Study title

A DOUBLE-BLIND, RANDOMISED, PLACEBO-CONTROLLED PHASE I TRIAL TO INVESTIGATE SAFETY, TOLERABILITYAND PHARMACOKINETICS OF SINGLE ASCENDING TOPICAL DOSES OF GZ21T IN HEALTHY VOLUNTEERS

NCT Number

NCT06888362

Statistical Analysis Plan

v4.0; 28APR2025

Statistical Analysis Plan	
EU Trial No.	2024-512893-86-00
Investigational medicinal product	GZ21T
Trial code	A24-0001
Protocol version and date	Final v2.0; 20NOV2024
SAP version and date	Final v4.0; 28APR2025

A DOUBLE-BLIND, RANDOMISED, PLACEBO-CONTROLLED PHASE I TRIAL TO INVESTIGATE SAFETY, TOLERABILITYAND PHARMACOKINETICS OF SINGLE ASCENDING TOPICAL DOSES OF GZ21T IN HEALTHY VOLUNTEERS

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CTC biostatistician: [redacted]

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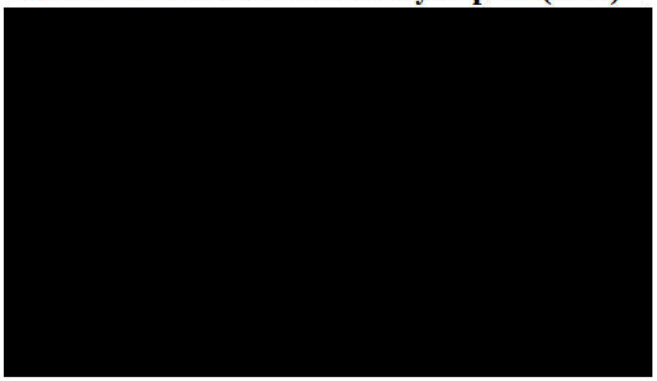
Table 1 SAP version history

SAP version	Approval date	Description of changes
1.0, original version	04OCT2024	
2.0	28JAN2025	The SAP was updated in accordance with the changes in the clinical trial protocol (CTP) v2.0 to include an additional part (Part B). This part consists of 1 cohort (3 participants), with the option to include up to 2 additional cohorts of 3 participants each, in order to evaluate the optimum amount of cream to be applied to a given body area (dose/area).
3.0	05JAN2025	Updated Sections 9.1.7 and 10.2.2.7 regarding the presentation of "time until adequate abruption" based on how the data is collected in the eCRF.
4.0	28APR2025	Updated • Section 7 to include full CDSIC compliance. • Section 9.3.3 and Tables CM1 to CM4 to use WHODrug coding instead of ATC coding • Changed CTC biostatistician

1 SIGNATURES

Author of this statistical analysis plan (SAP)



Sponsor signatory

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3 LIST OF ABBREVIATIONS AND DEFINITION OF TERMS

Abbreviation	Explanation
ADaM	Analysis Data Model
AE	Adverse event
ATC	Anatomical therapeutic chemical
AUC	Area under the plasma concentration *vs.* time curve
$AUC_{0\text{-inf}}$	AUC from 0 to infinity
$AUC_{0\text{-last}}$	AUC from 0 to time of last measurable plasma concentration
BLQ	Below lower limit of quantification
BMI	Body mass index
CDISC	Clinical Data Interchange Standards Consortium
C_{last}	Last observed plasma concentration
C_{max}	Maximum observed concentration
CTC	Clinical Trial Consultants AB
CTP	Clinical trial protocol
CV	Coefficient of variation
DDP	Data display plan
ECG	Electrocardiogram
eCRF	Electronic case report form
FAS	Full analysis set
FDA	United States Food and Drug Administration
FIH	First-in-human
Geo	Geometric
IG	Implementation guide
IMP	Investigational medicinal product
lin	Linear
LLOQ	Lower limit of quantification
LS	Least square
MAD	Multiple-ascending dose
Max	Maximum
MedDRA	Medical dictionary for regulatory activities
Min	Minimum
NA	Not applicable/not available
NC	Not calculated

Abbreviation	Explanation
NCA	Non-compartmental analysis
PK	Pharmacokinetic(s)
PKAS	PK analysis set
PT	Preferred term
SAD	Single-ascending dose
SAE	Serious adverse event
SAP	Statistical analysis plan
SAS	Statistical analysis system
SD	Standard deviation
SDTM	Trial data tabulation model
SOC	System organ class
T_{last}	Time of occurrence of C_{last}
T_{max}	Time of occurrence of C_{max}
$T_{1/2}$	Terminal elimination half-life
ULOQ	Upper limit of quantification
ULQ	Above upper limit of quantification
WHO	World Health Organization

4 INTRODUCTION

This SAP gives a detailed description of the planned statistical analysis for trial A24-0001.

4.1 Trial design

This trial is a Phase I-trial divided into 2 parts. Part A is, double-blind, placebo-controlled, and designed to evaluate the safety, tolerability, and PK after topical administration of single ascending doses of GZ21T in healthy male and female volunteers. Part B is open-label and designed to evaluate the optimum amount of cream applied to a given body area (dose/area) of single doses of GZ21T in healthy volunteers.

In Part A, participants will receive a single topical application of GZ21T or placebo in 2 sequential cohorts (cohorts 1 and 2) followed by 2 cohorts starting in parallel (cohorts 3 and 4) with planned doses as follows:

In Part B, participants in cohort 1 will receive a single topical application of GZ21T. Based on the extent of the cream's absorption, up to 2 additional cohorts can be explored (optional cohorts 2 and 3). The maximum administered dose will not exceed

The trial design and the proposed dose levels are shown in Figure 1. Please see the CTP for additional details.

Figure 1 Trial design and proposed doses

The dose levels for Part A cohorts 2, 3 and 4 are tentative. The internal safety review committee will review the safety, tolerability and PK data prior to initiating cohort 2, cohorts 3 and 4. The dose levels for Part B, optional cohorts 2 and 3, will be based on the result from preceding cohorts. BSA=body surface area.

4.2 Trial objectives and endpoints

Table 2 Trial objectives and endpoints (Part A)

Objectives	Endpoints	Assessments	Analysis	Data display plan (DDP)
Primary				
To evaluate the safety and tolerability of GZ21T after single topical dose applications.	Frequency, severity and intensity of adverse events (AEs).	AE reporting and questioning	Descriptive statistics, Section 9.1.1	Section 10.2.2.1
	Local tolerability reactions: Erythema, swelling, pruritus, burning, blistering and urticaria, discolouration and dryness (Investigator's assessment 0-3 none/mild/moderate/severe).	Local tolerability reactions	Descriptive statistics, Section 9.1.2	Section 10.2.2.2
	Clinically significant changes in vital signs, electrocardiograms (ECGs), safety laboratory measurements (haematology, clinical chemistry, coagulation) and physical examination findings.	Blood pressure and pulse	Descriptive statistics, Section 9.1.3	Section 10.2.2.3
		12-lead ECG	Descriptive statistics, Section 9.1.4	Section 10.2.2.4
		Blood sampling for haematology, clinical chemistry and coagulation	Descriptive statistics, Section 9.1.5	Section 10.2.2.5
		Physical examinations	Descriptive statistics, Section 9.1.6	Section 10.2.2.6
Secondary				
To investigate the potential systemic exposure and pharmacokinetic (PK) properties of GZ21T after single topical dose applications.	Plasma concentrations of GZ21T after single dose applications.	PK sampling and analysis	Descriptive statistics, Section 9.2.1	Section 10.2.3.1
	PK parameters after a single dose application (to be calculated if data permits): area under the plasma concentration curve from time 0 to infinity (AUC_{inf}), AUC from time 0 to the last measurable concentration (AUC_{last}), maximum plasma concentration (C_{max}), time to C_{max} (T_{max}), terminal elimination half-life ($T_{½}$).			

Table 3 Trial objectives and endpoints (Part B)

Objectives	Endpoints	Assessments	Analysis	DDP
Primary				
To investigate the optimum amount of cream applied to a given area (dose/area) after single topical dose applications.	Cream absorption after single dose applications.	Evaluation of cream absorption	Section 9.1.7	Section 10.2.2.7

4.3 Randomisation (Part A)

On Day 1 (Visit 2), participants in each cohort (Part A) were randomised in a 6:2 ratio to receive either GZ21T or placebo. Sentinel dosing was applied for the first 2 participants in each cohort who received either GZ21T or placebo as randomised.

4.4 Participant replacement

Participants who were prematurely withdrawn from the trial for any reason except the occurrence of AEs assessed as possibly or probably related to the trial treatment may have been replaced.

4.5 Blinding

Part A of the trial is double-blinded. The allocation of treatments will not be disclosed until clean file has been declared and the database has been locked.

Part B of the trial is open-label and therefore no blinding will be performed.

5 STATISTICAL AND ANALYTICAL PLANS

5.1 Sample size calculation and number of participants

No formal sample size calculation has been performed for this trial. The proposed sample size is considered sufficient to provide adequate information to meet the trial objectives.

Part A: Approximately 64 participants were planned to be screened to achieve 32 randomised participants (8 in each cohort).

Part B: Approximately 18 potential participants were planned be screened to achieve up to 9 included participants, 3 subjects per cohort.

5.2 Definition of analysis sets

The analysis sets defined for the trial are outlined in Table 4.

Table 4 Analysis sets

Analysis set	Definition	Comment	Use of analysis set
Full analysis set (FAS)	All enrolled participants who received IMP.	Participants will only receive 1 dose of IMP. Therefore, the phrase (as stated in the CTP) "at least 1 dose of" before "IMP" is removed from the definitions to minimise confusion.	Part A and Part B: Safety endpoints and description of trial population.
Pharmacokinetic analysis set (PKAS)	All randomised participants in Part A who received IMP and provided an evaluable plasma concentration profile, and who have no AEs or protocol deviations judged to affect the PK analysis. Individual PK values may be excluded from the analysis.		Part A: PK endpoints.

5.3 Compliance

All IMP were administered at the trial site under medical supervision to ensure compliance.

5.4 Definition of baseline

Baseline is defined as the last non-missing data collection point prior to the administration of IMP.

5.5 Rounding principles

Generally, no rounding of data will be done prior to calculating statistics. However, if reported data contains more than 8 significant digits it will be rounded to 8 significant digits in the database.

In statistical output and descriptive summaries, the following principles will be used:

- Data will be presented as reported in input data in listings.
- Two (2) significant digits will be used for percentages (for example relative change from baseline).
- p-values and similar statistical output will be presented using 4 decimal places.
- Three (3) significant digits will be used for PK parameters when presenting min and max values in tables.

- Descriptive summaries (e.g., mean, SD, median etc.) of PK parameters will be presented with 4 significant digits.
- Descriptive summaries (e.g., mean, SD, median etc.) of all other numerical data will be presented with one extra decimal compared to reported input data.

5.6 Handling of dropouts, missing data and outliers

Outliers will be included in summary tables and listings and will not be handled separately in any analyses. All collected data, even if not tabulated, will be listed. Generally, no imputation of data will be performed. However, when calculating statistics for PK plasma concentrations, concentrations under LLOQ will be replaced with LLOQ/2 if more than 50% of the values for a given time point are above LLOQ. Otherwise, no statistics will be calculated for that time point. For figures presenting individual PK concentrations, no imputation is performed for values under LLOQ. For imputation of PK plasma concentration below LLOQ with the purpose of calculating PK parameters, see Section 9.2.1.

Safety laboratory concentrations under LLOQ will be replaced with LLOQ/2 and concentrations over ULOQ will be replaced with ULOQ for the purpose of calculating descriptive statistics.

In case of missing start and stop times of AEs that cannot be investigated further, missing data will be imputed according to a worst-case scenario, i.e., start time will be imputed as the closest time point post first intake of IMP and end time as 23:59, resulting in the longest possible treatment emergent duration of the AE.

6 CHANGES FROM THE CLINICAL TRIAL PROTOCOL

Changes to the planned analyses and the timing of these are summarised in Table 5.

Table 5 Changes in the planned statistical analyses

Change category	Timing of change	Description of change	Reason for change
Change in the SAP compared to the CTP	Prior to DBL	A minor change has been made to the phrasing of the definitions for FAS and PKAS. This change does not affect whether participants are included in the analysis sets or not. See Table 4 for details.	To minimise confusion.
		In section 9.1.1, definitely related AEs has been added to the definition of causally related AEs, which is missing from sections 11.3.1.11 and 17.6.1 of the CTP.	"Definitely related" was missing from the AE definitions in sections 11.3.1.11 and 17.6.1 of the CTP
		Frequency tables for safety laboratory interpretations have been added.	To provide a better overview of the safety laboratory data.
		The overall/total column has been removed from all safety tabulations, except for AEs and LTs.	Redundant information.

7 CLINICAL DATABASE PROCESSING

7.1 General information

The clinical database is processed and generated according to The Clinical Data Interchange Standards Consortium (CDISC). CDISC is a Standard Developing Organization which develops and publishes standards to normalise the structure of clinical trial data and thereby simplify submissions to and reviews by authorities such as the Food and Drug Administration (FDA).

The CDISC standards for clinical studies are the Trial Data Tabulation Model (SDTM) and the Analysis Data Model (ADaM). The trial data will be structured into a database model reflecting the SDTM and will be compliant to SDTM Implementation Guide (SDTM-IG) version 3.3. The data used for statistical analysis will be structured to reflect the ADaM and be compliant to ADaM Implementation Guide (ADaM-IG) version 1.3.

Data values are collected according to, or mapped into, controlled terminology codelists defined by CDISC, whenever possible. The codelists are updated quarterly at CTC and the latest version available at trial start will be used. As per default, controlled terminology codelists will be used in all tables, listings, and figures. Custom codelists for test or parameter names will be used if applicable upon Sponsor's request, to align with protocol texts, or to adhere to other standard naming conventions (e.g., PK parameter name "Tmax" will be used instead of the CDISC term "Time of CMAX"). These custom codelists will be mapped in the "Parameter Name" field in the ADaM structure, while the CT will be kept in the SDTM predecessor fields to provide traceability back to CDISC codelists.

7.1.1 CDISC Compliance

The trial database will be CDISC compliant which means that the clinical database will be processed and generated according to CDISC standard. The database will be validated against SDTM and ADaM Validation rules using Pinnacle 21.

The following CDISC documentation will be generated:

- SDTM Data Definition Specification (also referred to as a Define -XML)
  - Define-XML transmits metadata that describes any tabular dataset structure and supports the interchange of dataset metadata for clinical research applications in a machine-readable format.
- ADaM Data Definition Specification (also referred to as a Define -XML)
  - Define-XML transmits metadata that describes any tabular dataset structure and supports the interchange of dataset metadata for clinical research applications in a machine-readable format.
- Annotated Electronic Case Report Form (eCRF)
  - Links the data collection fields used to capture trial data to the corresponding variables in the trial database. It enables the user to understand how the trial data were collected and to trace back from trial analysis results to the origin where it was collected.
- SDTM Reviewers' Guide
  - Intended to provide additional context and act as a single point of orientation for the SDTM datasets.
- ADaM Reviewers' Guide
  - Provides regulatory agency reviewers an orientation to the submitted analysis data in a consistent way and usable format.

7.2 Database modeling of trial design

The trial design is mapped to a SDTM trial design model containing the following structural components:

EPOCH: An interval of time in the planned conduct of a trial. An epoch is associated with a purpose (e.g., screening, randomisation, treatment, follow-up), and applies across all arms of the trial. Trial epochs follow a controlled terminology to represent the different trial parts (e.g., SCREENING, TREATMENT [X], FOLLOW-UP)

ELEMENT: Building blocks used to build up the entire trial length for all participants. Information on ELEMENTs is extracted from the trial design and schedule of events in the protocol. ELEMENTs are defined to span the entire trial without gaps. One EPOCH may contain one or several ELEMENTs. All ELEMENTs must have transition rules in accordance with the protocol to determine start and end.

ARM: Participants are allocated to trial arms depending on the trial design, either by randomisation or other allocation processes defined in the trial protocol. ARMs are defined as the total number of planned ways a participant can go through the trial (unique combination of trial ELEMENTs). All ARMs must contain a unique sequence of ELEMENTs.

VISIT: Trial visits are defined as planned timepoints during the trial where trial data is collected. A visit can be performed in clinic, by off-site contact with trial personnel (phone call, video conference or similar), or by participant initiated recordings of data. The visit schedule is extracted from protocol and eCRF design.

A schematic representation of the SDTM trial design is presented in Figure 2. Replace the figure below with a relevant version for the trial.

8 STATISTICAL DELIVERABLES

The following items will be delivered:

- Statistical analyses, summary tables, listings and figures as described under Section 10.
- Clinical trial database delivered as a SAS-export file and Excel files.

9 STATISTICAL METHODOLOGY

All collected data will be listed by part, participant, cohort and treatment, and, where applicable, by assessment time.

The data for participants receiving placebo will be presented pooled across groups.

Details on statistical analyses and descriptive summaries are specified below.

All statistical analyses and descriptive summaries will be performed using SAS version 9.4 (SAS institute, Cary, NC).

PK parameters will be calculated by Non-Compartmental Analysis (NCA) using the software Phoenix WinNonlin® version 8.3 (Certara, U.S.A).

9.1 Analysis of the primary endpoints

9.1.1 Adverse events

An overview of all AEs, including SAEs, intensity, relationship to IMP, and deaths will be presented by part, cohort treatment, and overall. The incidence of AEs and SAEs will be summarised by SOC and PT by treatment, cohort and overall. A summary of any treatment-related (probably/possibly/definitely related) AEs will be summarised by SOC and PT and by treatment, cohort and overall if considered appropriate.

9.1.2 Local tolerability

An overview of all local tolerability reactions including maximum intensity grade per local tolerability reaction will be presented by part, cohort, treatment, and overall. Intensity grade for each local tolerability reaction will also be presented by cohort, treatment, and overall using a frequency table. Changes from baseline in intensity grade at each time point will be summarised in a shift table.

9.1.3 Vital signs

Vital signs will be summarised by treatment and cohort, and by assessment time point. Data will be presented with absolute and percent change from baseline. Vital signs data (blood pressure and pulse) for eligibility (screening) in Part B will only be listed.

9.1.4 Electrocardiogram

All ECGs will be categorised as ”normal”, ”abnormal, not clinically significant”, or ”abnormal, clinically significant” (as judged by the Investigator) and summarised by treatment and cohort, and by assessment time point using frequency tables. Changes over time will be presented using a shift table if considered appropriate. All measured ECG values will be summarised by treatment, cohort and overall, and assessment timepoint with absolute and percent change from baseline. ECG data for eligibility (screening) in Part B will only be listed.

9.1.5 Safety laboratory

Safety laboratory data will be summarised by treatment and cohort, and by assessment time point with absolute and percent change from baseline.

All safety laboratory measurements will be categorised as ”normal”, ”abnormal, not clinically significant”, or ”abnormal, clinically significant” (as judged by the Investigator) and

summarised by treatment and cohort, and by assessment time point using frequency tables. Safety laboratory data for eligibility (screening) in Part B will only be listed.

9.1.6 Physical examinations

Normal and clinically significant and non-clinically significant abnormal findings will be specified and summarised by treatment and cohort, and by assessment time point. Changes over time will be presented using shift tables, if appropriate. Physical examination data for eligibility (screening) in Part B will only be listed.

9.1.7 Cream absorption (Part B)

Cream absorption measured on a 4-point scale will be presented using a frequency table by cohort. The time until adequate abruption, measured at 30 min, 1h, and 2 h, will be presented by cohort in the same frequency table. Adequate abruption will be interpreted as equivalent to a cream absorption score of at least "3 = Mostly absorbed" on the 4-point cream absorption scale.

9.2 Analysis of secondary endpoints

9.2.1 Pharmacokinetic analysis (Part A)

The following non-compartmental plasma PK parameters will be determined/calculated (if data permits) during the trial conduct:

- T_{max} – Time to reach C_{max}
- C_{max} – The maximum observed plasma concentration
- $AUC_{0\text{-}last}$ – Area under the plasma concentration versus time curve (AUC) from timepoint 0 to t, where t represents the timepoint of the last detectable plasma concentration
- $AUC_{0\text{-}inf}$ – AUC from timepoint 0 extrapolated to infinity
- $T_{1/2}$ – Terminal plasma elimination half-life

Parameters that are only presented in listings

- $Lambda_z$ – Eliminate rate constant associated with the terminal phase
- $Lambda_z$ lower – Lower limit on time for values to be included in the calculation of $Lambda_z$
- $Lambda_z$ upper – Upper limit on time for values to be included in the calculation of $Lambda_z$
- No points $lambda_z$ – Number of points used in computing $lambda_z$
- Span – The ratio between the interval used for determination of $lambda_z$ and the terminal $T_{1/2}$
- Rsq adj – Goodness of fit statistic for the terminal phase, adjusted for the number of points used in the estimation of $lambda_Z$.
- $AUC_{extr\%}$ – Percentage of $AUC_{0\text{-}inf}$ due to extrapolation from T_{last} to infinity
- T_{last} – Last observed concentration

Following units will be used:

- Time: h

- Concentration: nmol/L
- AUCs: h* nmol/L
- Lambda$_z$: /h

Non-compartmental analysis will be based on the actual sampling times recorded during the trial.. For the purpose of calculating PK parameters, concentrations below lower limit of quantification (LLOQ) occurring before C_{max} will be treated as zero. Concentrations below LLOQ occurring after C_{max} will be omitted from the analysis.

T_{max}, T_{last} and C_{max} will be based on the observed plasma concentration data.

All AUC will be assessed by integration of the plasma concentration vs time curve using linear interpolation for increasing plasma levels and logarithmic interpolation for decreasing plasma levels (Linear Up-Log Down method).

$AUC_{0\text{-}last}$ will be calculated from time 0 to the time t of the last detectable plasma concentration.

For $AUC_{0\text{-}inf}$ the area will be calculated to the last timepoint showing a measurable plasma concentration and then extrapolated to infinity using the concentration in the last quantifiable sample and lambda$_z$.

$$AUC_{0-inf} = AUC_{0-last} + \frac{C_{last}}{lambda_z}$$

Formulas for calculation of AUC

- Linear trapezoidal rule:

$$AUC|_{t1}^{t2} = \delta t \times \frac{C_1 + C_2}{2}$$

- Logarithmic trapezoidal rule:

$$AUC|_{t1}^{t2} = \delta t \times \frac{C_2 - C_1}{ln(\frac{C_2}{C_1})}$$

where t = time, c = concentration, $\delta t = t_2 - t_1$.

Formulas for interpolation (to find C* at time t* for t1 < t* < t2)

- Linear interpolation rule:

$$C^* = C_1 + |\frac{t^* - t_1}{t_2 - t_1}| (C_2 - C_1)$$

- Logarithmic interpolation rule:

$$C^* = exp\ (ln(C_1) + |\frac{t^* - t_1}{t_2 - t_1}| * (ln(C_2) - ln(C_1)))$$

where t = time, c = concentration

$Lambda_z$, the first order rate constant associated with the terminal portion of the curve will be determined by lin-logarithmic regression of the terminal elimination phase of individual plasma concentration vs time curves. Determination of $lambda_z$ requires identification of a sufficiently linear terminal phase (as determined by visual inspection of the lin-log plasma concentration vs time plot with the regression line) consisting of at least 3 terminal concentration values (not including C_{max}). If this is not achieved, $lambda_z$ and its dependent PK parameters will not be reported for that profile.

In the following cases, $lambda_z$ dependent PK parameters will be flagged in listings as potentially unreliable:

- $Lambda_z$ estimation is based on a period of less than 1.5 times the resulting $T_{1/2.}$
- The Rsq adjusted value of the regression line is < 0.85.
- The estimated % extrapolated AUC is > 20% (($AUC_{0\text{-}inf}$ -$AUC_{0\text{-}last}$ / $AUC_{0\text{-}inf}$)*100).

$T_{1/2}$ will be calculated accordingly:

$$T_{1/2} = \frac{\ln (2)}{lambda_z}$$

Span will be calculated accordingly:

$$Span = \frac{lambda_z\ upper - \ lambda_z\ lower}{T_{1/2}}$$

If there is a confirmed dosing error during the trial, the pharmacokinetic data for that period will only be included in the listings but excluded from descriptive and statistical analyses. In case of missed blood samples, potential impact on PK parameters will be assessed for each individual case. PK parameters with a high degree of uncertainty due to missing samples (e.g., multiple samples missing around C_{max}) will be flagged as unreliable in the report and may in rare cases be excluded from summary tables, descriptive statistics, and statistical analysis.

9.3 Description of trial population

9.3.1 Disposition

A participant disposition will be presented by part, showing the number of screened participants; the number of withdrawn participants prior to dose, including the reason for withdrawal; the number of included participants in each cohort; the number of withdrawn participants, including the reason for withdrawal; the number of completed participants; the number of participants included in the analysis sets, and the number of participants at each visit.

9.3.2 Demographics and baseline characteristics

Descriptive statistics for demographics, weight and height will be presented for all participants, by part.

9.3.3 Medical/surgical history and prior/concomitant medication

Medical/surgical history will be presented by part, system organ class (SOC) and preferred term (PT). Prior/concomitant medications will be presented by ATC level 4 and WHODrug Preferred name.

9.3.4 Investigational medicinal product use

Individual IMP use will be listed.

10 DATA DISPLAY PLAN

Tables and figures will only be generated if sufficient data, with sufficient variability exist to justify specific output being produced. Unscheduled/extra visits will generally not be presented in tables and summary figures but will be included in listings.

10.1 Table of contents DDP

List of tables

List of figures

10.2 Trial tables

10.2.1 Demographic data

Table DM 1 Baseline characteristics and demographics – Part A (Full analysis set)

Assessment (unit)		[redacted]					
Age (years)	n	x	x	x	x	x	x
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
	Median (Min, Max)	xx.x (xx, xx)	xx.x (xx, xx)	xx.x (xx, xx)	xx.x (xx, xx)	xx.x (xx, xx)	xx.x (xx, xx)
Height (cm)	n	x	x	x	x	x	x
	Mean (SD)	xxx.x (xx.x)	xxx.x (xx.x)	xxx.x (xx.x)	xxx.x (xx.x)	xxx.x (xx.x)	xxx.x (xx.x)
	Median (Min, Max)	xxx.x (xxx, xxx)	xxx.x (xxx, xxx)	xxx.x (xxx, xxx)	xxx.x (xxx, xxx)	xxx.x (xxx, xxx)	xxx.x (xxx, xxx)
Weight (kg)	n	x	x	x	x	x	x
	Mean (SD)	xx.xx (xx.xx)	xx.xx (xx.xx)	xx.xx (xx.xx)	xx.xx (xx.xx)	xx.xx (xx.xx)	xx.xx (xx.xx)
	Median (Min, Max)	xx.xx (xx.x, xx.x)	xx.xx (xx.x, xx.x)	xx.xx (xx.x, xx.x)	xx.xx (xx.x, xx.x)	xx.xx (xx.x, xx.x)	xx.xx (xx.x, xx.x)
Body Mass Index (kg/m2)	n	x	x	x	x	x	x
	Mean (SD)	xx.xx (xx.xx)	xx.xx (xx.xx)	xx.xx (xx.xx)	xx.xx (xx.xx)	xx.xx (xx.xx)	xx.xx (xx.xx)
	Median (Min, Max)	xx.xx (xx.x, xx.x)	xx.xx (xx.x, xx.x)	xx.xx (xx.x, xx.x)	xx.xx (xx.x, xx.x)	xx.xx (xx.x, xx.x)	xx.xx (xx.x, xx.x)
BSA (m2)	n	x	x	x	x	x	x
	Mean (SD)	xx.xx (xx.xx)	xx.xx (xx.xx)	xx.xx (xx.xx)	xx.xx (xx.xx)	xx.xx (xx.xx)	xx.xx (xx.xx)
	Median (Min, Max)	xx.xx (xx.x, xx.x)	xx.xx (xx.x, xx.x)	xx.xx (xx.x, xx.x)	xx.xx (xx.x, xx.x)	xx.xx (xx.x, xx.x)	xx.xx (xx.x, xx.x)
Sex	Female	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Male	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Ethnicity	Hispanic or latino	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Not hispanic or latino	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Not reported	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)

Assessment (unit)		[redacted]					
	Unknown	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Race	American Indian or Alaska Native	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Asian	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Black or African American	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Native Hawaiian or Other Pacific Islander	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	White	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)

Data based on [ANALYSIS SET]. BSA: Body surface area. N: number of participants in treatment group. Percentages are based on the number of observations. n: Number of observations. SD: Standard deviation. SAS program: [PROGRAM NAME].sas.
Dataset version: ADXX YYYY-MM-DDTHH:MM:SS. Run by: [USERNAME] YYYY-MM-DDTHH:MM:SS. EDC data extracted: YYYY-MM-DDTHH:MM:SS.

Table DM 2 Baseline characteristics and demographics – [redacted]

[redacted]		[redacted]			
Age (years)	n	x	x	x	x
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
	Median (Min, Max)	xx.x (xx, xx)	xx.x (xx, xx)	xx.x (xx, xx)	xx.x (xx, xx)
Height (cm)	n	x	x	x	x
	Mean (SD)	xxx.x (xx.x)	xxx.x (xx.x)	xxx.x (xx.x)	xxx.x (xx.x)
	Median (Min, Max)	xxx.x (xxx, xxx)	xxx.x (xxx, xxx)	xxx.x (xxx, xxx)	xxx.x (xxx, xxx)
Weight (kg)	n	x	x	x	x
	Mean (SD)	xx.xx (xx.xx)	xx.xx (xx.xx)	xx.xx (xx.xx)	xx.xx (xx.xx)
	Median (Min, Max)	xx.xx (xx.x, xx.x)	xx.xx (xx.x, xx.x)	xx.xx (xx.x, xx.x)	xx.xx (xx.x, xx.x)
Body Mass Index (kg/m2)	n	x	x	x	x
	Mean (SD)	xx.xx (xx.xx)	xx.xx (xx.xx)	xx.xx (xx.xx)	xx.xx (xx.xx)
	Median (Min, Max)	xx.xx (xx.x, xx.x)	xx.xx (xx.x, xx.x)	xx.xx (xx.x, xx.x)	xx.xx (xx.x, xx.x)

Assessment (unit)		[redacted]			
BSA (m2)	n	x	x	x	x
	Mean (SD)	xx.xx (xx.xx)	xx.xx (xx.xx)	xx.xx (xx.xx)	xx.xx (xx.xx)
	Median (Min, Max)	xx.xx (xx.x, xx.x)	xx.xx (xx.x, xx.x)	xx.xx (xx.x, xx.x)	xx.xx (xx.x, xx.x)
Sex	Female	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Male	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Ethnicity	Hispanic or latino	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Not hispanic or latino	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Not reported	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Unknown	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Race	American Indian or Alaska Native	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Asian	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Black or African American	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Native Hawaiian or Other Pacific Islander	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	White	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)

Data based on [ANALYSIS SET]. BSA: Body surface area. N: number of participants in treatment group. Percentages are based on the number of observations. n: Number of observations. SD: Standard deviation. SAS program: [PROGRAM NAME].sas.
Dataset version: ADXX YYYY-MM-DDTHH:MM:SS. Run by: [USERNAME] YYYY-MM-DDTHH:MM:SS. EDC data extracted: YYYY-MM-DDTHH:MM:SS.

Table DS 1 Participant disposition – Part A (All participants)

	Total (N=XXX)
Screened participants	xxx
Withdrawn prior to dose	xxx
Reason for withdrawal prior to dose	
--- Reason 1	xxx
--- Reason 2	xxx
--- …	xxx
Participants included in trial	xxx
Allocated to arm	
[redacted]	xxx
	xxx
	xxx
	xxx
	xxx
Withdrawn participants	
--- Reason 1	xxx
--- Reason 2	xxx
--- …	xxx
Completed participants	xxx
Included in Full analysis set	xxx
Included in Pharmacokinetic analysis set	xxx
Participants at each visit	
--- Visit 1 - Screening	xxx
--- Visit 2 - Inpatient stay	xxx
--- Visit 3 - Follow-up	xxx

Data based on All participants. BSA: Body surface area. [1]The data for participants receiving placebo is presented pooled across groups. SAS program: [PROGRAM NAME].sas. Dataset version: ADXX YYYY-MM-DDTHH:MM:SS. Run by: [USERNAME] YYYY-MM-DDTHH:MM:SS. EDC data extracted: YYYY-MM-DDTHH:MM:SS.

Table DS 2 Participant disposition – Part B (All participants)

	Total (N=XXX)
Screened participants	xxx
Withdrawn prior to dose	xxx
Reason for withdrawal prior to dose	
--- Reason 1	xxx
--- Reason 2	xxx
--- …	xxx
Participants included in trial	xxx
Allocated to arm	
[redacted]	xxx
	xxx
	xxx
Withdrawn participants	
--- Reason 1	xxx
--- Reason 2	xxx
--- …	xxx
Completed participants	xxx
Included in Full analysis set	xxx
Participants at each visit	
--- Visit 1 - Screening	xxx
--- Visit 2 – Treatment visit	xxx
--- Visit 3 - Follow-up	xxx

Data based on All participants. BSA: Body surface area. SAS program: [PROGRAM NAME].sas. Dataset version: ADXX YYYY-MM-DDTHH:MM:SS. Run by: [USERNAME] YYYY-MM-DDTHH:MM:SS. EDC data extracted: YYYY-MM-DDTHH:MM:SS.

Table MH 1 Medical history events by system organ class and preferred term – Part A (Full analysis set)

System organ class Preferred term	[redacted]											m
Total	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**
[SOC 1]	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**
[SOC 1 PT 1]	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx
[SOC 1 PT 2]	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx
[SOC 1 PT …]	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx
[SOC 2]	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**
[SOC 2 PT 1]	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx
[SOC 2 PT 2]	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx
[SOC 2 PT …]	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx
[SOC …]	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**
[SOC … PT 1]	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx
[SOC … PT 2]	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx
[SOC … PT …]	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx

Data based on [ANALYSIS SET]. BSA: Body surface area. N: number of participants in the treatment group. Percentages are based on N. n: number of participants. m: number of events. The following events are coded with multiple terms and are represented as separate events in tables and listings: '[MH TERM 1], [MH TERM 2]'. See listings for detailed information. SAS program: [PROGRAM NAME].sas.
Dataset version: ADXX YYYY-MM-DDTHH:MM:SS. Run by: [USERNAME] YYYY-MM-DDTHH:MM:SS. EDC data extracted: YYYY-MM-DDTHH:MM:SS.

Table MH 2 Medical history events by system organ class and preferred term – Part B (Full analysis set)

System organ class Preferred term	[redacted]							
Total	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**

System organ class Preferred term	[redacted]							m
[SOC 1]	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**
[SOC 1 PT 1]	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx
[SOC 1 PT 2]	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx
[SOC 1 PT …]	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx
[SOC 2]	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**
[SOC 2 PT 1]	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx
[SOC 2 PT 2]	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx
[SOC 2 PT …]	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx
[SOC …]	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**
[SOC … PT 1]	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx
[SOC … PT 2]	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx
[SOC … PT …]	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx

Data based on [ANALYSIS SET]. BSA: Body surface area. N: number of participants in the treatment group. Percentages are based on N. n: number of participants. m: number of events. The following events are coded with multiple terms and are represented as separate events in tables and listings: '[MH TERM 1], [MH TERM 2]'. See listings for detailed information. SAS program: [PROGRAM NAME].sas.
Dataset version: ADXX YYYY-MM-DDTHH:MM:SS. Run by: [USERNAME] YYYY-MM-DDTHH:MM:SS. EDC data extracted: YYYY-MM-DDTHH:MM:SS.

Table CM 1 Prior medications by ATC level 4 and preferred name – Part A (Full analysis set)

ATC Name Level 4 Preferred Name	[redacted]										Total (N=XX)	
										m	n (%)	m
Total	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**
[L4 1]	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**
[L4 1 PN 1]	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx

ATC Name Level 4 Preferred Name	[redacted]								Total (N=XX)			
	n (%)	m	n (%)	m	n (%)	m	n (%)	m	n (%)	m	n (%)	m
[L4 1 PN 2]	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx
[L4 1 PN …]	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx
[L4 2]	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**
[L4 2 PN 1]	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx
[L4 2 PN 2]	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx
[L4 2 PN …]	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx
[L4 …]	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**
[L4 … PN 1]	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx
[L4 … PN 2]	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx
[L4 … PN …]	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx

Data based on [ANALYSIS SET]. BSA: Body surface area. N: number of participants in the treatment group. Percentages are based on N. n: number of participants. m: number of events. The following records are coded with multiple terms and are represented as separate events in tables and listings: '[CM TERM 1], [CM TERM 2]'. See listings for detailed information. SAS program: [PROGRAM NAME].sas
Dataset version: ADXX YYYY-MM-DDTHH:MM:SS. Run by: [USERNAME] YYYY-MM-DDTHH:MM:SS. EDC data extracted: YYYY-MM-DDTHH:MM:SS.

Table CM 2 Prior medications by ATC level 4 and preferred name – Part B (Full analysis set)

ATC Name Level 4 Preferred Name	[redacted]							m
Total	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**
[L4 1]	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**
[L4 1 PN 1]	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx
[L4 1 PN 2]	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx
[L4 1 PN …]	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx

ATC Name Level 4 Preferred Name	[redacted]							m
[L4 2]	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**
[L4 2 PN 1]	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx
[L4 2 PN 2]	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx
[L4 2 PN …]	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx
[L4 …]	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**
[L4 … PN 1]	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx
[L4 … PN 2]	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx
[L4 … PN …]	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx

Data based on [ANALYSIS SET]. BSA: Body surface area. N: number of participants in the treatment group. Percentages are based on N. n: number of participants. m: number of events. The following records are coded with multiple terms and are represented as separate events in tables and listings: '[CM TERM 1], [CM TERM 2]'. See listings for detailed information. SAS program: [PROGRAM NAME].sas
Dataset version: ADXX YYYY-MM-DDTHH:MM:SS. Run by: [USERNAME] YYYY-MM-DDTHH:MM:SS. EDC data extracted: YYYY-MM-DDTHH:MM:SS.

Table CM 3 Concomitant medications by ATC level 4 and preferred name – Part A (Full analysis set)

ATC Name Level 4 Preferred Name	[redacted]										Total (N=XX)	
										m	n (%)	m
Total	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**
[L4 1]	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**
[L4 1 PN 1]	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx
[L4 1 PN 2]	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx
[L4 1 PN …]	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx
[L4 2]	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**
[L4 2 PN 1]	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx

ATC Name Level 4 Preferred Name	[redacted]										Total (N=XX)	
											m	n (%)	m
[L4 2 PN 2]	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx
[L4 2 PN …]	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx
[L4 …]	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**
[L4 … PN 1]	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx
[L4 … PN 2]	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx
[L4 … PN …]	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx

Data based on [ANALYSIS SET]. BSA: Body surface area. N: number of participants in the treatment group. Percentages are based on N. n: number of participants. m: number of events. The following records are coded with multiple terms and are represented as separate events in tables and listings: '[CM TERM 1], [CM TERM 2]'. See listings for detailed information. SAS program: [PROGRAM NAME].sas.
Dataset version: ADXX YYYY-MM-DDTHH:MM:SS. Run by: [USERNAME] YYYY-MM-DDTHH:MM:SS. EDC data extracted: YYYY-MM-DDTHH:MM:SS.

Table CM 4 Concomitant medications by ATC level 4 and preferred name – Part B (Full analysis set)

ATC Name Level 4 Preferred Name	[redacted]							
								m
Total	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**
[L4 1]	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**
[L4 1 PN 1]	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx
[L4 1 PN 2]	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx
[L4 1 PN …]	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx
[L4 2]	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**
[L4 2 PN 1]	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx
[L4 2 PN 2]	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx
[L4 2 PN …]	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx

ATC Name Level 4 Preferred Name	[redacted]							m
[L4 …]	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**
[L4 … PN 1]	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx
[L4 … PN 2]	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx
[L4 … PN …]	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx

Data based on [ANALYSIS SET]. BSA: Body surface area. N: number of participants in the treatment group. Percentages are based on N. n: number of participants. m: number of events. The following records are coded with multiple terms and are represented as separate events in tables and listings: '[CM TERM 1], [CM TERM 2]'. See listings for detailed information. SAS program: [PROGRAM NAME].sas.
Dataset version: ADXX YYYY-MM-DDTHH:MM:SS. Run by: [USERNAME] YYYY-MM-DDTHH:MM:SS. EDC data extracted: YYYY-MM-DDTHH:MM:SS.

10.2.2 Primary endpoints

10.2.2.1 Adverse events

Table AE 1 Overview of adverse events – Part A (Full analysis set)

	[redacted]											
Any AE	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx
Any SAE	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx
Any AE leading to withdrawal from trial	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx
Any AE leading to death	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx
Causality												
Not related	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx
Unlikely related	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx
Possibly related	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx

	[redacted]	m
Probably related	xx (xx%) xx xx (xx%) xx xx (xx%) xx xx (xx%) xx xx (xx%) xx xx (xx%)	xx
Definitely related	xx (xx%) xx xx (xx%) xx xx (xx%) xx xx (xx%) xx xx (xx%) xx xx (xx%)	xx
Severity		
Mild	xx (xx%) xx xx (xx%) xx xx (xx%) xx xx (xx%) xx xx (xx%) xx xx (xx%)	xx
Moderate	xx (xx%) xx xx (xx%) xx xx (xx%) xx xx (xx%) xx xx (xx%) xx xx (xx%)	xx
Severe	xx (xx%) xx xx (xx%) xx xx (xx%) xx xx (xx%) xx xx (xx%) xx xx (xx%)	xx
Life-Threatening	xx (xx%) xx xx (xx%) xx xx (xx%) xx xx (xx%) xx xx (xx%) xx xx (xx%)	xx
Death	xx (xx%) xx xx (xx%) xx xx (xx%) xx xx (xx%) xx xx (xx%) xx xx (xx%)	xx

Data based on [ANALYSIS SET]. BSA: Body surface area. N: number of participants in the treatment group. Percentages are based on N. n: number of participants. m: number of events. The following AEs are coded with multiple MedDRA terms and are represented as separate AEs in tables and listings: '[AE TERM 1]', '[AE TERM 2]', '[AE TERM 3]. See listings for detailed information. SAS program: [PROGRAM NAME].sas.
Dataset version: ADXX YYYY-MM-DDTHH:MM:SS. Run by: [USERNAME] YYYY-MM-DDTHH:MM:SS. EDC data extracted: YYYY-MM-DDTHH:MM:SS.

Table AE 2 Overview of adverse events – Part [redacted]

[redacted]

	[redacted]							
Probably related	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx
Definitely related	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx
Severity								
Mild	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx
Moderate	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx
Severe	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx
Life-Threatening	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx
Death	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx

Data based on [ANALYSIS SET]. BSA: Body surface area. N: number of participants in the treatment group. Percentages are based on N. n: number of participants. m: number of events. The following AEs are coded with multiple MedDRA terms and are represented as separate AEs in tables and listings: '[AE TERM 1]', '[AE TERM 2]', '[AE TERM 3]. See listings for detailed information. SAS program: [PROGRAM NAME].sas.
Dataset version: ADXX YYYY-MM-DDTHH:MM:SS. Run by: [USERNAME] YYYY-MM-DDTHH:MM:SS. EDC data extracted: YYYY-MM-DDTHH:MM:SS.

Table AE 3 Adverse events by system organ class and preferred term – Part A (Full analysis set)

System organ class Preferred term	[redacted]											
	n (%)	m	n (%)	m	n (%)	m	n (%)	m	n (%)	m	n (%)	m
Total	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**
[SOC 1]	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**
[SOC 1 PT 1]	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx
[SOC 1 PT 2]	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx
[SOC 1 PT …]	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx
[SOC 2]	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**
[SOC 2 PT 1]	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx
[SOC 2 PT 2]	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx

System organ class Preferred term	[redacted]											
[SOC 2 PT …]	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx
[SOC …]	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**
[SOC … PT 1]	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx
[SOC … PT 2]	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx
[SOC … PT …]	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx

Data based on [ANALYSIS SET]. BSA: Body surface area. N: number of participants in the treatment group. Percentages are based on N. n: number of participants. m: number of events. The following events are coded with multiple terms and are represented as separate events in tables and listings: '[AE TERM 1], [AE TERM 2]'. See listings for detailed information. SAS program: [PROGRAM NAME].sas.
Dataset version: ADXX YYYY-MM-DDTHH:MM:SS. Run by: [USERNAME] YYYY-MM-DDTHH:MM:SS. EDC data extracted: YYYY-MM-DDTHH:MM:SS.

Table AE 4 Adverse events by system organ class and preferred term – Part B (Full analysis set)

System organ class Preferred term	[redacted]							m
Total	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**
[SOC 1]	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**
[SOC 1 PT 1]	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx
[SOC 1 PT 2]	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx
[SOC 1 PT …]	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx
[SOC 2]	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**
[SOC 2 PT 1]	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx
[SOC 2 PT 2]	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx
[SOC 2 PT …]	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx
[SOC …]	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**	**xx (xx%)**	**xx**

System organ class Preferred term	[redacted]							m
[SOC … PT 1]	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx
[SOC … PT 2]	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx
[SOC … PT …]	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx

Data based on [ANALYSIS SET]. BSA: Body surface area. N: number of participants in the treatment group. Percentages are based on N. n: number of participants. m: number of events. The following events are coded with multiple terms and are represented as separate events in tables and listings: '[AE TERM 1], [AE TERM 2]'. See listings for detailed information. SAS program: [PROGRAM NAME].sas.
Dataset version: ADXX YYYY-MM-DDTHH:MM:SS. Run by: [USERNAME] YYYY-MM-DDTHH:MM:SS. EDC data extracted: YYYY-MM-DDTHH:MM:SS.

Table AE 5 Serious adverse events by system organ class and preferred term – Part A (Full analysis set)

Same layout as Table AE 3

Table AE 6 Serious adverse events by system organ class and preferred term – Part B (Full analysis set)

Same layout as Table AE 4

Table AE 7 Treatment related adverse events by system organ class and preferred term – Part A (Full analysis set)

Same layout as Table AE 3. Add footnote: An AE is considered causally related to the use of the IMP when the causality assessment is probably, possibly or definitely related.

Table AE 8 Treatment related adverse events by system organ class and preferred term – Part B (Full analysis set)

Same layout as Table AE 4. Add footnote: An AE is considered causally related to the use of the IMP when the causality assessment is probably, possibly or definitely related.

10.2.2.2 Local tolerability

Table LT 1 Overview of local tolerability – Part A (Full analysis set)

	[redacted]											m
Any LT reaction graded higher than None	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx
Any Erythema	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx
Maximum grade Erythema												
None	xx (xx%)		xx (xx%)		xx (xx%)	xx	xx (xx%)		xx (xx%)	xx	xx (xx%)	
Mild	xx (xx%)		xx (xx%)		xx (xx%)	xx	xx (xx%)		xx (xx%)	xx	xx (xx%)	
Moderate	xx (xx%)		xx (xx%)		xx (xx%)	xx	xx (xx%)		xx (xx%)	xx	xx (xx%)	
Severe	xx (xx%)		xx (xx%)		xx (xx%)	xx	xx (xx%)		xx (xx%)	xx	xx (xx%)	
Any Swelling	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx
Maximum grade Swelling												
None	xx (xx%)		xx (xx%)		xx (xx%)	xx	xx (xx%)		xx (xx%)	xx	xx (xx%)	
Mild	xx (xx%)		xx (xx%)		xx (xx%)	xx	xx (xx%)		xx (xx%)	xx	xx (xx%)	
Moderate	xx (xx%)		xx (xx%)		xx (xx%)	xx	xx (xx%)		xx (xx%)	xx	xx (xx%)	
Severe	xx (xx%)		xx (xx%)		xx (xx%)	xx	xx (xx%)		xx (xx%)	xx	xx (xx%)	
Any Pruritus	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx
Maximum grade Pruritus												
None	xx (xx%)		xx (xx%)		xx (xx%)	xx	xx (xx%)		xx (xx%)	xx	xx (xx%)	
Mild	xx (xx%)		xx (xx%)		xx (xx%)	xx	xx (xx%)		xx (xx%)	xx	xx (xx%)	
Moderate	xx (xx%)		xx (xx%)		xx (xx%)	xx	xx (xx%)		xx (xx%)	xx	xx (xx%)	
Severe	xx (xx%)		xx (xx%)		xx (xx%)	xx	xx (xx%)		xx (xx%)	xx	xx (xx%)	
Any Burning	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx
Maximum grade Burning												
None	xx (xx%)		xx (xx%)		xx (xx%)	xx	xx (xx%)		xx (xx%)	xx	xx (xx%)	

	[redacted]											m
Mild	xx (xx%)		xx (xx%)		xx (xx%)	xx	xx (xx%)		xx (xx%)	xx	xx (xx%)	
Moderate	xx (xx%)		xx (xx%)		xx (xx%)	xx	xx (xx%)		xx (xx%)	xx	xx (xx%)	
Severe	xx (xx%)		xx (xx%)		xx (xx%)	xx	xx (xx%)		xx (xx%)	xx	xx (xx%)	
Any Blistering	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx
Maximum grade Blistering												
None	xx (xx%)		xx (xx%)		xx (xx%)	xx	xx (xx%)		xx (xx%)	xx	xx (xx%)	
Mild	xx (xx%)		xx (xx%)		xx (xx%)	xx	xx (xx%)		xx (xx%)	xx	xx (xx%)	
Moderate	xx (xx%)		xx (xx%)		xx (xx%)	xx	xx (xx%)		xx (xx%)	xx	xx (xx%)	
Severe	xx (xx%)		xx (xx%)		xx (xx%)	xx	xx (xx%)		xx (xx%)	xx	xx (xx%)	
Any Urticaria	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx
Maximum grade Urticaria												
None	xx (xx%)		xx (xx%)		xx (xx%)	xx	xx (xx%)		xx (xx%)	xx	xx (xx%)	
Mild	xx (xx%)		xx (xx%)		xx (xx%)	xx	xx (xx%)		xx (xx%)	xx	xx (xx%)	
Moderate	xx (xx%)		xx (xx%)		xx (xx%)	xx	xx (xx%)		xx (xx%)	xx	xx (xx%)	
Severe	xx (xx%)		xx (xx%)		xx (xx%)	xx	xx (xx%)		xx (xx%)	xx	xx (xx%)	
Any Discolouration	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx
Maximum grade Discolouration												
None	xx (xx%)		xx (xx%)		xx (xx%)	xx	xx (xx%)		xx (xx%)	xx	xx (xx%)	
Mild	xx (xx%)		xx (xx%)		xx (xx%)	xx	xx (xx%)		xx (xx%)	xx	xx (xx%)	
Moderate	xx (xx%)		xx (xx%)		xx (xx%)	xx	xx (xx%)		xx (xx%)	xx	xx (xx%)	
Severe	xx (xx%)		xx (xx%)		xx (xx%)	xx	xx (xx%)		xx (xx%)	xx	xx (xx%)	
Any Dryness	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx
Maximum grade Dryness												
None	xx (xx%)		xx (xx%)		xx (xx%)	xx	xx (xx%)		xx (xx%)	xx	xx (xx%)	
Mild	xx (xx%)		xx (xx%)		xx (xx%)	xx	xx (xx%)		xx (xx%)	xx	xx (xx%)	

	[redacted]							m
Moderate	xx (xx%)	xx (xx%)	xx (xx%)	xx	xx (xx%)	xx (xx%)	xx	xx (xx%)
Severe	xx (xx%)	xx (xx%)	xx (xx%)	xx	xx (xx%)	xx (xx%)	xx	xx (xx%)

Data based on [ANALYSIS SET]. BSA: Body surface area. N: number of participants in the treatment group. Percentages are based on N. n: number of participants. m: number of events. SAS program: [PROGRAM NAME].sas.
Dataset version: ADXX YYYY-MM-DDTHH:MM:SS. Run by: [USERNAME] YYYY-MM-DDTHH:MM:SS. EDC data extracted: YYYY-MM-DDTHH:MM:SS.

Table LT 2 Overview of local tolerability – Part B (Full analysis set)

	[redacted]							m
Any LT reaction graded higher than None	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx
Any Erythema	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx
Maximum grade Erythema								
None	xx (xx%)		xx (xx%)		xx (xx%)	xx	xx (xx%)	
Mild	xx (xx%)		xx (xx%)		xx (xx%)	xx	xx (xx%)	
Moderate	xx (xx%)		xx (xx%)		xx (xx%)	xx	xx (xx%)	
Severe	xx (xx%)		xx (xx%)		xx (xx%)	xx	xx (xx%)	
Any Swelling	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx
Maximum grade Swelling								
None	xx (xx%)		xx (xx%)		xx (xx%)	xx	xx (xx%)	
Mild	xx (xx%)		xx (xx%)		xx (xx%)	xx	xx (xx%)	
Moderate	xx (xx%)		xx (xx%)		xx (xx%)	xx	xx (xx%)	
Severe	xx (xx%)		xx (xx%)		xx (xx%)	xx	xx (xx%)	
Any Pruritus	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx
Maximum grade Pruritus								

	[redacted]							
None	xx (xx%)		xx (xx%)		xx (xx%)	xx	xx (xx%)	
Mild	xx (xx%)		xx (xx%)		xx (xx%)	xx	xx (xx%)	
Moderate	xx (xx%)		xx (xx%)		xx (xx%)	xx	xx (xx%)	
Severe	xx (xx%)		xx (xx%)		xx (xx%)	xx	xx (xx%)	
Any Burning	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx
Maximum grade Burning								
None	xx (xx%)		xx (xx%)		xx (xx%)	xx	xx (xx%)	
Mild	xx (xx%)		xx (xx%)		xx (xx%)	xx	xx (xx%)	
Moderate	xx (xx%)		xx (xx%)		xx (xx%)	xx	xx (xx%)	
Severe	xx (xx%)		xx (xx%)		xx (xx%)	xx	xx (xx%)	
Any Blistering	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx
Maximum grade Blistering								
None	xx (xx%)		xx (xx%)		xx (xx%)	xx	xx (xx%)	
Mild	xx (xx%)		xx (xx%)		xx (xx%)	xx	xx (xx%)	
Moderate	xx (xx%)		xx (xx%)		xx (xx%)	xx	xx (xx%)	
Severe	xx (xx%)		xx (xx%)		xx (xx%)	xx	xx (xx%)	
Any Urticaria	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx
Maximum grade Urticaria								
None	xx (xx%)		xx (xx%)		xx (xx%)	xx	xx (xx%)	
Mild	xx (xx%)		xx (xx%)		xx (xx%)	xx	xx (xx%)	
Moderate	xx (xx%)		xx (xx%)		xx (xx%)	xx	xx (xx%)	
Severe	xx (xx%)		xx (xx%)		xx (xx%)	xx	xx (xx%)	
Any Discolouration	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx
Maximum grade Discolouration								
None	xx (xx%)		xx (xx%)		xx (xx%)	xx	xx (xx%)	
Mild	xx (xx%)		xx (xx%)		xx (xx%)	xx	xx (xx%)	

	[redacted]						m
Moderate	xx (xx%)		xx (xx%)		xx (xx%)	xx	xx (xx%)	
Severe	xx (xx%)		xx (xx%)		xx (xx%)	xx	xx (xx%)	
Any Dryness	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx	xx (xx%)	xx
Maximum grade Dryness								
None	xx (xx%)		xx (xx%)		xx (xx%)	xx	xx (xx%)	
Mild	xx (xx%)		xx (xx%)		xx (xx%)	xx	xx (xx%)	
Moderate	xx (xx%)		xx (xx%)		xx (xx%)	xx	xx (xx%)	
Severe	xx (xx%)		xx (xx%)		xx (xx%)	xx	xx (xx%)	

Data based on [ANALYSIS SET]. BSA: Body surface area. N: number of participants in the treatment group. Percentages are based on N. n: number of participants. m: number of events. SAS program: [PROGRAM NAME].sas.
Dataset version: ADXX YYYY-MM-DDTHH:MM:SS. Run by: [USERNAME] YYYY-MM-DDTHH:MM:SS. EDC data extracted: YYYY-MM-DDTHH:MM:SS.

Table LT 3 Local tolerability intensity grades – Part [redacted]

[redacted]								
[PARAMETER 1]	[Assessment timepoint 1]	[RESULT 1]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
		[RESULT 2]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
		[RESULT 3]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
	[Assessment timepoint 2]	[RESULT 1]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
		[RESULT 2]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
		[RESULT 3]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)

Data based on [population]. SAS program: [PROGRAM NAME].sas. BSA: Body surface area. N: Number of participants in the treatment group. Percentages are based on the number of observations.
Dataset version: ADXX YYYY-MM-DDTHH:MM:SS. Run by: [USERNAME] YYYY-MM-DDTHH:MM:SS. EDC data extracted: YYYY-MM-DDTHH:MM:SS.

Table LT 4 Local tolerability intensity grades – Part B (Full analysis set)

Assessment	Assessment timepoint		[redacted]			
[PARAMETER 1]	[Assessment timepoint 1]	[RESULT 1]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
		[RESULT 2]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
		[RESULT 3]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
	[Assessment timepoint 2]	[RESULT 1]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
		[RESULT 2]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
		[RESULT 3]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)

Data based on [population]. SAS program: [PROGRAM NAME].sas. BSA: Body surface area. N: Number of participants in the treatment group. Percentages are based on the number of observations.
Dataset version: ADXX YYYY-MM-DDTHH:MM:SS. Run by: [USERNAME] YYYY-MM-DDTHH:MM:SS. EDC data extracted: YYYY-MM-DDTHH:MM:SS.

Table LT 5 Local tolerability intensity grades shift table – Part A (Full analysis set)

Parameter	Assessment timepoint	Baseline value	Post-baseline value	[redacted]					
[PARAMETER 1]	[BASELINE]	[RESPONSE 1]	NA	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
		[RESPONSE 2]	NA	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
		[RESPONSE 3]	NA	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
	[POST BASELINE 1]	[RESPONSE 1]	[RESPONSE 1]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
			[RESPONSE 2]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
			[RESPONSE 3]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
		[RESPONSE 2]	[RESPONSE 1]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
			[RESPONSE 2]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
			[RESPONSE 3]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
		[RESPONSE 3]	[RESPONSE 1]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
			[RESPONSE 2]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)

Parameter	Assessment timepoint	Baseline value	Post-baseline value	[redacted]					
			[RESPONSE 3]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
	[POST BASELINE 2]	[RESPONSE 1]	[RESPONSE 1]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
			[RESPONSE 2]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
			[RESPONSE 3]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
		[RESPONSE 2]	[RESPONSE 1]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
			[RESPONSE 2]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
			[RESPONSE 3]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
		[RESPONSE 3]	[RESPONSE 1]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
			[RESPONSE 2]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
			[RESPONSE 3]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)

Data based on [population]. SAS program: [PROGRAM NAME].sas. BSA: Body surface area. N: Number of participants in the treatment group. Percentages are based on the number of observations.
Dataset version: ADXX YYYY-MM-DDTHH:MM:SS. Run by: [USERNAME] YYYY-MM-DDTHH:MM:SS. EDC data extracted: YYYY-MM-DDTHH:MM:SS.

Table LT 6 Local tolerability intensity grades shift table – Part B (Full analysis set)

Parameter	Assessment timepoint	Baseline value	[redacted]				
[PARAMETER 1]	[BASELINE]	[RESPONSE 1]	NA	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
		[RESPONSE 2]	NA	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
		[RESPONSE 3]	NA	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
	[POST BASELINE 1]	[RESPONSE 1]	[RESPONSE 1]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
			[RESPONSE 2]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
			[RESPONSE 3]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
		[RESPONSE 2]	[RESPONSE 1]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
			[RESPONSE 2]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)

Parameter	Assessment timepoint	Baseline value	Post-baseline value	[redacted]			
			[RESPONSE 3]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
		[RESPONSE 3]	[RESPONSE 1]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
			[RESPONSE 2]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
			[RESPONSE 3]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
	[POST BASELINE 2]	[RESPONSE 1]	[RESPONSE 1]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
			[RESPONSE 2]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
			[RESPONSE 3]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
		[RESPONSE 2]	[RESPONSE 1]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
			[RESPONSE 2]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
			[RESPONSE 3]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
		[RESPONSE 3]	[RESPONSE 1]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
			[RESPONSE 2]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
			[RESPONSE 3]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)

Data based on [population]. SAS program: [PROGRAM NAME].sas. BSA: Body surface area. N: Number of participants in the treatment group. Percentages are based on the number of observations.
Dataset version: ADXX YYYY-MM-DDTHH:MM:SS. Run by: [USERNAME] YYYY-MM-DDTHH:MM:SS. EDC data extracted: YYYY-MM-DDTHH:MM:SS.

10.2.2.3 Vital signs (Part A)

Table VS 1 Vital signs measurements – Part A (Full analysis set)

Assessment (unit)	Result category	Assessment timepoint		[redacted]				
[PARAMETER 1] (unit)	Measured value	[Assessment timepoint 1]	n	xx	xx	xx	xx	xx
			n/BLQ/ULQ	xx/xx/xx	xx/xx/xx	xx/xx/xx	xx/xx/xx	xx/xx/xx
			Mean (SD	x.xx (x.xx)	x.xx (x.xx)	x.xx (x.xx)	x.xx (x.xx)	x.xx (x.xx)

Assessment (unit)	Result category	Assessment timepoint		[redacted]				
		[Assessment timepoint 2]	Median (Min, Max)	x.xx (x.x, x.x)	x.xx (x.x, x.x)	x.xx (x.x, x.x)	x.xx (x.x, x.x)	x.xx (x.x, x.x)
			n	xx	xx	xx	xx	xx
			n/BLQ/ULQ	xx/xx/xx	xx/xx/xx	xx/xx/xx	xx/xx/xx	xx/xx/xx
			Mean (SD	x.xx (x.xx)	x.xx (x.xx)	x.xx (x.xx)	x.xx (x.xx)	x.xx (x.xx)
	Change from baseline	[Assessment timepoint 2]	Median (Min, Max)	x.xx (x.x, x.x)	x.xx (x.x, x.x)	x.xx (x.x, x.x)	x.xx (x.x, x.x)	x.xx (x.x, x.x)
			n	xx	xx	xx	xx	xx
			n/BLQ/ULQ	xx/xx/xx	xx/xx/xx	xx/xx/xx	xx/xx/xx	xx/xx/xx
			Mean (SD	x.xx (x.xx)	x.xx (x.xx)	x.xx (x.xx)	x.xx (x.xx)	x.xx (x.xx)
	Relative change from baseline (%)	[Assessment timepoint 2]	Median (Min, Max)	x.xx (x.x, x.x)	x.xx (x.x, x.x)	x.xx (x.x, x.x)	x.xx (x.x, x.x)	x.xx (x.x, x.x)
			n	xx	xx	xx	xx	xx
			n/BLQ/ULQ	xx/xx/xx	xx/xx/xx	xx/xx/xx	xx/xx/xx	xx/xx/xx
			Mean (SD	x.xx (x.xx)	x.xx (x.xx)	x.xx (x.xx)	x.xx (x.xx)	x.xx (x.xx)
			Median (Min, Max)	x.xx (x.x, x.x)	x.xx (x.x, x.x)	x.xx (x.x, x.x)	x.xx (x.x, x.x)	x.xx (x.x, x.x)

Data based on [population]. BSA: Body surface area. n: Number of observations. SD: Standard deviation. CV%: Coefficient of variation described as percentage. IQR: Inter-quartile range. Q1: Lower quartile. Q3: Upper quartile. NC: Not calculated - number of evaluable observations less than 3. NA: Not available - no evaluable observations. SAS program: [PROGRAM NAME].sas.
Dataset version: ADXX YYYY-MM-DDTHH:MM:SS. Run by: [USERNAME] YYYY-MM-DDTHH:MM:SS. EDC data extracted: YYYY-MM-DDTHH:MM:SS.

10.2.2.4 12-lead ECG (Part A)

Table EG 1 ECG measurements – Part A (Full analysis set)

Assessment (unit)	Result category	Assessment timepoint		[redacted]				
[PARAMETER 1] (unit)	Measured value	[Assessment timepoint 1]	n	xx	xx	xx	xx	xx
			n/BLQ/ULQ	xx/xx/xx	xx/xx/xx	xx/xx/xx	xx/xx/xx	xx/xx/xx

Assessment (unit)	Result category	Assessment timepoint		[redacted]				
			Mean (SD	x.xx (x.xx)	x.xx (x.xx)	x.xx (x.xx)	x.xx (x.xx)	x.xx (x.xx)
			Median (Min, Max)	x.xx (x.x, x.x)	x.xx (x.x, x.x)	x.xx (x.x, x.x)	x.xx (x.x, x.x)	x.xx (x.x, x.x)
		[Assessment timepoint 2]	n	xx	xx	xx	xx	xx
			n/BLQ/ULQ	xx/xx/xx	xx/xx/xx	xx/xx/xx	xx/xx/xx	xx/xx/xx
	Change from baseline	[Assessment timepoint 2]	Mean (SD	x.xx (x.xx)	x.xx (x.xx)	x.xx (x.xx)	x.xx (x.xx)	x.xx (x.xx)
			Median (Min, Max)	x.xx (x.x, x.x)	x.xx (x.x, x.x)	x.xx (x.x, x.x)	x.xx (x.x, x.x)	x.xx (x.x, x.x)
			n	xx	xx	xx	xx	xx
			n/BLQ/ULQ	xx/xx/xx	xx/xx/xx	xx/xx/xx	xx/xx/xx	xx/xx/xx
	Relative change from baseline (%)	[Assessment timepoint 2]	Mean (SD	x.xx (x.xx)	x.xx (x.xx)	x.xx (x.xx)	x.xx (x.xx)	x.xx (x.xx)
			Median (Min, Max)	x.xx (x.x, x.x)	x.xx (x.x, x.x)	x.xx (x.x, x.x)	x.xx (x.x, x.x)	x.xx (x.x, x.x)
			n	xx	xx	xx	xx	xx
			n/BLQ/ULQ	xx/xx/xx	xx/xx/xx	xx/xx/xx	xx/xx/xx	xx/xx/xx
			Mean (SD	x.xx (x.xx)	x.xx (x.xx)	x.xx (x.xx)	x.xx (x.xx)	x.xx (x.xx)
			Median (Min, Max)	x.xx (x.x, x.x)	x.xx (x.x, x.x)	x.xx (x.x, x.x)	x.xx (x.x, x.x)	x.xx (x.x, x.x)

Data based on [population]. BSA: Body surface area. n: Number of observations. SD: Standard deviation. CV%: Coefficient of variation described as percentage. IQR: Inter-quartile range. Q1: Lower quartile. Q3: Upper quartile. NC: Not calculated - number of evaluable observations less than 3. NA: Not available - no evaluable observations. SAS program: [PROGRAM NAME].sas.
Dataset version: ADXX YYYY-MM-DDTHH:MM:SS. Run by: [USERNAME] YYYY-MM-DDTHH:MM:SS. EDC data extracted: YYYY-MM-DDTHH:MM:SS.

Table EG 2 ECG interpretations – Part A (Full analysis set)

Assessment	Assessment timepoint		[redacted]				
[PARAMETER 1]	[Assessment timepoint 1]	[RESULT 1]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
		[RESULT 2]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
		[RESULT 3]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)

Assessment	Assessment timepoint		[redacted]				
	[Assessment timepoint 2]	[RESULT 1]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
		[RESULT 2]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
		[RESULT 3]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)

Data based on [population]. SAS program: [PROGRAM NAME].sas. BSA: Body surface area. N: Number of participants in the treatment group. Percentages are based on the number of observations.
Dataset version: ADXX YYYY-MM-DDTHH:MM:SS. Run by: [USERNAME] YYYY-MM-DDTHH:MM:SS. EDC data extracted: YYYY-MM-DDTHH:MM:SS.

Table EG 3 ECG interpretations shift table – Part A (Full analysis set)

Parameter	Assessment timepoint	Baseline value	Post-baseline value	[redacted]				
[PARAMETER 1]	[BASELINE]	[RESPONSE 1]	NA	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
		[RESPONSE 2]	NA	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
		[RESPONSE 3]	NA	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
	[POST BASELINE 1]	[RESPONSE 1]	[RESPONSE 1]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
			[RESPONSE 2]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
			[RESPONSE 3]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
		[RESPONSE 2]	[RESPONSE 1]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
			[RESPONSE 2]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
			[RESPONSE 3]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
		[RESPONSE 3]	[RESPONSE 1]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
			[RESPONSE 2]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
			[RESPONSE 3]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
	[POST BASELINE 2]	[RESPONSE 1]	[RESPONSE 1]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
			[RESPONSE 2]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)

Parameter	Assessment timepoint	Baseline value	[redacted]				
			[RESPONSE 3]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
		[RESPONSE 2]	[RESPONSE 1]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
			[RESPONSE 2]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
			[RESPONSE 3]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
		[RESPONSE 3]	[RESPONSE 1]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
			[RESPONSE 2]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
			[RESPONSE 3]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)

Data based on [population]. SAS program: [PROGRAM NAME].sas. BSA: Body surface area. N: Number of participants in the treatment group. Percentages are based on the number of observations.
Dataset version: ADXX YYYY-MM-DDTHH:MM:SS. Run by: [USERNAME] YYYY-MM-DDTHH:MM:SS. EDC data extracted: YYYY-MM-DDTHH:MM:SS.

10.2.2.5 Safety laboratory (Part A)

Table LB 1 Safety laboratory measurements: Clinical chemistry – Part A (Full analysis set)

Assessment (unit)	Result category	Assessment timepoint		[redacted]				
[PARAMETER 1] (unit)	Measured value	[Assessment timepoint 1]	n					
			n/BLQ/ULQ	xx/xx/xx	xx/xx/xx	xx/xx/xx	xx/xx/xx	xx/xx/xx
			Mean (SD	x.xx (x.xx)	x.xx (x.xx)	x.xx (x.xx)	x.xx (x.xx)	x.xx (x.xx)
			Median (Min, Max)	x.xx (x.x, x.x)	x.xx (x.x, x.x)	x.xx (x.x, x.x)	x.xx (x.x, x.x)	x.xx (x.x, x.x)
		[Assessment timepoint 2]	n	xx	xx	xx	xx	xx
			n/BLQ/ULQ	xx/xx/xx	xx/xx/xx	xx/xx/xx	xx/xx/xx	xx/xx/xx
			Mean (SD	x.xx (x.xx)	x.xx (x.xx)	x.xx (x.xx)	x.xx (x.xx)	x.xx (x.xx)
			Median (Min, Max)	x.xx (x.x, x.x)	x.xx (x.x, x.x)	x.xx (x.x, x.x)	x.xx (x.x, x.x)	x.xx (x.x, x.x)

Assessment (unit)	Result category	Assessment timepoint		[redacted]				
	Change from baseline	[Assessment timepoint 2]	n	xx	xx	xx	xx	xx
			n/BLQ/ULQ	xx/xx/xx	xx/xx/xx	xx/xx/xx	xx/xx/xx	xx/xx/xx
			Mean (SD	x.xx (x.xx)	x.xx (x.xx)	x.xx (x.xx)	x.xx (x.xx)	x.xx (x.xx)
			Median (Min, Max)	x.xx (x.x, x.x)	x.xx (x.x, x.x)	x.xx (x.x, x.x)	x.xx (x.x, x.x)	x.xx (x.x, x.x)
	Relative change from baseline (%)	[Assessment timepoint 2]	n	xx	xx	xx	xx	xx
			n/BLQ/ULQ	xx/xx/xx	xx/xx/xx	xx/xx/xx	xx/xx/xx	xx/xx/xx
			Mean (SD	x.xx (x.xx)	x.xx (x.xx)	x.xx (x.xx)	x.xx (x.xx)	x.xx (x.xx)
			Median (Min, Max)	x.xx (x.x, x.x)	x.xx (x.x, x.x)	x.xx (x.x, x.x)	x.xx (x.x, x.x)	x.xx (x.x, x.x)

Data based on [population]. BSA: Body surface area. n: Number of observations. SD: Standard deviation. CV%: Coefficient of variation described as percentage. IQR: Inter-quartile range. Q1: Lower quartile. Q3: Upper quartile. NC: Not calculated - number of evaluable observations less than 3. NA: Not available - no evaluable observations. SAS program: [PROGRAM NAME].sas.
Dataset version: ADXX YYYY-MM-DDTHH:MM:SS. Run by: [USERNAME] YYYY-MM-DDTHH:MM:SS. EDC data extracted: YYYY-MM-DDTHH:MM:SS.

Table LB 2 Safety laboratory interpretations: Clinical chemistry – Part A (Full analysis set)

Assessment	Assessment timepoint		[redacted]				
[PARAMETER 1]	[Assessment timepoint 1]	[RESULT 1]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
		[RESULT 2]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
		[RESULT 3]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
	[Assessment timepoint 2]	[RESULT 1]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
		[RESULT 2]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
		[RESULT 3]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)

Data based on [population]. SAS program: [PROGRAM NAME].sas. BSA: Body surface area.
Dataset version: ADXX YYYY-MM-DDTHH:MM:SS. Run by: [USERNAME] YYYY-MM-DDTHH:MM:SS. EDC data extracted: YYYY-MM-DDTHH:MM:SS.

Table LB 3 Safety laboratory measurements: Haematology – Part A (Full analysis set)

Same layout as Table LB 1

Table LB 4 Safety laboratory interpretations: Haematology – Part A (Full analysis set)

Same layout as Table LB 2

Table LB 5 Safety laboratory measurements: Coagulation – Part A (Full analysis set)

Same layout as Table LB 1

Table LB 6 Safety laboratory interpretations: Coagulation – Part A (Full analysis set)

Same layout as Table LB 2

10.2.2.6 Physical examinations (Part A)

Table PE 1 Physical examinations – Part A (Full analysis set)

Assessment	Assessment timepoint		[redacted]				
[PARAMETER 1]	[Assessment timepoint 1]	[RESULT 1]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
		[RESULT 2]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
		[RESULT 3]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
	[Assessment timepoint 2]	[RESULT 1]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
		[RESULT 2]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
		[RESULT 3]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)

Data based on [population]. SAS program: [PROGRAM NAME].sas. BSA: Body surface area. N: Number of participants in the treatment group. Percentages are based on the number of observations.
Dataset version: ADXX YYYY-MM-DDTHH:MM:SS. Run by: [USERNAME] YYYY-MM-DDTHH:MM:SS. EDC data extracted: YYYY-MM-DDTHH:MM:SS.

Table PE 2 Physical examinations shift table – Part A (Full analysis set)

Parameter	Assessment timepoint	Baseline value	Post-baseline value	[redacted]				
[PARAMETER 1]	[BASELINE]	[RESPONSE 1]	NA	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
		[RESPONSE 2]	NA	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
		[RESPONSE 3]	NA	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
	[POST BASELINE 1]	[RESPONSE 1]	[RESPONSE 1]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
			[RESPONSE 2]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
			[RESPONSE 3]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
		[RESPONSE 2]	[RESPONSE 1]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
			[RESPONSE 2]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
			[RESPONSE 3]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
		[RESPONSE 3]	[RESPONSE 1]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
			[RESPONSE 2]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
			[RESPONSE 3]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
	[POST BASELINE 2]	[RESPONSE 1]	[RESPONSE 1]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
			[RESPONSE 2]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
			[RESPONSE 3]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
		[RESPONSE 2]	[RESPONSE 1]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
			[RESPONSE 2]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
			[RESPONSE 3]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
		[RESPONSE 3]	[RESPONSE 1]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
			[RESPONSE 2]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
			[RESPONSE 3]	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)

Data based on [population]. SAS program: [PROGRAM NAME].sas. BSA: Body surface area. N: Number of participants in the treatment group. Percentages are based on the number of observations.
Dataset version: ADXX YYYY-MM-DDTHH:MM:SS. Run by: [USERNAME] YYYY-MM-DDTHH:MM:SS. EDC data extracted: YYYY-MM-DDTHH:MM:SS.

10.2.2.7 Cream absorption (Part B)

Table QS 1 Cream absorption – Part B (Full analysis set)

Assessment (unit)	Assessment timepoint		[redacted]		
Cream absorption	[Assessment timepoint 1]	1= Not absorbed	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
		2= Somewhat absorbed	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
		3= Mostly absorbed	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
		4= Completely absorbed	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
	[Assessment timepoint 2]	1= Not absorbed	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
		2= Somewhat absorbed	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
		3= Mostly absorbed	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
		4= Completely absorbed	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
Time until adequate abruption (unit)	[Assessment timepoint 1]	30 min	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
		1 h	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
		2 h	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
	[Assessment timepoint 2]	30 min	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
		1 h	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)
		2 h	xx/XX (xx%)	xx/XX (xx%)	xx/XX (xx%)

Data based on [population]. SAS program: [PROGRAM NAME].sas. Adequate abruption is interpreted as equivalent to a cream absorption score of at least "3 = Mostly absorbed" on the 4-point cream absorption scale. BSA: Body surface area N: Number of participants in the treatment group. n: Number of observations.
Dataset version: ADXX YYYY-MM-DDTHH:MM:SS. Run by: [USERNAME] YYYY-MM-DDTHH:MM:SS. EDC data extracted: YYYY-MM-DDTHH:MM:SS.

10.2.3 Secondary endpoints (Part A)

10.2.3.1 Pharmacokinetic analysis (Part A)

Table PC 1 Plasma concentrations – Part A (Pharmacokinetic analysis set)

Assessment (unit)	Assessment timepoint		[redacted]			
[PARAMETER 1] (unit)	[Assessment timepoint 1]	n/BLQ	xx/xx	xx/xx	xx/xx	xx/xx
		Mean (SD)	x.xx (x.xx)	x.xx (x.xx)	x.xx (x.xx)	x.xx (x.xx)
		Median (Min, Max)	x.xx (x.x, x.x)	x.xx (x.x, x.x)	x.xx (x.x, x.x)	x.xx (x.x, x.x)
		Geometric Mean (geo CV%)	x.xxx (x.x%)	x.xxx (x.x%)	x.xxx (x.x%)	x.xxx (x.x%)
	[Assessment timepoint 2]	n/BLQ	xx/xx	xx/xx	xx/xx	xx/xx
		Mean (SD)	x.xx (x.xx)	x.xx (x.xx)	x.xx (x.xx)	x.xx (x.xx)
		Median (Min, Max)	x.xx (x.x, x.x)	x.xx (x.x, x.x)	x.xx (x.x, x.x)	x.xx (x.x, x.x)
		Geometric Mean (geo CV%)	x.xxx (x.x%)	x.xxx (x.x%)	x.xxx (x.x%)	x.xxx (x.x%)

Data based on [population]. BSA: Body surface area. LLOQ is xx (unit). See listing 16.2.5-1 for a per participant LLOQ summary. n: Number of observations. BLQ: Below lower limit of quantification. SD: Standard deviation. CV%: Coefficient of variation described as percentage. Geo CV%: Geometric coefficient of variation described as percentage calculated using log-transformed standard deviation. NC: Not calculated - number of evaluable observations less than 3 or more than half of the observations are BLQ. NA: Not available - no evaluable observations. SAS program: [PROGRAM NAME].sas.
Dataset version: ADXX YYYY-MM-DDTHH:MM:SS. Run by: [USERNAME] YYYY-MM-DDTHH:MM:SS. EDC data extracted: YYYY-MM-DDTHH:MM:SS.

Table PP 1 PK parameters – Part A (Pharmacokinetic analysis set)

Assessment (unit)		[redacted]			
Tmax (unit)	n	xx	xx	xx	xx
	Median (Min, Max)	x.xx (x.x, x.x)	x.xx (x.x, x.x)	x.xx (x.x, x.x)	x.xx (x.x, x.x)

Assessment (unit)		[redacted]			
Cmax (unit)	n	xx	xx	xx	xx
	Mean (SD)	x.xx (x.xx)	x.xx (x.xx)	x.xx (x.xx)	x.xx (x.xx)
	Median (Min, Max)	x.xx (x.x, x.x)	x.xx (x.x, x.x)	x.xx (x.x, x.x)	x.xx (x.x, x.x)
	Geometric Mean (geo CV%)	x.xxx (x.x%)	x.xxx (x.x%)	x.xxx (x.x%)	x.xxx (x.x%)
AUC0-last (unit)	n	xx	xx	xx	xx
	Mean (SD)	x.xx (x.xx)	x.xx (x.xx)	x.xx (x.xx)	x.xx (x.xx)
	Median (Min, Max)	x.xx (x.x, x.x)	x.xx (x.x, x.x)	x.xx (x.x, x.x)	x.xx (x.x, x.x)
	Geometric Mean (geo CV%)	x.xxx (x.x%)	x.xxx (x.x%)	x.xxx (x.x%)	x.xxx (x.x%)
AUC0-inf (unit)	n	xx	xx	xx	xx
	Mean (SD)	x.xx (x.xx)	x.xx (x.xx)	x.xx (x.xx)	x.xx (x.xx)
	Median (Min, Max)	x.xx (x.x, x.x)	x.xx (x.x, x.x)	x.xx (x.x, x.x)	x.xx (x.x, x.x)
	Geometric Mean (geo CV%)	x.xxx (x.x%)	x.xxx (x.x%)	x.xxx (x.x%)	x.xxx (x.x%)
T1/2 (unit)	n	xx	xx	xx	xx
	Mean (SD)	x.xx (x.xx)	x.xx (x.xx)	x.xx (x.xx)	x.xx (x.xx)
	Median (Min, Max)	x.xx (x.x, x.x)	x.xx (x.x, x.x)	x.xx (x.x, x.x)	x.xx (x.x, x.x)
	Geometric Mean (geo CV%)	x.xxx (x.x%)	x.xxx (x.x%)	x.xxx (x.x%)	x.xxx (x.x%)

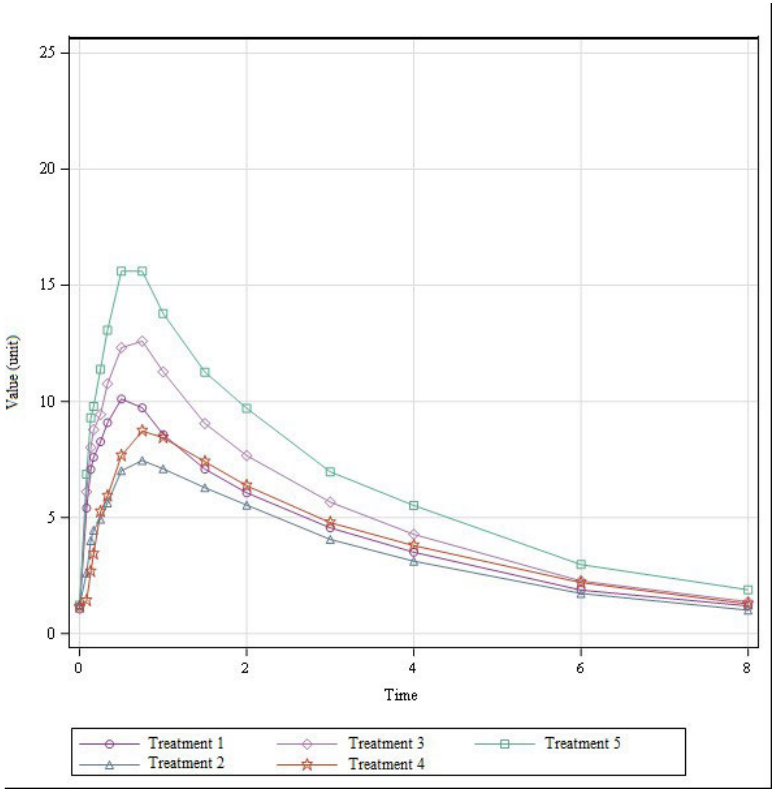
Data based on [population].: Body surface area. n: Number of observations. SD: Standard deviation. CV%: Coefficient of variation described as percentage. Geo CV%: Geometric coefficient of variation described as percentage calculated using log-transformed standard deviation. NC: Not calculated - number of evaluable observations less than 3 or more than half of the observations are BLQ. NA: Not available - no evaluable observations. SAS program: [PROGRAM NAME].sas.
Dataset version: ADXX YYYY-MM-DDTHH:MM:SS. Run by: [USERNAME] YYYY-MM-DDTHH:MM:SS. EDC data extracted: YYYY-MM-DDTHH:MM:SS.

10.3 Trial figures

10.3.1 Secondary endpoints (Part A)

10.3.1.1 Pharmacokinetic analysis (Part A)

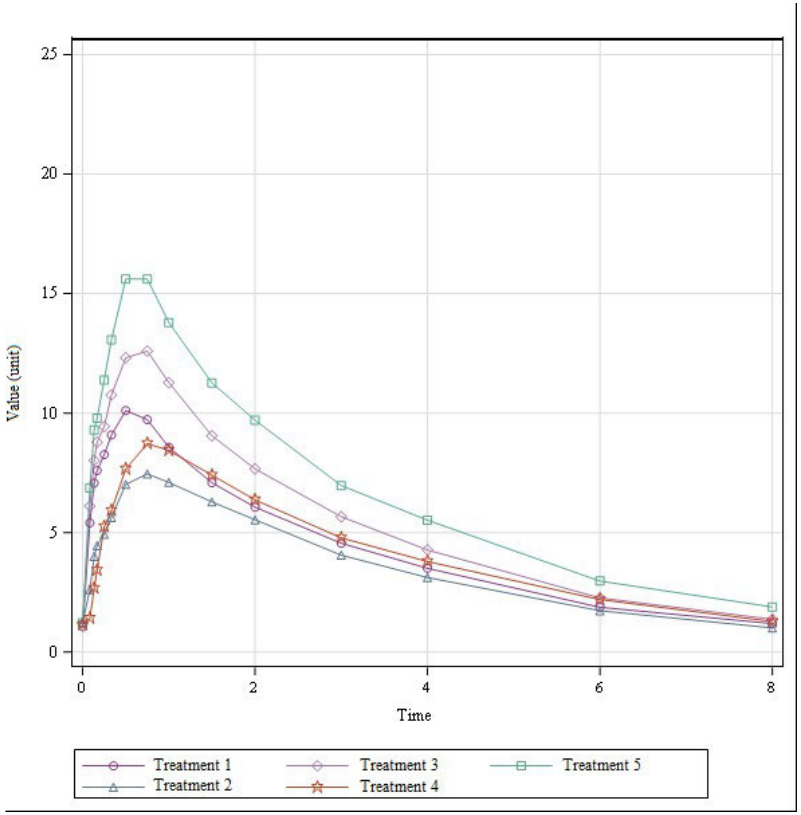
Figure PC 1 Geometric mean plasma concentrations over time (lin-log) – Part A (Pharmacokinetic analysis set)



Example figure. Note that the numbers do not reflect real data. This template figure will be adjusted as needed depending on the collected data.

Data based on [population]. BSA: Body surface area. Individual values under LLOQ are excluded from the figure. LLOQ is xx (unit). See listing 16.2.5-1 for a per participant LLOQ summary. SAS program: [PROGRAM NAME].sas. Dataset version: ADXX YYYY-MM-DDTHH:MM:SS. Run by: [USERNAME] YYYY-MM-DDTHH:MM:SS. EDC data extracted: YYYY-MM-DDTHH:MM:SS.

Figure PC 2 Geometric mean plasma concentrations over time (lin-lin) – Part A (Pharmacokinetic analysis set)

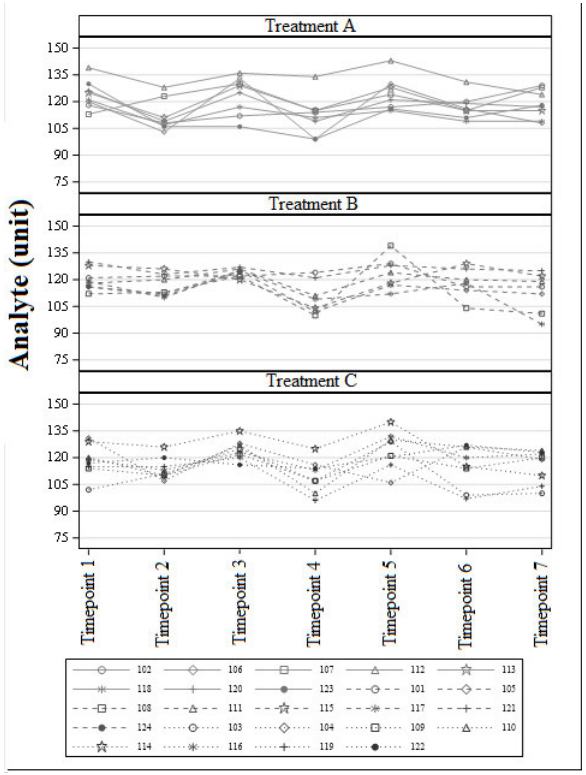


Example figure. Note that the numbers do not reflect real data. This template figure will be adjusted as needed depending on the collected data.

Data based on [population]. BSA: Body surface area. Individual values under LLOQ are excluded from the figure. LLOQ is xx (unit). See listing 16.2.5-1 for a per participant LLOQ summary. SAS program: [PROGRAM NAME].sas. Dataset version: ADXX YYYY-MM-DDTHH:MM:SS. Run by: [USERNAME] YYYY-MM-DDTHH:MM:SS. EDC data extracted: YYYY-MM-DDTHH:MM:SS.

Figure PC 3 Individual plasma concentrations over time (lin-log) – Part A (Full analysis set)

Individual values under LLOQ will be excluded from the figure.

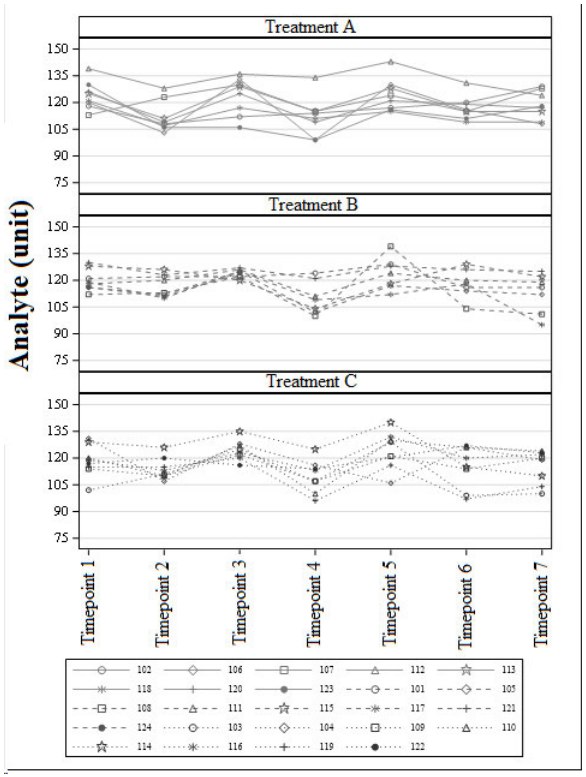


Example figure. Note that the numbers do not reflect real data. This template figure will be adjusted as needed depending on the collected data.

Data based on [population]. BSA: Body surface area. Individual values under LLOQ are excluded from the figure. LLOQ is xx (unit). See listing 16.2.5-1 for a per participant LLOQ summary. SAS program: [PROGRAM NAME].sas. Dataset version: ADXX YYYY-MM-DDTHH:MM:SS. Run by: [USERNAME] YYYY-MM-DDTHH:MM:SS. EDC data extracted: YYYY-MM-DDTHH:MM:SS.

Figure PC 4 Individual plasma concentrations over time (lin-lin) – Part A (Full analysis set)

Individual values under LLOQ will be excluded from the figure.



Example figure. Note that the numbers do not reflect real data. This template figure will be adjusted as needed depending on the collected data.

```
Data based on [population]. BSA: Body surface area. Individual values under LLOQ are excluded from the figure. LLOQ is xx (unit). See listing
16.2.5-1 for a per participant LLOQ summary. lin: Linear. SAS program: [PROGRAM NAME].sas. Dataset version: ADXX YYYY-MM-DDTHH:MM:SS. Run by:
[USERNAME] YYYY-MM-DDTHH:MM:SS. EDC data extracted: YYYY-MM-DDTHH:MM:SS.
```

10.4 Trial listings

16.2.1 Discontinued participants

- **Listing 16.2.1- 1 Discontinued participants – Part A**
- **Listing 16.2.1- 2 Discontinued participants – Part B**
- **Listing 16.2.1- 3 Non-eligible participants – Part A**
- **Listing 16.2.1- 4 Non-eligible participants – Part B**
- **Listing 16.2.1- 5 Disposition – Part A (All participants)**
- **Listing 16.2.1- 6 Disposition – Part B (All participants)**
- **Listing 16.2.1- 7 Participant visits – Part A (All participants)**
- **Listing 16.2.1- 8 Participant visits – Part B (All participants)**
- **Listing 16.2.1- 9 Participant elements – Part A (All participants)**
- **Listing 16.2.1- 10 Participant elements – Part B (All participants)**

16.2.2 Protocol deviations

- **Listing 16.2.2- 1 Protocol deviations – Part A (All participants)**
- **Listing 16.2.2- 2 Protocol deviations – Part B (All participants)**

16.2.3 Participants excluded from the analysis

- **Listing 16.2.3- 1 Population definitions – Part A (All participants)**
- **Listing 16.2.3- 2 Population definitions – Part B (All participants)**

16.2.4 Demographic data

- **Listing 16.2.4- 1 Demography – Part A (All participants)**
- **Listing 16.2.4- 2 Demography – Part B (All participants)**
- **Listing 16.2.4- 3 Medical History – Part A (All participants)**
- **Listing 16.2.4- 4 Medical History – Part B (All participants)**
- **Listing 16.2.4- 5 Prior and concomitant medications – Part A (All participants)**
- **Listing 16.2.4- 6 Prior and concomitant medications – Part B (All participants)**

16.2.5 Compliance and/or Drug Concentration Data

- **Listing 16.2.5- 1 Plasma concentration data – Part A (All participants)**
- **Listing 16.2.5- 2 Pharmacokinetic parameters – Part A (All participants)**
- **Listing 16.2.5- 3 IMP administration – Part A (All participants)**
- **Listing 16.2.5- 4 IMP administration – Part B (All participants)**
- **Listing 16.2.5- 5 Cream absorption evaluation – Part B (All participants)**

16.2.6 Individual Efficacy Response Data

NA

16.2.7 Adverse event listings (each participant)

- **Listing 16.2.7- 1 Adverse events – Part A (All participants)**
- **Listing 16.2.7- 2 Adverse events – Part B (All participants)**
- **Listing 16.2.7- 3 Serious adverse events – Part A (All participants)**
- **Listing 16.2.7- 4 Serious adverse events – Part B (All participants)**

16.2.8 Listings of individual laboratory measurements by participant

- **Listing 16.2.8- 1 Safety laboratory measurements: Clinical chemistry – Part A (All participants)**
- **Listing 16.2.8- 2 Safety laboratory measurements: Clinical chemistry – Part B (All participants)**

- **Listing 16.2.8- 3 Safety laboratory measurements: Haematology – Part A (All participants)**
- **Listing 16.2.8- 4 Safety laboratory measurements: Haematology – Part B (All participants)**
- **Listing 16.2.8- 5 Safety laboratory measurements: Coagulation – Part A (All participants)**
- **Listing 16.2.8- 6 Safety laboratory measurements: Coagulation – Part B (All participants)**
- **Listing 16.2.8- 7 Other laboratory measurements – Part A (All participants)** Urine drug screen, alcohol test, pregnancy test
- **Listing 16.2.8- 8 Other laboratory measurements – Part B (All participants)** Urine drug screen, alcohol test, pregnancy test
- **Listing 16.2.8- 9 Virology – Part A (All participants)**
- **Listing 16.2.8- 10 Virology – Part B (All participants)**

16.2.9 Listings of vital signs, ECG, physical examination data by participant

- **Listing 16.2.9- 1 Vital signs – Part A (All participants)**
- **Listing 16.2.9- 2 Vital signs – Part B (All participants)**
- **Listing 16.2.9- 3 ECG – Part A (All participants)**
- **Listing 16.2.9- 4 ECG – Part B (All participants)**
- **Listing 16.2.9- 5 Physical examinations – Part A (All participants)**
- **Listing 16.2.9- 6 Physical examinations – Part B (All participants)**