
			Low Flag (< x)	**High Flag (>x)**
Calcium	mmol/L		2	2.75
Creatinine	µmol/L	Δ from BL		↑ 44.2
Glucose	mmol/L		3	9
Potassium	mmol/L		3	5.5
Sodium	mmol/L		130	150

Note: ↑ indicates a positive direction of the change from baseline.

Liver Function			
Test Analyte	**Units**	**Category**	**Clinical Concern Range**
ALT/SGPT	U/L	High	≥ 2x ULN
AST/SGOT	U/L	High	≥ 2x ULN
AlkPhos	U/L	High	≥ 2x ULN
T Bilirubin	µmol/L	High	≥ 1.5xULN
T. Bilirubin + ALT	µmol/L	High	1.5xULN T. Bilirubin
	U/L		+ ≥ 2x ULN ALT

11.8.2. ECG

ECG Parameter	Units	Clinical Concern Range	
		Lower	Upper
Absolute			
Absolute QTc (QTcF) Interval	msec		> 450
Absolute PR Interval	msec	< 110	> 220
Absolute QRS Interval	msec	< 75	> 110
Change from Baseline			
Increase from Baseline QTc (QTcF)	msec		> 60

11.8.3. Vital Signs

Vital Sign Parameter (Absolute)	Units	Clinical Concern Range	
		Lower	Upper
Systolic Blood Pressure	mmHg	< 85	> 160
Diastolic Blood Pressure	mmHg	< 45	> 100
Heart Rate (Pulse Rate)	bpm	< 40	> 110

11.9. Appendix 9: Abbreviations & Trade Marks

11.9.1. Abbreviations

Abbreviation	Description
AE	Adverse Event
A&R	Analysis and Reporting
AUC	Area under concentration-time curve
AUC(0-inf)	Area under the concentration-time curve from time zero (pre-dose) extrapolated to infinite time
%AUCex	Percentage of AUC(0-inf) obtained by extrapolation
AUC(0-t)	Area under the concentration-time curve from pre-dose to last time of quantifiable concentration within a subject across all treatments
BE	Bioequivalence
BMI	Body mass index
CI	Confidence Interval
CIL	Clinical Investigation Leader
CL/F	Apparent clearance following oral dosing
Cmax	Maximum observed concentration
CSR	Clinical Study Report
CV_b / CV_w	Coefficient of Variation (Between) / Coefficient of Variation (Within)
DBF	Database Freeze
DBR	Database Release
DQL	Data Quality Leader
ECG	Electrocardiogram
eCRF	Electronic Case Record Form
GSK	GlaxoSmithKline
ICF	Informed Consent Form
IDSL	Integrated Data Standards Library
IP	Investigational Product
LLQ	Lower Limit of Quantification
LS	Least Squar
MedDRA	Medical dictionary for regulatory activities
MSE	Mean Square Error
OSL	Operations and Science Leader
PCI	Potential Clinical Importance
PDMP	Protocol Deviation Management Plan
PK	Pharmacokinetic
QC	Quality Control
QTcF	Frederica's QT Interval Corrected for Heart Rate
RAP	Reporting & Analysis Plan
SAC	Statistical Analysis Complete
SOP	Standard Operation Procedure
t1/2	Terminal phase half-life
tmax	Time of occurrence of Cmax
TOST	Two one-sided t-test

Abbreviation	Description
Vz/F	Apparent volume of distribution after oral administration

11.9.2. Trademarks

Trademarks of the GlaxoSmithKline Group of Companies
None

Trademarks not owned by the GlaxoSmithKline Group of Companies
SAS
WinNonlin

11.10. Appendix 10: List of Data Displays

11.10.1. Data Display Numbering

The following numbering will be applied for RAP generated displays:

Part 1:

Section	Tables	Figures
Study Population	1.101 to 1.107	N/A
Safety	2.101 to 2.118	N/A
Pharmacokinetic	3.101 to 3.106	3.101 to 3.105
Exploratory	4.101	N/A
Section	**Listings**	
ICH Listings	101 to 138	
Other Listings	139	

Part 2:

Section	Tables	Figures
Study Population	1.201 to 1.207	N/A
Safety	2.201 to 2.218	N/A
Pharmacokinetic	3.201 to 3.206	3.201 to 3.205
Exploratory	4.201	N/A
Section	**Listings**	
ICH Listings	201 to 238	
Other Listings	239	

If an add-on subject study will be conducted, the data of two studies will be combined for analysis. The following numbering will be applied for RAP generated displays:

Part 1:

Section	Tables	Figures
Study Population	1.301 to 1.307	N/A
Safety	2.301 to 2.318	N/A
Pharmacokinetic	3.301 to 3.306	3.301 to 3.305
Explanatory	4.301	N/A
Section	**Listings**	
ICH Listings	301 to 338	
Other Listings	339	

Part 2:

Section	Tables	Figures
Study Population	1.401 to 1.407	N/A
Safety	2.401 to 2.418	N/A
Pharmacokinetic	3.401 to 3.406	3.401 to 3.405
Explanatory	4.401	N/A

Section	Listings
ICH Listings	401 to 438
Other Listings	439

11.10.2. Mock Example Shell Referencing

Non IDSL specifications will be referenced as indicated and if required example mock-up displays provided in Appendix 11: Example Mock Shells for Data Displays.

Section	Figure	Table	Listing
Study Population	POP_Fn	POP_Tn	POP_Ln
Safety	SAFE_Fn	SAFE_Tn	SAFE_Ln
Pharmacokinetic	PK_Fn	PK_Tn	PK_Ln
Exploratory	EXP_Fn	EXP_Tn	EXP_Ln

NOTES:

- Non-Standard displays are indicated in the 'IDSL / Example Shell' or 'Programming Notes' column as '[Non-Standard] + Reference.'

11.10.3. Deliverables

Delivery [Priority] [1]	Description
TR [X]	Topline Report
SAC [X]	Final Statistical Analysis Complete

NOTES:

1. Indicates priority (i.e. order) in which displays will be generated for the reporting effort

11.10.4. Part 1

11.10.4.1. Study Population Tables

Study Population Tables					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Subject Disposition					
1.101	Safety	CP_ES1	Summary of Subject Disposition (Part 1)	Completed or withdrawn and the reason for withdrawal.	SAC [1]
1.102	Screened	ES6	Summary of Screening Status and Reasons for Screen Failure (Part 1)	The number (%) of Randomized or screening failure subjects as the screening status, and the reason for screening failure.	SAC [1]
Protocol Deviation					
1.103	Safety	DV1	Summary of Important Protocol Deviations (Part 1)	Data is from DV dataset.	SAC [1]
Study Populations					
1.104	Safety	SP1	Summary of Study Populations (Part 1)		SAC [1]
Demographics					
1.105	Safety	DM3	Summary of Demographic Characteristics (Part 1)		TR [2]
1.106	Screened	DM11	Summary of Age Ranges (Part 1)	Adults (18-64 years)	SAC [1]
1.107	Safety	DM5	Summary of Race and Racial Combinations (Part 1)		SAC [1]

11.10.4.2. Safety Tables

Safety Tables					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Adverse Events					
2.101	Safety	AE1CP	Summary of All Adverse Events by System Organ Class and Preferred Term (Part 1)		TR [2]
2.102	Safety	AE5A	Summary of All Adverse Events by System Organ Class and Maximum Intensity (Part 1)		SAC [1]
2.103	Safety	AE1CP	Summary of All Drug-Related Adverse Events by System Organ Class and Preferred Term (Part 1)		SAC [1]
2.104	Safety	AE5A	Summary of All Drug-Related Adverse Events by Maximum Intensity (Part 1)		SAC [1]
2.105	Safety	AE1CP	Summary of Serious Adverse Events by System Organ Class (Part 1)		SAC [1]
Labs					
2.106	Safety	LB1	Summary of Chemistry Results (Part 1)		SAC [1]
2.107	Safety	LB1	Summary of Chemistry Changes from Baseline (Part 1)		SAC [1]
2.108	Safety	LB4	Summary of Chemistry Data Shifts from Baseline with Respect to the Normal Range (Part 1)	Worst Case Post-Baseline is not needed	SAC [1]
2.109	Safety	LB1	Summary of Hematology Results (Part 1)		SAC [1]

Safety Tables					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
2.110	Safety	LB1	Summary of Hematology Changes from Baseline (Part 1)		SAC [1]
2.111	Safety	LB4	Summary of Hematology Data Shifts from Baseline with Respect to the Normal Range (Part 1)	Worst Case Post-Baseline is not needed	SAC [1]
2.112	Safety	UR3b	Summary of Urinalysis (Glucose, Protein, Blood, Ketones) Data (Part 1)		SAC [1]
2.113	Safety	LB1	Summary of Urinalysis (Gravity and pH) (Part 1)		SAC [1]
ECGs					
2.114	Safety	EG1	Summary of ECG Findings (Part 1)		SAC [1]
2.115	Safety	EG2	Summary of ECG Values (Part 1).		SAC [1]
2.116	Safety	EG2	Summary of Change from Baseline in ECG Values (Part 1).		SAC [1]
Vital Signs					
2.117	Safety	VS1	Summary of Vital Signs (Part 1)		SAC [1]
2.118	Safety	VS1	Summary of Change from Baseline in Vital Signs (Part 1).		SAC [1]

11.10.4.3. Pharmacokinetic Tables

Pharmacokinetic Tables

No.	Population	IDSL / TST ID / Example Shell	Title	Programming Notes	Deliverable [Priority]
PK Concentration Data					
3.101	PK	PK01: PKCT1	Summary of Levocetirizine Plasma Concentration (ng/mL) (Part 1)	Summary statistics: N, n, Number of imputed, mean, 95% confidence interval, standard deviation, median, minimum, maximum	SAC [1]
Derived PK Parameters					
3.102	PK	PK03: PKPT1	Summary of Levocetirizine Plasma Pharmacokinetic Parameters (non-transformed) (Part 1)	Summary statistics: N, n, Number of imputed, mean, 95% confidence interval, standard deviation, median, minimum, maximum	TR [2]
3.103	PK	PK05: PKPT3	Summary of Levocetirizine Plasma Pharmacokinetic Parameters (loge-transformed) (Part 1)	Summary statistics: N, n, Number of imputed, geometric mean, 95% confidence interval for the geometric mean, standard deviation of logarithmically transformed data (SD(logs)), coefficient of variation (%CVb). tmax is not included in this table.	TR [2]
3.104	PK	Study Specific (PK_T1)	Summary of Bioequivalence Analysis on Pharmacokinetic Parameters (AUC(0-t) and Cmax) (Part 1)	PK Parameters: AUC(0-t), Cmax	TR [2]
3.105	PK	Study Specific (PK_T1)	Summary of Bioequivalence Analysis on Pharmacokinetic Parameters (AUC(0-inf), kel, MRT) (Part 1)	PK Parameters: AUC(0-inf), kel, MRT	TR [2]
3.106	PK	Study Specific (PK_T2)	Summary of Bioequivalence Analysis on Pharmacokinetic Parameters (tmax) (Part 1)	PK Parameter: tmax. Non-parametric Wilcoxon Matched Pairs Method for median difference.	TR [2]

11.10.4.4. Pharmacokinetic Figures

Pharmacokinetic Figures					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Individual Concentration Plots					
3.101	PK	PK16b: PKCF1x	Individual Levocetirizine Plasma Concentration-Time Plots by Subject (Linear and Semi-Log) (Part 1)	Paginate by Subject. Include line for LLQ along with footnote defining LLQ value (2.0 ng/mL)	SAC [1]
3.102	PK	PK16b: PKCF1x	Individual Levocetirizine Plasma Concentration-Time Plots by Treatment (Linear and Semi-Log) (Part 1)	Paginate by Treatment. Include line for LLQ along with footnote defining LLQ value (2.0 ng/mL)	SAC [1]
Mean / Median Concentration Plots					
3.103	PK	PK17: PKCF2	Mean (+SD) Levocetirizine Plasma Concentration-Time Plots (Part 1)	1. Include the + SD bars at each time point. 2. X-axis displays planned relative time 3. Include line for LLQ along with footnote defining LLQ value (2.0 ng/mL)	TR [2]
3.104	PK	PK18: PKCF3	Median Levocetirizine Plasma Concentration-Time Plots (Part 1)		TR [2]
PK parameter Plots (Bioequivalence Analysis)					
3.105	PK	Study Specific (PK_F1)	Plot of Levocetirizine Treatment Ratio and 90% CI for Bioequivalence Analysis on PK Parameters (AUC(0-t) and Cmax) (Part 1)	PK Parameters: AUC(0-t), Cmax. Plot the comparison on the Y-axis and Ratio on X axis.	TR [1]

11.10.4.5. Exploratory Tables

Palatability Questionnaire Tables					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Palatability Questionnaire Tables					
4.101	Safety	Study Specific (EXP_T1)	Summary of Palatability Questionnaire (Part 1)	Q2 to Q5. Summary statistics and frequency count will be performed for all questions except for Q3 of frequency only.	SAC [1]

11.10.4.6. ICH Listings

Note: 'Inv.' in the standard displays will be replaced to 'Centre'.

ICH Listings					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Randomisation					
101	Safety	CP_TA2	Listing of Randomised and Actual Treatments (Part 1)		SAC [1]
Subject Disposition					
102	Safety	CP_ES10x	Listing of Reasons for Premature Withdrawal (Part 1)		SAC [1]
103	Screening Failure	ES7	Listing of Reasons for Screening Failure (Part 1)		SAC [1]

ICH Listings					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
104	Safety	DV2	Listing of Subjects with Important Protocol Deviations (Part 1)		SAC [1]
105	Screened	IE4	Listing of Subjects with Inclusion/Exclusion Criteria Deviations (Part 1)		SAC [1]
106	Safety	Study Specific (SAFE_L1)	Listing of Subjects Excluded from PK Population (Part 1)		SAC [1]
Demographics					
107	Safety	DM4	Listing of Demographic Characteristics (Part 1)	Informed consent date is included.	SAC [1]
108	Screening Failure	DM2	Listing of Demographic Characteristics for Screening Failure Subjects (Part 1)	Informed consent date is included.	SAC [1]
109	Safety	DM10	Listing of Race (Part 1)		SAC [1]
110	Screening Failure	DM10	Listing of Race for Screening Failure Subjects (Part 1)		SAC [1]
Medical Conditions					
111	Screened	MH3	Listing of Medical Conditions (Part 1)		SAC [1]
Concomitant Medications					
112	Screened	CP_CM4	Listing of Concomitant Medications (Part 1)		SAC [1]
113	Safety	CM6	Relationship between ATC Level 1, Ingredient and Verbatim Text (Part 1)		SAC [1]

ICH Listings					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Exposure					
114	Safety	EX4	Listing of Exposure (Part 1)		SAC [1]
Adverse Events					
115	Safety	CP_AE9	Listing of All Adverse Event (Part 1)		TR [2]
116	Safety	CP_AE9	Listing of Serious Adverse Events (Part 1)		TR [2]
117	Screening Failure	CP_AE9	Listing of Serious Adverse Events for Screening Failure Subject (Part 1)		SAC [1]
118	Safety	CP_AE9	Listing of Adverse Events Leading to Discontinuation of Investigational Product or Withdrawal from Study (Part 1)		SAC [1]
119	Safety	AE7	Listing of Subject Numbers for Individual Adverse Events (Part 1)		SAC [1]
120	Screened	AE2	Listing of Relationship between System Organ Class, Preferred Term and Verbatim Text (Part 1)		SAC [1]
LABS					
121	Safety	CP_LB6	Listing of All Chemistry Data (Part 1)	Change from baseline is included.	SAC [1]
122	Safety	CP_LB6	Listing of All Chemistry Data for Subjects with Potential Clinical Importance (Part 1)		SAC [1]
123	Safety	CP_LB6	Listing of All Hematology Data (Part 1)	Change from baseline is included.	SAC [1]

ICH Listings					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
124	Safety	CP_LB6	Listing of All Hematology Data for Subjects with Potential Clinical Importance (Part 1)		SAC [1]
125	Safety	CP_LB6	Listing of Urinalysis (Gravity and pH) Data (Part 1)		SAC [1]
126	Safety	UR2b	Listing of Urinalysis (Glucose, Protein, Blood, Ketones, Bilirubin, Urobilinogen and microscopic examination) Data (Part 1)		SAC [1]
Vital Signs					
127	Safety	CP_VS5	Listing of All Vital Signs (Part 1)		SAC [1]
128	Safety	CP_VS5	Listing of Change from Baseline in Vital Signs (Part 1)		SAC [1]
129	Safety	CP_VS5	Listing of All Vital Signs for Subjects with any Value of Potential Clinical Importance (Part 1)		SAC [1]
ECG					
130	Safety	CP_EG6	Listing of ECG Findings (Part 1)		SAC [1]
131	Safety	CP_EG4	Listing of All ECG Values (Part 1)		SAC [1]
132	Safety	CP_EG4	Listing of Change from Baseline in ECG Values (Part 1)		SAC [1]
133	Safety	CP_EG4	Listing of All ECG Values for Subjects with Any Value of Potential Clinical Importance (Part 1)		SAC [1]

ICH Listings					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Liver event					
134	Safety	LIVER5	Listing of Liver Monitoring/Stopping Event Reporting (Part 1)		SAC [1]
135	Safety	MH3	Listing of Medical Conditions for Subjects with Liver Stopping Events (Part 1)		SAC [1]
136	Safety	SU2	Listing of Substance Use for Subjects with Liver Stopping Events (Part 1)		SAC [1]
Pharmacokinetics					
137	PK	PK08: PKCL1x	Listing of Levocetirizine Plasma Concentration (Part 1)		SAC [1]
138	PK	PK14: PKPL1x	Listing of Levocetirizine Plasma Pharmacokinetic Parameters (Part 1)		SAC [1]

11.10.4.7. Non-ICH Listings

Non-ICH Listings					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Palatability Questionnaire					
139	Safety	Study Specific (EXP_L1)	Listing of Palatability Questionnaire (Part 1)		SAC [1]

11.10.5. Part 2

11.10.5.1. Study Population Tables

Study Population Tables					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Subject Disposition					
1.201	Safety	CP_ES1	Summary of Subject Disposition (Part 2)	Completed or withdrawn and the reason for withdrawal.	SAC [1]
1.202	Screened	ES6	Summary of Screening Status and Reasons for Screen Failure (Part 2)	The number (%) of Randomized or screening failure subjects as the screening status, and the reason for screening failure.	SAC [1]
Protocol Deviation					
1.203	Safety	DV1	Summary of Important Protocol Deviations (Part 2)	Data is from DV dataset.	SAC [1]
Study Populations					
1.204	Safety	SP1	Summary of Study Populations (Part 2)		SAC [1]
Demographics					
1.205	Safety	DM3	Summary of Demographic Characteristics (Part 2)		TR [1]
1.206	Screened	DM11	Summary of Age Ranges (Part 2)	Adults (18-64 years)	SAC [1]
1.207	Safety	DM5	Summary of Race and Racial Combinations (Part 2)		SAC [1]

11.10.5.2. Safety Tables

Safety Tables					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Adverse Events					
2.201	Safety	AE1CP	Summary of All Adverse Events by System Organ Class and Preferred Term (Part 2)		TR [1]
2.202	Safety	AE5A	Summary of All Adverse Events by System Organ Class and Maximum Intensity (Part 2)		SAC [1]
2.203	Safety	AE1CP	Summary of All Drug-Related Adverse Events by System Organ Class and Preferred Term (Part 2)		SAC [1]
2.204	Safety	AE5A	Summary of All Drug-Related Adverse Events by Maximum Intensity (Part 2)		SAC [1]
2.205	Safety	AE1CP	Summary of Serious Adverse Events by System Organ Class (Part 2)		SAC [1]
Labs					
2.206	Safety	LB1	Summary of Chemistry Results (Part 2)		SAC [1]
2.207	Safety	LB1	Summary of Chemistry Changes from Baseline (Part 2)		SAC [1]
2.208	Safety	LB4	Summary of Chemistry Data Shifts from Baseline with Respect to the Normal Range (Part 2)	Worst Case Post-Baseline is not needed	SAC [1]
2.209	Safety	LB1	Summary of Hematology Results (Part 2)		SAC [1]

Safety Tables					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
2.210	Safety	LB1	Summary of Hematology Changes from Baseline (Part 2)		SAC [1]
2.211	Safety	LB4	Summary of Hematology Data Shifts from Baseline with Respect to the Normal Range (Part 2)	Worst Case Post-Baseline is not needed	SAC [1]
2.212	Safety	UR3b	Summary of Urinalysis (Glucose, Protein, Blood, Ketones) Data (Part 2)		SAC [1]
2.213	Safety	LB1	Summary of Urinalysis (Gravity and pH) (Part 2)		SAC [1]
ECGs					
2.214	Safety	EG1	Summary of ECG Findings (Part 2)		SAC [1]
2.215	Safety	EG2	Summary of ECG Values (Part 2).		SAC [1]
2.216	Safety	EG2	Summary of Change from Baseline in ECG Values (Part 2).		SAC [1]
Vital Signs					
2.217	Safety	VS1	Summary of Vital Signs (Part 2)		SAC [1]
2.218	Safety	VS1	Summary of Change from Baseline in Vital Signs (Part 2).		SAC [1]

11.10.5.3. Pharmacokinetic Tables

Pharmacokinetic Tables

No.	Population	IDSL / TST ID / Example Shell	Title	Programming Notes	Deliverable [Priority]
PK Concentration Data					
3.201	PK	PK01: PKCT1	Summary of Levocetirizine Plasma Concentration (ng/mL) (Part 2)	Summary statistics: N, n, Number of imputed, mean, 95% confidence interval, standard deviation, median, minimum, maximum	SAC [1]
Derived PK Parameters					
3.202	PK	PK03: PKPT1	Summary of Levocetirizine Plasma Pharmacokinetic Parameters (non-transformed) (Part 2)	Summary statistics: N, n, Number of imputed, mean, 95% confidence interval, standard deviation, median, minimum, maximum	TR [1]
3.203	PK	PK05: PKPT3	Summary of Levocetirizine Plasma Pharmacokinetic Parameters (loge-transformed) (Part 2)	Summary statistics: N, n, Number of imputed, geometric mean, 95% confidence interval for the geometric mean, standard deviation of logarithmically transformed data (SD(logs)), coefficient of variation (%CVb). tmax is not included in this table.	TR [1]
3.204	PK	Study Specific (PK_T1)	Summary of Bioequivalence Analysis on Pharmacokinetic Parameters (AUC(0-t) and Cmax) (Part 2)	PK Parameters: AUC(0-t), Cmax	TR [1]
3.205	PK	Study Specific (PK_T1)	Summary of Bioequivalence Analysis on Pharmacokinetic Parameters (AUC(0-inf), kel, MRT) (Part 2)	PK Parameters: AUC(0-inf), kel, MRT	TR [1]
3.206	PK	Study Specific (PK_T2)	Summary of Bioequivalence Analysis on Pharmacokinetic Parameters (tmax) (Part 2)	PK Parameter: tmax. Non-parametric Wilcoxon Matched Pairs Method for median difference.	TR [1]

11.10.5.4. Pharmacokinetic Figures

Pharmacokinetic Figures					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Individual Concentration Plots					
3.201	PK	PK16b: PKCF1x	Individual Levocetirizine Plasma Concentration-Time Plots by Subject (Linear and Semi-Log) (Part 2)	Paginate by Subject. Include line for LLQ along with footnote defining LLQ value (2.0 ng/mL)	SAC [1]
3.202	PK	PK16b: PKCF1x	Individual Levocetirizine Plasma Concentration-Time Plots by Treatment (Linear and Semi-Log) (Part 2)	Paginate by Treatment. Include line for LLQ along with footnote defining LLQ value (2.0 ng/mL)	SAC [1]
Mean / Median Concentration Plots					
3.203	PK	PK17: PKCF2	Mean (+SD) Levocetirizine Plasma Concentration-Time Plots (Part 2)	1. Include the + SD bars at each time point. 2. X-axis displays planned relative time 3. Include line for LLQ along with footnote defining LLQ value (2.0 ng/mL)	TR [1]
3.204	PK	PK18: PKCF3	Median Levocetirizine Plasma Concentration-Time Plots (Part 2)		TR [1]
PK parameter Plots (Bioequivalence Analysis)					
3.205	PK	Study Specific (PK_F1)	Plot of Levocetirizine Treatment Ratio and 90% CI for Bioequivalence Analysis on PK Parameters (AUC(0-t) and Cmax) (Part 2)	PK Parameters: AUC (0-t), Cmax. Plot the comparison on the Y-axis and Ratio on X axis.	TR [1]

11.10.5.5. Exploratory Tables

Palatability Questionnaire Tables					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Palatability Questionnaire Tables					
3.206	Safety	Study Specific (EXP_T1)	Summary of Palatability Questionnaire (Part 2)	Q2 to Q5. Summary statistics and frequency count will be performed for all questions except for Q3 of frequency only.	SAC [1]

11.10.5.6. ICH Listings

Note: 'Inv.' in the standard displays will be replaced to 'Centre'.

ICH Listings					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Randomisation					
201	Safety	CP_TA2	Listing of Randomised and Actual Treatments (Part 2)		SAC [1]
Subject Disposition					
202	Safety	CP_ES10x	Listing of Reasons for Premature Withdrawal (Part 2)		SAC [1]
203	Screening Failure	ES7	Listing of Reasons for Screening Failure (Part 2)		SAC [1]

ICH Listings					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
204	Safety	DV2	Listing of Subjects with Important Protocol Deviations (Part 2)		SAC [1]
205	Screened	IE4	Listing of Subjects with Inclusion/Exclusion Criteria Deviations (Part 2)		SAC [1]
206	Safety	Study Specific (SAFE_L1)	Listing of Subjects Excluded from PK Population (Part 2)		SAC [1]
Demographics					
207	Safety	DM4	Listing of Demographic Characteristics (Part 2)	Informed consent date is included.	SAC [1]
208	Screening Failure	DM2	Listing of Demographic Characteristics for Screening Failure Subjects (Part 2)	Informed consent date is included.	SAC [1]
209	Safety	DM10	Listing of Race (Part 2)		SAC [1]
210	Screening Failure	DM10	Listing of Race for Screening Failure Subjects (Part 2)		SAC [1]
Medical Conditions					
211	Screened	MH3	Listing of Medical Conditions (Part 2)		SAC [1]
Concomitant Medications					
212	Screened	CP_CM4	Listing of Concomitant Medications (Part 2)		SAC [1]
213	Safety	CM6	Relationship between ATC Level 1, Ingredient and Verbatim Text (Part 2)		SAC [1]

ICH Listings					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Exposure					
214	Safety	EX4	Listing of Exposure (Part 2)		SAC [1]
Adverse Events					
215	Safety	CP_AE9	Listing of All Adverse Event (Part 2)		TR [1]
216	Safety	CP_AE9	Listing of Serious Adverse Events (Part 2)		TR [1]
217	Screening Failure	CP_AE9	Listing of Serious Adverse Events for Screening Failure Subject (Part 2)		SAC [1]
218	Safety	CP_AE9	Listing of Adverse Events Leading to Discontinuation of Investigational Product or Withdrawal from Study (Part 2)		SAC [1]
219	Safety	AE7	Listing of Subject Numbers for Individual Adverse Events (Part 2)		SAC [1]
220	Screened	AE2	Listing of Relationship between System Organ Class, Preferred Term and Verbatim Text (Part 2)		SAC [1]
LABS					
221	Safety	CP_LB6	Listing of All Chemistry Data (Part 2)	Change from baseline is included.	SAC [1]
222	Safety	CP_LB6	Listing of All Chemistry Data for Subjects with Potential Clinical Importance (Part 2)		SAC [1]
223	Safety	CP_LB6	Listing of All Hematology Data (Part 2)	Change from baseline is included.	SAC [1]

ICH Listings					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
224	Safety	CP_LB6	Listing of All Hematology Data for Subjects with Potential Clinical Importance (Part 2)		SAC [1]
225	Safety	CP_LB6	Listing of Urinalysis (Gravity and pH) Data (Part 2)		SAC [1]
226	Safety	UR2b	Listing of Urinalysis (Glucose, Protein, Blood, Ketones, Bilirubin, Urobilinogen and microscopic examination) Data (Part 2)		SAC [1]
Vital Signs					
227	Safety	CP_VS5	Listing of All Vital Signs (Part 2)		SAC [1]
228	Safety	CP_VS5	Listing of Change from Baseline in Vital Signs (Part 2)		SAC [1]
229	Safety	CP_VS5	Listing of All Vital Signs for Subjects with any Value of Potential Clinical Importance (Part 2)		SAC [1]
ECG					
230	Safety	CP_EG6	Listing of ECG Findings (Part 2)		SAC [1]
231	Safety	CP_EG4	Listing of All ECG Values (Part 2)		SAC [1]
232	Safety	CP_EG4	Listing of Change from Baseline in ECG Values (Part 2)		SAC [1]
233	Safety	CP_EG4	Listing of All ECG Values for Subjects with Any Value of Potential Clinical Importance (Part 2)		SAC [1]

ICH Listings					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Liver event					
234	Safety	LIVER5	Listing of Liver Monitoring/Stopping Event Reporting (Part 2)		SAC [1]
235	Safety	MH3	Listing of Medical Conditions for Subjects with Liver Stopping Events (Part 2)		SAC [1]
236	Safety	SU2	Listing of Substance Use for Subjects with Liver Stopping Events (Part 2)		SAC [1]
Pharmacokinetics					
237	PK	PK08: PKCL1x	Listing of Levocetirizine Plasma Concentration (Part 2)		SAC [1]
238	PK	PK14: PKPL1x	Listing of Levocetirizine Plasma Pharmacokinetic Parameters (Part 2)		SAC [1]

11.10.5.7. Non-ICH Listings

Non-ICH Listings					
No.	**Population**	**IDSL / TST ID / Example Shell**	**Title**	**Programming Notes**	**Deliverable [Priority]**
Palatability Questionnaire					
239	Safety	Study Specific (EXP_L1)	Listing of Palatability Questionnaire (Part 2)		SAC [1]

11.11. Appendix 11: Example Mock Shells for Data Displays

Study specific mock shells are shown only.

Example: Study Specific (PK_T1) Page 1 of n
Protocol: 204706
Population: PK

Table X.XX
Summary of Bioequivalence Analysis on Pharmacokinetic Parameters (AUC(0-t) and Cmax) (Part X)

Parameter	N	Treatment	n	Geometric LS Mean	Ratio [1]	90% CI of the Ratio	%CVw [2]
AUC(0-t) (hr*ng/mL)	xx	Levocetirizine ODT 5 mg	xx	xxx.xx	xx.xx	(x.xxx, x.xxx)	xx.x
		Levocetirizine IRT 5 mg	xx	xxx.xx			
Cmax (ng/mL)	xx	Levocetirizine ODT 5 mg	xx	xxxx.xx	xx.xx	(xx.xxx, xx.xxx)	xx.x
		Levocetirizine IRT 5 mg	xx	xxxx.xx			

[1] Ratio = Geometric LS Mean of Levocetirizine ODT 5 mg / Geometric LS Mean of Levocetirizine IRT 5 mg
[2] %CVw = sqrt[exp(MSE) - 1] * 100

Example: Study Specific (PK_T2)
Protocol: 204706
Population: PK

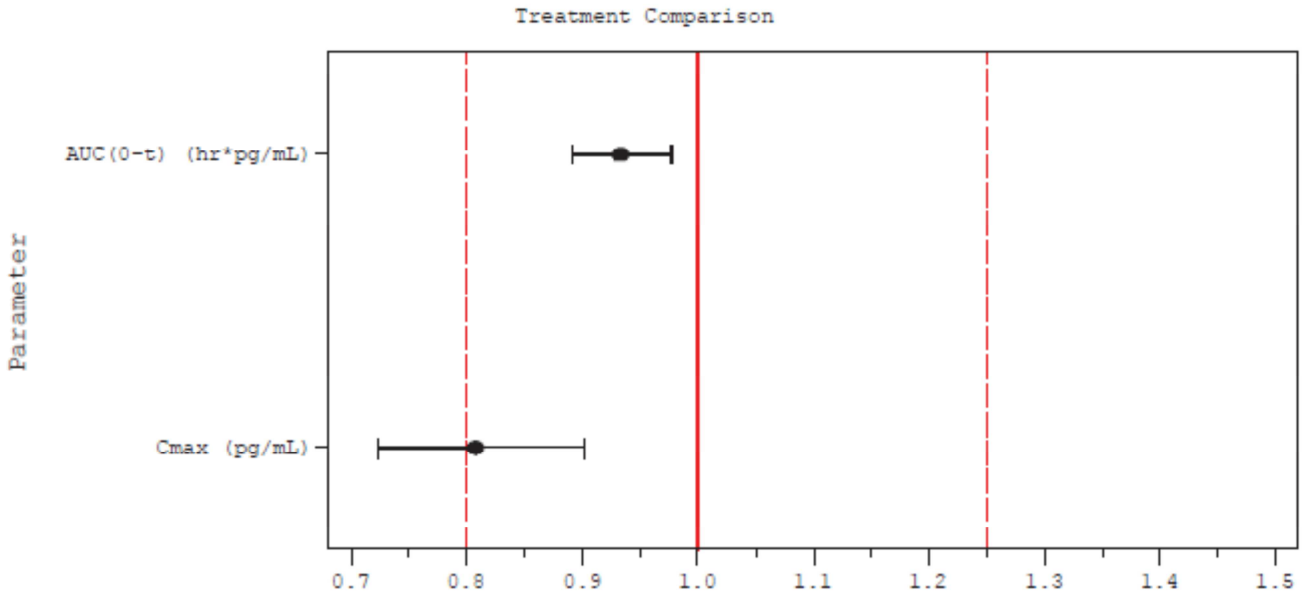
Table X.XX
Summary of Bioequivalence Analysis on Pharmacokinetic Parameters (tmax) (Part X)

Parameter	N	Treatment	n	Median	n	Median Difference	90% CI of the Difference
tmax (hr)	xx	Levocetirizine ODT 5 mg	xx	xxxx.xx	xx	xx.xx	(xx.xxx, xx.xxx)
		Levocetirizine IRT 5 mg	xx	xxxx.xx			

Note: tmax will be analyzed with the non-parametric Wilcoxon Matched Pairs Method (Signed Rank Method) to compute point estimate and associated 90% confidence interval for the median difference, Levocetirizine ODT 5 mg – Levocetirizine IRT 5 mg, using normal approximation.

Example: Study Specific (PK_F1)
Protocol: 204706
Population: PK

Figure X.XX
Plot of Levocetirizine Treatment Ratio and 90% CI for Bioequivalence Analysis on PK Parameters (AUC(0-t) and Cmax) (Part X)



Note: Ratio = Geometric LS Mean of Levocetirizine ODT 5 mg / Geometric LS Mean of Levocetirizine IRT 5 mg

AUC(0-t) (hr*ng/mL), Cmax (ng/mL)

Example: Study Specific (EXP_T1) Page 1 of n
Protocol: 204706
Population: Safety

Table X.XX
Summary of Palatability Questionnaire (Part X)

Questions		ODT 5mg (N=XX)
Q2. Palatability Rate	n	XX
	Mean	x.x
	SD	x.xx
	Median	x.x
	Min.	x
	Max.	x
	n	x
	1 Unacceptable	x (xx%)
	2 Neutral/Acceptable	x (xx%)
	3 Very good	x (xx%)
Q3. All Description Associated	n	x
	Bitter	x (xx%)
	Chalky	x (xx%)
	Fruity	x (xx%)
	Medicinal	x (xx%)
	Nutty	x (xx%)
	Sour	x (xx%)
	Sweet	x (xx%)

Q4. Mouth Feel Rate, Q5a. Best Description (Sweetness), Q5b. Best Description (Sour/tartness), Q5c. Best Description (Bitter). Summary statistics and frequency count with % will be performed for all questions except for Q3.

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204706

Example: Study Specific (EXP_L1) Page 1 of n
Protocol: 204706
Population: SP

Listing X.XX
Listing of Subjects Palatability Questionnaire (Part X)

Treatment/ Site Id./ Unique Subject Id.	Age(y)/ Sex/ Race/ Assessor	Q1	Q2	Q3	Q4	Q5 a	Q5 b	Q5 c
Levocetirizine ODT 5mg/ PPD	26/ Male/ White/ Subject	xxx	1:Unacceptable	Sweet, Fruity	2:Neutral/Acceptable	1	1	3
Levocetirizine IRT 5mg/ PPD	39/ Male/ White/ Subject	xxx	2:Neutral/Acceptable	Bitter	3: Very good	3	2	1

Note:

Q1. Please briefly describe the taste of the product in your own words (one word, short phrase descriptions are acceptable)

Q2. Please rate the palatability (acceptability of taste) of the product by checking a rating.

Q3. Please check all the descriptors that apply to the product. (Multiple Answer allowed)

Q4. Please rate the mouth feel of the product by checking a rating.

Q5. Please circle the number that best describes your perception of each attribute: a=Sweetness b=Sour/tartness c=Bitter

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204706

Example: Study Specific (SP_L1) Page 1 of n
Protocol: 204706
Population: Safety

Listing X.XX
Listing of Subjects Excluded from PK population (Part X)

Treatment/ Site Id./ Unique Subject Id.	Age(y)/ Sex/ Race	PK Population
PPD	26/ Male/ White	N
	39/ Male/ White	N