STATISTICAL ANALYSIS PLAN

Study CRO-PK-24-374 - Sponsor code VFC224-101

A single center, open label study to assess the pharmacokinetics of cannabidiol inhaled via a Hemp Heat-not-Burn (HHnB) device in healthy participants

An open label study to assess the pharmacokinetics (PK) of inhaled cannabidiol in healthy participants

Study product:	Cannabidiol (CBD) inhaled via an HHnB device
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Development phase:	I
Version and date:	Final version 1.0, 24SEP2025 (based on protocol version 2.0 dated 09-May-2025)

This study will be conducted in accordance with current version of Good Clinical Practice (GCP), ICH topic E6 (R3)

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This document comprises 38 pages plus appendices

VERSIONS' HISTORY

Version	Date of Issue	Reason for change
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APPROVAL AND ACKNOWLEDGEMENT

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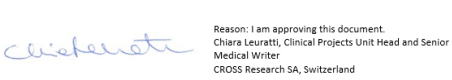
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STUDY SCHEDULE

	Study Stage	Screening	Admission	Standardized product administration					Non-standardized product administration			Final visit /ETV
	Study Day	-14 to -2	-1	1			2	3	4			5
				Before	Adm	After			Before	Adm	After	
1	Informed consent	x										
2	Inclusion/exclusion criteria	x	x									
3	Demographic data/Lifestyle/Medical and surgical history	x										
4	History of cannabis use	x										
5	Prior medications	x										
6	Concomitant medications	x	x	x	x	x	x	x	x	x	x	x
7	Admission in Phase 1 unit		x									
8	Discharge from Phase 1 unit											x
9	Ambulatory visit	x										
10	Physical examination	x										x
11	Body measurements (height, weight, BMI)	x										x (BW only)
12	C-SSRS	x										x
13	Serology tests	x										
14	Clinical laboratory tests (hematology and biochemistry)	x										x
15	Urinalysis	x										
16	Pregnancy test serum	x										
17	Pregnancy test urine		x									
18	Visual oral inspection/OMAS			x		x	x	x	x		x	x
19	Vital signs full	x	x									x
20	Vital signs brief			x		x	x	x	x		x	
21	Urine drugs test	x	x									
22	Alcohol saliva test	x	x									
23	Eligibility evaluation		x									
24	Enrolment		x									
25	Training in product use		x									
26	Standardized product administration				x							
27	Non-standardized product administration									x		
	PK and Safety											
28	PK sample collection			x	x	x	x	x	x	x	x	
29	12-lead ECG	x				x						x
30	Carboxyhemoglobin fraction			x		x	x	x	x		x	
31	Exhaled air CO			x		x			x		x	
32	Spirometry	x	X (see Note 32 below)	x		x	x optional		x		x	
33	Cough assessment				x	x				x	x	

	Study Stage	Screening	Admission	Standardized product administration					Non-standardized product administration			Final visit /ETV
	Study Day	-14 to -2	-1	1			2	3	4			5
34	Collection of used devices					x					x	
35	Adverse events	x	x	x	x	x	x	x	x	x	x	x
	Exploratory											
36	Puffing topography				x							
37	Product Effect Questionnaire					x Part 1					x Part 1 & 2	

Abbreviations: AE = adverse event; BMI = body mass index; CBD = Cannabidiol; C-SSRS = Columbia suicidality severity rating scale; ECG = electrocardiogram; EOS = end of study; ETV = early termination visit; HBsAg = hepatitis B surface antigen; HCV = hepatitis C virus; HIV = human immunodeficiency virus; OMAS = Oral Mucositis Assessment Scale; PK = pharmacokinetic; EOT= end of treatment (prematurely); EOS= end of study (as per protocol).

10	**Physical examination**	**Complete physical exam as per protocol at screening.**
13	**Serology tests**	Serology tests include HBsAg, HCV antibody, and HIV antigen and antibody.
16	**Pregnancy test serum**	A serum pregnancy test will be performed at screening for all female participants
19	**Vital signs full**	Blood pressure**,** heart rate**,** respiration rate**, and** ear temperature.
20	**Vital signs brief**	Blood pressure**,** heart rate only. On days 1 and 4 at pre-dose and at 2, 4 and 6 h post-dose.
28	**PK sample collection**	PK sampling to be performed as follows: • Day 1: pre-dose (within 30 min of dosing) and 1, 3, 6, 10, 15, 20, 30 minutes, 1, 2, 4, 6, 8, 12, 24, 48 and 72 h after the start of the first standardized administration • Day 4: pre-dose (corresponding to the 72 h post-dose above) and at 1, 3, 6, 10, 15, 20, 30 minutes, 1, 2, 4, 6 h after the start of the first non-standardized administration
29	**12-lead ECG**	ECG must be done before spirometry and after the use of the stick within approximately 15 minutes.
30	**CarboxiHb fraction**	On day 1 and 4: before product administration and approx. 10 min and 30 min after complete use of the stick. On day 2 and 3 must be done before PK sampling,
31	**Exhaled air CO**	On day 1 and 4: before product administration and at approx. 10 and 30 min after complete use of the stick
32	**Spirometry**	Spirometry includes the reversibility test only for inclusion at screening. The test will not be repeated on Day -1, if done between Day -7 and Day -2 of screening. If the spirometry is repeated on Day -1, no reversibility test will be done. Spirometry on Day 2 is optional and should be repeated only if abnormal on Day 1 after the standardized study product administration.

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ABBREVIATIONS

$\%AUC_{extra}$	Percentage of $AUC_{0\text{-}inf}$ due to extrapolation from the time of the last observed concentration to infinity, calculated, if feasible, as $[1 – (AUC_{0\text{-}t}/AUC_{0\text{-}inf})] \times 100$
ADaM	Analysis Data Model
AE	Adverse Event
AESI	AE of special interest
ALT	Alanine aminotransferase
AST	Aspartate aminotransferase
$AUC_{0\text{-}t}$	Area under the concentration-time curve from time zero until the last observed concentration
$AUC_{0\text{-}inf}$	Area under the concentration-time curve from time zero to infinity (extrapolated)
BLQL	Below Lower Quantification Limit
BMI	Body Mass Index
CBD	Cannabidiol
CDISC	Clinical Data Interchange Standards Consortium
CL/F	Apparent clearance
C_{max}	Maximal observed concentration
CO	Carbon monoxide
COHb	Carboxyhemoglobin
CRO	Contract Research Organisation
CSP	Clinical Study Protocol
C-SSRS	Columbia suicidality severity rating scale
CV	Coefficient of Variation
DD	Device deficiency
DIABP	Diastolic Blood Pressure
DRM	Data Review Meeting
EC	Ethics Committee
ECG	Electrocardiogram
eCRF	electronic Case Report Form
EOS	End of study
ETV	Early Termination Visit
FCOHb	Fractionated Carboxyhemoglobin
FEV1	Forced expiratory volume in one second
FVC	Forced vital capacity
GCP	Good Clinical Practice
HHnB	Hemp Heat-not-Burn
HnB	Heat-not-Burn
HPT	Human puffing topography
HR	Heart Rate
ICH	International Conference on Harmonisation
IRB/IEC	Institutional Review Board/Independent Ethics Committee
K_{el}	Terminal elimination rate constant
MedDRA	Medical Dictionary for Regulatory Activities
OMAS	Oral Mucositis Assessment Scale
OTC	Over The Counter
PK	Pharmacokinetics
PT	Preferred Term
SAE	Serious Adverse Event
SAP	Statistical analysis plan
SYSBP	Systolic Blood Pressure
SD	Standard Deviation
SOC	System Organ Class
SOP	Standard Operating Procedure
SDTM	Study Data Tabulation Model

SPA-M	Smoking Puff Analyser – Mobile
$t_{1/2\ el}$	Terminal elimination half-life
TEAE	Treatment-Emergent Adverse Event
THC	Tetrahydrocannabinol
T_{max}	Time when the maximal concentration is observed
ULN	Upper limit of normal
Vz/F	Apparent volume of distribution
WHODD	World Health Organisation Drug Dictionary

1 INTRODUCTION

Statistical analysis will be performed by the CROSS Research Biometry Unit. The end-points and methods of analysis specified in this SAP are consistent with ICH E6 (R3) and E9 guidelines (1, 2). The SAP has been compiled by the CRO Biometry Unit on the basis of the final version 2.0 of the clinical study protocol dated 09-May-2025 (3), reviewed by the Sponsor and finalized before the database lock.

1.1 Changes with respect to the study protocol

The following changes with respect to the study protocol dated 09-May-2025 (3) were introduced in the SAP:

- A separate reporting for adverse events indicating abuse potential (as defined in §9.2.6 Adverse Events of Special Interest) will be provided
- Differently from what is stated in §10.3.3.2 “Puffing topography results” of the study protocol “Comparisons between product use regimens might be performed, when applicable.”, no comparison will be performed because puffing topography results are not collected during non-standardized product use
- C-SSRS are collected only at screening and end of study, no score frequency by product use will be provided. C-SSRS scores will only be listed
- Pre-treatment Adverse Events (to be read pre-dosing, due to non medical use of the product) will be named pre-treatment unfavourable medical events according to GCP (R3) terminology
- Major protocol deviations will be identified as important protocol deviations according to GCP (R3) terminology

2 STUDY OBJECTIVES

The aims of the study are to evaluate the pharmacokinetics (PK), safety and tolerability of Cannabidiol (CBD) and Tetrahydrocannabinol (THC) and their metabolites.

The objectives and their corresponding endpoints are the following:

Objectives	Endpoints
Primary	
• To evaluate the PK of inhaled CBD, administered as standardized regimen (fixed number of puffs) and administered as non-standardized puff regimen (i.e. *ad libitum*) in healthy adult male and female participants.	PK Parameters for CBD: • Plasma CBD AUC_{0-t}, AUC_{0-inf}, $\%AUC_{ext}$, C_{max}, T_{max}, $T_{½\ el}$, K_{el}, CL/F, Vz/F
Secondary	
Pharmacokinetics: • To assess the PK of CBD metabolites (7-OH-CBD and 7-COOH-CBD), as well as THC and its metabolites (11-OH-THC and 11-COOH-THC) following standardized (fixed number of puffs) and non-standardized (*ad libitum*) administration.	PK parameters for CBD metabolites (i.e. 7-OH-CBD and 7-COOH-CBD), for THC and for THC metabolites (i.e. 11-OH-THC and 11-COOH-THC): • Plasma AUC_{0-t}, AUC_{0-inf}, $\%AUC_{ext}$, C_{max}, T_{max}, $T_{½\ el}$, Kel
Safety and Tolerability: • To evaluate the safety and tolerability of CBD inhaled via an HHnB device, following standardized (fixed number of puffs) and non-standardized (*ad libitum*) administration.	• Incidence and frequency of treatment-emergent adverse events (TEAEs), and AE of special interest (AESI) • Vital signs measurements changes from baseline (blood pressure, heart rate, respiration rate, and body temperature (ear measurement)) • Cough assessment (number, duration, intensity of cough) • Change from baseline in overall hematological/biochemistry parameters • Liver function (liver enzymes, total bilirubin, phosphatase alkaline) • 12-lead electrocardiogram (ECG) recordings • Respiratory tests (spirometry, FCOHb, exhaled CO)

Objectives	Endpoints
	• Change from baseline in Visual oral inspection (OMAS scores)
Exploratory Objectives	
• To assess product effect and perception. • To assess the remaining CBD in the stick and mouthpiece after use. • To assess human puffing topography parameters. • Evaluate variability in puffing pattern across dosages.	• Product effect evaluation, using a Product Effect Questionnaire • Remaining amount of CBD in stick and mouthpiece after use • Human puffing topography measured with a SPA-M device

3 INVESTIGATIONAL PLAN

3.1 Overall study design

This is a single center, Phase 1, open-label study to assess the PK of CBD (up to 20% CBD/stick) inhaled via an HHnB device. This is a single-arm study, where all participants receive the same study product for the duration of the study. The aims of the study are to evaluate the PK, safety and tolerability of CBD and THC and their metabolites. Exploratory objectives will also be assessed, evaluating the product effect, remaining amount of CBD in devices and human puffing topography.

The study includes 40 healthy male and female volunteers who are occasional users of cannabis.

All participants receive the same study products, as follows:

- Standardized administration of CBD (1 stick): Day 1
  and
- Non-standardized administration of CBD (1 stick): Day 4

No control is foreseen for this descriptive PK study. Randomization is therefore not applicable.

3.2 Discussion of design

This is an exploratory study to assess the PK of CBD when inhaled via an HHnB device in healthy participants. The product which are be tested contains less than 1% THC and could be marketed legally in Switzerland.

The primary objective of the study is to characterize the PK and safety profile of CBD when inhaled via an HHnB device according to two different administration regimens. The PK of CBD metabolites as well as THC and its metabolites is being evaluated as a secondary objective.

The number of participants to be enrolled in the study (N= 40) was selected to allow PK data interpretation, considering the anticipated high interindividual variability both for CBD metabolism and for vaping patterns. No sample size calculation was performed due to the exploratory nature of this study.

The study enrolled healthy volunteers, in line with the standard population for a Phase 1 study, taking also into consideration the risks possibly linked to first time exposure to CBD inhalation. A risk assessment is presented in Section 2.3 of the study protocol (3).

Study participants must be occasional smokers of cannabis in order to avoid including cannabis naive participants or participants that developed tolerance to the effects of cannabis (chronic users).

Up to approximately 20 % is the amount of CBD in one stick. Two regimens i.e. standardized (fixed number of puffs) and non-standardized (*ad libitum*) are investigated.

The standardized regimen with consistent inhaling procedure among participants is applied to minimize variability in the context of this early phase study. The *ad libitum* inhaling procedure will provide information on CBD PK when participants inhale CBD via the HHnB device as desired (according to their personal choice) until the device switches off. The *ad libitum* cohort is introduced in order to assess PK, safety and tolerability when the device is used closer to a real-world setting.

Sampling timepoints for determination of CBD concentrations were selected to ensure reliable estimation of PK parameters. Frequent sampling during the first 15 minutes allows to assess T_{max} which is expected to be around 2.5-5 minutes. The washout period between the two administration regimens was calculated based on the inhaled plasma CBD estimated half-life (i.e. 2 h).

CBD is metabolized mainly by CYP2C19 and 3A4 enzymes, therefore, participants who consume any drug known to induce or inhibit hepatic drug metabolism are excluded from the study.

The participants of this study were admitted to the Phase 1 Unit for the entire investigational period and until the assessments on the day of discharge were completed.

The administration of the study products was conducted under investigator supervision.

The study product is not intended to provide a therapeutic effect, hence a therapeutic dose justification is not applicable. A dose of up to 20 % of CBD has been considered sufficient to provide a satisfactory experience with an HHnB device and is anticipated to lead to plasma blood levels which are within safety margins.

4 STUDY POPULATION

4.1 Study population

Study participants must be occasional smokers of cannabis.

4.2 Inclusion criteria

To be enrolled in this study, participants had to fulfil all these criteria:

Sex, Age, BMI, tobacco use

1. Male or female non-tobacco smokers or mild tobacco smokers (1-10 cigarettes or nicotine e-cigarette per day) that are willing to comply with the study restrictions related to smoking.
2. Age ≥18 and ≤55 years of age.
3. BMI ≥ 18.5 and ≤ 30.0 kg/m^2.

Type of Participant and Disease Characteristics

4. Occasional smokers of cannabis (i.e. individuals who smoked cannabis products maximum once a week in the past 3 months) willing to refrain from cannabis products for 2 weeks prior to Day -1.
5. Healthy participants, defined as:
   - The absence of clinically significant illness and surgery within 4 weeks prior to dosing.
   - The absence of clinically significant history of neurological, endocrine, cardiovascular, dermatological, hematological, immunological, psychiatric (e.g., history of major depression or (C-SSRS) score above Type 1 ideation), gastrointestinal, renal, hepatic, and metabolic disease (e.g. diabetes) as well as any other medical history event considered clinically significant in the opinion of the Investigator.
   - The absence of clinically significant history of respiratory (e.g., significant history of acute or chronic bronchospastic) disease (including asthma and chronic obstructive pulmonary disease treated or not treated).
   - The absence of any history of diagnosis of any other pulmonary disease that in the judgment of the investigator is likely to be exacerbated by inhalation of CBD from the device.

Sex and Contraceptive/Barrier Requirements

6. Female participants of childbearing potential must have a negative pregnancy test result before administration of the study product and must agree not to donate ova (or egg(s)) for at least 30 days after the last dose of study product administration.
7. Female participants of non-childbearing potential must be:
   a. At least 12 months of spontaneous amenorrhea; or
   b. postsurgically sterile (documented bilateral oophorectomy with or without hysterectomy) for at least 3 months prior to dosing.
8. Female participants of childbearing potential who are sexually active with a non-sterile male partner (sterile male partners are defined as men vasectomized for at least 3 months prior to dosing) must be willing to use two of the following acceptable

contraceptive methods throughout the study and for 30 days after the last dose:

a. simultaneous use of hormonal contraceptive (e.g., oral, patch, depot injection, implant, vaginal ring, intrauterine device) or non-hormonal intrauterine device used for at least 4 weeks prior to dosing (must agree to use the same contraceptive throughout the study) and condom for the male partner;

b. simultaneous use of diaphragm or cervical cap with spermicide and condom for the male partner, started at least 21 days prior to dosing.

c. True abstinence (i.e., refraining from heterosexual intercourse when this is in line with the preferred and usual lifestyle of the participant). Periodic abstinence (e.g., calendar, ovulation, symptothermal, post-ovulation methods), lactational amenorrhea, and withdrawal are not acceptable.

9. Male participants who are not vasectomized for at least 3 months prior to dosing, and who are sexually active with a female partner of childbearing potential must be willing to use one of the following acceptable contraceptive methods from the first dose and for 90 days after the last dose:
   a. simultaneous use of condom and hormonal contraceptive (e.g., oral, patch, depot injection, implant, vaginal ring, intrauterine device) or non-hormonal intrauterine device used for at least 4 weeks prior to sexual intercourse for the female partner;
   b. simultaneous use of condom and a diaphragm or cervical cap with spermicide for the female partner.
10. Male participants (including men who have had a vasectomy) with a pregnant partner must agree to use a condom from the first dose until 90 days after the last dose.
11. Male participants must be willing not to donate sperm from the first dose until 90 days after the last dose.

Informed Consent

12. Able to understand the study procedures, restrictions and visit schedule and provide signed informed consent to participate in the study.

4.3 Exclusion criteria

Participants meeting any of these criteria were not enrolled in the study:

Medical Conditions

1. Any clinically significant abnormal finding at physical examination at screening that could interfere with the objectives of the study.
2. Clinically significant abnormal laboratory test results which in the opinion of the investigator could prevent participation in the study, at screening.
3. Positive serology test results for HBsAg, HCV antibody, or HIV antigen and antibody at screening
4. Positive pregnancy test (at screening or Day -1) or lactating female participant.
5. Positive urine drug (including cannabis related substances) screen and alcohol saliva

test at screening or Day -1.

6. Participant with abnormal lung function defined by spirometry testing such as: FEV1 < 80% of predicted normal value OR FEV1/FVC ratio < 0.70 at screening OR with post-bronchodilator FEV1 ≥ 12% increase from pre-bronchodilator values (Reversibility testing).
7. Clinically significant ECG abnormalities at screening.
8. Clinically significant vital signs abnormalities (systolic blood pressure lower than 90 or over 140 mmHg, resting diastolic blood pressure lower than 50 or over 90 mmHg, or resting heart rate less than 50 or over 100 bpm) at screening.
9. History of cannabis use disorder (i.e. mental health condition in which there is a problematic pattern of cannabis use that causes distress or impairs life) within 1 year prior to screening or of hard products (such as cocaine, phencyclidine [PCP], crack, opioid derivatives including heroin, and amphetamine derivatives) within 3 months prior to screening.
10. History of alcohol use disorder (defined as a problematic pattern of alcohol use leading to clinically significant life impairment or distress) within 1 year prior to screening or regular use of alcohol within 6 months prior to screening that exceeds 10 units for women or 15 units for men of alcohol per week (1 unit = 340 mL of beer 5%, 140 mL of wine 12%, or 45 mL of distilled alcohol 40%).
11. Known allergic reaction to CBD, or other related products, or to any excipient in the formulation.
12. Any of the following laboratory parameters above 1.5 x upper limit of normal (ULN) at screening or baseline (Day -1): aspartate aminotransferase (AST), alanine aminotransferase (ALT), and total bilirubin. Analyses may be repeated once for confirmation.
13. History of liver disease or hepatic dysfunction (including cirrhosis), hyperbilirubinemia, jaundice, or elevated liver enzymes.
14. History of epilepsy, major depression, schizophrenia or any other psychotic disorders.

Prior/Concomitant Therapy

15. Use of medications for the timeframes specified below, except for medications exempted by the investigator on a case-by-case basis because they are judged unlikely to affect the PK profile of the study product or participant's safety (e.g., topical drug products without significant systemic absorption):
    a. current use of clobazam or valproate sodium, or use within 4 weeks prior to dosing; no other prescription medication from 14 days and over the counter (OTC) products from 7 days prior to dosing and throughout the study;
    b. depot injection or implant within 3 months prior to dosing (excluding depot injection for contraception);
    c. any product known to induce or inhibit CYP3A4, CYP2C9 or CYP2C19 mediated hepatic drug metabolism, including St. John's wort and cytochrome p450 (CYP) substrates of CYP1A2 (e.g., theophylline) and CYP2B6 (e.g., bupropion, efavirenz), CYP2C8 (e.g., montelukast), CYP2C9 (e.g. phenytoin), CYP2C19 (e.g., diazepam) and uridine 5' diphospho-glucuronosyltransferase (UGT) substrates of UGT1A9 (e.g., diflunisal, propofol, fenofibrate), and

UGT2B7 (e.g., gemfibrozil, lamotrigine, morphine, lorazepam) within 30 days prior to dosing until the last PK blood draw;

d. any vaccine, including COVID-19 vaccine, within 14 days prior to dosing;

e. OTC medications and natural health products (including herbal remedies, homeopathic and traditional medicines, probiotics, food supplements such as vitamins, minerals, amino acids, essential fatty acids, and protein supplements used in sports) within 7 days prior to dosing, with the exception of the occasional use of paracetamol (acetaminophen) (up to 2 g daily);

f. any food or beverages containing grapefruit, starfruit, Seville orange, pomegranate, pineapple, or pomelo from 7 days prior to dosing until the last PK blood draw;

g. any food containing poppy seeds from 24 hours prior to admission until the last PK blood draw;

h. any alcohol-based products from 24 hours prior to admission until the last PK blood draw;

Prior/Concurrent Clinical Study Experience

16. Participation in the evaluation of any investigational product for 3 months before this study. The 3-month interval is calculated as the time between the first calendar day of the month that follows the last visit of the previous study and the first day of the present study.

Other Exclusion Criteria

17. Blood donations for 3 months before screening.
18. Any reason which, in the opinion of the investigator, would prevent the participant or make him/her inappropriate from participating in the study.

5 STUDY SCHEDULE

The schedule of the study is summarized at page 5.

5.1 Study visits and procedures

Study procedures and their timing are summarized in the schedule of the study (5). Protocol waivers or exemptions are not allowed.

Adherence to the study design requirements, including those specified in the schedule, is essential and required for study conduct.

Unless otherwise specified, study procedures are conducted in accordance with clinical site SOPs. From screening through EOS, participants undergo study procedures at pre-defined times as specified in the schedule.

All screening evaluations must be completed and reviewed to confirm that potential participants meet all eligibility criteria. The investigator maintains a screening log to record details of all participants screened and to confirm eligibility or record reasons for screening failure, as applicable.

In the event of a significant study-continuity issue (e.g., caused by a pandemic), alternate strategies for participant visits, assessments, medication distribution and monitoring may be implemented by the sponsor or the investigator, as per local health authority/ethics requirements.

A written informed consent is obtained before any study assessment or procedure. The first participant first visit (FPFV) is defined as the first date the first participant signs his/her first informed consent to participate in activities that are protocol directed interventions. The last participant last visit (LPLV) is defined as the last visit of the last participant, i.e. the last visit at the clinical site (or telephone follow-up, if applicable), independently of the fact that the participant is a completer or a withdrawn participant.

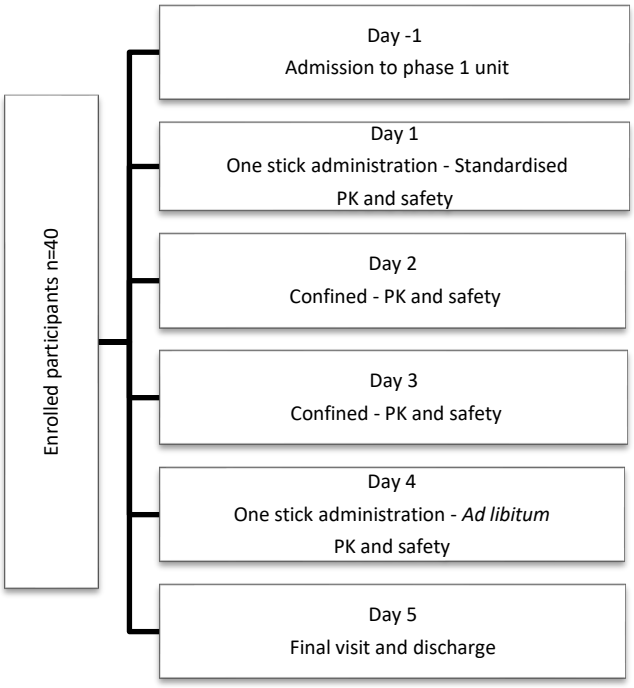
Each participant attends a total of 6 visits (one outpatient visit and 5 in-patient visits). Each study participant undergoes the following phases and procedures:

- Screening and admission phase
  - Screening (Visit 1): between Day -14 and Day -2
  - Admission (Visit 2): Day -1
- Interventional phase
  - Standardized administration (Visit 3): Day 1
  - Assessments and washout (Visit 4): Day 2 and Day 3
  - Non-standardized administration (Visit 5): Day 4
- Final phase
  - Discharge and end of study (Visit 6): Day 5.

In case of early discontinuation, discontinued participants undergo an Early Termination Visit (ETV).

The study flow-chart is presented in the figure below:

Figure 1. Study Flow Chart



5.2 Lifestyle Considerations

5.2.1 Meals and Dietary Restrictions

A standard diet is provided to the participants for the whole confinement period. Participants are not allowed to bring their own food or beverages to the investigational site.

Meals are served according to the schedules provided here:

- On Day -1 (admission) evening all participants receive a standardized low-fat dinner.
- On Day 1 and Day 4, participants are allowed to have a low-fat breakfast at approximately 1 to 2 hours before they start using the study product. Standardized lunch and dinner will be served at approximately 5 h and 12 h post-dose.
- On Days 2 and 3, standardized breakfast, lunch and dinner are served at about 08:00, 13:00 and 20:00, respectively.

Additional light snacks, fruits, and raw vegetables can be distributed to the participants without restrictions at any time during confinement (except during the product use periods) as long as they comply with the standard diet.

Consumption of water is allowed as desired. In addition, on Days 1 and 4, in order to maintain adequate hydration, the participants are encouraged to drink at least 150 mL of mineral water every 2 h for 5 h post-dose, starting at 1 h post-dose.

One cup of coffee or tea is allowed after each meal only. Any other coffee, tea or food containing xanthines (i.e. cola, chocolate, etc.) is prohibited during confinement.

Alcohol based products and food containing poppy seeds are allowed from 24 h prior to admission until the end of confinement.

Participants should refrain from ingesting food or beverages containing grapefruit, starfruit, Seville-type (sour) oranges, pomegranate, pineapple or pomelo from 7 days before dosing until study end. Consumption of quinine-containing drinks (e.g., tonic water) is not allowed.

The same menu and meal schedule is administered uniformly for all participants.

5.2.2 Drugs, Nicotine and Alcohol

Participants are required to fulfill the requirements listed under exclusion criteria.

Electronic cigarettes with nicotine are considered conventional cigarettes and similarly managed. Electronic cigarettes without nicotine are forbidden during confinement.

On dosing days (Day 1 and Day 4), smoking is not allowed from 12 hours before dosing until the last study assessment of the day.

On the other study days at the Phase I Unit, one cigarette after each meal is allowed.

5.2.3 Activity

Participants abstain from vigorous activity from 3 days before admission to the clinic until the end of confinement. During confinement, routine ambulant daily activities are recommended, except for at least 2 hours after each study product use.

5.2.4 Other Restrictions

During the study, the participants are confined in the clinical Phase 1 unit from the evening prior to dosing (study Day -1; Admission) until the morning of Day 5.

For safety reasons, participants are recommended to remain seated or semi-reclined and avoid lying down or sleeping for at least 2 h after each study product use. Failure of the participant to comply with these requirements does not constitute a deviation from the protocol if it is medically necessary, required for procedures, or for physiological needs. When appropriate, participants are accompanied by a staff member while walking.

6 STUDY PARTICIPANT IDENTIFICATION METHOD AND PRODUCT ASSIGNMENT METHOD

6.1 Unique participant identifier

All the participants who sign the informed consent form for the present study are coded with "unique participant identifiers" when data are extracted from the study database into the domains of the CDISC SDTM model. The unique participant identifier consists of the sponsor study code (i.e. VFC224-101), the 6-digit screening number (e.g., 01-001, etc., where 01 is the site number) and the 3-digit participant study number (e.g. 001, 002, etc.) for the participants enrolled for the study. Study code, site number, screening number and participant study number are separated by slashes ("/").
The unique participant identifier will be in the format VFC224-101/01-001/002.

6.2 Participant identifier for the study

The last 10 digits of the unique participant identifier (enrolled participants), corresponding to the participant screening and participant study numbers separated by a slash (e.g. 01-001/002), or the last 6 digits of the unique participant identifier (not enrolled participants), corresponding to the participant screening number (e.g. 01-001), will appear as participant identifier in the individual listings and figures of the clinical study report and will be used to identify the participants in in-text tables or wording (if applicable).

6.3 Randomisation

This is a one arm study. All participants are assigned to the same study product throughout the study. Randomization is therefore not applicable.

6.4 Product allocation

The enrolment is performed through non-randomized allocation to the study intervention.

6.5 Blinding

This is an open study. No masking procedure is applied.

7 STUDY EVALUATION PARAMETERS

7.1 PK parameters

The following PK parameters will be measured and/or calculated for plasma CBD (primary endpoints) and its metabolites (i.e. 7-OH-CBD and 7-COOH-CBD) and THC and its metabolites (i.e. 11-OH-THC and 11-COOH-THC) (secondary endpoints), using the validated software Phoenix WinNonlin® version 8.3.5 (5) or higher (the actual version will be stated in the final clinical study report).

7.1.1 PK parameters

C_{max}	Maximum observed plasma concentration
T_{max}	Time to achieve C_{max}
K_{el}	Terminal elimination rate constant, calculated, if feasible, by log-linear regression using at least 3 points
$t_{1/2\ el}$	Terminal elimination half-life, calculated, if feasible, as ln(2)/ K_{el}
AUC_{0-t}	Area under the concentration-time curve from administration to the last observed concentration time t, calculated with the linear trapezoidal method
AUC_{0-inf}	Area under the concentration-time curve extrapolated to infinity, calculated, if feasible, as $AUC_{0-t} + C_t/\lambda_z$, where C_t is the last measurable drug concentration
$\%AUC_{extra}$	Percentage of AUC_{0-inf} due to extrapolation from the time of the last observed concentration to infinity, calculated, if feasible, as $[1 – (AUC_{0-t}/AUC_{0-inf})] \times 100$
CL/F	Apparent clearance – only for CBD
Vz/F	Apparent volume of distribution – only for CBD

Other PK parameters could be calculated, if applicable.

The quality of log-linear regression (and, consequently, the reliability of the extrapolated PK parameters) should be demonstrated by a determination coefficient $R^2 \geq 0.8$.

7.2 Safety and tolerability parameters

The assessment of safety and tolerability of the study product is based on:

- Incidence and frequency of TEAEs and AESI
- Vital signs (SYSBP, DIABP, HR, respiration rate and body temperature)
- Cough assessment
- Change from baseline in overall hematological/biochemistry parameters
- Liver function
- ECG
- Respiratory tests
- Change from baseline in Visual oral inspection

7.3 Exploratory parameters

The exploratory parameters are:

- Product effect evaluation

- Remaining amount of CBD in stick and mouthpiece after use
- Human puffing topography

8 DATA MONITORING COMMITTEE AND BLIND REVIEW MEETING

8.1 Composition of data monitoring committee

Not applicable

8.2 Purpose and scope of the data review meeting

A data review meeting will take place before database lock.

According to ICH and EMA guidelines (1, 2), the main objectives of the data review meeting are:

- definition of analysis sets
- review of the protocol deviations
- review of the current version of the SAP
- detection and discussion of any other relevant data issue, which may affect the analysis

Analysis sets definition, protocol deviations and data issues are reviewed on a case-by-case basis by the study team, before database lock. Protocol deviations are also categorized as important and minor.

9 STATISTICAL METHOD

The statistical analysis of demographic, baseline and background characteristics, efficacy, safety and tolerability data will be performed using SAS® version 9.3 (TS1M1) (4) or higher (the actual version will be stated in the final report).

The PK analysis and the statistical analysis of PK parameters will be performed using Phoenix WinNonlin® version 8.3.5 (5) or higher and SAS® version 9.3 (TS1M1) (4) or higher (the actual version will be stated in the final clinical study report).

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

Not available data will be evaluated as “missing values”.

9.1 Tables, listings and figures layout

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

- Background: White
- Foreground: Black
- Font face: Times
- Font style: Roman
- Font size: 10 pt
- Font weight: Medium (data, footers and notes), Bold (titles and headers)
- Font width: Normal
- Layout: Landscape
- Top Margin: 2.5 cm
- Bottom Margin: 2.5 cm
- Left Margin: 0.8 cm
- Right Margin: 0.8 cm
- Study product label: HHnB CBD
- Use regimen labels: Standardized, Non-standardized
- Date format: ddMMMyyyy
- Means, standard deviations, percent coefficient of variations, medians, lower confidence limits and upper confidence limits will be rounded to one digit more than the original data
- Minima and maxima will keep the same number of decimal digits as the source values
- p-values will be rounded to the fourth decimal digit and will be flagged by an asterisk (*) in case of statistical significance (i.e. p-value < 0.05 or, in case of centre by treatment interaction, p-value < 0.10)
- p-values lower than 0.0001 will be reported as "<.0001 *".

9.2 Analysis sets

9.2.1 Definitions

A participant is defined as screened after the signature of the informed consent, regardless of the completion of all the screening procedures.

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

A participant is defined as enrolled in the study if he/she is included in the interventional phase of the study. The enrolment is performed through non-randomized allocation to the study intervention.

An eligible but not enrolled participant is defined as a reserve.

- *Enrolled Set*: all enrolled participants. This analysis set is used for demographic, baseline and background characteristics
- *Safety Set*: all participants who are exposed to at least one dose of study product. This analysis set is used for the safety analysis
- *PK Set*: All participants from the safety population who have at least one quantifiable post-dose PK concentration (≥ lower limit of quantification [LLOQ]). This analysis set is used for the PK analysis.
- *PK Per Protocol (PKPP) Set*: All participants from the PK set, who completed the use of the study product as per protocol and who have at least one PK parameter and who have not experienced any important protocol deviation or other circumstances that may affect study results. This analysis set is used for the PK (sensitivity) analysis

Each participant will be coded during the data review meeting as valid or not valid for the Enrolled Set, Safety Set, PK Set and PKPP Set before database lock.

9.2.2 Reasons for exclusion from the Safety Set

Reason for exclusion of participants from the Safety Set is the following:

- failure to take at least one dose of study product

9.2.3 Reasons for exclusion from the PK Set

Reasons for exclusion of participants from the PK Set are the following:

- failure to take at least one dose of study product
- lack of any measurable concentrations

9.2.4 Reasons for exclusion from the PKPP Set

Reasons for exclusion of participants from the PKPP Set are the following.

9.2.4.1 Reasons for exclusion from the PKPP Set before bioanalysis

- vomiting and diarrhoea after drug intake which could render the plasma concentration-time profile unreliable
- intake of concomitant medications which could render the plasma concentration-time profile unreliable
- AEs which could render the plasma concentration-time profile unreliable
- administration errors which could render the plasma concentration-time profile unreliable
- protocol deviations which could render the plasma concentration-time profile unreliable
- other events which could render the plasma concentration-time profile unreliable

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

9.2.4.2 Reasons for exclusion from the PKPP Set after bioanalysis

Exclusion of participants on the basis of pharmacokinetic reasons is possible only for:

- participants with lack of any measurable concentrations
- participants with lack of any calculated PK parameter
- participants with non-zero baseline concentrations > 5% of C_{max}

The samples from the participants excluded from the PK and PKPP sets should still be assayed and the results listed. Participants should not be excluded from the PKPP set if the correlation coefficient R^2 is < 0.8.

9.3 Sample size and power considerations

The sample size was not powered on the basis of statistical hypothesis testing considering the descriptive nature of this study.

The sample size of 40 participants was selected to allow data interpretation, keeping in mind the anticipated high individual variability both for CBD metabolism and vaping pattern.

Discontinued study participants were not replaced.

9.4 Evaluation of compliance

Each individual study product for the participants is prepared at the site from a bulk supply of hemp sticks and HHnB devices and the preparation of each dose is confirmed by a second member of the study site staff.

Participants are provided with the study product by the investigator or designee and self-administer the product at the site under supervision of the clinical staff.

When participants are dosed at the site under standardized or non-standardized conditions, they receive the study product directly from the investigator or designee, under medical supervision, therefore compliance is expected unless safety issues arise that require study product interruption.

For standardized administration, the time of start and end of the inhalation process (i.e. time of initiation of the first puff and last puff) is recorded by the SPA-M device and reported in the eCRF from the source data. For non-standardized administration, the time of start and end of the inhalation process (i.e. time of initiation of the first puff and last puff) is recorded by the study staff and the number of puffs is recorded by the participant and reported by study staff in the eCRF from the source data. Further information on the SPA-M device functioning and timing recording in the source data is provided in the training manual for the site staff. If there is any temporary or permanent interruption, this should be recorded alongside the time of the interruption and the reason for the interruption or discontinuation alongside the number of puffs until the point of interruption. These data are recorded both in the source data and eCRF.

A record of the quantity of the HHnB devices and hemp sticks dispensed to each participant must be maintained and reconciled with the study product received in the compliance records.

9.4.1 Post-use Device Assessment

The used HHnB device and hemp stick are collected and placed into individual pre-labelled polyethylene bags for shipment to the sponsor's assigned facility for assessment.

Post-use device assessments are performed by the sponsor to confirm product delivery (by assessing device post use, capsules post use, etc.).

9.5 Handling of missing data

Not available data will be evaluated as "missing values".

9.6 Demographic, baseline and background characteristics

Demographic, baseline and background characteristics will be examined according to qualitative or quantitative data. Qualitative data will be summarized in contingency tables. Quantitative data will be summarized using classic descriptive statistics.

9.6.1 Participants' disposition

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

9.6.2 Analysis sets

The participants included in each analysis set will be summarized (Table 14.1.1.2).

9.6.3 Participants excluded from safety and/or PK analysis

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

9.6.4 Discontinued participants

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

9.6.5 Protocol deviations

All the protocol deviations reported during the study will be listed (Listing 16.2.2.1) and summarized (Table 14.1.1.5) for each analysis set. The number and proportion of participants for each deviation will be reported.

9.6.6 Demography

Demographic data will be listed (Listing 16.2.4.2) and summarized (Table 14.1.1.3) for each analysis set. The number and proportion of participants in each category for categorical variables (e.g. sex) and descriptive statistics (mean, SD, CV%, minimum, median and maximum) for continuous variables (e.g. age, weight) will be presented.

9.6.7 Inclusion/exclusion criteria not met

All the unmet inclusion/exclusion criteria will be listed (Listing 16.2.4.3) and summarized (Table 14.1.1.4) for each analysis set.

9.6.8 Medical and surgical history

All the diseases of medical history and the surgeries of all participants enrolled in the study will be coded using the Medical Dictionary for Regulatory Activities (MedDRA) version 28.0 and listed (Listing 16.2.10.1).

9.6.9 Prior and concomitant medication

All prior and concomitant medications will be coded using the World Health Organization Drug Dictionary (WHODD) March 2025, listed (Listing 16.2.10.2) and summarized (Table 14.1.1.6, Table 14.3.5.11).

9.6.10 Participants' study visits

The dates and the days of all participants study visits will be listed (Listing 16.2.10.4).

9.6.11 Fertility status and contraceptive method

For women, the fertility status and the use of any acceptable contraceptive methods will be listed (Listing 16.2.10.5).
For men, reproductive status and contraception will be listed (Listing 16.2.10.6).

9.6.12 Salivary alcohol test, pregnancy and urine drug tests

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

9.6.13 Tobacco and cannabis consumption

Individual tobacco consumption habits will be listed (Listing 16.2.10.7).

Cannabis use history will be listed (Listing 16.2.10.8).

9.6.14 Meals

The date/time of the standardized meals will be listed (Listing 16.2.10.9).

9.6.15 HHnB Device Deficiencies

All the recorded HHnB device deficiencies will be listed (Listing 16.2.10.10).

9.7 Study product administration

The start and end date/time and the number of puffs of all study product administrations and the smoking abstention conditions will be listed (Listing 16.2.5.1), the number of puffs will be summarized (Table 14.2.3.7) for each product use (standardized and non-standardized).
If applicable, study product administration interruptions will be listed (Listing 16.2.5.2).

9.8 Interim analyses

Not applicable.

9.9 PK analysis

The PK analysis will be performed on the participants included in the PK set and PKPP Set. The analysis for the PKPP set will be performed separately only if PKPP set is different from PK set.

9.9.1 PK blood samples collection

The actual date/time of PK blood samples collection and the time elapsed from study product administration will be listed (Listing 16.2.5.3).

9.9.2 Descriptive pharmacokinetics

Individual participant concentrations of CBD and its metabolites and of THC and its metabolites will be presented in data listings (Listing 16.2.5.4, Listing 16.2.5.5, Listing

16.2.5.6, Listing 16.2.5.7, Listing 16.2.5.8, Listing 16.2.5.9) for each product use (standardized and non-standardized).

A descriptive PK will be presented for each product use (standardized and non-standardized). Descriptive statistics, which include but is not restricted to mean, SD, CV%, median, minimum, and maximum, interquartile ranges will be calculated for each PK parameter.

Concentrations of CBD and its metabolites and of THC and its metabolites will be tabulated at each time point (Table 14.2.1.1, Table 14.2.1.2, Table 14.2.1.3, Table 14.2.1.4, Table 14.2.1.5, Table 14.2.1.6 for PK set and Table 14.2.1.7, Table 14.2.1.8, Table 14.2.1.9, Table 14.2.1.10, Table 14.2.1.11, Table 14.2.1.12 for PKPP set) for each product use (standardized and non-standardized).

Individual and mean curves (+SD at sampling times), indicating inter-participant variability, will be plotted.
Data below the lower quantification limit (BLQL) will be considered as 0 in the calculations and presented as BLQL in listings and tables. As a consequence of BLQL (i.e. 0) values, calculated geometric means (if requested) could be null. For this reason, in the presence of any null value, the geometric mean will be reported as not calculated (NC).

PK parameters will be estimated using a standard noncompartmental method from individual plasma concentrations. Actual sampling times will be used to determine PK parameters.

CBD and its metabolites and THC and its metabolites PK parameters will be listed (Listing 16.2.6.1, Listing 16.2.6.2, Listing 16.2.6.3, Listing 16.2.6.4, Listing 16.2.6.5, Listing 16.2.6.6) for each product use (standardized and non-standardized) and summarized (Table 14.2.2.1, Table 14.2.2.2, Table 14.2.2.3, Table 14.2.2.4, Table 14.2.2.5, Table 14.2.2.6 for PK set and, Table 14.2.2.7, Table 14.2.2.8, Table 14.2.2.9, Table 14.2.2.10, Table 14.2.2.11, Table 14.2.2.12 for PKPP set).

9.9.3 Statistical comparison of pharmacokinetic parameters

A comparison of $AUC_{0\text{-}t}$, $AUC_{0\text{-}inf}$, C_{max} and T_{max} between standardized and non-standardized product use regimens will be performed by means of Wilcoxon Signed rank test (Table 14.2.3.6), if applicable.
The comparison will be performed on the difference of parameters value between standardized and non-standardized product use regimens with the SAS procedure proc univariate and the option TestsForLocation:

```
proc univariate data=<input_table>;
  var <difference>;
  ods output TestsForLocation=<output_table> (where=(Test eq "Signed Rank"));
run;
```

9.10 Exploratory analysis

9.10.1 Product Effect Questionnaire

Product effect Questionnaire scores results will be listed (Listing 16.2.6.7) and summarized (Table 14.2.3.1, Table 14.2.3.2) for each product use (standardized and non-standardized) and questionnaire part using descriptive statistics and/or score frequency, as applicable.
Comparisons between product use regimens might be performed, if applicable.

9.10.2 Puffing topography results

HPT parameters will be listed (Listing 16.2.6.8, Listing 16.2.6.9) and summarized (Table 14.2.3.3), for standardized product use regimen only, using descriptive statistics. The following HPT parameters will be presented: Puff Volume [Vi], Puff Duration [Di], Average Flow [Qmi], Peak Flow [Qci], Inter Puff Interval [Li], the sum of Puff duration and Inter Puff Interval [DFi] and finally the Peak flow Position [PosQci].

The analysis on the HPT parameters will be repeated on a sub-group of patients: smokers versus non-smokers or past smokers.

9.10.3 Remaining CBD on stick and mouthpiece after use

Remaining CBD on the stick and mouthpiece after use will be listed (Listing 16.2.6.10) by standardized and non-standardized product use and summarized (Table 14.2.3.4) by descriptive statistics.

The correlation between the remaining CBD product in the HHnB device (overall remaining quantity after each product use regimen) and the corresponding CBD blood levels after the standardized and the non-standardized inhalation, respectively, will be analyzed using Pearson or Spearman coefficients for each product use regimen and tabulated (Table 14.2.3.5), if applicable.

The correlation will be calculated using the SAS procedure proc corr:

```
proc corr data=<input_table>;
  var <remaining CBD> <PK parameter>;
run;
```

where <remaining CBD> will be remaining CBD on the stick and remaining CBD on the mouthpiece values and <PK parameter> will be AUC_{0-t} and C_{max} values.

9.10.4 Additional PK analysis

If feasible, data from this study will be used for additional analysis of untransformed k_{el} and $t_{1/2}$.
A comparison of untransformed k_{el} and $t_{1/2}$ between standardized and non-standardized regimen will be performed by means of Wilcoxon Signed rank test. Results from this additional analysis will be presented in the clinical study report (Table 14.2.3.6).
The comparison will be performed on the difference of parameters value between standardized and non-standardized product use regimens with the SAS procedure proc univariate and the option TestsForLocation:

```
proc univariate data=<input_table>;
```

```
    var <difference>;
    ods output TestsForLocation=<output_table> (where=(Test eq "Signed Rank"));
run;
```

9.11 Safety analysis

The safety analysis will be performed on the participants included in the Safety Set.

Safety and tolerability data will be reported using descriptive statistics including number of non-missing values, mean, median, SD, minimum and maximum for continuous variables and number and percentage for categorical variables.

9.11.1 Adverse events

Adverse events (AEs) will be coded by System Organ Class (SOC) and Preferred Term (PT), using the Medical Dictionary for Regulatory Activities (MedDRA) version 28.0.

AEs will be classified as pre-treatment Unfavourable Medical Events and Treatment-emergent AEs (TEAEs), according to the period of occurrence, as follows:

- Pre-treatment Unfavourable Medical Events: all AEs occurring before the first dose of the study product
- TEAEs: all AEs occurring or worsening after the first dose of the study product

Individual Pre-treatment Unfavourable Medical Events (Listing 16.2.7.4) and TEAEs (Listing 16.2.7.1) will be listed in participant data listings by product use (standardized and non-standardized).

No summary table will be provided for Pre-treatment Unfavourable Medical Events.

TEAEs will be summarized by product use (standardized and non-standardized) and overall (Table 14.3.1.1).
The number and percentage of subjects with any TEAE and the number of TEAEs will be tabulated by SOC and PT (Table 14.3.1.2), severity (Table 14.3.1.3), relationship to study product (Table 14.3.1.4), and seriousness (Table 14.3.1.5, Table 14.3.1.6) by product use and overall.

The following AEs must be reported as adverse event of special interest (AESI):

- ALT or AST greater than or equal to 5 x Upper limit of normal (ULN)
- Total bilirubin equal or greater than 2 x ULN (if ALT is equal or greater than 3 x ULN)
- ALP equal or greater than 2 x ULN (if the source of the ALP increase is the liver)

AESI will also be listed (Listing 16.2.7.2) and summarized separately (Table 14.3.1.7) by product use and overall.

Particular attention will be given to the following events indicating abuse potential:

- Euphoric mood; Elevated mood; Feeling abnormal; Feeling drunk; Feeling of relaxation; Dizziness; Thinking abnormal; Hallucination; Inappropriate affect

- Disturbance in attention, cognition (such as cognitive disorder), and mood (such as Mood altered, Mood swings, Depressed mood), Somnolence.
- Dissociative/psychotic terms: Dissociative disorder, Psychotic disorder; Aggression; Confusional state and Disorientation

AEs indicating abuse potential will also be listed (Listing 16.2.7.3) and summarized separately (Table 14.3.1.8) by product use and overall.
TEAEs leading to death, serious adverse events or TEAEs leading to discontinuation are also described (Table 14.3.2.1).

9.11.2 Physical examination

Date of the physical examination, overall Investigator's interpretation (as normal or abnormal and, if abnormal, clinically significant or not clinically significant) and clinically significant abnormalities (if any) will be listed (Listing 16.2.10.3).

9.11.3 C-SSRS

Date of the C-SSRS Questionnaire and C-SSRS scores will be listed (Listing 16.2.10.11).

9.11.4 Laboratory data

Date of samples collection, overall Investigator's interpretation (as normal or abnormal and, if abnormal, clinically significant or not clinically significant) and clinically significant findings (if any) will be listed (Listing 16.2.8.2) summarized using tables of frequency (Table 14.3.4.3).

All laboratory results will be listed (Listing 16.2.8.1) and a table of all the abnormal values will be presented (Table 14.3.4.1).
All laboratory results and their changes from baseline to final visit/ETV will be summarized (Table 14.3.4.2).

9.11.5 Body weight

The date/time of body weight assessments and the values of body weight will be listed (Listing 16.2.9.2) and descriptive statistics of the values of body weight and their changes from baseline to final visit/ETV will be presented (Table 14.3.5.3).

9.11.6 Vital signs

The date/time of vital signs assessments, the values of vital signs (blood pressure, heart rate, respiration rate and body temperature) and overall Investigator's interpretation (as normal or abnormal and, if abnormal, clinically significant or not clinically significant) will be listed (Listing 16.2.9.1) and descriptive statistics of the values of vital signs and their changes from baseline to post-dose timepoints will be presented (Table 14.3.5.2).

A table of all the abnormal vital signs' values will be presented (Table 14.3.5.1).

9.11.7 ECG

The date/time of ECG recording and the overall investigator's interpretation (as normal, abnormal, not clinically significant or abnormal, clinically significant) and clinically significant abnormalities (if any) will be listed (Listing 16.2.9.4).
The investigator's interpretations will be summarized using contingency tables (Table 14.3.5.5)

The values of ECG parameters will be listed (Listing 16.2.9.3) and descriptive statistics of the values of ECG parameters and their changes from baseline to final visit/ETV will be presented (Table 14.3.5.4).

9.11.8 Visual oral inspection analyses

The global OMAS score is the sum of erythema and ulceration scores across multiple oral sites. The mouth is divided into 9 regions (upper lip, lower lip, right/left cheek, right/left lateral tongue, ventral tongue/floor, soft palate/fauces, hard palate).

At each site, two things are scored:

- Erythema (0 = none, 1 = not severe, 2 = severe)
- Ulceration/pseudo membrane (0 = none, 1 = <1 cm^2, 2 = 1–3 cm^2, 3 = >3 cm^2)

The global OMAS score is the sum of all subscores across sites.

- Minimum = 0 (no mucositis)
- Maximum = 45 (severe, widespread mucositis)

The date/time of Visual oral inspection (OMAS) assessments and OMAS scores will be listed (Listing 16.2.9.5) and summarized (Table 14.3.5.6) by standardized and non-standardized product use regimen using score frequency. Change from baseline will be calculated, when possible.

The Global OMAS score will be calculated by timepoint and the corresponding change from baseline will be listed (Listing 16.2.9.6) and summarized (Table 14.3.5.7) by standardized and non-standardized product use regimen.

9.11.9 Cough assessment

Cough assessment results and date/time of the assessments will be listed (Listing 16.2.9.6) and summarized (Table 14.3.5.8) by product use regimen using descriptive statistics and/or score frequency, as applicable. Potential comparisons between product use regimens might be performed.

9.11.10 Respiratory parameters

Spirometry parameters, FCOHb and exhaled CO values will be listed (Listing 16.2.9.7, Listing 16.2.9.8) and summarized (Table 14.3.5.9, Table 14.3.5.10) by descriptive statistics. Changes in the parameters' values from baseline to post-dose time points will be summarized, as applicable.

The analyses of the respiratory parameters will be repeated on a sub-group of patients: smokers versus non-smokers or past smokers.

9.12 Analysis datasets

The Biometry Unit of the CRO will extract data from the eCRF and will provide tabulation datasets according the SDTM model of the CDISC (6). Analysis datasets will be created according to the version 2.1 of the ADaM model of CDISC (6).
SDTM and ADaM domains will be validated using the Pinnacle 21 Community validator. The original export of the eCRF data and the final data files will be transferred to the Sponsor in the agreed format with the relevant CDISC documents (i.e., output reports for both SDTM and ADaM datasets from the Pinnacle 21 validation tool) together with all other study documentation.

10 REFERENCES

1 ICH Topic E6 (R3): Guideline for good clinical practice.

2 ICH Topic E9: Statistical principles for clinical trials.

3 Study Protocol VFC224-101. "A single center, open label study to assess the pharmacokinetics of cannabidiol inhaled via a Hemp Heat-not-Burn (HHnB) device in healthy participants". Final version 2.0, 09MAY2025

4 SAS/STAT® User's Guide

5 Phoenix 1.3 User's Guide, Pharsight Corporation

6 CDISC Study Data Tabulation Model, Version 1.7, 20NOV2018

7 CDISC Analysis Data Model Version 2.1

11 APPENDICES

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2. Section 16.2 - Individual Participant Data Listings and Figures Shells

Section 14 - Tables and Figures Shells

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Section 14 - Tables and Figures Shells

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Table 14.1.1.1 - Participants' disposition

	Overall n (%)
Screened	nn
Screen Failures[1]	nn (xx.x)
Enrolled[1]	nn (xx.x)
Discontinued before treatment [2]	nn (xx.x)
Treated [2]	nn (xx.x)
Completed [3]	nn (xx.x)
Discontinued [3]	nn (xx.x)
Adverse event [3]	nn (xx.x)
Withdrawal by participant [3]	nn (xx.x)
...	...

Note: The number and the proportion of participants of each disposition event are reported
Note 1: The denominator for calculating the proportion is the number of screened participants
Note 2: The denominator for calculating the proportion is the number of enrolled participants
Note 3: The denominator for calculating the proportion is the number of enrolled and treated participants
Source:Listing 16.2.4.1 - participants' disposition
Program: Tables\k374-ds-tbl.sas

Table 14.1.1.2 - Analysis sets - Enrolled set

	Overall N=XX n (%)
Safety Set [1]	nn (xx.x)
PK Set [2]	nn (xx.x)
PKPP Set [3]	nn (xx.x)

Note: The number and the proportion of participants included in each analysis set are reported

The denominator for calculating the proportions is the number of participants in the enrolled set

Note 1: Safety set: all participants who are exposed to at least one dose of study product

Note 2: PK set: all participants from the safety population who have at least one quantifiable post-dose PK concentration

Note 3: PKPP set: all participants from the PK set, who completed the use of the study product as per protocol and who have at least one PK parameter and who have not experienced any important protocol deviation or other circumstances that may affect study results

Source: Listing 16.2.3.1 - Participants excluded from the analysis sets - Listing 16.2.4.1 - Participants' disposition

Program: Tables\k374-ds-tbl.sas

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

		Statistics	**Safety Set N=XX**	**PK Set N=XX**	**PKPP Set N=XX**
Sex	Female	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	Male	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
Age (years)		N	nn	nn	nn
		Mean	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x
		CV%	xx.x	xx.x	xx.x
		Min	xx	xx	xx
		Median	xx.x	xx.x	xx.x
		Max	xx	xx	xx
Height (cm)		N	nn	nn	nn
		Mean	xxx.x	xxx.x	xx.xx
		SD	xxx.x	xxx.x	xx.xx
		CV%	xxx.x	xxx.x	xx.xx
		Min	xxx	xxx	xx.x
		Median	xxx.x	xxx.x	xx.x
		Max	xxx	xxx	xx.x

Note: The number and the proportion of participants of each sex are reported
The denominator for calculating the proportions is the number of participants in each analysis set
Source: Listing 16.2.4.2 - Demography
Program: Tables\k374-dm-tbl.sas

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

	Statistics	Safety Set N=XX	PK Set N=XX	PKPP Set N=XX
Weight (kg)	N	nn	nn	nn
	Mean	xx.xx	xx.xx	xx.xx
	SD	xx.xx	xx.xx	xx.xx
	CV%	xx.xx	xx.xx	xx.xx
	Min	xx.x	xx.x	xx.x
	Median	xx.xx	xx.xx	xx.x
	Max	xx.x	xx.x	xx.x
Body Mass Index (kg/m^2)	N	nn	nn	nn
	Mean	xx.xx	xx.xx	xx.xx
	SD	xx.xx	xx.xx	xx.xx
	CV%	xx.xx	xx.xx	xx.xx
	Min	xx.x	xx.x	xx.x
	Median	xx.xx	xx.xx	xx.xx
	Max	xx.x	xx.x	xx.x

Note: The number and the proportion of participants of each sex are reported
The denominator for calculating the proportions is the number of participants in each analysis set
Source: Listing 16.2.4.2 - Demography
Program: Tables\k374-dm-tbl.sas

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

	Enrolled Set N=XX	Safety Set N=XX	PK Set N=XX	PKPP Set N=XX
Number of participants with any inclusion/exclusion criteria not met	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
Inclusion	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
Inclusion criterion 1	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
Inclusion criterion 2	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
...	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
Exclusion	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
Exclusion criterion 1	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
Exclusion criterion 2	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
...	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)

Note: The number and the proportion of participants for any criterion not met are reported
The denominator for calculating the proportions is the number of participants in each analysis set
Source: Listing 16.2.4.3 - Inclusion/Exclusion criteria not met
Program: Tables\k374-ie-tbl.sas

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

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

Note: The number and the proportion of participants for any protocol violation are reported
The denominator for calculating the proportions is the number of participants in each analysis set
Source: Listing 16.2.2.1 - Protocol deviations
Program: Tables\k374-dv-tbl.sas

Table 14.1.1.6 - Prior medications - Enrolled set

Medication Class [1,2] **Standardised Medication Name** [1]	**Overall** **N=XX** **n (%)**
Number of subjects with any prior medication	nn (xx.x)
Intravaginal contraceptives	nn (xx.x)
Ethinylestradiol; Etonogestrel	nn (xx.x)
...	nn (xx.x)

Note: The number and the proportion of participants with any prior medication for each classification level are reported
The denominator for calculating the percentages is the number of participants in the enrolled set
Note 1: WHO Drug Dictionary March 1, 2025
Note 2: Anatomical Therapeutic Chemical classification, 4th level term, 3rd level term or 2nd level term as applicable
Source: Source: Listing 16.2.10.2 - Prior and concomitant medications
Program: Tables\k374-cm-tbl.sas

Table 14.2.1.1 - Summary of CBD concentrations (pg/mL) measured in blood - PK set

Product Use: Standardized

Statistics	Pre dose	1 min post dose	3 min post dose	6 min post dose	10 min post dose	15 min post dose	20 min post dose	30 min post dose	1 h post dose	2 h post dose	4 h post dose	6 h post dose	8 h post dose	12 h post dose	24 h post dose	48 h post dose	72 h post dose
N	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
Geo.Mean	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
Min	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
Mean	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
Max	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
SD	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
CV%	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
Q1	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
Median	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
Q3	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx

Source: Listing 16.2.5.4 - CBD concentrations (pg/mL) measured in blood
Program: pk-analysis\k374-tlf.sas

Table 14.2.1.1 - Summary of CBD concentrations (pg/mL) measured in blood - PK set

Product Use: Non-standardized

Statistics	Pre dose	1 min post dose	3 min post dose	6 min post dose	10 min post dose	15 min post dose	20 min post dose	30 min post dose	1 h post dose	2 h post dose	4 h post dose	6 h post dose	8 h post dose	12 h post dose	24 h post dose	48 h post dose	72 h post dose
N	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	---	---	---	---	---
Geo.Mean	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	---	---	---	---	---
Min	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	---	---	---	---	---
Mean	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	---	---	---	---	---
Max	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	---	---	---	---	---
SD	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	---	---	---	---	---
CV%	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	---	---	---	---	---
Q1	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	---	---	---	---	---
Median	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	---	---	---	---	---
Q3	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	---	---	---	---	---

Source: Listing 16.2.5.4 - CBD concentrations (pg/mL) measured in blood
Program: pk-analysis\k374-tlf.sas

Table 14.2.1.2 - Summary of 7-OH-CBD concentrations (pg/mL) measured in blood - PK set

Product Use: Standardized

Statistics	Pre dose	1 min post dose	3 min post dose	6 min post dose	10 min post dose	15 min post dose	20 min post dose	30 min post dose	1 h post dose	2 h post dose	4 h post dose	6 h post dose	8 h post dose	12 h post dose	24 h post dose	48 h post dose	72 h post dose
N	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
Geo.Mean	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
Min	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
Mean	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
Max	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
SD	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
CV%	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
Q1	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
Median	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
Q3	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx

Source: Listing 16.2.5.5 - 7-OH-CBD concentrations (pg/mL) measured in blood
Program: pk-analysis\k374-tlf.sas

Table 14.2.1.2 - Summary of 7-OH-CBD concentrations (pg/mL) measured in blood - PK set

Product Use: Non-standardized

Statistics	Pre dose	1 min post dose	3 min post dose	6 min post dose	10 min post dose	15 min post dose	20 min post dose	30 min post dose	1 h post dose	2 h post dose	4 h post dose	6 h post dose	8 h post dose	12 h post dose	24 h post dose	48 h post dose	72 h post dose
N	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	---	---	---	---	---
Geo.Mean	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	---	---	---	---	---
Min	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	---	---	---	---	---
Mean	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	---	---	---	---	---
Max	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	---	---	---	---	---
SD	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	---	---	---	---	---
CV%	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	---	---	---	---	---
Q1	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	---	---	---	---	---
Median	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	---	---	---	---	---
Q3	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	---	---	---	---	---

Source: Listing 16.2.5.5 - 7-OH-CBD concentrations (pg/mL) measured in blood
Program: pk-analysis\k374-tlf.sas

Table 14.2.1.3 - Summary of 7-COOH-CBD concentrations (pg/mL) measured in blood - PK set

Product Use: Standardized

Statistics	Pre dose	1 min post dose	3 min post dose	6 min post dose	10 min post dose	15 min post dose	20 min post dose	30 min post dose	1 h post dose	2 h post dose	4 h post dose	6 h post dose	8 h post dose	12 h post dose	24 h post dose	48 h post dose	72 h post dose
N	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
Geo.Mean	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
Min	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
Mean	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
Max	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
SD	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
CV%	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
Q1	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
Median	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
Q3	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx

Source: Listing 16.2.5.6 - 7-COOH-CBD concentrations (pg/mL) measured in blood
Program: pk-analysis\k374-tlf.sas

Table 14.2.1.3 - Summary of 7-COOH-CBD concentrations (pg/mL) measured in blood - PK set

Product Use: Non-standardized

Statistics	Pre dose	1 min post dose	3 min post dose	6 min post dose	10 min post dose	15 min post dose	20 min post dose	30 min post dose	1 h post dose	2 h post dose	4 h post dose	6 h post dose	8 h post dose	12 h post dose	24 h post dose	48 h post dose	72 h post dose
N	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	---	---	---	---	---
Geo.Mean	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	---	---	---	---	---
Min	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	---	---	---	---	---
Mean	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	---	---	---	---	---
Max	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	---	---	---	---	---
SD	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	---	---	---	---	---
CV%	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	---	---	---	---	---
Q1	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	---	---	---	---	---
Median	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	---	---	---	---	---
Q3	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	---	---	---	---	---

Source: Listing 16.2.5.6 - 7-COOH-CBD concentrations (pg/mL) measured in blood
Program: pk-analysis\k374-tlf.sas

Table 14.2.1.4 - Summary of THC concentrations (pg/mL) measured in blood - PK set

Product Use: Standardized

Statistics	Pre dose	1 min post dose	3 min post dose	6 min post dose	10 min post dose	15 min post dose	20 min post dose	30 min post dose	1 h post dose	2 h post dose	4 h post dose	6 h post dose	8 h post dose	12 h post dose	24 h post dose	48 h post dose	72 h post dose
N	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
Geo.Mean	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
Min	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
Mean	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
Max	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
SD	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
CV%	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
Q1	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
Median	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
Q3	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx

Source: Listing 16.2.5.7 - THC concentrations (pg/mL) measured in blood
Program: pk-analysis\k374-tlf.sas

Table 14.2.1.4 - Summary of THC concentrations (pg/mL) measured in blood - PK set

Product Use: Non-standardized

Statistics	Pre dose	1 min post dose	3 min post dose	6 min post dose	10 min post dose	15 min post dose	20 min post dose	30 min post dose	1 h post dose	2 h post dose	4 h post dose	6 h post dose	8 h post dose	12 h post dose	24 h post dose	48 h post dose	72 h post dose
N	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	---	---	---	---	---
Geo.Mean	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	---	---	---	---	---
Min	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	---	---	---	---	---
Mean	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	---	---	---	---	---
Max	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	---	---	---	---	---
SD	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	---	---	---	---	---
CV%	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	---	---	---	---	---
Q1	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	---	---	---	---	---
Median	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	---	---	---	---	---
Q3	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	---	---	---	---	---

Source: Listing 16.2.5.7 - THC concentrations (pg/mL) measured in blood
Program: pk-analysis\k374-tlf.sas

Table 14.2.1.5 - Summary of 11-OH-THC concentrations (pg/mL) measured in blood - PK set

Product Use: Standardized

Statistics	Pre dose	1 min post dose	3 min post dose	6 min post dose	10 min post dose	15 min post dose	20 min post dose	30 min post dose	1 h post dose	2 h post dose	4 h post dose	6 h post dose	8 h post dose	12 h post dose	24 h post dose	48 h post dose	72 h post dose
N	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
Geo.Mean	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
Min	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
Mean	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
Max	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
SD	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
CV%	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
Q1	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
Median	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
Q3	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx

Source: Listing 16.2.5.8 - 11-OH-THC concentrations (pg/mL) measured in blood
Program: pk-analysis\k374-tlf.sas

Table 14.2.1.5 - Summary of 11-OH-THC concentrations (pg/mL) measured in blood - PK set

Product Use: Non-standardized

Statistics	Pre dose	1 min post dose	3 min post dose	6 min post dose	10 min post dose	15 min post dose	20 min post dose	30 min post dose	1 h post dose	2 h post dose	4 h post dose	6 h post dose	8 h post dose	12 h post dose	24 h post dose	48 h post dose	72 h post dose
N	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	---	---	---	---	---
Geo.Mean	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	---	---	---	---	---
Min	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	---	---	---	---	---
Mean	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	---	---	---	---	---
Max	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	---	---	---	---	---
SD	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	---	---	---	---	---
CV%	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	---	---	---	---	---
Q1	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	---	---	---	---	---
Median	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	---	---	---	---	---
Q3	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	---	---	---	---	---

Source: Listing 16.2.5.8 - 11-OH-THC concentrations (pg/mL) measured in blood
Program: pk-analysis\k374-tlf.sas

Table 14.2.1.6 - Summary of 11-COOH-THC concentrations (pg/mL) measured in blood - PK set

Product Use: Standardized

Statistics	Pre dose	1 min post dose	3 min post dose	6 min post dose	10 min post dose	15 min post dose	20 min post dose	30 min post dose	1 h post dose	2 h post dose	4 h post dose	6 h post dose	8 h post dose	12 h post dose	24 h post dose	48 h post dose	72 h post dose
N	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
Geo.Mean	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
Min	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
Mean	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
Max	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
SD	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
CV%	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
Q1	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
Median	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
Q3	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx

Source: Listing 16.2.5.9 - 11-COOH-THC concentrations (pg/mL) measured in blood
Program: pk-analysis\k374-tlf.sas

Table 14.2.1.6 - Summary of 11-COOH-THC concentrations (pg/mL) measured in blood - PK set

Product Use: Non-standardized

Statistics	Pre dose	1 min post dose	3 min post dose	6 min post dose	10 min post dose	15 min post dose	20 min post dose	30 min post dose	1 h post dose	2 h post dose	4 h post dose	6 h post dose	8 h post dose	12 h post dose	24 h post dose	48 h post dose	72 h post dose
N	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	---	---	---	---	---
Geo.Mean	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	---	---	---	---	---
Min	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	---	---	---	---	---
Mean	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	---	---	---	---	---
Max	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	---	---	---	---	---
SD	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	---	---	---	---	---
CV%	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	---	---	---	---	---
Q1	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	---	---	---	---	---
Median	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	---	---	---	---	---
Q3	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	---	---	---	---	---

Source: Listing 16.2.5.9 - 11-COOH-THC concentrations (pg/mL) measured in blood
Program: pk-analysis\k374-tlf.sas

Table 14.2.1.7 - Summary of CBD concentrations (pg/mL) measured in blood - PKPP set

Product Use: Standardized

Statistics	Pre dose	1 min post dose	3 min post dose	6 min post dose	10 min post dose	15 min post dose	20 min post dose	30 min post dose	1 h post dose	2 h post dose	4 h post dose	6 h post dose	8 h post dose	12 h post dose	24 h post dose	48 h post dose	72 h post dose
N	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
Geo.Mean	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
Min	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
Mean	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
Max	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
SD	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
CV%	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
Q1	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
Median	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
Q3	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx

Source: Listing 16.2.5.4 - CBD concentrations (pg/mL) measured in blood
Program: pk-analysis\k374-tlf.sas

Table 14.2.1.7 - Summary of CBD concentrations (pg/mL) measured in blood - PKPP set

Product Use: Non-standardized

Statistics	Pre dose	1 min post dose	3 min post dose	6 min post dose	10 min post dose	15 min post dose	20 min post dose	30 min post dose	1 h post dose	2 h post dose	4 h post dose	6 h post dose	8 h post dose	12 h post dose	24 h post dose	48 h post dose	72 h post dose
N	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	---	---	---	---	---
Geo.Mean	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	---	---	---	---	---
Min	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	---	---	---	---	---
Mean	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	---	---	---	---	---
Max	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	---	---	---	---	---
SD	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	---	---	---	---	---
CV%	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	---	---	---	---	---
Q1	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	---	---	---	---	---
Median	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	---	---	---	---	---
Q3	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	---	---	---	---	---

Source: Listing 16.2.5.4 - CBD concentrations (pg/mL) measured in blood
Program: pk-analysis\k374-tlf.sas

Table 14.2.1.8 - Summary of 7-OH-CBD concentrations (pg/mL) measured in blood - PKPP set

Product Use: Standardized

Statistics	Pre dose	1 min post dose	3 min post dose	6 min post dose	10 min post dose	15 min post dose	20 min post dose	30 min post dose	1 h post dose	2 h post dose	4 h post dose	6 h post dose	8 h post dose	12 h post dose	24 h post dose	48 h post dose	72 h post dose
N	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
Geo.Mean	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
Min	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
Mean	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
Max	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
SD	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
CV%	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
Q1	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
Median	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
Q3	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx

Source: Listing 16.2.5.5 - 7-OH-CBD concentrations (pg/mL) measured in blood
Program: pk-analysis\k374-tlf.sas

Table 14.2.1.8 - Summary of 7-OH-CBD concentrations (pg/mL) measured in blood - PKPP set

Product Use: Non-standardized

Statistics	Pre dose	1 min post dose	3 min post dose	6 min post dose	10 min post dose	15 min post dose	20 min post dose	30 min post dose	1 h post dose	2 h post dose	4 h post dose	6 h post dose	8 h post dose	12 h post dose	24 h post dose	48 h post dose	72 h post dose
N	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	---	---	---	---	---
Geo.Mean	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	---	---	---	---	---
Min	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	---	---	---	---	---
Mean	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	---	---	---	---	---
Max	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	---	---	---	---	---
SD	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	---	---	---	---	---
CV%	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	---	---	---	---	---
Q1	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	---	---	---	---	---
Median	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	---	---	---	---	---
Q3	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	---	---	---	---	---

Source: Listing 16.2.5.5 - 7-OH-CBD concentrations (pg/mL) measured in blood
Program: pk-analysis\k374-tlf.sas

Table 14.2.1.9 - Summary of 7-COOH-CBD concentrations (pg/mL) measured in blood - PKPP set

Product Use: Standardized

Statistics	Pre dose	1 min post dose	3 min post dose	6 min post dose	10 min post dose	15 min post dose	20 min post dose	30 min post dose	1 h post dose	2 h post dose	4 h post dose	6 h post dose	8 h post dose	12 h post dose	24 h post dose	48 h post dose	72 h post dose
N	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
Geo.Mean	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
Min	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
Mean	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
Max	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
SD	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
CV%	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
Q1	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
Median	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
Q3	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx

Source: Listing 16.2.5.6 - 7-COOH-CBD concentrations (pg/mL) measured in blood
Program: pk-analysis\k374-tlf.sas

Table 14.2.1.9 - Summary of 7-COOH-CBD concentrations (pg/mL) measured in blood - PKPP set

Product Use: Non-standardized

Statistics	Pre dose	1 min post dose	3 min post dose	6 min post dose	10 min post dose	15 min post dose	20 min post dose	30 min post dose	1 h post dose	2 h post dose	4 h post dose	6 h post dose	8 h post dose	12 h post dose	24 h post dose	48 h post dose	72 h post dose
N	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	---	---	---	---	---
Geo.Mean	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	---	---	---	---	---
Min	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	---	---	---	---	---
Mean	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	---	---	---	---	---
Max	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	---	---	---	---	---
SD	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	---	---	---	---	---
CV%	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	---	---	---	---	---
Q1	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	---	---	---	---	---
Median	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	---	---	---	---	---
Q3	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	---	---	---	---	---

Source: Listing 16.2.5.6 - 7-COOH-CBD concentrations (pg/mL) measured in blood
Program: pk-analysis\k374-tlf.sas

Table 14.2.1.10 - Summary of THC concentrations (pg/mL) measured in blood - PKPP set

Product Use: Standardized

Statistics	Pre dose	1 min post dose	3 min post dose	6 min post dose	10 min post dose	15 min post dose	20 min post dose	30 min post dose	1 h post dose	2 h post dose	4 h post dose	6 h post dose	8 h post dose	12 h post dose	24 h post dose	48 h post dose	72 h post dose
N	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
Geo.Mean	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
Min	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
Mean	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
Max	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
SD	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
CV%	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
Q1	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
Median	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
Q3	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx

Source: Listing 16.2.5.7 - THC concentrations (pg/mL) measured in blood
Program: pk-analysis\k374-tlf.sas

Table 14.2.1.10 - Summary of THC concentrations (pg/mL) measured in blood - PKPP set

Product Use: Non-standardized

Statistics	Pre dose	1 min post dose	3 min post dose	6 min post dose	10 min post dose	15 min post dose	20 min post dose	30 min post dose	1 h post dose	2 h post dose	4 h post dose	6 h post dose	8 h post dose	12 h post dose	24 h post dose	48 h post dose	72 h post dose
N	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	---	---	---	---	---
Geo.Mean	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	---	---	---	---	---
Min	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	---	---	---	---	---
Mean	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	---	---	---	---	---
Max	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	---	---	---	---	---
SD	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	---	---	---	---	---
CV%	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	---	---	---	---	---
Q1	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	---	---	---	---	---
Median	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	---	---	---	---	---
Q3	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	---	---	---	---	---

Source: Listing 16.2.5.7 - THC concentrations (pg/mL) measured in blood
Program: pk-analysis\k374-tlf.sas

Table 14.2.1.11 - Summary of 11-OH-THC concentrations (pg/mL) measured in blood - PKPP set

Product Use: Standardized

Statistics	Pre dose	1 min post dose	3 min post dose	6 min post dose	10 min post dose	15 min post dose	20 min post dose	30 min post dose	1 h post dose	2 h post dose	4 h post dose	6 h post dose	8 h post dose	12 h post dose	24 h post dose	48 h post dose	72 h post dose
N	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
Geo.Mean	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
Min	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
Mean	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
Max	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
SD	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
CV%	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
Q1	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
Median	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
Q3	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx

Source: Listing 16.2.5.8 - 11-OH-THC concentrations (pg/mL) measured in blood
Program: pk-analysis\k374-tlf.sas

Table 14.2.1.11 - Summary of 11-OH-THC concentrations (pg/mL) measured in blood - PKPP set

Product Use: Non-standardized

Statistics	Pre dose	1 min post dose	3 min post dose	6 min post dose	10 min post dose	15 min post dose	20 min post dose	30 min post dose	1 h post dose	2 h post dose	4 h post dose	6 h post dose	8 h post dose	12 h post dose	24 h post dose	48 h post dose	72 h post dose
N	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	---	---	---	---	---
Geo.Mean	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	---	---	---	---	---
Min	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	---	---	---	---	---
Mean	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	---	---	---	---	---
Max	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	---	---	---	---	---
SD	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	---	---	---	---	---
CV%	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	---	---	---	---	---
Q1	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	---	---	---	---	---
Median	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	---	---	---	---	---
Q3	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	---	---	---	---	---

Source: Listing 16.2.5.8 - 11-OH-THC concentrations (pg/mL) measured in blood
Program: pk-analysis\k374-tlf.sas

Table 14.2.1.12 - Summary of 11-COOH-THC concentrations (pg/mL) measured in blood - PKPP set

Product Use: Standardized

Statistics	Pre dose	1 min post dose	3 min post dose	6 min post dose	10 min post dose	15 min post dose	20 min post dose	30 min post dose	1 h post dose	2 h post dose	4 h post dose	6 h post dose	8 h post dose	12 h post dose	24 h post dose	48 h post dose	72 h post dose
N	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
Geo.Mean	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
Min	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
Mean	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
Max	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
SD	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
CV%	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
Q1	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
Median	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
Q3	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx

Source: Listing 16.2.5.9 - 11-COOH-THC concentrations (pg/mL) measured in blood
Program: pk-analysis\k374-tlf.sas

Table 14.2.1.12 - Summary of 11-COOH-THC concentrations (pg/mL) measured in blood - PKPP set

Product Use: Non-standardized

Statistics	Pre dose	1 min post dose	3 min post dose	6 min post dose	10 min post dose	15 min post dose	20 min post dose	30 min post dose	1 h post dose	2 h post dose	4 h post dose	6 h post dose	8 h post dose	12 h post dose	24 h post dose	48 h post dose	72 h post dose
N	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	---	---	---	---	---
Geo.Mean	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	---	---	---	---	---
Min	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	---	---	---	---	---
Mean	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	---	---	---	---	---
Max	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	---	---	---	---	---
SD	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	---	---	---	---	---
CV%	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	---	---	---	---	---
Q1	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	---	---	---	---	---
Median	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	---	---	---	---	---
Q3	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	---	---	---	---	---

Source: Listing 16.2.5.9 - 11-COOH-THC concentrations (pg/mL) measured in blood
Program: pk-analysis\k374-tlf.sas

Table 14.2.2.1 - Summary of CBD PK parameters - PK set

Product Use: Standardized

Statistics	**C_{max} (pg/mL)**	**t_{max} (h)**	**AUC_{0-t} (h*pg/mL)**	**AUC_{0-inf} (h*pg/mL)**	**AUC_{extra} (%)**	**$t_{½\ el}$ (h)**	**K_{el} (1/h)**	**CL/F (mL/min)**	**Vz/F (mL)**
N	xx	xx	xx	xx	xx	xx	xx	xx	xx
Geo.Mean	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Min	xxx.xx	xx.x	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Mean	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Max	xxx.xx	xx.x	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
SD	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
CV%	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Q1	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Median	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Q3	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx

Source: Listing 16.2.6.1 - CBD PK parameters
Program: pk-analysis\k374-tlf.sas

Table 14.2.2.1 - Summary of CBD PK parameters - PK set

Product Use: Non-standardized

Statistics	**C_{max} (pg/mL)**	**t_{max} (h)**	**AUC_{0-t} (h*pg/mL)**	**AUC_{0-inf} (h*pg/mL)**	**AUC_{extra} (%)**	**$t_{½\ el}$ (h)**	**K_{el} (1/h)**	**CL/F (mL/min)**	**Vz/F (mL)**
N	xx	xx	xx	xx	xx	xx	xx	xx	xx
Geo.Mean	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Min	xxx.xx	xx.x	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Mean	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Max	xxx.xx	xx.x	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
SD	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
CV%	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Q1	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Median	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Q3	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx

Source: Listing 16.2.6.1 - CBD PK parameters
Program: pk-analysis\k374-tlf.sas

Table 14.2.2.2 - Summary of 7-OH-CBD PK parameters - PK set

Product Use: Standardized

Statistics	**C_{max} (pg/mL)**	**t_{max} (h)**	**AUC_{0-t} (h*pg/mL)**	**AUC_{0-inf} (h*pg/mL)**	**AUC_{extra} (%)**	**$t_{½\ el}$ (h)**	**K_{el} (1/h)**
N	xx	xx	xx	xx	xx	xx	xx
Geo.Mean	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Min	xxx.xx	xx.x	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Mean	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Max	xxx.xx	xx.x	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
SD	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
CV%	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Q1	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Median	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Q3	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx

Source: Listing 16.2.6.2 - 7-OH-CBD PK parameters
Program: pk-analysis\k374-tlf.sas

Table 14.2.2.2 - Summary of 7-OH-CBD PK parameters - PK set

Product Use: Non-standardized

Statistics	**C_{max} (pg/mL)**	**t_{max} (h)**	**AUC_{0-t} (h*pg/mL)**	**AUC_{0-inf} (h*pg/mL)**	**AUC_{extra} (%)**	**$t_{½\ el}$ (h)**	**K_{el} (1/h)**
N	xx	xx	xx	xx	xx	xx	xx
Geo.Mean	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Min	xxx.xx	xx.x	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Mean	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Max	xxx.xx	xx.x	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
SD	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
CV%	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Q1	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Median	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Q3	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx

Source: Listing 16.2.6.2 - 7-OH-CBD PK parameters
Program: pk-analysis\k374-tlf.sas

Table 14.2.2.3 - Summary of 7-COOH-CBD PK parameters - PK set

Product Use: Standardized

Statistics	**C_{max} (pg/mL)**	**t_{max} (h)**	**AUC_{0-t} (h*pg/mL)**	**AUC_{0-inf} (h*pg/mL)**	**AUC_{extra} (%)**	**$t_{½\ el}$ (h)**	**K_{el} (1/h)**
N	xx	xx	xx	xx	xx	xx	xx
Geo.Mean	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Min	xxx.xx	xx.x	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Mean	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Max	xxx.xx	xx.x	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
SD	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
CV%	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Q1	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Median	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Q3	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx

Source: Listing 16.2.6.3 - 7-COOH-CBD PK parameters
Program: pk-analysis\k374-tlf.sas

Table 14.2.2.3 - Summary of 7-COOH-CBD PK parameters - PK set

Product Use: Non-standardized

Statistics	**C_{max} (pg/mL)**	**t_{max} (h)**	**AUC_{0-t} (h*pg/mL)**	**AUC_{0-inf} (h*pg/mL)**	**AUC_{extra} (%)**	**$t_{½\ el}$ (h)**	**K_{el} (1/h)**
N	xx	xx	xx	xx	xx	xx	xx
Geo.Mean	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Min	xxx.xx	xx.x	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Mean	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Max	xxx.xx	xx.x	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
SD	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
CV%	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Q1	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Median	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Q3	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx

Source: Listing 16.2.6.3 - 7-COOH-CBD PK parameters
Program: pk-analysis\k374-tlf.sas

Table 14.2.2.4 - Summary of THC PK parameters - PK set

Product Use: Standardized

Statistics	**C_{max} (pg/mL)**	**t_{max} (h)**	**AUC_{0-t} (h*pg/mL)**	**AUC_{0-inf} (h*pg/mL)**	**AUC_{extra} (%)**	**$t_{½\ el}$ (h)**	**K_{el} (1/h)**
N	xx	xx	xx	xx	xx	xx	xx
Geo.Mean	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Min	xxx.xx	xx.x	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Mean	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Max	xxx.xx	xx.x	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
SD	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
CV%	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Q1	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Median	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Q3	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx

Source: Listing 16.2.6.4 - THC PK parameters
Program: pk-analysis\k374-tlf.sas

Table 14.2.2.4 - Summary of THC PK parameters - PK set

Product Use: Non-standardized

Statistics	**C_{max} (pg/mL)**	**t_{max} (h)**	**AUC_{0-t} (h*pg/mL)**	**AUC_{0-inf} (h*pg/mL)**	**AUC_{extra} (%)**	**$t_{½\ el}$ (h)**	**K_{el} (1/h)**
N	xx	xx	xx	xx	xx	xx	xx
Geo.Mean	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Min	xxx.xx	xx.x	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Mean	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Max	xxx.xx	xx.x	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
SD	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
CV%	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Q1	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Median	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Q3	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx

Source: Listing 16.2.6.4 - THC PK parameters
Program: pk-analysis\k374-tlf.sas

Table 14.2.2.5 - Summary of 11-OH-THC PK parameters - PK set

Product Use: Standardized

Statistics	**C_{max} (pg/mL)**	**t_{max} (h)**	**AUC_{0-t} (h*pg/mL)**	**AUC_{0-inf} (h*pg/mL)**	**AUC_{extra} (%)**	**$t_{½\ el}$ (h)**	**K_{el} (1/h)**
N	xx	xx	xx	xx	xx	xx	xx
Geo.Mean	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Min	xxx.xx	xx.x	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Mean	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Max	xxx.xx	xx.x	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
SD	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
CV%	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Q1	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Median	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Q3	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx

Source: Listing 16.2.6.5 - 11-OH-THC PK parameters
Program: pk-analysis\k374-tlf.sas

Table 14.2.2.5 - Summary of 11-OH-THC PK parameters - PK set

Product Use: Non-standardized

Statistics	**C_{max} (pg/mL)**	**t_{max} (h)**	**AUC_{0-t} (h*pg/mL)**	**AUC_{0-inf} (h*pg/mL)**	**AUC_{extra} (%)**	**$t_{½\ el}$ (h)**	**K_{el} (1/h)**
N	xx	xx	xx	xx	xx	xx	xx
Geo.Mean	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Min	xxx.xx	xx.x	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Mean	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Max	xxx.xx	xx.x	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
SD	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
CV%	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Q1	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Median	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Q3	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx

Source: Listing 16.2.6.5 - 11-OH-THC PK parameters
Program: pk-analysis\k374-tlf.sas

Table 14.2.2.6 - Summary of 11-COOH-THC PK parameters - PK set

Product Use: Standardized

Statistics	**C_{max} (pg/mL)**	**t_{max} (h)**	**AUC_{0-t} (h*pg/mL)**	**AUC_{0-inf} (h*pg/mL)**	**AUC_{extra} (%)**	**$t_{½\ el}$ (h)**	**K_{el} (1/h)**
N	xx	xx	xx	xx	xx	xx	xx
Geo.Mean	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Min	xxx.xx	xx.x	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Mean	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Max	xxx.xx	xx.x	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
SD	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
CV%	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Q1	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Median	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Q3	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx

Source: Listing 16.2.6.6 - 11-COOH-THC PK parameters
Program: pk-analysis\k374-tlf.sas

Table 14.2.2.6 - Summary of 11-COOH-THC PK parameters - PK set

Product Use: Non-standardized

Statistics	**C_{max} (pg/mL)**	**t_{max} (h)**	**AUC_{0-t} (h*pg/mL)**	**AUC_{0-inf} (h*pg/mL)**	**AUC_{extra} (%)**	**$t_{½\ el}$ (h)**	**K_{el} (1/h)**
N	xx	xx	xx	xx	xx	xx	xx
Geo.Mean	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Min	xxx.xx	xx.x	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Mean	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Max	xxx.xx	xx.x	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
SD	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
CV%	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Q1	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Median	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Q3	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx

Source: Listing 16.2.6.6 - 11-COOH-THC PK parameters
Program: pk-analysis\k374-tlf.sas

Table 14.2.2.7 - Summary of CBD PK parameters - PKPP set

Product Use: Standardized

Statistics	**C_{max} (pg/mL)**	**t_{max} (h)**	**AUC_{0-t} (h*pg/mL)**	**AUC_{0-inf} (h*pg/mL)**	**AUC_{extra} (%)**	**$t_{½\ el}$ (h)**	**K_{el} (1/h)**	**CL/F (mL/min)**	**Vz/F (mL)**
N	xx	xx	xx	xx	xx	xx	xx	xx	xx
Geo.Mean	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Min	xxx.xx	xx.x	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Mean	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Max	xxx.xx	xx.x	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
SD	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
CV%	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Q1	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Median	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Q3	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx

Source: Listing 16.2.6.1 - CBD PK parameters
Program: pk-analysis\k374-tlf.sas

Table 14.2.2.7 - Summary of CBD PK parameters - PKPP set

Product Use: Non-standardized

Statistics	**C_{max} (pg/mL)**	**t_{max} (h)**	**AUC_{0-t} (h*pg/mL)**	**AUC_{0-inf} (h*pg/mL)**	**AUC_{extra} (%)**	**$t_{½\ el}$ (h)**	**K_{el} (1/h)**	**CL/F (mL/min)**	**Vz/F (mL)**
N	xx	xx	xx	xx	xx	xx	xx	xx	xx
Geo.Mean	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Min	xxx.xx	xx.x	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Mean	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Max	xxx.xx	xx.x	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
SD	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
CV%	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Q1	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Median	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Q3	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx

Source: Listing 16.2.6.1 - CBD PK parameters
Program: pk-analysis\k374-tlf.sas

Table 14.2.2.8 - Summary of 7-OH-CBD PK parameters - PKPP set

Product Use: Standardized

Statistics	**C_{max} (pg/mL)**	**t_{max} (h)**	**AUC_{0-t} (h*pg/mL)**	**AUC_{0-inf} (h*pg/mL)**	**AUC_{extra} (%)**	**$t_{½\ el}$ (h)**	**K_{el} (1/h)**
N	xx	xx	xx	xx	xx	xx	xx
Geo.Mean	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Min	xxx.xx	xx.x	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Mean	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Max	xxx.xx	xx.x	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
SD	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
CV%	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Q1	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Median	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Q3	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx

Source: Listing 16.2.6.2 - 7-OH-CBD PK parameters
Program: pk-analysis\k374-tlf.sas

Table 14.2.2.8 - Summary of 7-OH-CBD PK parameters - PKPP set

Product Use: Non-standardized

Statistics	**C_{max} (pg/mL)**	**t_{max} (h)**	**AUC_{0-t} (h*pg/mL)**	**AUC_{0-inf} (h*pg/mL)**	**AUC_{extra} (%)**	**$t_{½\ el}$ (h)**	**K_{el} (1/h)**
N	xx	xx	xx	xx	xx	xx	xx
Geo.Mean	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Min	xxx.xx	xx.x	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Mean	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Max	xxx.xx	xx.x	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
SD	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
CV%	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Q1	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Median	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Q3	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx

Source: Listing 16.2.6.2 - 7-OH-CBD PK parameters
Program: pk-analysis\k374-tlf.sas

Table 14.2.2.9 - Summary of 7-COOH-CBD PK parameters - PKPP set

Product Use: Standardized

Statistics	**C_{max} (pg/mL)**	**t_{max} (h)**	**AUC_{0-t} (h*pg/mL)**	**AUC_{0-inf} (h*pg/mL)**	**AUC_{extra} (%)**	**$t_{½\ el}$ (h)**	**K_{el} (1/h)**
N	xx	xx	xx	xx	xx	xx	xx
Geo.Mean	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Min	xxx.xx	xx.x	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Mean	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Max	xxx.xx	xx.x	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
SD	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
CV%	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Q1	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Median	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Q3	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx

Source: Listing 16.2.6.3 - 7-COOH-CBD PK parameters
Program: pk-analysis\k374-tlf.sas

Table 14.2.2.9 - Summary of 7-COOH-CBD PK parameters - PKPP set

Product Use: Non-standardized

Statistics	**C_{max} (pg/mL)**	**t_{max} (h)**	**AUC_{0-t} (h*pg/mL)**	**AUC_{0-inf} (h*pg/mL)**	**AUC_{extra} (%)**	**$t_{½\ el}$ (h)**	**K_{el} (1/h)**
N	xx	xx	xx	xx	xx	xx	xx
Geo.Mean	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Min	xxx.xx	xx.x	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Mean	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Max	xxx.xx	xx.x	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
SD	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
CV%	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Q1	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Median	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Q3	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx

Source: Listing 16.2.6.3 - 7-COOH-CBD PK parameters
Program: pk-analysis\k374-tlf.sas

Table 14.2.2.10 - Summary of THC PK parameters - PKPP set

Product Use: Standardized

Statistics	**C_{max} (pg/mL)**	**t_{max} (h)**	**AUC_{0-t} (h*pg/mL)**	**AUC_{0-inf} (h*pg/mL)**	**AUC_{extra} (%)**	**$t_{½\ el}$ (h)**	**K_{el} (1/h)**
N	xx	xx	xx	xx	xx	xx	xx
Geo.Mean	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Min	xxx.xx	xx.x	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Mean	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Max	xxx.xx	xx.x	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
SD	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
CV%	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Q1	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Median	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Q3	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx

Source: Listing 16.2.6.4 - THC PK parameters
Program: pk-analysis\k374-tlf.sas

Table 14.2.2.10 - Summary of THC PK parameters - PKPP set

Product Use: Non-standardized

Statistics	**C_{max} (pg/mL)**	**t_{max} (h)**	**AUC_{0-t} (h*pg/mL)**	**AUC_{0-inf} (h*pg/mL)**	**AUC_{extra} (%)**	**$t_{½\ el}$ (h)**	**K_{el} (1/h)**
N	xx	xx	xx	xx	xx	xx	xx
Geo.Mean	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Min	xxx.xx	xx.x	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Mean	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Max	xxx.xx	xx.x	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
SD	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
CV%	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Q1	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Median	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Q3	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx

Source: Listing 16.2.6.4 - THC PK parameters
Program: pk-analysis\k374-tlf.sas

Table 14.2.2.11 - Summary of 11-OH-THC PK parameters - PKPP set

Product Use: Standardized

Statistics	**C_{max} (pg/mL)**	**t_{max} (h)**	**AUC_{0-t} (h*pg/mL)**	**AUC_{0-inf} (h*pg/mL)**	**AUC_{extra} (%)**	**$t_{½\ el}$ (h)**	**K_{el} (1/h)**
N	xx	xx	xx	xx	xx	xx	xx
Geo.Mean	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Min	xxx.xx	xx.x	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Mean	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Max	xxx.xx	xx.x	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
SD	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
CV%	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Q1	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Median	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Q3	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx

Source: Listing 16.2.6.5 - 11-OH-THC PK parameters
Program: pk-analysis\k374-tlf.sas

Table 14.2.2.11 - Summary of 11-OH-THC PK parameters - PKPP set

Product Use: Non-standardized

Statistics	**C_{max} (pg/mL)**	**t_{max} (h)**	**AUC_{0-t} (h*pg/mL)**	**AUC_{0-inf} (h*pg/mL)**	**AUC_{extra} (%)**	**$t_{½\ el}$ (h)**	**K_{el} (1/h)**
N	xx	xx	xx	xx	xx	xx	xx
Geo.Mean	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Min	xxx.xx	xx.x	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Mean	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Max	xxx.xx	xx.x	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
SD	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
CV%	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Q1	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Median	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Q3	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx

Source: Listing 16.2.6.5 - 11-OH-THC PK parameters
Program: pk-analysis\k374-tlf.sas

Table 14.2.2.12 - Summary of 11-COOH-THC PK parameters - PKPP set

Product Use: Standardized

Statistics	**C_{max} (pg/mL)**	**t_{max} (h)**	**AUC_{0-t} (h*pg/mL)**	**AUC_{0-inf} (h*pg/mL)**	**AUC_{extra} (%)**	**$t_{½\ el}$ (h)**	**K_{el} (1/h)**
N	xx	xx	xx	xx	xx	xx	xx
Geo.Mean	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Min	xxx.xx	xx.x	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Mean	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Max	xxx.xx	xx.x	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
SD	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
CV%	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Q1	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Median	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Q3	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx

Source: Listing 16.2.6.6 - 11-COOH-THC PK parameters
Program: pk-analysis\k374-tlf.sas

Table 14.2.2.12 - Summary of 11-COOH-THC PK parameters - PKPP set

Product Use: Non-standardized

Statistics	**C_{max} (pg/mL)**	**t_{max} (h)**	**AUC_{0-t} (h*pg/mL)**	**AUC_{0-inf} (h*pg/mL)**	**AUC_{extra} (%)**	**$t_{½\ el}$ (h)**	**K_{el} (1/h)**
N	xx	xx	xx	xx	xx	xx	xx
Geo.Mean	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Min	xxx.xx	xx.x	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Mean	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Max	xxx.xx	xx.x	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
SD	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
CV%	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Q1	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Median	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx
Q3	xxx.xxx	xx.xx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx	xxx.xxx

Source: Listing 16.2.6.6 - 11-COOH-THC PK parameters
Program: pk-analysis\k374-tlf.sas

Table 14.2.3.1 - Descriptive statistics and contingency tables of Product Effect Questionnaire - Part 1 - Safety set

		Statistics	Standardized Use N=XX	Non-standardized Use N=XX
How soon after intake did you observe an effect?	After 15 min or less	n (%)	nn (xx.x)	nn (xx.x)
	After 15-30 min	n (%)	nn (xx.x)	nn (xx.x)
	After 30-60 min	n (%)	nn (xx.x)	nn (xx.x)
	After 60-120 min (1 to 2 hrs)	n (%)	nn (xx.x)	nn (xx.x)
	After 120 min and more (2hrs +)	n (%)	nn (xx.x)	nn (xx.x)
	I have not observed an effect yet	n (%)	nn (xx.x)	nn (xx.x)
Did you experience any of the following effects?	Stress reduction	n (%)	nn (xx.x)	nn (xx.x)
	Calming effects	n (%)	nn (xx.x)	nn (xx.x)
	Mindfulness	n (%)	nn (xx.x)	nn (xx.x)
	...	n (%)	nn (xx.x)	nn (xx.x)
How long did the effect last?	1 hour or less	n (%)	nn (xx.x)	nn (xx.x)
	1-3 hours	n (%)	nn (xx.x)	nn (xx.x)
	3-6 hours	n (%)	nn (xx.x)	nn (xx.x)
	Over 6 hours	n (%)	nn (xx.x)	nn (xx.x)
	I have not observed an effect yet	n (%)	nn (xx.x)	nn (xx.x)
How would you describe the effect of the product in words?	Cheerful	n (%)	nn (xx.x)	nn (xx.x)
	Disgusted	n (%)	nn (xx.x)	nn (xx.x)
	Attentive	n (%)	nn (xx.x)	nn (xx.x)
	Bashful	n (%)	nn (xx.x)	nn (xx.x)
	Sluggish	n (%)	nn (xx.x)	nn (xx.x)
	...	n (%)	nn (xx.x)	nn (xx.x)

Source: Listing 16.2.6.7 - Product Effect Questionnaire
Program: Tables\k374-qs-tbl.sas

Table 14.2.3.1 - Descriptive statistics and contingency tables of Product Effect Questionnaire - Part 1 - Safety set

		Statistics	Standardized Use N=XX	Non-standardized Use N=XX
How would you assess the intensity of the effect of this product? [cm]		N	nn	nn
		Mean	xx.x	xx.x
		SD	xx.x	xx.x
		CV%	xx.x	xx.x
		Min	xx	xx
		Median	xx.x	xx.x
		Max	xx	xx
How would you qualify your overall experience with this product?	Extremely dissatisfied	n (%)	nn (xx.x)	nn (xx.x)
	Somewhat dissatisfied	n (%)	nn (xx.x)	nn (xx.x)
	Neutral	n (%)	nn (xx.x)	nn (xx.x)
	Somewhat satisfied	n (%)	nn (xx.x)	nn (xx.x)
	Extremely satisfied	n (%)	nn (xx.x)	nn (xx.x)
How would you rate the taste/flavour of this product?	Poor	n (%)	nn (xx.x)	nn (xx.x)
	Fair	n (%)	nn (xx.x)	nn (xx.x)
	Good	n (%)	nn (xx.x)	nn (xx.x)
	Very good	n (%)	nn (xx.x)	nn (xx.x)
	Excellent	n (%)	nn (xx.x)	nn (xx.x)
	Not applicable	n (%)	nn (xx.x)	nn (xx.x)
How would you rate the aftertaste of this product?	Poor	n (%)	nn (xx.x)	nn (xx.x)
	Fair	n (%)	nn (xx.x)	nn (xx.x)
	Good	n (%)	nn (xx.x)	nn (xx.x)

Source: Listing 16.2.6.7 - Product Effect Questionnaire
Program: Tables\k374-qs-tbl.sas

Table 14.2.3.1 - Descriptive statistics and contingency tables of Product Effect Questionnaire - Part 1 - Safety set

		Statistics	Standardized Use N=XX	Non-standardized Use N=XX
How would you rate the aftertaste of this product?	Very good	n (%)	nn (xx.x)	nn (xx.x)
	Excellent	n (%)	nn (xx.x)	nn (xx.x)
	Not applicable	n (%)	nn (xx.x)	nn (xx.x)
How would you rate the mouthfeel/texture of this product?	Poor	n (%)	nn (xx.x)	nn (xx.x)
	Fair	n (%)	nn (xx.x)	nn (xx.x)
	Good	n (%)	nn (xx.x)	nn (xx.x)
	Very good	n (%)	nn (xx.x)	nn (xx.x)
	Excellent	n (%)	nn (xx.x)	nn (xx.x)
	Not applicable	n (%)	nn (xx.x)	nn (xx.x)
How would you rate the ease of use of this product?	Poor	n (%)	nn (xx.x)	nn (xx.x)
	Fair	n (%)	nn (xx.x)	nn (xx.x)
	Good	n (%)	nn (xx.x)	nn (xx.x)
	Very good	n (%)	nn (xx.x)	nn (xx.x)
	Excellent	n (%)	nn (xx.x)	nn (xx.x)
	Not applicable	n (%)	nn (xx.x)	nn (xx.x)

Source: Listing 16.2.6.7 - Product Effect Questionnaire
Program: Tables\k374-qs-tbl.sas

Table 14.2.3.2 - Descriptive statistics and contingency tables of Product Effect Questionnaire - Part 2 - Safety set

		Statistics	Non-standardized Use N=XX
Which CBD products have you taken in the past?	Oil (ingested)	n (%)	nn (xx.x)
	Oil (oral spray)	n (%)	nn (xx.x)
	Capsules/softgels	n (%)	nn (xx.x)
	Dissolvable lozenges	n (%)	nn (xx.x)
	...	n (%)	nn (xx.x)
What is the purpose for which you have taken CBD products?	Sleep issues	n (%)	nn (xx.x)
	Anxiety or stress	n (%)	nn (xx.x)
	Depression or low mood	n (%)	nn (xx.x)
	...	n (%)	nn (xx.x)
	Stress reduction	n (%)	nn (xx.x)
	Mindfulness	n (%)	nn (xx.x)
	Relaxation –calming effects	n (%)	nn (xx.x)
	...	n (%)	nn (xx.x)
	Recreational purposes	n (%)	nn (xx.x)
How often do you take CBD products?	Occasionally, less than once per month	n (%)	nn (xx.x)
	Once per month	n (%)	nn (xx.x)
	2-3 times every two weeks	n (%)	nn (xx.x)
	Once per week	n (%)	nn (xx.x)
	2-3 times per week	n (%)	nn (xx.x)
	Daily	n (%)	nn (xx.x)

Source: Listing 16.2.6.7 - Product Effect Questionnaire
Program: Tables\k374-qs-tbl.sas

Table 14.2.3.2 - Descriptive statistics and contingency tables of Product Effect Questionnaire - Part 2 - Safety set

		Statistics	Non-standardized Use N=XX
If daily, how much do you take on average per day? [mg]		N	nn
		Mean	xx.x
		SD	xx.x
		CV%	xx.x
		Min	xx
		Median	xx.x
		Max	xx
On a scale of 0 to 10, how likely are you to take the product you tested in this study again?	0 (Not at all likely)	n (%)	nn (xx.x)
	1	n (%)	nn (xx.x)
	2	n (%)	nn (xx.x)
	3	n (%)	nn (xx.x)
	4	n (%)	nn (xx.x)
	...	n (%)	nn (xx.x)
How much would you be willing to pay for the product you tested in the study?	Minimum and maximum price willing to pay	n (%)	nn (xx.x)
	I'mnot willing to pay for this product	n (%)	nn (xx.x)
	Unsure if I want to use/buy it	n (%)	nn (xx.x)
Minimum price willing to pay		N	nn
		Mean	xx.x
		SD	xx.x
		CV%	xx.x
		Min	xx

Source: Listing 16.2.6.7 - Product Effect Questionnaire
Program: Tables\k374-qs-tbl.sas

Table 14.2.3.2 - Descriptive statistics and contingency tables of Product Effect Questionnaire - Part 2 - Safety set

	Statistics	**Non-standardized Use N=XX**
Minimum price willing to pay	Median	xx.x
	Max	xx
Maximum price willing to pay	N	nn
	Mean	xx.x
	SD	xx.x
	CV%	xx.x
	Min	xx
	Median	xx.x
	Max	xx

Source: Listing 16.2.6.7 - Product Effect Questionnaire
Program: Tables\k374-qs-tbl.sas

Table 14.2.3.3 - Summary of Per-puff Parameters - Safety set

Product Use: Standardized
Smoking history: Overall

Statistics	Puff volume [Vi] (mL)	Puff duration [Di] (s)	Average flow [Qmi] (mL/s)	Peak flow [Qci] (mL/s)	Inter puff interval [Ii] (s)	Sum of Ii and Di [DFi] (s)	Peak flow position [PosQci] (%)
N	xx	xx	xx	xx	xx	xx	xx
Mean	x.xxxx	x.xxxx	x.xxxx	x.xxxx	x.xxxx	x.xxxx	x.xxxx
SD	x.xxxx	x.xxxx	x.xxxx	x.xxxx	x.xxxx	x.xxxx	x.xxxx
CV%	x.xxxx	x.xxxx	x.xxxx	x.xxxx	x.xxxx	x.xxxx	x.xxxx
Min	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
Median	x.xxxx	x.xxxx	x.xxxx	x.xxxx	x.xxxx	x.xxxx	x.xxxx
Max	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx

Source: Listing 16.2.6.8 - Per-puff Parameters
Program: pk-analysis\k374-tlf.sas

Table 14.2.3.3 - Summary of Per-puff Parameters - Safety set

Product Use: Standardized
Smoking history: Smokers

Statistics	Puff volume [Vi] (mL)	Puff duration [Di] (s)	Average flow [Qmi] (mL/s)	Peak flow [Qci] (mL/s)	Inter puff interval [Ii] (s)	Sum of Ii and Di [DFi] (s)	Peak flow position [PosQci] (%)
N	xx	xx	xx	xx	xx	xx	xx
Mean	x.xxxx	x.xxxx	x.xxxx	x.xxxx	x.xxxx	x.xxxx	x.xxxx
SD	x.xxxx	x.xxxx	x.xxxx	x.xxxx	x.xxxx	x.xxxx	x.xxxx
CV%	x.xxxx	x.xxxx	x.xxxx	x.xxxx	x.xxxx	x.xxxx	x.xxxx
Min	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
Median	x.xxxx	x.xxxx	x.xxxx	x.xxxx	x.xxxx	x.xxxx	x.xxxx
Max	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx

Source: Listing 16.2.6.8 - Per-puff Parameters
Program: pk-analysis\k374-tlf.sas

Table 14.2.3.3 - Summary of Per-puff Parameters - Safety set

Product Use: Standardized
Smoking history: Non-smokers or past smokers

Statistics	Puff volume [Vi] (mL)	Puff duration [Di] (s)	Average flow [Qmi] (mL/s)	Peak flow [Qci] (mL/s)	Inter puff interval [Ii] (s)	Sum of Ii and Di [DFi] (s)	Peak flow position [PosQci] (%)
N	xx	xx	xx	xx	xx	xx	xx
Mean	x.xxxx	x.xxxx	x.xxxx	x.xxxx	x.xxxx	x.xxxx	x.xxxx
SD	x.xxxx	x.xxxx	x.xxxx	x.xxxx	x.xxxx	x.xxxx	x.xxxx
CV%	x.xxxx	x.xxxx	x.xxxx	x.xxxx	x.xxxx	x.xxxx	x.xxxx
Min	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
Median	x.xxxx	x.xxxx	x.xxxx	x.xxxx	x.xxxx	x.xxxx	x.xxxx
Max	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx

Source: Listing 16.2.6.8 - Per-puff Parameters
Program: pk-analysis\k374-tlf.sas

Table 14.2.3.4 - Descriptive statistics of remaining CBD on stick and mouthpiece after use - Safety set

	Statistics	Standardized Use N=XX	Non-standardized Use N=XX
Remaining CBD on the stick (mg)	N	nn	nn
	Mean	x.xxxx	x.xxxx
	SD	x.xxxx	x.xxxx
	CV%	x.xxxx	x.xxxx
	Min	x.xxx	x.xxx
	Median	x.xxxx	x.xxxx
	Max	x.xxx	x.xxx
Remaining CBD on the mouthpiece (mg)	N	nn	nn
	Mean	x.xxxx	x.xxxx
	SD	x.xxxx	x.xxxx
	CV%	x.xxxx	x.xxxx
	Min	x.xxx	x.xxx
	Median	x.xxxx	x.xxxx
	Max	x.xxx	x.xxx

Source: Listing 16.2.6.10 - Remaining CBD on stick and mouthpiece after use
Program: Tables\k374-ex-tbl.sas

Table 14.2.3.5 - Correlation between the remaining CBD product in the HHnB device and the CBD blood levels - Safety set

	Standardized Use N=XX		Non-standardized Use N=XX	
	Coefficient	**p-value**	**Coefficient**	**p-value**
Remaining CBD on the stick vs. CBD AUC_{0-t}	xx.x	<0.001	xx.x	0.045
Remaining CBD on the stick vs. CBD C_{max}	xx.x	<0.001	xx.x	0.045
Remaining CBD on the mouthpiece vs. CBD AUC_{0-t}	xx.x	<0.001	xx.x	0.045
Remaining CBD on the mouthpiece vs. CBD C_{max}	xx.x	<0.001	xx.x	0.045

Note: Results are calculated using Pearson correlation coefficient
Source: Listing 16.2.6.10 - Remaining CBD on stick and mouthpiece after use, Listing 16.2.6.1 - CBD PK parameters
Program: Tables\k374-ex-tbl.sas

Table 14.2.3.6 - Statistical analysis on CBD PK parameters standardized VS non-standardized product use - PKPP set

Analysis	Dependent Variable	p Value
Wilcoxon signed-rank test	K_{el}	x.xxxx
Wilcoxon signed-rank test	$t_{½\ el}$	x.xxxx
Wilcoxon signed-rank test	AUC_{0-t}	x.xxxx
Wilcoxon signed-rank test	AUC_{0-inf}	x.xxxx
Wilcoxon signed-rank test	C_{max}	x.xxxx
Wilcoxon signed-rank test	t_{max}	x.xxxx

Source: Listing 16.2.6.1 - CBD PK parameters
Program: pk-analysis\k374-tlf.sas

Table 14.2.3.7 - Descriptive statistics of number of puffs - Safety set

	Statistics	**Standardized Use N=XX**	**Non-standardized Use N=XX**
Number of puffs	N	nn	nn
	Mean	xx.x	xx.x
	SD	xx.x	xx.x
	CV%	xx.x	xx.x
	Min	xx	xx
	Median	xx.x	xx.x
	Max	xx	xx

Source: Listing 16.2.5.1 - Study product administration
Program: Tables\k374-ex-tbl.sas

Table 14.3.1.1 - Global incidence of participants with treatment-emergent adverse events - Safety set

	Standardized Use N=XX n (%) [n AE]	Non-standardized Use N=XX n (%) [n AE]	Overall N=XX n (%) [n AE]
Treatment-emergent Adverse Events	nn (xx.x) [kk]	nn (xx.x) [kk]	nn (xx.x) [kk]
Adverse Event of Special Interest (AESI)	nn (xx.x) [kk]	nn (xx.x) [kk]	nn (xx.x) [kk]
Adverse Event indicating abuse potential	nn (xx.x) [kk]	nn (xx.x) [kk]	nn (xx.x) [kk]
Relationship	nn (xx.x) [kk]	nn (xx.x) [kk]	nn (xx.x) [kk]
Related	nn (xx.x) [kk]	nn (xx.x) [kk]	nn (xx.x) [kk]
Not related	nn (xx.x) [kk]	nn (xx.x) [kk]	nn (xx.x) [kk]
Severity	nn (xx.x) [kk]	nn (xx.x) [kk]	nn (xx.x) [kk]
Mild	nn (xx.x) [kk]	nn (xx.x) [kk]	nn (xx.x) [kk]
Moderate	nn (xx.x) [kk]	nn (xx.x) [kk]	nn (xx.x) [kk]
Severe	nn (xx.x) [kk]	nn (xx.x) [kk]	nn (xx.x) [kk]
Leading to study discontinuation	nn (xx.x) [kk]	nn (xx.x) [kk]	nn (xx.x) [kk]

Note:participants are summarised according to the relationship and intensity reported
The number (n) and the proportion of participants with any adverse event and the number of adverse events (n AE) for each classification level are reported _
The denominator for calculating the proportions is the number of participants in the safety set of each product use and overall
Source: Listing 16.2.7.1 - Treatment-emergent adverse events
Program: Tables\k374-ae-01-tbl.sas

Table 14.3.1.1 - Global incidence of participants with treatment-emergent adverse events - Safety set

	Standardized Use N=XX n (%) [n AE]	**Non-standardized Use N=XX n (%) [n AE]**	**Overall N=XX n (%) [n AE]**
Serious Treatment-emergent Adverse Events	nn (xx.x) [kk]	nn (xx.x) [kk]	nn (xx.x) [kk]
Adverse Event of Special Interest (AESI)	nn (xx.x) [kk]	nn (xx.x) [kk]	nn (xx.x) [kk]
Adverse Event indicating abuse potential	nn (xx.x) [kk]	nn (xx.x) [kk]	nn (xx.x) [kk]
Relationship	nn (xx.x) [kk]	nn (xx.x) [kk]	nn (xx.x) [kk]
Related	nn (xx.x) [kk]	nn (xx.x) [kk]	nn (xx.x) [kk]
Not related	nn (xx.x) [kk]	nn (xx.x) [kk]	nn (xx.x) [kk]
Severity	nn (xx.x) [kk]	nn (xx.x) [kk]	nn (xx.x) [kk]
Mild	nn (xx.x) [kk]	nn (xx.x) [kk]	nn (xx.x) [kk]
Moderate	nn (xx.x) [kk]	nn (xx.x) [kk]	nn (xx.x) [kk]
Severe	nn (xx.x) [kk]	nn (xx.x) [kk]	nn (xx.x) [kk]
Leading to study discontinuation	nn (xx.x) [kk]	nn (xx.x) [kk]	nn (xx.x) [kk]

Note:participants are summarised according to the relationship and intensity reported
The number (n) and the proportion of participants with any adverse event and the number of adverse events (n AE) for each classification level are reported _
The denominator for calculating the proportions is the number of participants in the safety set of each product use and overall
Source: Listing 16.2.7.1 - Treatment-emergent adverse events
Program: Tables\k374-ae-01-tbl.sas

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

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

Note: The number (n) and the proportion of Participants with any adverse event and the number of adverse events (n AE) for each classification level are reported
The denominator for calculating the proportions is the number of Participants in the safety set of each product use and overall
Note 1: MedDRA version 28.0
Source: Listing 16.2.7.1 - Treatment-emergent adverse events
Program: Tables\k374-ae-02-tbl.sas

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

	Standardized Use N=XX			Non-standardized Use N=XX			Overall N=XX		
System Organ Class [1] **Preferred Term [1]**	**Mild** **n (%) [n AE]**	**Moderate** **n (%) [n AE]**	**Severe** **n (%) [n AE]**	**Mild** **n (%) [n AE]**	**Moderate** **n (%) [n AE]**	**Severe** **n (%) [n AE]**	**Mild** **n (%) [n AE]**	**Moderate** **n (%) [n AE]**	**Severe** **n (%) [n AE]**
Treatment-emergent Adverse Events	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]
Nervous system disorders	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]
Headache	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]
...	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]
Gastrointestinal disorders	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]
Abdominal pain upper	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]
Diarrhoea	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]
...	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]

Note: The number (n) and the proportion of participants with any adverse event and the number of adverse events (n AE) for each classification level are reported
The denominator for calculating the proportions is the number of Participants in the safety set of each product use and overall
Note 1: MedDRA version 28.0
Source: Listing 16.2.7.1 - Treatment-emergent adverse events
Program: Tables\k374-ae-02-tbl.sas

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

System Organ Class [1] **Preferred Term** [1]	**Standardized Use** **N=XX** **n (%) [n AE]**	**Non-standardized Use** **N=XX** **n (%) [n AE]**	**Overall** **N=XX** **n (%) [n AE]**
Treatment-emergent Adverse Events related to the study product	nn (xx.x) [kk]	nn (xx.x) [kk]	nn (xx.x) [kk]
Nervous system disorders	nn (xx.x) [kk]	nn (xx.x) [kk]	nn (xx.x) [kk]
Headache	nn (xx.x) [kk]	nn (xx.x) [kk]	nn (xx.x) [kk]
...	nn (xx.x) [kk]	nn (xx.x) [kk]	nn (xx.x) [kk]
Gastrointestinal disorders	nn (xx.x) [kk]	nn (xx.x) [kk]	nn (xx.x) [kk]
Abdominal pain upper	nn (xx.x) [kk]	nn (xx.x) [kk]	nn (xx.x) [kk]
Diarrhoea	nn (xx.x) [kk]	nn (xx.x) [kk]	nn (xx.x) [kk]
...	nn (xx.x) [kk]	nn (xx.x) [kk]	nn (xx.x) [kk]

Note: The number (n) and the proportion of participants with any related adverse event and the number of related adverse events (n AE) for each classification level are reported
The denominator for calculating the proportions is the number of Participants in the safety set of each product use and overall
Note 1: MedDRA version 28.0
Source: Listing 16.2.7.1 - Treatment-emergent adverse events
Program: Tables\k374-ae-02-tbl.sas

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

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

Note: The number (n) and the proportion of participants with any serious adverse event and the number of serious adverse events (n AE) for each classification level are reported
The denominator for calculating the proportions is the number of Participants in the safety set of each product use and overall
Note 1: MedDRA version 28.0
Source: Listing 16.2.7.1 - Treatment-emergent adverse events
Program: Tables\k374-ae-02-tbl.sas

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

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

Note: The number (n) and the proportion of participants with any serious related adverse event and the number of serious related adverse events (n AE) for each classification level a re reported

The denominator for calculating the proportions is the number of Participants in the safety set of each product use and overall _

Note 1: MedDRA version 28.0

Source: Listing 16.2.7.1 - Treatment-emergent adverse events

Program: Tables\k374-ae-02-tbl.sas

Table 14.3.1.7 - Participants with treatment-emergent adverse events of special interest (AESI) by system organ class and preferred term - Safety set

System Organ Class [1] **Preferred Term** [1]	**Standardized Use** **N=XX** **n (%) [n AE]**	**Non-standardized Use** **N=XX** **n (%) [n AE]**	**Overall** **N=XX** **n (%) [n AE]**
Treatment-emergent Adverse Events of Special Interest (AESI)	nn (xx.x) [kk]	nn (xx.x) [kk]	nn (xx.x) [kk]
Nervous system disorders	nn (xx.x) [kk]	nn (xx.x) [kk]	nn (xx.x) [kk]
Headache	nn (xx.x) [kk]	nn (xx.x) [kk]	nn (xx.x) [kk]
...	nn (xx.x) [kk]	nn (xx.x) [kk]	nn (xx.x) [kk]
Gastrointestinal disorders	nn (xx.x) [kk]	nn (xx.x) [kk]	nn (xx.x) [kk]
Abdominal pain upper	nn (xx.x) [kk]	nn (xx.x) [kk]	nn (xx.x) [kk]
Diarrhoea	nn (xx.x) [kk]	nn (xx.x) [kk]	nn (xx.x) [kk]
...	nn (xx.x) [kk]	nn (xx.x) [kk]	nn (xx.x) [kk]

Note: The number (n) and the proportion of participants with any AESI and the number of AESI (n AE) for each classification level are reported
The denominator for calculating the proportions is the number of Participants in the safety set of each product use and overall
Note 1: MedDRA version 28.0
Source: Listing 16.2.7.1 - Treatment-emergent adverse events
Program: Tables\k374-ae-02-tbl.sas

Table 14.3.1.8 - Participants with treatment-emergent adverse events indicating abuse potential by system organ class and preferred term - Safety set

System Organ Class [1] **Preferred Term** [1]	**Standardized Use** **N=XX** **n (%) [n AE]**	**Non-standardized Use** **N=XX** **n (%) [n AE]**	**Overall** **N=XX** **n (%) [n AE]**
Treatment-emergent Adverse Events indicating abuse potential	nn (xx.x) [kk]	nn (xx.x) [kk]	nn (xx.x) [kk]
Nervous system disorders	nn (xx.x) [kk]	nn (xx.x) [kk]	nn (xx.x) [kk]
Headache	nn (xx.x) [kk]	nn (xx.x) [kk]	nn (xx.x) [kk]
...	nn (xx.x) [kk]	nn (xx.x) [kk]	nn (xx.x) [kk]
Gastrointestinal disorders	nn (xx.x) [kk]	nn (xx.x) [kk]	nn (xx.x) [kk]
Abdominal pain upper	nn (xx.x) [kk]	nn (xx.x) [kk]	nn (xx.x) [kk]
Diarrhoea	nn (xx.x) [kk]	nn (xx.x) [kk]	nn (xx.x) [kk]
...	nn (xx.x) [kk]	nn (xx.x) [kk]	nn (xx.x) [kk]

Note: The number (n) and the proportion of Participants with any AE indicating abuse potential and the number of AE indicating abuse potential (n AE) for each classification level are reported

The denominator for calculating the proportions is the number of Participants in the safety set of each product use and overall

Note 1: MedDRA version 28.0

Source: Listing 16.2.7.1 - Treatment-emergent adverse events

Program: Tables\k374-ae-02-tbl.sas

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

Product Use: Standardized

Participant ID	Adverse Event ID	Follow Up ID		
S001/001	1		Description:	Headache
			Preferred Term [1]:	Headache
			System Organ Class [1]:	Nervous system disorders
			Adverse event of special interest (AESI)?	N
			Body Area Affected:	NA
			Visit Date of AE recording (Day):	ddMMMyyyy (k)
			AE Frequency:	Single Event
			Severity:	Mild
			Serious Adverse Event?	N
			Reasonable possibility of a causal relationship with study product?	Y
			Other Causal Relationship:	NA
			Action taken with Study Product:	Dose Not Changed
			Concomitant Therapy?	Y
			Other Action Taken:	N
			Start - End Date/Time (Day):	ddMMMyyyy hh:mm (k) - ddMMMyyyy hh:mm (k+n)
			AE Duration:	hh:mm
			Has the Adverse Event Started After the Administration of the Study Product?	Y
			Last Study Product Administration Date/Time Before Onset (Day):	ddMMMyyyy hh:mm:ss (k)
			Time Elapsed form Last Study Product intake before AE:	hh:mm
			Outcome:	Recovered/Resolved
			Caused Study Discontinuation?	N
...	...	...	...	...

Note 1: MedDRA version 28.0
Source: Listing 16.2.7.1 - Treatment-emergent adverse events
Program: Tables\k374-ae-03-tbl.sas

Table 14.3.4.1 - Abnormal laboratory values - Safety set

Category of Laboratory Parameters: HAEMATOLOGY

Participant ID	Time Point	Collection Date/time	Parameter	Value and Abnormality [1]	Normal Range or Reference Value	Clinically Significant?
01-001/001	Screening	ddMMMyyyy hh:mm	Leukocytes [10^9/L]	10.02 [A]	4.00 - 10.00	N
01-001/001	End of Study	ddMMMyyyy hh:mm	Monocytes [10^9/L]	1.2 [A]	0.1 - 0.9	N
...	...	...	...	...	...	...

Note 1: N=Normal, A=Abnormal
Source: Listing 16.2.8.1 - Individual laboratory measurements
Program: Tables\k374-lb-tbl.sas

Table 14.3.4.1 - Abnormal laboratory values - Safety set

Category of Laboratory Parameters: BLOOD CHEMISTRY

Participant ID	Time Point	Collection Date/time	Parameter	Value and Abnormality [1]	Normal Range or Reference Value	Clinically Significant?
01-001/001	Screening	ddMMMyyyy hh:mm	Chloride [mmol/L]	84 [A]	96-110	N
01-001/001	End of Study	ddMMMyyyy hh:mm	Phosphate [mmol/L]	1.53 [A]	0.87 - 1.45	N
...	...	...	...	...	...	...

Note 1: N=Normal, A=Abnormal
Source: Listing 16.2.8.1 - Individual laboratory measurements
Program: Tables\k374-lb-tbl.sas

Table 14.3.4.1 - Abnormal laboratory values - Safety set

Category of Laboratory Parameters: URINE ANALYSIS

Participant ID	Time Point	Collection Date/time	Parameter	Value and Abnormality [1]	Normal Range or Reference Value	Clinically Significant?
01-001/001	Screening	ddMMMyyyy hh:mm	Urinary Haemoglobin	+++ [A]	Absent	N
01-001/001	End of Study	ddMMMyyyy hh:mm	Ketones	+ [A]	Absent	N
...	...	...	...	...	...	...

Note 1: N=Normal, A=Abnormal
Source: Listing 16.2.8.1 - Individual laboratory measurements
Program: Tables\k374-lb-tbl.sas

Table 14.3.4.2 - Descriptive statistics of laboratory results and their changes from baseline - Safety set

Category of Laboratory Parameters: HAEMATOLOGY

Parameter	Time Point	Statistics	Overall N=XX Value	Change from baseline
Erythrocytes [10^12/L]	Screening	N	nn	
		Mean	xxx.x	---
		SD	xxx.x	---
		CV%	xxx.x	---
		Min	xxx	---
		Median	xxx.x	---
		Max	xxx	---
Erythrocytes [10^12/L]	End of Study	N	nn	nn
		Mean	xxx.x	xxx.x
		SD	xxx.x	xxx.x
		CV%	xxx.x	xxx.x
		Min	xxx	xxx
		Median	xxx.x	xxx.x
		Max	xxx	xxx
Leukocytes [10^9/L]	Screening	N	nn	
		Mean	xxx.x	---
		SD	xxx.x	---
		CV%	xxx.x	---
		Min	xxx	---
		Median	xxx.x	---
		Max	xxx	---

Source: Listing 16.2.8.1 - Individual laboratory measurements
Program: Tables\k374-lb-tbl.sas

Table 14.3.4.2 - Descriptive statistics of laboratory results and their changes from baseline - Safety set

Category of Laboratory Parameters: HAEMATOLOGY

Parameter	Time Point	Statistics	Overall N=XX Value	Change from baseline
Leukocytes [10^9/L]	End of Study	N	nn	nn
		Mean	xxx.x	xxx.x
		SD	xxx.x	xxx.x
		CV%	xxx.x	xxx.x
		Min	xxx	xxx
		Median	xxx.x	xxx.x
		Max	xxx	xxx
....	Screening	N	nn	
		Mean	xxx.x	---
		SD	xxx.x	---
		CV%	xxx.x	---
		Min	xxx	---
		Median	xxx.x	---
		Max	xxx	---
....	End of Study	N	nn	nn
		Mean	xxx.x	xxx.x
		SD	xxx.x	xxx.x
		CV%	xxx.x	xxx.x
		Min	xxx	xxx
		Median	xxx.x	xxx.x
		Max	xxx	xxx

Source: Listing 16.2.8.1 - Individual laboratory measurements
Program: Tables\k374-lb-tbl.sas

Table 14.3.4.2 - Descriptive statistics of laboratory results and their changes from baseline - Safety set

Category of Laboratory Parameters: BLOOD CHEMISTRY

Parameter	Time Point	Statistics	Overall N=XX Value	Change from baseline
Sodium [mmol/L]	Screening	N	nn	
		Mean	xxx.x	---
		SD	xxx.x	---
		CV%	xxx.x	---
		Min	xxx	---
		Median	xxx.x	---
		Max	xxx	---
Sodium [mmol/L]	End of Study	N	nn	nn
		Mean	xxx.x	xxx.x
		SD	xxx.x	xxx.x
		CV%	xxx.x	xxx.x
		Min	xxx	xxx
		Median	xxx.x	xxx.x
		Max	xxx	xxx
Potassium [mmol/L]	Screening	N	nn	
		Mean	xxx.x	---
		SD	xxx.x	---
		CV%	xxx.x	---
		Min	xxx	---
		Median	xxx.x	---
		Max	xxx	---

Source: Listing 16.2.8.1 - Individual laboratory measurements
Program: Tables\k374-lb-tbl.sas

Table 14.3.4.2 - Descriptive statistics of laboratory results and their changes from baseline - Safety set

Category of Laboratory Parameters: BLOOD CHEMISTRY

Parameter	Time Point	Statistics	Overall N=XX Value	Change from baseline
Potassium [mmol/L]	End of Study	N	nn	nn
		Mean	xxx.x	xxx.x
		SD	xxx.x	xxx.x
		CV%	xxx.x	xxx.x
		Min	xxx	xxx
		Median	xxx.x	xxx.x
		Max	xxx	xxx
....	Screening	N	nn	
		Mean	xxx.x	---
		SD	xxx.x	---
		CV%	xxx.x	---
		Min	xxx	---
		Median	xxx.x	---
		Max	xxx	---
....	End of Study	N	nn	nn
		Mean	xxx.x	xxx.x
		SD	xxx.x	xxx.x
		CV%	xxx.x	xxx.x
		Min	xxx	xxx
		Median	xxx.x	xxx.x
		Max	xxx	xxx

Source: Listing 16.2.8.1 - Individual laboratory measurements
Program: Tables\k374-lb-tbl.sas

Table 14.3.4.3 - Contingency tables of investigator's interpretation of laboratory test results - Safety set

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

Note: The number and the proportion of Participants for each classification level are reported
The denominator for calculating the proportions is the number of participants in the safety set
Source: Listing 16.2.8.2 - Investigator's interpretation of laboratory test results
Program: Tables\k374-lb-tbl.sas

Table 14.3.5.1 - Abnormal vital signs - Safety set

Participant ID	Product Use	Time Point	Assessment Date/Time	Parameter	Value	Normal Range
01-001/001		Screening	ddMMMyyyy hh:mm	Systolic Blood Pressure [mmHg]	96	100-139
01-001/001		End of Study	ddMMMyyyy hh:mm	Diastolic Blood Pressure [mmHg]	48	50-89
01-003/002	Standardized	Visit 3 - Day 1 - Pre-dose	ddMMMyyyy hh:mm	Systolic Blood Pressure [mmHg]	141	100-139
...	...	...	...	...	...	...

Source: Listing 16.2.9.1 - Vital signs and changes from baseline
Program: Tables\k374-vs-tbl.sas

Table 14.3.5.2 - Descriptive statistics of vital signs and their changes from baseline - Safety set

Parameter	Time Point	Statistics	Overall N=XX Value	Change from baseline
Systolic Blood Pressure [mmHg]	Screening	N	nn	---
		Mean	xxx.x	---
		SD	xxx.x	---
		CV%	xxx.x	---
		Min	xxx	---
		Median	xxx.x	---
		Max	xxx	---
Systolic Blood Pressure [mmHg]	Visit 2 - Day -1	N	nn	---
		Mean	xxx.x	---
		SD	xxx.x	---
		CV%	xxx.x	---
		Min	---	---
		Median	xxx.x	---
		Max	---	---
Systolic Blood Pressure [mmHg]	Visit 3 - Day 1 - Pre-dose	N	nn	---
		Mean	xxx.x	---
		SD	xxx.x	---
		CV%	xxx.x	---
		Min	xxx	---
		Median	xxx.x	---
		Max	xxx	---

Source: Listing 16.2.9.1 - Vital signs and changes from baseline
Program: Tables\k374-vs-tbl.sas

Table 14.3.5.2 - Descriptive statistics of vital signs and their changes from baseline - Safety set

Parameter	Time Point	Statistics	Overall N=XX Value	Change from baseline
Systolic Blood Pressure [mmHg]	Visit 3 - Day 1 - 2h post-dose	N	nn	nn
		Mean	xxx.x	xxx.x
		SD	xxx.x	xxx.x
		CV%	xxx.x	xxx.x
		Min	xxx	xxx
		Median	xxx.x	xxx.x
		Max	xxx	xxx
Systolic Blood Pressure [mmHg]	Visit 3 - Day 1 - 4h post-dose	N	nn	nn
		Mean	xxx.x	xxx.x
		SD	xxx.x	xxx.x
		CV%	xxx.x	xxx.x
		Min	xxx	xxx
		Median	xxx.x	xxx.x
		Max	xxx	xxx
Systolic Blood Pressure [mmHg]	Visit 3 - Day 1 - 6h post-dose	N	nn	nn
		Mean	xxx.x	xxx.x
		SD	xxx.x	xxx.x
		CV%	xxx.x	xxx.x
		Min	xxx	xxx
		Median	xxx.x	xxx.x
		Max	xxx	xxx

Source: Listing 16.2.9.1 - Vital signs and changes from baseline
Program: Tables\k374-vs-tbl.sas

Table 14.3.5.2 - Descriptive statistics of vital signs and their changes from baseline - Safety set

Parameter	Time Point	Statistics	Overall N=XX Value	Change from baseline
Systolic Blood Pressure [mmHg]	...	N	nn	nn
		Mean	xxx.x	xxx.x
		SD	xxx.x	xxx.x
		CV%	xxx.x	xxx.x
		Min	xxx	xxx
		Median	xxx.x	xxx.x
		Max	xxx	xxx
Diastolic Blood Pressure [mmHg]	Screening	N	nn	---
		Mean	xxx.x	---
		SD	xxx.x	---
		CV%	xxx.x	---
		Min	xxx	---
		Median	xxx.x	---
		Max	xxx	---
Diastolic Blood Pressure [mmHg]	Visit 2 - Day -1	N	nn	---
		Mean	xxx.x	---
		SD	xxx.x	---
		CV%	xxx.x	---
		Min	---	---
		Median	xxx.x	---
		Max	---	---

Source: Listing 16.2.9.1 - Vital signs and changes from baseline
Program: Tables\k374-vs-tbl.sas

Table 14.3.5.2 - Descriptive statistics of vital signs and their changes from baseline - Safety set

Parameter	Time Point	Statistics	Overall N=XX Value	Change from baseline
Diastolic Blood Pressure [mmHg]	Visit 3 - Day 1 - Pre-dose	N	nn	---
		Mean	xxx.x	---
		SD	xxx.x	---
		CV%	xxx.x	---
		Min	xxx	---
		Median	xxx.x	---
		Max	xxx	---
Diastolic Blood Pressure [mmHg]	Visit 3 - Day 1 - 2h post-dose	N	nn	nn
		Mean	xxx.x	xxx.x
		SD	xxx.x	xxx.x
		CV%	xxx.x	xxx.x
		Min	xxx	xxx
		Median	xxx.x	xxx.x
		Max	xxx	xxx
Diastolic Blood Pressure [mmHg]	Visit 3 - Day 1 - 4h post-dose	N	nn	nn
		Mean	xxx.x	xxx.x
		SD	xxx.x	xxx.x
		CV%	xxx.x	xxx.x
		Min	xxx	xxx
		Median	xxx.x	xxx.x
		Max	xxx	xxx

Source: Listing 16.2.9.1 - Vital signs and changes from baseline
Program: Tables\k374-vs-tbl.sas

Table 14.3.5.2 - Descriptive statistics of vital signs and their changes from baseline - Safety set

Parameter	Time Point	Statistics	Overall N=XX Value	Change from baseline
Diastolic Blood Pressure [mmHg]	Visit 3 - Day 1 - 6h post-dose	N	nn	nn
		Mean	xxx.x	xxx.x
		SD	xxx.x	xxx.x
		CV%	xxx.x	xxx.x
		Min	xxx	xxx
		Median	xxx.x	xxx.x
		Max	xxx	xxx
Diastolic Blood Pressure [mmHg]	...	N	nn	nn
		Mean	xxx.x	xxx.x
		SD	xxx.x	xxx.x
		CV%	xxx.x	xxx.x
		Min	xxx	xxx
		Median	xxx.x	xxx.x
		Max	xxx	xxx
Pulse Rate [beats/min]	Screening	N	nn	---
		Mean	xxx.x	---
		SD	xxx.x	---
		CV%	xxx.x	---
		Min	xxx	---
		Median	xxx.x	---
		Max	xxx	---

Source: Listing 16.2.9.1 - Vital signs and changes from baseline
Program: Tables\k374-vs-tbl.sas

Table 14.3.5.2 - Descriptive statistics of vital signs and their changes from baseline - Safety set

Parameter	Time Point	Statistics	Overall N=XX Value	Change from baseline
Pulse Rate [beats/min]	Visit 2 - Day -1	N	nn	---
		Mean	xxx.x	---
		SD	xxx.x	---
		CV%	xxx.x	---
		Min	---	---
		Median	xxx.x	---
		Max	---	---
Pulse Rate [beats/min]	Visit 3 - Day 1 - Pre-dose	N	nn	---
		Mean	xxx.x	---
		SD	xxx.x	---
		CV%	xxx.x	---
		Min	xxx	---
		Median	xxx.x	---
		Max	xxx	---
Pulse Rate [beats/min]	Visit 3 - Day 1 - 2h post-dose	N	nn	nn
		Mean	xxx.x	xxx.x
		SD	xxx.x	xxx.x
		CV%	xxx.x	xxx.x
		Min	xxx	xxx
		Median	xxx.x	xxx.x
		Max	xxx	xxx

Source: Listing 16.2.9.1 - Vital signs and changes from baseline
Program: Tables\k374-vs-tbl.sas

Table 14.3.5.2 - Descriptive statistics of vital signs and their changes from baseline - Safety set

Parameter	Time Point	Statistics	Overall N=XX Value	Change from baseline
Pulse Rate [beats/min]	Visit 3 - Day 1 - 4h post-dose	N	nn	nn
		Mean	xxx.x	xxx.x
		SD	xxx.x	xxx.x
		CV%	xxx.x	xxx.x
		Min	xxx	xxx
		Median	xxx.x	xxx.x
		Max	xxx	xxx
Pulse Rate [beats/min]	Visit 3 - Day 1 - 6h post-dose	N	nn	nn
		Mean	xxx.x	xxx.x
		SD	xxx.x	xxx.x
		CV%	xxx.x	xxx.x
		Min	xxx	xxx
		Median	xxx.x	xxx.x
		Max	xxx	xxx
Pulse Rate [beats/min]	...	N	nn	nn
		Mean	xxx.x	xxx.x
		SD	xxx.x	xxx.x
		CV%	xxx.x	xxx.x
		Min	xxx	xxx
		Median	xxx.x	xxx.x
		Max	xxx	xxx

Source: Listing 16.2.9.1 - Vital signs and changes from baseline
Program: Tables\k374-vs-tbl.sas

Table 14.3.5.2 - Descriptive statistics of vital signs and their changes from baseline - Safety set

Parameter	Time Point	Statistics	Value Overall N=XX	Change from baseline
Respiratory Rate [breaths/min]	Screening	N	nn	---
		Mean	xxx.x	---
		SD	xxx.x	---
		CV%	xxx.x	---
		Min	xxx	---
		Median	xxx.x	---
		Max	xxx	---
Respiratory Rate [breaths/min]	Visit 2 - Day -1	N	nn	---
		Mean	xxx.x	---
		SD	xxx.x	---
		CV%	xxx.x	---
		Min	---	---
		Median	xxx.x	---
		Max	---	---
Tympanic body temperature [°C]	Screening	N	nn	---
		Mean	xxx.x	---
		SD	xxx.x	---
		CV%	xxx.x	---
		Min	xxx	---
		Median	xxx.x	---
		Max	xxx	---

Source: Listing 16.2.9.1 - Vital signs and changes from baseline
Program: Tables\k374-vs-tbl.sas

Table 14.3.5.2 - Descriptive statistics of vital signs and their changes from baseline - Safety set

Parameter	Time Point	Statistics	Overall N=XX Value	Change from baseline
Tympanic body temperature [°C]	Visit 2 - Day -1	N	nn	---
		Mean	xxx.x	---
		SD	xxx.x	---
		CV%	xxx.x	---
		Min	---	---
		Median	xxx.x	---
		Max	---	---

Source: Listing 16.2.9.1 - Vital signs and changes from baseline
Program: Tables\k374-vs-tbl.sas

Table 14.3.5.3 - Descriptive statistics of body weight and their changes from baseline - Safety set

Parameter	Time Point	Statistics	Value	Change from baseline
Body weight [kg]	Screening	N	nn	---
		Mean	xxx.x	---
		SD	xxx.x	---
		CV%	xxx.x	---
		Min	xxx	---
		Median	xxx.x	---
		Max	xxx	---
Body weight [kg]	End of Study	N	nn	nn
		Mean	xxx.x	xxx.x
		SD	xxx.x	xxx.x
		CV%	xxx.x	xxx.x
		Min	xxx	xxx
		Median	xxx.x	xxx.x
		Max	xxx	xxx

Source: Listing 16.2.9.2 - Body weight and changes from baseline
Program: Tables\k374-vs-tbl.sas

Table 14.3.5.4 - Descriptive statistics of ECG parameters and their changes from baseline - Safety set

Parameter	Time Point	Statistics	Value	Change from baseline
Heart Rate [beats/min]	Screening	N	nn	--
		Mean	xxx.x	---
		SD	xxx.x	---
		CV%	xxx.x	---
		Min	xxx	---
		Median	xxx.x	---
		Max	xxx	---
Heart Rate [beats/min]	Day 1 - Post-dose	N	nn	--
		Mean	xxx.x	---
		SD	xxx.x	---
		CV%	xxx.x	---
		Min	xxx	---
		Median	xxx.x	---
		Max	xxx	---
Heart Rate [beats/min]	End of Study	N	nn	nn
		Mean	xxx.x	xxx.x
		SD	xxx.x	xxx.x
		CV%	xxx.x	xxx.x
		Min	xxx	xxx
		Median	xxx.x	xxx.x
		Max	xxx	xxx

Source: Listing 16.2.9.3 - ECG parameters and changes from baseline
Program: Tables\k374-eg-tbl.sas

Table 14.3.5.4 - Descriptive statistics of ECG parameters and their changes from baseline - Safety set

Parameter	Time Point	Statistics	Value	Change from baseline
PR Interval [msec]	Screening	N	nn	--
		Mean	xxx.x	---
		SD	xxx.x	---
		CV%	xxx.x	---
		Min	xxx	---
		Median	xxx.x	---
		Max	xxx	---
PR Interval [msec]	Day 1 - Post-dose	N	nn	--
		Mean	xxx.x	---
		SD	xxx.x	---
		CV%	xxx.x	---
		Min	xxx	---
		Median	xxx.x	---
		Max	xxx	---
PR Interval [msec]	End of Study	N	nn	nn
		Mean	xxx.x	xxx.x
		SD	xxx.x	xxx.x
		CV%	xxx.x	xxx.x
		Min	xxx	xxx
		Median	xxx.x	xxx.x
		Max	xxx	xxx

Source: Listing 16.2.9.3 - ECG parameters and changes from baseline
Program: Tables\k374-eg-tbl.sas

Table 14.3.5.4 - Descriptive statistics of ECG parameters and their changes from baseline - Safety set

Parameter	Time Point	Statistics	Value	Change from baseline
QRS Duration [msec]	Screening	N	nn	--
		Mean	xxx.x	---
		SD	xxx.x	---
		CV%	xxx.x	---
		Min	xxx	---
		Median	xxx.x	---
		Max	xxx	---
QRS Duration [msec]	Day 1 - Post-dose	N	nn	--
		Mean	xxx.x	---
		SD	xxx.x	---
		CV%	xxx.x	---
		Min	xxx	---
		Median	xxx.x	---
		Max	xxx	---
QRS Duration [msec]	End of Study	N	nn	nn
		Mean	xxx.x	xxx.x
		SD	xxx.x	xxx.x
		CV%	xxx.x	xxx.x
		Min	xxx	xxx
		Median	xxx.x	xxx.x
		Max	xxx	xxx

Source: Listing 16.2.9.3 - ECG parameters and changes from baseline
Program: Tables\k374-eg-tbl.sas

Table 14.3.5.4 - Descriptive statistics of ECG parameters and their changes from baseline - Safety set

Parameter	Time Point	Statistics	Value	Change from baseline
QT Interval [msec]	Screening	N	nn	--
		Mean	xxx.x	---
		SD	xxx.x	---
		CV%	xxx.x	---
		Min	xxx	---
		Median	xxx.x	---
		Max	xxx	---
QT Interval [msec]	Day 1 - Post-dose	N	nn	--
		Mean	xxx.x	---
		SD	xxx.x	---
		CV%	xxx.x	---
		Min	xxx	---
		Median	xxx.x	---
		Max	xxx	---
QT Interval [msec]	End of Study	N	nn	nn
		Mean	xxx.x	xxx.x
		SD	xxx.x	xxx.x
		CV%	xxx.x	xxx.x
		Min	xxx	xxx
		Median	xxx.x	xxx.x
		Max	xxx	xxx

Source: Listing 16.2.9.3 - ECG parameters and changes from baseline
Program: Tables\k374-eg-tbl.sas

Table 14.3.5.4 - Descriptive statistics of ECG parameters and their changes from baseline - Safety set

Parameter	Time Point	Statistics	Value	Change from baseline
...	Screening	N	nn	--
		Mean	xxx.x	---
		SD	xxx.x	---
		CV%	xxx.x	---
		Min	xxx	---
		Median	xxx.x	---
		Max	xxx	---
...	Day 1 - Post-dose	N	nn	--
		Mean	xxx.x	---
		SD	xxx.x	---
		CV%	xxx.x	---
		Min	xxx	---
		Median	xxx.x	---
		Max	xxx	---
...	End of Study	N	nn	nn
		Mean	xxx.x	xxx.x
		SD	xxx.x	xxx.x
		CV%	xxx.x	xxx.x
		Min	xxx	xxx
		Median	xxx.x	xxx.x
		Max	xxx	xxx

Source: Listing 16.2.9.3 - ECG parameters and changes from baseline
Program: Tables\k374-eg-tbl.sas

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

Time Point	Investigator's interpretation	Overall N=XX
Screening	Normal	nn (xx.x)
	Abnormal, Not Clinically Significant	nn (xx.x)
	Abnormal, Clinically Significant	nn (xx.x)
Day 1 - Post-dose	Normal	nn (xx.x)
	Abnormal, Not Clinically Significant	nn (xx.x)
	Abnormal, Clinically Significant	nn (xx.x)
End of Study	Normal	nn (xx.x)
	Abnormal, Not Clinically Significant	nn (xx.x)
	Abnormal, Clinically Significant	nn (xx.x)

Note: The number and the proportion of participants for each classification level are reported
The denominator for calculating the proportions is the number of participants in the safety set
Source: Listing 16.2.9.4 - Investigator's interpretation of ECG
Program: Tables\k374-eg-tbl.sas

Table 14.3.5.6 - Contingency tables of Visual Oral Inspection OMAS score - Safety set

Parameter	Time Point	OMAS score	Standardized Use N=XX	Non-standardized Use N=XX
Upper Lip - Ulceration/Pseudo membrane	Pre-dose	0 = no lesion	nn (xx.x)	nn (xx.x)
		1 = < 1 cm2	nn (xx.x)	nn (xx.x)
		2 = 1 to 3 cm2	nn (xx.x)	nn (xx.x)
		3 = > 3 cm2	nn (xx.x)	nn (xx.x)
	Post-dose	0 = no lesion	nn (xx.x)	nn (xx.x)
		1 = < 1 cm2	nn (xx.x)	nn (xx.x)
		2 = 1 to 3 cm2	nn (xx.x)	nn (xx.x)
		3 = > 3 cm2	nn (xx.x)	nn (xx.x)
	Day 2	0 = no lesion	nn (xx.x)	---
		1 = < 1 cm2	nn (xx.x)	---
		2 = 1 to 3 cm2	nn (xx.x)	---
		3 = > 3 cm2	nn (xx.x)	---
	Day 3	0 = no lesion	nn (xx.x)	---
		1 = < 1 cm2	nn (xx.x)	---
		2 = 1 to 3 cm2	nn (xx.x)	---
		3 = > 3 cm2	nn (xx.x)	---
	End of Study	0 = no lesion	---	nn (xx.x)
		1 = < 1 cm2	---	nn (xx.x)
		2 = 1 to 3 cm2	---	nn (xx.x)
		3 = > 3 cm2	---	nn (xx.x)

Note: The number and the proportion of participants for each classification level are reported
The denominator for calculating the proportions is the number of participants in the safety set of each product use
Source: Listing 16.2.9.5 - Visual Oral Inspection
Program: Tables\k374-fa-tbl.sas

Table 14.3.5.6 - Contingency tables of Visual Oral Inspection OMAS score - Safety set

Parameter	Time Point	OMAS score	Standardized Use N=XX	Non-standardized Use N=XX
Upper Lip - Erythema	Pre-dose	0 = none	nn (xx.x)	nn (xx.x)
		1 = not severe	nn (xx.x)	nn (xx.x)
		2 = severe	nn (xx.x)	nn (xx.x)
	Post-dose	0 = none	nn (xx.x)	nn (xx.x)
		1 = not severe	nn (xx.x)	nn (xx.x)
		2 = severe	nn (xx.x)	nn (xx.x)
	Day 2	0 = none	nn (xx.x)	---
		1 = not severe	nn (xx.x)	---
		2 = severe	nn (xx.x)	---
	Day 3	0 = none	nn (xx.x)	---
		1 = not severe	nn (xx.x)	---
		2 = severe	nn (xx.x)	---
	End of Study	0 = none	---	nn (xx.x)
		1 = not severe	---	nn (xx.x)
		2 = severe	---	nn (xx.x)
Lower Lip - Ulceration/Pseudo membrane	Pre-dose	0 = no lesion	nn (xx.x)	nn (xx.x)
		1 = < 1 cm2	nn (xx.x)	nn (xx.x)
		2 = 1 to 3 cm2	nn (xx.x)	nn (xx.x)
		3 = > 3 cm2	nn (xx.x)	nn (xx.x)

Note: The number and the proportion of participants for each classification level are reported
The denominator for calculating the proportions is the number of participants in the safety set of each product use
Source: Listing 16.2.9.5 - Visual Oral Inspection
Program: Tables\k374-fa-tbl.sas

Table 14.3.5.6 - Contingency tables of Visual Oral Inspection OMAS score - Safety set

Parameter	Time Point	OMAS score	Standardized Use N=XX	Non-standardized Use N=XX
Lower Lip - Ulceration/Pseudo membrane	Post-dose	0 = no lesion	nn (xx.x)	nn (xx.x)
		1 = < 1 cm2	nn (xx.x)	nn (xx.x)
		2 = 1 to 3 cm2	nn (xx.x)	nn (xx.x)
		3 = > 3 cm2	nn (xx.x)	nn (xx.x)
	Day 2	0 = no lesion	nn (xx.x)	---
		1 = < 1 cm2	nn (xx.x)	---
		2 = 1 to 3 cm2	nn (xx.x)	---
		3 = > 3 cm2	nn (xx.x)	---
	Day 3	0 = no lesion	nn (xx.x)	---
		1 = < 1 cm2	nn (xx.x)	---
		2 = 1 to 3 cm2	nn (xx.x)	---
		3 = > 3 cm2	nn (xx.x)	---
	End of Study	0 = no lesion	---	nn (xx.x)
		1 = < 1 cm2	---	nn (xx.x)
		2 = 1 to 3 cm2	---	nn (xx.x)
		3 = > 3 cm2	---	nn (xx.x)
Lower Lip - Erythema	Pre-dose	0 = none	nn (xx.x)	nn (xx.x)
		1 = not severe	nn (xx.x)	nn (xx.x)
		2 = severe	nn (xx.x)	nn (xx.x)
	Post-dose	0 = none	nn (xx.x)	nn (xx.x)

Note: The number and the proportion of participants for each classification level are reported
The denominator for calculating the proportions is the number of participants in the safety set of each product use
Source: Listing 16.2.9.5 - Visual Oral Inspection
Program: Tables\k374-fa-tbl.sas

Table 14.3.5.6 - Contingency tables of Visual Oral Inspection OMAS score - Safety set

Parameter	Time Point	OMAS score	Standardized Use N=XX	Non-standardized Use N=XX
Lower Lip - Erythema	Post-dose	1 = not severe	nn (xx.x)	nn (xx.x)
		2 = severe	nn (xx.x)	nn (xx.x)
	Day 2	0 = none	nn (xx.x)	---
		1 = not severe	nn (xx.x)	---
		2 = severe	nn (xx.x)	---
	Day 3	0 = none	nn (xx.x)	---
		1 = not severe	nn (xx.x)	---
		2 = severe	nn (xx.x)	---
	End of Study	0 = none	---	nn (xx.x)
		1 = not severe	---	nn (xx.x)
		2 = severe	---	nn (xx.x)
Right Cheek - Ulceration/Pseudo membrane	Pre-dose	0 = no lesion	nn (xx.x)	nn (xx.x)
		1 = < 1 cm2	nn (xx.x)	nn (xx.x)
		2 = 1 to 3 cm2	nn (xx.x)	nn (xx.x)
		3 = > 3 cm2	nn (xx.x)	nn (xx.x)
	Post-dose	0 = no lesion	nn (xx.x)	nn (xx.x)
		1 = < 1 cm2	nn (xx.x)	nn (xx.x)
		2 = 1 to 3 cm2	nn (xx.x)	nn (xx.x)
		3 = > 3 cm2	nn (xx.x)	nn (xx.x)
	Day 2	0 = no lesion	nn (xx.x)	---

Note: The number and the proportion of participants for each classification level are reported
The denominator for calculating the proportions is the number of participants in the safety set of each product use
Source: Listing 16.2.9.5 - Visual Oral Inspection
Program: Tables\k374-fa-tbl.sas

Table 14.3.5.6 - Contingency tables of Visual Oral Inspection OMAS score - Safety set

Parameter	Time Point	OMAS score	Standardized Use N=XX	Non-standardized Use N=XX
Right Cheek - Ulceration/Pseudo membrane	Day 2	1 = < 1 cm2	nn (xx.x)	---
		2 = 1 to 3 cm2	nn (xx.x)	---
		3 = > 3 cm2	nn (xx.x)	---
	Day 3	0 = no lesion	nn (xx.x)	---
		1 = < 1 cm2	nn (xx.x)	---
		2 = 1 to 3 cm2	nn (xx.x)	---
		3 = > 3 cm2	nn (xx.x)	---
	End of Study	0 = no lesion	---	nn (xx.x)
		1 = < 1 cm2	---	nn (xx.x)
		2 = 1 to 3 cm2	---	nn (xx.x)
		3 = > 3 cm2	---	nn (xx.x)
Right Cheek - Erythema	Pre-dose	0 = none	nn (xx.x)	nn (xx.x)
		1 = not severe	nn (xx.x)	nn (xx.x)
		2 = severe	nn (xx.x)	nn (xx.x)
	Post-dose	0 = none	nn (xx.x)	nn (xx.x)
		1 = not severe	nn (xx.x)	nn (xx.x)
		2 = severe	nn (xx.x)	nn (xx.x)
	Day 2	0 = none	nn (xx.x)	---
		1 = not severe	nn (xx.x)	---
		2 = severe	nn (xx.x)	---

Note: The number and the proportion of participants for each classification level are reported
The denominator for calculating the proportions is the number of participants in the safety set of each product use
Source: Listing 16.2.9.5 - Visual Oral Inspection
Program: Tables\k374-fa-tbl.sas

Table 14.3.5.6 - Contingency tables of Visual Oral Inspection OMAS score - Safety set

Parameter	Time Point	OMAS score	Standardized Use N=XX	Non-standardized Use N=XX
Right Cheek - Erythema	Day 3	0 = none	nn (xx.x)	---
		1 = not severe	nn (xx.x)	---
		2 = severe	nn (xx.x)	---
	End of Study	0 = none	---	nn (xx.x)
		1 = not severe	---	nn (xx.x)
		2 = severe	---	nn (xx.x)
.... - Ulceration/Pseudo membrane	Pre-dose	0 = no lesion	nn (xx.x)	nn (xx.x)
		1 = < 1 cm2	nn (xx.x)	nn (xx.x)
		2 = 1 to 3 cm2	nn (xx.x)	nn (xx.x)
		3 = > 3 cm2	nn (xx.x)	nn (xx.x)
	Post-dose	0 = no lesion	nn (xx.x)	nn (xx.x)
		1 = < 1 cm2	nn (xx.x)	nn (xx.x)
		2 = 1 to 3 cm2	nn (xx.x)	nn (xx.x)
		3 = > 3 cm2	nn (xx.x)	nn (xx.x)
	Day 2	0 = no lesion	nn (xx.x)	---
		1 = < 1 cm2	nn (xx.x)	---
		2 = 1 to 3 cm2	nn (xx.x)	---
		3 = > 3 cm2	nn (xx.x)	---
	Day 3	0 = no lesion	nn (xx.x)	---
		1 = < 1 cm2	nn (xx.x)	---

Note: The number and the proportion of participants for each classification level are reported
The denominator for calculating the proportions is the number of participants in the safety set of each product use
Source: Listing 16.2.9.5 - Visual Oral Inspection
Program: Tables\k374-fa-tbl.sas

Table 14.3.5.6 - Contingency tables of Visual Oral Inspection OMAS score - Safety set

Parameter	Time Point	OMAS score	Standardized Use N=XX	Non-standardized Use N=XX
.... - Ulceration/Pseudo membrane	Day 3	2 = 1 to 3 cm2	nn (xx.x)	---
		3 = > 3 cm2	nn (xx.x)	---
	End of Study	0 = no lesion	---	nn (xx.x)
		1 = < 1 cm2	---	nn (xx.x)
		2 = 1 to 3 cm2	---	nn (xx.x)
		3 = > 3 cm2	---	nn (xx.x)
.... - Erythema	Pre-dose	0 = none	nn (xx.x)	nn (xx.x)
		1 = not severe	nn (xx.x)	nn (xx.x)
		2 = severe	nn (xx.x)	nn (xx.x)
	Post-dose	0 = none	nn (xx.x)	nn (xx.x)
		1 = not severe	nn (xx.x)	nn (xx.x)
		2 = severe	nn (xx.x)	nn (xx.x)
	Day 2	0 = none	nn (xx.x)	---
		1 = not severe	nn (xx.x)	---
		2 = severe	nn (xx.x)	---
	Day 3	0 = none	nn (xx.x)	---
		1 = not severe	nn (xx.x)	---
		2 = severe	nn (xx.x)	---
	End of Study	0 = none	---	nn (xx.x)

Note: The number and the proportion of participants for each classification level are reported
The denominator for calculating the proportions is the number of participants in the safety set of each product use
Source: Listing 16.2.9.5 - Visual Oral Inspection
Program: Tables\k374-fa-tbl.sas

Table 14.3.5.6 - Contingency tables of Visual Oral Inspection OMAS score - Safety set

Parameter	Time Point	OMAS score	Standardized Use N=XX	Non-standardized Use N=XX
.... - Erythema	End of Study	1 = not severe	---	nn (xx.x)
		2 = severe	---	nn (xx.x)

Note: The number and the proportion of participants for each classification level are reported
The denominator for calculating the proportions is the number of participants in the safety set of each product use
Source: Listing 16.2.9.5 - Visual Oral Inspection
Program: Tables\k374-fa-tbl.sas

Table 14.3.5.7 - Descriptive statistics of Global OMAS score - Safety set

			Standardized Use N=XX		Non-standardized Use N=XX	
Parameter	**Time Point**	**Statistics**	**Value**	**Change from baseline**	**Value**	**Change from baseline**
Global OMAS score	Pre-dose	N	nn	---	nn	---
		Mean	xxx.x	---	xxx.x	---
		SD	xxx.x	---	xxx.x	---
		CV%	xxx.x	---	xxx.x	---
		Min	xxx	---	xxx	---
		Median	xxx.x	---	xxx.x	---
		Max	xxx	---	xxx	---
Global OMAS score	Post-dose	N	nn	nn	nn	nn
		Mean	xxx.x	xxx.x	xxx.x	xxx.x
		SD	xxx.x	xxx.x	xxx.x	xxx.x
		CV%	xxx.x	xxx.x	xxx.x	xxx.x
		Min	xxx	xxx	xxx	xxx
		Median	xxx.x	xxx.x	xxx.x	xxx.x
		Max	xxx	xxx	xxx	xxx
Global OMAS score	Day 2	N	nn	nn	---	---
		Mean	xxx.x	xxx.x	---	---
		SD	xxx.x	xxx.x	---	---
		CV%	xxx.x	xxx.x	---	---
		Min	xxx	xxx	---	---
		Median	xxx.x	xxx.x	---	---
		Max	xxx	xxx	---	---

Source: Listing 16.2.9.6 - Visual Oral Inspection - Global OMAS score
Program: Tables\k374-fa-tbl.sas

Table 14.3.5.7 - Descriptive statistics of Global OMAS score - Safety set

			Standardized Use N=XX		Non-standardized Use N=XX	
Parameter	**Time Point**	**Statistics**	**Value**	**Change from baseline**	**Value**	**Change from baseline**
Global OMAS score	Day 3	N	nn	nn	---	---
		Mean	xxx.x	xxx.x	---	---
		SD	xxx.x	xxx.x	---	---
		CV%	xxx.x	xxx.x	---	---
		Min	xxx	xxx	---	---
		Median	xxx.x	xxx.x	---	---
		Max	xxx	xxx	---	---
Global OMAS score	End of Study	N	---	---	nn	nn
		Mean	---	---	xxx.x	xxx.x
		SD	---	---	xxx.x	xxx.x
		CV%	---	---	xxx.x	xxx.x
		Min	---	---	xxx	xxx
		Median	---	---	xxx.x	xxx.x
		Max	---	---	xxx	xxx

Source: Listing 16.2.9.6 - Visual Oral Inspection - Global OMAS score
Program: Tables\k374-fa-tbl.sas

Table 14.3.5.8 - Descriptive statistics and contingency tables of Cough Assessment - Safety set

		Statistics	Standardized Use N=XX	Non-standardized Use N=XX
Number of Coughs		N	nn	nn
		Mean	xx.x	xx.x
		SD	xx.x	xx.x
		CV%	xx.x	xx.x
		Min	xx	xx
		Median	xx.x	xx.x
		Max	xx	xx
Cough Occurrence:	During inhalation	n (%)	nn (xx.x)	nn (xx.x)
	After inhalation	n (%)	nn (xx.x)	nn (xx.x)
Cough duration and pattern:	Seconds and non-repetitive	n (%)	nn (xx.x)	nn (xx.x)
	Continuous, below 1 minute	n (%)	nn (xx.x)	nn (xx.x)
	Continuous, more than 1 minute	n (%)	nn (xx.x)	nn (xx.x)
Cough severity:	Clearing throat/short cough after inhalation	n (%)	nn (xx.x)	nn (xx.x)
	Mild Cough	n (%)	nn (xx.x)	nn (xx.x)
	Medium/Severe Cough/choking episodes	n (%)	nn (xx.x)	nn (xx.x)
Water Need:	Yes	n (%)	nn (xx.x)	nn (xx.x)
	No	n (%)	nn (xx.x)	nn (xx.x)

Source: Listing 16.2.9.7 - Cough assessments
Program: Tables\k374-fa-tbl.sas

Table 14.3.5.9 - Descriptive statistics of Spirometry parameters and their changes from baseline - Safety set

Smoking history: Overall

Parameter	Time Point	Statistics	Safety set N=XX	Standardized Use N=XX		Non-standardized Use N=XX	
			Value	Value	Change from baseline	Value	Change from baseline
FEV1 [L]	Screening	N	nn	---	---	---	---
		Mean	xxx.x	---	---	---	---
		SD	xxx.x	---	---	---	---
		CV%	xxx.x	---	---	---	---
		Min	xxx	---	---	---	---
		Median	xxx.x	---	---	---	---
		Max	xxx	---	---	---	---
FEV1 [L]	Visit 2 - Day -1	N	nn	---	---	---	---
		Mean	xxx.x	---	---	---	---
		SD	xxx.x	---	---	---	---
		CV%	xxx.x	---	---	---	---
		Min	xxx	---	---	---	---
		Median	xxx.x	---	---	---	---
		Max	xxx	---	---	---	---

Source: Listing 16.2.9.8 - Spirometry parameters and changes from baseline
Program: Tables\k374-fa-tbl.sas

Table 14.3.5.9 - Descriptive statistics of Spirometry parameters and their changes from baseline - Safety set

Smoking history: Overall

Parameter	Time Point	Statistics	Safety set N=XX	Standardized Use N=XX		Non-standardized Use N=XX	
			Value	Value	Change from baseline	Value	Change from baseline
FEV1 [L]	Pre-dose	N	---	nn	---	nn	---
		Mean	---	xxx.x	---	xxx.x	---
		SD	---	xxx.x	---	xxx.x	---
		CV%	---	xxx.x	---	xxx.x	---
		Min	---	xxx	---	xxx	---
		Median	---	xxx.x	---	xxx.x	---
		Max	---	xxx	---	xxx	---
FEV1 [L]	Post-dose	N	---	nn	nn	nn	nn
		Mean	---	xxx.x	xxx.x	xxx.x	xxx.x
		SD	---	xxx.x	xxx.x	xxx.x	xxx.x
		CV%	---	xxx.x	xxx.x	xxx.x	xxx.x
		Min	---	xxx	xxx	xxx	xxx
		Median	---	xxx.x	xxx.x	xxx.x	xxx.x
		Max	---	xxx	xxx	xxx	xxx

Source: Listing 16.2.9.8 - Spirometry parameters and changes from baseline
Program: Tables\k374-fa-tbl.sas

Table 14.3.5.9 - Descriptive statistics of Spirometry parameters and their changes from baseline - Safety set

Smoking history: Overall

Parameter	Time Point	Statistics	Safety set N=XX	Standardized Use N=XX		Non-standardized Use N=XX	
			Value	Value	Change from baseline	Value	Change from baseline
FVC [L]	Screening	N	nn	---	---	---	---
		Mean	xxx.x	---	---	---	---
		SD	xxx.x	---	---	---	---
		CV%	xxx.x	---	---	---	---
		Min	xxx	---	---	---	---
		Median	xxx.x	---	---	---	---
		Max	xxx	---	---	---	---
FVC [L]	Visit 2 - Day -1	N	nn	---	---	---	---
		Mean	xxx.x	---	---	---	---
		SD	xxx.x	---	---	---	---
		CV%	xxx.x	---	---	---	---
		Min	xxx	---	---	---	---
		Median	xxx.x	---	---	---	---
		Max	xxx	---	---	---	---

Source: Listing 16.2.9.8 - Spirometry parameters and changes from baseline
Program: Tables\k374-fa-tbl.sas

Table 14.3.5.9 - Descriptive statistics of Spirometry parameters and their changes from baseline - Safety set

Smoking history: Overall

Parameter	Time Point	Statistics	Safety set N=XX	Standardized Use N=XX		Non-standardized Use N=XX	
			Value	Value	Change from baseline	Value	Change from baseline
FVC [L]	Pre-dose	N	---	nn	---	nn	---
		Mean	---	xxx.x	---	xxx.x	---
		SD	---	xxx.x	---	xxx.x	---
		CV%	---	xxx.x	---	xxx.x	---
		Min	---	xxx	---	xxx	---
		Median	---	xxx.x	---	xxx.x	---
		Max	---	xxx	---	xxx	---
FVC [L]	Post-dose	N	---	nn	nn	nn	nn
		Mean	---	xxx.x	xxx.x	xxx.x	xxx.x
		SD	---	xxx.x	xxx.x	xxx.x	xxx.x
		CV%	---	xxx.x	xxx.x	xxx.x	xxx.x
		Min	---	xxx	xxx	xxx	xxx
		Median	---	xxx.x	xxx.x	xxx.x	xxx.x
		Max	---	xxx	xxx	xxx	xxx

Source: Listing 16.2.9.8 - Spirometry parameters and changes from baseline
Program: Tables\k374-fa-tbl.sas

Table 14.3.5.9 - Descriptive statistics of Spirometry parameters and their changes from baseline - Safety set

Smoking history: Overall

Parameter	Time Point	Statistics	Safety set N=XX	Standardized Use N=XX		Non-standardized Use N=XX	
			Value	Value	Change from baseline	Value	Change from baseline
FEV1/FVC ratio	Screening	N	nn	---	---	---	---
		Mean	xxx.x	---	---	---	---
		SD	xxx.x	---	---	---	---
		CV%	xxx.x	---	---	---	---
		Min	xxx	---	---	---	---
		Median	xxx.x	---	---	---	---
		Max	xxx	---	---	---	---
FEV1/FVC ratio	Visit 2 - Day -1	N	nn	---	---	---	---
		Mean	xxx.x	---	---	---	---
		SD	xxx.x	---	---	---	---
		CV%	xxx.x	---	---	---	---
		Min	xxx	---	---	---	---
		Median	xxx.x	---	---	---	---
		Max	xxx	---	---	---	---

Source: Listing 16.2.9.8 - Spirometry parameters and changes from baseline
Program: Tables\k374-fa-tbl.sas

Table 14.3.5.9 - Descriptive statistics of Spirometry parameters and their changes from baseline - Safety set

Smoking history: Overall

Parameter	Time Point	Statistics	Safety set N=XX	Standardized Use N=XX		Non-standardized Use N=XX	
			Value	Value	Change from baseline	Value	Change from baseline
FEV1/FVC ratio	Pre-dose	N	---	nn	---	nn	---
		Mean	---	xxx.x	---	xxx.x	---
		SD	---	xxx.x	---	xxx.x	---
		CV%	---	xxx.x	---	xxx.x	---
		Min	---	xxx	---	xxx	---
		Median	---	xxx.x	---	xxx.x	---
		Max	---	xxx	---	xxx	---
FEV1/FVC ratio	Post-dose	N	---	nn	nn	nn	nn
		Mean	---	xxx.x	xxx.x	xxx.x	xxx.x
		SD	---	xxx.x	xxx.x	xxx.x	xxx.x
		CV%	---	xxx.x	xxx.x	xxx.x	xxx.x
		Min	---	xxx	xxx	xxx	xxx
		Median	---	xxx.x	xxx.x	xxx.x	xxx.x
		Max	---	xxx	xxx	xxx	xxx

Source: Listing 16.2.9.8 - Spirometry parameters and changes from baseline
Program: Tables\k374-fa-tbl.sas

Table 14.3.5.9 - Descriptive statistics of Spirometry parameters and their changes from baseline - Safety set

Smoking history: Smokers

Parameter	Time Point	Statistics	Safety set N=XX	Standardized Use N=XX		Non-standardized Use N=XX	
			Value	Value	Change from baseline	Value	Change from baseline
FEV1 [L]	Screening	N	nn	---	---	---	---
		Mean	xxx.x	---	---	---	---
		SD	xxx.x	---	---	---	---
		CV%	xxx.x	---	---	---	---
		Min	xxx	---	---	---	---
		Median	xxx.x	---	---	---	---
		Max	xxx	---	---	---	---
FEV1 [L]	Visit 2 - Day -1	N	nn	---	---	---	---
		Mean	xxx.x	---	---	---	---
		SD	xxx.x	---	---	---	---
		CV%	xxx.x	---	---	---	---
		Min	xxx	---	---	---	---
		Median	xxx.x	---	---	---	---
		Max	xxx	---	---	---	---

Source: Listing 16.2.9.8 - Spirometry parameters and changes from baseline
Program: Tables\k374-fa-tbl.sas

Table 14.3.5.9 - Descriptive statistics of Spirometry parameters and their changes from baseline - Safety set

Smoking history: Smokers

Parameter	Time Point	Statistics	Safety set N=XX	Standardized Use N=XX		Non-standardized Use N=XX	
			Value	Value	Change from baseline	Value	Change from baseline
FEV1 [L]	Pre-dose	N	---	nn	---	nn	---
		Mean	---	xxx.x	---	xxx.x	---
		SD	---	xxx.x	---	xxx.x	---
		CV%	---	xxx.x	---	xxx.x	---
		Min	---	xxx	---	xxx	---
		Median	---	xxx.x	---	xxx.x	---
		Max	---	xxx	---	xxx	---
FEV1 [L]	Post-dose	N	---	nn	nn	nn	nn
		Mean	---	xxx.x	xxx.x	xxx.x	xxx.x
		SD	---	xxx.x	xxx.x	xxx.x	xxx.x
		CV%	---	xxx.x	xxx.x	xxx.x	xxx.x
		Min	---	xxx	xxx	xxx	xxx
		Median	---	xxx.x	xxx.x	xxx.x	xxx.x
		Max	---	xxx	xxx	xxx	xxx

Source: Listing 16.2.9.8 - Spirometry parameters and changes from baseline
Program: Tables\k374-fa-tbl.sas

Table 14.3.5.9 - Descriptive statistics of Spirometry parameters and their changes from baseline - Safety set

Smoking history: Smokers

Parameter	Time Point	Statistics	Safety set N=XX	Standardized Use N=XX		Non-standardized Use N=XX	
			Value	Value	Change from baseline	Value	Change from baseline
FVC [L]	Screening	N	nn	---	---	---	---
		Mean	xxx.x	---	---	---	---
		SD	xxx.x	---	---	---	---
		CV%	xxx.x	---	---	---	---
		Min	xxx	---	---	---	---
		Median	xxx.x	---	---	---	---
		Max	xxx	---	---	---	---
FVC [L]	Visit 2 - Day -1	N	nn	---	---	---	---
		Mean	xxx.x	---	---	---	---
		SD	xxx.x	---	---	---	---
		CV%	xxx.x	---	---	---	---
		Min	xxx	---	---	---	---
		Median	xxx.x	---	---	---	---
		Max	xxx	---	---	---	---

Source: Listing 16.2.9.8 - Spirometry parameters and changes from baseline
Program: Tables\k374-fa-tbl.sas

Table 14.3.5.9 - Descriptive statistics of Spirometry parameters and their changes from baseline - Safety set

Smoking history: Smokers

Parameter	Time Point	Statistics	Safety set N=XX	Standardized Use N=XX		Non-standardized Use N=XX	
			Value	Value	Change from baseline	Value	Change from baseline
FVC [L]	Pre-dose	N	---	nn	---	nn	---
		Mean	---	xxx.x	---	xxx.x	---
		SD	---	xxx.x	---	xxx.x	---
		CV%	---	xxx.x	---	xxx.x	---
		Min	---	xxx	---	xxx	---
		Median	---	xxx.x	---	xxx.x	---
		Max	---	xxx	---	xxx	---
FVC [L]	Post-dose	N	---	nn	nn	nn	nn
		Mean	---	xxx.x	xxx.x	xxx.x	xxx.x
		SD	---	xxx.x	xxx.x	xxx.x	xxx.x
		CV%	---	xxx.x	xxx.x	xxx.x	xxx.x
		Min	---	xxx	xxx	xxx	xxx
		Median	---	xxx.x	xxx.x	xxx.x	xxx.x
		Max	---	xxx	xxx	xxx	xxx

Source: Listing 16.2.9.8 - Spirometry parameters and changes from baseline
Program: Tables\k374-fa-tbl.sas

Table 14.3.5.9 - Descriptive statistics of Spirometry parameters and their changes from baseline - Safety set

Smoking history: Smokers

Parameter	Time Point	Statistics	Safety set N=XX	Standardized Use N=XX		Non-standardized Use N=XX	
			Value	Value	Change from baseline	Value	Change from baseline
FEV1/FVC ratio	Screening	N	nn	---	---	---	---
		Mean	xxx.x	---	---	---	---
		SD	xxx.x	---	---	---	---
		CV%	xxx.x	---	---	---	---
		Min	xxx	---	---	---	---
		Median	xxx.x	---	---	---	---
		Max	xxx	---	---	---	---
FEV1/FVC ratio	Visit 2 - Day -1	N	nn	---	---	---	---
		Mean	xxx.x	---	---	---	---
		SD	xxx.x	---	---	---	---
		CV%	xxx.x	---	---	---	---
		Min	xxx	---	---	---	---
		Median	xxx.x	---	---	---	---
		Max	xxx	---	---	---	---

Source: Listing 16.2.9.8 - Spirometry parameters and changes from baseline
Program: Tables\k374-fa-tbl.sas

Table 14.3.5.9 - Descriptive statistics of Spirometry parameters and their changes from baseline - Safety set

Smoking history: Smokers

Parameter	Time Point	Statistics	Safety set N=XX	Standardized Use N=XX		Non-standardized Use N=XX	
			Value	Value	Change from baseline	Value	Change from baseline
FEV1/FVC ratio	Pre-dose	N	---	nn	---	nn	---
		Mean	---	xxx.x	---	xxx.x	---
		SD	---	xxx.x	---	xxx.x	---
		CV%	---	xxx.x	---	xxx.x	---
		Min	---	xxx	---	xxx	---
		Median	---	xxx.x	---	xxx.x	---
		Max	---	xxx	---	xxx	---
FEV1/FVC ratio	Post-dose	N	---	nn	nn	nn	nn
		Mean	---	xxx.x	xxx.x	xxx.x	xxx.x
		SD	---	xxx.x	xxx.x	xxx.x	xxx.x
		CV%	---	xxx.x	xxx.x	xxx.x	xxx.x
		Min	---	xxx	xxx	xxx	xxx
		Median	---	xxx.x	xxx.x	xxx.x	xxx.x
		Max	---	xxx	xxx	xxx	xxx

Source: Listing 16.2.9.8 - Spirometry parameters and changes from baseline
Program: Tables\k374-fa-tbl.sas

Table 14.3.5.9 - Descriptive statistics of Spirometry parameters and their changes from baseline - Safety set

Smoking history: Non-smokers or past smokers

Parameter	Time Point	Statistics	Safety set N=XX	Standardized Use N=XX		Non-standardized Use N=XX	
			Value	Value	Change from baseline	Value	Change from baseline
FEV1 [L]	Screening	N	nn	---	---	---	---
		Mean	xxx.x	---	---	---	---
		SD	xxx.x	---	---	---	---
		CV%	xxx.x	---	---	---	---
		Min	xxx	---	---	---	---
		Median	xxx.x	---	---	---	---
		Max	xxx	---	---	---	---
FEV1 [L]	Visit 2 - Day -1	N	nn	---	---	---	---
		Mean	xxx.x	---	---	---	---
		SD	xxx.x	---	---	---	---
		CV%	xxx.x	---	---	---	---
		Min	xxx	---	---	---	---
		Median	xxx.x	---	---	---	---
		Max	xxx	---	---	---	---

Source: Listing 16.2.9.8 - Spirometry parameters and changes from baseline
Program: Tables\k374-fa-tbl.sas

Table 14.3.5.9 - Descriptive statistics of Spirometry parameters and their changes from baseline - Safety set

Smoking history: Non-smokers or past smokers

Parameter	Time Point	Statistics	Safety set N=XX	Standardized Use N=XX		Non-standardized Use N=XX	
			Value	Value	Change from baseline	Value	Change from baseline
FEV1 [L]	Pre-dose	N	---	nn	---	nn	---
		Mean	---	xxx.x	---	xxx.x	---
		SD	---	xxx.x	---	xxx.x	---
		CV%	---	xxx.x	---	xxx.x	---
		Min	---	xxx	---	xxx	---
		Median	---	xxx.x	---	xxx.x	---
		Max	---	xxx	---	xxx	---
FEV1 [L]	Post-dose	N	---	nn	nn	nn	nn
		Mean	---	xxx.x	xxx.x	xxx.x	xxx.x
		SD	---	xxx.x	xxx.x	xxx.x	xxx.x
		CV%	---	xxx.x	xxx.x	xxx.x	xxx.x
		Min	---	xxx	xxx	xxx	xxx
		Median	---	xxx.x	xxx.x	xxx.x	xxx.x
		Max	---	xxx	xxx	xxx	xxx

Source: Listing 16.2.9.8 - Spirometry parameters and changes from baseline
Program: Tables\k374-fa-tbl.sas

Table 14.3.5.9 - Descriptive statistics of Spirometry parameters and their changes from baseline - Safety set

Smoking history: Non-smokers or past smokers

Parameter	Time Point	Statistics	Safety set N=XX	Standardized Use N=XX		Non-standardized Use N=XX	
			Value	Value	Change from baseline	Value	Change from baseline
FVC [L]	Screening	N	nn	---	---	---	---
		Mean	xxx.x	---	---	---	---
		SD	xxx.x	---	---	---	---
		CV%	xxx.x	---	---	---	---
		Min	xxx	---	---	---	---
		Median	xxx.x	---	---	---	---
		Max	xxx	---	---	---	---
FVC [L]	Visit 2 - Day -1	N	nn	---	---	---	---
		Mean	xxx.x	---	---	---	---
		SD	xxx.x	---	---	---	---
		CV%	xxx.x	---	---	---	---
		Min	xxx	---	---	---	---
		Median	xxx.x	---	---	---	---
		Max	xxx	---	---	---	---

Source: Listing 16.2.9.8 - Spirometry parameters and changes from baseline
Program: Tables\k374-fa-tbl.sas

Table 14.3.5.9 - Descriptive statistics of Spirometry parameters and their changes from baseline - Safety set

Smoking history: Non-smokers or past smokers

Parameter	Time Point	Statistics	Safety set N=XX	Standardized Use N=XX		Non-standardized Use N=XX	
			Value	Value	Change from baseline	Value	Change from baseline
FVC [L]	Pre-dose	N	---	nn	---	nn	---
		Mean	---	xxx.x	---	xxx.x	---
		SD	---	xxx.x	---	xxx.x	---
		CV%	---	xxx.x	---	xxx.x	---
		Min	---	xxx	---	xxx	---
		Median	---	xxx.x	---	xxx.x	---
		Max	---	xxx	---	xxx	---
FVC [L]	Post-dose	N	---	nn	nn	nn	nn
		Mean	---	xxx.x	xxx.x	xxx.x	xxx.x
		SD	---	xxx.x	xxx.x	xxx.x	xxx.x
		CV%	---	xxx.x	xxx.x	xxx.x	xxx.x
		Min	---	xxx	xxx	xxx	xxx
		Median	---	xxx.x	xxx.x	xxx.x	xxx.x
		Max	---	xxx	xxx	xxx	xxx

Source: Listing 16.2.9.8 - Spirometry parameters and changes from baseline
Program: Tables\k374-fa-tbl.sas

Table 14.3.5.9 - Descriptive statistics of Spirometry parameters and their changes from baseline - Safety set

Smoking history: Non-smokers or past smokers

Parameter	Time Point	Statistics	Safety set N=XX	Standardized Use N=XX		Non-standardized Use N=XX	
			Value	Value	Change from baseline	Value	Change from baseline
FEV1/FVC ratio	Screening	N	nn	---	---	---	---
		Mean	xxx.x	---	---	---	---
		SD	xxx.x	---	---	---	---
		CV%	xxx.x	---	---	---	---
		Min	xxx	---	---	---	---
		Median	xxx.x	---	---	---	---
		Max	xxx	---	---	---	---
FEV1/FVC ratio	Visit 2 - Day -1	N	nn	---	---	---	---
		Mean	xxx.x	---	---	---	---
		SD	xxx.x	---	---	---	---
		CV%	xxx.x	---	---	---	---
		Min	xxx	---	---	---	---
		Median	xxx.x	---	---	---	---
		Max	xxx	---	---	---	---

Source: Listing 16.2.9.8 - Spirometry parameters and changes from baseline
Program: Tables\k374-fa-tbl.sas

Table 14.3.5.9 - Descriptive statistics of Spirometry parameters and their changes from baseline - Safety set

Smoking history: Non-smokers or past smokers

Parameter	Time Point	Statistics	Safety set N=XX	Standardized Use N=XX		Non-standardized Use N=XX	
			Value	Value	Change from baseline	Value	Change from baseline
FEV1/FVC ratio	Pre-dose	N	---	nn	---	nn	---
		Mean	---	xxx.x	---	xxx.x	---
		SD	---	xxx.x	---	xxx.x	---
		CV%	---	xxx.x	---	xxx.x	---
		Min	---	xxx	---	xxx	---
		Median	---	xxx.x	---	xxx.x	---
		Max	---	xxx	---	xxx	---
FEV1/FVC ratio	Post-dose	N	---	nn	nn	nn	nn
		Mean	---	xxx.x	xxx.x	xxx.x	xxx.x
		SD	---	xxx.x	xxx.x	xxx.x	xxx.x
		CV%	---	xxx.x	xxx.x	xxx.x	xxx.x
		Min	---	xxx	xxx	xxx	xxx
		Median	---	xxx.x	xxx.x	xxx.x	xxx.x
		Max	---	xxx	xxx	xxx	xxx

Source: Listing 16.2.9.8 - Spirometry parameters and changes from baseline
Program: Tables\k374-fa-tbl.sas

Table 14.3.5.10 - Descriptive statistics of respiratory tests parameters and their changes from baseline - Safety set

Smoking history: Overall

			Standardized Use N=XX		Non-standardized Use N=XX	
Parameter	**Time Point**	**Statistics**	**Value**	**Change from baseline**	**Value**	**Change from baseline**
FCOHb [%]	Pre-dose	N	nn	---	nn	---
		Mean	xxx.x	---	xxx.x	---
		SD	xxx.x	---	xxx.x	---
		CV%	xxx.x	---	xxx.x	---
		Min	xxx	---	xxx	---
		Median	xxx.x	---	xxx.x	---
		Max	xxx	---	xxx	---
FCOHb [%]	10 min post-dose	N	nn	nn	nn	nn
		Mean	xxx.x	xxx.x	xxx.x	xxx.x
		SD	xxx.x	xxx.x	xxx.x	xxx.x
		CV%	xxx.x	xxx.x	xxx.x	xxx.x
		Min	xxx	xxx	xxx	xxx
		Median	xxx.x	xxx.x	xxx.x	xxx.x
		Max	xxx	xxx	xxx	xxx
FCOHb [%]	30 min post-dose	N	nn	nn	nn	nn
		Mean	xxx.x	xxx.x	xxx.x	xxx.x
		SD	xxx.x	xxx.x	xxx.x	xxx.x
		CV%	xxx.x	xxx.x	xxx.x	xxx.x
		Min	xxx	xxx	xxx	xxx
		Median	xxx.x	xxx.x	xxx.x	xxx.x
		Max	xxx	xxx	xxx	xxx

Source: Listing 16.2.9.9 - Respiratory tests and changes from baseline
Program: Tables\k374-fa-tbl.sas

Table 14.3.5.10 - Descriptive statistics of respiratory tests parameters and their changes from baseline - Safety set

Smoking history: Overall

			Standardized Use N=XX		Non-standardized Use N=XX	
Parameter	**Time Point**	**Statistics**	**Value**	**Change from baseline**	**Value**	**Change from baseline**
FCOHb [%]	Visit 4 - Day 2	N	nn	nn	nn	nn
		Mean	xxx.x	xxx.x	xxx.x	xxx.x
		SD	xxx.x	xxx.x	xxx.x	xxx.x
		CV%	xxx.x	xxx.x	xxx.x	xxx.x
		Min	xxx	xxx	xxx	xxx
		Median	xxx.x	xxx.x	xxx.x	xxx.x
		Max	xxx	xxx	xxx	xxx
FCOHb [%]	Visit 4 - Day 3	N	nn	nn	nn	nn
		Mean	xxx.x	xxx.x	xxx.x	xxx.x
		SD	xxx.x	xxx.x	xxx.x	xxx.x
		CV%	xxx.x	xxx.x	xxx.x	xxx.x
		Min	xxx	xxx	xxx	xxx
		Median	xxx.x	xxx.x	xxx.x	xxx.x
		Max	xxx	xxx	xxx	xxx
exhaled CO [L]	Pre-dose	N	nn	---	nn	---
		Mean	xxx.x	---	xxx.x	---
		SD	xxx.x	---	xxx.x	---
		CV%	xxx.x	---	xxx.x	---
		Min	xxx	---	xxx	---
		Median	xxx.x	---	xxx.x	---
		Max	xxx	---	xxx	---

Source: Listing 16.2.9.9 - Respiratory tests and changes from baseline
Program: Tables\k374-fa-tbl.sas

Table 14.3.5.10 - Descriptive statistics of respiratory tests parameters and their changes from baseline - Safety set

Smoking history: Overall

			Standardized Use N=XX		Non-standardized Use N=XX	
Parameter	**Time Point**	**Statistics**	**Value**	**Change from baseline**	**Value**	**Change from baseline**
exhaled CO [L]	10 min post-dose	N	nn	nn	nn	nn
		Mean	xxx.x	xxx.x	xxx.x	xxx.x
		SD	xxx.x	xxx.x	xxx.x	xxx.x
		CV%	xxx.x	xxx.x	xxx.x	xxx.x
		Min	xxx	xxx	xxx	xxx
		Median	xxx.x	xxx.x	xxx.x	xxx.x
		Max	xxx	xxx	xxx	xxx
exhaled CO [L]	30 min post-dose	N	nn	nn	nn	nn
		Mean	xxx.x	xxx.x	xxx.x	xxx.x
		SD	xxx.x	xxx.x	xxx.x	xxx.x
		CV%	xxx.x	xxx.x	xxx.x	xxx.x
		Min	xxx	xxx	xxx	xxx
		Median	xxx.x	xxx.x	xxx.x	xxx.x
		Max	xxx	xxx	xxx	xxx

Source: Listing 16.2.9.9 - Respiratory tests and changes from baseline
Program: Tables\k374-fa-tbl.sas

Table 14.3.5.10 - Descriptive statistics of respiratory tests parameters and their changes from baseline - Safety set

Smoking history: Smokers

			Standardized Use N=XX		Non-standardized Use N=XX	
Parameter	**Time Point**	**Statistics**	**Value**	**Change from baseline**	**Value**	**Change from baseline**
FCOHb [%]	Pre-dose	N	nn	---	nn	---
		Mean	xxx.x	---	xxx.x	---
		SD	xxx.x	---	xxx.x	---
		CV%	xxx.x	---	xxx.x	---
		Min	xxx	---	xxx	---
		Median	xxx.x	---	xxx.x	---
		Max	xxx	---	xxx	---
FCOHb [%]	10 min post-dose	N	nn	nn	nn	nn
		Mean	xxx.x	xxx.x	xxx.x	xxx.x
		SD	xxx.x	xxx.x	xxx.x	xxx.x
		CV%	xxx.x	xxx.x	xxx.x	xxx.x
		Min	xxx	xxx	xxx	xxx
		Median	xxx.x	xxx.x	xxx.x	xxx.x
		Max	xxx	xxx	xxx	xxx
FCOHb [%]	30 min post-dose	N	nn	nn	nn	nn
		Mean	xxx.x	xxx.x	xxx.x	xxx.x
		SD	xxx.x	xxx.x	xxx.x	xxx.x
		CV%	xxx.x	xxx.x	xxx.x	xxx.x
		Min	xxx	xxx	xxx	xxx
		Median	xxx.x	xxx.x	xxx.x	xxx.x
		Max	xxx	xxx	xxx	xxx

Source: Listing 16.2.9.9 - Respiratory tests and changes from baseline
Program: Tables\k374-fa-tbl.sas

Table 14.3.5.10 - Descriptive statistics of respiratory tests parameters and their changes from baseline - Safety set

Smoking history: Smokers

			Standardized Use N=XX		Non-standardized Use N=XX	
Parameter	**Time Point**	**Statistics**	**Value**	**Change from baseline**	**Value**	**Change from baseline**
FCOHb [%]	Visit 4 - Day 2	N	nn	nn	nn	nn
		Mean	xxx.x	xxx.x	xxx.x	xxx.x
		SD	xxx.x	xxx.x	xxx.x	xxx.x
		CV%	xxx.x	xxx.x	xxx.x	xxx.x
		Min	xxx	xxx	xxx	xxx
		Median	xxx.x	xxx.x	xxx.x	xxx.x
		Max	xxx	xxx	xxx	xxx
FCOHb [%]	Visit 4 - Day 3	N	nn	nn	nn	nn
		Mean	xxx.x	xxx.x	xxx.x	xxx.x
		SD	xxx.x	xxx.x	xxx.x	xxx.x
		CV%	xxx.x	xxx.x	xxx.x	xxx.x
		Min	xxx	xxx	xxx	xxx
		Median	xxx.x	xxx.x	xxx.x	xxx.x
		Max	xxx	xxx	xxx	xxx
exhaled CO [L]	Pre-dose	N	nn	---	nn	---
		Mean	xxx.x	---	xxx.x	---
		SD	xxx.x	---	xxx.x	---
		CV%	xxx.x	---	xxx.x	---
		Min	xxx	---	xxx	---
		Median	xxx.x	---	xxx.x	---
		Max	xxx	---	xxx	---

Source: Listing 16.2.9.9 - Respiratory tests and changes from baseline
Program: Tables\k374-fa-tbl.sas

Table 14.3.5.10 - Descriptive statistics of respiratory tests parameters and their changes from baseline - Safety set

Smoking history: Smokers

			Standardized Use N=XX		Non-standardized Use N=XX	
Parameter	**Time Point**	**Statistics**	**Value**	**Change from baseline**	**Value**	**Change from baseline**
exhaled CO [L]	10 min post-dose	N	nn	nn	nn	nn
		Mean	xxx.x	xxx.x	xxx.x	xxx.x
		SD	xxx.x	xxx.x	xxx.x	xxx.x
		CV%	xxx.x	xxx.x	xxx.x	xxx.x
		Min	xxx	xxx	xxx	xxx
		Median	xxx.x	xxx.x	xxx.x	xxx.x
		Max	xxx	xxx	xxx	xxx
exhaled CO [L]	30 min post-dose	N	nn	nn	nn	nn
		Mean	xxx.x	xxx.x	xxx.x	xxx.x
		SD	xxx.x	xxx.x	xxx.x	xxx.x
		CV%	xxx.x	xxx.x	xxx.x	xxx.x
		Min	xxx	xxx	xxx	xxx
		Median	xxx.x	xxx.x	xxx.x	xxx.x
		Max	xxx	xxx	xxx	xxx

Source: Listing 16.2.9.9 - Respiratory tests and changes from baseline
Program: Tables\k374-fa-tbl.sas

Table 14.3.5.10 - Descriptive statistics of respiratory tests parameters and their changes from baseline - Safety set

Smoking history: Non-smokers or past smokers

			Standardized Use N=XX		Non-standardized Use N=XX	
Parameter	**Time Point**	**Statistics**	**Value**	**Change from baseline**	**Value**	**Change from baseline**
FCOHb [%]	Pre-dose	N	nn	---	nn	---
		Mean	xxx.x	---	xxx.x	---
		SD	xxx.x	---	xxx.x	---
		CV%	xxx.x	---	xxx.x	---
		Min	xxx	---	xxx	---
		Median	xxx.x	---	xxx.x	---
		Max	xxx	---	xxx	---
FCOHb [%]	10 min post-dose	N	nn	nn	nn	nn
		Mean	xxx.x	xxx.x	xxx.x	xxx.x
		SD	xxx.x	xxx.x	xxx.x	xxx.x
		CV%	xxx.x	xxx.x	xxx.x	xxx.x
		Min	xxx	xxx	xxx	xxx
		Median	xxx.x	xxx.x	xxx.x	xxx.x
		Max	xxx	xxx	xxx	xxx
FCOHb [%]	30 min post-dose	N	nn	nn	nn	nn
		Mean	xxx.x	xxx.x	xxx.x	xxx.x
		SD	xxx.x	xxx.x	xxx.x	xxx.x
		CV%	xxx.x	xxx.x	xxx.x	xxx.x
		Min	xxx	xxx	xxx	xxx
		Median	xxx.x	xxx.x	xxx.x	xxx.x
		Max	xxx	xxx	xxx	xxx

Source: Listing 16.2.9.9 - Respiratory tests and changes from baseline
Program: Tables\k374-fa-tbl.sas

Table 14.3.5.10 - Descriptive statistics of respiratory tests parameters and their changes from baseline - Safety set

Smoking history: Non-smokers or past smokers

			Standardized Use N=XX		Non-standardized Use N=XX	
Parameter	**Time Point**	**Statistics**	**Value**	**Change from baseline**	**Value**	**Change from baseline**
FCOHb [%]	Visit 4 - Day 2	N	nn	nn	nn	nn
		Mean	xxx.x	xxx.x	xxx.x	xxx.x
		SD	xxx.x	xxx.x	xxx.x	xxx.x
		CV%	xxx.x	xxx.x	xxx.x	xxx.x
		Min	xxx	xxx	xxx	xxx
		Median	xxx.x	xxx.x	xxx.x	xxx.x
		Max	xxx	xxx	xxx	xxx
FCOHb [%]	Visit 4 - Day 3	N	nn	nn	nn	nn
		Mean	xxx.x	xxx.x	xxx.x	xxx.x
		SD	xxx.x	xxx.x	xxx.x	xxx.x
		CV%	xxx.x	xxx.x	xxx.x	xxx.x
		Min	xxx	xxx	xxx	xxx
		Median	xxx.x	xxx.x	xxx.x	xxx.x
		Max	xxx	xxx	xxx	xxx
exhaled CO [L]	Pre-dose	N	nn	---	nn	---
		Mean	xxx.x	---	xxx.x	---
		SD	xxx.x	---	xxx.x	---
		CV%	xxx.x	---	xxx.x	---
		Min	xxx	---	xxx	---
		Median	xxx.x	---	xxx.x	---
		Max	xxx	---	xxx	---

Source: Listing 16.2.9.9 - Respiratory tests and changes from baseline
Program: Tables\k374-fa-tbl.sas

Table 14.3.5.10 - Descriptive statistics of respiratory tests parameters and their changes from baseline - Safety set

Smoking history: Non-smokers or past smokers

			Standardized Use N=XX		Non-standardized Use N=XX	
Parameter	**Time Point**	**Statistics**	**Value**	**Change from baseline**	**Value**	**Change from baseline**
exhaled CO [L]	10 min post-dose	N	nn	nn	nn	nn
		Mean	xxx.x	xxx.x	xxx.x	xxx.x
		SD	xxx.x	xxx.x	xxx.x	xxx.x
		CV%	xxx.x	xxx.x	xxx.x	xxx.x
		Min	xxx	xxx	xxx	xxx
		Median	xxx.x	xxx.x	xxx.x	xxx.x
		Max	xxx	xxx	xxx	xxx
exhaled CO [L]	30 min post-dose	N	nn	nn	nn	nn
		Mean	xxx.x	xxx.x	xxx.x	xxx.x
		SD	xxx.x	xxx.x	xxx.x	xxx.x
		CV%	xxx.x	xxx.x	xxx.x	xxx.x
		Min	xxx	xxx	xxx	xxx
		Median	xxx.x	xxx.x	xxx.x	xxx.x
		Max	xxx	xxx	xxx	xxx

Source: Listing 16.2.9.9 - Respiratory tests and changes from baseline
Program: Tables\k374-fa-tbl.sas

Table 14.3.5.10 - Descriptive statistics of respiratory tests parameters and their changes from baseline - Safety set

Smoking history: Non-smokers or past smokers

			Safety set N=XX	Standardized Use N=XX		Non-standardized Use N=XX	
Parameter	**Time Point**	**Statistics**	**Value**	**Value**	**Change from baseline**	**Value**	**Change from baseline**
FCOHb [%]	30 min post-dose	N	---	nn	nn	nn	nn
		Mean	---	xxx.x	xxx.x	xxx.x	xxx.x
		SD	---	xxx.x	xxx.x	xxx.x	xxx.x
		CV%	---	xxx.x	xxx.x	xxx.x	xxx.x
		Min	---	xxx	xxx	xxx	xxx
		Median	---	xxx.x	xxx.x	xxx.x	xxx.x
		Max	---	xxx	xxx	xxx	xxx
FCOHb [%]	Visit 4 - Day 2	N	---	nn	nn	nn	nn
		Mean	---	xxx.x	xxx.x	xxx.x	xxx.x
		SD	---	xxx.x	xxx.x	xxx.x	xxx.x
		CV%	---	xxx.x	xxx.x	xxx.x	xxx.x
		Min	---	xxx	xxx	xxx	xxx
		Median	---	xxx.x	xxx.x	xxx.x	xxx.x
		Max	---	xxx	xxx	xxx	xxx
FCOHb [%]	Visit 4 - Day 3	N	---	nn	nn	nn	nn
		Mean	---	xxx.x	xxx.x	xxx.x	xxx.x
		SD	---	xxx.x	xxx.x	xxx.x	xxx.x
		CV%	---	xxx.x	xxx.x	xxx.x	xxx.x
		Min	---	xxx	xxx	xxx	xxx
		Median	---	xxx.x	xxx.x	xxx.x	xxx.x
		Max	---	xxx	xxx	xxx	xxx

Source: Listing 16.2.9.9 - Respiratory tests and changes from baseline
Program: Tables\k374-fa-tbl.sas

Table 14.3.5.10 - Descriptive statistics of respiratory tests parameters and their changes from baseline - Safety set

Smoking history: Non-smokers or past smokers

			Safety set N=XX	Standardized Use N=XX		Non-standardized Use N=XX	
Parameter	**Time Point**	**Statistics**	**Value**	**Value**	**Change from baseline**	**Value**	**Change from baseline**
exhaled CO [L]	Screening	N	nn	---	---	---	---
		Mean	xxx.x	---	---	---	---
		SD	xxx.x	---	---	---	---
		CV%	xxx.x	---	---	---	---
		Min	xxx	---	---	---	---
		Median	xxx.x	---	---	---	---
		Max	xxx	---	---	---	---
exhaled CO [L]	Pre-dose	N	---	nn	---	nn	---
		Mean	---	xxx.x	---	xxx.x	---
		SD	---	xxx.x	---	xxx.x	---
		CV%	---	xxx.x	---	xxx.x	---
		Min	---	xxx	---	xxx	---
		Median	---	xxx.x	---	xxx.x	---
		Max	---	xxx	---	xxx	---
exhaled CO [L]	10 min post-dose	N	---	nn	nn	nn	nn
		Mean	---	xxx.x	xxx.x	xxx.x	xxx.x
		SD	---	xxx.x	xxx.x	xxx.x	xxx.x
		CV%	---	xxx.x	xxx.x	xxx.x	xxx.x
		Min	---	xxx	xxx	xxx	xxx
		Median	---	xxx.x	xxx.x	xxx.x	xxx.x
		Max	---	xxx	xxx	xxx	xxx

Source: Listing 16.2.9.9 - Respiratory tests and changes from baseline
Program: Tables\k374-fa-tbl.sas

Table 14.3.5.10 - Descriptive statistics of respiratory tests parameters and their changes from baseline - Safety set

Smoking history: Non-smokers or past smokers

			Safety set N=XX	Standardized Use N=XX		Non-standardized Use N=XX	
Parameter	**Time Point**	**Statistics**	**Value**	**Value**	**Change from baseline**	**Value**	**Change from baseline**
exhaled CO [L]	30 min post-dose	N	---	nn	nn	nn	nn
		Mean	---	xxx.x	xxx.x	xxx.x	xxx.x
		SD	---	xxx.x	xxx.x	xxx.x	xxx.x
		CV%	---	xxx.x	xxx.x	xxx.x	xxx.x
		Min	---	xxx	xxx	xxx	xxx
		Median	---	xxx.x	xxx.x	xxx.x	xxx.x
		Max	---	xxx	xxx	xxx	xxx

Source: Listing 16.2.9.9 - Respiratory tests and changes from baseline
Program: Tables\k374-fa-tbl.sas

Table 14.3.5.11 - Concomitant medications - Safety set

Medication Class [1,2] **Standardised Medication Name** [1]	**Overall** **N=XX** **n (%)**
Number of subjects with any concomitant medication	nn (xx.x)
Selective beta-2-adrenoreceptor agonists	nn (xx.x)
Salbutamol	nn (xx.x)
Ventolin	nn (xx.x)
...	nn (xx.x)
Anilides	nn (xx.x)
Paracetamol	nn (xx.x)
...	nn (xx.x)

Note: The number and the proportion of participants with any concomitant medication for each classification level are reported
The denominator for calculating the percentages is the number of participants in the safety set
Note 1: WHO Drug Dictionary March 1, 2025
Note 2: Anatomical Therapeutic Chemical classification, 4th level term, 3rd level term or 2nd level term as applicable
Source: Source: Listing 16.2.10.2 - Prior and concomitant medications
Program: Tables\k374-cm-tbl.sas

Figure 14.2.1.1 - Mean (+SD) CBD concentration (pg/mL) in blood vs. time profiles. Linear scale (top) and logarithmic/linear scale (bottom)

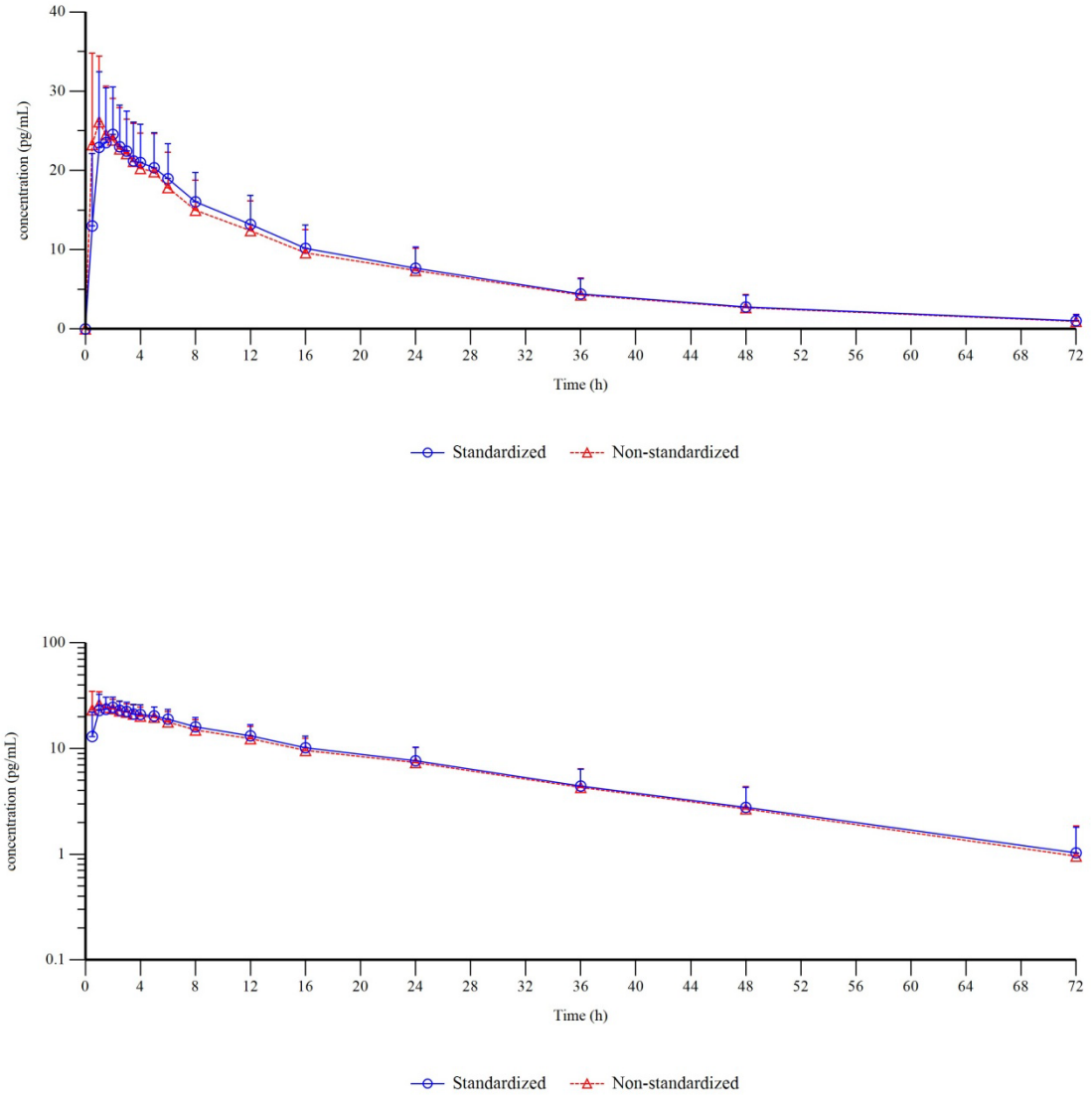
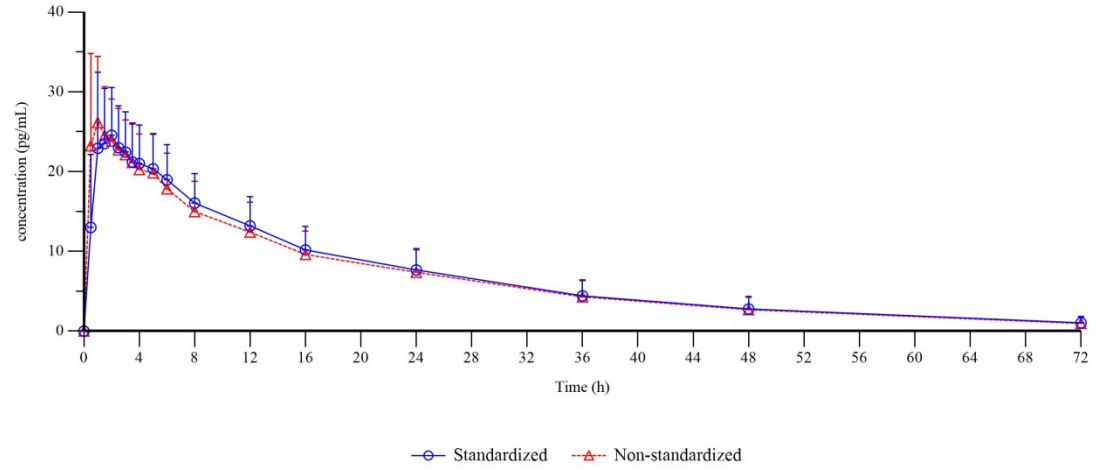


Figure 14.2.1.2 - Mean (+SD) 7-OH-CBD concentration (pg/mL) in blood vs. time profiles. Linear scale (top) and logarithmic/linear scale (bottom)



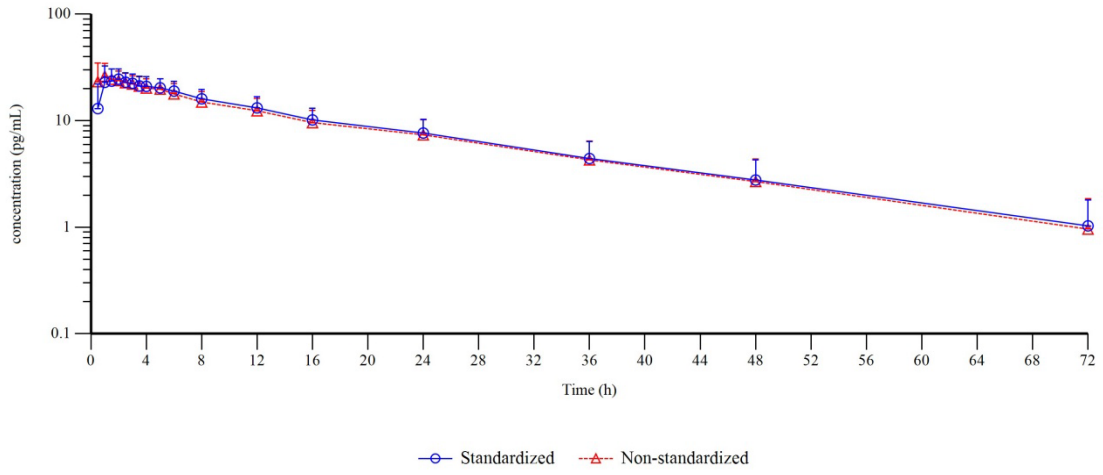
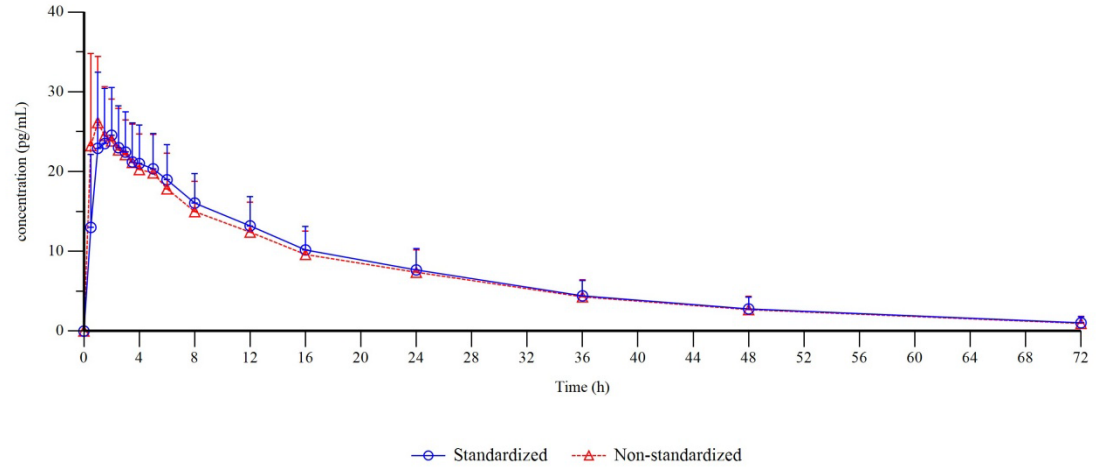


Figure 14.2.1.3 - Mean (+SD) 7-COOH-CBD concentration (pg/mL) in blood vs. time profiles. Linear scale (top) and logarithmic/linear scale (bottom)



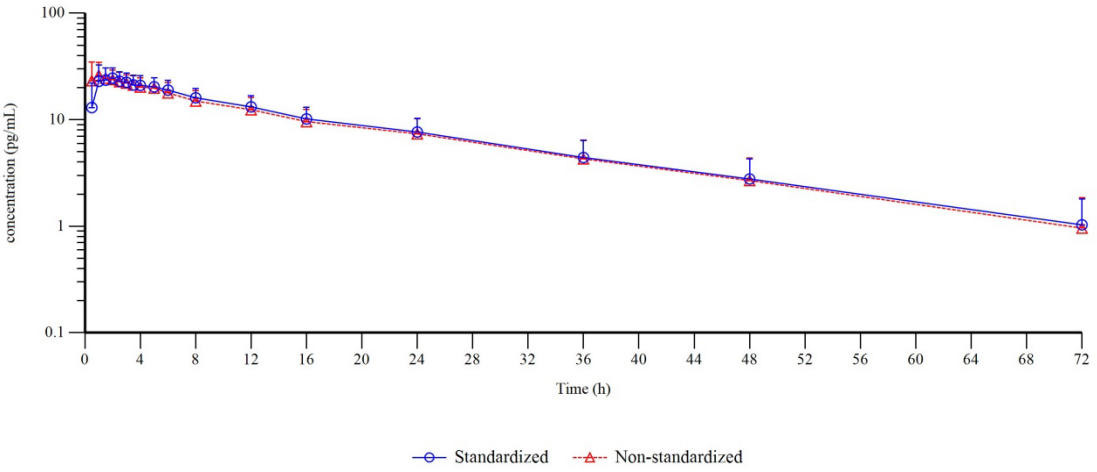


Figure 14.2.1.4 - Mean (+SD) THC concentration (pg/mL) in blood vs. time profiles. Linear scale (top) and logarithmic/linear scale (bottom)

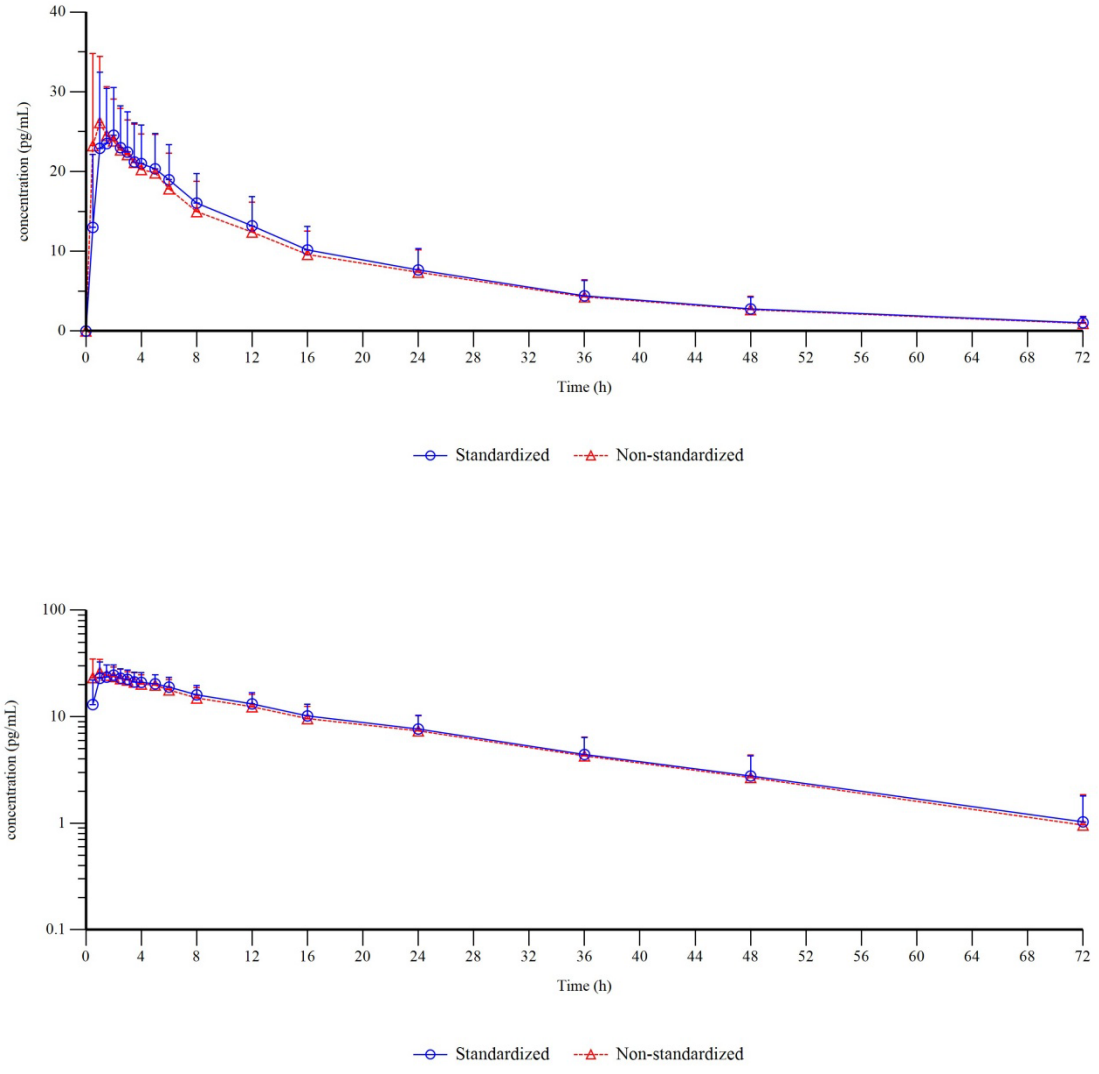
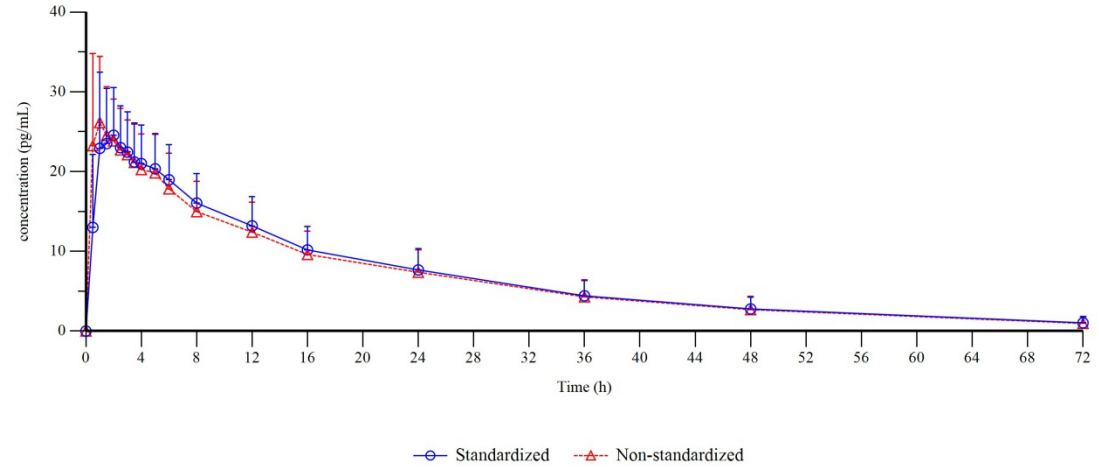


Figure 14.2.1.5 - Mean (+SD) 11-OH-THC concentration (pg/mL) in blood vs. time profiles. Linear scale (top) and logarithmic/linear scale (bottom)



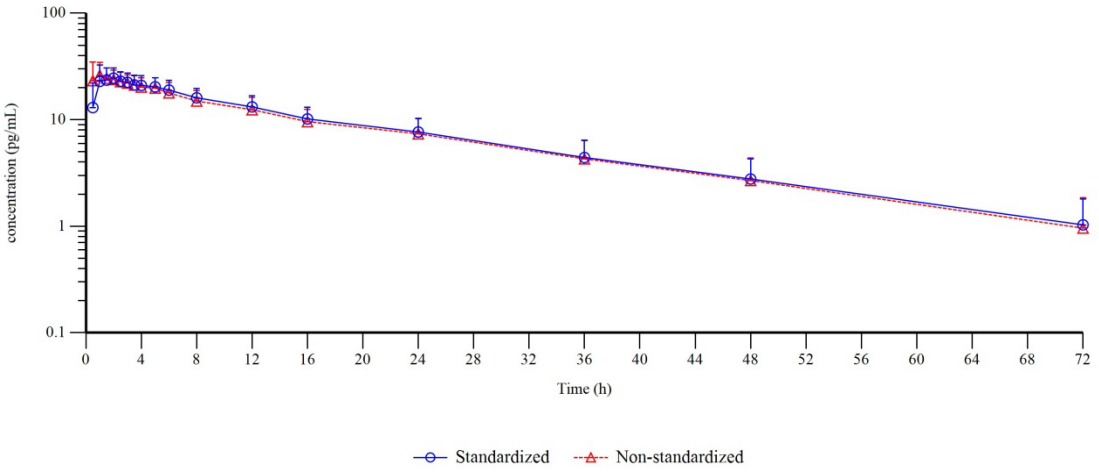
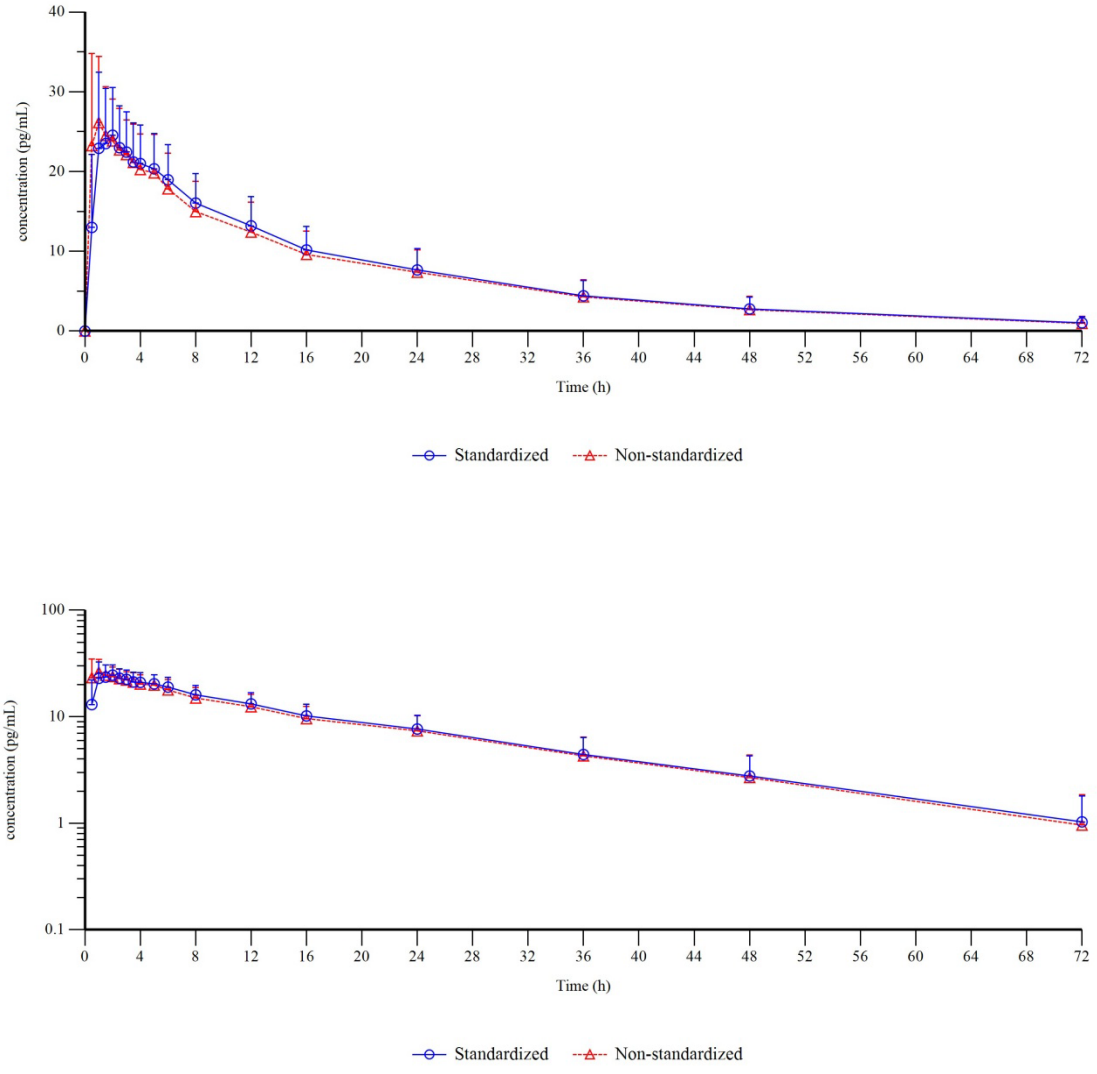


Figure 14.2.1.6 - Mean (+SD) 11-COOH-THC concentration (pg/mL) in blood vs. time profiles. Linear scale (top) and logarithmic/linear scale (bottom)



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Listing 16.2.1.1 - Discontinued participants

Participant ID	Last administration before discontinuation	Sex	Age (years)	Last visit	Time elapsed from last administration (hours) [1]	Date of premature discontinuation	Primary reason for Participant premature study termination
01-001/001	Day 1 - Standardized administration	M	45	Visit 3	1	ddMMMyyyy	Withdrawal by Participant
01-003/002	Day 4 –Non-Standardized administration	F	60	Visit 5	19	ddMMMyyyy	Adverse event
...	...	...		...	...	...	...

Note 1: Time elapsed from last administration is the difference in hours between the last Participant study evaluation and the last study product administration
Program: Listings\k374-ds-lst.sas

Listing 16.2.2.1 - Protocol deviations

Participant ID	Deviation Number	Deviation Category	Deviation Coded Term	Deviation Description
01-001/001	1	Minor	Deviation from scheduled blood sampling time	Sample number 22 was collected outside the window of 15 min ± 3 min after study product administration
01-007/006	1	Important	Administration error	Standardized administration not performed according to schedule
...		...	...	...

Program: Listings\k374-dv-lst.sas

Listing 16.2.3.1 - Participants excluded from the analysis sets

Participant ID	Sex	Age (years)	Enrolled Set	Safety Set	PK Set	PKPP Set	Reason for the exclusion
01-010/008	F	45	Y	N	N	N	Lack of study product administration
01-015/013	F	50	Y	Y	Y	N	Important protocol deviations
...	...		.	.	.	.	...

Program: Listings\k374-ds-lst.sas

Listing 16.2.4.1 - Participants' disposition

Participant ID	Date of Informed Consent	Date of Screening	Date/time of Enrolment	Date/time of First Administration	Date/time of Last Administration	Status at the End of the Study	Date of Study Completion or Discontinuation [1]	Date of End of Study
01-005	ddMMMyyyy	ddMMMyyyy	---	---	---	Screen failure	---	ddMMMyyyy
01-001/001	ddMMMyyyy	ddMMMyyyy	ddMMMyyyy hh:mm	ddMMMyyyy hh:mm:ss	ddMMMyyyy hh:mm:ss	Discontinued	ddMMMyyyy	ddMMMyyyy
01-002/002	ddMMMyyyy	ddMMMyyyy	ddMMMyyyy hh:mm	ddMMMyyyy hh:mm:ss	ddMMMyyyy hh:mm:ss	Completed	ddMMMyyyy	ddMMMyyyy
...	...	...	...	...	...	...	...	...

Note 1 : Only for enrolled participants
Listings\k374-ds-lst.sas

Listing 16.2.4.2 - Demography

Participant ID	Sex	Birth Year	Age (years)	Height (cm)	Body Weight (kg)	Body Mass Index (kg/m^2)
01-001/001	F	1972	50	170	55.0	19.0
01-002/002	M	1977	55	187	91.0	26.0
...	...	...		...	...	...

Note:Program:Listings\k374-dm-lst.sas

Listing 16.2.4.3 - Inclusion/Exclusion criteria not met

Participant ID	Criterion	Verbatim
01-001/001	Inclusion criterion 3	BMI: 18.5-30 kg/m2
...	...	...

Program: Listings\k374-ie-lst.sas

Listing 16.2.5.1 - Study product administration

Participant ID	Product Use	First Puff Date/time	Last Puff Date/time	Nr. of puffs	Smoking abstention Conditions From 12 h before administration?
01-001/001	Standardized	ddMMMyyyy hh:mm:ss	ddMMMyyyy hh:mm:ss	6	Y
01-001/001	Non-Standardized	ddMMMyyyy hh:mm:ss	ddMMMyyyy hh:mm:ss	5	Y
...	...	...	...	...	...

Program: Listings\k374-ex-lst.sas

Listing 16.2.5.2 - Study product administration interruptions

Participant ID	Product Use		
01-001/001	Standardized	Was the administration temporarily interrupted?	Y
01-001/001	Standardized	Start time of interruption:	ddMMMyyyy hh:mm:ss
01-001/001	Standardized	End time of interruption:	ddMMMyyyy hh:mm:ss
01-001/001	Standardized	Nr. of Puffs until interruption:	2
01-001/001	Standardized	Was the administration permanently interrupted?	N
01-001/001	Non-Standardized	Was the administration temporarily interrupted?	N
01-001/001	Non-Standardized	Was the administration permanently interrupted?	N
...	...	...	...

Program: Listings\k374-ex-lst.sas

Listing 16.2.5.3 - PK samples collection dates and times

Product Use: Standardized

Participant ID	Administration Date/Time	Time Point	Sample Number	Collection Date/time	Time from Administration
01-001/001	ddMMMyyyy hh:mm:ss	Pre-dose (0) –Day 1 - Within 30 min prior to dosing	1	ddMMMyyyy hh:mm	-xx min
01-001/001	ddMMMyyyy hh:mm:ss	1 min ± 20 sec post-dose	2	ddMMMyyyy hh:mm:ss	xx h xx min xx sec
01-001/001	ddMMMyyyy hh:mm:ss	3 min ± 30 sec post-dose	3	ddMMMyyyy hh:mm:ss	xx h xx min xx sec
01-001/001	ddMMMyyyy hh:mm:ss	6 min ± 1 min post-dose	4	ddMMMyyyy hh:mm:ss	xx h xx min xx sec
01-001/001	ddMMMyyyy hh:mm:ss	10 min ± 2 min post-dose	5	ddMMMyyyy hh:mm	xx h xx min
01-001/001	ddMMMyyyy hh:mm:ss	15 min ± 3 min post-dose	6	ddMMMyyyy hh:mm	xx h xx min
01-001/001	ddMMMyyyy hh:mm:ss	20 min ± 3 min post-dose	7	ddMMMyyyy hh:mm	xx h xx min
01-001/001	ddMMMyyyy hh:mm:ss	30 min ± 5 min post-dose	8	ddMMMyyyy hh:mm	xx h xx min
01-001/001	ddMMMyyyy hh:mm:ss	1 hour ± 5 min post-dose	9	ddMMMyyyy hh:mm	xx h xx min
01-001/001	ddMMMyyyy hh:mm:ss	2 hours ± 10 min post-dose	10	ddMMMyyyy hh:mm	xx h xx min
01-001/001	ddMMMyyyy hh:mm:ss	4 hours ± 15 min post-dose	11	ddMMMyyyy hh:mm	xx h xx min
01-001/001	ddMMMyyyy hh:mm:ss	6 hours ± 15 min post-dose	12	ddMMMyyyy hh:mm	xx h xx min
01-001/001	ddMMMyyyy hh:mm:ss	8 hours ± 30 min post-dose	13	ddMMMyyyy hh:mm	xx h xx min
01-001/001	ddMMMyyyy hh:mm:ss	12 hours ± 1 hour post-dose	14	ddMMMyyyy hh:mm	xx h xx min
01-001/001	ddMMMyyyy hh:mm:ss	24 hours ± 1 hour post-dose	15	ddMMMyyyy hh:mm	xx h xx min
01-001/001	ddMMMyyyy hh:mm:ss	48 hours ± 2 hour post-dose	16	ddMMMyyyy hh:mm	xx h xx min
01-001/001	ddMMMyyyy hh:mm:ss	72 hours ± 2 hour post-dose	17	ddMMMyyyy hh:mm	xx h xx min
...	...	...	...	...	...

Program: Listings\k374-pc-lst.sas

Listing 16.2.5.3 - PK samples collection dates and times

Product Use: Non-standardized

Participant ID	Administration Date/Time	Time Point	Sample Number	Collection Date/time	Time from Administration
01-001/001	ddMMMyyyy hh:mm:ss	Pre-dose (0) –Day 4 - Within 30 min prior to dosing[1]	17	ddMMMyyyy hh:mm	-xx min
01-001/001	ddMMMyyyy hh:mm:ss	1 min ± 20 sec post-dose	18	ddMMMyyyy hh:mm:ss	xx h xx min xx sec
01-001/001	ddMMMyyyy hh:mm:ss	3 min ± 30 sec post-dose	19	ddMMMyyyy hh:mm:ss	xx h xx min xx sec
01-001/001	ddMMMyyyy hh:mm:ss	6 min ± 1 min post-dose	20	ddMMMyyyy hh:mm:ss	xx h xx min xx sec
01-001/001	ddMMMyyyy hh:mm:ss	10 min ± 2 min post-dose	21	ddMMMyyyy hh:mm	xx h xx min
01-001/001	ddMMMyyyy hh:mm:ss	15 min ± 3 min post-dose	22	ddMMMyyyy hh:mm	xx h xx min
01-001/001	ddMMMyyyy hh:mm:ss	20 min ± 3 min post-dose	23	ddMMMyyyy hh:mm	xx h xx min
01-001/001	ddMMMyyyy hh:mm:ss	30 min ± 5 min post-dose	24	ddMMMyyyy hh:mm	xx h xx min
01-001/001	ddMMMyyyy hh:mm:ss	1 hour ± 5 min post-dose	25	ddMMMyyyy hh:mm	xx h xx min
01-001/001	ddMMMyyyy hh:mm:ss	2 hours ± 10 min post-dose	26	ddMMMyyyy hh:mm	xx h xx min
01-001/001	ddMMMyyyy hh:mm:ss	4 hours ± 15 min post-dose	27	ddMMMyyyy hh:mm	xx h xx min
01-001/001	ddMMMyyyy hh:mm:ss	6 hours ± 15 min post-dose	28	ddMMMyyyy hh:mm	xx h xx min
...	...	...	...	...	...

Note 1: Corresponding to 72 hours ± 4 hour post-dose of standardized administration
Program: Listings\k374-pc-lst.sas

Listing 16.2.5.4 - CBD concentrations (pg/mL) measured in blood

Product Use: Standardized

Participant ID	Pre dose	1 min post dose	3 min post dose	6 min post dose	10 min post dose	15 min post dose	20 min post dose	30 min post dose	1 h post dose	2 h post dose	4 h post dose	6 h post dose	8 h post dose	12 h post dose	24 h post dose	48 h post dose	72 h post dose
01-001/001	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...

BLQL: Below Lower Quantification Limit of CBD (x.xx pg/mL)
Program: pk-analysis\k374-tlf.sas

Listing 16.2.5.4 - CBD concentrations (pg/mL) measured in blood

Product Use: Non-standardized

Participant ID	Pre dose	1 min post dose	3 min post dose	6 min post dose	10 min post dose	15 min post dose	20 min post dose	30 min post dose	1 h post dose	2 h post dose	4 h post dose	6 h post dose	8 h post dose	12 h post dose	24 h post dose	48 h post dose	72 h post dose
01-001/001	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	---	---	---	---	---
...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...

BLQL: Below Lower Quantification Limit of CBD (x.xx pg/mL)
Program: pk-analysis\k374-tlf.sas

Listing 16.2.5.5 - 7-OH-CBD concentrations (pg/mL) measured in blood

Product Use: Standardized

Participant ID	Pre dose	1 min post dose	3 min post dose	6 min post dose	10 min post dose	15 min post dose	20 min post dose	30 min post dose	1 h post dose	2 h post dose	4 h post dose	6 h post dose	8 h post dose	12 h post dose	24 h post dose	48 h post dose	72 h post dose
01-001/001	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...

BLQL: Below Lower Quantification Limit of 7-OH-CBD (x.xx pg/mL)
Program: pk-analysis\k374-tlf.sas

Listing 16.2.5.5 - 7-OH-CBD concentrations (pg/mL) measured in blood

Product Use: Non-standardized

Participant ID	Pre dose	1 min post dose	3 min post dose	6 min post dose	10 min post dose	15 min post dose	20 min post dose	30 min post dose	1 h post dose	2 h post dose	4 h post dose	6 h post dose	8 h post dose	12 h post dose	24 h post dose	48 h post dose	72 h post dose
01-001/001	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	---	---	---	---	---
...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...

BLQL: Below Lower Quantification Limit of 7-OH-CBD (x.xx pg/mL)
Program: pk-analysis\k374-tlf.sas

Listing 16.2.5.6 - 7-COOH-CBD concentrations (pg/mL) measured in blood

Product Use: Standardized

Participant ID	Pre dose	1 min post dose	3 min post dose	6 min post dose	10 min post dose	15 min post dose	20 min post dose	30 min post dose	1 h post dose	2 h post dose	4 h post dose	6 h post dose	8 h post dose	12 h post dose	24 h post dose	48 h post dose	72 h post dose
01-001/001	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...

BLQL: Below Lower Quantification Limit of 7-COOH-CBD (x.xx pg/mL)
Program: pk-analysis\k374-tlf.sas

Listing 16.2.5.6 - 7-COOH-CBD concentrations (pg/mL) measured in blood

Product Use: Non-standardized

Participant ID	Pre dose	1 min post dose	3 min post dose	6 min post dose	10 min post dose	15 min post dose	20 min post dose	30 min post dose	1 h post dose	2 h post dose	4 h post dose	6 h post dose	8 h post dose	12 h post dose	24 h post dose	48 h post dose	72 h post dose
01-001/001	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	---	---	---	---	---
...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...

BLQL: Below Lower Quantification Limit of 7-COOH-CBD (x.xx pg/mL)
Program: pk-analysis\k374-tlf.sas

Listing 16.2.5.7 - THC concentrations (pg/mL) measured in blood

Product Use: Standardized

Participant ID	Pre dose	1 min post dose	3 min post dose	6 min post dose	10 min post dose	15 min post dose	20 min post dose	30 min post dose	1 h post dose	2 h post dose	4 h post dose	6 h post dose	8 h post dose	12 h post dose	24 h post dose	48 h post dose	72 h post dose
01-001/001	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...

BLQL: Below Lower Quantification Limit of THC (x.xx pg/mL)
Program: pk-analysis\k374-tlf.sas

Listing 16.2.5.7 - THC concentrations (pg/mL) measured in blood

Product Use: Non-standardized

Participant ID	Pre dose	1 min post dose	3 min post dose	6 min post dose	10 min post dose	15 min post dose	20 min post dose	30 min post dose	1 h post dose	2 h post dose	4 h post dose	6 h post dose	8 h post dose	12 h post dose	24 h post dose	48 h post dose	72 h post dose
01-001/001	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	---	---	---	---	---
...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...

BLQL: Below Lower Quantification Limit of THC (x.xx pg/mL)
Program: pk-analysis\k374-tlf.sas

Listing 16.2.5.8 - 11-OH-THC concentrations (pg/mL) measured in blood

Product Use: Standardized

Participant ID	Pre dose	1 min post dose	3 min post dose	6 min post dose	10 min post dose	15 min post dose	20 min post dose	30 min post dose	1 h post dose	2 h post dose	4 h post dose	6 h post dose	8 h post dose	12 h post dose	24 h post dose	48 h post dose	72 h post dose
01-001/001	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...

BLQL: Below Lower Quantification Limit of 11-OH-THC (x.xx pg/mL)
Program: pk-analysis\k374-tlf.sas

Listing 16.2.5.8 - 11-OH-THC concentrations (pg/mL) measured in blood

Product Use: Non-standardized

Participant ID	Pre dose	1 min post dose	3 min post dose	6 min post dose	10 min post dose	15 min post dose	20 min post dose	30 min post dose	1 h post dose	2 h post dose	4 h post dose	6 h post dose	8 h post dose	12 h post dose	24 h post dose	48 h post dose	72 h post dose
01-001/001	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	---	---	---	---	---
...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...

BLQL: Below Lower Quantification Limit of 11-OH-THC (x.xx pg/mL)
Program: pk-analysis\k374-tlf.sas

Listing 16.2.5.9 - 11-COOH-THC concentrations (pg/mL) measured in blood

Product Use: Standardized

Participant ID	Pre dose	1 min post dose	3 min post dose	6 min post dose	10 min post dose	15 min post dose	20 min post dose	30 min post dose	1 h post dose	2 h post dose	4 h post dose	6 h post dose	8 h post dose	12 h post dose	24 h post dose	48 h post dose	72 h post dose
01-001/001	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...

BLQL: Below Lower Quantification Limit of 11-COOH-THC (x.xx pg/mL)
Program: pk-analysis\k374-tlf.sas

Listing 16.2.5.9 - 11-COOH-THC concentrations (pg/mL) measured in blood

Product Use: Non-standardized

Participant ID	Pre dose	1 min post dose	3 min post dose	6 min post dose	10 min post dose	15 min post dose	20 min post dose	30 min post dose	1 h post dose	2 h post dose	4 h post dose	6 h post dose	8 h post dose	12 h post dose	24 h post dose	48 h post dose	72 h post dose
01-001/001	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	---	---	---	---	---
...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...

BLQL: Below Lower Quantification Limit of 11-COOH-THC (x.xx pg/mL)
Program: pk-analysis\k374-tlf.sas

Listing 16.2.6.1 - CBD PK parameters

Product Use: Standardized

Participant ID	C_{max} (pg/mL)	t_{max} (h)	AUC_{0-t} (h*pg/mL)	AUC_{0-inf} (h*pg/mL)	AUC_{extra} (%)	$t_{½\ el}$ (h)	K_{el} (1/h)	Number of Points for K_{el}	R^2	CL/F (mL/min)	Vz/F (mL)
01-020/001	xxxxx.xx	x.xx	xxxx.xx	xxxx.xx	x.xx	x.xx	x.xx	x	x.xxxx	xxxx.xx	xxxx.xx
...	...	...	...	...	...	...	...	...	...	...	...

Program: pk-analysis\k374-tlf.sas

Listing 16.2.6.1 - CBD PK parameters

Product Use: Non-standardized

Participant ID	C_{max} (pg/mL)	t_{max} (h)	AUC_{0-t} (h*pg/mL)	AUC_{0-inf} (h*pg/mL)	AUC_{extra} (%)	$t_{½\ el}$ (h)	K_{el} (1/h)	Number of Points for K_{el}	R^2	CL/F (mL/min)	Vz/F (mL)
01-020/001	xxxxx.xx	x.xx	xxxx.xx	xxxx.xx	x.xx	x.xx	x.xx	x	x.xxxx	xxxx.xx	xxxx.xx
...	...	...	...	...	...	...	...	...	...	...	...

Program: pk-analysis\k374-tlf.sas

Listing 16.2.6.2 - 7-OH-CBD PK parameters

Product Use: Standardized

Participant ID	C_{max} (pg/mL)	t_{max} (h)	AUC_{0-t} (h*pg/mL)	AUC_{0-inf} (h*pg/mL)	AUC_{extra} (%)	$t_{½\ el}$ (h)	K_{el} (1/h)	Number of Points for K_{el}	R^2
01-020/001	xxxxx.xx	x.xx	xxxx.xx	xxxx.xx	x.xx	x.xx	x.xx	x	x.xxxx
...	...	...	...	...	...	...	...	...	...

Program: pk-analysis\k374-tlf.sas

Listing 16.2.6.2 - 7-OH-CBD PK parameters

Product Use: Non-standardized

Participant ID	C_{max} (pg/mL)	t_{max} (h)	AUC_{0-t} (h*pg/mL)	AUC_{0-inf} (h*pg/mL)	AUC_{extra} (%)	$t_{½\ el}$ (h)	K_{el} (1/h)	Number of Points for K_{el}	R^2
01-020/001	xxxxx.xx	x.xx	xxxx.xx	xxxx.xx	x.xx	x.xx	x.xx	x	x.xxxx
...	...	...	...	...	...	...	...	...	...

Program: pk-analysis\k374-tlf.sas

Listing 16.2.6.3 - 7-COOH-CBD PK parameters

Product Use: Standardized

Participant ID	C_{max} (pg/mL)	t_{max} (h)	AUC_{0-t} (h*pg/mL)	AUC_{0-inf} (h*pg/mL)	AUC_{extra} (%)	$t_{½\ el}$ (h)	K_{el} (1/h)	Number of Points for K_{el}	R^2
01-020/001	xxxxx.xx	x.xx	xxxx.xx	xxxx.xx	x.xx	x.xx	x.xx	x	x.xxxx
...	...	...	...	...	...	...	...	...	...

Program: pk-analysis\k374-tlf.sas

Listing 16.2.6.3 - 7-COOH-CBD PK parameters

Product Use: Non-standardized

Participant ID	C_{max} (pg/mL)	t_{max} (h)	AUC_{0-t} (h*pg/mL)	AUC_{0-inf} (h*pg/mL)	AUC_{extra} (%)	$t_{½\ el}$ (h)	K_{el} (1/h)	Number of Points for K_{el}	R^2
01-020/001	xxxxx.xx	x.xx	xxxx.xx	xxxx.xx	x.xx	x.xx	x.xx	x	x.xxxx
...	...	...	...	...	...	...	...	...	...

Program: pk-analysis\k374-tlf.sas

Listing 16.2.6.4 - THC PK parameters

Product Use: Standardized

Participant ID	C_{max} (pg/mL)	t_{max} (h)	AUC_{0-t} (h*pg/mL)	AUC_{0-inf} (h*pg/mL)	AUC_{extra} (%)	$t_{½\ el}$ (h)	K_{el} (1/h)	Number of Points for K_{el}	R^2
01-020/001	xxxxx.xx	x.xx	xxxx.xx	xxxx.xx	x.xx	x.xx	x.xx	x	x.xxxx
...	...	...	...	...	...	...	...	...	...

Program: pk-analysis\k374-tlf.sas

Listing 16.2.6.4 - THC PK parameters

Product Use: Non-standardized

Participant ID	C_{max} (pg/mL)	t_{max} (h)	AUC_{0-t} (h*pg/mL)	AUC_{0-inf} (h*pg/mL)	AUC_{extra} (%)	$t_{½\ el}$ (h)	K_{el} (1/h)	Number of Points for K_{el}	R^2
01-020/001	xxxxx.xx	x.xx	xxxx.xx	xxxx.xx	x.xx	x.xx	x.xx	x	x.xxxx
...	...	...	...	...	...	...	...	...	...

Program: pk-analysis\k374-tlf.sas

Listing 16.2.6.5 - 11-OH-THC PK parameters

Product Use: Standardized

Participant ID	C_{max} (pg/mL)	t_{max} (h)	AUC_{0-t} (h*pg/mL)	AUC_{0-inf} (h*pg/mL)	AUC_{extra} (%)	$t_{½\ el}$ (h)	K_{el} (1/h)	Number of Points for K_{el}	R^2
01-020/001	xxxxx.xx	x.xx	xxxx.xx	xxxx.xx	x.xx	x.xx	x.xx	x	x.xxxx
...	...	...	...	...	...	...	...	...	...

Program: pk-analysis\k374-tlf.sas

Listing 16.2.6.5 - 11-OH-THC PK parameters

Product Use: Non-standardized

Participant ID	C_{max} (pg/mL)	t_{max} (h)	AUC_{0-t} (h*pg/mL)	AUC_{0-inf} (h*pg/mL)	AUC_{extra} (%)	$t_{½\ el}$ (h)	K_{el} (1/h)	Number of Points for K_{el}	R^2
01-020/001	xxxxx.xx	x.xx	xxxx.xx	xxxx.xx	x.xx	x.xx	x.xx	x	x.xxxx
...	...	...	...	...	...	...	...	...	...

Program: pk-analysis\k374-tlf.sas

Listing 16.2.6.6 - 11-COOH-THC PK parameters

Product Use: Standardized

Participant ID	C_{max} (pg/mL)	t_{max} (h)	AUC_{0-t} (h*pg/mL)	AUC_{0-inf} (h*pg/mL)	AUC_{extra} (%)	$t_{½\ el}$ (h)	K_{el} (1/h)	Number of Points for K_{el}	R^2
01-020/001	xxxxx.xx	x.xx	xxxx.xx	xxxx.xx	x.xx	x.xx	x.xx	x	x.xxxx
...	...	...	...	...	...	...	...	...	...

Program: pk-analysis\k374-tlf.sas

Listing 16.2.6.6 - 11-COOH-THC PK parameters

Product Use: Non-standardized

Participant ID	C_{max} (pg/mL)	t_{max} (h)	AUC_{0-t} (h*pg/mL)	AUC_{0-inf} (h*pg/mL)	AUC_{extra} (%)	$t_{½\ el}$ (h)	K_{el} (1/h)	Number of Points for K_{el}	R^2
01-020/001	xxxxx.xx	x.xx	xxxx.xx	xxxx.xx	x.xx	x.xx	x.xx	x	x.xxxx
...	...	...	...	...	...	...	...	...	...

Program: pk-analysis\k374-tlf.sas

Listing 16.2.6.7 - Product Effect Questionnaire

Product Use: Standardized

Participant ID	Questionnaire Part	Administration Date/time		
01-001/001	1	ddMMMyyyy hh:mm	How soon after intake did you observe an effect?	After 15 min or less
			Did you experience any of the following effects?	Mindfulness
			How long did the effect last?	1-3 hours
			How would you describe the effect of the productin words?	Fearless, Sleepy
			How would you assess the intensity of the effect of this product?	5 cm
			How would you qualify your overall experience with this product?	Neutral
			How would you rate the taste/flavour of this product?	Good
			How would you rate the aftertaste of this product?	Excellent
			How would you rate the mouthfeel/texture of this product?	Poor
			How would you rate the ease of use of this product?	Very good

Program: Listings\k374-qs-lst.sas

Listing 16.2.6.7 - Product Effect Questionnaire

Product Use: Non-standardized

Participant ID	Questionnaire Part	Administration Date/time		
01-001/001	1	ddMMMyyyy hh:mm	How soon after intake did you observe an effect?	After 30-60 min
			Did you experience any of the following effects?	I haven't observed an effect yet
			How long did the effect last?	I haven't observed an effect yet
			How would you describe the effect of the productin words?	---
			How would you assess the intensity of the effect of this product?	1 cm
			How would you qualify your overall experience with this product?	Neutral
			How would you rate the taste/flavour of this product?	Poor
			How would you rate the aftertaste of this product?	Neutral
			How would you rate the mouthfeel/texture of this product?	Poor
			How would you rate the ease of use of this product?	Good
	2	ddMMMyyyy hh:mm	Which CBD products have you taken in the past?	Edibles, Suppository
			What is the purpose for which you have taken CBD products?	Sleep issues, Energizing, Creativity
			How often do you take CBD products?	Once per month
			On a scale of 0 to 10, how likely are you to take the product again?	4
			How much would you be willing to pay for the product you tested in the study?	Unsure if I want to use/buy it
...	...	...	...	...

Program: Listings\k374-qs-lst.sas

Listing 16.2.6.8 - Per-puff Parameters

Product Use: Standardized

Participant ID	Smoking History	Puff number	Assessment Date	Puff volume [Vi] (mL)	Puff duration [Di] (s)	Average flow [Qmi] (mL/s)	Peak flow [Qci] (mL/s)	Inter puff interval [Ii] (s)	Sum of Ii and Di [DFi] (s)	Peak flow position [PosQci] (%)
01-001/001	Smokers	1	ddMMMyyyy	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
01-001/001	Smokers	2	ddMMMyyyy	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
...	...	...	...	...	...	...	...	...	...	...

Program: Listings\k374-pp-lst.sas

Listing 16.2.6.9 - Per-product Use Experience Parameters

Participant ID	Product Use	Parameter	Unit	Value
01-001/001	Standardized	Total number of puffs [NPC]		xxx
01-001/001	Standardized	Total puff volume [TVOL]	mL	xxx
01-001/001	Standardized	Average puff volume [AvgVi]	mL	xxx
01-001/001	Standardized	Average puff duration [AvgDi]	s	xxx
01-001/001	Standardized	Total puff duration [TDi]	s	xxx
01-001/001	Standardized	Average flow [AvgQmi]	mL/s	xxx
01-001/001	Standardized	Peak flow [AvgQci]	mL/s	xxx
01-001/001	Standardized	Total inter puff interval [TIi]	s	xxx
01-001/001	Standardized	Average inter puff interval [AvgIi]	s	xxx
01-001/001	Standardized	Total puffing duration [TDFi]	s	xxx
01-001/001	Standardized	Puffing Intensity [SMINT]	mL/s	xxx
01-001/001	Standardized	Puffing Time Index [PTI]	%	xxx
01-001/001	Standardized	Puff Frequency [PFeq]		xxx
...	...	...		...

Program: Listings\k374-pp-lst.sas

Listing 16.2.6.10 - Remaining CBD on stick and mouthpiece after use

Participant ID	Product Use	Remaining CBD on the stick (mg)	Remaining CBD on the mouthpiece (mg)
01-001/001	Standardized	x.xxx	x.xxx
01-001/001	Non-standardized	x.xxx	x.xxx
...	...	...	...

Program: Listings\k374-ex-lst.sas

Listing 16.2.7.1 - Treatment-emergent adverse events

Product Use: Standardized

Participant ID	Adverse Event ID	Follow Up ID		
01-001/001	1	-	Description:	Headache
			Preferred Term [1]:	Headache
			System Organ Class [1]:	Nervous system disorders
			Adverse event of special interest (AESI)?	N
			Body Area Affected:	NA
			Visit Date of AE recording (Day):	ddMMMyyyy (k)
			AE Frequency:	Single Event
			Severity:	Mild
			Serious Adverse Event?	N
			Reasonable possibility of a causal relationship with study product?	Y
			Other Causal Relationship:	NA
			Action taken with Study Product:	Dose Not Changed
			Concomitant Therapy?	Y
			Other Action Taken:	N
			Start - End Date/Time (Day):	ddMMMyyyy hh:mm (k) - ddMMMyyyy hh:mm (k+n)
			AE Duration:	hh:mm
			Has the Adverse Event Started After the Administration of the Study Product?	Y
			Last Study Product Administration Date/Time Before Onset (Day):	ddMMMyyyy hh:mm:ss (k)
			Time Elapsed form Last Study Product intake before AE:	hh:mm
			Outcome:	Recovered/Resolved
			Caused Study Discontinuation?	N
...	...	...	...	...

Note 1: MedDRA version 28.0
Program: Listings\k374-ae-lst.sas

Listing 16.2.7.1 - Treatment-emergent adverse events

Product Use: Non-standardized

Participant ID	Adverse Event ID	Follow Up ID		
01-020/003	1	-	Description:	ALT high
			Preferred Term [1]:	Alanine aminotransferase increased
			System Organ Class [1]:	Investigations
			Adverse event of special interest (AESI)?	Y
			Body Area Affected:	NA
			Visit Date of AE recording (Day):	ddMMMyyyy (k)
			AE Frequency:	Single Event
			Severity:	Moderate
			Serious Adverse Event?	N
			Reasonable possibility of a causal relationship with study product?	Y
			Other Causal Relationship:	NA
			Action taken with Study Product:	Not Applicable
			Concomitant Therapy?	N
			Other Action Taken:	N
			Start - End Date/Time (Day):	ddMMMyyyy hh:mm (k) - Ongoing
			AE Duration:	hh:mm
			Has the Adverse Event Started After the Administration of the Study Product?	Y
			Last Study Product Administration Date/Time Before Onset (Day):	ddMMMyyyy hh:mm:ss (k)
			Time Elapsed form Last Study Product intake before AE:	hh:mm
			Outcome:	Not Recovered/Not Resolved
			Caused Study Discontinuation?	N
...	...	...	...	...

Note 1: MedDRA version 28.0
Program: Listings\k374-ae-lst.sas

Listing 16.2.7.2 - Adverse events of special interest

Product Use: Standardized

Participant ID	Adverse Event ID	Follow Up ID		
01-001/001	1	-	Description:	Total bilirubin increased
			Preferred Term [1]:	Blood bilirubin increased
			System Organ Class [1]:	Investigations
			Adverse event of special interest (AESI)?	Y
			Body Area Affected:	NA
			Visit Date of AE recording (Day):	ddMMMyyyy (k)
			AE Frequency:	Single Event
			Severity:	Mild
			Serious Adverse Event?	N
			Reasonable possibility of a causal relationship with study product?	Y
			Other Causal Relationship:	NA
			Action taken with Study Product:	Dose Not Changed
			Concomitant Therapy?	Y
			Other Action Taken:	N
			Start - End Date/Time (Day):	ddMMMyyyy hh:mm (k) - ddMMMyyyy hh:mm (k+n)
			AE Duration:	hh:mm
			Has the Adverse Event Started After the Administration of the Study Product?	Y
			Last Study Product Administration Date/Time Before Onset (Day):	ddMMMyyyy hh:mm:ss (k)
			Time Elapsed form Last Study Product intake before AE:	hh:mm
			Outcome:	Recovered/Resolved
			Caused Study Discontinuation?	N
...	...	...	...	...

Note 1: MedDRA version 28.0
Program: Listings\k374-ae-lst.sas

Listing 16.2.7.2 - Adverse events of special interest

Product Use: Non-standardized

Participant ID	Adverse Event ID	Follow Up ID		
01-020/003	1	-	Description:	ALT high
			Preferred Term [1]:	Alanine aminotransferase increased
			System Organ Class [1]:	Investigations
			Adverse event of special interest (AESI)?	Y
			Body Area Affected:	NA
			Visit Date of AE recording (Day):	ddMMMyyyy (k)
			AE Frequency:	Single Event
			Severity:	Moderate
			Serious Adverse Event?	N
			Reasonable possibility of a causal relationship with study product?	Y
			Other Causal Relationship:	NA
			Action taken with Study Product:	Not Applicable
			Concomitant Therapy?	N
			Other Action Taken:	N
			Start - End Date/Time (Day):	ddMMMyyyy hh:mm (k) - Ongoing
			AE Duration:	hh:mm
			Has the Adverse Event Started After the Administration of the Study Product?	Y
			Last Study Product Administration Date/Time Before Onset (Day):	ddMMMyyyy hh:mm:ss (k)
			Time Elapsed form Last Study Product intake before AE:	hh:mm
			Outcome:	Not Recovered/Not Resolved
			Caused Study Discontinuation?	N
...	...	...	...	...

Note 1: MedDRA version 28.0
Program: Listings\k374-ae-lst.sas

Listing 16.2.7.3 - Adverse events indicating abuse potential

Product Use: Standardized

Participant ID	Adverse Event ID	Follow Up ID		
01-001/001	1	-	Description:	Dizziness
			Preferred Term [1]:	Dizziness
			System Organ Class [1]:	Nervous system disorders
			Adverse event of special interest (AESI)?	N
			Body Area Affected:	NA
			Visit Date of AE recording (Day):	ddMMMyyyy (k)
			AE Frequency:	Single Event
			Severity:	Mild
			Serious Adverse Event?	N
			Reasonable possibility of a causal relationship with study product?	Y
			Other Causal Relationship:	NA
			Action taken with Study Product:	Dose Not Changed
			Concomitant Therapy?	Y
			Other Action Taken:	N
			Start - End Date/Time (Day):	ddMMMyyyy hh:mm (k) - ddMMMyyyy hh:mm (k+n)
			AE Duration:	hh:mm
			Has the Adverse Event Started After the Administration of the Study Product?	Y
			Last Study Product Administration Date/Time Before Onset (Day):	ddMMMyyyy hh:mm:ss (k)
			Time Elapsed form Last Study Product intake before AE:	hh:mm
			Outcome:	Recovered/Resolved
			Caused Study Discontinuation?	N
...	...	...	...	...

Note 1: MedDRA version 28.0
Program: Listings\k374-ae-lst.sas

Listing 16.2.7.3 - Adverse events indicating abuse potential

Product Use: Non-standardized

Participant ID	Adverse Event ID	Follow Up ID		
01-020/003	1	-	Description:	Somnolence
			Preferred Term [1]:	Somnolence
			System Organ Class [1]:	Nervous system disorders
			Adverse event of special interest (AESI)?	Y
			Body Area Affected:	NA
			Visit Date of AE recording (Day):	ddMMMyyyy (k)
			AE Frequency:	Single Event
			Severity:	Moderate
			Serious Adverse Event?	N
			Reasonable possibility of a causal relationship with study product?	Y
			Other Causal Relationship:	NA
			Action taken with Study Product:	Not Applicable
			Concomitant Therapy?	N
			Other Action Taken:	N
			Start - End Date/Time (Day):	ddMMMyyyy hh:mm (k) - Ongoing
			AE Duration:	hh:mm
			Has the Adverse Event Started After the Administration of the Study Product?	Y
			Last Study Product Administration Date/Time Before Onset (Day):	ddMMMyyyy hh:mm:ss (k)
			Time Elapsed form Last Study Product intake before AE:	hh:mm
			Outcome:	Not Recovered/Not Resolved
			Caused Study Discontinuation?	N
...	...	...	...	...

Note 1: MedDRA version 28.0
Program: Listings\k374-ae-lst.sas

Listing 16.2.7.4 - Pre-treatment Unfavourable Medical Events

Participant ID	Adverse Event ID	Follow Up ID		
01-001/001	1	-	Description:	Headache
			Preferred Term [1]:	Headache
			System Organ Class [1]:	Nervous system disorders
			Adverse event of special interest (AESI)?	N
			Body Area Affected:	NA
			Visit Date of AE recording (Day):	ddMMMyyyy (k)
			AE Frequency:	Single Event
			Severity:	Mild
			Serious Adverse Event?	N
			Reasonable possibility of a causal relationship with study product?	N
			Other Causal Relationship:	NA
			Action taken with Study Product:	Dose Not Changed
			Concomitant Therapy?	Y
			Other Action Taken:	N
			Start - End Date/Time (Day):	ddMMMyyyy hh:mm (k) - ddMMMyyyy hh:mm (k+n)
			AE Duration:	hh:mm
			Has the Adverse Event Started After the Administration of the Study Product?	N
			Last Study Product Administration Date/Time Before Onset (Day):	---
			Time Elapsed form Last Study Product intake before AE:	---
			Outcome:	Recovered/Resolved
			Caused Study Discontinuation?	N
...	...	...	...	...

Note 1: MedDRA version 28.0
Program: Listings\k374-ae-lst.sas

Listing 16.2.8.1 - Individual laboratory measurements

Category of Laboratory Parameters: HAEMATOLOGY

Participant ID	Time Point	Collection Date/time	Parameter	Value and Abnormality [1]	Change from baseline [2]	Normal Range or Reference Value	Clinically Significant?
01-001/001	Screening	ddMMMyyyy hh:mm	Erythrocytes [10^12/L]	5.19 [N]		4.30 - 5.90	N
01-001/001	Screening	ddMMMyyyy hh:mm	Leukocytes [10^9/L]	10.02 [A]		4.00 - 10.00	N
01-001/001	Screening	ddMMMyyyy hh:mm	Neutrophils [10^9/L]	3.43 [N]		1.5 - 7.7	N
01-001/001	Screening	ddMMMyyyy hh:mm	Lymphocytes [10^9/L]	2.49 [N]		1.1 - 4.5	N
01-001/001	Screening	ddMMMyyyy hh:mm	Monocytes [10^9/L]	0.43 [N]		0.1 - 0.9	N
01-001/001	Screening	ddMMMyyyy hh:mm	Eosinophils [10^9/L]	0.18 [N]		0.02 - 0.5	N
01-001/001	Screening	ddMMMyyyy hh:mm	Basophils [10^9/L]	0.07 [N]		<= 0.2	N
01-001/001	Screening	ddMMMyyyy hh:mm	Neutrophils [%]	52 [N]		42 - 77	N
01-001/001	Screening	ddMMMyyyy hh:mm	Lymphocytes [%]	37.7 [N]		20 - 44	N
01-001/001	Screening	ddMMMyyyy hh:mm	Monocytes [%]	6.5 [N]		2 - 9.5	N
01-001/001	Screening	ddMMMyyyy hh:mm	Eosinophils [%]	2.7 [N]		0.5 - 5.5	N
01-001/001	Screening	ddMMMyyyy hh:mm	Basophils [%]	1.1 [N]		<= 1.75	N
01-001/001	Screening	ddMMMyyyy hh:mm	Thrombocytes [10^9/L]	219 [N]		150 - 370	N
01-001/001	Screening	ddMMMyyyy hh:mm	Haemoglobin [g/L]	157 [N]		135 - 172	N
01-001/001	Screening	ddMMMyyyy hh:mm	Haematocrit [L/L]	0.457 [N]		0.395 - 0.505	N
01-001/001	Screening	ddMMMyyyy hh:mm	Ery. Mean Corpuscular Volume [fL]	84 [N]		83 - 100	N
01-001/001	Screening	ddMMMyyyy hh:mm	Ery. Mean Corpuscular Haemoglobin [pg]	30 [N]		27 - 34	N
01-001/001	Screening	ddMMMyyyy hh:mm	Ery. Mean Corpuscular HGB Concentration [g/dL]	35 [N]		32 - 36	N
...	...	...	...	...		...	...
01-001/001	End of Study	ddMMMyyyy hh:mm	Erythrocytes [10^12/L]	5.19 [N]	xxx	4.30 - 5.90	N

Note 1: N=Normal, A=Abnormal
Note 2: Baseline = screening
Program: Listings\k374-lb-lst.sas

Listing 16.2.8.1 - Individual laboratory measurements

Category of Laboratory Parameters: HAEMATOLOGY

Participant ID	Time Point	Collection Date/time	Parameter	Value and Abnormality [1]	Change from baseline [2]	Normal Range or Reference Value	Clinically Significant?
01-001/001	End of Study	ddMMMyyyy hh:mm	Leukocytes [10^9/L]	10.02 [A]	xxx	4.00 - 10.00	N
01-001/001	End of Study	ddMMMyyyy hh:mm	Neutrophils [10^9/L]	3.43 [N]	xxx	1.5 - 7.7	N
01-001/001	End of Study	ddMMMyyyy hh:mm	Lymphocytes [10^9/L]	2.49 [N]	xxx	1.1 - 4.5	N
01-001/001	End of Study	ddMMMyyyy hh:mm	Monocytes [10^9/L]	0.43 [N]	xxx	0.1 - 0.9	N
01-001/001	End of Study	ddMMMyyyy hh:mm	Eosinophils [10^9/L]	0.18 [N]	xxx	0.02 - 0.5	N
01-001/001	End of Study	ddMMMyyyy hh:mm	Basophils [10^9/L]	0.07 [N]	xxx	<= 0.2	N
01-001/001	End of Study	ddMMMyyyy hh:mm	Neutrophils [%]	52 [N]	xxx	42 - 77	N
01-001/001	End of Study	ddMMMyyyy hh:mm	Lymphocytes [%]	37.7 [N]	xxx	20 - 44	N
01-001/001	End of Study	ddMMMyyyy hh:mm	Monocytes [%]	6.5 [N]	xxx	2 - 9.5	N
01-001/001	End of Study	ddMMMyyyy hh:mm	Eosinophils [%]	2.7 [N]	xxx	0.5 - 5.5	N
01-001/001	End of Study	ddMMMyyyy hh:mm	Basophils [%]	1.1 [N]	xxx	<= 1.75	N
01-001/001	End of Study	ddMMMyyyy hh:mm	Thrombocytes [10^9/L]	219 [N]	xxx	150 - 370	N
01-001/001	End of Study	ddMMMyyyy hh:mm	Haemoglobin [g/L]	157 [N]	xxx	135 - 172	N
01-001/001	End of Study	ddMMMyyyy hh:mm	Haematocrit [L/L]	0.457 [N]	xxx	0.395 - 0.505	N
01-001/001	End of Study	ddMMMyyyy hh:mm	Ery. Mean Corpuscular Volume [fL]	84 [N]	xxx	83 - 100	N
01-001/001	End of Study	ddMMMyyyy hh:mm	Ery. Mean Corpuscular Haemoglobin [pg]	30 [N]	xxx	27 - 34	N
01-001/001	End of Study	ddMMMyyyy hh:mm	Ery. Mean Corpuscular HGB Concentration [g/dL]	35 [N]	xxx	32 - 36	N
...	...	...	...	...	...	...	...

Note 1: N=Normal, A=Abnormal
Note 2: Baseline = screening
Program: Listings\k374-lb-lst.sas

Listing 16.2.8.1 - Individual laboratory measurements

Category of Laboratory Parameters: BLOOD CHEMISTRY

Participant ID	Time Point	Collection Date/time	Parameter	Value and Abnormality [1]	Change from baseline [2]	Normal Range or Reference Value	Clinically Significant?
01-001/001	Screening	ddMMMyyyy hh:mm	Sodium [mmol/L]	138 [N]		136 - 145	N
01-001/001	Screening	ddMMMyyyy hh:mm	Potassium [mmol/L]	4.4 [N]		3.5 - 5.1	N
01-001/001	Screening	ddMMMyyyy hh:mm	Calcium [mmol/L]	2.27 [N]		2.10 - 2.55	N
01-001/001	Screening	ddMMMyyyy hh:mm	Chloride [mmol/L]	103 [N]		96 - 110	N
01-001/001	Screening	ddMMMyyyy hh:mm	Inorganic Phosphorus [mmol/L]	0.84 [A]		0.87 - 1.45	N
01-001/001	Screening	ddMMMyyyy hh:mm	Alkaline Phosphatase [U/L]	95 [N]		<= 129	N
01-001/001	Screening	ddMMMyyyy hh:mm	Gamma Glutamyl Transferase [U/L]	17 [N]		<= 66	N
01-001/001	Screening	ddMMMyyyy hh:mm	Aspartate Aminotransferase [U/L]	24 [N]		<= 50	N
01-001/001	Screening	ddMMMyyyy hh:mm	Alanine Aminotransferase [U/L]	30 [N]		<= 50	N
01-001/001	Screening	ddMMMyyyy hh:mm	Total bilirubin [umol/L]	9.9 [N]		<= 21	N
01-001/001	Screening	ddMMMyyyy hh:mm	Creatinine [umol/L]	78 [N]		62 - 115	N
01-001/001	Screening	ddMMMyyyy hh:mm	Glucose [mmol/L]	4.9 [N]		3.9 - 6.1	N
01-001/001	Screening	ddMMMyyyy hh:mm	Urea [mmol/L]	6.51 [N]		1.7 - 8.3	N
01-001/001	Screening	ddMMMyyyy hh:mm	Uric acid [umol/L]	228 [N]		210 - 420	N
01-001/001	Screening	ddMMMyyyy hh:mm	Total cholesterol [mmol/L]	4.7 [N]		<= 5	N
01-001/001	Screening	ddMMMyyyy hh:mm	Triglycerides [mmol/L]	2.03 [A]		<= 1.7	N
01-001/001	Screening	ddMMMyyyy hh:mm	Total proteins [g/L]	72 [N]		60 - 80	N
...	...	...	...	...		...	...
01-001/001	End of Study	ddMMMyyyy hh:mm	Sodium [mmol/L]	138 [N]	xxx	136 - 145	N
01-001/001	End of Study	ddMMMyyyy hh:mm	Potassium [mmol/L]	4.4 [N]	xxx	3.5 - 5.1	N

Note 1: N=Normal, A=Abnormal
Note 2: Baseline = screening
Program: Listings\k374-lb-lst.sas

Listing 16.2.8.1 - Individual laboratory measurements

Category of Laboratory Parameters: BLOOD CHEMISTRY

Participant ID	Time Point	Collection Date/time	Parameter	Value and Abnormality [1]	Change from baseline [2]	Normal Range or Reference Value	Clinically Significant?
01-001/001	End of Study	ddMMMyyyy hh:mm	Calcium [mmol/L]	2.27 [N]	xxx	2.10 - 2.55	N
01-001/001	End of Study	ddMMMyyyy hh:mm	Chloride [mmol/L]	103 [N]	xxx	96 - 110	N
01-001/001	End of Study	ddMMMyyyy hh:mm	Inorganic Phosphorus [mmol/L]	0.84 [A]	xxx	0.87 - 1.45	N
01-001/001	End of Study	ddMMMyyyy hh:mm	Alkaline Phosphatase [U/L]	95 [N]	xxx	<= 129	N
01-001/001	End of Study	ddMMMyyyy hh:mm	Gamma Glutamyl Transferase [U/L]	17 [N]	xxx	<= 66	N
01-001/001	End of Study	ddMMMyyyy hh:mm	Aspartate Aminotransferase [U/L]	24 [N]	xxx	<= 50	N
01-001/001	End of Study	ddMMMyyyy hh:mm	Alanine Aminotransferase [U/L]	30 [N]	xxx	<= 50	N
01-001/001	End of Study	ddMMMyyyy hh:mm	Total bilirubin [umol/L]	9.9 [N]	xxx	<= 21	N
01-001/001	End of Study	ddMMMyyyy hh:mm	Creatinine [umol/L]	78 [N]	xxx	62 - 115	N
01-001/001	End of Study	ddMMMyyyy hh:mm	Glucose [mmol/L]	4.9 [N]	xxx	3.9 - 6.1	N
01-001/001	End of Study	ddMMMyyyy hh:mm	Urea [mmol/L]	6.51 [N]	xxx	1.7 - 8.3	N
01-001/001	End of Study	ddMMMyyyy hh:mm	Uric acid [umol/L]	228 [N]	xxx	210 - 420	N
01-001/001	End of Study	ddMMMyyyy hh:mm	Total cholesterol [mmol/L]	4.7 [N]	xxx	<= 5	N
01-001/001	End of Study	ddMMMyyyy hh:mm	Triglycerides [mmol/L]	2.03 [A]	xxx	<= 1.7	N
01-001/001	End of Study	ddMMMyyyy hh:mm	Total proteins [g/L]	72 [N]	xxx	60 - 80	N
...	...	...	...	...	...	...	...

Note 1: N=Normal, A=Abnormal
Note 2: Baseline = screening
Program: Listings\k374-lb-lst.sas

Listing 16.2.8.1 - Individual laboratory measurements

Category of Laboratory Parameters: URINE ANALYSIS

Participant ID	Time Point	Collection Date/time	Parameter	Value and Abnormality [1]	Change from baseline [2]	Normal Range or Reference Value	Clinically Significant?
01-001/001	Screening	ddMMMyyyy hh:mm	Ph	7 [N]		5 - 7.5	N
01-001/001	Screening	ddMMMyyyy hh:mm	Specific weight	1.01 [N]		1.015 - 1.028	N
01-001/001	Screening	ddMMMyyyy hh:mm	Appearance	Slightly cloudy [N]		---	N
01-001/001	Screening	ddMMMyyyy hh:mm	Colour	Golden Yellow [N]		---	N
01-001/001	Screening	ddMMMyyyy hh:mm	Nitrites	Negative [N]		Negative	N
01-001/001	Screening	ddMMMyyyy hh:mm	Urinary proteins	Absent [N]		Absent	N
01-001/001	Screening	ddMMMyyyy hh:mm	Urinary glucose	Absent [N]		Absent	N
01-001/001	Screening	ddMMMyyyy hh:mm	Urobilinogen	Normal [N]		Normal (<17	N
01-001/001	Screening	ddMMMyyyy hh:mm	Urinary bilirubin	Absent [N]		Absent	N
01-001/001	Screening	ddMMMyyyy hh:mm	Ketones	Absent [N]		Absent	N
01-001/001	Screening	ddMMMyyyy hh:mm	Urinary haematic pigments	Absent [N]		Absent	N
01-001/001	Screening	ddMMMyyyy hh:mm	Urinary leukocytes	Absent [N]		Absent	N
01-001/001	Screening	ddMMMyyyy hh:mm	Urinary Sediment Leukocytes	Absent [N]		Absent or 0-2 per	N
01-001/001	Screening	ddMMMyyyy hh:mm	Urinary Sediment Erythrocytes	0-2 per field [N]		Absent or 0-2 per	N
01-001/001	Screening	ddMMMyyyy hh:mm	Urinary Sediment Flat Epithelial Cells	0-2 per field [N]		Absent or 0-2 per	N
01-001/001	Screening	ddMMMyyyy hh:mm	Urinary Sediment Round Epithelial Cells	0-2 per field [N]		Absent or 0-2 per	N
01-001/001	Screening	ddMMMyyyy hh:mm	Urinary Sediment Crystals	Absent [N]		Absent or 0-2 per	N
01-001/001	Screening	ddMMMyyyy hh:mm	Urinary Sediment Cylinders	Absent [N]		Absent or 0-2 per	N
01-001/001	Screening	ddMMMyyyy hh:mm	Urinary Sediment Mucous Threads	Absent [N]		Absent or 0-2 per	N
01-001/001	Screening	ddMMMyyyy hh:mm	Urinary Sediment Bacteria	Absent [N]		Absent	N

Note 1: N=Normal, A=Abnormal
Note 2: Baseline = screening
Program: Listings\k374-lb-lst.sas

Listing 16.2.8.1 - Individual laboratory measurements

Category of Laboratory Parameters: URINE ANALYSIS

Participant ID	Time Point	Collection Date/time	Parameter	Value and Abnormality [1]	Change from baseline [2]	Normal Range or Reference Value	Clinically Significant?
01-001/001	Screening	ddMMMyyyy hh:mm	Urinary Sediment Glomerular Erythrocytes	Absent [N]		Absent or 0-2 per	N
...	...	...	...	...		...	...
01-001/001	End of Study	ddMMMyyyy hh:mm	Ph	7 [N]	xxx	5 - 7.5	N
01-001/001	End of Study	ddMMMyyyy hh:mm	Specific weight	1.01 [N]	xxx	1.015 - 1.028	N
01-001/001	End of Study	ddMMMyyyy hh:mm	Appearance	Slightly cloudy [N]	---	---	N
01-001/001	End of Study	ddMMMyyyy hh:mm	Colour	Golden Yellow [N]	---	---	N
01-001/001	End of Study	ddMMMyyyy hh:mm	Nitrites	Negative [N]	---	Negative	N
01-001/001	End of Study	ddMMMyyyy hh:mm	Urinary proteins	Absent [N]	---	Absent	N
01-001/001	End of Study	ddMMMyyyy hh:mm	Urinary glucose	Absent [N]	---	Absent	N
01-001/001	End of Study	ddMMMyyyy hh:mm	Urobilinogen	Normal [N]	---	Normal (<17	N
01-001/001	End of Study	ddMMMyyyy hh:mm	Urinary bilirubin	Absent [N]	---	Absent	N
01-001/001	End of Study	ddMMMyyyy hh:mm	Ketones	Absent [N]	---	Absent	N
01-001/001	End of Study	ddMMMyyyy hh:mm	Urinary haematic pigments	Absent [N]	---	Absent	N
01-001/001	End of Study	ddMMMyyyy hh:mm	Urinary leukocytes	Absent [N]	---	Absent	N
01-001/001	End of Study	ddMMMyyyy hh:mm	Urinary Sediment Leukocytes	Absent [N]	---	Absent or 0-2 per	N
01-001/001	End of Study	ddMMMyyyy hh:mm	Urinary Sediment Erythrocytes	0-2 per field [N]	---	Absent or 0-2 per	N
01-001/001	End of Study	ddMMMyyyy hh:mm	Urinary Sediment Flat Epithelial Cells	0-2 per field [N]	---	Absent or 0-2 per	N
01-001/001	End of Study	ddMMMyyyy hh:mm	Urinary Sediment Round Epithelial Cells	0-2 per field [N]	---	Absent or 0-2 per	N
01-001/001	End of Study	ddMMMyyyy hh:mm	Urinary Sediment Crystals	Absent [N]	---	Absent or 0-2 per	N
01-001/001	End of Study	ddMMMyyyy hh:mm	Urinary Sediment Cylinders	Absent [N]	---	Absent or 0-2 per	N

Note 1: N=Normal, A=Abnormal
Note 2: Baseline = screening
Program: Listings\k374-lb-lst.sas

Listing 16.2.8.1 - Individual laboratory measurements

Category of Laboratory Parameters: URINE ANALYSIS

Participant ID	Time Point	Collection Date/time	Parameter	Value and Abnormality [1]	Change from baseline [2]	Normal Range or Reference Value	Clinically Significant?
01-001/001	End of Study	ddMMMyyyy hh:mm	Urinary Sediment Mucous Threads	Absent [N]	---	Absent or 0-2 per	N
01-001/001	End of Study	ddMMMyyyy hh:mm	Urinary Sediment Bacteria	Absent [N]	---	Absent	N
01-001/001	End of Study	ddMMMyyyy hh:mm	Urinary Sediment Glomerular Erythrocytes	Absent [N]	---	Absent or 0-2 per	N
...	...	...	...	...	...	...	...

Note 1: N=Normal, A=Abnormal
Note 2: Baseline = screening
Program: Listings\k374-lb-lst.sas

Listing 16.2.8.1 - Individual laboratory measurements

Category of Laboratory Parameters: URINE DRUG SCREENING

Participant ID	Time Point	Collection Date/time	Parameter	Value and Abnormality [1]	Change from baseline [2]	Normal Range or Reference Value	Clinically Significant?
01-001/001	Screening	ddMMMyyyy hh:mm	Drug Test	Negative [N]		Negative	N
01-001/001	Day -1	ddMMMyyyy hh:mm	Drug Test	Negative [N]		Negative	N
...	...	...	...	...		...	...

Note 1: N=Normal, A=Abnormal
Note 2: Baseline = screening
Program: Listings\k374-lb-lst.sas

Listing 16.2.8.1 - Individual laboratory measurements

Category of Laboratory Parameters: VIROLOGY

Participant ID	Time Point	Collection Date/time	Parameter	Value and Abnormality [1]	Change from baseline [2]	Normal Range or Reference Value	Clinically Significant?
01-001/001	Screening	ddMMMyyyy hh:mm	Hepatitis B Virus Surface Antigen	Negative [N]		Negative	N
01-001/001	Screening	ddMMMyyyy hh:mm	Hepatitis C Virus Antibody	Negative [N]		Negative	N
01-001/001	Screening	ddMMMyyyy hh:mm	HIV Ag/Ab Combo	Negative [N]		Negative	N
...	...	...	...	...		...	...

Note 1: N=Normal, A=Abnormal
Note 2: Baseline = screening
Program: Listings\k374-lb-lst.sas

Listing 16.2.8.1 - Individual laboratory measurements

Category of Laboratory Parameters: ALCOHOL TEST AND PREGNANCY TEST

Participant ID	Time Point	Collection Date/time	Parameter	Value and Abnormality [1]	Change from baseline [2]	Normal Range or Reference Value	Clinically Significant?
01-001/001	Screening	ddMMMyyyy hh:mm	Pregnancy Test	Negative [N]		Negative	N
01-001/001	Screening	ddMMMyyyy hh:mm	Alcohol Saliva Test	Negative [N]		Negative	N
01-001/001	Day -1	ddMMMyyyy hh:mm	Pregnancy Test	Negative [N]		Negative	N
01-001/001	Day -1	ddMMMyyyy hh:mm	Alcohol Saliva Test	Negative [N]		Negative	N
...	...	...	...	...		...	...

Note 1: N=Normal, A=Abnormal
Note 2: Baseline = screening
Program: Listings\k374-lb-lst.sas

Listing 16.2.8.2 - Investigator's interpretation of laboratory test results

Participant ID	Time Point	Assessment Date	Investigator's Interpretation
01-001/001	Screening	ddMMMyyyy	Abnormal, Not Clinically Significant
01-001/001	End of Study	ddMMMyyyy	Abnormal, Not Clinically Significant
...	...	...	...

Program: Listings\k374-lb-lst.sas

Listing 16.2.9.1 - Vital signs and changes from baseline

Participant ID	Product Use	Time Point	Assessment Date/Time	Parameter	Value[1]	Change from baseline[2]
01-001/001		Screening	ddMMMyyyy hh:mm	Systolic Blood Pressure [mmHg]	96	---
01-001/001		Screening	ddMMMyyyy hh:mm	Diastolic Blood Pressure [mmHg]	58	---
01-001/001		Screening	ddMMMyyyy hh:mm	Heart Rate [beats/min]	88	---
01-001/001		Screening	ddMMMyyyy hh:mm	Respiratory Rate [breaths/min]	50	---
01-001/001		Screening	ddMMMyyyy hh:mm	Tympanic body temperature [°C]	36.5	---
01-001/001		Screening	ddMMMyyyy hh:mm	Investigator's Interpretation	Normal	---
01-001/001		Visit 2 - Day -1	ddMMMyyyy hh:mm	Systolic Blood Pressure [mmHg]	96	---
01-001/001		Visit 2 - Day -1	ddMMMyyyy hh:mm	Diastolic Blood Pressure [mmHg]	58	---
01-001/001		Visit 2 - Day -1	ddMMMyyyy hh:mm	Heart Rate [beats/min]	88	---
01-001/001		Visit 2 - Day -1	ddMMMyyyy hh:mm	Respiratory Rate [breaths/min]	50	---
01-001/001		Visit 2 - Day -1	ddMMMyyyy hh:mm	Tympanic body temperature [°C]	36.5	---
01-001/001		Visit 2 - Day -1	ddMMMyyyy hh:mm	Investigator's Interpretation	Normal	---
01-001/001	Standardized	Visit 3 - Day 1 - Pre-dose	ddMMMyyyy hh:mm	Systolic Blood Pressure [mmHg]	96	---
01-001/001	Standardized	Visit 3 - Day 1 - Pre-dose	ddMMMyyyy hh:mm	Diastolic Blood Pressure [mmHg]	58	---
01-001/001	Standardized	Visit 3 - Day 1 - Pre-dose	ddMMMyyyy hh:mm	Heart Rate [beats/min]	88	---
01-001/001	Standardized	Visit 3 - Day 1 - Pre-dose	ddMMMyyyy hh:mm	Investigator's Interpretation	Abnormal, NCS	---
01-001/001	Standardized	Visit 3 - Day 1 - 2h post-dose	ddMMMyyyy hh:mm	Systolic Blood Pressure [mmHg]	98	2
01-001/001	Standardized	Visit 3 - Day 1 - 2h post-dose	ddMMMyyyy hh:mm	Diastolic Blood Pressure [mmHg]	56	-2
01-001/001	Standardized	Visit 3 - Day 1 - 2h post-dose	ddMMMyyyy hh:mm	Heart Rate [beats/min]	88	0
01-001/001	Standardized	Visit 3 - Day 1 - 2h post-dose	ddMMMyyyy hh:mm	Investigator's Interpretation	Abnormal, NCS	---
01-001/001	Standardized	Visit 3 - Day 1 - 4h post-dose	ddMMMyyyy hh:mm	Systolic Blood Pressure [mmHg]	98	2
01-001/001	Standardized	Visit 3 - Day 1 - 4h post-dose	ddMMMyyyy hh:mm	Diastolic Blood Pressure [mmHg]	56	-2
01-001/001	Standardized	Visit 3 - Day 1 - 4h post-dose	ddMMMyyyy hh:mm	Heart Rate [beats/min]	88	0
01-001/001	Standardized	Visit 3 - Day 1 - 4h post-dose	ddMMMyyyy hh:mm	Investigator's Interpretation	Normal	---

Note: End of Study = Final Visit or Early Termination Visit
Note 1: NCS=Not Clinically Significant, CS=Clinically Significant _
Note 2: baseline=Pre-dose
Program: Listings\k374-vs-lst.sas

Listing 16.2.9.1 - Vital signs and changes from baseline

Participant ID	Product Use	Time Point	Assessment Date/Time	Parameter	Value[1]	Change from baseline[2]
01-001/001	Standardized	Visit 3 - Day 1 - 6h post-dose	ddMMMyyyy hh:mm	Systolic Blood Pressure [mmHg]	99	3
01-001/001	Standardized	Visit 3 - Day 1 - 6h post-dose	ddMMMyyyy hh:mm	Diastolic Blood Pressure [mmHg]	57	-1
01-001/001	Standardized	Visit 3 - Day 1 - 6h post-dose	ddMMMyyyy hh:mm	Heart Rate [beats/min]	89	1
01-001/001	Standardized	Visit 3 - Day 1 - 6h post-dose	ddMMMyyyy hh:mm	Investigator's Interpretation	Abnormal, NCS	---
01-001/001	Standardized	Visit 4 - Day 2	ddMMMyyyy hh:mm	Systolic Blood Pressure [mmHg]	96	---
01-001/001	Standardized	Visit 4 - Day 2	ddMMMyyyy hh:mm	Diastolic Blood Pressure [mmHg]	58	---
01-001/001	Standardized	Visit 4 - Day 2	ddMMMyyyy hh:mm	Heart Rate [beats/min]	88	---
01-001/001	Standardized	Visit 4 - Day 2	ddMMMyyyy hh:mm	Investigator's Interpretation	Abnormal, NCS	---
01-001/001	Standardized	Visit 4 - Day 3	ddMMMyyyy hh:mm	Systolic Blood Pressure [mmHg]	96	---
01-001/001	Standardized	Visit 4 - Day 3	ddMMMyyyy hh:mm	Diastolic Blood Pressure [mmHg]	58	---
01-001/001	Standardized	Visit 4 - Day 3	ddMMMyyyy hh:mm	Heart Rate [beats/min]	88	---
01-001/001	Standardized	Visit 4 - Day 3	ddMMMyyyy hh:mm	Investigator's Interpretation	Abnormal, NCS	---
01-001/001	Non-standardized	Visit 5 - Day 4 - Pre-dose	ddMMMyyyy hh:mm	Systolic Blood Pressure [mmHg]	96	---
01-001/001	Non-standardized	Visit 5 - Day 4 - Pre-dose	ddMMMyyyy hh:mm	Diastolic Blood Pressure [mmHg]	58	---
01-001/001	Non-standardized	Visit 5 - Day 4 - Pre-dose	ddMMMyyyy hh:mm	Heart Rate [beats/min]	88	---
01-001/001	Non-standardized	Visit 5 - Day 4 - Pre-dose	ddMMMyyyy hh:mm	Investigator's Interpretation	Abnormal, NCS	---
01-001/001	Non-standardized	Visit 5 - Day 4 - 2h post-dose	ddMMMyyyy hh:mm	Systolic Blood Pressure [mmHg]	98	2
01-001/001	Non-standardized	Visit 5 - Day 4 - 2h post-dose	ddMMMyyyy hh:mm	Diastolic Blood Pressure [mmHg]	56	-2
01-001/001	Non-standardized	Visit 5 - Day 4 - 2h post-dose	ddMMMyyyy hh:mm	Heart Rate [beats/min]	88	0
01-001/001	Non-standardized	Visit 5 - Day 4 - 2h post-dose	ddMMMyyyy hh:mm	Investigator's Interpretation	Abnormal, NCS	---
01-001/001	Non-standardized	Visit 5 - Day 4 - 4h post-dose	ddMMMyyyy hh:mm	Systolic Blood Pressure [mmHg]	98	2
01-001/001	Non-standardized	Visit 5 - Day 4 - 4h post-dose	ddMMMyyyy hh:mm	Diastolic Blood Pressure [mmHg]	56	-2
01-001/001	Non-standardized	Visit 5 - Day 4 - 4h post-dose	ddMMMyyyy hh:mm	Heart Rate [beats/min]	88	0
01-001/001	Non-standardized	Visit 5 - Day 4 - 4h post-dose	ddMMMyyyy hh:mm	Investigator's Interpretation	Normal	---

Note: End of Study = Final Visit or Early Termination Visit
Note 1: NCS=Not Clinically Significant, CS=Clinically Significant _
Note 2: baseline=Pre-dose
Program: Listings\k374-vs-lst.sas

Listing 16.2.9.1 - Vital signs and changes from baseline

Participant ID	Product Use	Time Point	Assessment Date/Time	Parameter	Value[1]	Change from baseline[2]
01-001/001	Non-standardized	Visit 5 - Day 4 - 6h post-dose	ddMMMyyyy hh:mm	Systolic Blood Pressure [mmHg]	99	3
01-001/001	Non-standardized	Visit 5 - Day 4 - 6h post-dose	ddMMMyyyy hh:mm	Diastolic Blood Pressure [mmHg]	57	-1
01-001/001	Non-standardized	Visit 5 - Day 4 - 6h post-dose	ddMMMyyyy hh:mm	Heart Rate [beats/min]	89	1
01-001/001	Non-standardized	Visit 5 - Day 4 - 6h post-dose	ddMMMyyyy hh:mm	Investigator's Interpretation	Abnormal, NCS	---
01-001/001		End of Study	ddMMMyyyy hh:mm	Systolic Blood Pressure [mmHg]	96	---
01-001/001		End of Study	ddMMMyyyy hh:mm	Diastolic Blood Pressure [mmHg]	58	---
01-001/001		End of Study	ddMMMyyyy hh:mm	Heart Rate [beats/min]	88	---
01-001/001		End of Study	ddMMMyyyy hh:mm	Respiratory Rate [breaths/min]	50	---
01-001/001		End of Study	ddMMMyyyy hh:mm	Tympanic body temperature [°C]	36.5	---
01-001/001		End of Study	ddMMMyyyy hh:mm	Investigator's Interpretation	Normal	---
...	...	...	...	...	...	...

Note: End of Study = Final Visit or Early Termination Visit
Note 1: NCS=Not Clinically Significant, CS=Clinically Significant _
Note 2: baseline=Pre-dose
Program: Listings\k374-vs-lst.sas

Listing 16.2.9.2 - Body weight and changes from baseline

Participant ID	Time Point	Assessment Date/Time	Parameter	Value	Change from baseline[1]
01-001/001	Screening	ddMMMyyyy hh:mm	Weight [kg]	55.5	---
01-001/001	End of Study	ddMMMyyyy hh:mm	Weight [kg]	55.4	-0.1
...	...	...	...	...	...

Note: End of Study = Final Visit or Early Termination Visit
Note 1: Baseline=Screening
Program: Listings\k374-vs-lst.sas

Listing 16.2.9.3 - ECG parameters and changes from baseline

Participant ID	Time Point	Assessment Date/Time	Parameter	Repetition 1	Repetition 2	Repetition 3	Value[1]	Change from baseline[2]
01-001/001	Screening	ddMMMyyyy hh:mm	Heart Rate [beats/min]	xxx	xxx	xxx	xxx	---
01-001/001	Screening	ddMMMyyyy hh:mm	PR Interval [msec]	xxx	xxx	xxx	xxx	---
01-001/001	Screening	ddMMMyyyy hh:mm	QRS Duration [msec]	xxx	xxx	xxx	xxx	---
01-001/001	Screening	ddMMMyyyy hh:mm	QT Interval [msec]	xxx	xxx	xxx	xxx	---
01-001/001	Screening	ddMMMyyyy hh:mm	QTcB Interval [msec]	xxx	xxx	xxx	xxx	---
01-001/001	Screening	ddMMMyyyy hh:mm	QTcF Interval [msec]	xxx	xxx	xxx	xxx	---
01-001/001	Day 1 - Post-dose	ddMMMyyyy hh:mm	Heart Rate [beats/min]	xxx	xxx	xxx	xxx	---
01-001/001	Day 1 - Post-dose	ddMMMyyyy hh:mm	PR Interval [msec]	xxx	xxx	xxx	xxx	---
01-001/001	Day 1 - Post-dose	ddMMMyyyy hh:mm	QRS Duration [msec]	xxx	xxx	xxx	xxx	---
01-001/001	Day 1 - Post-dose	ddMMMyyyy hh:mm	QT Interval [msec]	xxx	xxx	xxx	xxx	---
01-001/001	Day 1 - Post-dose	ddMMMyyyy hh:mm	QTcB Interval [msec]	xxx	xxx	xxx	xxx	---
01-001/001	Day 1 - Post-dose	ddMMMyyyy hh:mm	QTcF Interval [msec]	xxx	xxx	xxx	xxx	---
01-001/001	End of Study	ddMMMyyyy hh:mm	Heart Rate [beats/min]	xxx	xxx	xxx	xxx	xxx
01-001/001	End of Study	ddMMMyyyy hh:mm	PR Interval [msec]	xxx	xxx	xxx	xxx	xxx
01-001/001	End of Study	ddMMMyyyy hh:mm	QRS Duration [msec]	xxx	xxx	xxx	xxx	xxx
01-001/001	End of Study	ddMMMyyyy hh:mm	QT Interval [msec]	xxx	xxx	xxx	xxx	xxx
01-001/001	End of Study	ddMMMyyyy hh:mm	QTcB Interval [msec]	xxx	xxx	xxx	xxx	xxx
01-001/001	End of Study	ddMMMyyyy hh:mm	QTcF Interval [msec]	xxx	xxx	xxx	xxx	xxx
...	...	...	...	...	...	...	...	

Note: End of Study = Final Visit or Early Termination Visit
Note 1: value has been calculated as the mean of the 3 repetitions values
Note 2: baseline=screening
Program: Listings\k374-eg-lst.sas

Listing 16.2.9.4 - Investigator's interpretation of ECG

Participant ID	Time Point	Assessment Date/Time	Investigator's Interpretation	Clinically Significant Abnormalites
01-001/001	Screening	ddMMMyyyy hh:mm	Abnormal, Not Clinically Significant	---
01-001/001	Day 1 - Post-dose	ddMMMyyyy hh:mm	Abnormal, Not Clinically Significant	---
01-001/001	End of Study	ddMMMyyyy hh:mm	Normal	---
...	...	...	...	...

Note: End of Study = Final Visit or Early Termination Visit
Program: Listings\k374-eg-lst.sas

Listing 16.2.9.5 - Visual Oral Inspection

Participant ID	Product Use	Time Point	Assessment Date/time	Location	Ulceration/Pseudo membrane		Erythema	
					OMAS score	Change from baseline[1]	OMAS score	Change from baseline[1]
01-001/001	Standardized	Day 1 - Pre-dose	ddMMMyyyy hh:mm	Upper Lip	0 = no lesion	---	0 = none	---
01-001/001	Standardized	Day 1 - Pre-dose	ddMMMyyyy hh:mm	Lower Lip	0 = no lesion	---	0 = none	---
01-001/001	Standardized	Day 1 - Pre-dose	ddMMMyyyy hh:mm	Right Cheek	0 = no lesion	---	0 = none	---
01-001/001	Standardized	Day 1 - Pre-dose	ddMMMyyyy hh:mm	Left Cheek	0 = no lesion	---	0 = none	---
01-001/001	Standardized	Day 1 - Pre-dose	ddMMMyyyy hh:mm	Right ventral and lateral tongue	0 = no lesion	---	0 = none	---
01-001/001	Standardized	Day 1 - Pre-dose	ddMMMyyyy hh:mm	Left ventral and lateral tongue	0 = no lesion	---	0 = none	---
01-001/001	Standardized	Day 1 - Pre-dose	ddMMMyyyy hh:mm	Floor of mouth	0 = no lesion	---	0 = none	---
01-001/001	Standardized	Day 1 - Pre-dose	ddMMMyyyy hh:mm	Soft palate/fauces	0 = no lesion	---	0 = none	---
01-001/001	Standardized	Day 1 - Pre-dose	ddMMMyyyy hh:mm	Hard palate	0 = no lesion	---	0 = none	---
01-001/001	Standardized	Day 1 - Post-dose	ddMMMyyyy hh:mm	Upper Lip	1 = < 1 cm2	1	0 = none	0
01-001/001	Standardized	Day 1 - Post-dose	ddMMMyyyy hh:mm	Lower Lip	1 = < 1 cm2	1	0 = none	0
01-001/001	Standardized	Day 1 - Post-dose	ddMMMyyyy hh:mm	Right Cheek	1 = < 1 cm2	1	0 = none	0
01-001/001	Standardized	Day 1 - Post-dose	ddMMMyyyy hh:mm	Left Cheek	1 = < 1 cm2	1	0 = none	0
01-001/001	Standardized	Day 1 - Post-dose	ddMMMyyyy hh:mm	Right ventral and lateral tongue	1 = < 1 cm2	1	0 = none	0
01-001/001	Standardized	Day 1 - Post-dose	ddMMMyyyy hh:mm	Left ventral and lateral tongue	1 = < 1 cm2	1	0 = none	0
01-001/001	Standardized	Day 1 - Post-dose	ddMMMyyyy hh:mm	Floor of mouth	1 = < 1 cm2	1	0 = none	0
01-001/001	Standardized	Day 1 - Post-dose	ddMMMyyyy hh:mm	Soft palate/fauces	1 = < 1 cm2	1	0 = none	0
01-001/001	Standardized	Day 1 - Post-dose	ddMMMyyyy hh:mm	Hard palate	1 = < 1 cm2	1	0 = none	0
01-001/001	Standardized	Day 2	ddMMMyyyy hh:mm	Upper Lip	1 = < 1 cm2	1	1 = not severe	1
01-001/001	Standardized	Day 2	ddMMMyyyy hh:mm	Lower Lip	1 = < 1 cm2	1	1 = not severe	1
01-001/001	Standardized	Day 2	ddMMMyyyy hh:mm	Right Cheek	1 = < 1 cm2	1	1 = not severe	1
01-001/001	Standardized	Day 2	ddMMMyyyy hh:mm	Left Cheek	1 = < 1 cm2	1	1 = not severe	1
01-001/001	Standardized	Day 2	ddMMMyyyy hh:mm	Right ventral and lateral tongue	1 = < 1 cm2	1	1 = not severe	1
01-001/001	Standardized	Day 2	ddMMMyyyy hh:mm	Left ventral and lateral tongue	1 = < 1 cm2	1	1 = not severe	1
01-001/001	Standardized	Day 2	ddMMMyyyy hh:mm	Floor of mouth	1 = < 1 cm2	1	1 = not severe	1

Note 1: Baseline=Pre-dose
Program:Listings\k374-fa-lst.sas

Listing 16.2.9.5 - Visual Oral Inspection

Participant ID	Product Use	Time Point	Assessment Date/time	Location	Ulceration/Pseudo membrane		Erythema	
					OMAS score	Change from baseline[1]	OMAS score	Change from baseline[1]
01-001/001	Standardized	Day 2	ddMMMyyyy hh:mm	Soft palate/fauces	1 = < 1 cm2	1	1 = not severe	1
01-001/001	Standardized	Day 2	ddMMMyyyy hh:mm	Hard palate	1 = < 1 cm2	1	1 = not severe	1
01-001/001	Standardized	Day 3	ddMMMyyyy hh:mm	Upper Lip	1 = < 1 cm2	1	2 = severe	2
01-001/001	Standardized	Day 3	ddMMMyyyy hh:mm	Lower Lip	1 = < 1 cm2	1	2 = severe	2
01-001/001	Standardized	Day 3	ddMMMyyyy hh:mm	Right Cheek	1 = < 1 cm2	1	2 = severe	2
01-001/001	Standardized	Day 3	ddMMMyyyy hh:mm	Left Cheek	1 = < 1 cm2	1	2 = severe	2
01-001/001	Standardized	Day 3	ddMMMyyyy hh:mm	Right ventral and lateral tongue	1 = < 1 cm2	1	2 = severe	2
01-001/001	Standardized	Day 3	ddMMMyyyy hh:mm	Left ventral and lateral tongue	1 = < 1 cm2	1	2 = severe	2
01-001/001	Standardized	Day 3	ddMMMyyyy hh:mm	Floor of mouth	1 = < 1 cm2	1	2 = severe	2
01-001/001	Standardized	Day 3	ddMMMyyyy hh:mm	Soft palate/fauces	1 = < 1 cm2	1	2 = severe	2
01-001/001	Standardized	Day 3	ddMMMyyyy hh:mm	Hard palate	1 = < 1 cm2	1	2 = severe	2
01-001/001	Non-standardized	Day 4 - Pre-dose	ddMMMyyyy hh:mm	Upper Lip	0 = no lesion	---	0 = none	---
01-001/001	Non-standardized	Day 4 - Pre-dose	ddMMMyyyy hh:mm	Lower Lip	0 = no lesion	---	0 = none	---
01-001/001	Non-standardized	Day 4 - Pre-dose	ddMMMyyyy hh:mm	Right Cheek	0 = no lesion	---	0 = none	---
01-001/001	Non-standardized	Day 4 - Pre-dose	ddMMMyyyy hh:mm	Left Cheek	0 = no lesion	---	0 = none	---
01-001/001	Non-standardized	Day 4 - Pre-dose	ddMMMyyyy hh:mm	Right ventral and lateral tongue	0 = no lesion	---	0 = none	---
01-001/001	Non-standardized	Day 4 - Pre-dose	ddMMMyyyy hh:mm	Left ventral and lateral tongue	0 = no lesion	---	0 = none	---
01-001/001	Non-standardized	Day 4 - Pre-dose	ddMMMyyyy hh:mm	Floor of mouth	0 = no lesion	---	0 = none	---
01-001/001	Non-standardized	Day 4 - Pre-dose	ddMMMyyyy hh:mm	Soft palate/fauces	0 = no lesion	---	0 = none	---
01-001/001	Non-standardized	Day 4 - Pre-dose	ddMMMyyyy hh:mm	Hard palate	0 = no lesion	---	0 = none	---
01-001/001	Non-standardized	Day 4 - Post-dose	ddMMMyyyy hh:mm	Upper Lip	1 = < 1 cm2	1	0 = none	0
01-001/001	Non-standardized	Day 4 - Post-dose	ddMMMyyyy hh:mm	Lower Lip	1 = < 1 cm2	1	0 = none	0
01-001/001	Non-standardized	Day 4 - Post-dose	ddMMMyyyy hh:mm	Right Cheek	1 = < 1 cm2	1	0 = none	0
01-001/001	Non-standardized	Day 4 - Post-dose	ddMMMyyyy hh:mm	Left Cheek	1 = < 1 cm2	1	0 = none	0
01-001/001	Non-standardized	Day 4 - Post-dose	ddMMMyyyy hh:mm	Right ventral and lateral tongue	1 = < 1 cm2	1	0 = none	0

Note 1: Baseline=Pre-dose
Program:Listings\k374-fa-lst.sas

Listing 16.2.9.5 - Visual Oral Inspection

Participant ID	Product Use	Time Point	Assessment Date/time	Location	Ulceration/Pseudo membrane		Erythema	
					OMAS score	Change from baseline[1]	OMAS score	Change from baseline[1]
01-001/001	Non-standardized	Day 4 - Post-dose	ddMMMyyyy hh:mm	Left ventral and lateral tongue	1 = < 1 cm2	1	0 = none	0
01-001/001	Non-standardized	Day 4 - Post-dose	ddMMMyyyy hh:mm	Floor of mouth	1 = < 1 cm2	1	0 = none	0
01-001/001	Non-standardized	Day 4 - Post-dose	ddMMMyyyy hh:mm	Soft palate/fauces	1 = < 1 cm2	1	0 = none	0
01-001/001	Non-standardized	Day 4 - Post-dose	ddMMMyyyy hh:mm	Hard palate	1 = < 1 cm2	1	0 = none	0
01-001/001	Non-standardized	End of Study	ddMMMyyyy hh:mm	Upper Lip	1 = < 1 cm2	1	2 = severe	2
01-001/001	Non-standardized	End of Study	ddMMMyyyy hh:mm	Lower Lip	1 = < 1 cm2	1	2 = severe	2
01-001/001	Non-standardized	End of Study	ddMMMyyyy hh:mm	Right Cheek	1 = < 1 cm2	1	2 = severe	2
01-001/001	Non-standardized	End of Study	ddMMMyyyy hh:mm	Left Cheek	1 = < 1 cm2	1	2 = severe	2
01-001/001	Non-standardized	End of Study	ddMMMyyyy hh:mm	Right ventral and lateral tongue	1 = < 1 cm2	1	2 = severe	2
01-001/001	Non-standardized	End of Study	ddMMMyyyy hh:mm	Left ventral and lateral tongue	1 = < 1 cm2	1	2 = severe	2
01-001/001	Non-standardized	End of Study	ddMMMyyyy hh:mm	Floor of mouth	1 = < 1 cm2	1	2 = severe	2
01-001/001	Non-standardized	End of Study	ddMMMyyyy hh:mm	Soft palate/fauces	1 = < 1 cm2	1	2 = severe	2
01-001/001	Non-standardized	End of Study	ddMMMyyyy hh:mm	Hard palate	1 = < 1 cm2	1	2 = severe	2
...	...	...	...	...	...	...	...	...

Note 1: Baseline=Pre-dose
Program:Listings\k374-fa-lst.sas

Listing 16.2.9.6 - Visual Oral Inspection - Global OMAS score

Participant ID	Product Use	Time Point	Assessment Date/time	Parameter	Value	Change from baseline[1]
01-001/001	Standardized	Day 1 - Pre-dose	ddMMMyyyy hh:mm	Global OMAS score	0	---
01-001/001	Standardized	Day 1 - Post-dose	ddMMMyyyy hh:mm	Global OMAS score	9	9
01-001/001	Standardized	Day 2	ddMMMyyyy hh:mm	Global OMAS score	9	9
01-001/001	Standardized	Day 3	ddMMMyyyy hh:mm	Global OMAS score	8	8
01-001/001	Non-standardized	Day 4 - Pre-dose	ddMMMyyyy hh:mm	Global OMAS score	2	---
01-001/001	Non-standardized	Day 4 - Post-dose	ddMMMyyyy hh:mm	Global OMAS score	7	5
01-001/001	Non-standardized	End of Study	ddMMMyyyy hh:mm	Global OMAS score	44	42
...	...	...	...	...	...	...

Note 1: Baseline=Pre-dose
Program:Listings\k374-fa-lst.sas

Listing 16.2.9.7 - Cough assessments

Product Use: Standardized

Participant ID	Cough ID		
01-001/001	1	Occurrence:	During inhalation
		Date/time of occurrence (Day):	ddMMMyyyy hh:mm (k)
		Duration and pattern:	Seconds and non-repetitive
		Severity:	Mild cough
		Number of coughs:	2
		Water need:	Y
...	...	...	...

Program: Listings\k374-fa-lst.sas

Listing 16.2.9.7 - Cough assessments

Product Use: Non-standardized

Participant ID	Cough ID		
01-020/003	1	Occurrence:	After inhalation
		Date/time of occurrence (Day):	ddMMMyyyy hh:mm (k)
		Duration and pattern:	Continuous, below 1 minute
		Severity:	Clearing throat/short cough after inhalation
		Number of coughs:	1
		Water need:	N
...	...	...	...

Program: Listings\k374-fa-lst.sas

Listing 16.2.9.8 - Spirometry parameters and changes from baseline

Participant ID	Smoking History	Product Use	Time Point	Assessment Date/Time	Parameter	Value[1]	Change from baseline[2]
01-001/001	Smokers		Screening	ddMMMyyyy hh:mm	FEV1 [L]	xxx	---
01-001/001	Smokers		Screening	ddMMMyyyy hh:mm	FEV1 vs pred normal values [%]	xxx	---
01-001/001	Smokers		Screening	ddMMMyyyy hh:mm	FVC [L]	xxx	---
01-001/001	Smokers		Screening	ddMMMyyyy hh:mm	FEV1/FVC ratio	xxx	---
01-001/001	Smokers		Screening	ddMMMyyyy hh:mm	FEV1 post-bronchodilator [L]	xxx	---
01-001/001	Smokers		Screening	ddMMMyyyy hh:mm	Reversibility testing [%]	xxx	---
01-001/001	Smokers		Screening	ddMMMyyyy hh:mm	Investigator's Interpretation	Normal	---
01-001/001	Smokers		Visit 2 - Day -1	ddMMMyyyy hh:mm	FEV1 [L]	xxx	---
01-001/001	Smokers		Visit 2 - Day -1	ddMMMyyyy hh:mm	FVC [L]	xxx	---
01-001/001	Smokers		Visit 2 - Day -1	ddMMMyyyy hh:mm	FEV1/FVC ratio	xxx	---
01-001/001	Smokers		Visit 2 - Day -1	ddMMMyyyy hh:mm	Investigator's Interpretation	Abnormal, NCS	---
01-001/001	Smokers	Standardized	Visit 3 - Day 1 - Pre-dose	ddMMMyyyy hh:mm	FEV1 [L]	xxx	---
01-001/001	Smokers	Standardized	Visit 3 - Day 1 - Pre-dose	ddMMMyyyy hh:mm	FVC [L]	xxx	---
01-001/001	Smokers	Standardized	Visit 3 - Day 1 - Pre-dose	ddMMMyyyy hh:mm	FEV1/FVC ratio	xxx	---
01-001/001	Smokers	Standardized	Visit 3 - Day 1 - Pre-dose	ddMMMyyyy hh:mm	Investigator's Interpretation	Abnormal, NCS	---
01-001/001	Smokers	Standardized	Visit 3 - Day 1 - Post-dose	ddMMMyyyy hh:mm	FEV1 [L]	xxx	yyy
01-001/001	Smokers	Standardized	Visit 3 - Day 1 - Post-dose	ddMMMyyyy hh:mm	FVC [L]	xxx	yyy
01-001/001	Smokers	Standardized	Visit 3 - Day 1 - Post-dose	ddMMMyyyy hh:mm	FEV1/FVC ratio	xxx	yyy
01-001/001	Smokers	Standardized	Visit 3 - Day 1 - Post-dose	ddMMMyyyy hh:mm	Investigator's Interpretation	Abnormal, NCS	---
01-001/001	Smokers	Standardized	Visit 4 - Day 2	ddMMMyyyy hh:mm	FEV1 [L]	xxx	---
01-001/001	Smokers	Standardized	Visit 4 - Day 2	ddMMMyyyy hh:mm	FVC [L]	xxx	---
01-001/001	Smokers	Standardized	Visit 4 - Day 2	ddMMMyyyy hh:mm	FEV1/FVC ratio	xxx	---
01-001/001	Smokers	Standardized	Visit 4 - Day 2	ddMMMyyyy hh:mm	Investigator's Interpretation	Abnormal, NCS	---
01-001/001	Smokers	Non-standardized	Visit 5 - Day 4 - Pre-dose	ddMMMyyyy hh:mm	FEV1 [L]	xxx	---

Note 1: NCS=Not Clinically Significant, CS=Clinically Significant
Note 2: baseline=Pre-dose
Program: Listings\k374-fa-lst.sas

Listing 16.2.9.8 - Spirometry parameters and changes from baseline

Participant ID	Smoking History	Product Use	Time Point	Assessment Date/Time	Parameter	Value[1]	Change from baseline[2]
01-001/001	Smokers	Non-standardized	Visit 5 - Day 4 - Pre-dose	ddMMMyyyy hh:mm	FVC [L]	xxx	---
01-001/001	Smokers	Non-standardized	Visit 5 - Day 4 - Pre-dose	ddMMMyyyy hh:mm	FEV1/FVC ratio	xxx	---
01-001/001	Smokers	Non-standardized	Visit 5 - Day 4 - Pre-dose	ddMMMyyyy hh:mm	Investigator's Interpretation	Abnormal, NCS	---
01-001/001	Smokers	Non-standardized	Visit 5 - Day 4 - Post-dose	ddMMMyyyy hh:mm	FEV1 [L]	xxx	yyy
01-001/001	Smokers	Non-standardized	Visit 5 - Day 4 - Post-dose	ddMMMyyyy hh:mm	FVC [L]	xxx	yyy
01-001/001	Smokers	Non-standardized	Visit 5 - Day 4 - Post-dose	ddMMMyyyy hh:mm	FEV1/FVC ratio	xxx	yyy
01-001/001	Smokers	Non-standardized	Visit 5 - Day 4 - Post-dose	ddMMMyyyy hh:mm	Investigator's Interpretation	Normal	---
...	...	...	...	...	...	...	...

Note 1: NCS=Not Clinically Significant, CS=Clinically Significant
Note 2: baseline=Pre-dose
Program: Listings\k374-fa-lst.sas

Listing 16.2.9.9 - Respiratory tests and changes from baseline

Participant ID	Smoking History	Product Use	Time Point	Assessment Date/Time	Parameter	Value	Change from baseline[1]
01-001/001	Smokers	Standardized	Visit 3 - Day 1 - Pre-dose	ddMMMyyyy hh:mm	FCOHb [%]	xxx	---
01-001/001	Smokers	Standardized	Visit 3 - Day 1 - Pre-dose	ddMMMyyyy hh:mm	exhaled CO [L]	xxx	---
01-001/001	Smokers	Standardized	Visit 3 - Day 1 - 10 min post-dose	ddMMMyyyy hh:mm	FCOHb [%]	xxx	yyy
01-001/001	Smokers	Standardized	Visit 3 - Day 1 - 10 min post-dose	ddMMMyyyy hh:mm	exhaled CO [L]	xxx	yyy
01-001/001	Smokers	Standardized	Visit 3 - Day 1 - 30 min post-dose	ddMMMyyyy hh:mm	FCOHb [%]	xxx	yyy
01-001/001	Smokers	Standardized	Visit 3 - Day 1 - 30 min post-dose	ddMMMyyyy hh:mm	exhaled CO [L]	xxx	yyy
01-001/001	Smokers	Standardized	Visit 4 - Day 2	ddMMMyyyy hh:mm	FCOHb [%]	xxx	---
01-001/001	Smokers	Standardized	Visit 4 - Day 3	ddMMMyyyy hh:mm	FCOHb [%]	xxx	---
01-001/001	Smokers	Non-standardized	Visit 5 - Day 4 - Pre-dose	ddMMMyyyy hh:mm	FCOHb [%]	xxx	---
01-001/001	Smokers	Non-standardized	Visit 5 - Day 4 - Pre-dose	ddMMMyyyy hh:mm	exhaled CO [L]	xxx	---
01-001/001	Smokers	Non-standardized	Visit 5 - Day 4 - 10 min post-dose	ddMMMyyyy hh:mm	FCOHb [%]	xxx	yyy
01-001/001	Smokers	Non-standardized	Visit 5 - Day 4 - 10 min post-dose	ddMMMyyyy hh:mm	exhaled CO [L]	xxx	yyy
01-001/001	Smokers	Non-standardized	Visit 5 - Day 4 - 30 min post-dose	ddMMMyyyy hh:mm	FCOHb [%]	xxx	yyy
01-001/001	Smokers	Non-standardized	Visit 5 - Day 4 - 30 min post-dose	ddMMMyyyy hh:mm	exhaled CO [L]	xxx	yyy
...	...	...	...	...	...	...	...

Note 1: baseline=Pre-dose
Program: Listings\k374-fa-lst.sas

Listing 16.2.10.1 - Medical and surgical history

Participant ID	Category	Disease/Surgery ID		
01-001/001	Medical History	M1	Verbatim:	Left shoulder luxation
			Preferred Term [1]:	Joint dislocation
			System Organ Class [1]:	Injury, poisoning and procedural complications
			Disease Start - End Date:	2012 - 2012
	Surgery	S1	Verbatim:	Right knee meniscectomy
			Preferred Term [1]:	Meniscus removal
			System Organ Class [1]:	Surgical and medical procedures
			Surgery Date:	04NOV1980
	...	...	...	...

Note 1: MedDRA version 28.0
Program: Listings\k374-mh-lst.sas

Listing 16.2.10.2 - Prior and concomitant medications

Participant ID	Category	Medication ID		
01-001/001	Prior	1	Verbatim:	Alerid
			Standardised Medication Name [1]:	Alerid
			Active Ingredients [1]:	Cetirizine hydrochloride
			Medication Class [1, 2]:	Piperazine derivatives (R06AE)
			Indication:	Pollinosis
			Dose:	10 mg
			Start - End Date/Time:	2013 - Ongoing
			Frequency - Formulation - Route:	1 time per day - Tablet - Oral
			Related to:	Disease M1
	Concomitant	2	Verbatim:	Paracen
			Standardised Medication Name [1]:	Paracen
			Active Ingredients [1]:	Paracetamol
			Medication Class [1, 2]:	Anilides (N02BE)
			Indication:	Headache
			Dose:	500 mg
			Start - End Date/Time:	15JUN2019 19:08 - 15JUN2019 19:08
			Frequency - Formulation - Route:	Once - Tablet - Oral
			Related to:	Adverse Event 1
	...	...	...	...

Note 1: WHO Drug Dictionary March 1, 2025
Note 2: Anatomical Therapeutic Chemical classification, 4th level term
Program: Listings\k374-cm-lst.sas

Listing 16.2.10.3 - Physical examination

Participant ID	Time Point	Physical Examination Date/time		
01-001/001	Screening	ddMMMyyyy hh:mm	head, eyes, ears, nose, throat examination:	Abnormal, Not Clinically Significant
			neck examination:	Normal
			chest examination:	Normal
			lungs examination:	Abnormal, Not Clinically Significant
			abdomen examination:	Normal
			musculoskeletal examination:	Normal
			dermatological examination	Normal
			cardiovascular/peripheral vascular examination:	Normal
			general neurological examination:	Normal
			Investigator's Interpretation:	Abnormal, Not Clinically Significant
	End of Study	ddMMMyyyy	Investigator's Interpretation:	Abnormal, Clinically Significant
			Clinically Significant Abnormalities:	Left shoulder luxation
			Preferred Term [1]:	Joint dislocation
			System Organ Class [1]:	Injury, poisoning and procedural complications
...	...	...	...	...

Note: End of Study = Final Visit or Early Termination Visit
Program: Listings\k374-pe-lst.sas

Listing 16.2.10.4 - Participants study visits

Participant ID	Visit	Visit Start Date (Day)	Visit End Date (Day)
01-001/001	Visit 1 - Screening - Day -14/-2	ddMMMyyyy (-j)	---
01-001/001	Visit 2 - Day -1	ddMMMyyyy (-1)	---
01-001/001	Visit 3 - Day 1	ddMMMyyyy (1)	---
01-001/001	Visit 4 - Day 2 and Day 3	ddMMMyyyy (2)	ddMMMyyyy (3)
01-001/001	Visit 5 - Day 4	ddMMMyyyy (4)	---
01-001/001	Visit 6 - Final Visit - Day 5	ddMMMyyyy (5)	---
...	...	...	...

Program: Listings\k374-sv-lst.sas

Listing 16.2.10.5 - Fertility status and contraception

Participant ID	Chilbearing Potential?	Non-childbearing Potential Status Onset	Menopausal Status?	Date of Menopause	Surgical Sterilisation?	Surgical Sterilisation Date	Acceptable Contraceptive Method Used?
01-001/001	No	ddMMMyyyy	Yes	ddMMMyyyy	Yes	ddMMMyyyy	---
...	...	...	...	...	...	...	...

Note: Only female participants are listed
Program: Listings\k374-rp-lst.sas

Listing 16.2.10.6 - Reproductive status and contraception

Participant ID	Is he Sterile?	Approved Contraceptive Method Used?
01-002/004	No	Yes
...	...	...

Note: Only male participants are listed
Program: Listings\k374-rp-lst.sas

Listing 16.2.10.7 - Tobacco consumption

Participant ID	Tobacco user	Amount consumed daily	Start date of consumption	End date of consumption
01-001/001	Former	---	2010	JUL2018
01-012/011	Current	<= 10 cigarettes (or equivalent)	2005	---
...	...	...	...	...

Program: Listings\k374-su-lst.sas

Listing 16.2.10.8 - Cannabis Use History

Participant ID		
01-001/001	Previous use of cannabis?	Y
	Frequency of cannabis use:	Once a week
	Type of cannabis products used:	Flowers (dried cannabis), Edibles
	THC:CBD ratio used:	Unknown
	Cannabis way of administration:	Smoking, Oral
	...	...

Program: Listings\k374-su-lst.sas

Listing 16.2.10.9 - Meals

Participant ID	Meal Number	Standardised Meal	Time Point	Meal Served?	Meal Start Date/Time	Meal End Date/Time
01-001/001	1	Breakfast	Day 1 - Approx. 1 to 2 h before Study Product admin	Y	ddMMMyyyy hh:mm	ddMMMyyyy hh:mm
01-001/001	2	Lunch	Day 1 - Approx. at 5 h post-dose	Y	ddMMMyyyy hh:mm	---
01-001/001	3	Dinner	Day 1 - Approx. at 12 h post-dose	Y	ddMMMyyyy hh:mm	---
01-001/001	4	Breakfast	Day 4 - Approx. 1 to 2 h before Study Product admin	Y	ddMMMyyyy hh:mm	ddMMMyyyy hh:mm
01-001/001	5	Lunch	Day 4 - Approx. at 5 h post-dose	Y	ddMMMyyyy hh:mm	---
01-001/001	6	Dinner	Day 4 - Approx. at 12 h post-dose	Y	ddMMMyyyy hh:mm	---
...	...	...	...	...	...	...

Program: Listings\k374-ml-lst.sas

Listing 16.2.10.10 - HHnB deficiencies

Participant ID	Deficiency ID		
01-001/001	1	Description:	HHnB broken
		Start - End Date/Time (Day):	ddMMMyyyy hh:mm (k) - ddMMMyyyy hh:mm (k+n)
		Duration:	hh:mm
		HHnB use start Date/Time Before deficiency (Day):	ddMMMyyyy hh:mm:ss (k)
		Time Elapsed form HHnB use start:	hh:mm
		Was the HHnB defice replaced?	N
		Any corrective action taken?	N
		Any AE due to deficiency?	N
		Could the deficiency have led to a medical occurrence?	N
	...	...	...

Program: Listings\k374-dd-lst.sas

Listing 16.2.10.11 - Columbia Suicidality Severity Rating Scale

Participant ID	Time Point	Questionnaire Date		
01-001/001	Screening	ddMMMyyyy	Wish to be Dead:	N
			Non-Specific Active Suicidal Thoughts:	N
			Active Suicidal Ideation with Any Methods (Not Plan) without Intent to Act:	N
			Active Suicidal Ideation with Some Intent to Act, without Specific Plan:	N
			Active Suicidal Ideation with Specific Plan and Intent:	N
			Most Severe Ideation:	---
			Description of Ideation:	---
			Frequency - Duration - Controllability:	---
			Deterrents - Reason for Ideation:	---
			Actual Attempt	N
			Has the subject engaged in Non-suicidal Self-Injurious Behaviour?	Y
			Interrupted Attempt:	Y (description, nr.)
			Aborted Attempt:	N
			Preparatory Acts or Behaviour:	Y (description)
			Suicidal Behaviour	Y
			Actual Lethality - Most Recent Attempt	1=Minor physical damage (yyyy)
			Actual Lethality - Most Lethal Attempt	---
			Actual Lethality - Initial/First Attempt	1=Minor physical damage (yyyy)
			Potential Lethality - Most Recent Attempt	---
	End of Study	ddMMMyyyy	Wish to be Dead:	N
			Non-Specific Active Suicidal Thoughts:	N
			Active Suicidal Ideation with Any Methods (Not Plan) without Intent to Act:	N
			Active Suicidal Ideation with Some Intent to Act, without Specific Plan:	N
			Active Suicidal Ideation with Specific Plan and Intent:	N
			Most Severe Ideation:	---
			Description of Ideation:	---
			Frequency - Duration - Controllability:	---

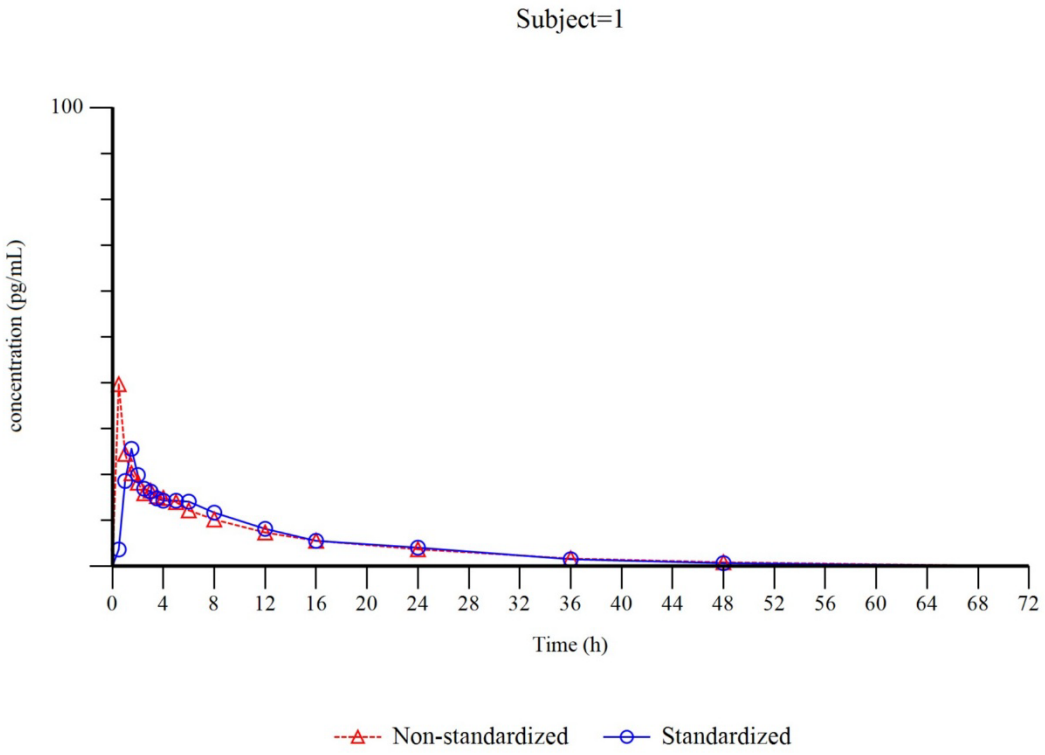
Program: Listings\k374-qs-lst.sas

Listing 16.2.10.11 - Columbia Suicidality Severity Rating Scale

Participant ID	Time Point	Questionnaire Date		
01-001/001	End of Study	ddMMMyyyy	Deterrents - Reason for Ideation:	---
			Actual Attempt	N
			Has the subject engaged in Non-suicidal Self-Injurious Behaviour?	Y
			Interrupted Attempt:	Y (description, nr.)
			Aborted Attempt:	N
			Preparatory Acts or Behaviour:	Y (description)
			Suicidal Behaviour	Y
			Actual Lethality - Most Lethal Attempt	---
			Potential Lethality - Most Lethal Attempt	---
...	...	...	...	...

Program: Listings\k374-qs-lst.sas

Figure 16.2.5.1 Subject 01-0xx/0xx - CBD concentration (pg/mL) in blood vs. time profiles. Linear scale (top) and logarithmic/linear scale (bottom)



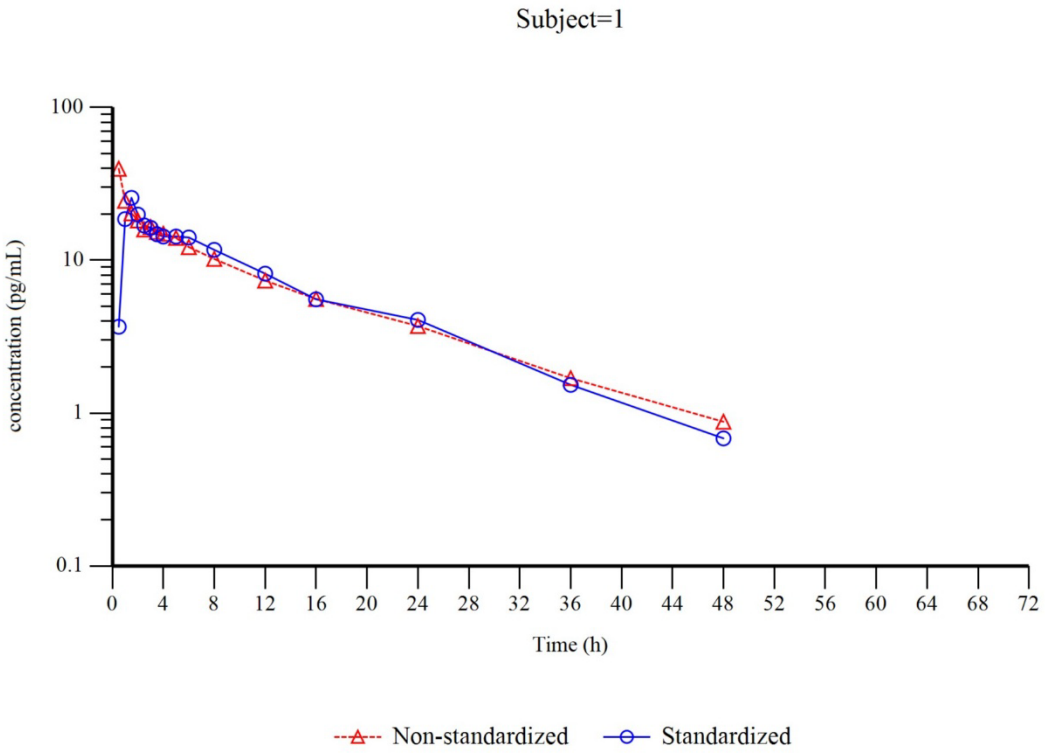
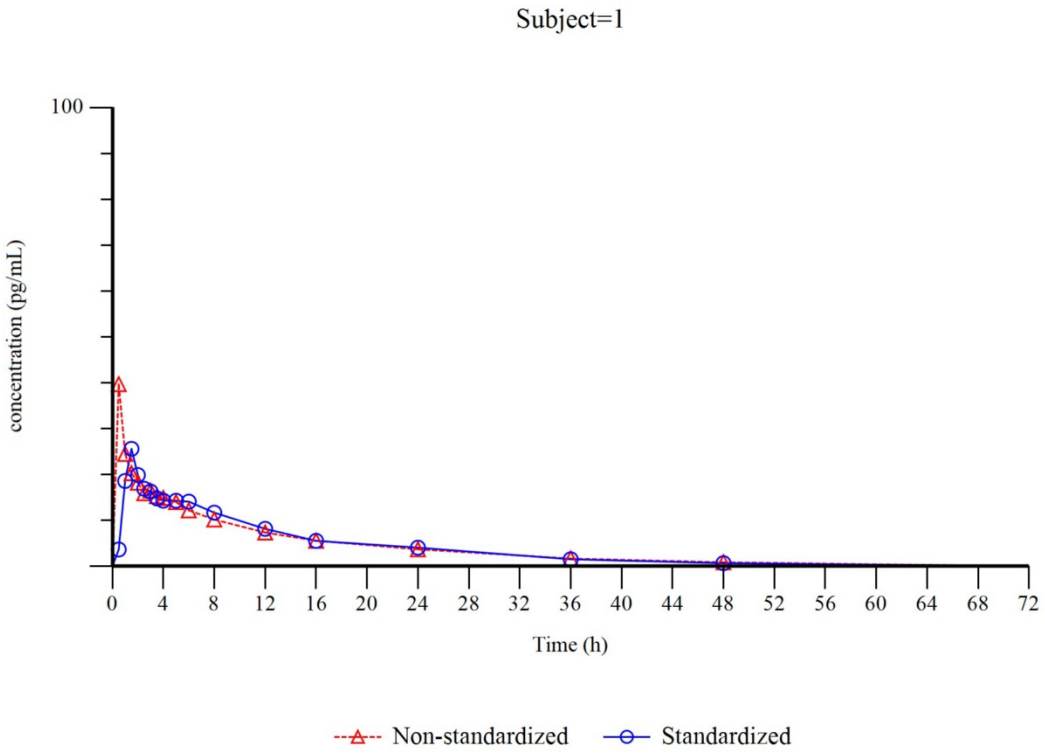


Figure 16.2.5.2 Subject 01-0xx/0xx - 7-OH-CBD concentration (pg/mL) in blood vs. time profiles. Linear scale (top) and logarithmic/linear scale (bottom)



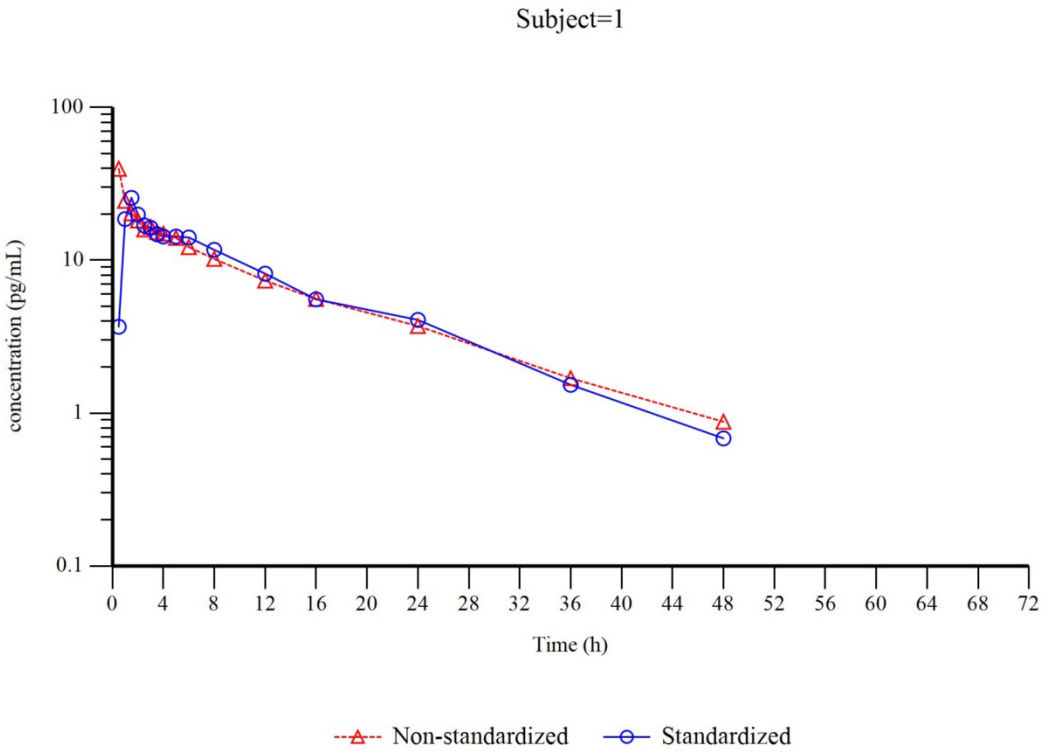
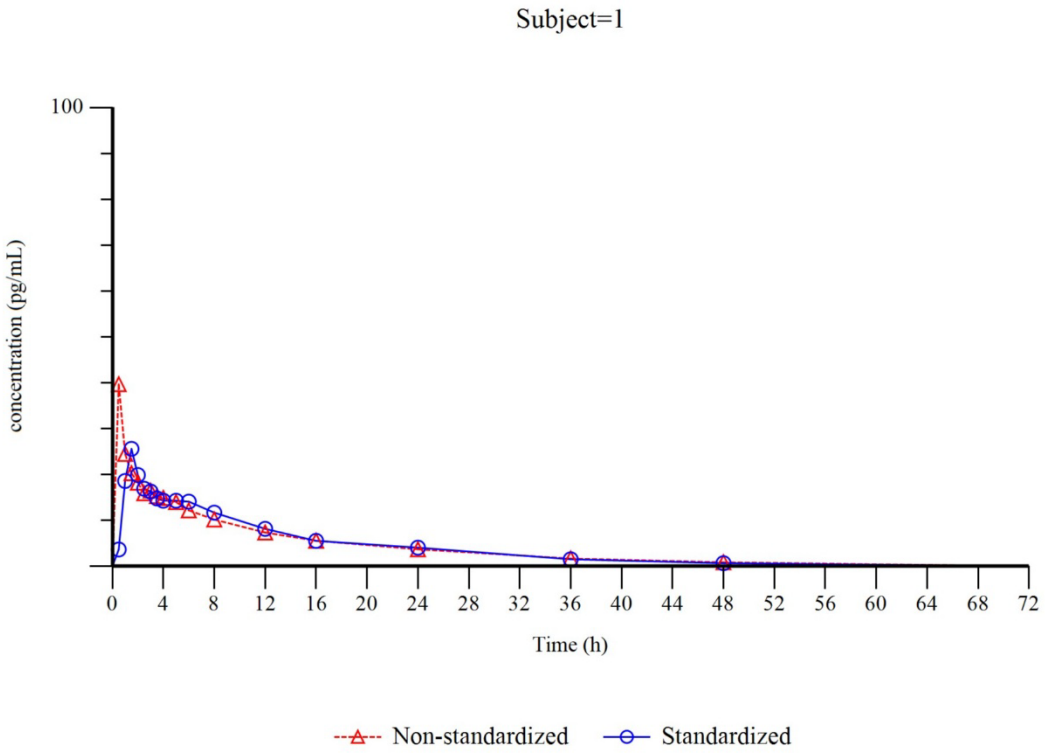


Figure 16.2.5.3 Subject 01-0xx/0xx - 7-COOH-CBD concentration (pg/mL) in blood vs. time profiles. Linear scale (top) and logarithmic/linear scale (bottom)



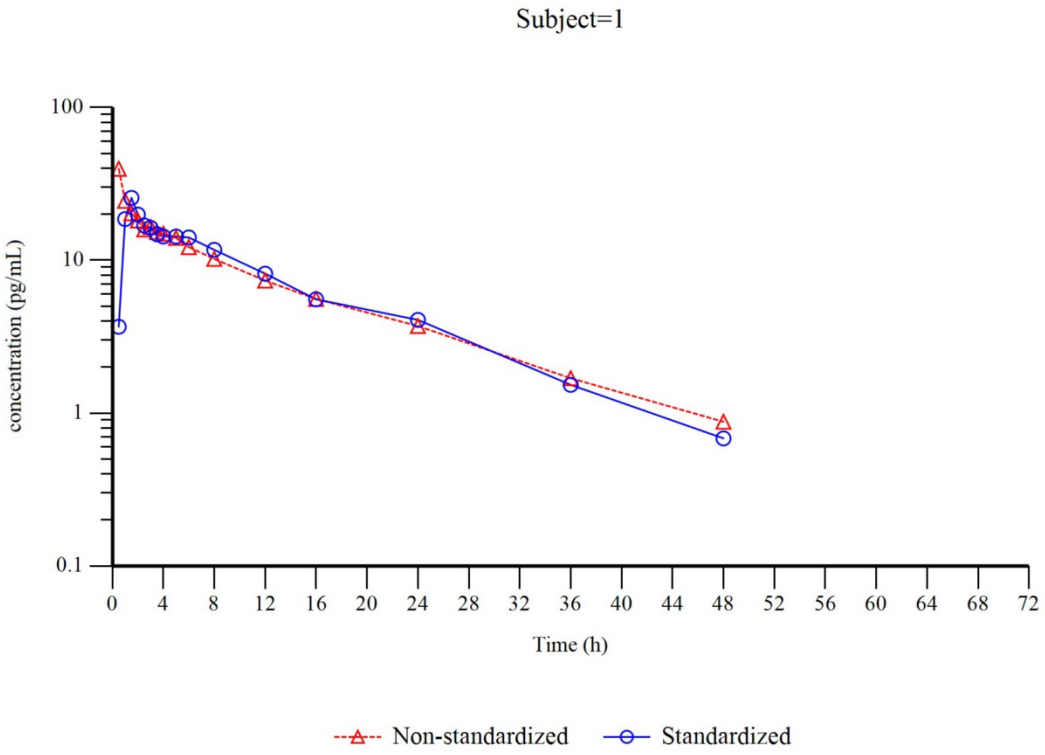
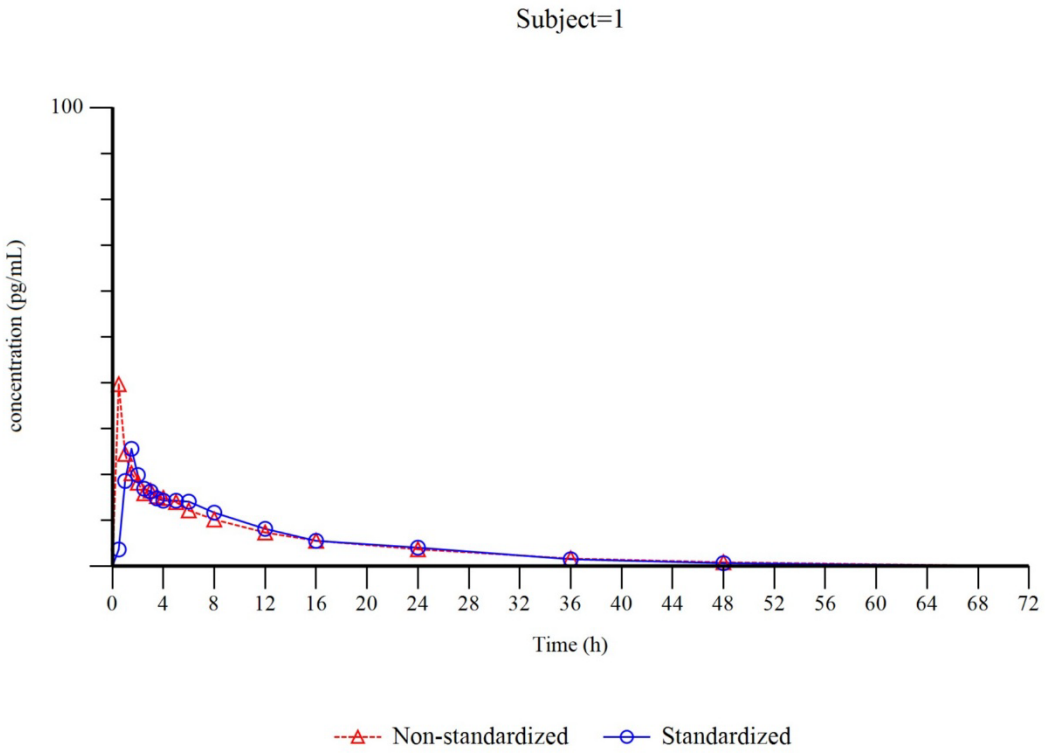


Figure 16.2.5.4 Subject 01-0xx/0xx - THC concentration (pg/mL) in blood vs. time profiles. Linear scale (top) and logarithmic/linear scale (bottom)



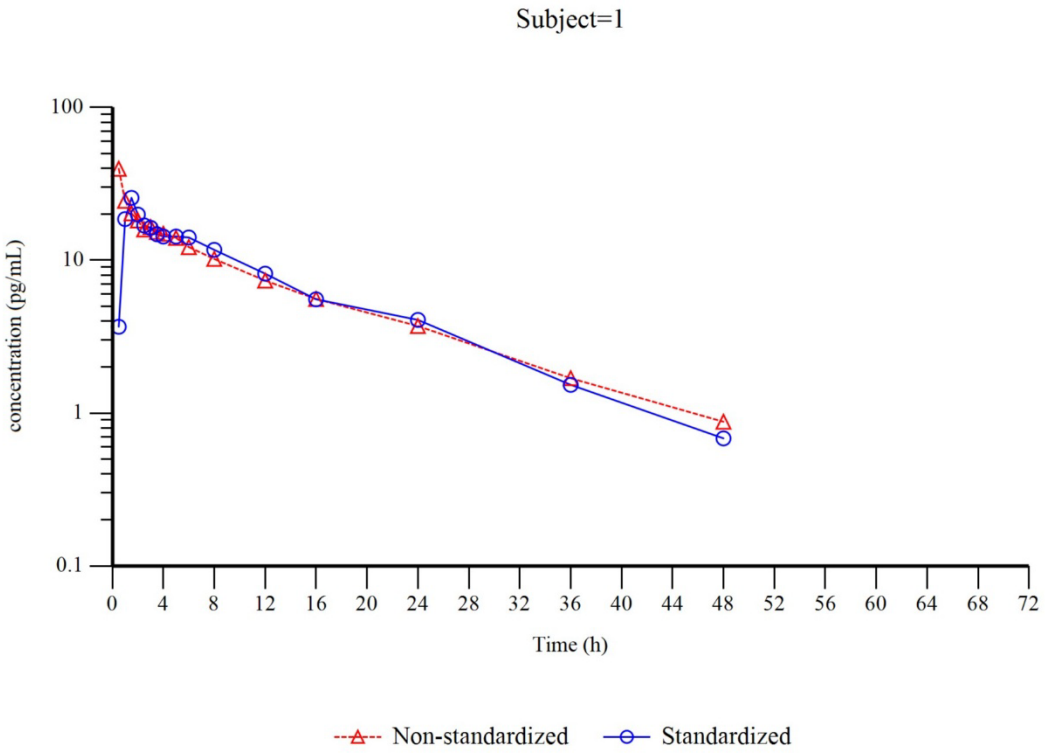
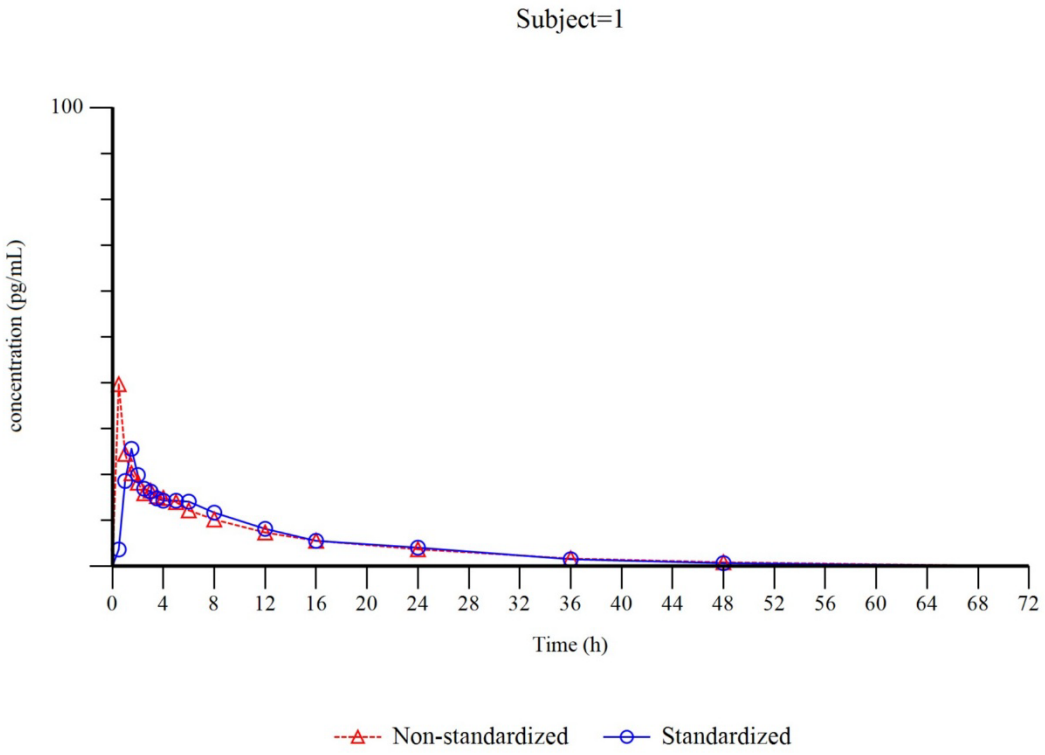


Figure 16.2.5.5 Subject 01-0xx/0xx - 11-OH-THC concentration (pg/mL) in blood vs. time profiles. Linear scale (top) and logarithmic/linear scale (bottom)



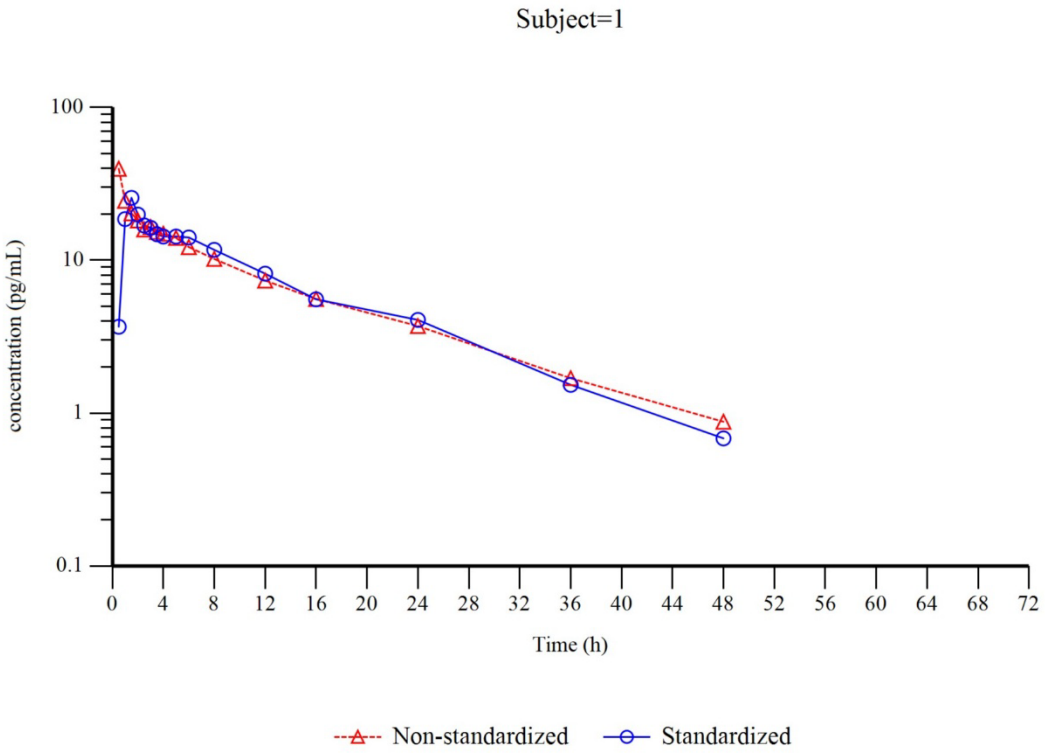
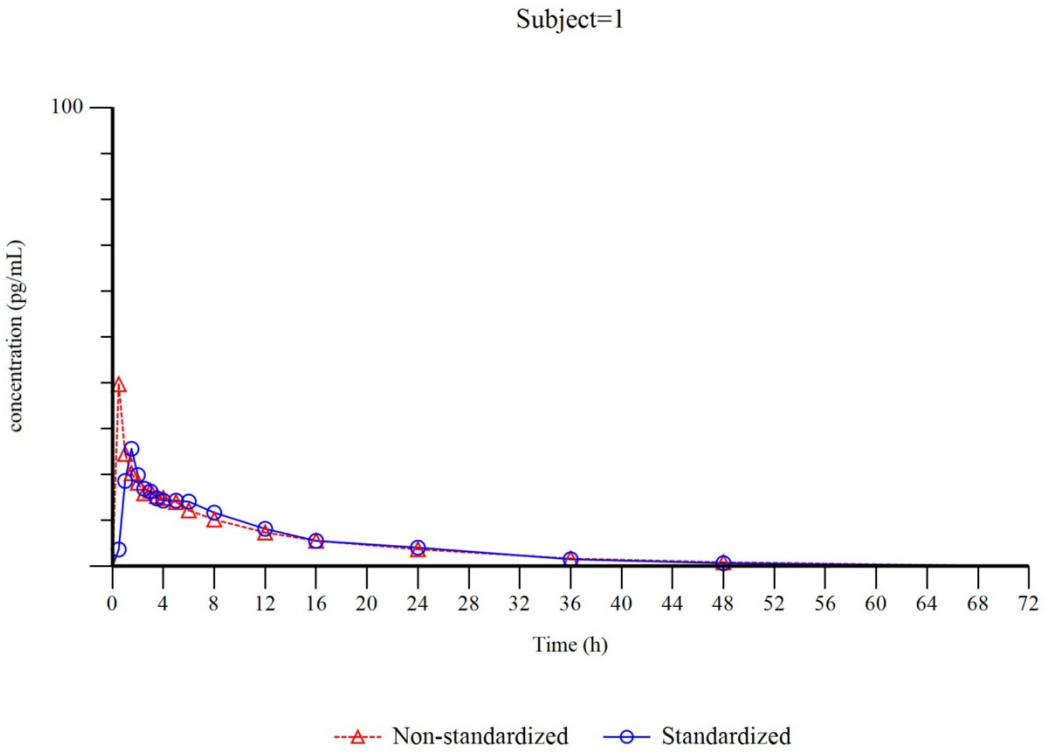
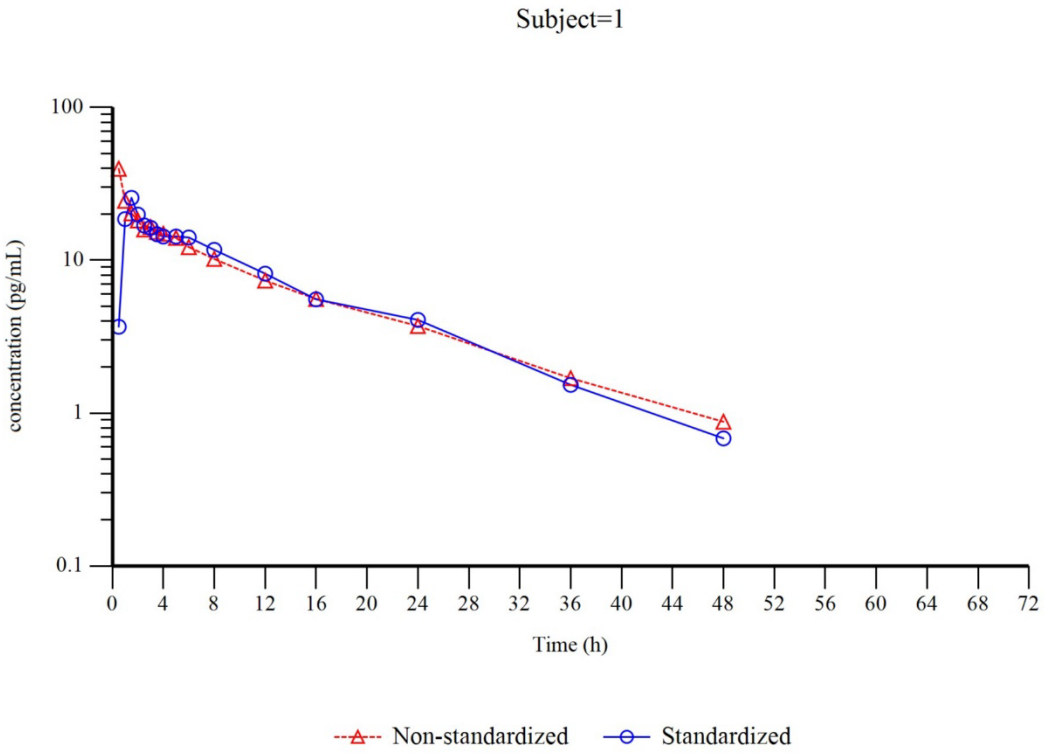


Figure 16.2.5.6 Subject 01-0xx/0xx - 11-COOH-THC concentration (pg/mL) in blood vs. time profiles. Linear scale (top) and logarithmic/linear scale (bottom)





20250924-k374-sap-with-shells-f-1-0_cross_signed

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Status:	Signed
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