STATISTICAL ANALYSIS PLAN

Trial Name:	105
Trial Title:	The effect of food on the oral bioavailability of AEF0117 in healthy volunteers
Protocol No.:	AEF0117-105
IND Number.:	126501

Reference to version and date of protocol on which report is based	
Protocol version:	2
Protocol date:	01 December 2022

Date:	19 January 2023
Version:	1.0

Performed by:	**Performed for:**
BIOCLever	AELIS FARMA

Index

Table index

Listing index

ABBREVATIONS AND DEFINITIONS

ACT	Anatomical Therapeutic Chemical
AE	Adverse Event
ALP	Alkaline Phosphatase
ALT (GPT)	Alanine transaminase
aPTT	Activated Partial Thromboplatin time
AST (GOT)	Aspartate Transaminase
AUC	Area Under the Curve
BMI	Body Mass Index
C_{24h}	Observed plasma concentration 24 hours after dose
CB1	Cannabinoid receptor type 1
CI	Confidence Interval
CL/F	Apparent clearance
C_{max}	Maximum observed plasma concentration
CPK	Creatine Phosphokinase
CRU	IMIM-Clinical Research Unit
CS	Clinically Significant
C-SSRS	Columbia Suicide Severity Rating Score
CUD	Cannabis User Disorder
CV	Coefficient of variation
DBP	Diastolic Blood Pressure
ECG	Electrocardiogram
FDA	Food and Drug Administration
FSH	Follicle-stimulating hormone
HDL	High-density Lipoprotein
IB	Investigator's Brochure
INR	International Normalized Ratio
INSERM	Institut National de la Santé et de la Recherche Médicale
LDL	Low-density Lipoprotein
MCHC	Mean corpuscular hemoglobin concentration
MCV	Mean Corpuscular Volume
MedDRA	Medical Dictionary for Regulatory Activities
NCS	Non-clinically significant
PK	Pharmacokinetic(s)
PT	Preferred Term
Q1, Q3	Quartiles 1 and 3
QTcF	QT interval corrected

RBC	Red blood cell count
SAF	Safety analysis set
SAS®	Statistical Analysis System
SBP	Systolic Blood Pressure
sCB1-SSi	Synthetic signaling specific inhibitor of the CB1 receptor
SD	Standard Deviation
SOC	System Organ Class
SOP	Standard Operating Procedure
TEAE	Treatment Emergent Adverse Event
THC	Tetrahydrocannabinol
t_{lag}	Time to first quantifiable plasma concentration
T_{max}	Time to observed maximum plasma concentration
Vd/F	Apparent volume of distribution
WBC	White blood cells
WHOdrug	World Health Organization-drug

1. Approvals (signatures)

The signatures on this page indicate review and approval of the statistical analysis plan and referenced Sections.

Bioclever

Written by: Josep Puig, Biostatiscian

(Sig.) _____Date: _____

Aelis Farma

Approved by: Lasse Steen Ravn, MD

(Sig.) _____Date: _____

2. Distribution List

Name	Function / Role	Office/Sponsor
Ghislaine Campistron	Sponsor	AELIS FARMA
Audrey Serpault	Sponsor	AELIS FARMA
Lasse Steen Ravn	Sponsor	AELIS FARMA
Arnau Lucas	CRO	Bioclever

3. Document Version History

Version	Effective Date	Significant Changes
0.1	25 October 2022	Minor changes.
0.2	09 November 2022	Minor changes.
0.3	05 December 2022	Minor changes.
0.4	09 January 2023	New protocol version. Urine collection for exploratory objective has been deleted.
0.5	13 January 2023	No changes.

4. Introduction

4.1 Background and rationale

Cannabis is the most widely used illicit drug with approximately 28 million individuals reporting past-month use [1], and 14% of those receiving substance use disorder treatment in the US reporting cannabis as their primary drug of abuse [2]. While psychotherapeutic approaches have some utility for treating Cannabis Use Disorder (CUD) [3, 4, 5, 6], the vast majority of patients have difficulty significantly reducing their use or achieving abstinence. Safe and effective medications to treat CUD are urgently needed [7, 8]. The overall goal of this clinical trial is to contribute to advancing a safe and effective pharmacotherapy for CUD along the FDA approval pipeline.

When the CB1 receptors are over-activated by very high doses of THC, quite higher than the doses of THC used by cannabis abusers, the concentration of the steroid hormone pregnenolone increases in the brain. Pregnenolone then binds to a specific site on the CB1 receptors, distinct for the one of CB1 agonists and THC, and acts as an endogenous signaling specific inhibitor of the CB1 receptors. However, pregnenolone does not modify the binding of CB1 agonists to the CB1 receptor. Despite this restricted molecular action, when pregnenolone is administered prior to the exposure to THC, it inhibits most of the THC-mediated behavioral effects in rodents and THC self-administration in non-human primates. Pregnenolone cannot be used as a pharmacological treatment because it is poorly bioavailable, has a very short half-life and is converted downstream to active steroids. Aelis Farma, in collaboration with researchers from the Institut National de la Santé et de la Recherche Médicale (INSERM), has developed a new pharmacological class, the synthetic signaling specific inhibitor of the CB1 receptor (sCB1-SSi), by modifying pregnenolone's chemical structure to prevent conversion to active steroids, and to increase absorption and biological stability while maintaining THC antagonism.

To date, 3 clinical studies have been completed with AEF0117 including 2 phase 1 studies in healthy volunteers (AEF0117-101 single ascending dose study and AEF0117-102, multiple ascending dose study), and a phase 2a trial in cannabis users (AEF0117-201). The phase 1 studies showed good safety and tolerability of AEF0117 in the dose range tested (0.2 mg as single dose and 0.6–6 mg/day as single and multiple doses) and the phase 2a trial found that the 1 mg/day dose of AEF0117 significantly reduced both the abuse-related subjective effects of cannabis and its self-administration, while the 0.06 mg dose did not. Importantly, AEF0117 was well tolerated in daily cannabis smokers, with no evidence of precipitated withdrawal, physical, or psychological discomfort. There were no SAEs and a limited number of TEAEs. These results confirm preclinical data showing that AEF0117 does not function as an orthosteric antagonist and does not produce any of the adverse effects associated with rimonabant. Thus, AEF0117 is to our knowledge the first medication to safely and robustly

attenuate the positive subjective and reinforcing effects of cannabis in participants with CUD. Further details are provided in the current edition of the IB [9].

In the 3 early studies conducted with AEF0117, AEF0117 was administered orally after a light breakfast. AEF0117 showed a good bioavailability and favorable, dose-proportional PK [9]. In this protocol, the effects of food on AEF0117 bioavailability in healthy volunteers will be investigated by comparing the rate and extent of AEF0117 absorption when 1 mg AEF0117 is administered in fed state versus fasting state.

The safety and tolerability of AE0117 has been demonstrated in the clinical studies conducted to date. This trial will provide data on the effect of food on the oral bioavailability of AEF0117 to support the next stage of the clinical development of the drug.

4.2 Objectives

4.2.1 Primary objective

To determine the bioavailability of orally administered AEF0117 after fed conditions relative to fasting conditions in healthy volunteers.

4.2.2 Secondary objectives

- To evaluate other PK parameters of AEF0117 in healthy volunteers.
- To evaluate safety and tolerability of a single dose of 1 mg AEF0117 in healthy volunteers.

4.2.3 Exploratory objective

To characterize potential metabolites regarding plasma PK.

5. Changes to the protocol

The protocol states “An analysis of variance model will be applied, with sequence, period, and state (fed, fasting) as factors”. This is not a cross-over study for that reason period and sequence variables do not apply. The analysis of variance model has been changed for a t-test analysis (See section 8.4).

6. Clinical trial methodology

6.1 Study design

This is a single center, randomized, parallel-group, 2-arm, open-label, single-dose trial in healthy male and female volunteers aged 18–55 years, both inclusive.

The total trial duration for an individual participant will be up to 6 weeks (42 days) from screening (up to 28 days prior to dosing) to the final follow-up visit (14 days after dosing).

After screening, the trial includes 2 days where the participants are confined at the research facility, and thereafter 7 visits to the site (6 visits and a follow-up visit). Participants will stay in the research facility from the afternoon prior to dosing on Day 1 and until collection of the blood sample 24 hours after dosing (i.e., Day 2) and then be discharged. Participants will be asked to return to the research facility for collection of blood samples each morning on Days 3, 4, 5, 7, 9, and 11, and at the follow-up visit on Day 14.

On Day 1, eligible participants will be randomized and receive a single dose of 1 mg AEF0117 in fed or fasting condition, and serial blood samples will be collected up to 312 hours after dose administration

6.2 Randomization

All participants will be assigned a unique trial participant number at the trial-specific screening.

A computer-generated randomization schedule will be prepared by a statistician. Eligible participants will be randomly assigned to 1 of the 2 groups. Randomization will be with a block size of 2 and stratified by sex.

The 2 groups will be divided into smaller cohorts of at least 2 participants for operational reasons (adjusted to in clinic facilities) and each cohort will include a similar number of participants from each group (fed or fasting).

6.3 Sample size

The sample size has been chosen based on previous experience in phase 1 studies with AEF0117 where the CV was in the order of 0.3 for Cmax and AUC after single doses. It is anticipated that food slightly increases the absorption of AEF0117 and a true ratio of 1.25 is assumed. To allow for potential participants who dropout early, i.e., not allowing for estimation of Cmax and/or AUC0-t, 32 participants should be included. The power for showing that the upper bound of the 2-sided 90% CI of the geometric mean ratio is ≤1.75 is 90% with 14 participants per treatment group and 86% with 12 participants per group.

6.4 Interim analyses

Not applicable.

7. General statistical considerations

7.1 Study population

- Safety analysis set (SAF): This set will include all randomized subjects in the study who recieved the study drug (AEF0117).
- Pharmacokinetic(s) analysis set (PK analysis set): This set will include all randomized subjects in the study who recieved the study drug (AEF0117) with sufficient and valid plasma drug concentration data to allow the determination of PK parameters (at least the 24-hour PK profile), without vomits within 3 hours after dose and without protocol deviations with significant influence on estimation of one or more PK parameter.

7.2 General issues

All data processing, summarization and analyses will be performed using SAS® version 9.4 or posterior.

7.3 Presentation/Format of results

Mean, median and standard deviation will be printed out to one more decimal place than the recorded data and rounded appropriately. Minimum and maximum values will be presented using the same number of decimal places as the recorded data. The number of subjects will be presented as a whole number.

Percentage values will be presented with one digit to the right of decimal point.

P-values will be presented to 4 decimal places (or as <0.0001 where appropriate).

7.4 Level of significance

Statistical comparisons will be made using two sided tests at the α=0.05 significance level unless specifically stated otherwise.

7.5 Handling of dropouts and missing data

No imputation method will be used.

8. Statistical analysis

8.1 Definitions of variables

- Age (years):

(Date of informed consent – Date of birth) / 365.25

- Duration of adverse events:

Duration (minutes) = (End time[hh:mm] and date – initial time[hh:mm] and date)

- Time between two events (hours, days and months):

Hours: (Most recent Date – Other Date) / 60 [Format date: Day/Month/Year, Hour:Minute]

Days: Most recent Date – Other Date [Format date: Day/Month/Year]

Months: (Most recent Date – Other Date) / 30.4375 [Format date: Day/Month/Year]

- C-SSRS:

Categories:

Category 1 – Wish to be Dead

Category 2 – Non-specific Active Suicidal Thoughts

Category 3 – Active Suicidal Ideation with Any Methods (Not Plan) without Intent to Act

Category 4 – Active Suicidal Ideation with Some Intent to Act, without Specific Plan

Category 5 – Active Suicidal Ideation with Specific Plan and Intent

Category 6 – Preparatory Acts or Behavior

Category 7 – Aborted Attempt

Category 8 – Interrupted Attempt

Category 9 – Actual Attempt (non-fatal)

Category 10 – Completed Suicide (not included at screening and baseline visit)

Suicidal Ideation or Behavior:

- Yes: If any category = “Yes”.
- No: All categories = “No”.

Suicidal Ideation:

- Yes: If any category 1-5 = “Yes”.
- No: All categories 1-5 = “No”.

Suicidal Behavior:

- Yes: If any category 6-10 = “Yes”.
- No: All categories 6-10 = “No”.

All suicidal endpoints will be calculated before study (screening visit and baseline visit) and during study (study visits)

- Treatment Emergent Adverse Event (TEAE):

Adverse Events with an onset equal or posterior to IMP administration

- ECG parameters:

For each timepoint 3 ECGs will be performed. The results of them will be summarized as:

- Normal/Abnormal:
  - Three Normal ECG -> “All normal”
  - One, two or three Abnormal ECG -> “Any Abnormal”
- Does the result meet the definition of adverse event? (Yes/No) [Overall ECG variable and per parameter variable (Heart rate, PR Inteval, QRS duration, QT interval, QTcF intervals)]:
  - Three “No” -> “All No”
  - One, two or three “Yes” -> “Any Yes”
- Heart rate: Mean value of 3 ECGs.
- PR interval: Mean value of 3 ECGs.
- QRS duration: Mean value of 3 ECGs.
- QT interval: Mean value of 3 ECGs.
- QTcF intervals: Mean value of 3 ECGs.

8.2 Hypothesis and statistical methods

8.2.1 Univariate analysis. Descriptive statistics

Unless otherwise noted, all variables will be described according to their character as follows:

- Categorical variables will be summarized using frequencies and percentages.
- Continuous variables will be summarized using measures of central tendency and dispersion: mean, standard deviation, median, 25% and 75% percentiles (Q1 and Q3) and extreme values (minimum and maximum).

8.2.2 Bivariate analysis

When it is of interest to answer the study objectives, the relationship between variables will be evaluated:

- For two categorical variables, contingency tables with the frequency in each category and the percentage by columns will be presented.
- For a numerical variable with a categorical, descriptive statistics will be presented by groups.

8.3 Demographic and baseline characteristics

Demographic data and baseline characteristics will be described following the methods that appear in section 8.2.

8.4 Primary analysis

Plasma PK parameters:

- Area under the concentration-time curve (AUC_{0-t}, $AUC_{0-\infty}$) where t is the last or the latest timepoint observed.
- Observed maximum plasma concentration: C_{max}.
- Time to observed maximum plasma concentration: T_{max}.
- Time lag (Time to first quantifiable plasma concentration): t_{lag}.

PK analysis will consist of a non-compartmental evaluation of AEF0117 plasma concentration-time profiles to determine PK parameters using a validated program. PK analysis will be performed at PK lab before transferred for statistical analysis.

For each PK parameter:

- A descriptive analysis by fed and fasting will be presented.
- A t-test will be fitted by using PROC TTEST (SAS) for all parameters except T_{max} and t_{lag}:
    - The natural logarithm transformation of each parameter will be the response variable.

- Exploratory variable will be:
  - State: Fed / Fasting.
- A table with the t-test p-value, the exponential of estimated mean difference (Geometric mean ratio) and its 90% confidence interval will be presented.
- Relative bioavailability is the ratio of AUCs. The relative bioavailability of AEF0117 under fed conditions compared to under fasting condition will be assessed as negligeable during therapeutic use if the two-sided 90% CI of fed vs fasting is <= 1.75. Bioequivalence will be declared if the 90% CI is included in 0.8-1.25 range.

8.5 Secondary pharmacokinetic analysis

Plasma PK parameters:

- $\%AUC_{extrap}$
- Observed concentration 24 hours after dose: C_{24h}.
- Terminal elimination half-life: $t_{1/2}$.
- Apparent clearance: CL/F.
- Apparent volume of distribution: Vd/F.

A descriptive analysis by fed and fasting will be presented.

8.6 Safety and tolerability analysis

Safety and tolerability endpoints:

- Any AE per subject and state.
- Any TEAE per subject and state.
- Vital signs.
- ECG.
- Laboratory parameters (Hematology, Chemistry, Coagulation profile and urinanalysis).
- Physical examination
- C-SSRS.

A descriptive analysis by fed/fasting will be presented.

Frequency and percentage of subjects and number of AE and TEAE will be included, by the following variables:

- Severity: Mild, Moderate, Severe.
- Causality: Not related, Related.

- Action taken with study treatment: Dose not changed, drug withdrawn, drug interrupted, dose increased, dose reduced, not applicable, unknown.
- Outcome: Recovered/Resolved, Recovering/Resolving, Not recovered/Not resolved, Recovered/Resolved with sequelae, Fatal, Unknown
- Serious: Yes, No.
- Serious criteria: Death, Hospitalization or prolongation of existing hospitalization, Congenital anomaly or birth defect, Other medically important event, Life threatening, Significant disability/incapacity.

Also a descriptive analysis of AE and TEAE by System Organ Class and Preferred Term (codificated by the dictionary MedDRA version 25.0) will be presented.

8.7 Exploratory objective

The exploratory analysis will be performed in the future. The analysis will be included in another document.

8.8 Concomitant medication

The concomitant medication prior to and during study per fed and fasting status will presented by using the WHOdrug dictionary version 2021, the ACT classification name will be shown.

9. References

1. Substance Abuse and Mental Health Services Administration. Key substance use and mental health indicators in the United States: Results from the 2018 National Survey on Drug Use and Health (HHS Publication No. PEP19-5068, NSDUH Series H-54). Rockville, MD: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration; 2019.
2. Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality. Treatment Episode Data Set (TEDS): 2005-2015. National Admissions to Substance Abuse Treatment Services. BHSIS Series S-91, HHS Publication No. (SMA) 17-5037. Rockville, MD: Substance Abuse and Mental Health Services Administration; 2017.
3. Budney AJ, Higgins ST, Radonovich KJ, Novy PL. Adding voucher-based incentives to coping skills and motivational enhancement improves outcomes during treatment for marijuana dependence. J Consult Clin Psychol. 2000;68(6):1051-61. doi: 10.1037//0022- 006x.68.6.1051.
4. Budney AJ, Moore BA, Rocha HL, Higgins ST. Clinical trial of abstinence-based vouchers and cognitive-behavioral therapy for cannabis dependence. J Consult Clin Psychol. 2006;74(2):307-16. doi: 10.1037/0022-006x.4.2.307.
5. Copeland J, Swift W, Roffman R, Stephens R. A randomized controlled trial of brief cognitive-behavioral interventions for cannabis use disorder. J Subst Abuse Treat. 2001;21(2):55-64; discussion 5-6. doi: 10.1016/s0740-5472(01)00179-9.
6. Stephens RS, Babor TF, Kadden R, Miller M. The Marijuana Treatment Project: rationale, design and participant characteristics. Addiction. 2002;97 Suppl 1:109-24. doi: 10.1046/j.1360-0443.97.s01.6.x.
7. Brezing CA, Levin FR. The Current State of Pharmacological Treatments for Cannabis Use Disorder and Withdrawal. Neuropsychopharmacology. 2018;43(1):173-94. doi: 10.1038/npp.2017.212.

8. Weinstein AM, Gorelick DA. Pharmacological treatment of cannabis dependence. Curr Pharm Des. 2011;17(14):1351-8. doi: 10.2174/138161211796150846.
9. Aelis Farma. AEF0117 Investigator's Brochure. Edition 5.0; March 2022.
10. FDA. Guidance for Industry. Food-Effect Bioavailability and Fed Bioequivalence Studies. U.S. Department of Health and Human Services. U.S. Department of Health and HumanServices. Food and Drug Administration. Center for Drug Evaluation and Research (CDER). December 2002. Available from: https://www.fda.gov/files/drugs/published/Food-Effect-Bioavailability-and-Fed-Bioequivalence-Studies.pdf..

10. Tables to be presented in the report

10.1 Analysis sets

Table 1.1.1 Analysis sets - Subjects recruited

	Total number of enrolled subjects (n=xx)	Fed (n=xx)	Fasting (n=xx)
Number of subjects in SAF	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of subjects excluded from SAF by reason for exclusion:			
Subjects who do not receive study medication	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of subjects in PK	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of subjects excluded from PK by reason for exclusion[1]:			
Subjects who do not receive study medication	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Subjects with plasma pharmacokinetic parameters not available	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Subjects who vomited within 3 hours after dose administration	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Subjects with protocol deviations with significant influence on estimation of one or more PK parameter	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[1]Subjects may present more than one reason.

Table 1.1.2 Visits - SAF

		Total subjects (n=xx)	Fed (n=xx)	Fasting (n=xx)
Screening visit (Day -28 to -2)	n (%)	xx (xx.x%)	-	-
Baseline visit (Day -1)	n (%)	xx (xx.x%)	-	-
Day 1	n (%)	xx (xx.x%)	-	-
Day 2	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Day 3	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Day 4	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Day 5	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Day 7	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Day 9	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Day 11	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Day 14 ±1	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Table 1.1.3 End of study - SAF

		Total subjects (n=xx)	Fed (n=xx)	Fasting (n=xx)
Status of the subject				
Completed	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Premature withdrawal	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Reason for premature withdrawal[1]				
Total no-missing	n	xx	xx	xx
Screen failure	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Adverse Event	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Protocol deviation	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Withdrawal by subject	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Lost to follow-up	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Study terminated by sponsor	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Technical problem	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Other	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Missing	n	xx	xx	xx

[1]Subjects with premature withdrawal.

10.2 Descriptive analysis - SAF

10.2.1 Screening visit (Day -28 to -2)

Table 2.1.1 Demographic - SAF

		Total subjects (n=xx)	Fed (n=xx)	Fasting (n=xx)
Age (years)	n	xx	xx	xx
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
	Median (Q1,Q3)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
	(Min,Max)	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)
	Missing	xx	xx	xx
Weight (Kg)	n	xx	xx	xx
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
	Median (Q1,Q3)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
	(Min,Max)	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)
	Missing	xx	xx	xx
Height (cm)	n	xx	xx	xx
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
	Median (Q1,Q3)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
	(Min,Max)	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)
	Missing	xx	xx	xx
BMI (Kg/m^2)	n	xx	xx	xx
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
	Median (Q1,Q3)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
	(Min,Max)	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)

		Total subjects (n=xx)	Fed (n=xx)	Fasting (n=xx)
	Missing	xx	xx	xx

Table 2.1.2 Sex, Ethnicity and Status - SAF

		Total subjects (n=xx)	Fed (n=xx)	Fasting (n=xx)
Sex				
Total no-missing	n	xx	xx	xx
Male	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Female	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Missing	n	xx	xx	xx
Ethnicity				
Total no-missing	n	xx	xx	xx
Hispanic or Latino	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Not Hispanic or Latino	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Missing	n	xx	xx	xx
Race				
Total no-missing	n	xx	xx	xx
White	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Black or African	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
American	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Asian	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
American Indian or Alaska native	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Native Hawaiian or other Pacific islander	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Other	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Missing	n	xx	xx	xx

Table 2.1.3 Contraception - SAF

		Total subjects (n=xx)	Fed (n=xx)	Fasting (n=xx)
Childbearing[1]				
Total no-missing	n	xx	xx	xx
Fertile	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Post-menopausal	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Infertile / Sterile	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Pregnant or nursing female	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Hysterectomy	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Annexectomy / Salpingectomy	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Tubal ligature / Tubal ligation	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Ovariectomy	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Missing	n	xx	xx	xx
Contraception method[2]				
Total no-missing	n	xx	xx	xx
Oral contraceptive	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Intra-uterine device	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Implant	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Diaphragm	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Condom with spermicide or jelly	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Other	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Missing	n	xx	xx	xx

[1]Only women.

[2]Patients with child-bearing potential.

Table 2.1.4 Medical history - SAF

		Total subjects (n=xx)	Fed (n=xx)	Fasting (n=xx)
Medical history				
Total no-missing	n	xx	xx	xx
Yes	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Missing	n	xx	xx	xx
Medical history				
Total no-missing	n	xx	xx	xx
SOC 1	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
PT 1	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
…				
Missing	n	xx	xx	xx

The medical history will be presented by using the dictionary MedDRA version 25.0.

Table 2.1.5 Ongoing medical history - SAF

		Total subjects (n=xx)	Fed (n=xx)	Fasting (n=xx)
Ongoing medical history				
Total no-missing	n	xx	xx	xx
Yes	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Missing	n	xx	xx	xx
Ongoing medical history				
Total no-missing	n	xx	xx	xx
SOC 1	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
PT 1	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
…				
Missing	n	xx	xx	xx

The ongoing medical history will be presented by using the dictionary MedDRA version 25.0.

Table 2.1.6 Physical examination (Screening) - SAF

	Total Subjects (n=xx)		Fed (n=xx)		Fasting (n=xx)	
	Total no-missing n	Normal n (%)	Total no-missing n	Normal n (%)	Total no-missing n	Normal n (%)
Skin	xx	xx (xx.x%)	xx	xx (xx.x%)	xx	xx (xx.x%)
Head	xx	xx (xx.x%)	xx	xx (xx.x%)	xx	xx (xx.x%)
Eyes – Throat	xx	xx (xx.x%)	xx	xx (xx.x%)	xx	xx (xx.x%)
Thyroid	xx	xx (xx.x%)	xx	xx (xx.x%)	xx	xx (xx.x%)
Lungs	xx	xx (xx.x%)	xx	xx (xx.x%)	xx	xx (xx.x%)
Cardiovascular system	xx	xx (xx.x%)	xx	xx (xx.x%)	xx	xx (xx.x%)
Abdomen (Liver/spleen)	xx	xx (xx.x%)	xx	xx (xx.x%)	xx	xx (xx.x%)
Extremities	xx	xx (xx.x%)	xx	xx (xx.x%)	xx	xx (xx.x%)
Neurological	xx	xx (xx.x%)	xx	xx (xx.x%)	xx	xx (xx.x%)

Table 2.1.7 Vital signs (Screening) - SAF

	n	Mean (SD)	Median (Q1, Q3)	Min, Max	Missing
Time between evaluation and visit Day 1 (days)					
Total subjects	xx	xx.x (xx.x)	xx (xx,xx)	xx,xx	xx
Fed	xx	xx.x (xx.x)	xx (xx,xx)	xx,xx	xx
Fasting	xx	xx.x (xx.x)	xx (xx,xx)	xx,xx	xx
Temperature (ºC)					
Total subjects	xx	xx.x (xx.x)	xx (xx,xx)	xx,xx	xx
Fed	xx	xx.x (xx.x)	xx (xx,xx)	xx,xx	xx
Fasting	xx	xx.x (xx.x)	xx (xx,xx)	xx,xx	xx
SBP - Supine (mmHg)					
Total subjects	xx	xx.x (xx.x)	xx (xx,xx)	xx,xx	xx
Fed	xx	xx.x (xx.x)	xx (xx,xx)	xx,xx	xx
Fasting	xx	xx.x (xx.x)	xx (xx,xx)	xx,xx	xx
DBP - Supine (mmHg)					
Total subjects	xx	xx.x (xx.x)	xx (xx,xx)	xx,xx	xx
Fed	xx	xx.x (xx.x)	xx (xx,xx)	xx,xx	xx
Fasting	xx	xx.x (xx.x)	xx (xx,xx)	xx,xx	xx
Heart rate - Supine (bpm)					
Total subjects	xx	xx.x (xx.x)	xx (xx,xx)	xx,xx	xx
Fed	xx	xx.x (xx.x)	xx (xx,xx)	xx,xx	xx
Fasting	xx	xx.x (xx.x)	xx (xx,xx)	xx,xx	xx

Table 2.1.8 Electrocardiogram (Normal/Abnormal) (Screening) - SAF

		Total subjects (n=xx)	Fed (n=xx)	Fasting (n=xx)
Electrocardiogram				
Total no-missing	n	xx	xx	xx
All Normal	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Any Abnormal	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Missing	n	xx	xx	xx
Does the result meet the definition of adverse event?				
Total no-missing	n	xx	xx	xx
Any Yes	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
All No	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Missing	n	xx	xx	xx
Does the result meet the definition of adverse event? (Any Yes per parameter)*				
Total no-missing	n	xx	xx	xx
Heart rate	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
PR intervals	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
QRS duration	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
QT interval	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
QTcF interval	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Missing	n	xx	xx	xx

*More than one option per patient will be possible.

Table 2.1.9 Electrocardiogram (Screening) - SAF

	n	Mean (SD)	Median (Q1, Q3)	Min, Max	Missing
Time between ECG and dose (hours)					
Total subjects	xx	xx.x (xx.x)	xx (xx,xx)	(xx,xx)	xx
Fed	xx	xx.x (xx.x)	xx (xx,xx)	(xx,xx)	xx
Fasting	xx	xx.x (xx.x)	xx (xx,xx)	(xx,xx)	xx
Heart rate (BPM)					
Total subjects	xx	xx.x (xx.x)	xx (xx,xx)	(xx,xx)	xx
Fed	xx	xx.x (xx.x)	xx (xx,xx)	(xx,xx)	xx
Fasting	xx	xx.x (xx.x)	xx (xx,xx)	(xx,xx)	xx
PR intervals (ms)					
Total subjects	xx	xx.x (xx.x)	xx (xx,xx)	(xx,xx)	xx
Fed	xx	xx.x (xx.x)	xx (xx,xx)	(xx,xx)	xx
Fasting	xx	xx.x (xx.x)	xx (xx,xx)	(xx,xx)	xx
QRS duration (ms)					
Total subjects	xx	xx.x (xx.x)	xx (xx,xx)	(xx,xx)	xx
Fed	xx	xx.x (xx.x)	xx (xx,xx)	(xx,xx)	xx
Fasting	xx	xx.x (xx.x)	xx (xx,xx)	(xx,xx)	xx
QT interval (ms)					
Total subjects	xx	xx.x (xx.x)	xx (xx,xx)	(xx,xx)	xx
Fed	xx	xx.x (xx.x)	xx (xx,xx)	(xx,xx)	xx
Fasting	xx	xx.x (xx.x)	xx (xx,xx)	(xx,xx)	xx
QTcF Interval (ms)					
Total subjects	xx	xx.x (xx.x)	xx (xx,xx)	(xx,xx)	xx
Fed	xx	xx.x (xx.x)	xx (xx,xx)	(xx,xx)	xx
Fasting	xx	xx.x (xx.x)	xx (xx,xx)	(xx,xx)	xx

Table 2.1.10 C-SSRS (Screening) - SAF

		Total subjects (n=xx)	Fed (n=xx)	Fasting (n=xx)
C-SSRS				
Total no-missing	n	xx	xx	xx
Suicidal Ideation or Behavior	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Suicidal Ideation	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Wish to dead	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Non-specific active suicidal thoughts	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Active suicidal ideation with any methods (not plan) without intent to act	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Active suicidal ideation with some intent to act, without specific plan	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Active suicidal ideation with specific plan and intent	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Suicidal Behavior	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preparatory acts or behavior	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Aborted attempt	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Interrupted attempt	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Non-fatal suicide attempt	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Self-injorious behavior without suicidal intent	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Missing	n	xx	xx	xx

Table 2.1.11 Laboratory evaluation (Screening) - SAF

	n	Mean (SD)	Median (Q1, Q3)	Min, Max	Missing
Time between evaluation and visit day 1 (days)					
Total subjects	xx	xx.x (xx.x)	xx (xx,xx)	(xx,xx)	xx
Fed	xx	xx.x (xx.x)	xx (xx,xx)	(xx,xx)	xx
Fasting	xx	xx.x (xx.x)	xx (xx,xx)	(xx,xx)	xx

Table 2.1.12 Percentage of numeric values and non-numeric values (Screening) - SAF

		Total subjects (n=xx)	Fed (n=xx)	Fasting (n=xx)
Chemistry				
Albumin (g/dl)				
Total no-missing	n	xx	xx	xx
Numeric	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Value 1	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
…				
Missing	n	xx	xx	xx
…				
Hematology				
…				
Coagulation				
…				

Table 2.1.13 Chemistry (Screening) - SAF

	n	Mean (SD)	Median (Q1, Q3)	Min, Max	Missing
Albumin (g/dL)					
Total subjects	xx	xx.x (xx.x)	xx (xx,xx)	(xx,xx)	xx
Fed	xx	xx.x (xx.x)	xx (xx,xx)	(xx,xx)	xx
Fasting	xx	xx.x (xx.x)	xx (xx,xx)	(xx,xx)	xx
ALP (U/L)					
…					
ALT (GPT) (U/L)					
…					
AST (GOT) (U/L)					
…					
Carbon Dioxide (mmol/L)					
…					
Blood urea nitrogen (mg/dL)					
…					
Calcium (mg/dL)					
…					
Cholesterol Total (mg/dL)					
…					
Creatinine (mg/dL)					
…					

	n	Mean (SD)	Median (Q1, Q3)	Min, Max	Missing

CPK (U/L)

…

Glucose (mg/dL)

…

HDL (mg/dL)

…

LDL (mg/dL)

…

Phosphorus (mg/dL)

…

Potassium (mmol/L)

…

Sodium (mmol/L)

…

Total Bilirubin (mg/dL)

…

Total protein (g/dL)

…

Triglycerides (mg/dL)

…

	n	Mean (SD)	Median (Q1, Q3)	Min, Max	Missing
Uric acid (mg/dL)					
…					
FSH (mIU/mL)					
…					

Table 2.1.14 Hematology (Screening) - SAF

	n	Mean (SD)	Median (Q1, Q3)	Min, Max	Missing
Hematocrit (%)					
Total subjects	xx	xx.x (xx.x)	xx (xx,xx)	(xx,xx)	xx
Fed	xx	xx.x (xx.x)	xx (xx,xx)	(xx,xx)	xx
Fasting	xx	xx.x (xx.x)	xx (xx,xx)	(xx,xx)	xx

Hemoglobin (g/dL)

…

MCV (fL)

…

MCHC (g/L)

…

Platelet count (x10^3 µL)

…

RBC (x10^6 µL)

…

WBC (x10^3 µL)

…

Basophils (x10^3 µL)

…

Eosinophils (x10^3 µL)

…

	n	Mean (SD)	Median (Q1, Q3)	Min, Max	Missing
Lymphocytes (x10^3 µL)					
…					
Monocytes (x10^3 µL)					
…					
Neutrophils (x10^3 µL)					
…					

Table 2.1.15 Coagulation (Screening) - SAF

	n	Mean (SD)	Median (Q1, Q3)	Min, Max	Missing
INR					
Total subjects	xx	xx.x (xx.x)	xx (xx,xx)	(xx,xx)	xx
Fed	xx	xx.x (xx.x)	xx (xx,xx)	(xx,xx)	xx
Fasting	xx	xx.x (xx.x)	xx (xx,xx)	(xx,xx)	xx
Prothrombine time (s)					
…					
aPTT (s)					
…					

Table 2.1.16 Urinary analysis (Screening) - SAF

		Total subjects (n=xx)	Fed (n=xx)	Fasting (n=xx)
Color and appearance				
Total no-missing	n	xx	xx	xx
Clear	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Cloudy	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Hematuria	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Missing	n	xx	xx	xx
pH	n	xx	xx	
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx
	Median (Q1,Q3)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx (xx.x%)
	(Min,Max)	(xx.x, xx.x)	(xx.x, xx.x)	xx (xx.x%)
	Missing	xx	xx	
Specific gravity	n	xx	xx	
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx
	Median (Q1,Q3)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx (xx.x%)
	(Min,Max)	(xx.x, xx.x)	(xx.x, xx.x)	xx (xx.x%)
	Missing	xx	xx	
Glucose				
Total no-missing	n	xx	xx	xx
Negative	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1+	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2+	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3+	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

		Total subjects (n=xx)	Fed (n=xx)	Fasting (n=xx)
Other	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Missing	n	xx	xx	xx
Protein				
Total no-missing	n	xx	xx	xx
Negative	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Trace	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1+	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2+	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3+	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Other	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Missing	n	xx	xx	xx
Red blood cells				
Total no-missing	n	xx	xx	xx
Negative	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Trace	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1+	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2+	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3+	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Other	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Missing	n	xx	xx	xx
Leukocytes				
Total no-missing	n	xx	xx	xx
Negative	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

		Total subjects (n=xx)	Fed (n=xx)	Fasting (n=xx)
Trace	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1+	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2+	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3+	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Other	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Missing	n	xx	xx	xx
Ketones				
Total no-missing	n	xx	xx	xx
Negative	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Trace	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1+	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2+	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3+	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Other	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Missing	n	xx	xx	xx
Bilirubin				
Total no-missing	n	xx	xx	xx
Negative	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Trace	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1+	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2+	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3+	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Other	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Missing	n	xx	xx	xx

		Total subjects (n=xx)	Fed (n=xx)	Fasting (n=xx)
Urobilinogen				
Total no-missing	n	xx	xx	xx
Negative	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Trace	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1+	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2+	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3+	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Other	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Missing	n	xx	xx	xx
Nitrite				
Total no-missing	n	xx	xx	xx
Negative	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Trace	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1+	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2+	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3+	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Other	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Missing	n	xx	xx	xx

10.2.2 Baseline (Day -1)

Table 2.2.1 Weight and BMI (Baseline) - SAF

		Total subjects (n=xx)	Fed (n=xx)	Fasting (n=xx)
Weight (Kg)	N	xx	xx	xx
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
	Median (Q1,Q3)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
	(Min,Max)	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)
	Missing	xx	xx	xx
BMI (Kg/m^2)	N	xx	xx	xx
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
	Median (Q1,Q3)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
	(Min,Max)	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)
	Missing	xx	xx	xx

Table 2.2.2 Physical examination (Baseline) - SAF

	Total Subjects (n=xx)		Fed (n=xx)		Fasting (n=xx)	
	Total no-missing n	Normal n (%)	Total no-missing n	Normal n (%)	Total no-missing n	Normal n (%)
Skin	xx	xx (xx.x%)	xx	xx (xx.x%)	xx	xx (xx.x%)
Head	xx	xx (xx.x%)	xx	xx (xx.x%)	xx	xx (xx.x%)
Eyes and Throat	xx	xx (xx.x%)	xx	xx (xx.x%)	xx	xx (xx.x%)
Thyroid	xx	xx (xx.x%)	xx	xx (xx.x%)	xx	xx (xx.x%)
Lungs	xx	xx (xx.x%)	xx	xx (xx.x%)	xx	xx (xx.x%)
Cardiovascular system	xx	xx (xx.x%)	xx	xx (xx.x%)	xx	xx (xx.x%)
Abdomen (Liver/spleen)	xx	xx (xx.x%)	xx	xx (xx.x%)	xx	xx (xx.x%)
Extremities	xx	xx (xx.x%)	xx	xx (xx.x%)	xx	xx (xx.x%)
Neurological	xx	xx (xx.x%)	xx	xx (xx.x%)	xx	xx (xx.x%)

Table 2.2.3 Vital signs (Baseline) - SAF

	N	Mean (SD)	Median (Q1, Q3)	Min, Max	Missing
Time between evaluation and visit day 1 (days)					
Total subjects	xx	xx.x (xx.x)	xx (xx,xx)	(xx,xx)	xx
Fed	xx	xx.x (xx.x)	xx (xx,xx)	(xx,xx)	xx
Fasting	xx	xx.x (xx.x)	xx (xx,xx)	(xx,xx)	xx
Temperature (ºC)					
Total subjects	xx	xx.x (xx.x)	xx (xx,xx)	(xx,xx)	xx
Fed	xx	xx.x (xx.x)	xx (xx,xx)	(xx,xx)	xx
Fasting	xx	xx.x (xx.x)	xx (xx,xx)	(xx,xx)	xx
SBP - Supine (mmHg)					
Total subjects	xx	xx.x (xx.x)	xx (xx,xx)	(xx,xx)	xx
Fed	xx	xx.x (xx.x)	xx (xx,xx)	(xx,xx)	xx
Fasting	xx	xx.x (xx.x)	xx (xx,xx)	(xx,xx)	xx
DBP - Supine (mmHg)					
Total subjects	xx	xx.x (xx.x)	xx (xx,xx)	(xx,xx)	xx
Fed	xx	xx.x (xx.x)	xx (xx,xx)	(xx,xx)	xx
Fasting	xx	xx.x (xx.x)	xx (xx,xx)	(xx,xx)	xx
Heart rate - Supine (bpm)					
Total subjects	xx	xx.x (xx.x)	xx (xx,xx)	(xx,xx)	xx
Fed	xx	xx.x (xx.x)	xx (xx,xx)	(xx,xx)	xx
Fasting	xx	xx.x (xx.x)	xx (xx,xx)	(xx,xx)	xx

Table 2.2.4 Electrocardiogram (Normal/Abnormal) (Baseline) - SAF

		Total subjects (n=xx)	Fed (n=xx)	Fasting (n=xx)
Electrocardiogram				
Total no-missing	n	xx	xx	xx
All Normal	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Any Abnormal	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Missing	n	xx	xx	xx
Does the result meet the definition of adverse event?				
Total no-missing	n	xx	xx	xx
Any Yes	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
All No	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Missing	n	xx	xx	xx
Does the result meet the definition of adverse event? (Any Yes per parameter)*				
Total no-missing	n	xx	xx	xx
Heart rate	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
PR intervals	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
QRS duration	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
QT interval	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
QTcF interval	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Missing	n	xx	xx	xx

*More than one option per patient will be possible

Table 2.2.5 Electrocardiogram (Baseline) - SAF

	n	Mean (SD)	Median (Q1, Q3)	Min, Max	Missing
Time between ECG and dose (hours)					
Total subjects	xx	xx.x (xx.x)	xx (xx,xx)	(xx,xx)	xx
Fed	xx	xx.x (xx.x)	xx (xx,xx)	(xx,xx)	xx
Fasting	xx	xx.x (xx.x)	xx (xx,xx)	(xx,xx)	xx
Heart rate (BPM)					
Total subjects	xx	xx.x (xx.x)	xx (xx,xx)	(xx,xx)	xx
Fed	xx	xx.x (xx.x)	xx (xx,xx)	(xx,xx)	xx
Fasting	xx	xx.x (xx.x)	xx (xx,xx)	(xx,xx)	xx
PR intervals (ms)					
Total subjects	xx	xx.x (xx.x)	xx (xx,xx)	(xx,xx)	xx
Fed	xx	xx.x (xx.x)	xx (xx,xx)	(xx,xx)	xx
Fasting	xx	xx.x (xx.x)	xx (xx,xx)	(xx,xx)	xx
QRS duration (ms)					
Total subjects	xx	xx.x (xx.x)	xx (xx,xx)	(xx,xx)	xx
Fed	xx	xx.x (xx.x)	xx (xx,xx)	(xx,xx)	xx
Fasting	xx	xx.x (xx.x)	xx (xx,xx)	(xx,xx)	xx
QT interval (ms)					
Total subjects	xx	xx.x (xx.x)	xx (xx,xx)	(xx,xx)	xx
Fed	xx	xx.x (xx.x)	xx (xx,xx)	(xx,xx)	xx
Fasting	xx	xx.x (xx.x)	xx (xx,xx)	(xx,xx)	xx
QTcF interval (ms)					
Total subjects	xx	xx.x (xx.x)	xx (xx,xx)	(xx,xx)	xx
Fed	xx	xx.x (xx.x)	xx (xx,xx)	(xx,xx)	xx
Fasting	xx	xx.x (xx.x)	xx (xx,xx)	(xx,xx)	xx

Table 2.2.6 C-SSRS (Baseline) - SAF

		Total subjects (n=xx)	Fed (n=xx)	Fasting (n=xx)
C-SSRS				
Total no-missing	n	xx	xx	xx
Suicidal Ideation or Behavior	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Suicidal Ideation	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Wish to dead	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Non-specific active suicidal thoughts	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Active suicidal ideation with any methods (not plan) without intent to act	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Active suicidal ideation with some intent to act, without specific plan	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Active suicidal ideation with specific plan and intent	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Suicidal Behavior	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preparatory acts or behavior	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Aborted attempt	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Interrupted attempt	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Non-fatal suicide attempt	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Self-injorious behavior without suicidal intent	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Missing	n	xx	xx	xx

Table 2.2.7 Laboratory evaluation (Baseline) - SAF

	n	Mean (SD)	Median (Q1, Q3)	Min, Max	Missing
Time between evaluation and visit day 1 (days)					
Total subjects	xx	xx.x (xx.x)	xx (xx,xx)	(xx,xx)	xx
Fed	xx	xx.x (xx.x)	xx (xx,xx)	(xx,xx)	xx
Fasting	xx	xx.x (xx.x)	xx (xx,xx)	(xx,xx)	xx

Table 2.2.8 Percentage of numeric and non-numeric values (Baseline) - SAF

		Total subjects (n=xx)	Fed (n=xx)	Fasting (n=xx)
Chemistry				
Albumin (g/dl)				
Total no-missing	n	xx	xx	xx
Numeric	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Value 1	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
…				
Missing	n	xx	xx	xx
…				
Hematology				
…				
Coagulation				
…				

Table 2.2.9 Chemistry (Baseline) - SAF

	n	Mean (SD)	Median (Q1, Q3)	Min, Max	Missing
Albumin (g/dL)					
Total subjects	xx	xx.x (xx.x)	xx (xx,xx)	(xx,xx)	xx
Fed	xx	xx.x (xx.x)	xx (xx,xx)	(xx,xx)	xx
Fasting	xx	xx.x (xx.x)	xx (xx,xx)	(xx,xx)	xx
ALP (U/L)					
…					
ALT (GPT) (U/L)					
…					
AST (GOT) (U/L)					
…					
Bicarbonate (mEq(L)					
…					
Blood urea nitrogen (mg/dL)					
…					
Calcium (mg/dL)					
…					
Cholesterol Total (mg/dL)					
…					
Creatinine (mg/dL)					
…					

	n	Mean (SD)	Median (Q1, Q3)	Min, Max	Missing

CPK (U/L)

…

Glucose (mg/dL)

…

HDL (mg/dL)

…

LDL (mg/dL)

…

Phosphorus (mg/dL)

…

Potassium (mmol/L)

…

Sodium (mmol/L)

…

Total Bilirubin (mg/dL)

…

Total protein (g/dL)

…

Triglycerides (mg/dL)

…

	n	Mean (SD)	Median (Q1, Q3)	Min, Max	Missing
Uric acid (mg/dL)					
…					

Table 2.2.10 Hematology (Baseline) - SAF

	n	Mean (SD)	Median (Q1, Q3)	Min, Max	Missing
Hematocrit (%)					
Total subjects	xx	xx.x (xx.x)	xx (xx,xx)	(xx,xx)	xx
Fed	xx	xx.x (xx.x)	xx (xx,xx)	(xx,xx)	xx
Fasting	xx	xx.x (xx.x)	xx (xx,xx)	(xx,xx)	xx
Hemoglobin (g/dL)					
…					
MCV (fL)					
…					
MCHC (g/L)					
…					
Platelet count (x10^3 µL)					
…					
RBC (x10^6 µL)					
…					
WBC (x10^3 µL)					
…					
Basophils (x10^3 µL)					
…					
Eosinophils (x10^3 µL)					
…					

	n	Mean (SD)	Median (Q1, Q3)	Min, Max	Missing
Lymphocytes (x10^3 µL)					
…					
Monocytes (x10^3 µL)					
…					
Neutrophils (x10^3 µL)					
…					

Table 2.2.11 Coagulation (Baseline) - SAF

	n	Mean (SD)	Median (Q1, Q3)	Min, Max	Missing
INR					
Total subjects	xx	xx.x (xx.x)	xx (xx,xx)	(xx,xx)	xx
Fed	xx	xx.x (xx.x)	xx (xx,xx)	(xx,xx)	xx
Fasting	xx	xx.x (xx.x)	xx (xx,xx)	(xx,xx)	xx
Prothrombine time (s)					
…					
aPTT (s)					
…					

Table 2.2.12 Urinary analysis (Baseline) - SAF

		Total subjects (n=xx)	Fed (n=xx)	Fasting (n=xx)
Color and appearance				
Total no-missing	n	xx	xx	xx
Limpid	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Cloudy	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Hematuria	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Missing	n	xx	xx	xx
pH	n	xx	xx	
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx
	Median (Q1,Q3)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx (xx.x%)
	(Min,Max)	(xx.x, xx.x)	(xx.x, xx.x)	xx (xx.x%)
	Missing	xx	xx	
Specific gravity	n	xx	xx	
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx
	Median (Q1,Q3)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx (xx.x%)
	(Min,Max)	(xx.x, xx.x)	(xx.x, xx.x)	xx (xx.x%)
	Missing	xx	xx	
Glucose				
Total no-missing	n	xx	xx	xx
Negative	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Trace	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1+	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2+	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

		Total subjects (n=xx)	Fed (n=xx)	Fasting (n=xx)
3+	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Other	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Missing	n	xx	xx	xx
Protein				
Total no-missing	n	xx	xx	xx
Negative	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Trace	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1+	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2+	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3+	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Other	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Missing	n	xx	xx	xx
Red blood cells				
Total no-missing	n	xx	xx	xx
Negative	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Trace	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1+	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2+	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3+	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Other	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Missing	n	xx	xx	xx
Leukocytes				
Total no-missing	n	xx	xx	xx

		Total subjects (n=xx)	Fed (n=xx)	Fasting (n=xx)
Negative	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Trace	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1+	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2+	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3+	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Other	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Missing	n	xx	xx	xx
Ketones				
Total no-missing	n	xx	xx	xx
Negative	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Trace	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1+	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2+	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3+	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Other	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Missing	n	xx	xx	xx
Bilirubin				
Total no-missing	n	xx	xx	xx
Negative	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Trace	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1+	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2+	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3+	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Other	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

		Total subjects (n=xx)	Fed (n=xx)	Fasting (n=xx)
Missing	n	xx	xx	xx
Urobilinogen				
Total no-missing	n	xx	xx	xx
Negative	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Trace	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1+	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2+	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3+	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Other	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Missing	n	xx	xx	xx
Nitrite				
Total no-missing	n	xx	xx	xx
Negative	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Trace	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1+	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2+	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3+	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Other	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Missing	n	xx	xx	xx

10.2.3 Follow-up

Table 2.3.1 CRU discharge (24 hours) - SAF

		Total subjects (n=xx)	Fed (n=xx)	Fasting (n=xx)
Was the subject experiencing any adverse event at the scheduled time of the CRU discharge?				
Total no-missing	n	xx	xx	xx
Yes	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Missing	n	xx	xx	xx
Was the subject discharged from CRU as scheduled?				
Total no-missing	n	xx	xx	xx
Yes	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Missing	n	xx	xx	xx
Reason[1]				
Total no-missing	n	xx	xx	xx
Adverse Event	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Other	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Missing	n	xx	xx	xx

[1]Subjects with discharge from CRU not as scheduled.

Table 2.3.2 Tests (days 3,4,5,7,9,11) - SAF

		Total subjects (n=xx)	Fed (n=xx)	Fasting (n=xx)
Alcohol breath test				
Total no-missing	n	xx	xx	xx
Any test Positive	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
All Negative	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Missing	n	xx	xx	xx

Amphetamine test

…

Benzodiazepines test

…

Barbiturates test

…

Cannabinoids test

…

Cocaine (metabolite) test

…

Methamphetamine test

…

Methadone test

	Total subjects (n=xx)	Fed (n=xx)	Fasting (n=xx)
…			

Table 2.3.3 Weight and BMI (312 h) - SAF

		Total subjects (n=xx)	Fed (n=xx)	Fasting (n=xx)
Weight (Kg)	n	xx	xx	xx
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
	Median (Q1,Q3)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
	(Min,Max)	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)
	Missing	xx	xx	xx
BMI (Kg/m^2)	n	xx	xx	xx
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
	Median (Q1,Q3)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
	(Min,Max)	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)
	Missing	xx	xx	xx

Table 2.3.4 Pregnancy test (312 hours) - SAF

		Total subjects (n=xx)	Fed (n=xx)	Fasting (n=xx)
Pregnancy test result[1]				
Total no-missing	n	xx	xx	xx
Positive	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Negative	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Missing	n	xx	xx	xx

[1]Women subjects.

10.3 Primary objective

10.3.1 Pharmacokinetic endpoints

Table 3.1.1 Descriptive analysis of pharmacokinetic endpoints - PK

	n	Mean (SD)	Geometric mean	CV	Median (Q1, Q3)	Min, Max	Missing
C_{max} (ng/mL)							
Fed	xx	xx.x (xx.x)	xx.x	xx.x	xx (xx,xx)	(xx,xx)	xx
Fasting	xx	xx.x (xx.x)	xx.x	xx.x	xx (xx,xx)	(xx,xx)	xx
T_{max} (hours)							
Fed	xx	-	-	-	xx (xx,xx)	(xx,xx)	xx
Fasting	xx	-	-	-	xx (xx,xx)	(xx,xx)	xx
t_{lag} (hours)							
Fed	xx	-	-	-	xx (xx,xx)	(xx,xx)	xx
Fasting	xx	-	-	-	xx (xx,xx)	(xx,xx)	xx
AUC_{0-t} (hours*ng/mL)							
Fed	xx	xx.x (xx.x)	xx.x	xx.x	xx (xx,xx)	(xx,xx)	xx
Fasting	xx	xx.x (xx.x)	xx.x	xx.x	xx (xx,xx)	(xx,xx)	xx
$AUC_{0-\infty}$ (hours*ng/mL)							
Fed	xx	xx.x (xx.x)	xx.x	xx.x	xx (xx,xx)	(xx,xx)	xx
Fasting	xx	xx.x (xx.x)	xx.x	xx.x	xx (xx,xx)	(xx,xx)	xx

Table 3.1.2 Regression analysis of pharmacokinetic endpoints - PK

	State effect p-value	Geometric Mean ratio CI 90%
C_{max} (ng/mL)	x.xxxx	xx.x (xx.x, xx.x)
AUC_{0-t} (hours*ng/mL)	x.xxxx	xx.x (xx.x, xx.x)
$AUC_{0-\infty}$ (hours*ng/mL)	x.xxxx	xx.x (xx.x, xx.x)

10.4 Secondary objectives

10.4.1 Pharmacokinetic secondary endpoints

Table 4.1.1 Descriptive analysis of pharmacokinetic secondary endpoints - PK

	n	Mean (SD)	Geometric mean	CV	Median (Q1, Q3)	Min, Max	Missing
AUC_{extrap} (%)							
Fed	xx	xx.x (xx.x)	xx.x	xx.x	xx (xx,xx)	(xx,xx)	xx
Fasting	xx	xx.x (xx.x)	xx.x	xx.x	xx (xx,xx)	(xx,xx)	xx
C_{24h} (ng/mL)							
Fed	xx	xx.x (xx.x)	xx.x	xx.x	xx (xx,xx)	(xx,xx)	xx
Fasting	xx	xx.x (xx.x)	xx.x	xx.x	xx (xx,xx)	(xx,xx)	xx
$t_{1/2}$ (hours)							
Fed	xx	-	-	-	xx (xx,xx)	(xx,xx)	xx
Fasting	xx	-	-	-	xx (xx,xx)	(xx,xx)	xx
CL/F (L/hours)							
Fed	xx	xx.x (xx.x)	xx.x	xx.x	xx (xx,xx)	(xx,xx)	xx
Fasting	xx	xx.x (xx.x)	xx.x	xx.x	xx (xx,xx)	(xx,xx)	xx
Vd/F (L)							
Fed	xx	xx.x (xx.x)	xx.x	xx.x	xx (xx,xx)	(xx,xx)	xx
Fasting	xx	xx.x (xx.x)	xx.x	xx.x	xx (xx,xx)	(xx,xx)	xx

10.4.2 Safety endpoints - Adverse Events

Table 4.2.1 General summary of adverse events – SAF

	Fed (n=xx)		Fasting (n=xx)	
	Number of subjects n (%)	Number of events E	Number of subjects n (%)	Number of events E
Any AE	xx (xx.x%)	xx	xx (xx.x%)	xx
Any related AE	xx (xx.x%)	xx	xx (xx.x%)	xx
Any serious AE	xx (xx.x%)	xx	xx (xx.x%)	xx
Any serious related AE	xx (xx.x%)	xx	xx (xx.x%)	xx
Any AE:				
Severity				
Mild	xx (xx.x%)	xx	xx (xx.x%)	xx
Moderate	xx (xx.x%)	xx	xx (xx.x%)	xx
Severe	xx (xx.x%)	xx	xx (xx.x%)	xx
Outcome				
Recovered/Resolved	xx (xx.x%)	xx	xx (xx.x%)	xx
Recovering/Resolving	xx (xx.x%)	xx	xx (xx.x%)	xx
Not recovered/Not resolved	xx (xx.x%)	xx	xx (xx.x%)	xx
Recovered/Resolved with sequelae	xx (xx.x%)	xx	xx (xx.x%)	xx
Fatal	xx (xx.x%)	xx	xx (xx.x%)	xx
Unknown	xx (xx.x%)	xx	xx (xx.x%)	xx
Action taken with study treatment				
Dose not changed	xx (xx.x%)	xx	xx (xx.x%)	xx
Drug withdrawn	xx (xx.x%)	xx	xx (xx.x%)	xx
Drug interrupted	xx (xx.x%)	xx	xx (xx.x%)	xx

	Fed (n=xx)		Fasting (n=xx)	
	Number of subjects n (%)	Number of events E	Number of subjects n (%)	Number of events E
Dose increased	xx (xx.x%)	xx	xx (xx.x%)	xx
Dose reduced	xx (xx.x%)	xx	xx (xx.x%)	xx
Not applicable	xx (xx.x%)	xx	xx (xx.x%)	xx
Unknown	xx (xx.x%)	xx	xx (xx.x%)	xx
Related with alternative causality or confounding factors				
Yes	xx (xx.x%)	xx	xx (xx.x%)	xx
No	xx (xx.x%)	xx	xx (xx.x%)	xx

Table 4.2.2 AE I (Fed) - SAF

				Severity			Causality		Related with alternative causality or confounding factors	
	Nº pat. (%)	Nº AE	Duration (minutes)*	Mild	Moderate	Severe	Not Related	Related	Yes	No
Overall	xx (xx.x)	xx	x.x (x.x)	xx	xx	xx	xx	xx	xx	xx
SOC 1	xx (xx.x)	xx	x.x (x.x)	xx	xx	xx	xx	xx	xx	xx
PT 1	xx (xx.x)	xx	x.x (x.x)	xx	xx	xx	xx	xx	xx	xx
PT 2	xx (xx.x)	xx	x.x (x.x)	xx	xx	xx	xx	xx	xx	xx
…										
SOC 2	xx (xx.x)	xx	x.x (x.x)	xx	xx	xx	xx	xx	xx	xx
PT 1	xx (xx.x)	xx	x.x (x.x)	xx	xx	xx	xx	xx	xx	xx
PT 2	xx (xx.x)	xx	x.x (x.x)	xx	xx	xx	xx	xx	xx	xx
…										
…										

*Mean(SD)

The AE will be presented by using the MedDRA dictionary version 25.0.

Table 4.2.3 AE II (Fed) - SAF

			Action / Study treatment							Outcome					
	Nº pat. (%)	Nº AE	Dose not changed	Drug withdrawn	Drug interrupted	Dose increased	Dose reduced	Not applicable	Unknown	Recovered / Resolved	Recovering / Resolving	Not recovered / Not resolved	With sequelae	Fatal	Unknown
Overall	xx (xx.x)	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
SOC 1	xx (xx.x)	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
PT 1	xx (xx.x)	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
PT 2	xx (xx.x)	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
…															
SOC 2	xx (xx.x)	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
PT 1	xx (xx.x)	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
PT 2	xx (xx.x)	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
…															
…															

The AE will be presented by using the MedDRA dictionary version 25.0.

Table 4.2.4 AE III (Fed) - SAF

			Serious		Serious criteria					
	Nº pat. (%)	Nº AE	No	Yes	Death	Hospitalization or prolongation of existing hospitalization	Congenital anomaly or birth defect	Other medically important event	Life threatening	Significant disability / incapacity
Overall	xx (xx.x)	xx	xx	xx	xx	xx	xx	xx	xx	xx
SOC 1	xx (xx.x)	xx	xx	xx	xx	xx	xx	xx	xx	xx
PT 1	xx (xx.x)	xx	xx	xx	xx	xx	xx	xx	xx	xx
PT 2	xx (xx.x)	xx	xx	xx	xx	xx	xx	xx	xx	xx
…										
SOC 2	xx (xx.x)	xx	xx	xx	xx	xx	xx	xx	xx	xx
PT 1	xx (xx.x)	xx	xx	xx	xx	xx	xx	xx	xx	xx
PT 2	xx (xx.x)	xx	xx	xx	xx	xx	xx	xx	xx	xx
…										
…										

The AE will be presented by using the MedDRA dictionary version 25.0.

Table 4.2.5 AE I (Fasting) - SAF
Table 4.2.6 AE II (Fasting) – SAF
Table 4.2.7 AE III (Fasting) - SAF

10.4.3 Safety endpoints - Treatment Emergent Adverse Events

Table 4.3.1 General summary of treatment emergent adverse events – SAF

	Fed (n=xx)		Fasting (n=xx)	
	Number of subjects n (%)	Number of events E	Number of subjects n (%)	Number of events E
Any TEAE	xx (xx.x%)	xx	xx (xx.x%)	xx
Any related TEAE	xx (xx.x%)	xx	xx (xx.x%)	xx
Any serious TEAE	xx (xx.x%)	xx	xx (xx.x%)	xx
Any serious related TEAE	xx (xx.x%)	xx	xx (xx.x%)	xx
Any TEAE:				
Severity				
Mild	xx (xx.x%)	xx	xx (xx.x%)	xx
Moderate	xx (xx.x%)	xx	xx (xx.x%)	xx
Severe	xx (xx.x%)	xx	xx (xx.x%)	xx
Outcome				
Recovered/Resolved	xx (xx.x%)	xx	xx (xx.x%)	xx
Recovering/Resolving	xx (xx.x%)	xx	xx (xx.x%)	xx
Not recovered/Not resolved	xx (xx.x%)	xx	xx (xx.x%)	xx
Recovered/Resolved with sequelae	xx (xx.x%)	xx	xx (xx.x%)	xx
Fatal	xx (xx.x%)	xx	xx (xx.x%)	xx
Unknown	xx (xx.x%)	xx	xx (xx.x%)	xx
Action taken with study treatment				
Dose not changed	xx (xx.x%)	xx	xx (xx.x%)	xx
Drug withdrawn	xx (xx.x%)	xx	xx (xx.x%)	xx
Drug interrupted	xx (xx.x%)	xx	xx (xx.x%)	xx
Dose increased	xx (xx.x%)	xx	xx (xx.x%)	xx

	Fed (n=xx)		Fasting (n=xx)	
	Number of subjects n (%)	Number of events E	Number of subjects n (%)	Number of events E
Dose reduced	xx (xx.x%)	xx	xx (xx.x%)	xx
Not applicable	xx (xx.x%)	xx	xx (xx.x%)	xx
Unknown	xx (xx.x%)	xx	xx (xx.x%)	xx
Related with alternative causality or confounding factors				
Yes	xx (xx.x%)	xx	xx (xx.x%)	xx
No	xx (xx.x%)	xx	xx (xx.x%)	xx

Table 4.3.2 TEAE I (Fed) - SAF

				Severity			Causality		Related with alternative causality or confounding factors	
	Nº pat. (%)	Nº TEAE	Duration (minutes)*	Mild	Moderate	Severe	Not Related	Related	Yes	No
Overall	xx (xx.x)	xx	x.x (x.x)	xx	xx	xx	xx	xx	xx	xx
SOC 1	xx (xx.x)	xx	x.x (x.x)	xx	xx	xx	xx	xx	xx	xx
PT 1	xx (xx.x)	xx	x.x (x.x)	xx	xx	xx	xx	xx	xx	xx
PT 2	xx (xx.x)	xx	x.x (x.x)	xx	xx	xx	xx	xx	xx	xx
…										
SOC 2	xx (xx.x)	xx	x.x (x.x)	xx	xx	xx	xx	xx	xx	xx
PT 1	xx (xx.x)	xx	x.x (x.x)	xx	xx	xx	xx	xx	xx	xx
PT 2	xx (xx.x)	xx	x.x (x.x)	xx	xx	xx	xx	xx	xx	xx
…										
…										

*Mean(SD)

The TEAE will be presented by using the MedDRA dictionary version 25.0.

Table 4.3.3 TEAE II (Fed) - SAF

			Action / Study treatment							Outcome					
	Nº pat. (%)	Nº TEAE	Dose not changed	Drug withdrawn	Drug interrupted	Dose increased	Dose reduced	Not applicable	Unknown	Recovered / Resolved	Recovering / Resolving	Not recovered / Not resolved	With sequelae	Fatal	Unknown
Overall	xx (xx.x)	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
SOC 1	xx (xx.x)	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
PT 1	xx (xx.x)	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
PT 2	xx (xx.x)	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
…															
SOC 2	xx (xx.x)	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
PT 1	xx (xx.x)	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
PT 2	xx (xx.x)	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
…															
…															

The TEAE will be presented by using the MedDRA dictionary version 25.0.

Table 4.3.4 TEAE III (Fed) - SAF

			Serious		Serious criteria					
	Nº pat. (%)	Nº TEAE	No	Yes	Death	Hospitalization or prolongation of existing hospitalization	Congenital anomaly or birth defect	Other medically important event	Life threatening	Significant disability / incapacity
Overall	xx (xx.x)	xx	xx	xx	xx	xx	xx	xx	xx	xx
SOC 1	xx (xx.x)	xx	xx	xx	xx	xx	xx	xx	xx	xx
PT 1	xx (xx.x)	xx	xx	xx	xx	xx	xx	xx	xx	xx
PT 2	xx (xx.x)	xx	xx	xx	xx	xx	xx	xx	xx	xx
…										
SOC 2	xx (xx.x)	xx	xx	xx	xx	xx	xx	xx	xx	xx
PT 1	xx (xx.x)	xx	xx	xx	xx	xx	xx	xx	xx	xx
PT 2	xx (xx.x)	xx	xx	xx	xx	xx	xx	xx	xx	xx
…										
…										

The TEAE will be presented by using the MedDRA dictionary version 25.0.

Table 4.3.5 TEAE III (Fed) - SAF

			Serious		Serious criteria					
	Nº pat. (%)	Nº TEAE	Yes	No	Death	Hospitalization or prolongation of existing hospitalization	Congenital anomaly or birth defect	Other medically important event	Life threatening	Significant disability / incapacity
Overall	xx (xx.x)	xx	xx	xx	xx	xx	xx	xx	xx	xx
SOC 1	xx (xx.x)	xx	xx	xx	xx	xx	xx	xx	xx	xx
PT 1	xx (xx.x)	xx	xx	xx	xx	xx	xx	xx	xx	xx
PT 2	xx (xx.x)	xx	xx	xx	xx	xx	xx	xx	xx	xx
…										
SOC 2	xx (xx.x)	xx	xx	xx	xx	xx	xx	xx	xx	xx
PT 1	xx (xx.x)	xx	xx	xx	xx	xx	xx	xx	xx	xx
PT 2	xx (xx.x)	xx	xx	xx	xx	xx	xx	xx	xx	xx
…										
…										

The TEAE will be presented by using the MedDRA dictionary version 25.0.

Table 4.3.6 TEAE I (Fasting) - SAF
Table 4.3.7 TEAE II (Fasting) – SAF
Table 4.3.8 TEAE III (Fasting) - SAF

10.4.4 Safety endpoints - Vital Signs

Table 4.4.1 Time between evaluation and dose (hours) - SAF

		Fed (n=xx)	Fasting (n=xx)
Pre-dose	n	xx	xx
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
	Median (Q1,Q3)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
	(Min,Max)	(xx.x, xx.x)	(xx.x, xx.x)
	Missing	xx	xx
1 hour	n	xx	xx
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
	Median (Q1,Q3)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
	(Min,Max)	(xx.x, xx.x)	(xx.x, xx.x)
	Missing	xx	xx
2 hours	n	xx	xx
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
	Median (Q1,Q3)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
	(Min,Max)	(xx.x, xx.x)	(xx.x, xx.x)
	Missing	xx	xx
4 hours	n	xx	xx
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
	Median (Q1,Q3)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
	(Min,Max)	(xx.x, xx.x)	(xx.x, xx.x)
	Missing	xx	xx
8 hours	n	xx	xx
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
	Median (Q1,Q3)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)

		Fed (n=xx)	Fasting (n=xx)
	(Min,Max)	(xx.x, xx.x)	(xx.x, xx.x)
	Missing	xx	xx
11 hours	n	xx	xx
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
	Median (Q1,Q3)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
	(Min,Max)	(xx.x, xx.x)	(xx.x, xx.x)
	Missing	xx	xx
24 hours	n	xx	xx
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
	Median (Q1,Q3)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
	(Min,Max)	(xx.x, xx.x)	(xx.x, xx.x)
	Missing	xx	xx
48 hours	n	xx	xx
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
	Median (Q1,Q3)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
	(Min,Max)	(xx.x, xx.x)	(xx.x, xx.x)
	Missing	xx	xx
240 hours	n	xx	xx
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
	Median (Q1,Q3)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
	(Min,Max)	(xx.x, xx.x)	(xx.x, xx.x)
	Missing	xx	xx
312 hours	n	xx	xx
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
	Median (Q1,Q3)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
	(Min,Max)	(xx.x, xx.x)	(xx.x, xx.x)

		Fed (n=xx)	Fasting (n=xx)
	Missing	xx	xx

For the heart rate and blood pressure variables same table format as Table 4.4.1:

Table 4.4.2 SBP - Supine (mmHg) - SAF

Table 4.4.3 DBP - Supine (mmHg) - SAF

Table 4.4.4 Heart rate - Supine (bpm) – SAF

Table 4.4.5 Oral temperature (ºC) - SAF

		Fed (n=xx)	Fasting (n=xx)
Baseline	n	xx	xx
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
	Median (Q1,Q3)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
	(Min,Max)	(xx.x, xx.x)	(xx.x, xx.x)
	Missing	xx	xx
24 hours	n	xx	xx
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
	Median (Q1,Q3)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
	(Min,Max)	(xx.x, xx.x)	(xx.x, xx.x)
	Missing	xx	xx
312 hours	n	xx	xx
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
	Median (Q1,Q3)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
	(Min,Max)	(xx.x, xx.x)	(xx.x, xx.x)
	Missing	xx	xx

10.4.5 Safety endpoints - Electrocardiogram

Table 4.5.1 Electrocardiogram (Normal/Abnormal) - SAF

		Fed (n=xx)	Fasting (n=xx)
Electrocardiogram (pre-dose)			
Total no-missing	n	xx	xx
All Normal	n (%)	xx (xx.x%)	xx (xx.x%)
Any Abnormal	n (%)	xx (xx.x%)	xx (xx.x%)
Missing	n	xx	xx
Does the result meet the definition of adverse event?			
Total no-missing	n	xx	xx
Any Yes	n (%)	xx (xx.x%)	xx (xx.x%)
All No	n (%)	xx (xx.x%)	xx (xx.x%)
Missing	n	xx	xx
Does the result meet the definition of adverse event? (Any Yes per parameter)*			
Total no-missing	n	xx	xx
Heart rate	n (%)	xx (xx.x%)	xx (xx.x%)
PR intervals	n (%)	xx (xx.x%)	xx (xx.x%)
QRS duration	n (%)	xx (xx.x%)	xx (xx.x%)
QT interval	n (%)	xx (xx.x%)	xx (xx.x%)
QTcF interval	n (%)	xx (xx.x%)	xx (xx.x%)
Missing	n	xx	xx
Electrocardiogram (1 hour)			
Total no-missing	n	xx	xx
All Normal	n (%)	xx (xx.x%)	xx (xx.x%)
Any Abnormal	n (%)	xx (xx.x%)	xx (xx.x%)

		Fed (n=xx)	Fasting (n=xx)
Missing	n	xx	xx
Does the result meet the definition of adverse event?			
Total no-missing	n	xx	xx
Any Yes	n (%)	xx (xx.x%)	xx (xx.x%)
All No	n (%)	xx (xx.x%)	xx (xx.x%)
Missing	n	xx	xx
Does the result meet the definition of adverse event? (Any Yes per parameter)*			
Total no-missing	n	xx	xx
Heart rate	n (%)	xx (xx.x%)	xx (xx.x%)
PR intervals	n (%)	xx (xx.x%)	xx (xx.x%)
QRS duration	n (%)	xx (xx.x%)	xx (xx.x%)
QT interval	n (%)	xx (xx.x%)	xx (xx.x%)
QTcF interval	n (%)	xx (xx.x%)	xx (xx.x%)
Missing	n	xx	xx
Electrocardiogram (2 hours)			
Total no-missing	n	xx	xx
All Normal	n (%)	xx (xx.x%)	xx (xx.x%)
Any Abnormal	n (%)	xx (xx.x%)	xx (xx.x%)
Missing	n	xx	xx
Does the result meet the definition of adverse event?			
Total no-missing	n	xx	xx
Any Yes	n (%)	xx (xx.x%)	xx (xx.x%)
All No	n (%)	xx (xx.x%)	xx (xx.x%)
Missing	n	xx	xx

		Fed (n=xx)	Fasting (n=xx)
Does the result meet the definition of adverse event? (Any Yes per parameter)*			
Total no-missing	n	xx	xx
Heart rate	n (%)	xx (xx.x%)	xx (xx.x%)
PR interval	n (%)	xx (xx.x%)	xx (xx.x%)
QRS duration	n (%)	xx (xx.x%)	xx (xx.x%)
QT interval	n (%)	xx (xx.x%)	xx (xx.x%)
QTcF intervals	n (%)	xx (xx.x%)	xx (xx.x%)
Missing	n	xx	xx
Electrocardiogram (4 hours)			
Total no-missing	n	xx	xx
All Normal	n (%)	xx (xx.x%)	xx (xx.x%)
Any Abnormal	n (%)	xx (xx.x%)	xx (xx.x%)
Missing	n	xx	xx
Does the result meet the definition of adverse event?			
Total no-missing	n	xx	xx
Any Yes	n (%)	xx (xx.x%)	xx (xx.x%)
All No	n (%)	xx (xx.x%)	xx (xx.x%)
Missing	n	xx	xx
Does the result meet the definition of adverse event? (Any Yes per parameter)*			
Total no-missing	n	xx	xx
Heart rate	n (%)	xx (xx.x%)	xx (xx.x%)
PR interval	n (%)	xx (xx.x%)	xx (xx.x%)
QRS duration	n (%)	xx (xx.x%)	xx (xx.x%)
QT interval	n (%)	xx (xx.x%)	xx (xx.x%)

		Fed (n=xx)	Fasting (n=xx)
QTcF intervals	n (%)	xx (xx.x%)	xx (xx.x%)
Missing	n	xx	xx
Electrocardiogram (8 hours)			
Total no-missing	n	xx	xx
All Normal	n (%)	xx (xx.x%)	xx (xx.x%)
Any Abnormal	n (%)	xx (xx.x%)	xx (xx.x%)
Missing	n	xx	xx
Does the result meet the definition of adverse event?			
Total no-missing	n	xx	xx
Any Yes	n (%)	xx (xx.x%)	xx (xx.x%)
All No	n (%)	xx (xx.x%)	xx (xx.x%)
Missing	n	xx	xx
Does the result meet the definition of adverse event? (Any Yes per parameter)*			
Total no-missing	n	xx	xx
Heart rate	n (%)	xx (xx.x%)	xx (xx.x%)
PR interval	n (%)	xx (xx.x%)	xx (xx.x%)
QRS duration	n (%)	xx (xx.x%)	xx (xx.x%)
QT interval	n (%)	xx (xx.x%)	xx (xx.x%)
QTcF intervals	n (%)	xx (xx.x%)	xx (xx.x%)
Missing	n	xx	xx
Electrocardiogram (11 hours)			
Total no-missing	n	xx	xx
All Normal	n (%)	xx (xx.x%)	xx (xx.x%)
Any Abnormal	n (%)	xx (xx.x%)	xx (xx.x%)
Missing	n	xx	xx

		Fed (n=xx)	Fasting (n=xx)
Does the result meet the definition of adverse event?			
Total no-missing	n	xx	xx
Any Yes	n (%)	xx (xx.x%)	xx (xx.x%)
All No	n (%)	xx (xx.x%)	xx (xx.x%)
Missing	n	xx	xx
Does the result meet the definition of adverse event? (Any Yes per parameter)*			
Total no-missing	n	xx	xx
Heart rate	n (%)	xx (xx.x%)	xx (xx.x%)
PR interval	n (%)	xx (xx.x%)	xx (xx.x%)
QRS duration	n (%)	xx (xx.x%)	xx (xx.x%)
QT interval	n (%)	xx (xx.x%)	xx (xx.x%)
QTcF intervals	n (%)	xx (xx.x%)	xx (xx.x%)
Missing	n	xx	xx
Electrocardiogram (24 hours)			
Total no-missing	n	xx	xx
All Normal	n (%)	xx (xx.x%)	xx (xx.x%)
Any Abnormal	n (%)	xx (xx.x%)	xx (xx.x%)
Missing	n	xx	xx
Does the result meet the definition of adverse event?			
Total no-missing	n	xx	xx
Any Yes	n (%)	xx (xx.x%)	xx (xx.x%)
All No	n (%)	xx (xx.x%)	xx (xx.x%)
Missing	n	xx	xx
Does the result meet the definition of adverse event? (Any Yes per parameter)*			

		Fed (n=xx)	Fasting (n=xx)
Total no-missing	n	xx	xx
Heart rate	n (%)	xx (xx.x%)	xx (xx.x%)
PR interval	n (%)	xx (xx.x%)	xx (xx.x%)
QRS duration	n (%)	xx (xx.x%)	xx (xx.x%)
QT interval	n (%)	xx (xx.x%)	xx (xx.x%)
QTcF intervals	n (%)	xx (xx.x%)	xx (xx.x%)
Missing	n	xx	xx
Electrocardiogram (240 hours)			
Total no-missing	n	xx	xx
All Normal	n (%)	xx (xx.x%)	xx (xx.x%)
Any Abnormal	n (%)	xx (xx.x%)	xx (xx.x%)
Missing	n	xx	xx
Does the result meet the definition of adverse event?			
Total no-missing	n	xx	xx
Any Yes	n (%)	xx (xx.x%)	xx (xx.x%)
All No	n (%)	xx (xx.x%)	xx (xx.x%)
Missing	n	xx	xx
Does the result meet the definition of adverse event? (Any Yes per parameter)*			
Total no-missing	n	xx	xx
Heart rate	n (%)	xx (xx.x%)	xx (xx.x%)
PR interval	n (%)	xx (xx.x%)	xx (xx.x%)
QRS duration	n (%)	xx (xx.x%)	xx (xx.x%)
QT interval	n (%)	xx (xx.x%)	xx (xx.x%)
QTcF intervals	n (%)	xx (xx.x%)	xx (xx.x%)
Missing	n	xx	xx

		Fed (n=xx)	Fasting (n=xx)
Electrocardiogram (312 hours)			
Total no-missing	n	xx	xx
All Normal	n (%)	xx (xx.x%)	xx (xx.x%)
Any Abnormal	n (%)	xx (xx.x%)	xx (xx.x%)
Missing	n	xx	xx
Does the result meet the definition of adverse event?			
Total no-missing	n	xx	xx
Any Yes	n (%)	xx (xx.x%)	xx (xx.x%)
All No	n (%)	xx (xx.x%)	xx (xx.x%)
Missing	n	xx	xx
Does the result meet the definition of adverse event? (Any Yes per parameter)*			
Total no-missing	n	xx	xx
Heart rate	n (%)	xx (xx.x%)	xx (xx.x%)
PR interval	n (%)	xx (xx.x%)	xx (xx.x%)
QRS duration	n (%)	xx (xx.x%)	xx (xx.x%)
QT interval	n (%)	xx (xx.x%)	xx (xx.x%)
QTcF intervals	n (%)	xx (xx.x%)	xx (xx.x%)
Missing	n	xx	xx

*More than one option per subject will be possible.

Table 4.5.2 Time between ECG and dose (hours) - SAF

		Fed (n=xx)	Fasting (n=xx)
Pre-dose	n	xx	xx
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
	Median (Q1,Q3)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
	(Min,Max)	(xx.x, xx.x)	(xx.x, xx.x)
	Missing	xx	xx
1 hour	n	xx	xx
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
	Median (Q1,Q3)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
	(Min,Max)	(xx.x, xx.x)	(xx.x, xx.x)
	Missing	xx	xx
2 hours	n	xx	xx
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
	Median (Q1,Q3)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
	(Min,Max)	(xx.x, xx.x)	(xx.x, xx.x)
	Missing	xx	xx
4 hours	n	xx	xx
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
	Median (Q1,Q3)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
	(Min,Max)	(xx.x, xx.x)	(xx.x, xx.x)
	Missing	xx	xx
8 hours	n	xx	xx
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
	Median (Q1,Q3)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
	(Min,Max)	(xx.x, xx.x)	(xx.x, xx.x)
	Missing	xx	xx

		Fed (n=xx)	Fasting (n=xx)
11 hours	n	xx	xx
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
	Median (Q1,Q3)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
	(Min,Max)	(xx.x, xx.x)	(xx.x, xx.x)
	Missing	xx	xx
24 hours	n	xx	xx
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
	Median (Q1,Q3)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
	(Min,Max)	(xx.x, xx.x)	(xx.x, xx.x)
	Missing	xx	xx
240 hours	n	xx	xx
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
	Median (Q1,Q3)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
	(Min,Max)	(xx.x, xx.x)	(xx.x, xx.x)
	Missing	xx	xx
312 hours	n	xx	xx
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
	Median (Q1,Q3)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
	(Min,Max)	(xx.x, xx.x)	(xx.x, xx.x)
	Missing	xx	xx

For the rest of ECG parameters same table format as table 5.3.2

Table 4.5.3 Heart rate (BPM) - SAF

Table 4.5.4 PR intervals (ms) - SAF

Table 4.5.5 QRS duration (ms) - SAF

Table 4.5.6 QT interval (ms) - SAF

Table 4.5.7 QTcF interval (ms) - SAF

10.5 Safety analysis

10.5.1 Laboratory parameters – SAF

Table 5.1.1 Time between evaluation and dose (days) - SAF

		Fed (n=xx)	Fasting (n=xx)
Baseline (Day -1)	n	xx	xx
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
	Median (Q1,Q3)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
	(Min,Max)	(xx.x, xx.x)	(xx.x, xx.x)
	Missing	xx	xx
24 hours	n	xx	xx
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
	Median (Q1,Q3)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
	(Min,Max)	(xx.x, xx.x)	(xx.x, xx.x)
	Missing	xx	xx
312 hours	n	xx	xx
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
	Median (Q1,Q3)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
	Missing	xx	xx

Table 5.1.2 Non numeric values – SAF

		Baseline		24 hours		312 hours	
		Fed (n=xx)	Fasting (n=xx)	Fed (n=xx)	Fasting (n=xx)	Fed (n=xx)	Fasting (n=xx)
Chemistry							
Albumin (g/dl)							
Total no-missing	n	xx	xx	xx	xx	xx	xx
Numeric	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Value 1	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
…							
Missing	n	xx	xx	xx	xx	xx	xx
…							
Hematology							
…							
Coagulation							
…							

Table 5.1.3 Chemistry - Albumin (g/dl) - SAF

		Fed (n=xx)	Fasting (n=xx)
Baseline (Day -1)	n	xx	xx
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
	Median (Q1,Q3)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
	(Min,Max)	(xx.x, xx.x)	(xx.x, xx.x)
	Missing	xx	xx
24 hours	n	xx	xx
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
	Median (Q1,Q3)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
	(Min,Max)	(xx.x, xx.x)	(xx.x, xx.x)
	Missing	xx	xx
312 hours	n	xx	xx
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
	Median (Q1,Q3)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
	(Min,Max)	(xx.x, xx.x)	(xx.x, xx.x)
	Missing	xx	xx

For the rest of chemistry, hematology and coagulation parameters same table format as table 5.1.3:

Table 5.1.4 Chemistry – ALP (U/L) - SAF
Table 5.1.5 Chemistry - ALT (GPT) (U/L) - SAF
Table 5.1.6 Chemistry - AST (GOT) (U/L) – SAF
Table 5.1.7 Chemistry – Bicarbonate (mEq/L) - SAF
Table 5.1.8 Chemistry – Blood urea nitrogen (mg/dL) - SAF
Table 5.1.9 Chemistry - Calcium (mg/dL) - SAF
Table 5.1.10 Chemistry - Total Cholesterol (mg/dL) – SAF
Table 5.1.11 Chemistry - Creatinine (mg/dL) – SAF
Table 5.1.12 Chemistry - CPK (U/L) – SAF
Table 5.1.13 Chemistry - Glucose (mg/dL) - SAF
Table 5.1.14 Chemistry - HDL (mg/dL) - SAF
Table 5.1.15 Chemistry - LDL (mg/dL) - SAF

Table 5.1.38 Urine analysis – Color and appearance – SAF

		Fed (n=xx)	Fasting (n=xx)
Baseline (Day -1)			
Total no-missing	n	xx	xx
Limpid	n(%)	xx.x (xx.x%)	xx.x (xx.x%)
Cloudy	n(%)	xx.x (xx.x%)	xx.x (xx.x%)
Hematuria	n(%)	xx.x (xx.x%)	xx.x (xx.x%)
Missing	n	xx	xx
24 hours			
Total no-missing	n	xx	xx
Limpid	n(%)	xx.x (xx.x%)	xx.x (xx.x%)
Cloudy	n(%)	xx.x (xx.x%)	xx.x (xx.x%)
Hematuria	n(%)	xx.x (xx.x%)	xx.x (xx.x%)
Missing	n	xx	xx
312 hours			
Total no-missing	n	xx	xx
Limpid	n(%)	xx.x (xx.x%)	xx.x (xx.x%)
Cloudy	n(%)	xx.x (xx.x%)	xx.x (xx.x%)
Hematuria	n(%)	xx.x (xx.x%)	xx.x (xx.x%)
Missing	n	xx	xx

Table 5.1.39 Urine Analysis – ph - SAF

		Fed (n=xx)	Fasting (n=xx)
Baseline (Day -1)	n	xx	xx
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
	Median (Q1,Q3)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
	(Min,Max)	(xx.x, xx.x)	(xx.x, xx.x)
	Missing	xx	xx
24 hours	n	xx	xx
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
	Median (Q1,Q3)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
	(Min,Max)	(xx.x, xx.x)	(xx.x, xx.x)
	Missing	xx	xx
312 hours	n	xx	xx
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
	Median (Q1,Q3)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
	(Min,Max)	(xx.x, xx.x)	(xx.x, xx.x)
	Missing	xx	xx

Same table format as table 5.1.39:

Table 5.1.40 Urine analysis – Specific gravity – SAF

Table 5.1.41 Urine Analysis - Glucose - SAF

		Fed (n=xx)	Fasting (n=xx)
Baseline (Day -1)			
Total no-missing	n	xx	xx
Negative	n(%)	xx.x (xx.x%)	xx.x (xx.x%)
Trace	n(%)	xx.x (xx.x%)	xx.x (xx.x%)
1+	n(%)	xx.x (xx.x%)	xx.x (xx.x%)
2+	n(%)	xx.x (xx.x%)	xx.x (xx.x%)
3+	n(%)	xx.x (xx.x%)	xx.x (xx.x%)
Other	n(%)	xx.x (xx.x%)	xx.x (xx.x%)
Missing	n	xx	xx
24 hours			
Total no-missing	n	xx	xx
Negative	n(%)	xx.x (xx.x%)	xx.x (xx.x%)
Trace	n(%)	xx.x (xx.x%)	xx.x (xx.x%)
1+	n(%)	xx.x (xx.x%)	xx.x (xx.x%)
2+	n(%)	xx.x (xx.x%)	xx.x (xx.x%)
3+	n(%)	xx.x (xx.x%)	xx.x (xx.x%)
Other	n(%)	xx.x (xx.x%)	xx.x (xx.x%)
Missing	n	xx	xx
312 hours			
Total no-missing	n	xx	xx
Negative	n(%)	xx.x (xx.x%)	xx.x (xx.x%)
Trace	n(%)	xx.x (xx.x%)	xx.x (xx.x%)
1+	n(%)	xx.x (xx.x%)	xx.x (xx.x%)
2+	n(%)	xx.x (xx.x%)	xx.x (xx.x%)
3+	n(%)	xx.x (xx.x%)	xx.x (xx.x%)

		Fed (n=xx)	Fasting (n=xx)
Other	n(%)	xx.x (xx.x%)	xx.x (xx.x%)
Missing	n	xx	xx

Same table format as table 5.1.41:

Table 5.1.42 Urine Analysis – Protein – SAF

Table 5.1.43 Urine Analysis –Red blood cells – SAF

Table 5.1.44 Urine Analysis – Leukocytes – SAF

Table 5.1.45 Urine Analysis – Ketones – SAF

Table 5.1.46 Urine Analysis –Bilirubin – SAF

Table 5.1.47 Urine Analysis – Urobilinogen – SAF

Table 5.1.48 Urine Analysis – Nitrite - SAF

10.5.2 Physical examination - SAF

Table 5.2.1 Physical examination - SAF

	Fed (n=xx)		Fasting (n=xx)	
	Total no-missing n	Normal n (%)	Total no-missing n	Normal n (%)
Overall appearance				
Baseline (day -1)	xx	xx (xx.x%)	xx	xx (xx.x%)
24 hours	xx	xx (xx.x%)	xx	xx (xx.x%)
312 hours	xx	xx (xx.x%)	xx	xx (xx.x%)
Skin				
Day1	xx	xx (xx.x%)	xx	xx (xx.x%)
…				
Head				
…				
Eyes and Throat				
…				
Thyroid				
…				
Lungs				
…				
Cardiovascular system				
…				
Abdomen (Liver/spleen)				
…				
Extremities				
…				

	Fed (n=xx)		Fasting (n=xx)	
	Total no-missing n	Normal n (%)	Total no-missing n	Normal n (%)
Neurological				
…				

10.5.3 C-SSRS

Table 5.3.1 C-SSRS - SAF

		Fed (n=xx)	Fasting (n=xx)
C-SSRS (Screening (day -28 to -2) and Baseline (day -1))			
Total no-missing	n	xx	xx
Suicidal Ideation or Behavior	n (%)	xx (xx.x%)	xx (xx.x%)
Suicidal Ideation	n (%)	xx (xx.x%)	xx (xx.x%)
Wish to dead	n (%)	xx (xx.x%)	xx (xx.x%)
Non-specific active suicidal thoughts	n (%)	xx (xx.x%)	xx (xx.x%)
Active suicidal ideation with any methods (not plan) without intent to act	n (%)	xx (xx.x%)	xx (xx.x%)
Active suicidal ideation with some intent to act, without specific plan	n (%)	xx (xx.x%)	xx (xx.x%)
Active suicidal ideation with specific plan and intent	n (%)	xx (xx.x%)	xx (xx.x%)
Suicidal Behavior	n (%)	xx (xx.x%)	xx (xx.x%)
Preparatory acts or behavior	n (%)	xx (xx.x%)	xx (xx.x%)
Aborted attempt	n (%)	xx (xx.x%)	xx (xx.x%)
Interrupted attempt	n (%)	xx (xx.x%)	xx (xx.x%)
Non-fatal suicide attempt	n (%)	xx (xx.x%)	xx (xx.x%)
Self-injorious behavior without suicidal intent	n (%)	xx (xx.x%)	xx (xx.x%)
Missing	n	xx	xx
C-SSRS (24 hours)			
Total no-missing	n	xx	xx
Suicidal Ideation or Behavior	n (%)	xx (xx.x%)	xx (xx.x%)
Suicidal Ideation	n (%)	xx (xx.x%)	xx (xx.x%)
Wish to dead	n (%)	xx (xx.x%)	xx (xx.x%)
Non-specific active suicidal thoughts	n (%)	xx (xx.x%)	xx (xx.x%)

		Fed (n=xx)	Fasting (n=xx)
Active suicidal ideation with any methods (not plan) without intent to act	n (%)	xx (xx.x%)	xx (xx.x%)
Active suicidal ideation with some intent to act, without specific plan	n (%)	xx (xx.x%)	xx (xx.x%)
Active suicidal ideation with specific plan and intent	n (%)	xx (xx.x%)	xx (xx.x%)
Suicidal Behavior	n (%)	xx (xx.x%)	xx (xx.x%)
Preparatory acts or behavior	n (%)	xx (xx.x%)	xx (xx.x%)
Aborted attempt	n (%)	xx (xx.x%)	xx (xx.x%)
Interrupted attempt	n (%)	xx (xx.x%)	xx (xx.x%)
Non-fatal suicide attempt	n (%)	xx (xx.x%)	xx (xx.x%)
Completed suicide	n (%)	xx (xx.x%)	xx (xx.x%)
Self-injorious behavior without suicidal intent	n (%)	xx (xx.x%)	xx (xx.x%)
Missing	n	xx	xx
C-SSRS (312 hours)			
Total no-missing	n	xx	xx
Suicidal Ideation or Behavior	n (%)	xx (xx.x%)	xx (xx.x%)
Suicidal Ideation	n (%)	xx (xx.x%)	xx (xx.x%)
Wish to dead	n (%)	xx (xx.x%)	xx (xx.x%)
Non-specific active suicidal thoughts	n (%)	xx (xx.x%)	xx (xx.x%)
Active suicidal ideation with any methods (not plan) without intent to act	n (%)	xx (xx.x%)	xx (xx.x%)
Active suicidal ideation with some intent to act, without specific plan	n (%)	xx (xx.x%)	xx (xx.x%)
Active suicidal ideation with specific plan and intent	n (%)	xx (xx.x%)	xx (xx.x%)
Suicidal Behavior	n (%)	xx (xx.x%)	xx (xx.x%)
Preparatory acts or behavior	n (%)	xx (xx.x%)	xx (xx.x%)
Aborted attempt	n (%)	xx (xx.x%)	xx (xx.x%)
Interrupted attempt	n (%)	xx (xx.x%)	xx (xx.x%)

		Fed (n=xx)	Fasting (n=xx)
Non-fatal suicide attempt	n (%)	xx (xx.x%)	xx (xx.x%)
Completed suicide	n (%)	xx (xx.x%)	xx (xx.x%)
Self-injorious behavior without suicidal intent	n (%)	xx (xx.x%)	xx (xx.x%)
Missing	n	xx	xx
C-SSRS (24 hours and 312 hours)			
Total no-missing	n	xx	xx
Suicidal Ideation or Behavior	n (%)	xx (xx.x%)	xx (xx.x%)
Suicidal Ideation	n (%)	xx (xx.x%)	xx (xx.x%)
Wish to dead	n (%)	xx (xx.x%)	xx (xx.x%)
Non-specific active suicidal thoughts	n (%)	xx (xx.x%)	xx (xx.x%)
Active suicidal ideation with any methods (not plan) without intent to act	n (%)	xx (xx.x%)	xx (xx.x%)
Active suicidal ideation with some intent to act, without specific plan	n (%)	xx (xx.x%)	xx (xx.x%)
Active suicidal ideation with specific plan and intent	n (%)	xx (xx.x%)	xx (xx.x%)
Suicidal Behavior	n (%)	xx (xx.x%)	xx (xx.x%)
Preparatory acts or behavior	n (%)	xx (xx.x%)	xx (xx.x%)
Aborted attempt	n (%)	xx (xx.x%)	xx (xx.x%)
Interrupted attempt	n (%)	xx (xx.x%)	xx (xx.x%)
Non-fatal suicide attempt	n (%)	xx (xx.x%)	xx (xx.x%)
Completed suicide	n (%)	xx (xx.x%)	xx (xx.x%)
Self-injorious behavior without suicidal intent	n (%)	xx (xx.x%)	xx (xx.x%)
Missing	n	xx	xx

10.6 Concomitant medication

Table 6.1.1 Previous concomitant medication

		Total subjects (n=xx)	Fed (n=xx)	Fasting (n=xx)
Previous concomitant medication				
Total no missing	n	xx	xx	xx
Yes	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Missing	n	xx	xx	xx
ACT classification name	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
…				

The concomitant medication will be presented by using the WHOdrug dictionary version 2021.

Table 6.1.2 Concomitant medication during study

		Total subjects (n=xx)	Fed (n=xx)	Fasting (n=xx)
Concomitant medication during study				
Total no missing	n	xx	xx	xx
Yes	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Indication:*				
AE	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Medical History	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Missing	n	xx	xx	xx
ACT classification name	n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
…				

The concomitant medication will be presented by using the WHOdrug dictionary version 2021.
*More than one option per patient could be possible.

10.7 Listings

Listing 7.1.1 Discontinued subjects

Subject ID	Fed/Fasting	Date of premature withdrawal	Reason for premature withdrawal
xx	xx	xx	xx

Listing 7.1.2 Protocol deviations

Subject ID	Fed/Fasting	Description	Type of deviation	Major/Minor
xx	xx	xx	xx	xx

Listing 7.1.3 Subjects excluded from population analysis

Subject ID	Fed/Fasting	SAF	PK	Reason for exclusion
xx	xx	xx	xx	xx

Listing 7.1.4 Baseline data

Subject ID	Fed/Fasting	Age (years)	Sex	BMI (Kg/m^2)
xx	xx	xx	xx	xx

Listing 7.1.5 Prior concomitant medication

Subject ID	Fed/Fasting	ACT level 4[1]	Dose	Unit	Route	Date start	Date end	Ongoing	Indication
xx	xx	xx	xx	xx	xx	xx	xx	xx	xx

[1]WHOdrug dictionary version 2021.

Listing 7.1.6 Concomitant medication during study

Subject ID	Fed/Fasting	ACT level 4[1]	Dose	Unit	Route	Date start	Date end	Ongoing	Indication
xx	xx	xx	xx	xx	xx	xx	xx	xx	xx

[1]WHOdrug dictionary version 2021.

Listing 7.1.7 Adverse Events

Subject ID	TEAE (yes/no)	Fed/Fasting	System Organ Class[1]	Preferred Term[1]	Serious	Severity	Causality	Alternative or confounding causality	Action	Corrective treatment	Outcome	Date start	Date end	Ongoing
xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx

[1]MedDRA dictionary version 25.0.

Listing 7.1.8 Serious adverse events

Subject ID	TEAE (yes/no)	Fed/Fasting	System Organ Class[1]	Preferred Term[1]	Death	Hospitalization or prolongation of existing hospitalization	Congenital anomaly or birth defect	Other medically important event	Life threatening	Significant disability / incapacity
xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx

[1]MedDRA dictionary version 25.0.

Listing 7.1.9 Abnormal findings on physical examination

Subject ID	Fed/Fasting	Visit	System	Abnormal finding
xx	xx	xx	xx	xx

Listing 7.1.10 Abnormal findings on vital signs, ECG and laboratory results

Subject ID	Fed/Fasting	Visit	Parameter	Value[1]	Unit[1]	Results[2]	AE	NCS/CS
xx	xx	xx	xx	xx	xx	xx	xx	xx

[1]Chemistry, Hematology, Coagulation, Vital signs and ECG parameters.

[2]Urine analysis parameters

Listing 7.1.11 COVID-19 tests

Subject ID	Fed/Fasting	Visit	Date	Result
xx	xx	xx	xx	xx