PHARMACOKINETIC REPORT

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Investigational Product: LB-102
Indication Studied: Schizophrenia
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1 SIGNATURE PAGE

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

We, the undersigned, have read this report and confirmed to the best of our knowledge it accurately describes the conduct and results of the study.

Signature	Date
	17 Sep 2020

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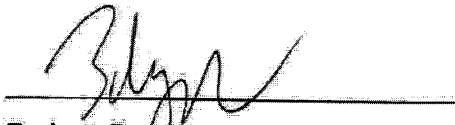	9/17/20

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2 EXECUTIVE SUMMARY

LB-102 was designed to be an improved version of the benzamide antipsychotic amisulpride having increased permeability across the blood-brain-barrier, potentially decreasing the plasma concentrations needed to achieve efficacy thereby decreasing the magnitude and frequency of adverse events typically observed in patients treated with amisulpride. The clinical trial described in this report is a Phase 1, randomized, double-blind, placebo-controlled study designed to evaluate the safety, tolerability, and pharmacokinetics (PK) of LB-102 in healthy subjects. There were two parts in this study:

- Part A – Single Ascending Dose (SAD): the actual treatments included LB-102 10 mg, 50 mg, 100 mg, 150 mg, 300 mg, or matching placebo at a ratio of 6:2;
- Part B – Multiple Ascending Dose (MAD): the actual treatments included LB-102 50 mg BID, 75 mg BID, 100 mg BID, or matching placebo at a ratio of 6:2.

All PK analyses were performed for the PK Population. The PK Population included all of the subjects who were randomized and had received at least one dose of LB-102 and had at least one post-dose measurable concentration of LB-102 or its metabolite, amisulpride. Sixty-four healthy male and female subjects (40 in Part A and 24 in Part B) were enrolled to participate in this clinical trial. Forty-eight subjects participated in the clinical trial as a part of the PK Population.

To explore the pharmacokinetic (PK) profiles of LB-102 and metabolite amisulpride, the concentrations of LB-102 and amisulpride were determined in plasma samples. Individual subject LB-102 and amisulpride concentration versus time data were listed and summarized for each study part and dose level. Individual and mean plots of LB-102 and amisulpride concentration versus time were constructed.

The PK parameters of LB-102 and amisulpride were calculated as data allowed by non-compartmental analysis; listed and summarized for each subject by study part and dose level. Dose proportionality was assessed using a power model. Achievement of steady state was assessed by visual inspection of plots of pre-dose concentrations. For Part B (MAD), all subjects in the group of LB-102 100 mg had the last dose on Day 2 or 3. Thus, the data after multiple doses from this group were not available for the PK analysis.

In Part A (SAD), LB-102 was rapidly absorbed and LB-102 concentration generally declined from peak in an apparent biphasic manner. The estimates of mean $t_{½}$ of LB-102 generally ranged from 11.993 to 14.146 hours; exposure (as measured by C_{max}, AUC_{0-t}, and AUC_{0-inf}) increased in a slightly greater than dose-proportional manner. Apparent clearance (CL/F) of LB-102 appeared to decrease as dose increased. Amisulpride was formed quickly over time after a single dose of LB-102 and generally declined with an approximate biphasic disposition.

In Part B (MAD), trough concentrations of LB-102 and amisulpride plateaued before the morning dose on Day 4. After multiple doses, there was slight to moderate accumulation across dose levels with mean R_{Cmax} values ranged from 1.121 to 1.798 and with mean R_{AUC} values ranged from 1.472 to 1.925. Amisulpride had a higher accumulation than LB-102 across dose levels with mean R_{Cmax} values ranged from 1.317 to 2.016 and with mean R_{AUC} values ranged from 1.801 to 2.232. Exposure (as measured by $C_{max, D7}$ and $AUC_{0-12, D7}$) to LB-102 increased in a dose-proportional manner. Apparent clearance at steady state (CL_{ss}/F) of LB-102 appeared to be similar as dose increased.

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6 LIST OF ABBREVIATIONS AND DEFINITION OF TERMS

Abbreviation	Definition
BID	Twice Daily
BLQ	Below the Lower Limit of Quantification
CI	Confidence Interval
CV	Coefficient of Variability
FDA	US Food and Drug Administration
GM	Geometric Mean
LLOQ	Lower Limit of Quantification
MAD	Multiple Ascending Dose
NCA	Non-compartmental Analysis
PK	Pharmacokinetic(s)
QD	Once Daily
SAD	Single Ascending Dose
SAS	Statistical Analysis System
SD	Standard Deviation

7 BACKGROUND

Schizophrenia is a chronic and debilitating mental illness that affects approximately one percent of the population. There are at least 22 drugs (both first and second generation antipsychotics) approved by the US Food and Drug Administration (FDA) indicated for the treatment of schizophrenia. Despite a seeming surfeit of available drugs to treat schizophrenia, adequate treatment of schizophrenia remains a challenge. LB-102 was designed to be an improved version of the benzamide antipsychotic amisulpride having increased permeability across the blood-brain-barrier, potentially decreasing the plasma concentrations needed to achieve efficacy thereby decreasing the magnitude and frequency of adverse events typically observed in patients treated with amisulpride.

Protocol LB-102-001 was the first in human study to evaluate the safety, tolerability, and pharmacokinetics (PK) of LB-102 in healthy subjects. This PK report describes the PK of LB-102 across different doses and regimens in healthy subjects.

8 PHARMACOKINETIC OBJECTIVES

The objectives of the study related to the PK analysis were:

- To evaluate the PK, including dose proportionality, of a single dose of LB-102
- To evaluate the PK, including dose proportionality, of multiple oral doses of LB-102

9 INVESTIGATIONAL PLAN

9.1 Overall Study Design and Plan

LB-102-001 was a Phase 1, randomized, double-blind, placebo-controlled study designed to evaluate the safety, tolerability, and PK of LB-102 in healthy subjects. The study consisted of two parts: Part A – Single Ascending Dose (SAD) and Part B – Multiple Ascending Dose (MAD). There were 5 cohorts in Part A and 3 Cohorts in Part B of this study. Each cohort consisted of 8 subjects, with 6 subjects assigned to LB-102 treatment and 2 subjects assigned to placebo treatment as follows.

Part A	
Cohort	**Treatment**
1 (n=8)[a]	LB-102 50 mg (n=6) or Matching Placebo (n=2) QD x 1 day
2 (n=8)[b]	LB-102 10 mg (n=6) or Matching Placebo (n=2) QD x 1 day
3 (n=8)[b]	LB-102 100 mg (n=6) or Matching Placebo (n=2) QD x 1 day
4 (n=8)[b]	LB-102 200 mg (n=6) or Matching Placebo (n=2) QD x 1 day
5 (n=8)[b]	LB-102 150 mg (n=6) or Matching Placebo (n=2) QD x 1 day
Part B	
6 (n=8)	LB-102 (n=6) 50 mg BID (100 mg/day) x 6 days (Days 1-6) and QD x 1 day (Day 7) or Matching Placebo (n=2) BID x 6 days (Days 1-6) and QD x 1 day (Day 7)
7 (n=8)	LB-102 (n=6) 100 mg BID (200 mg/day) x 6 days (Days 1-6) and QD x 1 day (Day 7) or Matching Placebo (n=2) BID x 6 days (Days 1-6) and QD x 1 day (Day 7)
8 (n=8)	LB-102 (n=6) 75 mg BID (150 mg/day) x 6 days (Days 1-6) and QD x 1 day (Day 7) or Matching Placebo (n=2) BID x 6 days (Days 1-6) and QD x 1 day (Day 7)

a – For Cohort 1, the first 2 subjects were randomized to receive LB-102 (n=1) or placebo (n=1) at least 24 hours prior to the remaining 6 subjects.
b – For Cohorts 2-5, the doses might be reduced based on the PK results of Cohort 1
QD = Once daily; BID = Twice daily

9.2 Drug Administration

For Part A of the protocol, subjects were dispensed either an LB-102 capsule or matching placebo based on their assigned treatment at 8 AM (±1 hour) after fasting for approximately 12 hours. Subjects took the capsule orally with 240 mL of water. Site personnel confirmed that the capsule had been taken by the study subject. In Cohort 1 (Part A), dosing of the first 2 subjects (1 active and 1 placebo) commenced at least 24 hours prior to the remaining 6 subjects. Dosing of the remaining subjects in the cohort might proceed if no safety issues were identified for the first 2 subjects.

For Part B of the protocol, subjects were dosed both at 8 AM (±1 hour) and approximately 12 hours later on Days 1-6, and once at 8 AM (±1 hour) on Day 7 for a total of 13 oral doses. Subjects were required to fast approximately 12 hours before prior to the first Day 1 dose.

9.3 Pharmacokinetic Assessments

Plasma PK samples were obtained at the following nominal time points:

- Part A (SAD)
    - Day 1: pre-dose, 15, 30, and 45 minutes (±5 minutes), and 1, 1.5, 2, 3, 4, 6, 8, 12, and 16 hours (±15 min) post-dose.
    - Days 2-3: 24, 32, and 48 hours (±15 min) post Day 1 dose.
    - Days 8 and 15 (For Cohort 5 only).
- Part B (MAD)
    - Day 1: prior to the first dose, 15, 30, and 45 minutes (±5 minutes), and 1, 1.5, 2, 3, 4, 6, 8, 12, and 16 hours (±15 min) post first dose.
    - Days 2-6: prior to first dose.
    - Day 7: pre-dose, 15, 30, and 45 minutes (±5 minutes), and 1, 1.5, 2, 3, 4, 6, 8, 12, and 16 hours (±15 min) post dose.
    - Days 8-9: 24, 32, and 48 hours (±15 min) post Day 7 dose.

9.4 Bioanalytical Analysis

A validated LC/MS/MS procedure was used to measure plasma concentrations of LB-102 and its metabolite, amisulpride. Samples from subjects who had at least one post-dose sample were analyzed. In brief, the lower limit of quantification (LLOQ) of the assay for LB-102 in plasma was 1 ng/mL and the calibration curve range was 1 to 1000 ng/mL; the LLOQ of the assay for amisulpride in plasma was 1 ng/mL and the calibration curve range was 1 to 1000 ng/mL. The precision and accuracy of the assay are presented in the method validation report.

9.5 Statistical Methods

9.5.1 General Statistical Consideration

Data were summarized descriptively including the number of subjects with data (n), mean, standard deviation (SD), median, minimum, maximum, coefficient of variability (CV%), geometric mean (GM), and GM CV%. The data point with a value of zero was excluded from the calculation of GM and GM CV%.

9.5.2 Pharmacokinetic Population

The PK Population included all of the subjects who were randomized and had received at least one dose of LB-102 and had at least one post-dose measurable concentration of LB-102 or its metabolite, amisulpride.

The PK Analysis Set was used to conduct PK analyses.

Deviation from procedures described in this protocol that impacted the quality of data required to meet the objectives of the study were documented and might result in exclusion of PK data from the analyses for a particular subject. This included any deviations or events that would invalidate the evaluation of the PK. Examples of deviations and events which could result in exclusion of PK data from the analyses included emesis after dosing (within the predetermined time), sample processing or assay errors that led to inaccurate bioanalytical results. Other deviations or events, which did not disqualify data from analyses, might require minor adjustments to calculations. If these occurred, data analyses were adjusted and documented accordingly such that conclusions were not biased. An example of such an event included, but was not limited to, minor deviations between the actual and scheduled time of sample collection.

9.5.3 Pharmacokinetic Analyses

9.5.3.1 Handling Missing Data or Concentration below the Lower Limit of Quantification

If the actual sampling time was missing, but a valid concentration value has been measured, the concentration value was flagged and the scheduled time point might be used for the calculation of PK parameters.

In cases of missing pre-dose on Day 1 (Part A or Part B), the missing components were assumed as zero. In cases of missing pre-dose on Day 7 in Part B, the minimum observed concentration during the dosing interval (dosing on Day 7 until 12 hours after dosing) was used as pre-dose concentration values. For the other cases, the missing data were not imputed.

The following rules were used to handle concentration below the lower limit of quantification (BLQ) for the PK parameter calculation and individual concentration data:

- If one or more BLQ values occurred before the first measurable concentration, they were assigned as zero concentration for single dose (Part A and the first dose of Part B) and as LLOQ for multiple dose (other than the first dose of Part B).
- If BLQ values occurred between measurable concentrations or after the last measurable concentration in a profile, the BLQ was omitted (set to missing).

The following general rules were applied for the concentration summary (including tabulation and plotting):

- Mean concentrations at any individual time point were only calculated if at least half of the subjects had valid values (i.e. quantifiable and not missing) at this time point for each treatment.
- In cases where a mean value was not calculated, due to the above criterion not being met, the mean value was set to missing for mean plotting purposes.
- BLQ was set to zero for the calculation of these mean values. The only exception was that the BLQ at pre-dose or before the last quantifiable measurement for multiple dose (other than Part A and the first dose of Part B) was imputed as LLOQ for multiple dose.

9.5.3.2 Pharmacokinetic Concentrations

Part A (SAD)

Individual plasma concentration of LB-102 and amisulpride were listed and summarized by treatment at each nominal time points descriptively.

Individual plasma concentration of LB-102 and amisulpride were plotted on a linear and semi-log scale against actual sampling time points for each treatment. Mean (±SD) plasma concentration of LB-102 and amisulpride were plotted on a linear and semi-logarithmic scale against nominal time points by treatment.

Part B (MAD)

Individual plasma concentration of LB-102 and amisulpride were listed and summarized by treatment at each nominal time points descriptively.

Individual plasma concentration of LB-102 and amisulpride were plotted on a linear and semi-log scale against actual sampling time points for each treatment. Mean (±SD) plasma concentration of LB-102 and amisulpride were plotted on a linear and semi-logarithmic scale against nominal time points by treatment.

The following figures were prepared for LB-102 and amisulpride:

- PK profile after the first and second dose (Day 1 including Day 2 pre-dose as Day 1 24 hours post-dose)
- PK profiles after the last dose (Day 7-9)
- Trough (i.e. pre-dose) concentration on Day 2 through Day 7.

For linear plots, zero concentration value(s) before the first measurable concentration was included in the plot. For semi-logarithmic plots, zero concentration value(s) before the first measurable concentration was assigned a missing value. A reference line indicating LLOQ was included in plots.

9.5.3.3 Pharmacokinetic Parameters

The PK parameters of LB-102 and amisulpride were derived using non-compartmental and/or compartmental methods as appropriate. No PK parameters were calculated for subjects with detectable concentrations for 2 or fewer time points.

Part A (SAD)

The following PK parameters of LB-102 and amisulpride were calculated (as appropriate) using non-compartmental analysis (NCA) method.

Parameters	**Description**
C_{max}	maximum plasma concentration; if the maximum value occurred at more than one time point, C_{max} was defined as the first maximum value
T_{max}	time to C_{max}
λ_z	apparent terminal elimination rate constant
$t_{½}$	apparent elimination half-life; calculated as $\ln(2)/\lambda_z$
AUC_{0-t}	area under the plasma concentration vs time curve (AUC) calculated using linear-up log-down trapezoidal summation from time 0 to the last quantifiable plasma concentration (C_{last})
AUC_{0-24}	AUC from time 0 to 24 hours post-dose; if the concentration at 24 hours post-dose was not available or could not be predicted for most subjects, the actual time for 24-hour sample was used in place of the nominal 24 hours
AUC_{0-inf}	AUC from time 0 to infinity
AUC_{extrap}	proportion of AUC_{0-inf} due to extrapolation (%), calculated as $100*(C_{last}/ \lambda_z)/AUC_{0-inf}$
CL/F	apparent clearance; calculated as Dose/AUC_{0-inf} (only for LB-102)

Part B (MAD)

The following PK parameters of LB-102 and amisulpride were calculated (as appropriate) using NCA method after the first dose. The individual concentration data before the second dose on Day 1 were used for PK parameter calculation.

Parameters	Description
$C_{max, D1}$	maximum plasma concentration on Day 1; if the maximum value occurred at more than one time point, C_{max} was defined as the first maximum value
$T_{max, D1}$	time to $C_{max, D1}$
$\lambda_{z, D1}$	apparent terminal elimination rate constant on Day 1
$t_{½, D1}$	terminal elimination half-life on Day 1, calculated as $ln(2)/\lambda_{z, D1}$
$AUC_{0-12, D1}$	AUC from time 0 to 12 hours post-dose; if the concentration at 12 hours post-dose was not available or could not be predicted for most subjects, the actual time for 12-hour sample was be used in place of the nominal 12 hours
$AUC_{0-24, D1}$	AUC from time 0 to 24 hours post-dose
$AUC_{0-inf, D1}$	AUC from time 0 to infinity on Day 1
$AUC_{extrap, D1}$	proportion of AUC_{0-inf} due to extrapolation (%) on Day 1, calculated as $100*(C_{last}/\lambda_{z\ D1})/AUC_{0-inf, D1}$

The following PK parameters of LB-102 and amisulpride were calculated (as appropriate) using the individual concentration profiles on Day 7-9, or by comparing the PK parameters on Day 1 with Day 7. The NCA method was used.

Parameters	Description
Tau	dosing interval; Tau=12 hours
$C_{max, D7}$	maximum plasma concentration on Day 7; between dose time and dose time + Tau. If the maximum value occurred at more than one time point, C_{max} was defined as the first maximum value
$T_{max, D7}$	time to $C_{max, D7}$
$\lambda_{z, D7}$	apparent terminal elimination rate constant on Day 7
$t_{½, D7}$	terminal elimination half-life on Day 7, calculated as $\ln(2)/\lambda_{z, D7}$
$AUC_{0\text{-}inf, D7}$	AUC from time 0 to infinity on Day 7
$AUC_{extrap, D7}$	proportion of $AUC_{0\text{-}inf}$ due to extrapolation (%) on Day 7, calculated as $100*(C_{last}/\lambda_{z, D7})/AUC_{0\text{-}inf}$
$AUC_{0\text{-}12, D7}$	AUC over the dosing interval; if the concentration at 12 hours post-dose was not available or could not be predicted for most subjects, the actual time for 12-hour sample was used in place of the nominal 12 hours
R_{Cmax}	accumulation ratio based on Cmax after the first dose and last dose, calculated as $C_{max, D7}/C_{max, D1}$
R_{AUC}	accumulation ratio based on AUC after the first dose and last dose, calculated as $AUC_{0\text{-}12, D7}/ AUC_{0\text{-}12, D1}$
LI	Linearity index; calculated as $AUC_{0\text{-}12, D7}/AUC_{0\text{-}inf, D1}$
CLss/F	apparent clearance at steady state; calculated as Dose/$AUC_{0\text{-}12, D7}$ (only for LB-102)

The actual collection times were used for the calculation of PK parameters. The Linear Up Log Down method (equivalent to the Linear Up/Log Down option in WinNonlin) was used in the computation of AUCs.

The apparent terminal elimination rate constant (λ_z), will not be presented for subjects who do not exhibit a terminal elimination phase in their concentration-time profiles. In order to estimate λ_z, linear regression of concentration in logarithm scale versus time was performed using at least 3 data points. Uniform weighting was selected to perform the regression analysis to estimate λ_z.

Generally, the λ_z will not be assigned if one of the following happens:

1. T_{max} is one of the 3 last data points,

2. The adjusted regression coefficient (R-squared) is less than 0.80,

3. The AUC_{extrap} exceeds 20%,

4. The estimated elimination rate indicates a positive slope, or

5. The terminal elimination phase is not linear (as appears in a semi-logarithmic scale) based on visual inspection.

If the λ_z is not assigned, the values of associated PK parameters (e.g. λ_z, $AUC_{0\text{-}inf}$, CL/F, or $t_{1/2}$) will not be calculated.

PK parameters of LB-102 and amisulpride was summarized by treatment using descriptive statistics.

9.5.3.4 Dose Proportionality

Dose proportionality was assessed using a linear regression, or other acceptable approach.

Part A (SAD)

Dose proportionality was assessed using power model based on PK Population. The power model was described below as:

$y = \alpha \times Dose^{\beta}$

where y denoted the plasma PK parameters (C_{max}, AUC_{0-t}, AUC_{0-inf}) of LB-102. Dose proportionality implied that $\beta=1$ and was assessed by estimating β along with its 90% confidence interval. The exponent, β, in the power model was estimated by regressing the ln-transformed PK parameter on ln-transformed dose. The power model was fitted by restricted maximum likelihood (REML) using SAS Proc Mixed. Both the intercept and slope were fitted as fixed effects. The mean slope was estimated and the corresponding 90% confidence interval (CI) was calculated.

Part B (MAD)

Dose proportionality was assessed using power model similarly using PK Population. The plasma PK parameters of LB-102 on Day 1 ($C_{max, D1}$, $AUC_{0-t, D1}$, and $AUC_{0-inf, D1}$) and those on Day 7 ($C_{max, D7}$ and $AUC_{0-12, D7}$) were used for the evaluation.

9.5.4 Statistical Software

The creation of analysis datasets and all statistical analyses were done using SAS Version 9.4. The Medpace standard operating procedures GL-DS-02-S3 and GL-DS-03-S2 were followed for the generation and validation of all SAS programs and outputs.

Phoenix WinNonlin version 8.1 was used in the determination of the PK terminal phase and the calculation of PK parameters. PK parameters were also calculated via SAS and verified with the Phoenix WinNonlin results.

9.6 Determination of Sample Size

The sample size for the study was based on clinical rather than statistical rationale. No formal sample size calculations were made. Cohorts of 8 subjects (6 active, 2 placebo) were sufficient to characterize the safety, tolerability, and PK profile of LB-102.

9.7 Changes in the Conduct of the Study or Planned Analyses

9.7.1 Changes in the Conduct of the Study

The original protocol was dated 18 May 2020. There were 2 clarification memo to the original protocol about PK sampling (Clarification Memo 9 dated 19 June 2020 and Clarification Memo 10 dated 23 June 2020).

The planned plasma PK samples for Part B (MAD) were obtained at the following nominal time points:

- Part B (MAD)
  - Day 1: prior to the first dose, 15, 30, and 45 minutes (±5 minutes), and 1, 1.5, 2, 3, 4, 6, 8, 12, and 16 hours (±15 min) post first dose.
  - Days 2-6: prior to first dose.
  - Day 7: pre-dose, 15, 30, and 45 minutes (±5 minutes), and 1, 1.5, 2, 3, 4, 6, 8, 12, and 16 hours (±15 min) post dose.
  - Days 8-9: 24, 32, and 48 hours (±15 min) post Day 7 dose.

Clarification Memo 9 specified the modification of PK sampling scheme as follows:

- Part B (MAD)
  - For Cohorts 6-7
    - Day 1: prior to the first dose, 15, 30, and 45 minutes (±5 minutes), and 1, 1.5, 2, 3, 4, 6, 8, 12, and 16 hours (±15 min) post first dose.
    - Days 2-6: prior to first dose.
    - Day 7: pre-dose, 15, 30, and 45 minutes (±5 minutes), and 1, 1.5, 2, 3, 4, 6, 8, 12, and 16 hours (±15 min) post dose.
    - Days 8-9: 24, 32, and 48 hours (±15 min) post Day 7 dose.
  - For Cohort 8 only
    - Day 1: prior to the first dose, 15, 30, and 45 minutes (±5 minutes), and 1, 1.5, 2, 3, 4, 6, 8, 12, and 16 hours (±15 min) post first dose.
    - Days 2-5: prior to first dose.
    - Day 6: pre-dose, 15 and 30 minutes (±5 minutes), and 1, 2, 4, 6, 8, 12, 12.25, 12.5, 13, 14, 16, 18 and 20 hours (±15 min) post dose.
    - Day 7: prior to first dose.
    - Days 8-9: 24, 32, and 48 hours (±15 min) post Day 7 dose.
    - Day 15

In Clarification Memo 10, the PK sampling on Day 15 for Cohort 8 was removed.

9.7.2 Changes in the Planned Analyses

The PK analysis plan included $AUC_{0\text{-}t,\ D1}$ as a parameter to assess the dose proportionality in a power model for Part B (MAD). $AUC_{0\text{-}12,\ D1}$, instead of $AUC_{0\text{-}t,\ D1}$, was used for dose proportionality assessment.

9.8 Data Storage

The SDTM datasets were obtained from Target Health Inc. and are stored electronically in a secure folder at Medpace, Inc.

Five datasets were used to prepare PK analysis, including ADSL, ADPCSAD, ADPCMAD, ADPPSAD, and ADPPMAD. These datasets are stored electronically in a secure folder at Medpace, Inc.

10 PHARMACOKINETIC RESULTS

10.1 Part A (SAD)

10.1.1 Pharmacokinetic Concentration after a Single Oral Dose

Figure 1 displays the plots of mean (±SD) plasma LB-102 concentrations versus time from 0 to 48 hours after a single dose of LB-102 by treatment on a linear and semi-log scale for the PK Population.

Following administration of a single oral dose, LB-102 was rapidly absorbed and generally declined from peak in an apparent biphasic manner.

Figure 2 displays the plots of mean (±SD) plasma amisulpride concentrations versus time from 0 to 48 hours after a single dose of LB-102 by treatment on a semi-log scale for the PK Population.

Amisulpride was formed quickly over time after a single dose of LB-102. Plasma concentrations of amisulpride generally declined with an approximate biphasic disposition.

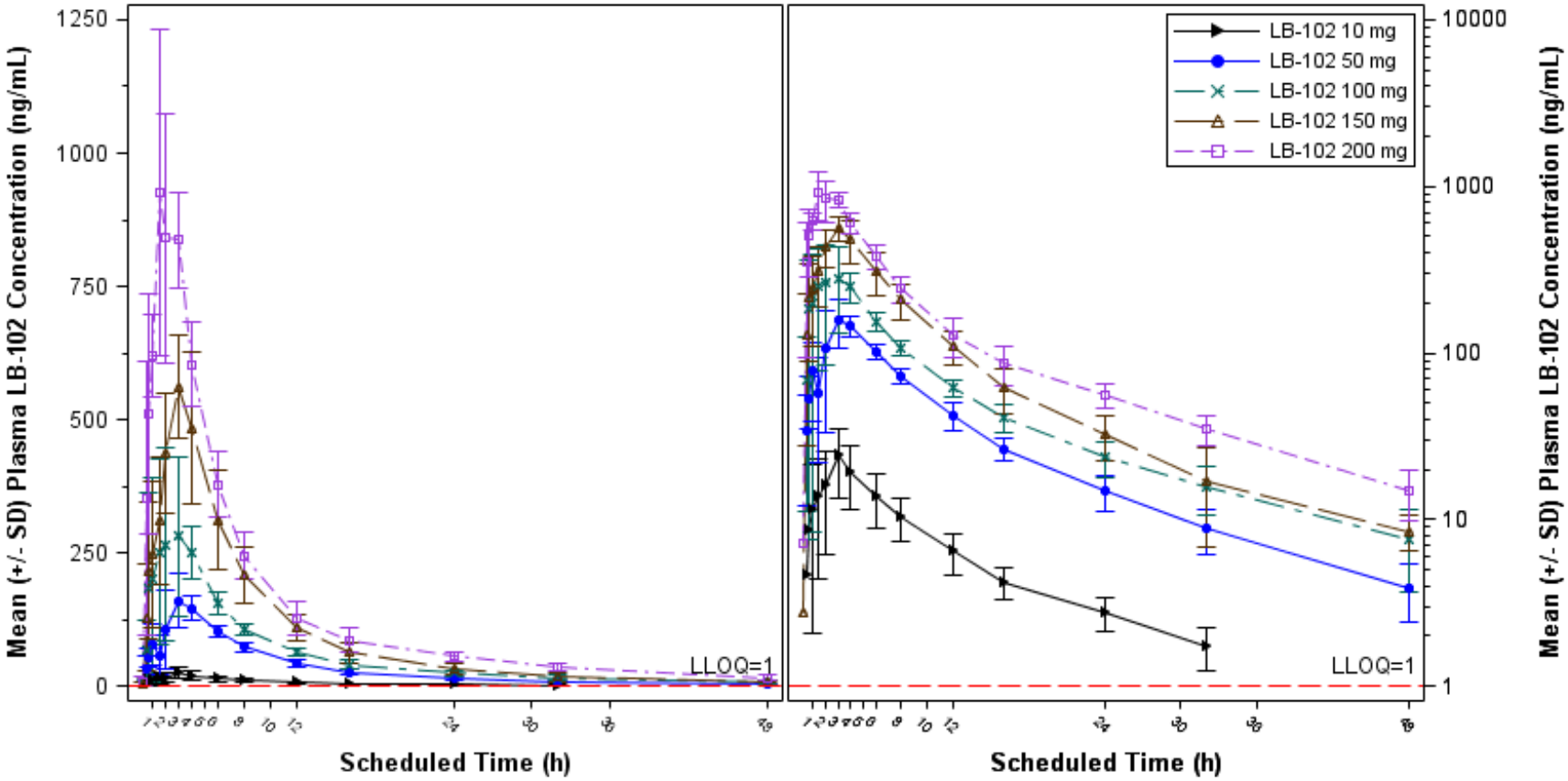
For descriptive statistics of plasma LB-102 and amisulpride concentrations after a single dose for PK Population in Part A (SAD), see Post-text Table 14.2.1.1.

For a listing of individual plasma concentration of LB-102 and amisulpride after a single dose of LB-102 for the PK Population in Part A (SAD), see Post-text Listing 16.2.6.2.

For the spaghetti plots of individual LB-102 concentrations versus time for the PK Population in Part A (SAD), see Post-text Figure 14.2.2.1. For the spaghetti plots of individual amisulpride concentrations versus time for the PK Population in Part A (SAD), see Post-text Figure 14.2.2.2.

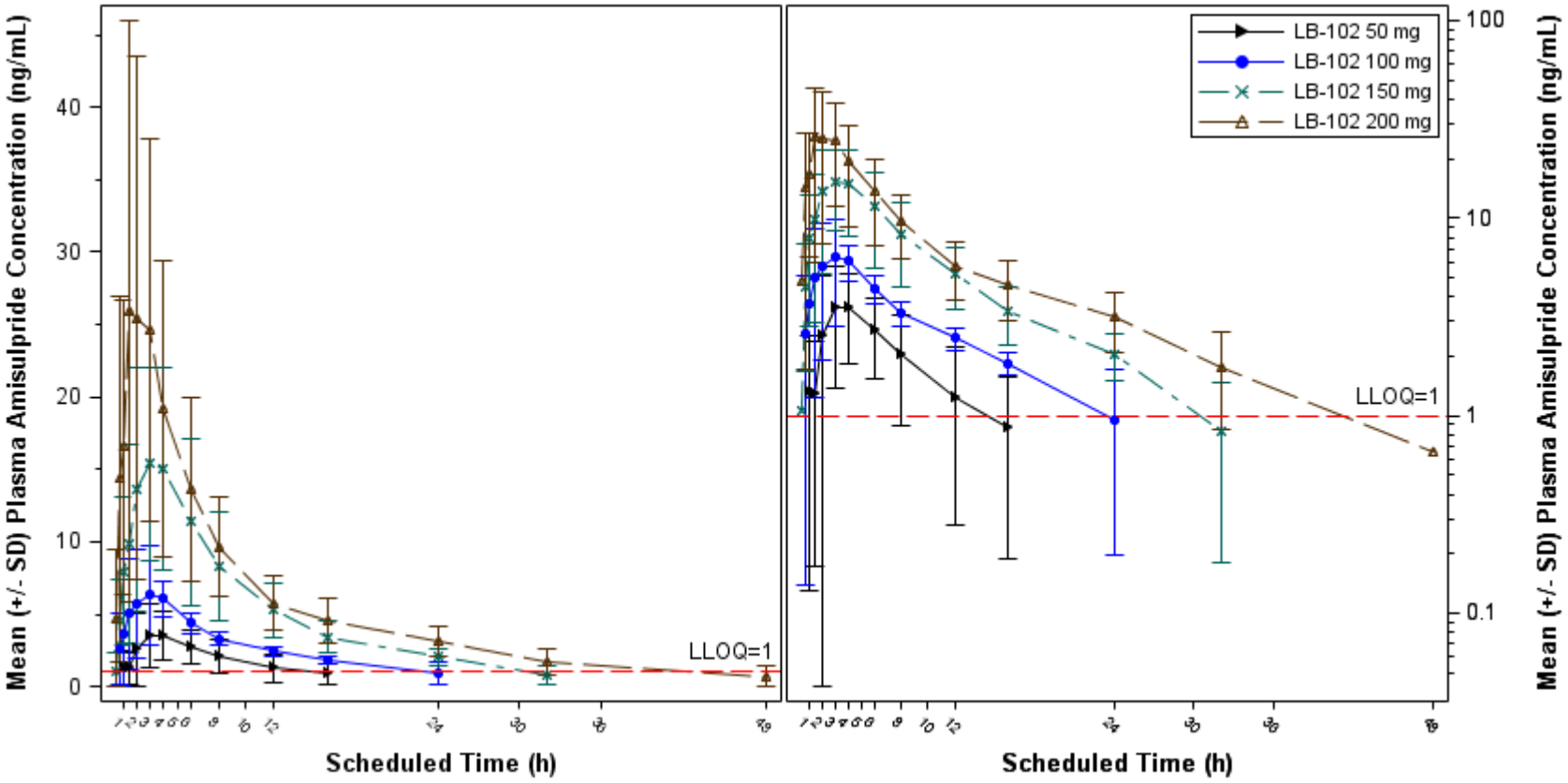
For the plots of individual LB-102 and amisulpride concentrations versus time for the PK Population in Part A (SAD), see Post-text Figures 14.2.3.1 through 14.2.3.5.

Figure 1. Plot of Mean (± SD) Plasma LB-102 Concentrations versus Time by Treatment on Linear and Semi-log Scale – Pharmacokinetic Population: Part A (SAD)



Note: Lower limit of quantitation for LB-102 = 1 ng/mL.
h = hours; SD = standard deviation.
Source: Post-text Figure 14.2.1.1

Figure 2. Plot of Mean (± SD) Plasma Amisulpride Concentrations versus Time by Treatment on Linear and Semi-log Scale – Pharmacokinetic Population: Part A (SAD)



Note: Lower limit of quantitation for amisulpride = 1 ng/mL.
h = hours; SD = standard deviation.
Source: Post-text Figure 14.2.1.2

10.1.2 Pharmacokinetic Parameters after a Single Oral Dose

Table 1 summarizes plasma PK parameters for LB-102 by treatment after a single dose of LB-102 for the PK Population. Systemic exposures to LB-102 generally increased with increasing dose and were somewhat variable, with GM CV% ranging from 11.7% to 45.6% for C_{max} and AUC values across treatment groups. CL/F appeared to decrease as dose increased.

Following administration of a single oral dose, LB-102 was rapidly absorbed, with mean peak plasma concentrations of LB-102 obtained within 3.01 hours post-dose (median T_{max} ranged from 1.75 to 3.01 hours). Plasma concentrations of LB-102 generally declined from peak in an apparent biphasic manner, with mean t½ ranged from 11.933 to 14.146 hours across treatment groups.

Table 2 summarizes plasma PK parameters for amisulpride after a single dose of LB-102 by treatment for the PK Population. Systemic exposures to amisulpride generally increased with increasing dose and were somewhat variable, with GM CV% ranging from 12.8% to 144.3% for C_{max} and AUC values across treatment groups.

Amisulpride was formed quickly over time after a single dose of LB-102 (median T_{max} ranged from 2 to 3.5 hours across treatment groups). Plasma concentrations of amisulpride generally declined with an approximate biphasic disposition with a mean t½ ranged from approximately 8.921 to 14.614 hours.

For the individual plasma parameters of LB-102 after a single dose of LB-102 for the PK Population, see Post-text Table 14.2.2.1.

For the individual plasma parameters of amisulpride after a single dose of LB-102 for the PK Population, see Post-text Table 14.2.2.2.

Table 1. Summary of Key Plasma LB-102 Pharmacokinetic Parameters – Pharmacokinetic Population

PK Parameter	Statistic	10 mg LB-102 (N=6)	50 mg LB-102 (N=6)	100 mg LB-102 (N=6)	150 mg LB-102 (N=6)	200 mg LB-102 (N=6)
	n	6	6	6	6	6
	Mean (SD)	24.1 (10.728)	176 (52.786)	348.167 (141.832)	596.5 (117.527)	975.667 (253.995)
C_{max} (ng/mL)	GM (GM CV%)	22.292 (44.5)	169.502 (30.8)	322.891 (45.6)	585.831 (21.7)	949.831 (25.4)
	n	6	6	6	6	6
T_{max} (h)	Median (min, max)	3 (3, 3)	3 (2, 4)	3.01 (1, 4)	3 (3, 4)	1.75 (1.5, 3)
	n	6	6	6	6	6
λ_z (1/h)	Mean (SD)	0.054 (0.01411)	0.0592 (0.00877)	0.0521 (0.0136)	0.0591 (0.00945)	0.0569 (0.01591)
	n	6	6	6	6	6
$t_{½}$ (h)	Mean (SD)	13.675 (3.9375)	11.933 (1.7797)	14.146 (3.9617)	11.969 (1.8897)	12.997 (3.5854)
	n	6	6	6	6	6
AUC_{0-t}	Mean (SD)	221.911 (69.4093)	1526.08 (176.5906)	2636.04 (481.5386)	4490.161 (741.2812)	6709.821 (834.9332)
(h•ng/mL)	GM (GM CV%)	212.353 (34.1)	1517.497 (11.7)	2594.86 (20.2)	4439.9 (16.5)	6668.19 (12.2)
	n	6	6	6	6	6
AUC_{0-24}	Mean (SD)	198.807 (66.9513)	1336.105 (167.6764)	2303.664 (533.1684)	4067.23 (685.9163)	5983.093 (833.9816)
(h•ng/mL)	GM (GM CV%)	189.498 (35.1)	1327.048 (12.9)	2244.225 (26.5)	4019.483 (17)	5938.059 (13.3)
	n	6	6	6	6	6
AUC_{0-inf}	Mean (SD)	252.637 (69.857)	1595.938 (189.1599)	2809.785 (477.7622)	4636.577 (745.7299)	7002.109 (820.7252)
(h•ng/mL)	GM (GM CV%)	244.171 (29.7)	1586.584 (11.9)	2773.559 (18.1)	4587.238 (16.1)	6962.173 (11.8)
	n	6	6	6	6	6
CL/F (L/h)	Mean (SD)	42.44 (12.598)	31.7 (3.794)	36.56 (6.935)	33.05 (5.25)	28.89 (3.381)

Note: GM CV% = 100 × (exp[SD^2]-1)^0.5, where SD was the SD of the logarithm-transformed data.

λ_z = apparent terminal elimination rate constant; AUC_{0-24} = area under the plasma concentration vs time curve from time 0 to 24 hours post-dose; AUC_{0-inf} = area under the plasma concentration vs time curve from time 0 to infinity; AUC_{0-t} = area under the plasma concentration vs time curve from time 0 to the last quantifiable concentration; CL/F = apparent clearance; C_{max} = maximum plasma concentration; CV = coefficient of variation; GM = geometric mean; h = hours; max = maximum; min = minimum; PK = pharmacokinetic(s); SD = standard deviation; $t_{½}$ = apparent elimination half-life; T_{max} = time to maximum plasma concentration.

Source: Post-text Table 14.2.2.1

Table 2. Summary of Key Plasma Amisulpride Pharmacokinetic Parameters – Pharmacokinetic Population

PK Parameter	Statistic	10 mg LB-102 (N=6)	50 mg LB-102 (N=6)	100 mg LB-102 (N=6)	150 mg LB-102 (N=6)	200 mg LB-102 (N=6)
	n	-	6	6	6	6
	Mean (SD)	-	4.167 (2.413)	7.648 (2.556)	17.283 (8.215)	27.747 (19.265)
C_{max} (ng/mL)	GM (GM CV%)	-	3.451 (83.6)	7.268 (37)	15.844 (47)	23.288 (72.1)
	n	-	6	6	6	6
T_{max} (h)	Median (min, max)	-	3 (2, 4)	3.5 (1.5, 4)	3 (2.05, 4)	2 (1.5, 3)
	n	-	-	-	5	5
λ_z (1/h)	Mean (SD)	-	-	-	0.0815 (0.01976)	0.0501 (0.0131)
	n	-	-	-	5	5
$t_{½}$ (h)	Mean (SD)	-	-	-	8.921 (2.1572)	14.614 (3.7087)
	n	-	6	6	6	6
AUC_{0-t}	Mean (SD)	-	31.183 (19.6105)	68.34 (9.1123)	162.189 (64.5423)	247.397 (111.3574)
(h•ng/mL)	GM (GM CV%)	-	22.378 (144.3)	67.808 (13.9)	152.936 (37.6)	220.341 (63.7)
	n	-	1	4	5	5
AUC_{0-24}	Mean (SD)	-	48.916 (-)	63.776 (8.2022)	152.976 (60.3055)	215.533 (94.741)
(h•ng/mL)	GM (GM CV%)	-	48.916 (-)	63.386 (12.8)	144.481 (37)	194.768 (57.4)
	n	-	-	-	5	5
AUC_{0-inf}	Mean (SD)	-	-	-	188.552 (64.7283)	314.264 (88.0822)
(h•ng/mL)	GM (GM CV%)	-	-	-	180.324 (33.8)	305.853 (25.5)

Note: GM CV% = 100 × (exp[SD^2]-1)^0.5, where SD was the SD of the logarithm-transformed data.
λ_z = apparent terminal elimination rate constant; AUC_{0-24} = area under the plasma concentration vs time curve from time 0 to 24 hours post-dose; AUC_{0-inf} = area under the plasma concentration vs time curve from time 0 to infinity; AUC_{0-t} = area under the plasma concentration vs time curve from time 0 to the last quantifiable concentration; C_{max} = maximum plasma concentration; CV = coefficient of variation; GM = geometric mean; h = hours; max = maximum; min = minimum; PK = pharmacokinetic(s); SD = standard deviation; $t_{½}$ = apparent elimination half-life; T_{max} = time to maximum plasma concentration.
Source: Post-text Table 14.2.2.2

10.1.3 Dose Proportionality Analysis of LB-102 after a Single Oral Dose

Although the current study was not designed or powered to formally assess dose proportionality, the data were subjected to a preliminary dose proportionality assessment to ascertain whether increases in exposure were generally proportional with increases in dose across the dose range studied.

Table 3 summarizes the analysis of dose proportionality for the PK Population for the 10, 50, 100, 150, and 200 mg LB-102 treatment groups. For all PK parameters tested (C_{max}, AUC_{0-t}, and AUC_{0-inf}), the 90% CI lower bound was slightly greater than unity, suggesting slightly greater than proportional increases in exposure with increases in dose.

Table 3. Power Model Analysis of Dose Proportionality of LB-102 – Pharmacokinetic Population

	LB-102 Dose Level				
PK Parameter Statistic	**10 mg LB-102 (N=6)**	**50 mg LB-102 (N=6)**	**100 mg LB-102 (N=6)**	**150 mg LB-102 (N=6)**	**200 mg LB-102 (N=6)**
C_{max} (ng/mL)					
n	6	6	6	6	6
GM (GM CV%)	22.292 (44.5)	169.502 (30.8)	322.891 (45.6)	585.831 (21.7)	949.831 (25.4)
Dose proportionality for C_{max}					
n				30	
Slope estimate (SE)				1.22 (0.0564)	
90% CI				(1.12, 1.32)	
AUC_{0-t} (h•ng/mL)					
n	6	6	6	6	6
GM (GM CV%)	212.353 (34.1)	1517.497 (11.7)	2594.86 (20.2)	4439.9 (16.5)	6668.19 (12.2)
Dose proportionality for AUC_{0-t}					
n				30	
Slope estimate (SE)				1.12 (0.0358)	
90% CI				(1.06, 1.19)	
AUC_{0-inf} (h•ng/mL)					
n	6	6	6	6	6
GM (GM CV%)	244.171 (29.7)	1586.584 (11.9)	2773.559 (18.1)	4587.238 (16.1)	6962.173 (11.8)
Dose proportionality for AUC_{0-inf}					
n				30	
Slope estimate (SE)				1.09 (0.0324)	
90% CI				(1.04, 1.15)	

Note: The power model was estimated by regressing the ln-transformed PK parameter on ln-transformed dose. The power model was fitted by restricted maximum likelihood (REML) using SAS Proc Mixed.
AUC_{0-inf} = area under the plasma concentration vs time curve from time 0 to infinity; AUC_{0-t} = area under the plasma concentration vs time curve from time 0 to the last quantifiable concentration; CI = confidence interval; C_{max} = maximum plasma concentration; CV = coefficient of variation; GM = geometric mean; h = hours; PK = pharmacokinetic(s); SE = standard error.
Source: Post-text Table 14.2.3.1

10.2 Part B (MAD)

10.2.1 Pharmacokinetic Concentration on Day 1 and after Multiple Doses

Figure 3 and Figure 4 display the plots of mean (±SD) plasma concentrations versus time on Day 1 by treatment on a linear and semi-log scale for LB-102 and amisulpride, respectively, for the PK Population.

For the first dose of LB-102 on Day 1, extensive samples were collected, including pre-dose, 15, 30, and 45 minutes, and 1, 1.5, 2, 3, 4, 6, 8, 12 post the first dose. Only sparse samples were collected for the second dose of LB-102 on Day 1, including pre-dose, 4, and 12 hour post the second dose.

Figure 5 and Figure 6 display the plots of mean (±SD) plasma concentrations versus time after multiple doses by treatment on a linear and semi-log scale for LB-102 and amisulpride, respectively, for the PK Population.

For LB-102 75 mg BID (Cohort 8), all subjects had dosing terminated on Day 7 and extensive PK sampling occurred on Day 6 rather than Day 7. For LB-102 100 mg BID (Cohort 7), most subjects had the last dose on Day 3 and there were no extensive PK samples collected after multiple dose.

As expected, exposures to LB-102 and amisulpride increased with increasing dose of LB-102. Peak plasma concentrations of LB-102 were attained rapidly following the first dose of LB-102. Concentrations were relatively well maintained over the dosing interval.

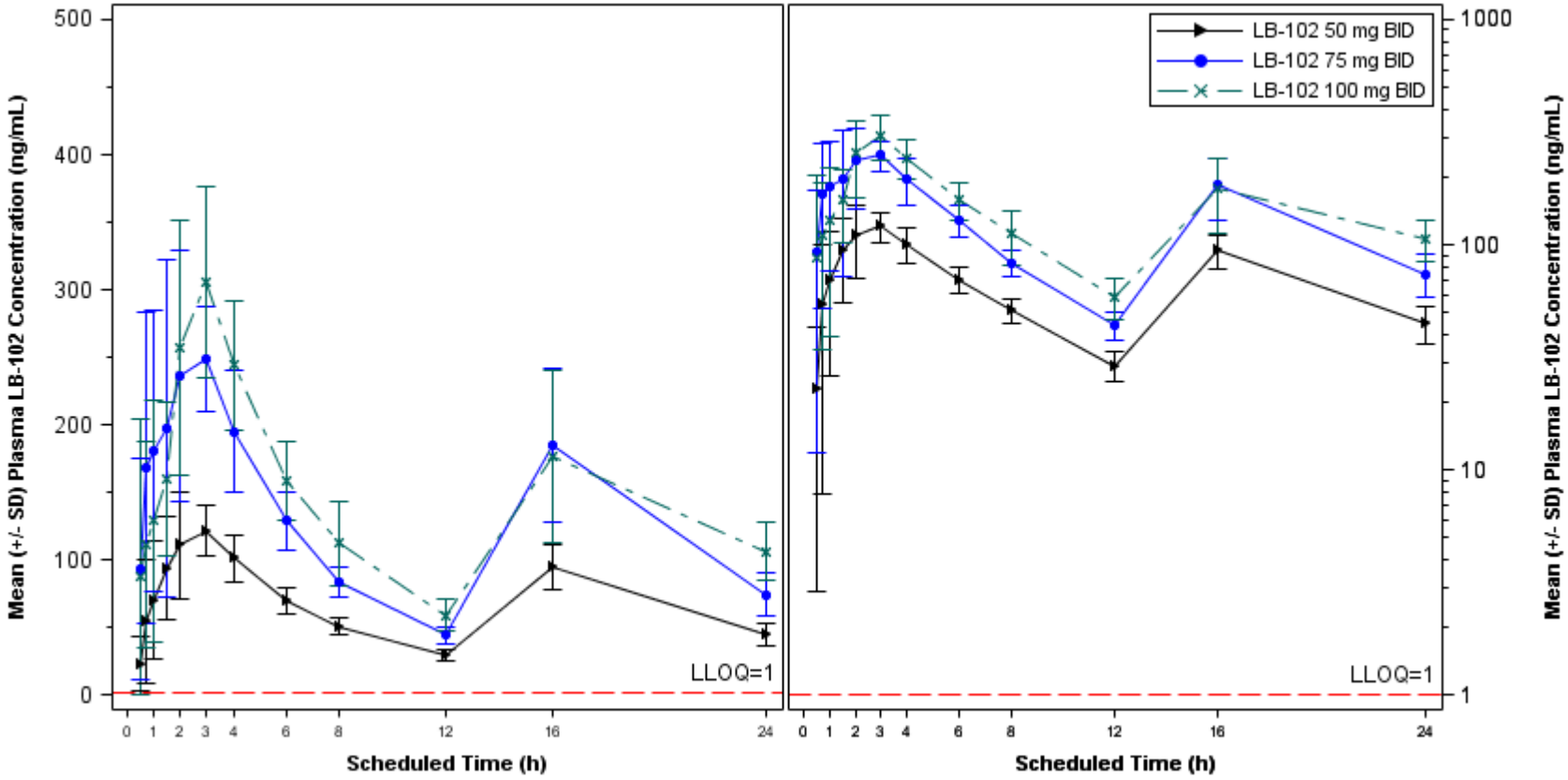
For descriptive statistics of plasma LB-102 and amisulpride concentrations on Day 1 and after multiple doses for PK Population in Part B (MAD), see Post-text Table 14.2.1.2.

For a listing of individual plasma concentration of LB-102 and amisulpride on Day 1 and after multiple doses for the PK Population in Part B (MAD), see Post-text Listing 16.2.6.3.

For the spaghetti plots of individual LB-102 concentrations versus time on Day 1 and after multiple doses for the PK Population in Part B (MAD), see Post-text Figures 14.2.2.3 and 14.2.2.4. For the spaghetti plots of individual amisulpride concentrations versus time on Day 1 and after multiple doses for the PK Population in Part B (MAD), see Post-text Figures 14.2.2.5 and 14.2.2.6.

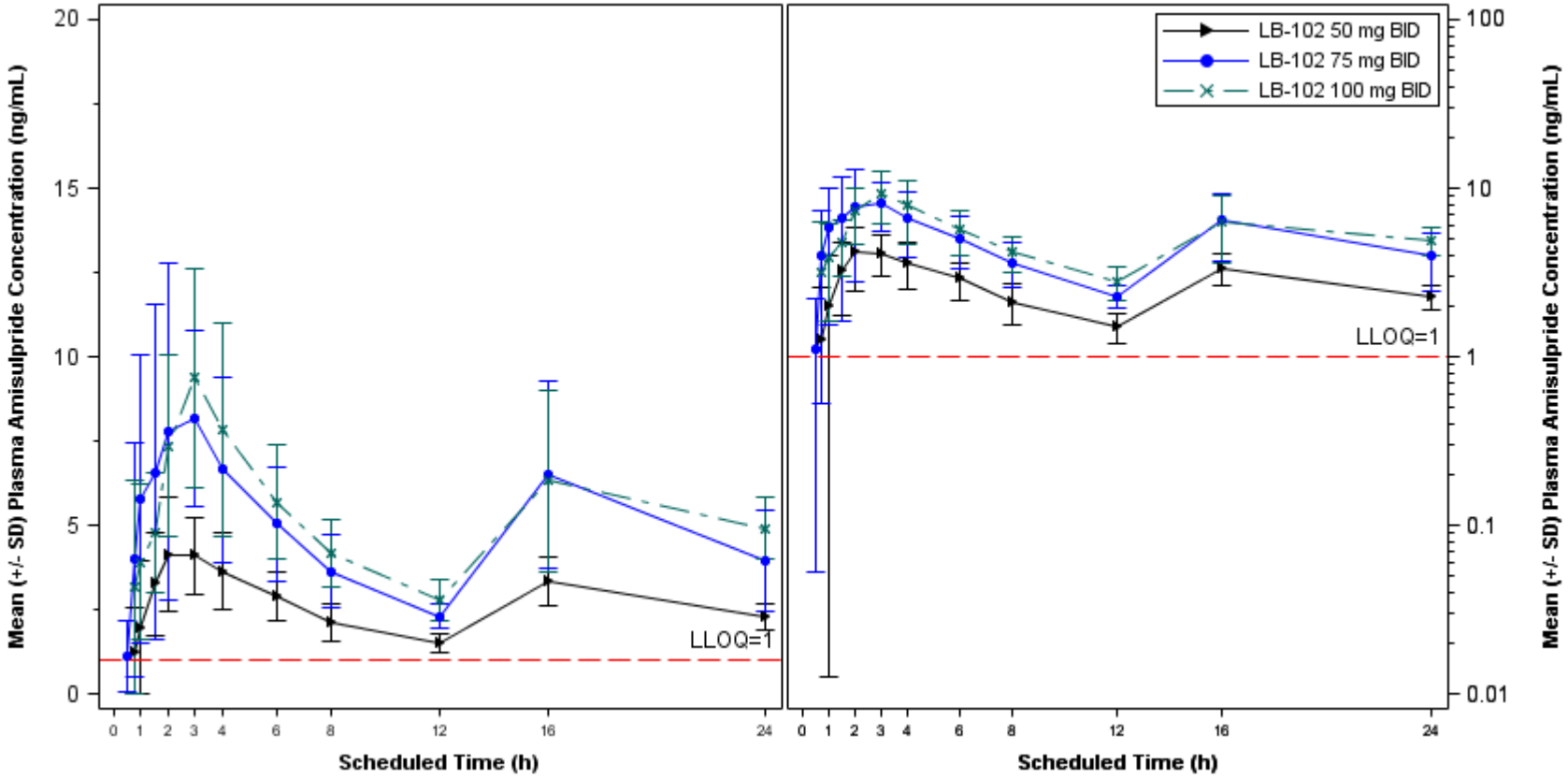
For the plots of individual LB-102 and amisulpride concentrations versus time for the PK Population in Part B (MAD), see Post-text Figures 14.2.4.1 through 14.2.4.5.

Figure 3. Plot of Mean (± SD) Plasma LB-102 Concentrations versus Time on Day 1 by Treatment on Linear and Semi-log Scale – Pharmacokinetic Population: Part B (MAD)



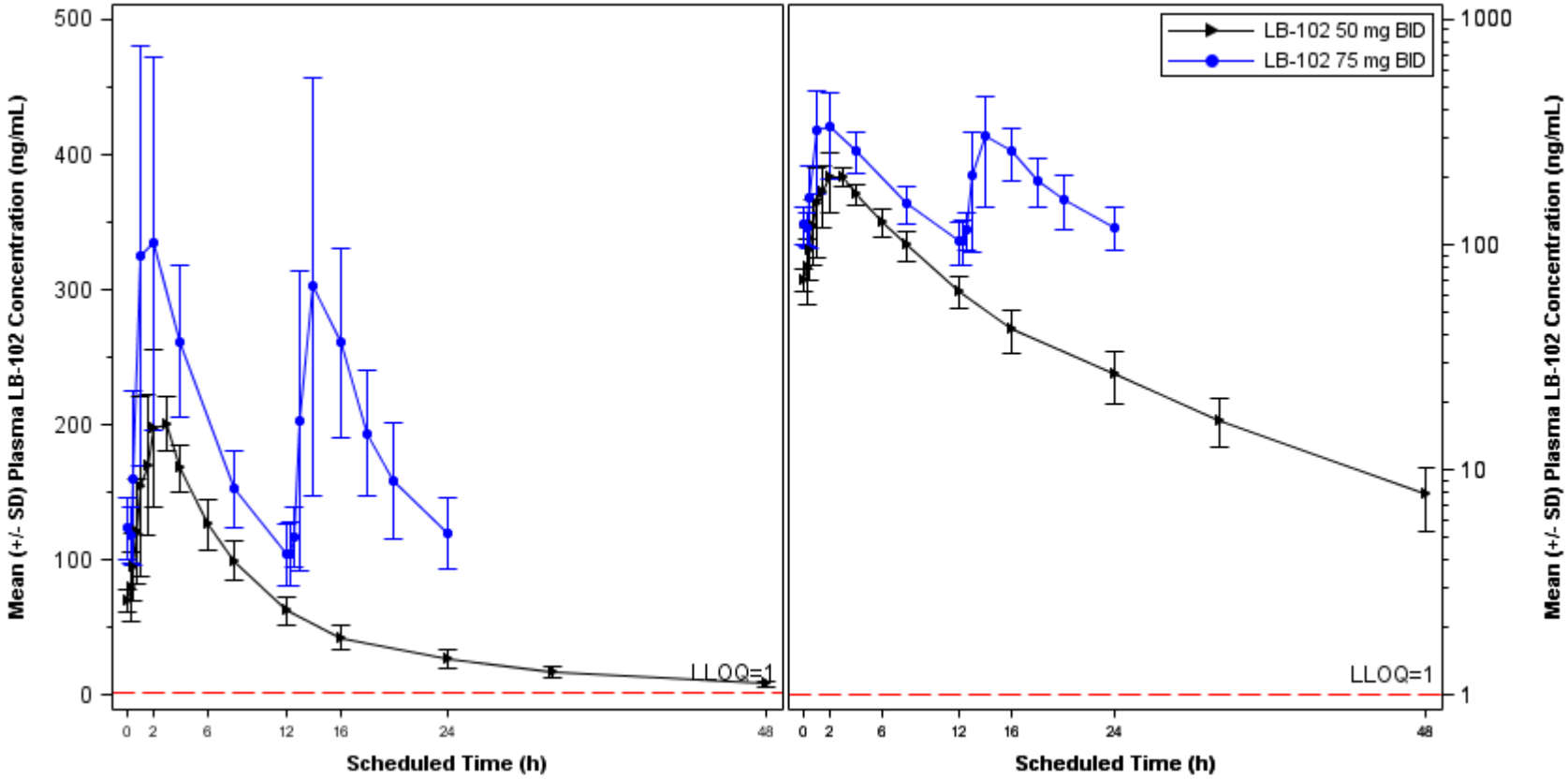
Note: Lower limit of quantitation for LB-102 = 1 ng/mL.
h = hours; SD = standard deviation.
Source: Post-text Figure 14.2.1.3

Figure 4. Plot of Mean (± SD) Plasma Amisulpride Concentrations versus Time on Day 1 by Treatment on Linear and Semi-log Scale – Pharmacokinetic Population: Part B (MAD)



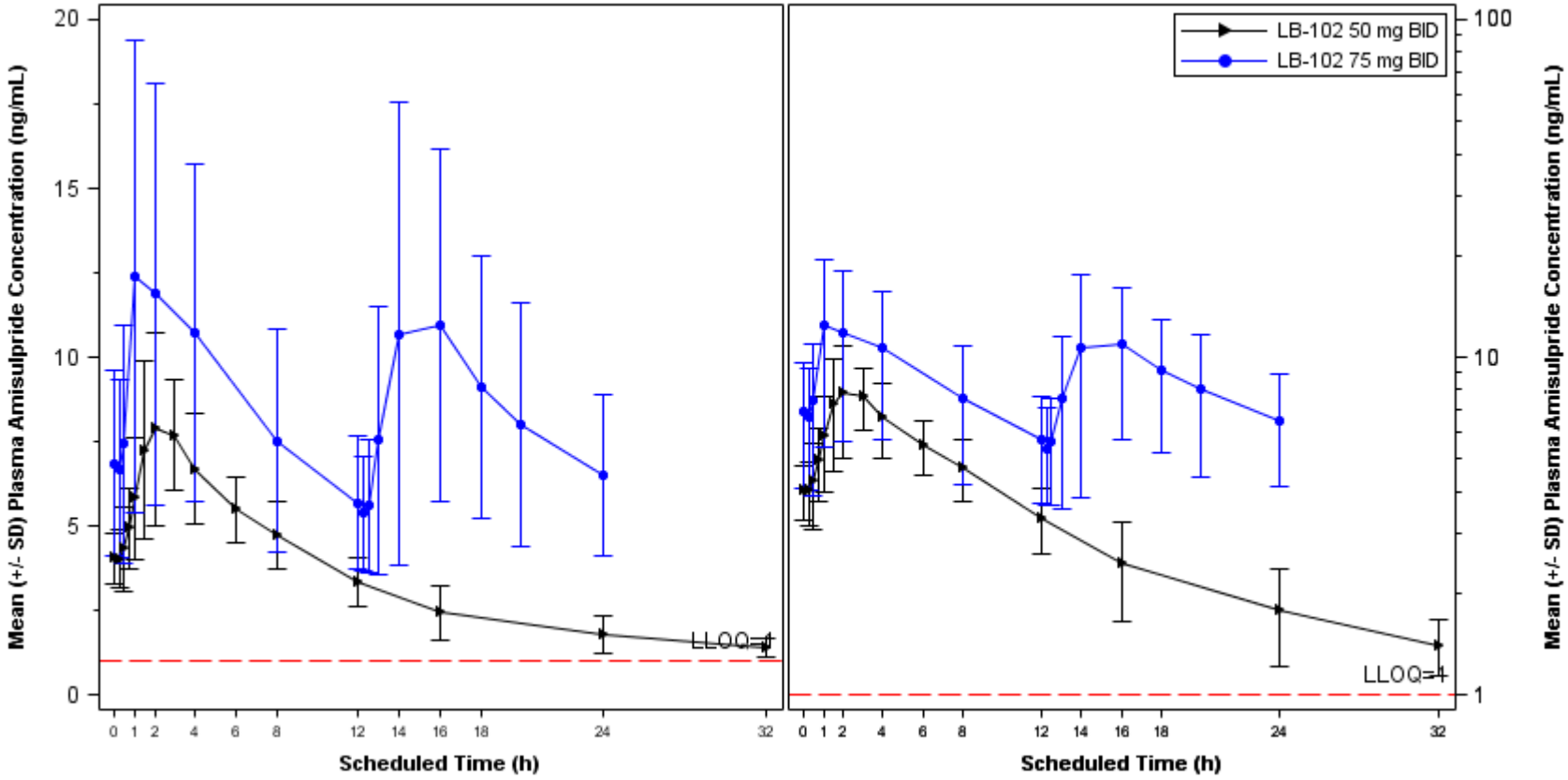
Note: Lower limit of quantitation for amisulpride = 1 ng/mL.
h = hours; SD = standard deviation.
Source: Post-text Figure 14.2.1.5

Figure 5. Plot of Mean (± SD) Plasma LB-102 Concentrations versus Time after Multiple Dose by Treatment on Linear and Semi-log Scale – Pharmacokinetic Population: Part B (MAD)



Note: Lower limit of quantitation for LB-102 = 1 ng/mL.
For Cohort 6 (LB-102 50 mg BID), the PK concentrations of the QD dosing on Day 7 were plotted. For Cohort 8 (LB-102 75 mg BID), the PK concentrations of both doses on Day 6 were plotted.
h = hours; SD = standard deviation.
Source: Post-text Figure 14.2.1.4

Figure 6. Plot of Mean (± SD) Plasma Amisulpride Concentrations versus Time after Multiple Dose by Treatment on Linear and Semi-log Scale – Pharmacokinetic Population: Part B (MAD)



Note: Lower limit of quantitation for amisulpride = 1 ng/mL.
For Cohort 6 (LB-102 50 mg BID), the PK concentrations of the QD dosing on Day 7 were plotted. For Cohort 8 (LB-102 75 mg BID), the PK concentrations of both doses on Day 6 were plotted.
h = hours; SD = standard deviation.
Source: Post-text Figure 14.2.1.6

10.2.2 Trough Concentrations

Figure 7 displays the plot of mean (±SD) trough plasma concentrations of LB-102 over time by treatment on a linear and semi-log scale for the PK Population.

Figure 8 displays the plot of mean (±SD) trough plasma concentrations of amisulpride over time by treatment on a linear and semi-log scale for the PK Population.

Trough concentrations of LB-102 and amisulpride plateaued before the morning dose on Day 4 for LB-102 50 mg BID and LB-102 75 mg BID. However, there was a transient decrease of concentration for both LB-102 and amisulpride before the evening dose on Day 6 for LB-102 75 mg BID.

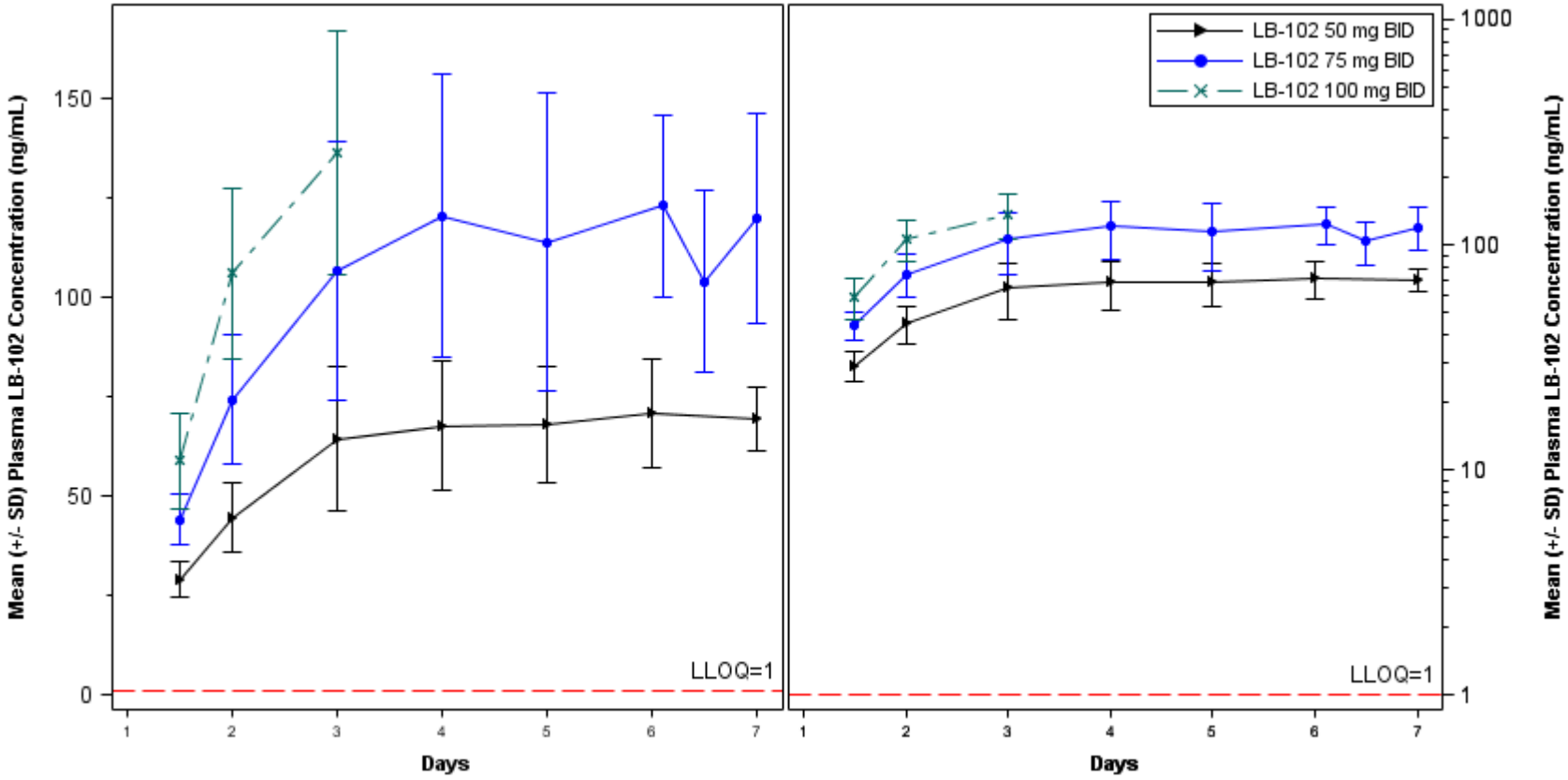
For descriptive statistics of plasma trough LB-102 and amisulpride concentrations for PK Population in Part B (MAD), see Post-text Table 14.2.1.2.

For a listing of individual plasma trough concentration of LB-102 and amisulpride for the PK Population in Part B (MAD), see Post-text Listing 16.2.6.3.

For the spaghetti plots of individual Trough LB-102 concentrations versus visit day for the PK Population in Part B (MAD), see Post-text Figure 14.2.2.7. For the spaghetti plots of individual trough amisulpride concentrations versus visit day for the PK Population in Part B (MAD), see Post-text Figure 14.2.2.8.

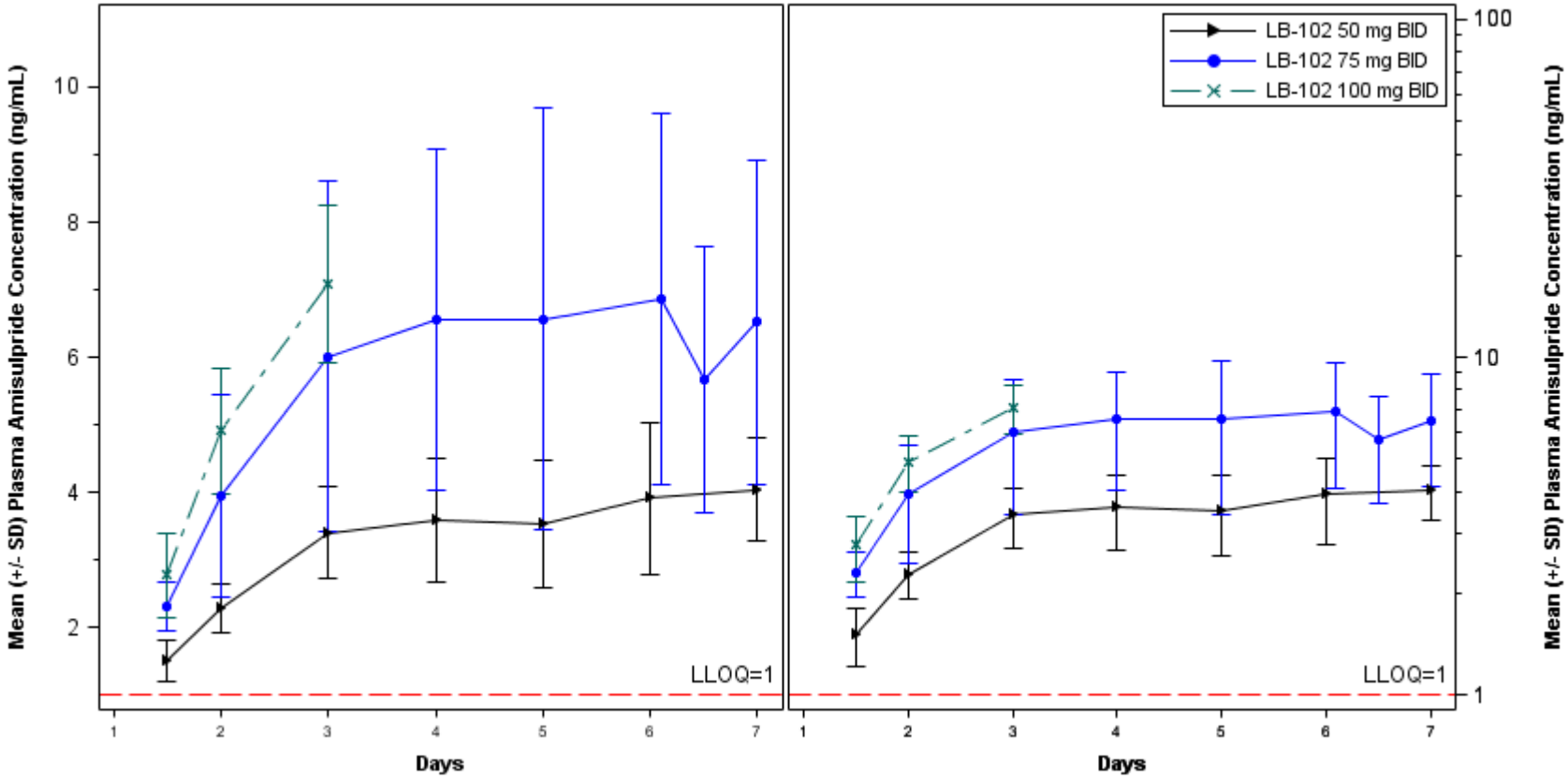
For the plots of individual trough LB-102 and amisulpride concentrations versus visit day for the PK Population in Part B (MAD), see Post-text Figures 14.2.4.6 through 14.2.4.8.

Figure 7. Plot of Mean (± SD) Plasma Trough LB-102 Concentrations versus Visit Day by Treatment on Linear and Semi-log Scale – Pharmacokinetic Population: Part B (MAD)



Note: Lower limit of quantitation for LB-102 = 1 ng/mL.
All pre-dose concentrations except that for the first dose on Day 1 were plotted as trough concentration.
h = hours; SD = standard deviation.
Source: Post-text Figure 14.2.1.7

Figure 8. Plot of Mean (± SD) Plasma Trough Amisulpride Concentrations versus Visit Day by Treatment on Linear and Semi-log Scale – Pharmacokinetic Population: Part B (MAD)



Note: Lower limit of quantitation for amisulpride = 1 ng/mL.
All pre-dose concentrations except that for the first dose on Day 1 were plotted as trough concentration.
h = hours; SD = standard deviation.
Source: Post-text Figure 14.2.1.8

10.2.3 Pharmacokinetic Parameters after a Single Dose and Multiple Doses

Table 4 summarizes the single dose and multiple dose plasma PK parameters for LB-102 by treatment for the PK Population. Systemic exposures to LB-102 generally increased with increasing dose.

After a single dose, LB-102 was rapidly absorbed, with a median $T_{max, D1}$ ranging from 2.5 to 3 hours across dosing regimens. Compared with Part A (SAD), the mean $t_{½, D1}$ was apparently shorter, ranging from 3.974 to 4.171 hours across treatment groups. This was likely due to the short PK sampling time after Day 1 Dose 1 and before Day 1 Dose 2 and the true terminal elimination phase not being adequately characterized, which might also cause the smaller $AUC_{0\text{-}inf}$ values compared with those in Part A (SAD) at the same dose level.

After multiple dose, peak exposure to LB-102 was higher than after a single dose (mean R_{Cmax} values ranged from 1.121 to 1.798). For AUC, there was a slightly more pronounced accumulation, with mean R_{AUC} ranged from 1.472 to 1.925. Apparent clearance after multiple doses appeared similar as dose increased.

Table 5 summarizes the single dose and multiple dose plasma PK parameters for amisulpride by treatment for the PK Population. Systemic exposures to amisulpride generally increased with increasing dose.

Amisulpride was quickly formed over time after a single dose of LB-102 with a median $T_{max, D1}$ of 3 hours across treatment groups.

After multiple doses, median $T_{max, D7}$ of amisulpride was ranged from 2.5 to 4 hours. Peak exposure to amisulpride was higher than after a single dose (mean R_{Cmax} values ranged from 1.317 to 2.016). For AUC, there was a slightly more pronounced accumulation, with mean R_{AUC} ranged from 1.801 to 2.232.

Table 4. Summary of Single Dose and Multiple Pharmacokinetic Parameters of LB-102 – Pharmacokinetic Population: Part B (MAD)

Day PK Parameter	Statistic	50 mg BID LB-102 (N=6)	75 mg BID LB-102 (N=6)	100 mg BID LB-102 (N=6)
Single Dose				
	n	6	6	6
	Mean (SD)	125.467 (22.721)	267.333 (69.373)	325.167 (67.744)
$C_{max, D1}$ (ng/mL)	GM (GM CV%)	123.746 (18.4)	260.708 (24.2)	318.589 (23.2)
	n	6	6	6
$T_{max, D1}$ (h)	Median (min, max)	2.5 (1.08, 3)	3 (2, 3.05)	2.5 (0.5, 3.02)
	n	4	6	5
$\lambda_{z, D1}$ (1/h)	Mean (SD)	0.1673 (0.01581)	0.1768 (0.0234)	0.1715 (0.02768)
	n	4	6	5
$t_{½, D1}$ (h)	Mean (SD)	4.171 (0.3951)	3.974 (0.4752)	4.121 (0.6106)
	n	6	6	6
	Mean (SD)	787.967 (117.2242)	1524.015 (323.0305)	1783.039 (323.7988)
$AUC_{0-12, D1}$ (h•ng/mL)	GM (GM CV%)	780.718 (15)	1497.374 (20.5)	1760.632 (17.2)
	n	4	6	5
	Mean (SD)	989.505 (98.5296)	1744.745 (315.2539)	2104.078 (428.5123)
$AUC_{0-24, D1}$ (h•ng/mL)	GM (GM CV%)	985.681 (10.3)	1722.519 (17.4)	2072.765 (19.1)
	n	4	6	5
	Mean (SD)	1012.649 (100.3718)	1777.932 (309.0153)	2152.886 (439.9467)
$AUC_{0-inf, D1}$ (h•ng/mL)	GM (GM CV%)	1008.802 (10.2)	1757 (16.7)	2120.916 (19)
Multiple Dose				
	n	6	5	-
	Mean (SD)	224 (39.8798)	309.4 (149.1452)	-
$C_{max, D7}$ (ng/mL)	GM (GM CV%)	221.115 (17.7)	287.044 (42.8)	-
	n	6	5	-
$T_{max, D7}$ (h)	Median (min, max)	2.5 (1, 3)	2 (2, 4)	-
	n	6	-	-
$\lambda_{z, D7}$ (1/h)	Mean (SD)	0.0514 (0.0137)	-	-
	n	6	-	-
$t_{½, D7}$ (h)	Mean (SD)	14.311 (3.7449)	-	-
	n	6	5	-
	Mean (SD)	1490.091 (130.1117)	2290.849 (708.461)	-
$AUC_{0-12, D7}$ (h•ng/mL)	GM (GM CV%)	1485.227 (8.9)	2215.515 (28.5)	-
	n	6	-	-
	Mean (SD)	2489.104 (312.4027)	-	-
$AUC_{0-inf, D7}$ (h•ng/mL)	GM (GM CV%)	2471.525 (13.4)	-	-
	n	6	5	-
CL_{ss}/F (L/h)	Mean (SD)	33.78 (3.082)	34.85 (8.792)	-

Note 1: GM CV% = 100*(exp(SD^2)-1)^0.5, where SD is the standard deviation of the log-transformed data.
Note 2: For Cohort 6 (LB-102 50 mg BID), the PK parameters after multiple doses were calculated using the PK concentration of the QD dosing on Day 7. For Cohort 8 (LB-102 75 mg BID), the PK parameters after multiple doses were calculated using the PK concentration of the second dosing on Day 6.
λz = apparent terminal elimination rate constant; AUC_{0-inf} = area under the plasma concentration vs time curve from time 0 to infinity; AUC_{0-12} = area under the plasma concentration vs time curve from time 0 to 12 hours; AUC_{0-24} = area under the plasma concentration vs time curve from time 0 to 24 hours; BID = twice daily; CLss/F = apparent clearance at steady state; C_{max} = maximum plasma concentration; GM = geometric mean; h = hours; LI = linear index; max = maximum; min = minimum; PK = pharmacokinetic(s); QD = once daily; R_{AUC} = accumulation ratio based on AUC after the first dose and last dose; R_{Cmax} = accumulation ratio based on C_{max} after the first dose and last dose; SD = standard deviation; t½ = terminal elimination half-life; T_{max} = time to maximum plasma concentration.
Sources: Post-text Table 14.2.2.3, 14.2.2.4, and 14.2.2.5

Table 4. Summary of Single Dose and Multiple Pharmacokinetic Parameters of LB-102 – Pharmacokinetic Population (Continued)

Day PK Parameter	Statistic	50 mg BID LB-102 (N=6)	75 mg BID LB-102 (N=6)	100 mg BID LB-102 (N=6)
Multiple Dose				
R_{Cmax}	n	6	5	-
	Mean (SD)	1.798 (0.215)	1.121 (0.4118)	-
R_{AUC}	n	6	5	-
	Mean (SD)	1.925 (0.3251)	1.472 (0.2833)	-
LI	n	4	5	-
	Mean (SD)	1.452 (0.1349)	1.254 (0.2246)	-

Note 1: GM CV% = 100*(exp(SD^2)-1)^0.5, where SD is the standard deviation of the log-transformed data.
Note 2: For Cohort 6 (LB-102 50 mg BID), the PK parameters after multiple doses were calculated using the PK concentration of the QD dosing on Day 7. For Cohort 8 (LB-102 75 mg BID), the PK parameters after multiple doses were calculated using the PK concentration of the second dosing on Day 6.
λz = apparent terminal elimination rate constant; $AUC_{0\text{-}inf}$ = area under the plasma concentration vs time curve from time 0 to infinity; $AUC_{0\text{-}12}$ = area under the plasma concentration vs time curve from time 0 to 12 hours; $AUC_{0\text{-}24}$ = area under the plasma concentration vs time curve from time 0 to 24 hours; BID = twice daily; CLss/F = apparent clearance at steady state; C_{max} = maximum plasma concentration; GM = geometric mean; h = hours; LI = linear index; max = maximum; min = minimum; PK = pharmacokinetic(s); QD = once daily; R_{AUC} = accumulation ratio based on AUC after the first dose and last dose; R_{Cmax} = accumulation ratio based on C_{max} after the first dose and last dose; SD = standard deviation; t½ = terminal elimination half-life; T_{max} = time to maximum plasma concentration.
Sources: Post-text Table 14.2.2.3, 14.2.2.4, and 14.2.2.5

Table 5. Summary of Single Dose and Multiple Pharmacokinetic Parameters of Amisulpride – Pharmacokinetic Population: Part B (MAD)

Day PK Parameter	Statistic	50 mg BID LB-102 (N=6)	75 mg BID LB-102 (N=6)	100 mg BID LB-102 (N=6)
Single Dose				
	n	6	6	6
	Mean (SD)	4.39 (1.475)	8.852 (4.187)	9.498 (3.122)
$C_{max, D1}$ (ng/mL)	GM (GM CV%)	4.17 (37.4)	8.229 (40.9)	9.154 (28.9)
	n	6	6	6
$T_{max, D1}$ (h)	Median (min, max)	3 (1.5, 4)	3 (1.5, 3.05)	3 (2, 3.02)
	n	-	1	1
$\lambda_{z, D1}$ (1/h)	Mean (SD)	-	0.1736 (-)	0.1542 (-)
	n	-	1	1
$t_{½, D1}$ (h)	Mean (SD)	-	3.992 (-)	4.496 (-)
	n	6	6	6
	Mean (SD)	30.316 (8.345)	55.681 (22.1069)	60.389 (17.6192)
$AUC_{0-12, D1}$ (h•ng/mL)	GM (GM CV%)	29.305 (29.7)	52.531 (37.5)	58.503 (27.4)
	n	-	1	1
	Mean (SD)	-	107.364 (-)	111.611 (-)
$AUC_{0-24, D1}$ (h•ng/mL)	GM (GM CV%)	-	107.364 (-)	111.611 (-)
	n	-	1	1
	Mean (SD)	-	109.344 (-)	115.297 (-)
$AUC_{0-inf, D1}$ (h•ng/mL)	GM (GM CV%)	-	109.344 (-)	115.297 (-)
Multiple Dose				
	n	6	5	-
	Mean (SD)	8.505 (2.5169)	11.552 (6.4064)	-
$C_{max, D7}$ (ng/mL)	GM (GM CV%)	8.22 (28.6)	10.352 (54.2)	-
	n	6	5	-
$T_{max, D7}$ (h)	Median (min, max)	2.5 (1.5, 3)	4 (2, 4)	-
	n	3	-	-
$\lambda_{z, D7}$ (1/h)	Mean (SD)	0.0562 (0.01173)	-	-
	n	3	-	-
$t_{½, D7}$ (h)	Mean (SD)	12.652 (2.3597)	-	-
	n	6	5	-
	Mean (SD)	64.787 (13.2513)	102.153 (47.7293)	-
$AUC_{0-12, D7}$ (h•ng/mL)	GM (GM CV%)	63.779 (19.1)	94.201 (46.3)	-
	n	3	-	-
	Mean (SD)	133.815 (47.7073)	-	-
$AUC_{0-inf, D7}$ (h•ng/mL)	GM (GM CV%)	128.265 (36.8)	-	-

Note 1: GM CV% = 100*(exp(SD^2)-1)^0.5, where SD is the standard deviation of the log-transformed data.

Note 2: For Cohort 6 (LB-102 50 mg BID), the PK parameters after multiple doses were calculated using the PK concentration of the QD dosing on Day 7. For Cohort 8 (LB-102 75 mg BID), the PK parameters after multiple doses were calculated using the PK concentration of the second dosing on Day 6.

λz = apparent terminal elimination rate constant; AUC_{0-inf} = area under the plasma concentration vs time curve from time 0 to infinity; AUC_{0-12} = area under the plasma concentration vs time curve from time 0 to 12 hours; AUC_{0-24} = area under the plasma concentration vs time curve from time 0 to 24 hours; BID = twice daily; C_{max} = maximum plasma concentration; GM = geometric mean; h = hours; LI = linear index; max = maximum; min = minimum; PK = pharmacokinetic(s); QD = once daily; R_{AUC} = accumulation ratio based on AUC after the first dose and last dose; R_{Cmax} = accumulation ratio based on C_{max} after the first dose and last dose; SD = standard deviation; t½ = terminal elimination half-life; T_{max} = time to maximum plasma concentration.

Sources: Post-text Table 14.2.2.6, 14.2.2.7, and 14.2.2.8

Table 4. Summary of Single Dose and Multiple Pharmacokinetic Parameters of LB-102 – Pharmacokinetic Population (Continued)

Day PK Parameter	Statistic	50 mg BID LB-102 (N=6)	75 mg BID LB-102 (N=6)	100 mg BID LB-102 (N=6)
Multiple Dose				
R_{Cmax}	n	6	5	-
	Mean (SD)	2.016 (0.4953)	1.317 (0.5755)	-
R_{AUC}	n	6	5	-
	Mean (SD)	2.232 (0.5958)	1.801 (0.4189)	-
LI	n	-	1	-
	Mean (SD)	-	1.173 (-)	-

Note 1: GM CV% = 100*(exp(SD^2)-1)^0.5, where SD is the standard deviation of the log-transformed data.
Note 2: For Cohort 6 (LB-102 50 mg BID), the PK parameters after multiple doses were calculated using the PK concentration of the QD dosing on Day 7. For Cohort 8 (LB-102 75 mg BID), the PK parameters after multiple doses were calculated using the PK concentration of the second dosing on Day 6.
λz = apparent terminal elimination rate constant; $AUC_{0\text{-}inf}$ = area under the plasma concentration vs time curve from time 0 to infinity; $AUC_{0\text{-}12}$ = area under the plasma concentration vs time curve from time 0 to 12 hours; $AUC_{0\text{-}24}$ = area under the plasma concentration vs time curve from time 0 to 24 hours; BID = twice daily; C_{max} = maximum plasma concentration; GM = geometric; h = hours; LI = linear index; max = maximum; min = minimum; PK = pharmacokinetic(s); QD = once daily; R_{AUC} = accumulation ratio based on AUC after the first dose and last dose; R_{Cmax} = accumulation ratio based on C_{max} after the first dose and last dose; SD = standard deviation; t½ = terminal elimination half-life; T_{max} = time to maximum plasma concentration.
Sources: Post-text Table 14.2.2.6, 14.2.2.7, and 14.2.2.8

10.2.4 Dose Proportionality Analysis of LB-102 after a Single Dose

Though the current study was not designed or powered to formally assess dose proportionality, the data were subjected to an exploratory dose proportionality assessment to ascertain whether increases in exposure were generally proportional with increases in dose across the dose range studied.

Table 6 summarizes the exploratory analysis of dose proportionality using a power model for $C_{max, D1}$, $AUC_{0\text{-}12, D1}$, and $AUC_{0\text{-}inf}$ after the first dose on Day 1 and for $C_{max, D7}$ and $AUC_{0\text{-}12, D7}$ after multiple doses for the PK Population.

For $C_{max, D1}$ after a single dose of LB-102, the 90% CI lower bound for $C_{max, D1}$ was slightly greater than unity, suggesting slightly greater than proportional increases in $C_{max, D1}$ with increases in dose. For $AUC_{0\text{-}12, D1}$ and $AUC_{0\text{-}inf, D1}$ after a single dose of LB-102, the 90% CI for $AUC_{0\text{-}12, D1}$ and $AUC_{0\text{-}inf, D1}$ contained unity, suggesting proportional increases in $AUC_{0\text{-}12, D1}$ and $AUC_{0\text{-}inf, D1}$ with increases in dose.

For $C_{max, D7}$ and $AUC_{0\text{-}12, D7}$ after multiple doses of LB-102, the 90% CI for both PK parameters contained unity, suggesting proportional increases in $C_{max, D7}$ and $AUC_{0\text{-}12, D1}$ with increases in dose.

Table 6. Power Model Analysis of Dose Proportionality of LB-102 – Pharmacokinetic Population

PK Parameter Statistic	LB-102 Dose Level		
	50 mg LB-102 (N=6)	75 mg LB-102 (N=6)	100 mg LB-102 (N=6)
Single Dose			
$C_{max, D1}$ (ng/mL)			
n	6	6	6
GM (GM CV%)	123.746 (18.4)	260.708 (24.2)	318.589 (23.2)
Dose proportionality for $C_{max, D1}$			
n			18
Slope estimate (SE)			1.4 (0.192)
90% CI			(1.06, 1.73)
$AUC_{0-12, D1}$ (h•ng/mL)			
n	6	6	6
GM (GM CV%)	780.718 (15)	1497.374 (20.5)	1760.632 (17.2)
Dose proportionality for $AUC_{0-12, D1}$			
n			18
Slope estimate (SE)			1.2 (0.1584)
90% CI			(0.93, 1.48)
$AUC_{0-inf, D1}$ (h•ng/mL)			
n	4	6	5
GM (GM CV%)	1008.802 (10.2)	1757 (16.7)	2120.916 (19)
Dose proportionality for $AUC_{0-inf, D1}$			
n			15
Slope estimate (SE)			1.08 (0.1614)
90% CI			(0.79, 1.37)
Multiple Dose			
$C_{max, D7}$ (ng/mL)			
n	6	5	-
GM (GM CV%)	221.115 (17.7)	287.044 (42.8)	-
Dose proportionality for $C_{max, D7}$			
n			11
Slope estimate (SE)			0.64 (0.4525)
90% CI			(-0.19, 1.47)
$AUC_{0-12, D7}$ (h•ng/mL)			
n	6	6	-
GM (GM CV%)	1485.227 (8.9)	2215.515 (28.5)	-
Dose proportionality for $AUC_{0-12, D7}$			
n			11
Slope estimate (SE)			0.99 (0.2959)
90% CI			(0.44, 1.53)

Note 1: The power model was estimated by regressing the ln-transformed PK parameter on ln-transformed dose. The power model was fitted by restricted maximum likelihood (REML) using SAS Proc Mixed.

Note 2: For Cohort 6 (LB-102 50 mg BID), the PK parameters after multiple dose were calculated using the PK concentration of the QD dosing on Day 7. For Cohort 8 (LB-102 75 mg BID), the PK parameters after multiple dose were calculated using the PK concentration of the 2nd dosing on Day 6.

AUC_{0-12} = area under the plasma concentration vs time curve from time 0 to 12 hours; AUC_{0-inf} = area under the plasma concentration vs time curve from time 0 to infinity; BID = twice daily; CI = confidence interval; C_{max} = maximum plasma concentration; CV = coefficient of variation; GM = geometric mean; h = hours; PK = pharmacokinetic(s); QD = once daily; SE = standard error.

Source: Post-text Table 14.2.3.2

11 DISCUSSION AND CONCLUSIONS

LB-102 was designed to be an improved version of the benzamide antipsychotic amisulpride having increased permeability across the blood-brain-barrier, potentially decreasing the plasma concentrations needed to achieve efficacy thereby decreasing the magnitude and frequency of adverse events typically observed in patients treated with amisulpride.

The current study was the first study of LB-102 in humans and was conducted as a Phase 1, randomized, double-blinded, placebo-controlled study. Both single ascending doses and multiple ascending doses of LB-102 were assessed in order to characterize the safety, tolerability, and PK in healthy adult subjects. A preliminary dose proportionality assessment was also included in this study.

In Part B (MAD), extensive PK sampling occurred on Day 6 rather than Day 7 and the last dose was given on Day 7. Thus, the PK profile for the seconding dose on Day 6 (including the pre-dose on Day 7) were used to calculate the PK parameter after multiple dose. For the calculation of $AUC_{0\text{-}12,\ D1}$, the actual time for 12-hour sample were used in place of the nominal 12 hour since the concentration at 12 hours post-dose could not be predicted.

In Part A (SAD), LB-102 was rapidly absorbed and LB-102 concentration generally declined from peak in an apparent biphasic manner. The estimates of mean $t_{½}$ of LB-102 generally ranged from 11.993 to 14.146 hours; exposure (as measured by C_{max}, $AUC_{0\text{-}t}$, and $AUC_{0\text{-}inf}$) increased in a slightly greater than dose-proportional manner. Apparent clearance (CL/F) appeared to decrease as dose increased. Amisulpride was formed quickly over time after a single dose of LB-102 and generally declined with an approximate biphasic disposition.

In Part B (MAD), trough concentrations of LB-102 and amisulpride plateaued before the morning dose on Day 4. After multiple doses, there was slight to moderate accumulation of LB-102 across dose levels with mean R_{Cmax} values ranged from 1.121 to 1.798 and with mean R_{AUC} values ranged from 1.472 to 1.925. Amisulpride had a higher accumulation than LB-102 across dose levels with mean R_{Cmax} values ranged from 1.317 to 2.016 and with mean R_{AUC} values ranged from 1.801 to 2.232. Exposure (as measured by $C_{max,\ D7}$ and $AUC_{0\text{-}12,\ D7}$) to LB-102 increased in a dose proportional manner. Apparent clearance at steady state (CL_{ss}/F) to LB-102 appeared to be similar as dose increased.

12 POST-TEXT TABLES AND FIGURES

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Table 14.2.1.1
Summary of Plasma LB-102 and Amisulpride Concentrations (ng/mL) by Treatment
Pharmacokinetic Population: Part A (SAD)

Treatment Analyte (Unit)	Visit	Scheduled Time Point	N	Mean	Standard Deviation	Median	Minimum	Maximum	Geometric Mean	Geometric CV%
LB-102 10 mg										
LB-102 (ng/mL)										
	Day 1	PRE DOSE*	6				0.00	0.00		
		15 MINS*	6				0.00	0.00		
		30 MINS	6	4.675	8.7357	0.580	0.00	22.10	4.970	278.9
		45 MINS	6	8.692	9.7266	4.100	1.98	26.60	5.327	144.0
		1 HOUR	6	11.625	9.5638	6.660	3.33	24.60	8.757	97.5
		1.5 HOURS	6	13.892	9.4575	10.495	6.00	30.70	11.690	69.4
		2 HOURS	6	16.060	9.8719	12.250	7.56	34.40	14.083	58.0
		3 HOURS	6	24.100	10.7285	19.800	14.50	39.00	22.292	44.5
		4 HOURS	6	19.417	7.9695	18.000	10.50	30.80	18.067	43.8
		6 HOURS	6	13.828	5.0802	13.550	8.39	21.80	13.064	38.5
		8 HOURS	6	10.420	3.0992	10.390	6.64	15.20	10.038	30.8
		12 HOURS	6	6.475	1.7993	6.550	3.94	8.52	6.251	30.5
		16 HOURS	6	4.187	0.9126	4.345	2.60	5.30	4.091	24.9
	Day 2	24 HOURS	6	2.753	0.6169	2.935	1.87	3.58	2.692	24.1
		32 HOURS	6	1.738	0.5016	1.570	1.32	2.64	1.685	26.9
	Day 3	48 HOURS*	6				0.00	1.56		

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
* Mean concentrations are only calculated for time points with at least 50% valid values (i.e. quantifiable and non-missing).
Geometric CV% = 100*(exp(SD^2)-1)^0.5, where SD is the standard deviation of the log-transformed data.

Table 14.2.1.1
Summary of Plasma LB-102 and Amisulpride Concentrations (ng/mL) by Treatment
Pharmacokinetic Population: Part A (SAD)

Treatment Analyte (Unit)	Visit	Scheduled Time Point	N	Mean	Standard Deviation	Median	Minimum	Maximum	Geometric Mean	Geometric CV%
LB-102 10 mg										
Amisulpride (ng/mL)										
	Day 1	PRE DOSE*	6				0.00	0.00		
		15 MINS*	6				0.00	0.00		
		30 MINS*	6				0.00	0.00		
		45 MINS*	6				0.00	0.00		
		1 HOUR*	6				0.00	0.00		
		1.5 HOURS*	6				0.00	0.00		
		2 HOURS*	6				0.00	0.00		
		3 HOURS*	6				0.00	0.00		
		4 HOURS*	6				0.00	0.00		
		6 HOURS*	6				0.00	0.00		
		8 HOURS*	6				0.00	0.00		
		12 HOURS*	6				0.00	0.00		
		16 HOURS*	6				0.00	0.00		
	Day 2	24 HOURS*	6				0.00	0.00		
		32 HOURS*	6				0.00	0.00		
	Day 3	48 HOURS*	6				0.00	0.00		

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
* Mean concentrations are only calculated for time points with at least 50% valid values (i.e. quantifiable and non-missing).
Geometric CV% = 100*(exp(SD^2)-1)^0.5, where SD is the standard deviation of the log-transformed data.

Table 14.2.1.1
Summary of Plasma LB-102 and Amisulpride Concentrations (ng/mL) by Treatment
Pharmacokinetic Population: Part A (SAD)

Treatment Analyte (Unit)	Visit	Scheduled Time Point	N	Mean	Standard Deviation	Median	Minimum	Maximum	Geometric Mean	Geometric CV%
LB-102 50 mg										
LB-102 (ng/mL)										
	Day 1	PRE DOSE*	6				0.00	0.00		
		15 MINS*	6				0.00	9.16		
		30 MINS	6	33.780	21.8187	33.400	8.18	62.90	26.785	95.6
		45 MINS	6	53.367	18.7288	58.350	18.30	68.30	49.160	53.4
		1 HOUR	6	77.467	38.7464	68.350	47.20	152.00	71.207	44.8
		1.5 HOURS	6	57.933	36.2083	57.550	0.00	112.00	66.464	33.1
		2 HOURS	6	106.817	73.7719	86.300	55.80	252.00	92.096	60.1
		3 HOURS	6	158.933	51.1229	163.000	91.60	224.00	151.554	35.7
		4 HOURS	6	146.500	21.1731	149.500	111.00	172.00	145.133	15.4
		6 HOURS	6	101.583	10.5755	103.500	82.00	111.00	101.086	11.1
		8 HOURS	6	72.933	7.4816	73.600	62.70	82.30	72.609	10.4
		12 HOURS	6	42.467	7.9301	40.550	33.70	52.40	41.866	18.6
		16 HOURS	6	26.500	3.9583	26.250	20.50	32.70	26.250	15.3
	Day 2	24 HOURS	6	14.867	3.5814	15.350	10.70	19.10	14.490	25.6
		32 HOURS	6	8.907	2.7244	9.465	5.01	12.20	8.518	34.9
	Day 3	48 HOURS	6	3.895	1.4703	3.920	1.79	5.56	3.630	45.1

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
* Mean concentrations are only calculated for time points with at least 50% valid values (i.e. quantifiable and non-missing).
Geometric CV% = 100*(exp(SD^2)-1)^0.5, where SD is the standard deviation of the log-transformed data.

Table 14.2.1.1
Summary of Plasma LB-102 and Amisulpride Concentrations (ng/mL) by Treatment
Pharmacokinetic Population: Part A (SAD)

Treatment Analyte (Unit)	Visit	Scheduled Time Point	N	Mean	Standard Deviation	Median	Minimum	Maximum	Geometric Mean	Geometric CV%
LB-102 50 mg										
Amisulpride (ng/mL)										
	Day 1	PRE DOSE*	6				0.00	0.00		
		15 MINS*	6				0.00	0.00		
		30 MINS*	6				0.00	0.00		
		45 MINS*	6				0.00	1.35		
		1 HOUR	6	1.332	1.2005	1.475	0.00	3.06	1.882	41.8
		1.5 HOURS	6	1.285	1.1138	1.490	0.00	2.71	1.841	37.1
		2 HOURS	6	2.550	2.5075	2.225	0.00	7.28	2.483	79.1
		3 HOURS	6	3.548	2.1755	3.310	1.16	6.27	2.934	80.9
		4 HOURS	6	3.542	1.6979	4.160	1.13	5.03	3.084	69.9
		6 HOURS	6	2.733	1.1850	3.250	1.01	3.71	2.451	59.9
		8 HOURS	6	2.062	1.1688	2.445	0.00	3.09	2.393	30.7
		12 HOURS	6	1.247	0.9690	1.805	0.00	1.96	1.868	5.7
		16 HOURS	6	0.877	0.6891	1.195	0.00	1.47	1.308	11.7
	Day 2	24 HOURS*	6				0.00	1.01		
		32 HOURS*	6				0.00	0.00		
	Day 3	48 HOURS*	6				0.00	0.00		

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
* Mean concentrations are only calculated for time points with at least 50% valid values (i.e. quantifiable and non-missing).
Geometric CV% = 100*(exp(SD^2)-1)^0.5, where SD is the standard deviation of the log-transformed data.

Table 14.2.1.1
Summary of Plasma LB-102 and Amisulpride Concentrations (ng/mL) by Treatment
Pharmacokinetic Population: Part A (SAD)

Treatment Analyte (Unit)	Visit	Scheduled Time Point	N	Mean	Standard Deviation	Median	Minimum	Maximum	Geometric Mean	Geometric CV%
LB-102 100 mg										
LB-102 (ng/mL)										
	Day 1	PRE DOSE*	6				0.00	0.00		
		15 MINS*	6				0.00	1.59		
		30 MINS	6	68.205	57.0640	77.600	0.00	148.00	53.831	228.3
		45 MINS	6	185.150	177.6188	173.500	0.00	484.00	146.865	194.0
		1 HOUR	6	199.670	191.3416	202.000	4.52	525.00	85.822	542.2
		1.5 HOURS	6	251.983	174.4165	257.500	19.50	468.00	169.688	179.0
		2 HOURS	6	265.450	181.5316	295.000	16.70	490.00	174.586	199.4
		3 HOURS	6	281.000	149.5085	307.500	51.00	474.00	229.882	96.1
		4 HOURS	6	250.000	48.7360	251.000	188.00	307.00	245.944	20.2
		6 HOURS	6	154.500	20.5694	162.000	120.00	175.00	153.267	14.2
		8 HOURS	6	106.233	10.7818	105.500	89.40	118.00	105.764	10.4
		12 HOURS	6	62.067	7.0772	61.950	54.30	71.40	61.731	11.4
		16 HOURS	6	40.817	7.8810	42.850	29.90	51.20	40.151	20.4
	Day 2	24 HOURS	6	23.550	5.5324	25.500	14.70	29.80	22.935	26.6
		32 HOURS	6	15.645	4.9665	16.150	9.07	22.00	14.943	35.0
	Day 3	48 HOURS	6	7.627	3.9784	7.730	3.36	13.30	6.715	61.8

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
* Mean concentrations are only calculated for time points with at least 50% valid values (i.e. quantifiable and non-missing).
Geometric CV% = 100*(exp(SD^2)-1)^0.5, where SD is the standard deviation of the log-transformed data.

Source Data: ADPCSAD; Reference listings(s): 16.2.6.2 SDTM Date: 04AUG2020 16:09
Program Name: tconcentration.sas Analysis Date: 20AUG2020 17:48

Table 14.2.1.1
Summary of Plasma LB-102 and Amisulpride Concentrations (ng/mL) by Treatment
Pharmacokinetic Population: Part A (SAD)

Treatment Analyte (Unit)	Visit	Scheduled Time Point	N	Mean	Standard Deviation	Median	Minimum	Maximum	Geometric Mean	Geometric CV%
LB-102 100 mg										
Amisulpride (ng/mL)										
	Day 1	PRE DOSE*	6				0.00	0.00		
		15 MINS*	6				0.00	0.00		
		30 MINS*	6				0.00	0.00		
		45 MINS	6	2.605	2.4658	2.605	0.00	6.48	3.626	45.7
		1 HOUR	6	3.675	3.7430	3.525	0.00	10.10	4.969	53.8
		1.5 HOURS	6	5.052	3.8084	5.570	0.00	10.60	5.188	77.7
		2 HOURS	6	5.697	3.7808	6.700	0.00	9.04	6.235	55.0
		3 HOURS	6	6.305	3.4825	6.370	1.38	10.20	5.218	87.8
		4 HOURS	6	6.050	1.2117	6.110	4.23	7.90	5.946	20.9
		6 HOURS	6	4.362	0.7027	4.285	3.38	5.57	4.316	16.0
		8 HOURS	6	3.307	0.4726	3.345	2.68	4.09	3.279	14.2
		12 HOURS	6	2.460	0.3353	2.525	1.82	2.73	2.438	15.1
		16 HOURS	6	1.848	0.2409	1.915	1.38	2.05	1.833	14.5
	Day 2	24 HOURS	6	0.955	0.7565	1.290	0.00	1.72	1.422	13.8
		32 HOURS*	6				0.00	1.06		
	Day 3	48 HOURS*	6				0.00	0.00		

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
* Mean concentrations are only calculated for time points with at least 50% valid values (i.e. quantifiable and non-missing).
Geometric CV% = 100*(exp(SD^2)-1)^0.5, where SD is the standard deviation of the log-transformed data.

Source Data: ADPCSAD; Reference listings(s): 16.2.6.2 SDTM Date: 04AUG2020 16:09
Program Name: tconcentration.sas Analysis Date: 20AUG2020 17:48

Table 14.2.1.1
Summary of Plasma LB-102 and Amisulpride Concentrations (ng/mL) by Treatment
Pharmacokinetic Population: Part A (SAD)

Treatment Analyte (Unit)	Visit	Scheduled Time Point	N	Mean	Standard Deviation	Median	Minimum	Maximum	Geometric Mean	Geometric CV%
LB-102 150 mg										
LB-102 (ng/mL)										
	Day 1	PRE DOSE*	6				0.00	0.00		
		15 MINS	6	2.762	3.1524	2.330	0.00	7.14	5.414	24.3
		30 MINS	6	128.053	100.4014	114.150	1.02	250.00	58.093	844.1
		45 MINS	6	216.867	128.5853	202.500	47.20	392.00	177.299	89.8
		1 HOUR	6	246.733	137.7471	263.500	74.40	445.00	209.059	76.0
		1.5 HOURS	6	310.333	119.7191	291.000	142.00	493.00	289.558	44.3
		2 HOURS	6	437.500	112.2475	430.500	293.00	584.00	425.232	26.9
		3 HOURS	6	561.000	96.0895	560.500	401.00	665.00	553.557	18.5
		4 HOURS	6	484.333	144.1051	470.500	308.00	739.00	467.664	29.4
		6 HOURS	6	311.667	92.0905	303.000	212.00	477.00	301.403	28.4
		8 HOURS	6	208.667	52.7206	207.000	153.00	304.00	203.629	24.1
		12 HOURS	6	109.050	24.9582	110.900	77.20	138.00	106.587	24.0
		16 HOURS	6	62.033	18.4268	65.350	33.60	80.90	59.407	34.6
	Day 2	24 HOURS	6	32.450	9.7369	34.900	17.90	41.60	31.054	34.8
		32 HOURS	6	16.817	9.9121	19.300	0.00	26.50	19.291	36.4
	Day 3	48 HOURS	6	8.473	2.0533	8.690	5.27	11.10	8.245	26.8
	Day 8	168 HOURS*	6				0.00	0.00		
	Day 15	336 HOURS*	6				0.00	0.00		

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
* Mean concentrations are only calculated for time points with at least 50% valid values (i.e. quantifiable and non-missing).
Geometric CV% = 100*(exp(SD^2)-1)^0.5, where SD is the standard deviation of the log-transformed data.

Source Data: ADPCSAD; Reference listings(s): 16.2.6.2 SDTM Date: 04AUG2020 16:09
Program Name: tconcentration.sas Analysis Date: 20AUG2020 17:48

Table 14.2.1.1
Summary of Plasma LB-102 and Amisulpride Concentrations (ng/mL) by Treatment
Pharmacokinetic Population: Part A (SAD)

Treatment Analyte (Unit)	Visit	Scheduled Time Point	N	Mean	Standard Deviation	Median	Minimum	Maximum	Geometric Mean	Geometric CV%
LB-102 150 mg										
Amisulpride (ng/mL)										
	Day 1	PRE DOSE*	6				0.00	0.00		
		15 MINS*	6				0.00	0.00		
		30 MINS	6	1.063	1.2522	0.645	0.00	2.60	2.029	40.8
		45 MINS	6	4.528	2.8424	4.125	1.26	8.34	3.702	84.5
		1 HOUR	6	7.950	5.1147	8.250	2.09	14.00	6.159	105.1
		1.5 HOURS	6	9.827	6.8424	9.365	2.90	21.50	7.813	91.1
		2 HOURS	6	13.618	8.4192	10.360	8.59	30.60	12.192	49.4
		3 HOURS	6	15.400	6.6792	13.250	10.40	28.20	14.451	38.4
		4 HOURS	6	15.070	7.0169	11.900	8.80	24.20	13.841	46.6
		6 HOURS	6	11.365	5.7508	8.030	7.36	19.90	10.326	49.0
		8 HOURS	6	8.290	3.7761	6.440	4.94	14.00	7.660	44.4
		12 HOURS	6	5.273	1.8484	4.475	3.74	8.13	5.031	33.7
		16 HOURS	6	3.393	1.0942	3.170	1.89	4.67	3.239	35.1
	Day 2	24 HOURS	6	2.053	0.5646	2.000	1.18	2.73	1.982	30.9
		32 HOURS	6	0.828	0.6490	1.140	0.00	1.39	1.238	10.2
	Day 3	48 HOURS*	6				0.00	0.00		
	Day 8	168 HOURS*	6				0.00	0.00		
	Day 15	336 HOURS*	6				0.00	0.00		

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
* Mean concentrations are only calculated for time points with at least 50% valid values (i.e. quantifiable and non-missing).
Geometric CV% = 100*(exp(SD^2)-1)^0.5, where SD is the standard deviation of the log-transformed data.

Source Data: ADPCSAD; Reference listings(s): 16.2.6.2 SDTM Date: 04AUG2020 16:09
Program Name: tconcentration.sas Analysis Date: 20AUG2020 17:48

Table 14.2.1.1
Summary of Plasma LB-102 and Amisulpride Concentrations (ng/mL) by Treatment
Pharmacokinetic Population: Part A (SAD)

Treatment Analyte (Unit)	Visit	Scheduled Time Point	N	Mean	Standard Deviation	Median	Minimum	Maximum	Geometric Mean	Geometric CV%
LB-102 200 mg										
LB-102 (ng/mL)										
	Day 1	PRE DOSE*	6				0.00	0.00		
		15 MINS	6	7.252	9.1078	3.405	0.00	22.30	7.597	140.4
		30 MINS	6	350.833	257.0707	429.000	32.70	623.00	212.239	221.4
		45 MINS	6	511.500	224.2898	541.500	241.00	790.00	465.037	53.2
		1 HOUR	6	621.167	77.1321	643.000	491.00	702.00	616.890	13.2
		1.5 HOURS	6	926.833	306.5181	857.500	569.00	1300.00	885.133	34.3
		2 HOURS	6	840.333	234.3883	752.000	637.00	1200.00	815.258	27.0
		3 HOURS	6	836.667	89.2808	825.000	737.00	984.00	832.820	10.5
		4 HOURS	6	603.333	79.2835	591.000	520.00	749.00	599.285	12.6
		6 HOURS	6	377.833	62.0207	353.500	313.00	483.00	373.864	15.8
		8 HOURS	6	244.667	43.7935	237.000	198.00	304.00	241.467	17.9
		12 HOURS	5	127.420	32.8433	109.000	95.10	172.00	124.188	25.5
		16 HOURS	6	86.267	22.2788	90.000	55.60	108.00	83.701	28.0
	Day 2	24 HOURS	6	55.633	9.1226	56.550	43.30	66.50	54.994	16.9
		32 HOURS	6	34.733	6.9833	34.150	25.70	43.60	34.142	20.6
	Day 3	48 HOURS	6	14.768	5.0599	16.250	8.07	19.90	13.931	40.6

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
* Mean concentrations are only calculated for time points with at least 50% valid values (i.e. quantifiable and non-missing).
Geometric CV% = 100*(exp(SD^2)-1)^0.5, where SD is the standard deviation of the log-transformed data.

Source Data: ADPCSAD; Reference listings(s): 16.2.6.2 SDTM Date: 04AUG2020 16:09
Program Name: tconcentration.sas Analysis Date: 20AUG2020 17:48

Table 14.2.1.1
Summary of Plasma LB-102 and Amisulpride Concentrations (ng/mL) by Treatment
Pharmacokinetic Population: Part A (SAD)

Treatment Analyte (Unit)	Visit	Scheduled Time Point	N	Mean	Standard Deviation	Median	Minimum	Maximum	Geometric Mean	Geometric CV%
LB-102 200 mg										
Amisulpride (ng/mL)										
	Day 1	PRE DOSE*	6				0.00	0.00		
		15 MINS*	6				0.00	0.00		
		30 MINS	6	4.742	4.7564	3.775	0.00	11.10	6.260	65.4
		45 MINS	6	14.342	12.6149	12.750	1.37	37.20	9.379	165.9
		1 HOUR	6	16.537	10.1583	15.250	3.62	34.80	13.696	85.0
		1.5 HOURS	6	25.947	20.0435	20.750	8.48	65.10	21.242	75.1
		2 HOURS	6	25.437	18.0349	21.000	6.32	59.90	20.809	82.0
		3 HOURS	6	24.635	13.2132	22.850	7.41	48.30	21.546	66.2
		4 HOURS	6	19.227	10.2395	17.950	5.96	37.40	16.860	65.1
		6 HOURS	6	13.630	6.3074	12.850	4.48	24.00	12.216	59.8
		8 HOURS	6	9.608	3.4240	10.205	3.62	13.80	8.909	49.6
		12 HOURS	5	5.728	1.8758	6.020	2.62	7.41	5.398	43.8
		16 HOURS	6	4.563	1.5596	4.840	1.84	6.64	4.268	46.0
	Day 2	24 HOURS	6	3.145	1.0747	3.210	1.36	4.61	2.954	43.5
		32 HOURS	6	1.755	0.9098	2.075	0.00	2.38	2.084	16.7
	Day 3	48 HOURS	6	0.648	0.7309	0.525	0.00	1.59	1.278	21.1

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
* Mean concentrations are only calculated for time points with at least 50% valid values (i.e. quantifiable and non-missing).
Geometric CV% = 100*(exp(SD^2)-1)^0.5, where SD is the standard deviation of the log-transformed data.

Source Data: ADPCSAD; Reference listings(s): 16.2.6.2
SDTM Date: 04AUG2020 16:09
Program Name: tconcentration.sas
Analysis Date: 20AUG2020 17:48

Table 14.2.1.2
Summary of Plasma LB-102 and Amisulpride Concentrations (ng/mL) by Treatment
Pharmacokinetic Population: Part B (MAD)

Treatment Analyte (Unit)	Visit	Scheduled Time point	N	Mean	Standard Deviation	Median	Minimum	Maximum	Geometric Mean	Geometric CV%
LB-102 50 mg BID										
LB-102 (ng/mL)	Day 1 Dose 1	PRE DOSE*	6				0.0	0.0		
		0.25 HOUR*	6				0.0	2.9		
		0.5 HOUR	6	22.78	19.924	20.55	0.0	55.0	22.25	85.8
		0.75 HOUR	6	54.18	46.323	50.60	8.7	136.0	36.72	143.6
		1 HOUR	6	69.97	43.609	60.95	26.6	133.0	58.53	75.4
		1.5 HOURS	6	93.70	38.204	85.90	47.4	144.0	87.07	44.7
		2 HOURS	6	111.08	39.568	112.15	46.5	157.0	103.67	46.0
		3 HOURS	6	121.13	18.767	123.50	95.8	143.0	119.88	16.0
		4 HOURS	6	100.88	17.542	106.00	73.0	118.0	99.50	18.8
		6 HOURS	6	70.00	9.812	71.25	52.3	80.3	69.37	15.3
		8 HOURS	6	50.72	6.155	52.30	41.7	56.2	50.39	12.6
		12 HOURS	6	28.95	4.393	27.35	26.2	37.7	28.71	13.9
	Day 1 Dose 2	PRE DOSE	6	28.95	4.393	27.35	26.2	37.7	28.71	13.9
		4 HOURS	6	94.17	16.508	91.05	75.6	122.0	93.02	17.1
		12 HOURS	6	44.65	8.572	43.70	33.6	57.9	43.97	19.3
	Day 2	PRE DOSE	6	44.65	8.572	43.70	33.6	57.9	43.97	19.3
	Day 3	PRE DOSE	6	64.48	17.993	61.30	47.3	98.8	62.70	25.5
	Day 4	PRE DOSE	6	67.75	16.302	68.70	49.3	90.5	66.09	25.0
	Day 5	PRE DOSE	6	68.18	14.572	69.05	46.7	89.9	66.84	22.5

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
* Mean concentrations are only calculated for time points with at least 50% valid values (i.e. quantifiable and non-missing).
Geometric CV% = 100*(exp(SD^2)-1)^0.5, where SD is the standard deviation of the log-transformed data.

Source Data: ADPCMAD; Reference Listing: 16.2.6.3 SDTM Date: 04AUG2020 16:09
Program Name: SumCon_mad.sas Analysis Date: 24AUG2020 18:30

Table 14.2.1.2
Summary of Plasma LB-102 and Amisulpride Concentrations (ng/mL) by Treatment
Pharmacokinetic Population: Part B (MAD)

Treatment Analyte (Unit)	Visit	Scheduled Time point	N	Mean	Standard Deviation	Median	Minimum	Maximum	Geometric Mean	Geometric CV%
LB-102 50 mg BID										
LB-102 (ng/mL)	Day 6	PRE DOSE	6	70.95	13.705	71.50	52.9	87.8	69.82	20.0
	Day 7	PRE DOSE	6	69.38	7.919	68.40	59.2	79.3	69.01	11.5
		0.25 HOUR	6	79.98	26.114	71.60	62.7	131.0	77.13	28.6
		0.5 HOUR	6	94.57	25.207	82.60	70.4	127.0	91.96	25.9
		0.75 HOUR	6	120.55	39.116	110.50	78.6	187.0	115.70	31.7
		1 HOUR	6	153.82	66.545	138.00	91.9	281.0	144.14	39.3
		1.5 HOURS	6	170.00	52.211	161.00	109.0	261.0	163.80	30.2
		2 HOURS	6	197.67	58.171	205.50	124.0	261.0	189.95	32.5
		3 HOURS	6	200.50	20.177	192.00	181.0	231.0	199.68	9.8
		4 HOURS	6	167.83	17.186	167.00	148.0	193.0	167.11	10.2
		6 HOURS	6	125.83	18.313	121.50	109.0	161.0	124.83	13.6
		8 HOURS	6	99.35	14.876	95.30	84.3	127.0	98.50	14.2
		12 HOURS	6	62.38	10.412	60.25	50.1	79.8	61.69	16.3
		16 HOURS	6	41.92	9.047	41.35	32.6	51.2	41.10	22.1
		24 HOURS	6	26.58	6.804	28.10	17.5	33.3	25.79	28.1
		32 HOURS	6	16.63	4.058	18.65	10.8	20.4	16.17	27.5
		48 HOURS	6	7.80	2.486	8.08	4.3	11.1	7.44	36.0
Amisulpride (ng/mL)	Day 1 Dose 1	PRE DOSE*	6				0.0	0.0		
		0.25 HOUR*	6				0.0	0.0		
		0.5 HOUR*	6				0.0	1.2		
		0.75 HOUR	6	1.25	1.304	1.07	0.0	3.5	1.65	61.0
		1 HOUR	6	1.98	1.962	1.80	0.0	5.1	2.67	55.9
		1.5 HOURS	6	3.26	1.522	3.02	1.5	5.8	2.97	51.0
		2 HOURS	6	4.14	1.681	4.12	1.6	6.7	3.80	52.2
		3 HOURS	6	4.11	1.137	4.30	2.3	5.6	3.96	32.1
		4 HOURS	6	3.64	1.152	3.66	2.1	5.2	3.48	34.6
		6 HOURS	6	2.91	0.732	3.08	2.0	3.9	2.83	27.0
		8 HOURS	6	2.13	0.563	2.04	1.6	3.1	2.07	25.6
		12 HOURS	6	1.51	0.300	1.42	1.3	2.0	1.48	19.1

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
* Mean concentrations are only calculated for time points with at least 50% valid values (i.e. quantifiable and non-missing).
Geometric CV% = 100*(exp(SD^2)-1)^0.5, where SD is the standard deviation of the log-transformed data.

Table 14.2.1.2
Summary of Plasma LB-102 and Amisulpride Concentrations (ng/mL) by Treatment
Pharmacokinetic Population: Part B (MAD)

Treatment Analyte (Unit)	Visit	Scheduled Time point	N	Mean	Standard Deviation	Median	Minimum	Maximum	Geometric Mean	Geometric CV%
LB-102 50 mg BID										
Amisulpride (ng/mL)	Day 1 Dose 2	PRE DOSE	6	1.51	0.300	1.42	1.3	2.0	1.48	19.1
		4 HOURS	6	3.33	0.705	3.21	2.6	4.2	3.27	21.2
		12 HOURS	6	2.28	0.370	2.33	1.9	2.9	2.26	16.3
	Day 2	PRE DOSE	6	2.28	0.370	2.33	1.9	2.9	2.26	16.3
	Day 3	PRE DOSE	6	3.40	0.689	3.46	2.4	4.2	3.34	21.4
	Day 4	PRE DOSE	6	3.58	0.909	3.54	2.5	4.6	3.48	26.4
	Day 5	PRE DOSE	6	3.52	0.939	3.54	2.2	4.8	3.41	28.8
	Day 6	PRE DOSE	6	3.91	1.118	3.86	2.6	5.2	3.78	30.1
	Day 7	PRE DOSE	6	4.04	0.758	3.83	3.4	5.5	3.99	17.2
		0.25 HOUR	6	4.03	0.858	3.79	3.4	5.7	3.96	19.0
		0.5 HOUR	6	4.33	1.258	3.93	3.5	6.8	4.20	25.2
		0.75 HOUR	6	4.93	1.196	4.53	3.9	6.7	4.82	23.8
		1 HOUR	6	5.82	1.819	4.94	4.3	8.9	5.61	29.5
		1.5 HOURS	6	7.24	2.633	6.01	5.1	11.9	6.90	33.6
		2 HOURS	6	7.89	2.863	6.89	5.3	11.5	7.48	36.3
		3 HOURS	6	7.68	1.634	7.29	6.0	10.6	7.55	20.2
		4 HOURS	6	6.68	1.642	6.09	5.6	10.0	6.54	21.4
		6 HOURS	6	5.48	0.985	5.33	4.5	7.2	5.41	17.4
		8 HOURS	6	4.72	0.980	4.56	3.5	6.3	4.64	20.7
		12 HOURS	6	3.35	0.726	3.09	2.7	4.7	3.29	20.2
		16 HOURS	6	2.44	0.799	2.27	1.7	3.9	2.35	30.6
		24 HOURS	6	1.79	0.569	1.78	1.1	2.8	1.71	32.0
		32 HOURS	6	0.94	0.754	1.25	0.0	1.8	1.39	18.8
		48 HOURS*	6				0.0	0.0		

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
* Mean concentrations are only calculated for time points with at least 50% valid values (i.e. quantifiable and non-missing).
Geometric CV% = 100*(exp(SD^2)-1)^0.5, where SD is the standard deviation of the log-transformed data.

Table 14.2.1.2
Summary of Plasma LB-102 and Amisulpride Concentrations (ng/mL) by Treatment
Pharmacokinetic Population: Part B (MAD)

Treatment Analyte (Unit)	Visit	Scheduled Time point	N	Mean	Standard Deviation	Median	Minimum	Maximum	Geometric Mean	Geometric CV%
LB-102 75 mg BID										
LB-102 (ng/mL)	Day 1 Dose 1	PRE DOSE*	6				0.0	0.0		
		0.25 HOUR*	6				0.0	3.4		
		0.5 HOUR	6	93.25	81.418	95.35	0.0	216.0	82.16	139.1
		0.75 HOUR	6	167.64	115.187	149.50	8.9	327.0	109.70	213.0
		1 HOUR	6	180.60	104.756	150.50	50.6	343.0	153.39	74.5
		1.5 HOURS	6	197.58	124.909	180.50	35.5	386.0	156.40	101.5
		2 HOURS	6	236.17	92.562	226.50	113.0	388.0	220.72	43.1
		3 HOURS	6	249.00	38.987	233.00	211.0	314.0	246.62	15.0
		4 HOURS	6	194.83	45.415	189.00	146.0	270.0	190.66	22.9
		6 HOURS	6	128.67	20.983	126.00	105.0	160.0	127.27	16.2
		8 HOURS	6	83.22	10.804	80.30	72.7	98.8	82.65	12.8
		12 HOURS	6	44.15	6.243	43.55	35.7	53.2	43.78	14.3
	Day 1 Dose 2	PRE DOSE	6	44.15	6.243	43.55	35.7	53.2	43.78	14.3
		4 HOURS	6	185.17	56.634	180.50	131.0	289.0	178.81	28.8
		12 HOURS	6	74.22	16.240	74.15	48.8	96.5	72.63	23.7
	Day 2	PRE DOSE	6	74.22	16.240	74.15	48.8	96.5	72.63	23.7
	Day 3	PRE DOSE	6	106.58	32.648	94.75	76.8	164.0	102.91	28.8
	Day 4	PRE DOSE	5	120.66	35.569	103.00	93.3	181.0	117.08	26.9
	Day 5	PRE DOSE	5	113.96	37.404	116.00	80.2	172.0	109.40	32.4

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
* Mean concentrations are only calculated for time points with at least 50% valid values (i.e. quantifiable and non-missing).
Geometric CV% = 100*(exp(SD^2)-1)^0.5, where SD is the standard deviation of the log-transformed data.

Table 14.2.1.2
Summary of Plasma LB-102 and Amisulpride Concentrations (ng/mL) by Treatment
Pharmacokinetic Population: Part B (MAD)

Treatment Analyte (Unit)	Visit	Scheduled Time point	N	Mean	Standard Deviation	Median	Minimum	Maximum	Geometric Mean	Geometric CV%
LB-102 75 mg BID										
LB-102 (ng/mL)	Day 6 Dose 1	PRE DOSE	5	123.12	22.801	128.00	89.6	152.0	121.33	19.7
		0.25 HOUR	5	118.00	20.579	124.00	86.0	139.0	116.42	19.0
		0.5 HOUR	5	160.24	64.280	134.00	87.2	230.0	149.75	43.5
		1 HOUR	5	325.20	155.970	381.00	156.0	470.0	290.25	60.5
		2 HOURS	5	334.40	138.075	330.00	185.0	511.0	310.89	45.5
		4 HOURS	5	261.60	56.047	249.00	184.0	331.0	256.57	22.7
		8 HOURS	5	152.40	28.815	147.00	120.0	199.0	150.35	18.3
		12 HOURS	5	104.08	22.822	109.00	72.9	129.0	101.94	23.5
	Day 6 Dose 2	PRE DOSE	5	104.08	22.822	109.00	72.9	129.0	101.94	23.5
		0.25 HOUR	5	104.06	23.326	111.00	68.3	128.0	101.70	25.2
		0.5 HOUR	5	116.24	22.167	121.00	83.2	137.0	114.40	20.7
		1 HOUR	5	202.80	110.733	151.00	122.0	385.0	183.05	51.7
		2 HOURS	5	302.60	154.823	263.00	191.0	568.0	277.64	46.4
		4 HOURS	5	260.60	70.365	237.00	201.0	379.0	253.97	25.0
		6 HOURS	5	193.60	46.865	184.00	150.0	273.0	189.59	22.5
		8 HOURS	5	158.80	42.962	153.00	115.0	230.0	154.62	25.7
		12 HOURS	5	119.94	26.304	125.00	83.7	154.0	117.52	23.3
	Day 7	PRE DOSE	5	119.94	26.304	125.00	83.7	154.0	117.52	23.3
		24 HOURS	5	58.12	19.109	59.40	31.9	85.0	55.41	36.8
		32 HOURS	5	38.54	14.711	38.20	19.4	60.6	36.19	42.5
		48 HOURS	5	17.26	6.897	20.50	6.3	23.3	15.70	58.0

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
* Mean concentrations are only calculated for time points with at least 50% valid values (i.e. quantifiable and non-missing).
Geometric CV% = 100*(exp(SD^2)-1)^0.5, where SD is the standard deviation of the log-transformed data.

Table 14.2.1.2
Summary of Plasma LB-102 and Amisulpride Concentrations (ng/mL) by Treatment
Pharmacokinetic Population: Part B (MAD)

Treatment Analyte (Unit)	Visit	Scheduled Time point	N	Mean	Standard Deviation	Median	Minimum	Maximum	Geometric Mean	Geometric CV%
LB-102 75 mg BID										
Amisulpride (ng/mL)	Day 1 Dose 1	PRE DOSE*	6				0.0	0.0		
		0.25 HOUR*	6				0.0	0.0		
		0.5 HOUR	6	1.12	1.067	1.07	0.0	2.8	1.55	48.8
		0.75 HOUR	6	3.99	3.460	3.19	0.0	9.9	4.04	72.4
		1 HOUR	6	5.78	4.251	3.96	1.4	12.9	4.58	90.0
		1.5 HOURS	6	6.59	4.951	5.06	1.4	15.1	5.09	99.4
		2 HOURS	6	7.79	4.985	6.41	3.2	17.0	6.70	64.3
		3 HOURS	6	8.15	2.605	7.34	5.9	12.8	7.85	29.9
		4 HOURS	6	6.65	2.739	5.55	4.1	11.1	6.23	40.1
		6 HOURS	6	5.04	1.697	4.35	3.4	7.8	4.82	32.4
		8 HOURS	6	3.64	1.083	3.18	2.7	5.3	3.52	28.6
		12 HOURS	6	2.30	0.359	2.25	1.8	2.8	2.27	16.0
	Day 1 Dose 2	PRE DOSE	6	2.30	0.359	2.25	1.8	2.8	2.27	16.0
		4 HOURS	6	6.51	2.791	5.46	3.7	11.1	6.07	42.3
		12 HOURS	6	3.96	1.497	3.60	2.5	6.0	3.73	39.2
	Day 2	PRE DOSE	6	3.96	1.497	3.60	2.5	6.0	3.73	39.2
	Day 3	PRE DOSE	6	6.01	2.586	4.86	3.9	10.0	5.60	41.9
	Day 4	PRE DOSE	5	6.56	2.528	5.16	4.6	10.5	6.21	36.8
	Day 5	PRE DOSE	5	6.57	3.130	5.83	3.4	11.2	6.00	50.3

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
* Mean concentrations are only calculated for time points with at least 50% valid values (i.e. quantifiable and non-missing).
Geometric CV% = 100*(exp(SD^2)-1)^0.5, where SD is the standard deviation of the log-transformed data.

Table 14.2.1.2
Summary of Plasma LB-102 and Amisulpride Concentrations (ng/mL) by Treatment
Pharmacokinetic Population: Part B (MAD)

Treatment Analyte (Unit)	Visit	Scheduled Time point	N	Mean	Standard Deviation	Median	Minimum	Maximum	Geometric Mean	Geometric CV%
LB-102 75 mg BID										
Amisulpride (ng/mL)	Day 6 Dose 1	PRE DOSE	5	6.86	2.750	5.96	4.2	10.4	6.44	41.7
		0.25 HOUR	5	6.68	2.642	5.46	4.3	10.1	6.29	40.3
		0.5 HOUR	5	7.43	3.535	5.58	4.5	11.8	6.80	49.5
		1 HOUR	5	12.41	6.992	9.36	6.2	20.2	10.88	62.7
		2 HOURS	5	11.87	6.260	7.96	6.8	19.2	10.63	55.5
		4 HOURS	5	10.70	4.999	8.20	6.1	16.6	9.81	49.2
		8 HOURS	5	7.52	3.307	5.52	4.6	12.0	6.98	44.5
		12 HOURS	5	5.67	1.972	4.91	3.7	8.6	5.42	34.9
	Day 6 Dose 2	PRE DOSE	5	5.67	1.972	4.91	3.7	8.6	5.42	34.9
		0.25 HOUR	5	5.37	1.704	5.01	3.3	7.7	5.15	33.3
		0.5 HOUR	5	5.60	1.961	4.78	3.7	8.2	5.34	35.4
		1 HOUR	5	7.54	3.974	5.45	4.2	13.4	6.79	53.6
		2 HOURS	5	10.68	6.846	6.46	6.0	21.7	9.25	62.8
		4 HOURS	5	10.93	5.219	7.83	6.5	18.6	10.04	47.7
		6 HOURS	5	9.11	3.876	7.02	5.7	14.7	8.51	42.4
		8 HOURS	5	8.00	3.605	6.49	4.8	13.4	7.41	45.1
		12 HOURS	5	6.52	2.399	5.65	4.0	9.9	6.18	37.5
	Day 7	PRE DOSE	5	6.52	2.399	5.65	4.0	9.9	6.18	37.5
		24 HOURS	5	3.73	1.052	4.19	2.2	4.7	3.59	32.3
		32 HOURS	5	2.38	0.852	2.68	1.2	3.4	2.24	42.2
		48 HOURS	5	1.03	0.964	1.34	0.0	1.9	1.69	20.2

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
* Mean concentrations are only calculated for time points with at least 50% valid values (i.e. quantifiable and non-missing).
Geometric CV% = 100*(exp(SD^2)-1)^0.5, where SD is the standard deviation of the log-transformed data.

Table 14.2.1.2
Summary of Plasma LB-102 and Amisulpride Concentrations (ng/mL) by Treatment
Pharmacokinetic Population: Part B (MAD)

Treatment Analyte (Unit)	Visit	Scheduled Time point	N	Mean	Standard Deviation	Median	Minimum	Maximum	Geometric Mean	Geometric CV%
LB-102 100 mg BID										
LB-102 (ng/mL)	Day 1 Dose 1	PRE DOSE*	6				0.0	0.0		
		0.25 HOUR*	6				0.0	34.9		
		0.5 HOUR	6	87.55	116.610	54.70	0.0	317.0	66.31	140.8
		0.75 HOUR	6	110.91	76.560	117.50	2.4	209.0	62.08	387.3
		1 HOUR	6	128.81	89.998	117.50	6.9	281.0	85.38	207.9
		1.5 HOURS	6	159.67	57.417	151.50	107.0	266.0	152.29	33.6
		2 HOURS	6	257.50	94.490	234.00	166.0	371.0	243.25	38.3
		3 HOURS	6	306.17	70.901	299.50	214.0	396.0	299.21	24.0
		4 HOURS	6	244.00	47.514	247.50	186.0	291.0	240.05	20.1
		6 HOURS	6	158.00	28.907	149.50	132.0	202.0	155.89	17.9
		8 HOURS	6	111.95	30.579	104.00	83.9	170.0	108.98	24.9
		12 HOURS	6	58.88	12.193	53.55	50.7	82.3	57.97	18.8
	Day 1 Dose 2	PRE DOSE	6	58.88	12.193	53.55	50.7	82.3	57.97	18.8
		4 HOURS	6	176.67	63.497	177.50	110.0	281.0	167.43	37.2
		12 HOURS	6	106.20	21.476	108.00	73.6	136.0	104.29	21.5
	Day 2	PRE DOSE	6	106.20	21.476	108.00	73.6	136.0	104.29	21.5
	Day 3	PRE DOSE	5	136.56	30.742	135.00	88.8	172.0	133.44	25.3
Amisulpride (ng/mL)	Day 1 Dose 1	PRE DOSE*	6				0.0	0.0		
		0.25 HOUR*	6				0.0	0.0		
		0.5 HOUR*	6				0.0	7.9		
		0.75 HOUR	6	3.15	3.213	2.84	0.0	8.3	4.11	70.7
		1 HOUR	6	3.92	2.279	4.50	0.0	6.4	4.53	32.2
		1.5 HOURS	6	4.78	1.766	4.91	1.9	6.7	4.42	49.2
		2 HOURS	6	7.35	2.689	6.77	4.2	12.3	6.98	35.7
		3 HOURS	6	9.38	3.248	8.45	6.2	15.6	8.99	31.4
		4 HOURS	6	7.85	3.155	6.70	5.1	14.0	7.43	35.3
		6 HOURS	6	5.69	1.693	5.13	4.1	8.9	5.52	27.0
		8 HOURS	6	4.18	0.996	3.91	3.1	5.9	4.09	23.1
		12 HOURS	6	2.77	0.622	2.84	2.0	3.5	2.71	23.8

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
* Mean concentrations are only calculated for time points with at least 50% valid values (i.e. quantifiable and non-missing).
Geometric CV% = 100*(exp(SD^2)-1)^0.5, where SD is the standard deviation of the log-transformed data.

Table 14.2.1.2
Summary of Plasma LB-102 and Amisulpride Concentrations (ng/mL) by Treatment
Pharmacokinetic Population: Part B (MAD)

Treatment Analyte (Unit)	Visit	Scheduled Time point	N	Mean	Standard Deviation	Median	Minimum	Maximum	Geometric Mean	Geometric CV%
LB-102 100 mg BID										
Amisulpride (ng/mL)	Day 1 Dose 2	PRE DOSE	6	2.77	0.622	2.84	2.0	3.5	2.71	23.8
		4 HOURS	6	6.31	2.675	5.77	3.1	10.5	5.85	45.5
		12 HOURS	6	4.91	0.928	4.84	4.0	5.9	4.83	19.2
	Day 2	PRE DOSE	6	4.91	0.928	4.84	4.0	5.9	4.83	19.2
	Day 3	PRE DOSE	5	7.08	1.177	7.52	5.4	8.1	7.00	17.6

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
* Mean concentrations are only calculated for time points with at least 50% valid values (i.e. quantifiable and non-missing).
Geometric CV% = 100*(exp(SD^2)-1)^0.5, where SD is the standard deviation of the log-transformed data.

Source Data: ADPCMAD; Reference Listing: 16.2.6.3 SDTM Date: 04AUG2020 16:09
Program Name: SumCon_mad.sas Analysis Date: 24AUG2020 18:30

Table 14.2.1.2
Summary of Plasma LB-102 and Amisulpride Concentrations (ng/mL) by Treatment
Pharmacokinetic Population: Part B (MAD)

Treatment Analyte (Unit)	Visit	Scheduled Time point	N	Mean	Standard Deviation	Median	Minimum	Maximum	Geometric Mean	Geometric CV%
LB-102 50 mg BID										
LB-102 (ng/mL)	Day 1 Dose 1	PRE DOSE*	6				0.0	0.0		
		0.25 HOUR*	6				0.0	2.9		
		0.5 HOUR	6	22.78	19.924	20.55	0.0	55.0	22.25	85.8
		0.75 HOUR	6	54.18	46.323	50.60	8.7	136.0	36.72	143.6
		1 HOUR	6	69.97	43.609	60.95	26.6	133.0	58.53	75.4
		1.5 HOURS	6	93.70	38.204	85.90	47.4	144.0	87.07	44.7
		2 HOURS	6	111.08	39.568	112.15	46.5	157.0	103.67	46.0
		3 HOURS	6	121.13	18.767	123.50	95.8	143.0	119.88	16.0
		4 HOURS	6	100.88	17.542	106.00	73.0	118.0	99.50	18.8
		6 HOURS	6	70.00	9.812	71.25	52.3	80.3	69.37	15.3
		8 HOURS	6	50.72	6.155	52.30	41.7	56.2	50.39	12.6
		12 HOURS	6	28.95	4.393	27.35	26.2	37.7	28.71	13.9
	Day 1 Dose 2	PRE DOSE	6	28.95	4.393	27.35	26.2	37.7	28.71	13.9
		4 HOURS	6	94.17	16.508	91.05	75.6	122.0	93.02	17.1
		12 HOURS	6	44.65	8.572	43.70	33.6	57.9	43.97	19.3
	Day 2	PRE DOSE	6	44.65	8.572	43.70	33.6	57.9	43.97	19.3
	Day 3	PRE DOSE	6	64.48	17.993	61.30	47.3	98.8	62.70	25.5

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
* Mean concentrations are only calculated for time points with at least 50% valid values (i.e. quantifiable and non-missing).
Geometric CV% = 100*(exp(SD^2)-1)^0.5, where SD is the standard deviation of the log-transformed data.

Source Data: ADPCMAD; Reference Listing: 16.2.6.3 SDTM Date: 04AUG2020 16:09
Program Name: SumCon_mad.sas Analysis Date: 09SEP2020 15:40

Table 14.2.1.2
Summary of Plasma LB-102 and Amisulpride Concentrations (ng/mL) by Treatment
Pharmacokinetic Population: Part B (MAD)

Treatment Analyte (Unit)	Visit	Scheduled Time point	N	Mean	Standard Deviation	Median	Minimum	Maximum	Geometric Mean	Geometric CV%
LB-102 50 mg BID										
LB-102 (ng/mL)	Day 4	PRE DOSE	6	67.75	16.302	68.70	49.3	90.5	66.09	25.0
	Day 5	PRE DOSE	6	68.18	14.572	69.05	46.7	89.9	66.84	22.5
	Day 6	PRE DOSE	6	70.95	13.705	71.50	52.9	87.8	69.82	20.0
	Day 7	PRE DOSE	6	69.38	7.919	68.40	59.2	79.3	69.01	11.5
		0.25 HOUR	6	79.98	26.114	71.60	62.7	131.0	77.13	28.6
		0.5 HOUR	6	94.57	25.207	82.60	70.4	127.0	91.96	25.9
		0.75 HOUR	6	120.55	39.116	110.50	78.6	187.0	115.70	31.7
		1 HOUR	6	153.82	66.545	138.00	91.9	281.0	144.14	39.3
		1.5 HOURS	6	170.00	52.211	161.00	109.0	261.0	163.80	30.2
		2 HOURS	6	197.67	58.171	205.50	124.0	261.0	189.95	32.5
		3 HOURS	6	200.50	20.177	192.00	181.0	231.0	199.68	9.8
		4 HOURS	6	167.83	17.186	167.00	148.0	193.0	167.11	10.2
		6 HOURS	6	125.83	18.313	121.50	109.0	161.0	124.83	13.6
		8 HOURS	6	99.35	14.876	95.30	84.3	127.0	98.50	14.2
		12 HOURS	6	62.38	10.412	60.25	50.1	79.8	61.69	16.3
		16 HOURS	6	41.92	9.047	41.35	32.6	51.2	41.10	22.1
		24 HOURS	6	26.58	6.804	28.10	17.5	33.3	25.79	28.1
		32 HOURS	6	16.63	4.058	18.65	10.8	20.4	16.17	27.5
		48 HOURS	6	7.80	2.486	8.08	4.3	11.1	7.44	36.0

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
* Mean concentrations are only calculated for time points with at least 50% valid values (i.e. quantifiable and non-missing).
Geometric CV% = 100*(exp(SD^2)-1)^0.5, where SD is the standard deviation of the log-transformed data.

Table 14.2.1.2
Summary of Plasma LB-102 and Amisulpride Concentrations (ng/mL) by Treatment
Pharmacokinetic Population: Part B (MAD)

Treatment Analyte (Unit)	Visit	Scheduled Time point	N	Mean	Standard Deviation	Median	Minimum	Maximum	Geometric Mean	Geometric CV%
LB-102 50 mg BID										
Amisulpride (ng/mL)	Day 1 Dose 1	PRE DOSE*	6				0.0	0.0		
		0.25 HOUR*	6				0.0	0.0		
		0.5 HOUR*	6				0.0	1.2		
		0.75 HOUR	6	1.25	1.304	1.07	0.0	3.5	1.65	61.0
		1 HOUR	6	1.98	1.962	1.80	0.0	5.1	2.67	55.9
		1.5 HOURS	6	3.26	1.522	3.02	1.5	5.8	2.97	51.0
		2 HOURS	6	4.14	1.681	4.12	1.6	6.7	3.80	52.2
		3 HOURS	6	4.11	1.137	4.30	2.3	5.6	3.96	32.1
		4 HOURS	6	3.64	1.152	3.66	2.1	5.2	3.48	34.6
		6 HOURS	6	2.91	0.732	3.08	2.0	3.9	2.83	27.0
		8 HOURS	6	2.13	0.563	2.04	1.6	3.1	2.07	25.6
		12 HOURS	6	1.51	0.300	1.42	1.3	2.0	1.48	19.1
	Day 1 Dose 2	PRE DOSE	6	1.51	0.300	1.42	1.3	2.0	1.48	19.1
		4 HOURS	6	3.33	0.705	3.21	2.6	4.2	3.27	21.2
		12 HOURS	6	2.28	0.370	2.33	1.9	2.9	2.26	16.3
	Day 2	PRE DOSE	6	2.28	0.370	2.33	1.9	2.9	2.26	16.3
	Day 3	PRE DOSE	6	3.40	0.689	3.46	2.4	4.2	3.34	21.4

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
* Mean concentrations are only calculated for time points with at least 50% valid values (i.e. quantifiable and non-missing).
Geometric CV% = 100*(exp(SD^2)-1)^0.5, where SD is the standard deviation of the log-transformed data.

Source Data: ADPCMAD; Reference Listing: 16.2.6.3 SDTM Date: 04AUG2020 16:09
Program Name: SumCon_mad.sas Analysis Date: 09SEP2020 15:40

Table 14.2.1.2
Summary of Plasma LB-102 and Amisulpride Concentrations (ng/mL) by Treatment
Pharmacokinetic Population: Part B (MAD)

Treatment Analyte (Unit)	Visit	Scheduled Time point	N	Mean	Standard Deviation	Median	Minimum	Maximum	Geometric Mean	Geometric CV%
LB-102 50 mg BID										
Amisulpride (ng/mL)	Day 4	PRE DOSE	6	3.58	0.909	3.54	2.5	4.6	3.48	26.4
	Day 5	PRE DOSE	6	3.52	0.939	3.54	2.2	4.8	3.41	28.8
	Day 6	PRE DOSE	6	3.91	1.118	3.86	2.6	5.2	3.78	30.1
	Day 7	PRE DOSE	6	4.04	0.758	3.83	3.4	5.5	3.99	17.2
		0.25 HOUR	6	4.03	0.858	3.79	3.4	5.7	3.96	19.0
		0.5 HOUR	6	4.33	1.258	3.93	3.5	6.8	4.20	25.2
		0.75 HOUR	6	4.93	1.196	4.53	3.9	6.7	4.82	23.8
		1 HOUR	6	5.82	1.819	4.94	4.3	8.9	5.61	29.5
		1.5 HOURS	6	7.24	2.633	6.01	5.1	11.9	6.90	33.6
		2 HOURS	6	7.89	2.863	6.89	5.3	11.5	7.48	36.3
		3 HOURS	6	7.68	1.634	7.29	6.0	10.6	7.55	20.2
		4 HOURS	6	6.68	1.642	6.09	5.6	10.0	6.54	21.4
		6 HOURS	6	5.48	0.985	5.33	4.5	7.2	5.41	17.4
		8 HOURS	6	4.72	0.980	4.56	3.5	6.3	4.64	20.7
		12 HOURS	6	3.35	0.726	3.09	2.7	4.7	3.29	20.2
		16 HOURS	6	2.44	0.799	2.27	1.7	3.9	2.35	30.6
		24 HOURS	6	1.79	0.569	1.78	1.1	2.8	1.71	32.0
		32 HOURS	6	0.94	0.754	1.25	0.0	1.8	1.39	18.8
		48 HOURS*	6				0.0	0.0		

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
* Mean concentrations are only calculated for time points with at least 50% valid values (i.e. quantifiable and non-missing).
Geometric CV% = 100*(exp(SD^2)-1)^0.5, where SD is the standard deviation of the log-transformed data.

Source Data: ADPCMAD; Reference Listing: 16.2.6.3 SDTM Date: 04AUG2020 16:09
Program Name: SumCon_mad.sas Analysis Date: 09SEP2020 15:40

Table 14.2.1.2
Summary of Plasma LB-102 and Amisulpride Concentrations (ng/mL) by Treatment
Pharmacokinetic Population: Part B (MAD)

Treatment Analyte (Unit)	Visit	Scheduled Time point	N	Mean	Standard Deviation	Median	Minimum	Maximum	Geometric Mean	Geometric CV%
LB-102 75 mg BID										
LB-102 (ng/mL)	Day 1 Dose 1	PRE DOSE*	6				0.0	0.0		
		0.25 HOUR*	6				0.0	3.4		
		0.5 HOUR	6	93.25	81.418	95.35	0.0	216.0	82.16	139.1
		0.75 HOUR	6	167.64	115.187	149.50	8.9	327.0	109.70	213.0
		1 HOUR	6	180.60	104.756	150.50	50.6	343.0	153.39	74.5
		1.5 HOURS	6	197.58	124.909	180.50	35.5	386.0	156.40	101.5
		2 HOURS	6	236.17	92.562	226.50	113.0	388.0	220.72	43.1
		3 HOURS	6	249.00	38.987	233.00	211.0	314.0	246.62	15.0
		4 HOURS	6	194.83	45.415	189.00	146.0	270.0	190.66	22.9
		6 HOURS	6	128.67	20.983	126.00	105.0	160.0	127.27	16.2
		8 HOURS	6	83.22	10.804	80.30	72.7	98.8	82.65	12.8
		12 HOURS	6	44.15	6.243	43.55	35.7	53.2	43.78	14.3
	Day 1 Dose 2	PRE DOSE	6	44.15	6.243	43.55	35.7	53.2	43.78	14.3
		4 HOURS	6	185.17	56.634	180.50	131.0	289.0	178.81	28.8
		12 HOURS	6	74.22	16.240	74.15	48.8	96.5	72.63	23.7
	Day 2	PRE DOSE	6	74.22	16.240	74.15	48.8	96.5	72.63	23.7
	Day 3	PRE DOSE	6	106.58	32.648	94.75	76.8	164.0	102.91	28.8

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
* Mean concentrations are only calculated for time points with at least 50% valid values (i.e. quantifiable and non-missing).
Geometric CV% = 100*(exp(SD^2)-1)^0.5, where SD is the standard deviation of the log-transformed data.

Source Data: ADPCMAD; Reference Listing: 16.2.6.3 SDTM Date: 04AUG2020 16:09
Program Name: SumCon_mad.sas Analysis Date: 09SEP2020 15:40

Table 14.2.1.2
Summary of Plasma LB-102 and Amisulpride Concentrations (ng/mL) by Treatment
Pharmacokinetic Population: Part B (MAD)

Treatment Analyte (Unit)	Visit	Scheduled Time point	N	Mean	Standard Deviation	Median	Minimum	Maximum	Geometric Mean	Geometric CV%
LB-102 75 mg BID										
LB-102 (ng/mL)	Day 4	PRE DOSE	5	120.66	35.569	103.00	93.3	181.0	117.08	26.9
	Day 5	PRE DOSE	5	113.96	37.404	116.00	80.2	172.0	109.40	32.4
	Day 6 Dose 1	PRE DOSE	5	123.12	22.801	128.00	89.6	152.0	121.33	19.7
		0.25 HOUR	5	118.00	20.579	124.00	86.0	139.0	116.42	19.0
		0.5 HOUR	5	160.24	64.280	134.00	87.2	230.0	149.75	43.5
		1 HOUR	5	325.20	155.970	381.00	156.0	470.0	290.25	60.5
		2 HOURS	5	334.40	138.075	330.00	185.0	511.0	310.89	45.5
		4 HOURS	5	261.60	56.047	249.00	184.0	331.0	256.57	22.7
		8 HOURS	5	152.40	28.815	147.00	120.0	199.0	150.35	18.3
		12 HOURS	5	104.08	22.822	109.00	72.9	129.0	101.94	23.5
	Day 6 Dose 2	PRE DOSE	5	104.08	22.822	109.00	72.9	129.0	101.94	23.5
		0.25 HOUR	5	104.06	23.326	111.00	68.3	128.0	101.70	25.2
		0.5 HOUR	5	116.24	22.167	121.00	83.2	137.0	114.40	20.7
		1 HOUR	5	202.80	110.733	151.00	122.0	385.0	183.05	51.7
		2 HOURS	5	302.60	154.823	263.00	191.0	568.0	277.64	46.4
		4 HOURS	5	260.60	70.365	237.00	201.0	379.0	253.97	25.0
		6 HOURS	5	193.60	46.865	184.00	150.0	273.0	189.59	22.5
		8 HOURS	5	158.80	42.962	153.00	115.0	230.0	154.62	25.7
		12 HOURS	5	119.94	26.304	125.00	83.7	154.0	117.52	23.3

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
* Mean concentrations are only calculated for time points with at least 50% valid values (i.e. quantifiable and non-missing).
Geometric CV% = 100*(exp(SD^2)-1)^0.5, where SD is the standard deviation of the log-transformed data.

Table 14.2.1.2
Summary of Plasma LB-102 and Amisulpride Concentrations (ng/mL) by Treatment
Pharmacokinetic Population: Part B (MAD)

Treatment Analyte (Unit)	Visit	Scheduled Time point	N	Mean	Standard Deviation	Median	Minimum	Maximum	Geometric Mean	Geometric CV%
LB-102 75 mg BID										
LB-102 (ng/mL)	Day 7	PRE DOSE	5	119.94	26.304	125.00	83.7	154.0	117.52	23.3
		24 HOURS	5	58.12	19.109	59.40	31.9	85.0	55.41	36.8
		32 HOURS	5	38.54	14.711	38.20	19.4	60.6	36.19	42.5
		48 HOURS	5	17.26	6.897	20.50	6.3	23.3	15.70	58.0
Amisulpride (ng/mL)	Day 1 Dose 1	PRE DOSE*	6				0.0	0.0		
		0.25 HOUR*	6				0.0	0.0		
		0.5 HOUR	6	1.12	1.067	1.07	0.0	2.8	1.55	48.8
		0.75 HOUR	6	3.99	3.460	3.19	0.0	9.9	4.04	72.4
		1 HOUR	6	5.78	4.251	3.96	1.4	12.9	4.58	90.0
		1.5 HOURS	6	6.59	4.951	5.06	1.4	15.1	5.09	99.4
		2 HOURS	6	7.79	4.985	6.41	3.2	17.0	6.70	64.3
		3 HOURS	6	8.15	2.605	7.34	5.9	12.8	7.85	29.9
		4 HOURS	6	6.65	2.739	5.55	4.1	11.1	6.23	40.1
		6 HOURS	6	5.04	1.697	4.35	3.4	7.8	4.82	32.4
		8 HOURS	6	3.64	1.083	3.18	2.7	5.3	3.52	28.6
		12 HOURS	6	2.30	0.359	2.25	1.8	2.8	2.27	16.0
	Day 1 Dose 2	PRE DOSE	6	2.30	0.359	2.25	1.8	2.8	2.27	16.0
		4 HOURS	6	6.51	2.791	5.46	3.7	11.1	6.07	42.3
		12 HOURS	6	3.96	1.497	3.60	2.5	6.0	3.73	39.2

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
* Mean concentrations are only calculated for time points with at least 50% valid values (i.e. quantifiable and non-missing).
Geometric CV% = 100*(exp(SD^2)-1)^0.5, where SD is the standard deviation of the log-transformed data.

Source Data: ADPCMAD; Reference Listing: 16.2.6.3 SDTM Date: 04AUG2020 16:09
Program Name: SumCon_mad.sas Analysis Date: 09SEP2020 15:40

Table 14.2.1.2
Summary of Plasma LB-102 and Amisulpride Concentrations (ng/mL) by Treatment
Pharmacokinetic Population: Part B (MAD)

Treatment Analyte (Unit)	Visit	Scheduled Time point	N	Mean	Standard Deviation	Median	Minimum	Maximum	Geometric Mean	Geometric CV%
LB-102 75 mg BID										
Amisulpride (ng/mL)	Day 2	PRE DOSE	6	3.96	1.497	3.60	2.5	6.0	3.73	39.2
	Day 3	PRE DOSE	6	6.01	2.586	4.86	3.9	10.0	5.60	41.9
	Day 4	PRE DOSE	5	6.56	2.528	5.16	4.6	10.5	6.21	36.8
	Day 5	PRE DOSE	5	6.57	3.130	5.83	3.4	11.2	6.00	50.3
	Day 6 Dose 1	PRE DOSE	5	6.86	2.750	5.96	4.2	10.4	6.44	41.7
		0.25 HOUR	5	6.68	2.642	5.46	4.3	10.1	6.29	40.3
		0.5 HOUR	5	7.43	3.535	5.58	4.5	11.8	6.80	49.5
		1 HOUR	5	12.41	6.992	9.36	6.2	20.2	10.88	62.7
		2 HOURS	5	11.87	6.260	7.96	6.8	19.2	10.63	55.5
		4 HOURS	5	10.70	4.999	8.20	6.1	16.6	9.81	49.2
		8 HOURS	5	7.52	3.307	5.52	4.6	12.0	6.98	44.5
		12 HOURS	5	5.67	1.972	4.91	3.7	8.6	5.42	34.9
	Day 6 Dose 2	PRE DOSE	5	5.67	1.972	4.91	3.7	8.6	5.42	34.9
		0.25 HOUR	5	5.37	1.704	5.01	3.3	7.7	5.15	33.3
		0.5 HOUR	5	5.60	1.961	4.78	3.7	8.2	5.34	35.4
		1 HOUR	5	7.54	3.974	5.45	4.2	13.4	6.79	53.6
		2 HOURS	5	10.68	6.846	6.46	6.0	21.7	9.25	62.8
		4 HOURS	5	10.93	5.219	7.83	6.5	18.6	10.04	47.7
		6 HOURS	5	9.11	3.876	7.02	5.7	14.7	8.51	42.4
		8 HOURS	5	8.00	3.605	6.49	4.8	13.4	7.41	45.1
		12 HOURS	5	6.52	2.399	5.65	4.0	9.9	6.18	37.5

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
* Mean concentrations are only calculated for time points with at least 50% valid values (i.e. quantifiable and non-missing).
Geometric CV% = 100*(exp(SD^2)-1)^0.5, where SD is the standard deviation of the log-transformed data.

Table 14.2.1.2
Summary of Plasma LB-102 and Amisulpride Concentrations (ng/mL) by Treatment
Pharmacokinetic Population: Part B (MAD)

Treatment Analyte (Unit)	Visit	Scheduled Time point	N	Mean	Standard Deviation	Median	Minimum	Maximum	Geometric Mean	Geometric CV%
LB-102 75 mg BID										
Amisulpride (ng/mL)	Day 7	PRE DOSE	5	6.52	2.399	5.65	4.0	9.9	6.18	37.5
		24 HOURS	5	3.73	1.052	4.19	2.2	4.7	3.59	32.3
		32 HOURS	5	2.38	0.852	2.68	1.2	3.4	2.24	42.2
		48 HOURS	5	1.03	0.964	1.34	0.0	1.9	1.69	20.2
LB-102 100 mg BID										
LB-102 (ng/mL)	Day 1 Dose 1	PRE DOSE*	6				0.0	0.0		
		0.25 HOUR*	6				0.0	34.9		
		0.5 HOUR	6	87.55	116.610	54.70	0.0	317.0	66.31	140.8
		0.75 HOUR	6	110.91	76.560	117.50	2.4	209.0	62.08	387.3
		1 HOUR	6	128.81	89.998	117.50	6.9	281.0	85.38	207.9
		1.5 HOURS	6	159.67	57.417	151.50	107.0	266.0	152.29	33.6
		2 HOURS	6	257.50	94.490	234.00	166.0	371.0	243.25	38.3
		3 HOURS	6	306.17	70.901	299.50	214.0	396.0	299.21	24.0
		4 HOURS	6	244.00	47.514	247.50	186.0	291.0	240.05	20.1
		6 HOURS	6	158.00	28.907	149.50	132.0	202.0	155.89	17.9
		8 HOURS	6	111.95	30.579	104.00	83.9	170.0	108.98	24.9
		12 HOURS	6	58.88	12.193	53.55	50.7	82.3	57.97	18.8
	Day 1 Dose 2	PRE DOSE	6	58.88	12.193	53.55	50.7	82.3	57.97	18.8
		4 HOURS	6	176.67	63.497	177.50	110.0	281.0	167.43	37.2
		12 HOURS	6	106.20	21.476	108.00	73.6	136.0	104.29	21.5

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
* Mean concentrations are only calculated for time points with at least 50% valid values (i.e. quantifiable and non-missing).
Geometric CV% = 100*(exp(SD^2)-1)^0.5, where SD is the standard deviation of the log-transformed data.

Table 14.2.1.2
Summary of Plasma LB-102 and Amisulpride Concentrations (ng/mL) by Treatment
Pharmacokinetic Population: Part B (MAD)

Treatment Analyte (Unit)	Visit	Scheduled Time point	N	Mean	Standard Deviation	Median	Minimum	Maximum	Geometric Mean	Geometric CV%
LB-102 100 mg BID										
LB-102 (ng/mL)	Day 2	PRE DOSE	6	106.20	21.476	108.00	73.6	136.0	104.29	21.5
	Day 3	PRE DOSE	5	136.56	30.742	135.00	88.8	172.0	133.44	25.3
Amisulpride (ng/mL)	Day 1 Dose 1	PRE DOSE*	6				0.0	0.0		
		0.25 HOUR*	6				0.0	0.0		
		0.5 HOUR*	6				0.0	7.9		
		0.75 HOUR	6	3.15	3.213	2.84	0.0	8.3	4.11	70.7
		1 HOUR	6	3.92	2.279	4.50	0.0	6.4	4.53	32.2
		1.5 HOURS	6	4.78	1.766	4.91	1.9	6.7	4.42	49.2
		2 HOURS	6	7.35	2.689	6.77	4.2	12.3	6.98	35.7
		3 HOURS	6	9.38	3.248	8.45	6.2	15.6	8.99	31.4
		4 HOURS	6	7.85	3.155	6.70	5.1	14.0	7.43	35.3
		6 HOURS	6	5.69	1.693	5.13	4.1	8.9	5.52	27.0
		8 HOURS	6	4.18	0.996	3.91	3.1	5.9	4.09	23.1
		12 HOURS	6	2.77	0.622	2.84	2.0	3.5	2.71	23.8
	Day 1 Dose 2	PRE DOSE	6	2.77	0.622	2.84	2.0	3.5	2.71	23.8
		4 HOURS	6	6.31	2.675	5.77	3.1	10.5	5.85	45.5
		12 HOURS	6	4.91	0.928	4.84	4.0	5.9	4.83	19.2

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
* Mean concentrations are only calculated for time points with at least 50% valid values (i.e. quantifiable and non-missing).
Geometric CV% = 100*(exp(SD^2)-1)^0.5, where SD is the standard deviation of the log-transformed data.

Source Data: ADPCMAD; Reference Listing: 16.2.6.3 SDTM Date: 04AUG2020 16:09
Program Name: SumCon_mad.sas Analysis Date: 09SEP2020 15:40

Table 14.2.1.2
Summary of Plasma LB-102 and Amisulpride Concentrations (ng/mL) by Treatment
Pharmacokinetic Population: Part B (MAD)

Treatment Analyte (Unit)	Visit	Scheduled Time point	N	Mean	Standard Deviation	Median	Minimum	Maximum	Geometric Mean	Geometric CV%
LB-102 100 mg BID										
Amisulpride (ng/mL)	Day 2	PRE DOSE	6	4.91	0.928	4.84	4.0	5.9	4.83	19.2
	Day 3	PRE DOSE	5	7.08	1.177	7.52	5.4	8.1	7.00	17.6

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
* Mean concentrations are only calculated for time points with at least 50% valid values (i.e. quantifiable and non-missing).
Geometric CV% = 100*(exp(SD^2)-1)^0.5, where SD is the standard deviation of the log-transformed data.

Source Data: ADPCMAD; Reference Listing: 16.2.6.3 SDTM Date: 04AUG2020 16:09
Program Name: SumCon_mad.sas Analysis Date: 09SEP2020 15:40

Table 14.2.2.1
Individual Values and Summary of Plasma LB-102 Pharmacokinetic Parameters by Treatment
Pharmacokinetic Population: Part A (SAD)

Treatment Subject Statistic	Cmax (ng/mL)	Tmax (h)	Lambda Z (1/h)	t1/2 (h)	AUC0-t (h*ng/mL)	AUC0-24h (h*ng/mL)	AUC0-inf (h*ng/mL)	AUCextrap (%)	CL/F (L/h)
LB-102 10 mg									
01S0029	19.30	3.00	0.064	10.87	190.67	174.20	212.77	10.39	47.0
01S0030	36.20	3.00	0.055	12.69	278.43	258.97	313.93	11.31	31.9
01S0032	39.00	3.00	0.073	9.44	308.95	294.83	327.88	5.77	30.5
01S0035	15.30	3.00	0.055	12.53	167.68	149.25	198.94	15.72	50.3
01S0042	20.30	3.00	0.034	20.17	254.98	197.45	300.38	15.11	33.3
01S0049	14.50	3.00	0.042	16.36	130.77	118.13	161.92	19.24	61.8
n	6	6	6	6	6	6	6	6	6
Mean	24.100	3.000	0.0540	13.675	221.911	198.807	252.637	12.924	42.44
Standard Deviation	10.728	0.0000	0.01411	3.9375	69.4093	66.9513	69.8570	4.7465	12.598
Median	19.800	3.000	0.0550	12.606	222.825	185.825	256.576	13.212	40.15
Minimum	14.50	3.00	0.034	9.44	130.77	118.13	161.92	5.77	30.5
Maximum	39.00	3.00	0.073	20.17	308.95	294.83	327.88	19.24	61.8
Geometric Mean	22.292				212.353	189.498	244.171	12.075	
Geometric CV%	44.5				34.1	35.1	29.7	44.6	

Note: Geometric CV% = 100*(exp(SD^2)-1)^0.5, where SD is the standard deviation of the log-transformed data.

Source Data: ADAM.ADPPSAD SDTM Date: 04AUG2020 16:09
Program Name: pksad.sas Analysis Date: 20AUG2020 18:48

Table 14.2.2.1
Individual Values and Summary of Plasma LB-102 Pharmacokinetic Parameters by Treatment
Pharmacokinetic Population: Part A (SAD)

Treatment Subject Statistic	Cmax (ng/mL)	Tmax (h)	Lambda Z (1/h)	t1/2 (h)	AUC0-t (h*ng/mL)	AUC0-24h (h*ng/mL)	AUC0-inf (h*ng/mL)	AUCextrap (%)	CL/F (L/h)
LB-102 50 mg									
01S0002	153.00	3.00	0.061	11.32	1638.11	1415.81	1712.09	4.32	29.2
01S0003	173.00	3.00	0.073	9.49	1558.20	1448.15	1582.70	1.55	31.6
01S0004	224.00	3.00	0.060	11.55	1456.48	1317.25	1504.97	3.22	33.2
01S0005	143.00	4.00	0.047	14.71	1452.17	1203.04	1570.16	7.51	31.8
01S0008	252.00	2.00	0.053	13.10	1782.70	1542.92	1882.32	5.29	26.6
01S0010	111.00	3.00	0.061	11.42	1268.83	1089.46	1323.39	4.12	37.8
n	6	6	6	6	6	6	6	6	6
Mean	176.000	3.000	0.0592	11.933	1526.080	1336.105	1595.938	4.337	31.70
Standard Deviation	52.786	0.6325	0.00877	1.7797	176.5906	167.6764	189.1599	2.0039	3.794
Median	163.000	3.000	0.0603	11.487	1507.336	1366.531	1576.432	4.222	31.72
Minimum	111.00	2.00	0.047	9.49	1268.83	1089.46	1323.39	1.55	26.6
Maximum	252.00	4.00	0.073	14.71	1782.70	1542.92	1882.32	7.51	37.8
Geometric Mean	169.502				1517.497	1327.048	1586.584	3.903	
Geometric CV%	30.8				11.7	12.9	11.9	57.5	

Note: Geometric CV% = 100*(exp(SD^2)-1)^0.5, where SD is the standard deviation of the log-transformed data.

Source Data: ADAM.ADPPSAD SDTM Date: 04AUG2020 16:09
Program Name: pksad.sas Analysis Date: 20AUG2020 18:48

Table 14.2.2.1
Individual Values and Summary of Plasma LB-102 Pharmacokinetic Parameters by Treatment
Pharmacokinetic Population: Part A (SAD)

Treatment Subject Statistic	Cmax (ng/mL)	Tmax (h)	Lambda Z (1/h)	t1/2 (h)	AUC0-t (h*ng/mL)	AUC0-24h (h*ng/mL)	AUC0-inf (h*ng/mL)	AUCextrap (%)	CL/F (L/h)
LB-102 100 mg									
01S0056	376.00	2.02	0.060	11.51	2890.04	2591.26	2985.00	3.18	33.5
01S0063	525.00	1.00	0.057	12.13	2875.30	2686.09	2940.21	2.21	34.0
01S0064	307.00	4.00	0.033	20.81	3015.64	2533.43	3414.97	11.69	29.3
01S0071	490.00	2.00	0.072	9.68	2959.23	2733.90	3006.14	1.56	33.3
01S0073	203.00	4.00	0.045	15.41	2230.11	1825.75	2450.92	9.01	40.8
01S0074	188.00	4.00	0.045	15.34	1845.91	1451.56	2061.47	10.46	48.5
n	6	6	6	6	6	6	6	6	6
Mean	348.167	2.837	0.0521	14.146	2636.040	2303.664	2809.785	6.351	36.56
Standard Deviation	141.832	1.3267	0.01360	3.9617	481.5386	533.1684	477.7622	4.5305	6.935
Median	341.500	3.010	0.0512	13.734	2882.671	2562.346	2962.608	6.095	33.76
Minimum	188.00	1.00	0.033	9.68	1845.91	1451.56	2061.47	1.56	29.3
Maximum	525.00	4.00	0.072	20.81	3015.64	2733.90	3414.97	11.69	48.5
Geometric Mean	322.891				2594.860	2244.225	2773.559	4.790	
Geometric CV%	45.6				20.2	26.5	18.1	107.3	

Note: Geometric CV% = 100*(exp(SD^2)-1)^0.5, where SD is the standard deviation of the log-transformed data.

Source Data: ADAM.ADPPSAD SDTM Date: 04AUG2020 16:09
Program Name: pksad.sas Analysis Date: 20AUG2020 18:48

Table 14.2.2.1
Individual Values and Summary of Plasma LB-102 Pharmacokinetic Parameters by Treatment
Pharmacokinetic Population: Part A (SAD)

Treatment Subject Statistic	Cmax (ng/mL)	Tmax (h)	Lambda Z (1/h)	t1/2 (h)	AUC0-t (h*ng/mL)	AUC0-24h (h*ng/mL)	AUC0-inf (h*ng/mL)	AUCextrap (%)	CL/F (L/h)
LB-102 150 mg									
01S0156	566.00	3.00	0.057	12.20	3799.61	3562.77	3892.37	2.38	38.5
01S0157	739.00	4.00	0.063	10.93	5646.54	5126.69	5801.66	2.67	25.9
01S0160	653.00	3.00	0.075	9.29	4866.98	4435.40	4964.13	1.96	30.2
01S0162	555.00	3.00	0.058	11.86	4449.55	3900.95	4639.52	4.09	32.3
01S0165	665.00	3.00	0.046	15.00	4572.95	4201.54	4750.64	3.74	31.6
01S0168	401.00	3.00	0.055	12.53	3605.33	3176.03	3771.14	4.40	39.8
n	6	6	6	6	6	6	6	6	6
Mean	596.500	3.167	0.0591	11.969	4490.161	4067.230	4636.577	3.208	33.05
Standard Deviation	117.527	0.4082	0.00945	1.8897	741.2812	685.9163	745.7299	1.0014	5.250
Median	609.500	3.000	0.0576	12.031	4511.247	4051.244	4695.080	3.207	31.95
Minimum	401.00	3.00	0.046	9.29	3605.33	3176.03	3771.14	1.96	25.9
Maximum	739.00	4.00	0.075	15.00	5646.54	5126.69	5801.66	4.40	39.8
Geometric Mean	585.831				4439.900	4019.483	4587.238	3.071	
Geometric CV%	21.7				16.5	17.0	16.1	33.7	

Note: Geometric CV% = 100*(exp(SD^2)-1)^0.5, where SD is the standard deviation of the log-transformed data.

Source Data: ADAM.ADPPSAD SDTM Date: 04AUG2020 16:09
Program Name: pksad.sas Analysis Date: 20AUG2020 18:48

Table 14.2.2.1
Individual Values and Summary of Plasma LB-102 Pharmacokinetic Parameters by Treatment
Pharmacokinetic Population: Part A (SAD)

Treatment Subject Statistic	Cmax (ng/mL)	Tmax (h)	Lambda Z (1/h)	t1/2 (h)	AUC0-t (h*ng/mL)	AUC0-24h (h*ng/mL)	AUC0-inf (h*ng/mL)	AUCextrap (%)	CL/F (L/h)
LB-102 200 mg									
01S0103	856.00	3.00	0.075	9.30	5869.01	5337.63	5977.28	1.81	33.5
01S0104	738.00	2.00	0.052	13.43	6624.57	5726.86	7010.09	5.50	28.5
01S0109	899.00	1.50	0.053	13.07	7024.77	6131.03	7385.05	4.88	27.1
01S0116	1300.00	1.50	0.037	18.55	6718.26	6020.25	7170.55	6.31	27.9
01S0119	1290.00	1.50	0.078	8.92	8127.06	7506.59	8243.37	1.41	24.3
01S0120	771.00	3.00	0.047	14.71	5895.26	5176.21	6226.31	5.32	32.1
n	6	6	6	6	6	6	6	6	6
Mean	975.667	2.083	0.0569	12.997	6709.821	5983.093	7002.109	4.204	28.89
Standard Deviation	253.995	0.7360	0.01591	3.5854	834.9332	833.9816	820.7252	2.0651	3.381
Median	877.500	1.750	0.0523	13.252	6671.415	5873.554	7090.319	5.098	28.21
Minimum	738.00	1.50	0.037	8.92	5869.01	5176.21	5977.28	1.41	24.3
Maximum	1300.00	3.00	0.078	18.55	8127.06	7506.59	8243.37	6.31	33.5
Geometric Mean	949.831				6668.190	5938.059	6962.173	3.633	
Geometric CV%	25.4				12.2	13.3	11.8	72.0	

Note: Geometric CV% = 100*(exp(SD^2)-1)^0.5, where SD is the standard deviation of the log-transformed data.

Source Data: ADAM.ADPPSAD SDTM Date: 04AUG2020 16:09
Program Name: pksad.sas Analysis Date: 20AUG2020 18:48

Table 14.2.2.2
Individual Values and Summary of Plasma Amisulpride Pharmacokinetic Parameters by Treatment
Pharmacokinetic Population: Part A (SAD)

Treatment Subject Statistic	Cmax (ng/mL)	Tmax (h)	Lambda Z (1/h)	t1/2 (h)	AUC0-t (h*ng/mL)	AUC0-24h (h*ng/mL)	AUC0-inf (h*ng/mL)	AUCextrap (%)
LB-102 50 mg								
01S0002	1.16	3.00			3.86			
01S0003	3.99	3.00			35.97			
01S0004	6.27	3.00			42.51			
01S0005	4.54	4.00			48.92	48.92		
01S0008	7.28	2.00			46.48			
01S0010	1.76	4.00			9.35			
n	6	6			6	1		
Mean	4.167	3.167			31.183	48.916		
Standard Deviation	2.413	0.7528			19.6105			
Median	4.265	3.000			39.244	48.916		
Minimum	1.16	2.00			3.86	48.92		
Maximum	7.28	4.00			48.92	48.92		
Geometric Mean	3.451				22.378	48.916		
Geometric CV%	83.6				144.3			

Note: Geometric CV% = 100*(exp(SD^2)-1)^0.5, where SD is the standard deviation of the log-transformed data.
No amisulpride PK parameters were calculated for cohort 2 (LB-102 10 mg) due to all subjects having 2 or fewer valid concentrations (i.e. quantifiable and non-missing).

Source Data: ADAM.ADPPSAD SDTM Date: 04AUG2020 16:09
Program Name: pksad.sas Analysis Date: 20AUG2020 18:48

Table 14.2.2.2
Individual Values and Summary of Plasma Amisulpride Pharmacokinetic Parameters by Treatment
Pharmacokinetic Population: Part A (SAD)

Treatment Subject Statistic	Cmax (ng/mL)	Tmax (h)	Lambda Z (1/h)	t1/2 (h)	AUC0-t (h*ng/mL)	AUC0-24h (h*ng/mL)	AUC0-inf (h*ng/mL)	AUCextrap (%)
LB-102 100 mg								
01S0056	8.64	2.02			73.80	73.80		
01S0063	10.60	1.50			76.51			
01S0064	6.28	4.00			76.09	66.96		
01S0071	10.20	3.00			58.39			
01S0073	4.23	4.00			55.76	55.76		
01S0074	5.94	4.00			69.49	58.58		
n	6	6			6	4		
Mean	7.648	3.087			68.340	63.776		
Standard Deviation	2.556	1.1104			9.1123	8.2022		
Median	7.460	3.500			71.646	62.773		
Minimum	4.23	1.50			55.76	55.76		
Maximum	10.60	4.00			76.51	73.80		
Geometric Mean	7.268				67.808	63.386		
Geometric CV%	37.0				13.9	12.8		

Note: Geometric CV% = 100*(exp(SD^2)-1)^0.5, where SD is the standard deviation of the log-transformed data.
No amisulpride PK parameters were calculated for cohort 2 (LB-102 10 mg) due to all subjects having 2 or fewer valid concentrations (i.e. quantifiable and non-missing).

Source Data: ADAM.ADPPSAD SDTM Date: 04AUG2020 16:09
Program Name: pksad.sas Analysis Date: 20AUG2020 18:48

Table 14.2.2.2
Individual Values and Summary of Plasma Amisulpride Pharmacokinetic Parameters by Treatment
Pharmacokinetic Population: Part A (SAD)

Treatment Subject Statistic	Cmax (ng/mL)	Tmax (h)	Lambda Z (1/h)	t1/2 (h)	AUC0-t (h*ng/mL)	AUC0-24h (h*ng/mL)	AUC0-inf (h*ng/mL)	AUCextrap (%)
LB-102 150 mg								
01S0156	16.30	3.00	0.107	6.49	124.75	124.75	135.79	8.13
01S0157	23.70	4.00	0.079	8.78	219.23	203.35	236.85	7.44
01S0160	11.70	3.00	0.067	10.37	127.39	115.24	144.90	12.09
01S0162	11.00	3.00	0.059	11.71	125.15	111.91	147.11	14.93
01S0165	30.60	2.05	0.096	7.25	266.49	252.49	278.11	4.18
01S0168	10.40	3.00			110.12	110.12		
n	6	6	5	5	6	6	5	5
Mean	17.283	3.008	0.0815	8.921	162.189	152.976	188.552	9.352
Standard Deviation	8.215	0.6168	0.01976	2.1572	64.5423	60.3055	64.7283	4.1981
Median	14.000	3.000	0.0789	8.784	126.269	119.997	147.108	8.131
Minimum	10.40	2.05	0.059	6.49	110.12	110.12	135.79	4.18
Maximum	30.60	4.00	0.107	11.71	266.49	252.49	278.11	14.93
Geometric Mean	15.844				152.936	144.481	180.324	8.545
Geometric CV%	47.0				37.6	37.0	33.8	52.2

Note: Geometric CV% = 100*(exp(SD^2)-1)^0.5, where SD is the standard deviation of the log-transformed data.
No amisulpride PK parameters were calculated for cohort 2 (LB-102 10 mg) due to all subjects having 2 or fewer valid concentrations (i.e. quantifiable and non-missing).

Table 14.2.2.2
Individual Values and Summary of Plasma Amisulpride Pharmacokinetic Parameters by Treatment
Pharmacokinetic Population: Part A (SAD)

Treatment Subject Statistic	Cmax (ng/mL)	Tmax (h)	Lambda Z (1/h)	t1/2 (h)	AUC0-t (h*ng/mL)	AUC0-24h (h*ng/mL)	AUC0-inf (h*ng/mL)	AUCextrap (%)
LB-102 200 mg								
01S0103	24.60	3.00	0.065	10.65	226.51	208.73	251.72	10.01
01S0104	21.90	3.00	0.043	16.19	253.51	203.35	282.71	10.33
01S0109	8.48	1.50			73.36	73.36		
01S0116	65.10	1.50	0.036	19.33	420.92	366.00	465.26	9.53
01S0119	24.60	2.00	0.063	11.01	277.54	250.66	315.03	11.90
01S0120	21.80	2.00	0.044	15.88	232.53	191.09	256.59	9.38
n	6	6	5	5	6	6	5	5
Mean	27.747	2.167	0.0501	14.614	247.397	215.533	314.264	10.230
Standard Deviation	19.265	0.6831	0.01310	3.7087	111.3574	94.7410	88.0822	1.0075
Median	23.250	2.000	0.0436	15.882	243.022	206.041	282.714	10.015
Minimum	8.48	1.50	0.036	10.65	73.36	73.36	251.72	9.38
Maximum	65.10	3.00	0.065	19.33	420.92	366.00	465.26	11.90
Geometric Mean	23.288				220.341	194.768	305.853	10.192
Geometric CV%	72.1				63.7	57.4	25.5	9.5

Note: Geometric CV% = 100*(exp(SD^2)-1)^0.5, where SD is the standard deviation of the log-transformed data.
No amisulpride PK parameters were calculated for cohort 2 (LB-102 10 mg) due to all subjects having 2 or fewer valid concentrations (i.e. quantifiable and non-missing).

Source Data: ADAM.ADPPSAD SDTM Date: 04AUG2020 16:09
Program Name: pksad.sas Analysis Date: 20AUG2020 18:48

Table 14.2.2.3
Individual Values and Summary of Plasma LB-102 Pharmacokinetic Parameters on Day 1 by Treatment
Pharmacokinetic Population: Part B (MAD)

Treatment Subject Statistic	Cmax,D1 (ng/mL)	Tmax,D1 (h)	Lambda Z,D1 (1/h)	t1/2,D1 (h)	AUC0-12h,D1 (h*ng/mL)	AUC0-24h,D1 (h*ng/mL)	AUC0-inf,D1 (h*ng/mL)	AUCextrap,D1 (%)
LB-102 50 mg BID								
01S2032	144.00	1.50	0.187	3.71	908.00	1035.03	1049.80	13.51
01S2034	95.80	3.00			668.14			
01S2045	109.00	1.08			671.11			
01S2050	130.00	3.00	0.170	4.09	838.55	982.92	1004.29	16.50
01S2053	117.00	3.00	0.164	4.22	717.20	855.47	879.18	18.42
01S2055	157.00	2.00	0.149	4.67	924.79	1084.60	1117.33	17.23
n	6	6	4	4	6	4	4	4
Mean	125.467	2.263	0.1673	4.171	787.967	989.505	1012.649	16.416
Standard Deviation	22.721	0.8579	0.01581	0.3951	117.2242	98.5296	100.3718	2.0947
Median	123.500	2.500	0.1669	4.154	777.878	1008.974	1027.046	16.868
Minimum	95.80	1.08	0.149	3.71	668.14	855.47	879.18	13.51
Maximum	157.00	3.00	0.187	4.67	924.79	1084.60	1117.33	18.42
Geometric Mean	123.746				780.718	985.681	1008.802	16.310
Geometric CV%	18.4				15.0	10.3	10.2	13.4

Note: Geometric CV% = 100*(exp(SD^2)-1)^0.5, where SD is the standard deviation of the log-transformed data.

Source Data: ADAM.ADPPMAD SDTM Date: 04AUG2020 16:09
Program Name: pkmad.sas Analysis Date: 25AUG2020 10:54

Table 14.2.2.3
Individual Values and Summary of Plasma LB-102 Pharmacokinetic Parameters on Day 1 by Treatment
Pharmacokinetic Population: Part B (MAD)

Treatment Subject Statistic	Cmax,D1 (ng/mL)	Tmax,D1 (h)	Lambda Z,D1 (1/h)	t1/2,D1 (h)	AUC0-12h,D1 (h*ng/mL)	AUC0-24h,D1 (h*ng/mL)	AUC0-inf,D1 (h*ng/mL)	AUCextrap,D1 (%)
LB-102 75 mg BID								
01S2080	314.00	3.00	0.181	3.83	1967.59	2226.14	2261.36	12.99
01S2087	234.00	3.00	0.181	3.82	1392.22	1627.49	1658.41	16.05
01S2092	225.00	3.00	0.164	4.24	1349.91	1565.29	1601.63	15.72
01S2093	211.00	3.00	0.158	4.39	1245.83	1463.72	1502.81	17.10
01S2094	388.00	2.00	0.219	3.16	1902.53	2053.31	2065.48	7.89
01S2102	232.00	3.05	0.157	4.41	1286.02	1532.52	1577.91	18.50
n	6	6	6	6	6	6	6	6
Mean	267.333	2.842	0.1768	3.974	1524.015	1744.745	1777.932	14.708
Standard Deviation	69.373	0.4128	0.02340	0.4752	323.0305	315.2539	309.0153	3.8041
Median	233.000	3.000	0.1724	4.031	1371.064	1596.391	1630.020	15.884
Minimum	211.00	2.00	0.157	3.16	1245.83	1463.72	1502.81	7.89
Maximum	388.00	3.05	0.219	4.41	1967.59	2226.14	2261.36	18.50
Geometric Mean	260.708				1497.374	1722.519	1757.000	14.194
Geometric CV%	24.2				20.5	17.4	16.7	31.9

Note: Geometric CV% = 100*(exp(SD^2)-1)^0.5, where SD is the standard deviation of the log-transformed data.

Source Data: ADAM.ADPPMAD SDTM Date: 04AUG2020 16:09
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Table 14.2.2.3
Individual Values and Summary of Plasma LB-102 Pharmacokinetic Parameters on Day 1 by Treatment
Pharmacokinetic Population: Part B (MAD)

Treatment Subject Statistic	Cmax,D1 (ng/mL)	Tmax,D1 (h)	Lambda Z,D1 (1/h)	t1/2,D1 (h)	AUC0-12h,D1 (h*ng/mL)	AUC0-24h,D1 (h*ng/mL)	AUC0-inf,D1 (h*ng/mL)	AUCextrap,D1 (%)
LB-102 100 mg BID								
01S2059	361.00	2.00	0.183	3.79	1851.13	2108.77	2141.99	13.58
01S2066	214.00	3.00	0.159	4.35	1462.36	1735.17	1782.92	17.98
01S2069	377.00	3.00	0.214	3.23	1784.41	2002.88	2020.92	11.70
01S2076	317.00	0.50	0.145	4.78	1543.82	1846.97	1915.18	19.39
01S2078	286.00	2.00			1682.38			
01S2079	396.00	3.02	0.155	4.46	2374.13	2826.59	2903.42	18.23
n	6	6	5	5	6	5	5	5
Mean	325.167	2.253	0.1715	4.121	1783.039	2104.078	2152.886	16.176
Standard Deviation	67.744	0.9905	0.02768	0.6106	323.7988	428.5123	439.9467	3.3376
Median	339.000	2.500	0.1594	4.348	1733.396	2002.880	2020.921	17.980
Minimum	214.00	0.50	0.145	3.23	1462.36	1735.17	1782.92	11.70
Maximum	396.00	3.02	0.214	4.78	2374.13	2826.59	2903.42	19.39
Geometric Mean	318.589				1760.632	2072.765	2120.916	15.880
Geometric CV%	23.2				17.2	19.1	19.0	22.2

Note: Geometric CV% = 100*(exp(SD^2)-1)^0.5, where SD is the standard deviation of the log-transformed data.

Source Data: ADAM.ADPPMAD SDTM Date: 04AUG2020 16:09
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Table 14.2.2.4
Individual Values and Summary of Plasma LB-102 Pharmacokinetic Parameters after Multiple Dose by Treatment
Pharmacokinetic Population: Part B (MAD)

Treatment Subject Statistic	Cmax,D7 (ng/mL)	Tmax,D7 (h)	Lambda Z,D7 (1/h)	t1/2,D7 (h)	AUC0-12,D7 (h*ng/mL)	AUC0-inf,D7 (h*ng/mL)	AUCextrap,D7 (%)	CLss/F (L/h)
LB-102 50 mg BID								
01S2032	220.00	3.00	0.037	18.68	1442.10	2270.56	8.43	34.7
01S2034	187.00	3.00	0.071	9.70	1604.07	2666.29	3.16	31.2
01S2045	214.00	2.00	0.048	14.31	1472.18	2589.83	7.22	34.0
01S2050	261.00	2.00	0.052	13.42	1647.40	2805.73	6.40	30.4
01S2053	181.00	3.00	0.062	11.11	1279.71	1963.66	3.47	39.1
01S2055	281.00	1.00	0.037	18.64	1495.09	2638.55	11.31	33.4
n	6	6	6	6	6	6	6	6
Mean	224.000	2.333	0.0514	14.311	1490.091	2489.104	6.665	33.78
Standard Deviation	39.8798	0.8165	0.01370	3.7449	130.1117	312.4027	3.0855	3.082
Median	217.000	2.500	0.0500	13.866	1483.635	2614.190	6.810	33.70
Minimum	181.00	1.00	0.037	9.70	1279.71	1963.66	3.16	30.4
Maximum	281.00	3.00	0.071	18.68	1647.40	2805.73	11.31	39.1
Geometric Mean	221.115				1485.227	2471.525	6.035	
Geometric CV%	17.7				8.9	13.4	53.7	

Note: Geometric CV% = 100*(exp(SD^2)-1)^0.5, where SD is the standard deviation of the log-transformed data.
For Cohort 6 (LB-102 50 mg BID), the PK parameters are calculated using the PK concentration of the QD dosing on Day 7. For Cohort 8 (LB-102 75 mg BID), the PK parameters are calculated using the PK concentration of the 2nd dosing on Day 6.

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Table 14.2.2.4
Individual Values and Summary of Plasma LB-102 Pharmacokinetic Parameters after Multiple Dose by Treatment
Pharmacokinetic Population: Part B (MAD)

Treatment Subject Statistic	Cmax,D7 (ng/mL)	Tmax,D7 (h)	Lambda Z,D7 (1/h)	t1/2,D7 (h)	AUC0-12,D7 (h*ng/mL)	AUC0-inf,D7 (h*ng/mL)	AUCextrap,D7 (%)	CLss/F (L/h)
LB-102 75 mg BID								
01S2080	568.00	2.00			3496.11			21.5
01S2087	201.00	4.00			1637.56			45.8
01S2093	220.00	4.00			1985.24			37.8
01S2094	295.00	2.00			2215.01			33.9
01S2102	263.00	2.00			2120.32			35.4
n	5	5			5			5
Mean	309.400	2.800			2290.849			34.85
Standard Deviation	149.1452	1.0954			708.4610			8.792
Median	263.000	2.000			2120.324			35.37
Minimum	201.00	2.00			1637.56			21.5
Maximum	568.00	4.00			3496.11			45.8
Geometric Mean	287.044				2215.515			
Geometric CV%	42.8				28.5			

Note: Geometric CV% = 100*(exp(SD^2)-1)^0.5, where SD is the standard deviation of the log-transformed data.
For Cohort 6 (LB-102 50 mg BID), the PK parameters are calculated using the PK concentration of the QD dosing on Day 7. For Cohort 8 (LB-102 75 mg BID), the PK parameters are calculated using the PK concentration of the 2nd dosing on Day 6.

Source Data: ADAM.ADPPMAD SDTM Date: 04AUG2020 16:09
Program Name: pkmad.sas Analysis Date: 25AUG2020 13:30

Table 14.2.2.5
Individual Values and Summary of Plasma LB-102 Pharmacokinetic Parameters Comparing Day 1 with Multiple Dose by Treatment
Pharmacokinetic Population: Part B (MAD)

Treatment Subject Statistic	RCmax	RAUC	LI
LB-102 50 mg BID			
01S2032	1.53	1.59	1.37
01S2034	1.95	2.40	
01S2045	1.96	2.19	
01S2050	2.01	1.96	1.64
01S2053	1.55	1.78	1.46
01S2055	1.79	1.62	1.34
n	6	6	4
Mean	1.798	1.925	1.452
Standard Deviation	0.2150	0.3251	0.1349
Median	1.871	1.874	1.415
Minimum	1.53	1.59	1.34
Maximum	2.01	2.40	1.64
Geometric Mean	1.787	1.902	1.447
Geometric CV%	12.3	16.8	9.1

Note: Geometric CV% = 100*(exp(SD^2)-1)^0.5, where SD is the standard deviation of the log-transformed data.
For Cohort 6 (LB-102 50 mg BID), the PK parameters are calculated using the PK concentration of the QD dosing on Day 7. For Cohort 8 (LB-102 75 mg BID), the PK parameters are calculated using the PK concentration of the 2nd dosing on Day 6.

Table 14.2.2.5
Individual Values and Summary of Plasma LB-102 Pharmacokinetic Parameters Comparing Day 1 with Multiple Dose by Treatment
Pharmacokinetic Population: Part B (MAD)

Treatment / Subject / Statistic	RCmax	RAUC	LI
LB-102 75 mg BID			
01S2080	1.81	1.78	1.55
01S2087	0.86	1.18	0.99
01S2093	1.04	1.59	1.32
01S2094	0.76	1.16	1.07
01S2102	1.13	1.65	1.34
n	5	5	5
Mean	1.121	1.472	1.254
Standard Deviation	0.4118	0.2833	0.2246
Median	1.043	1.594	1.321
Minimum	0.76	1.16	0.99
Maximum	1.81	1.78	1.55
Geometric Mean	1.069	1.449	1.238
Geometric CV%	34.3	20.1	18.3

Note: Geometric CV% = 100*(exp(SD^2)-1)^0.5, where SD is the standard deviation of the log-transformed data.
For Cohort 6 (LB-102 50 mg BID), the PK parameters are calculated using the PK concentration of the QD dosing on Day 7. For Cohort 8 (LB-102 75 mg BID), the PK parameters are calculated using the PK concentration of the 2nd dosing on Day 6.

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Table 14.2.2.6
Individual Values and Summary of Plasma Amisulpride Pharmacokinetic Parameters on Day 1 by Treatment
Pharmacokinetic Population: Part B (MAD)

Treatment Subject Statistic	Cmax,D1 (ng/mL)	Tmax,D1 (h)	Lambda Z,D1 (1/h)	t1/2,D1 (h)	AUC0-12h,D1 (h*ng/mL)	AUC0-24h,D1 (h*ng/mL)	AUC0-inf,D1 (h*ng/mL)	AUCextrap,D1 (%)
LB-102 50 mg BID								
01S2032	4.21	3.00			29.24			
01S2034	2.28	3.00			18.57			
01S2045	3.62	1.50			24.59			
01S2050	5.17	4.00			39.73			
01S2053	4.39	3.00			30.09			
01S2055	6.67	2.00			39.68			
n	6	6			6			
Mean	4.390	2.750			30.316			
Standard Deviation	1.475	0.8803			8.3450			
Median	4.300	3.000			29.664			
Minimum	2.28	1.50			18.57			
Maximum	6.67	4.00			39.73			
Geometric Mean	4.170				29.305			
Geometric CV%	37.4				29.7			

Note: Geometric CV% = 100*(exp(SD^2)-1)^0.5, where SD is the standard deviation of the log-transformed data.

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Table 14.2.2.6
Individual Values and Summary of Plasma Amisulpride Pharmacokinetic Parameters on Day 1 by Treatment
Pharmacokinetic Population: Part B (MAD)

Treatment Subject Statistic	Cmax,D1 (ng/mL)	Tmax,D1 (h)	Lambda Z,D1 (1/h)	t1/2,D1 (h)	AUC0-12h,D1 (h*ng/mL)	AUC0-24h,D1 (h*ng/mL)	AUC0-inf,D1 (h*ng/mL)	AUCextrap,D1 (%)
LB-102 75 mg BID								
01S2080	9.44	1.50			70.95			
01S2087	6.05	3.00			40.47			
01S2092	7.50	3.00			48.38			
01S2093	7.18	3.00			44.10			
01S2094	17.00	2.00	0.174	3.99	93.51	107.36	109.34	14.48
01S2102	5.94	3.05			36.68			
n	6	6	1	1	6	1	1	1
Mean	8.852	2.592	0.1736	3.992	55.681	107.364	109.344	14.483
Standard Deviation	4.187	0.6711			22.1069			
Median	7.340	3.000	0.1736	3.992	46.239	107.364	109.344	14.483
Minimum	5.94	1.50	0.174	3.99	36.68	107.36	109.34	14.48
Maximum	17.00	3.05	0.174	3.99	93.51	107.36	109.34	14.48
Geometric Mean	8.229				52.531	107.364	109.344	14.483
Geometric CV%	40.9				37.5			

Note: Geometric CV% = 100*(exp(SD^2)-1)^0.5, where SD is the standard deviation of the log-transformed data.

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Table 14.2.2.6
Individual Values and Summary of Plasma Amisulpride Pharmacokinetic Parameters on Day 1 by Treatment
Pharmacokinetic Population: Part B (MAD)

Treatment Subject Statistic	Cmax,D1 (ng/mL)	Tmax,D1 (h)	Lambda Z,D1 (1/h)	t1/2,D1 (h)	AUC0-12h,D1 (h*ng/mL)	AUC0-24h,D1 (h*ng/mL)	AUC0-inf,D1 (h*ng/mL)	AUCextrap,D1 (%)
LB-102 100 mg BID								
01S2059	15.60	3.00	0.154	4.50	92.66	111.61	115.30	19.63
01S2066	8.44	3.00			63.61			
01S2069	7.92	3.00			46.19			
01S2076	9.68	3.00			60.53			
01S2078	6.89	2.00			43.80			
01S2079	8.46	3.02			55.55			
n	6	6	1	1	6	1	1	1
Mean	9.498	2.837	0.1542	4.496	60.389	111.611	115.297	19.635
Standard Deviation	3.122	0.4100			17.6192			
Median	8.450	3.000	0.1542	4.496	58.042	111.611	115.297	19.635
Minimum	6.89	2.00	0.154	4.50	43.80	111.61	115.30	19.63
Maximum	15.60	3.02	0.154	4.50	92.66	111.61	115.30	19.63
Geometric Mean	9.154				58.503	111.611	115.297	19.635
Geometric CV%	28.9				27.4			

Note: Geometric CV% = 100*(exp(SD^2)-1)^0.5, where SD is the standard deviation of the log-transformed data.

Source Data: ADAM.ADPPMAD SDTM Date: 04AUG2020 16:09
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Table 14.2.2.7
Individual Values and Summary of Plasma Amisulpride Pharmacokinetic Parameters after Multiple Dose by Treatment
Pharmacokinetic Population: Part B (MAD)

Treatment Subject Statistic	Cmax,D7 (ng/mL)	Tmax,D7 (h)	Lambda Z,D7 (1/h)	t1/2,D7 (h)	AUC0-12,D7 (h*ng/mL)	AUC0-inf,D7 (h*ng/mL)	AUCextrap,D7 (%)
LB-102 50 mg BID							
01S2032	7.71	3.00	0.070	9.93	55.10	90.89	17.66
01S2034	6.67	3.00	0.049	14.18	62.79	125.38	18.11
01S2045	6.39	2.00			54.88		
01S2050	11.50	2.00	0.050	13.84	89.01	185.18	18.87
01S2053	6.86	3.00			56.70		
01S2055	11.90	1.50			70.24		
n	6	6	3	3	6	3	3
Mean	8.505	2.417	0.0562	12.652	64.787	133.815	18.215
Standard Deviation	2.5169	0.6646	0.01173	2.3597	13.2513	47.7073	0.6099
Median	7.285	2.500	0.0501	13.839	59.744	125.380	18.114
Minimum	6.39	1.50	0.049	9.93	54.88	90.89	17.66
Maximum	11.90	3.00	0.070	14.18	89.01	185.18	18.87
Geometric Mean	8.220				63.779	128.265	18.208
Geometric CV%	28.6				19.1	36.8	3.3

Note: Geometric CV% = 100*(exp(SD^2)-1)^0.5, where SD is the standard deviation of the log-transformed data.
For Cohort 6 (LB-102 50 mg BID), the PK parameters are calculated using the PK concentration of the QD dosing on Day 7. For Cohort 8 (LB-102 75 mg BID), the PK parameters are calculated using the PK concentration of the 2nd dosing on Day 6.

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Table 14.2.2.7
Individual Values and Summary of Plasma Amisulpride Pharmacokinetic Parameters after Multiple Dose by Treatment
Pharmacokinetic Population: Part B (MAD)

Treatment Subject Statistic	Cmax,D7 (ng/mL)	Tmax,D7 (h)	Lambda Z,D7 (1/h)	t1/2,D7 (h)	AUC0-12,D7 (h*ng/mL)	AUC0-inf,D7 (h*ng/mL)	AUCextrap,D7 (%)
LB-102 75 mg BID							
01S2080	21.70	2.00			173.82		
01S2087	6.53	4.00			61.66		
01S2093	7.60	4.00			76.53		
01S2094	14.10	4.00			128.22		
01S2102	7.83	4.00			70.53		
n	5	5			5		
Mean	11.552	3.600			102.153		
Standard Deviation	6.4064	0.8944			47.7293		
Median	7.830	4.000			76.533		
Minimum	6.53	2.00			61.66		
Maximum	21.70	4.00			173.82		
Geometric Mean	10.352				94.201		
Geometric CV%	54.2				46.3		

Note: Geometric CV% = 100*(exp(SD^2)-1)^0.5, where SD is the standard deviation of the log-transformed data.
For Cohort 6 (LB-102 50 mg BID), the PK parameters are calculated using the PK concentration of the QD dosing on Day 7. For Cohort 8 (LB-102 75 mg BID), the PK parameters are calculated using the PK concentration of the 2nd dosing on Day 6.

Table 14.2.2.8
Individual Values and Summary of Plasma Amisulpride Pharmacokinetic Parameters Comparing Day 1 with Multiple Dose by Treatment
Pharmacokinetic Population: Part B (MAD)

Treatment Subject Statistic	RCmax	RAUC	LI
LB-102 50 mg BID			
01S2032	1.83	1.88	
01S2034	2.93	3.38	
01S2045	1.77	2.23	
01S2050	2.22	2.24	
01S2053	1.56	1.88	
01S2055	1.78	1.77	
n	6	6	
Mean	2.016	2.232	
Standard Deviation	0.4953	0.5958	
Median	1.808	2.058	
Minimum	1.56	1.77	
Maximum	2.93	3.38	
Geometric Mean	1.971	2.176	
Geometric CV%	22.7	24.0	

Note: Geometric CV% = 100*(exp(SD^2)-1)^0.5, where SD is the standard deviation of the log-transformed data.
For Cohort 6 (LB-102 50 mg BID), the PK parameters are calculated using the PK concentration of the QD dosing on Day 7. For Cohort 8 (LB-102 75 mg BID), the PK parameters are calculated using the PK concentration of the 2nd dosing on Day 6.

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Table 14.2.2.8
Individual Values and Summary of Plasma Amisulpride Pharmacokinetic Parameters Comparing Day 1 with Multiple Dose by Treatment
Pharmacokinetic Population: Part B (MAD)

Treatment Subject Statistic	RCmax	RAUC	LI
LB-102 75 mg BID			
01S2080	2.30	2.45	
01S2087	1.08	1.52	
01S2093	1.06	1.74	
01S2094	0.83	1.37	1.17
01S2102	1.32	1.92	
n	5	5	1
Mean	1.317	1.801	1.173
Standard Deviation	0.5755	0.4189	
Median	1.079	1.735	1.173
Minimum	0.83	1.37	1.17
Maximum	2.30	2.45	1.17
Geometric Mean	1.235	1.764	1.173
Geometric CV%	39.9	22.7	

Note: Geometric CV% = 100*(exp(SD^2)-1)^0.5, where SD is the standard deviation of the log-transformed data.
For Cohort 6 (LB-102 50 mg BID), the PK parameters are calculated using the PK concentration of the QD dosing on Day 7. For Cohort 8 (LB-102 75 mg BID), the PK parameters are calculated using the PK concentration of the 2nd dosing on Day 6.

Source Data: ADAM.ADPPMAD SDTM Date: 04AUG2020 16:09
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Table 14.2.3.1
Analysis of Dose Proportionality LB-102: Power Model
Pharmacokinetic Population: Part A (SAD)

PK Parameter(Unit) Statistics	LB-102 10 mg (N= 6)	50 mg (N= 6)	100 mg (N= 6)	150 mg (N= 6)	200 mg (N= 6)	Dose Proportionality
Cmax (ng/mL)						
n	6	6	6	6	6	
Geometric Mean	22.292	169.502	322.891	585.831	949.831	
Geometric CV%	44.5	30.8	45.6	21.7	25.4	
Dose Proportionality for Cmax						
n						30
Slope Estimate						1.22
Standard Error						0.0564
90% CI						(1.12, 1.32)
AUC0-t (h*ng/mL)						
n	6	6	6	6	6	
Geometric Mean	212.353	1517.497	2594.860	4439.900	6668.190	
Geometric CV%	34.1	11.7	20.2	16.5	12.2	
Dose Proportionality for AUC0-t						
n						30
Slope Estimate						1.12
Standard Error						0.0358
90% CI						(1.06, 1.19)

Note: The power model is estimated by regressing the ln-transformed PK parameter on ln-transformed dose. The power model is fitted by restricted maximum likelihood (REML) using SAS Proc Mixed. CI = confidence interval.

Source Data: ADAM.ADPPSAD SDTM Date: 04AUG2020 16:09
Program Name: pksad.sas Analysis Date: 20AUG2020 18:48

Table 14.2.3.1
Analysis of Dose Proportionality LB-102: Power Model
Pharmacokinetic Population: Part A (SAD)

PK Parameter(Unit) Statistics	LB-102 10 mg (N= 6)	50 mg (N= 6)	100 mg (N= 6)	150 mg (N= 6)	200 mg (N= 6)	Dose Proportionality
AUC0-inf (h*ng/mL)						
n	6	6	6	6	6	
Geometric Mean	244.171	1586.584	2773.559	4587.238	6962.173	
Geometric CV%	29.7	11.9	18.1	16.1	11.8	
Dose Proportionality for AUC0-inf						
n						30
Slope Estimate						1.09
Standard Error						0.0324
90% CI						(1.04, 1.15)

Note: The power model is estimated by regressing the ln-transformed PK parameter on ln-transformed dose. The power model is fitted by restricted maximum likelihood (REML) using SAS Proc Mixed. CI = confidence interval.

Source Data: ADAM.ADPPSAD SDTM Date: 04AUG2020 16:09
Program Name: pksad.sas Analysis Date: 20AUG2020 18:48

Table 14.2.3.2
Analysis of Dose Proportionality LB-102: Power Model
Pharmacokinetic Population: Part B (MAD)

PK Parameter(Unit) Statistics	LB-102 50 mg (N= 6)	LB-102 75 mg (N= 6)	LB-102 100 mg (N= 6)	Dose Proportionality
Cmax,D1 (ng/mL)				
n	6	6	6	
Geometric Mean	123.746	260.708	318.589	
Geometric CV%	18.4	24.2	23.2	
Dose Proportionality for Cmax,D1				
n				18
Slope Estimate				1.40
Standard Error				0.1920
90% CI				(1.06, 1.73)
AUC0-12,D1 (h*ng/mL)				
n	6	6	6	
Geometric Mean	780.718	1497.374	1760.632	
Geometric CV%	15.0	20.5	17.2	
Dose Proportionality for AUC0-12,D1				
n				18
Slope Estimate				1.20
Standard Error				0.1584
90% CI				(0.93, 1.48)

Note: The power model is estimated by regressing the ln-transformed PK parameter on ln-transformed dose. The power model is fitted by restricted maximum likelihood (REML) using SAS Proc Mixed. CI = confidence interval.
For Cohort 6 (LB-102 50 mg BID), the PK parameters are calculated using the PK concentration of the QD dosing on Day 7. For Cohort 8 (LB-102 75 mg BID), the PK parameters are calculated using the PK concentration of the 2nd dosing on Day 6.

Source Data: ADAM.ADPPMAD SDTM Date: 04AUG2020 16:09
Program Name: pkmodel_mad.sas Analysis Date: 25AUG2020 13:30

Table 14.2.3.2
Analysis of Dose Proportionality LB-102: Power Model
Pharmacokinetic Population: Part B (MAD)

PK Parameter(Unit) Statistics	LB-102 50 mg (N= 6)	LB-102 75 mg (N= 6)	LB-102 100 mg (N= 6)	Dose Proportionality
AUC0-inf,D1 (h*ng/mL)				
n	4	6	5	
Geometric Mean	1008.802	1757.000	2120.916	
Geometric CV%	10.2	16.7	19.0	
Dose Proportionality for AUC0-inf,D1				
n				15
Slope Estimate				1.08
Standard Error				0.1614
90% CI				(0.79, 1.37)
Cmax,D7 (ng/mL)				
n	6	5		
Geometric Mean	221.115	287.044		
Geometric CV%	17.7	42.8		
Dose Proportionality for Cmax,D7				
n				11
Slope Estimate				0.64
Standard Error				0.4525
90% CI				(-0.19, 1.47)

Note: The power model is estimated by regressing the ln-transformed PK parameter on ln-transformed dose. The power model is fitted by restricted maximum likelihood (REML) using SAS Proc Mixed. CI = confidence interval.
For Cohort 6 (LB-102 50 mg BID), the PK parameters are calculated using the PK concentration of the QD dosing on Day 7. For Cohort 8 (LB-102 75 mg BID), the PK parameters are calculated using the PK concentration of the 2nd dosing on Day 6.

Source Data: ADAM.ADPPMAD SDTM Date: 04AUG2020 16:09
Program Name: pkmodel_mad.sas Analysis Date: 25AUG2020 13:30

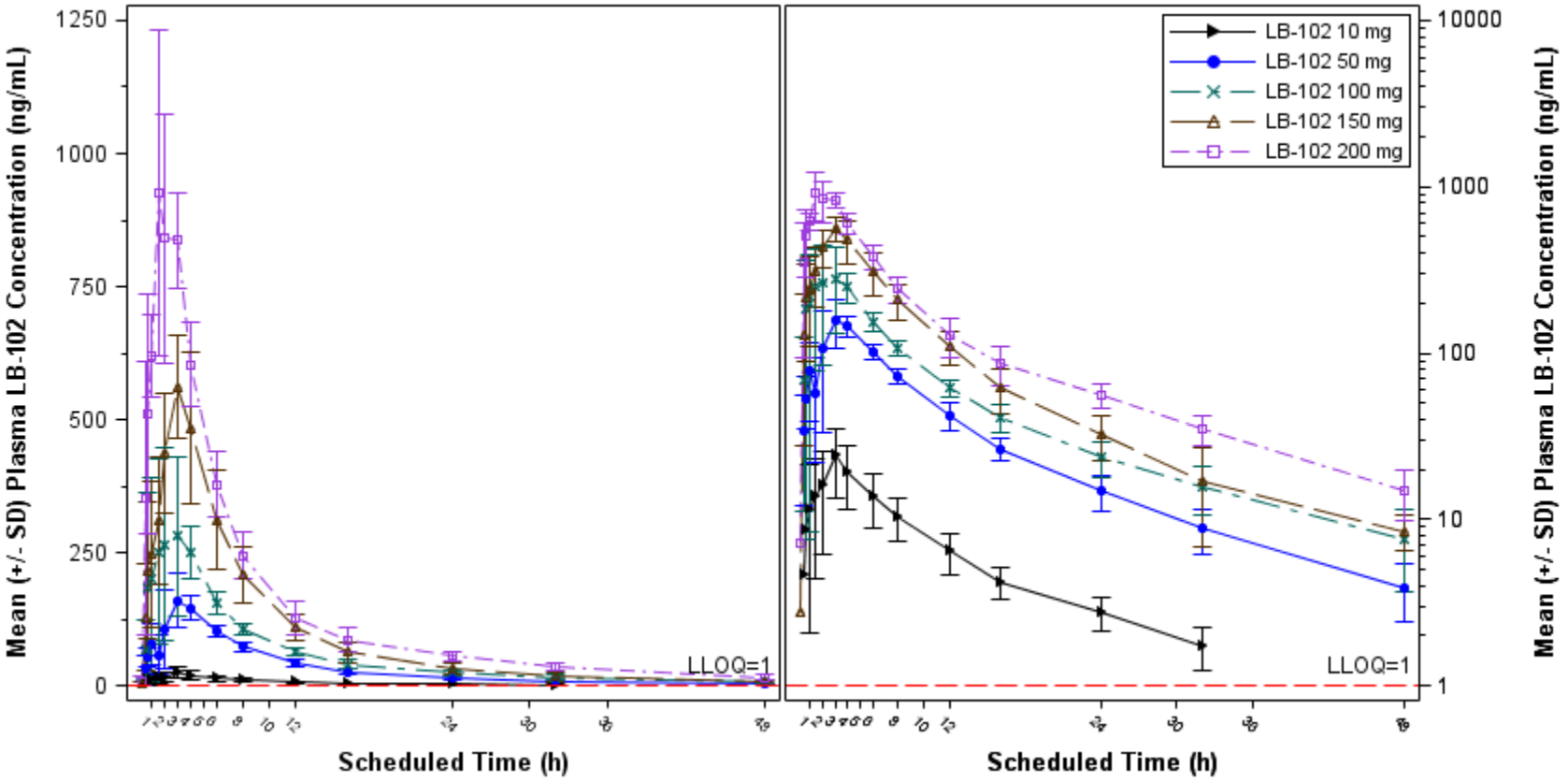
Table 14.2.3.2
Analysis of Dose Proportionality LB-102: Power Model
Pharmacokinetic Population: Part B (MAD)

PK Parameter(Unit) Statistics	LB-102 50 mg (N= 6)	LB-102 75 mg (N= 6)	LB-102 100 mg (N= 6)	Dose Proportionality
AUC0-12,D7 (h*ng/mL)				
n	6	5		
Geometric Mean	1485.227	2215.515		
Geometric CV%	8.9	28.5		
Dose Proportionality for AUC0-12,D7				
n				11
Slope Estimate				0.99
Standard Error				0.2959
90% CI				(0.44, 1.53)

Note: The power model is estimated by regressing the ln-transformed PK parameter on ln-transformed dose. The power model is fitted by restricted maximum likelihood (REML) using SAS Proc Mixed. CI = confidence interval.
For Cohort 6 (LB-102 50 mg BID), the PK parameters are calculated using the PK concentration of the QD dosing on Day 7. For Cohort 8 (LB-102 75 mg BID), the PK parameters are calculated using the PK concentration of the 2nd dosing on Day 6.

Source Data: ADAM.ADPPMAD SDTM Date: 04AUG2020 16:09
Program Name: pkmodel_mad.sas Analysis Date: 25AUG2020 13:30

Figure 14.2.1.1
Plot of Mean (+/-SD) Plasma LB-102 Concentrations by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part A (SAD)

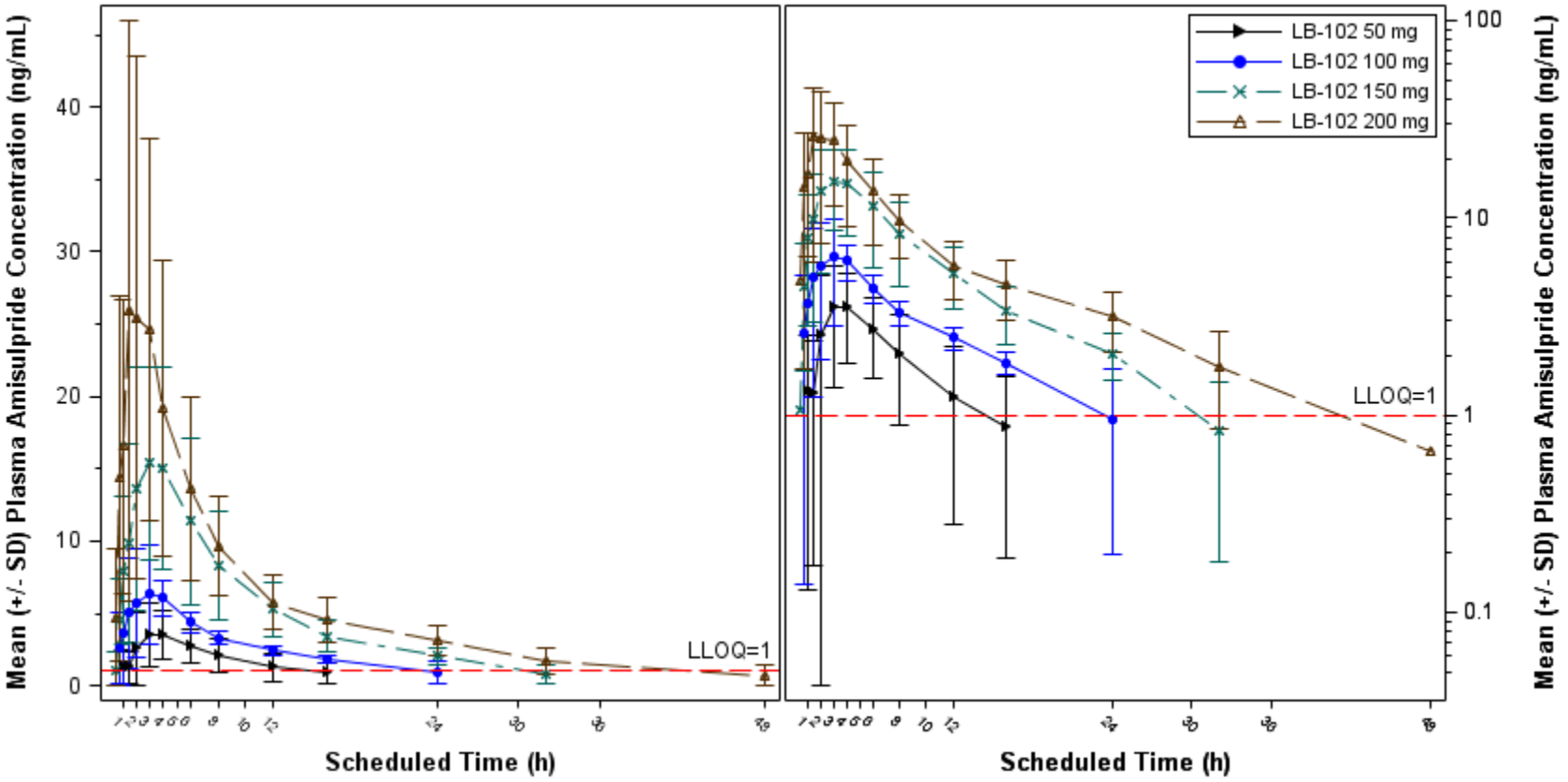


Note: Lower limit of quantification (LLOQ) for LB-102 = 1 ng/mL. SD = standard deviation.

Source Data: ADPC; Reference listing(s): 16.2.6.2
Program Name: Figure.sas

SDTM Date: 04AUG2020 16:09
Analysis Date: 20AUG2020 18:00

Figure 14.2.1.2
Plot of Mean (+/-SD) Plasma Amisulpride Concentrations by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part A (SAD)

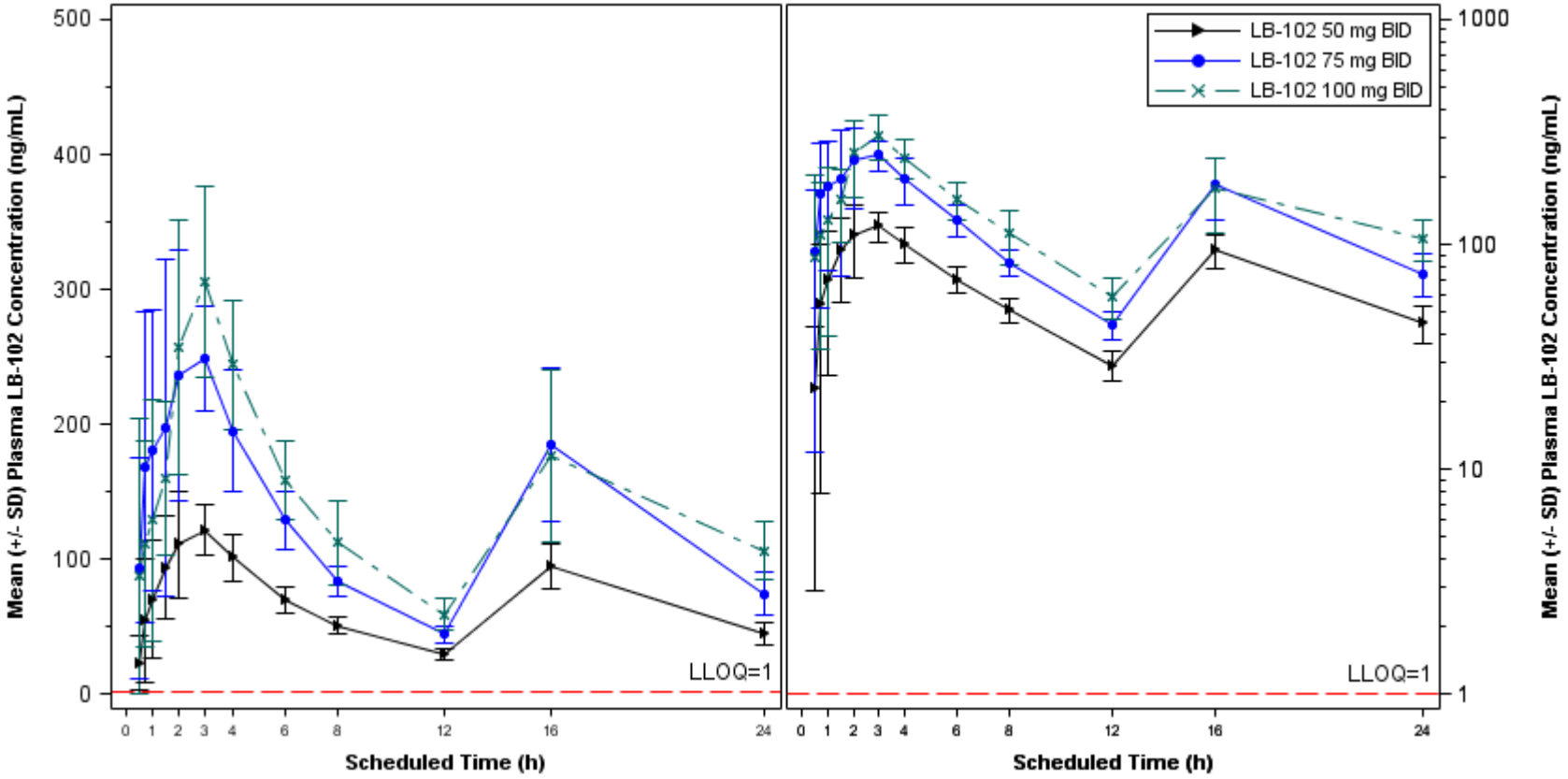


Note: Lower limit of quantification (LLOQ) for Amisulpride = 1 ng/mL. SD = standard deviation.

Source Data: ADPC; Reference listing(s): 16.2.6.2
Program Name: Figure.sas

SDTM Date: 04AUG2020 16:09
Analysis Date: 09SEP2020 15:54

Figure 14.2.1.3
Plot of Mean (+/-SD) Plasma LB-102 Concentrations on Day 1 by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part B (MAD)

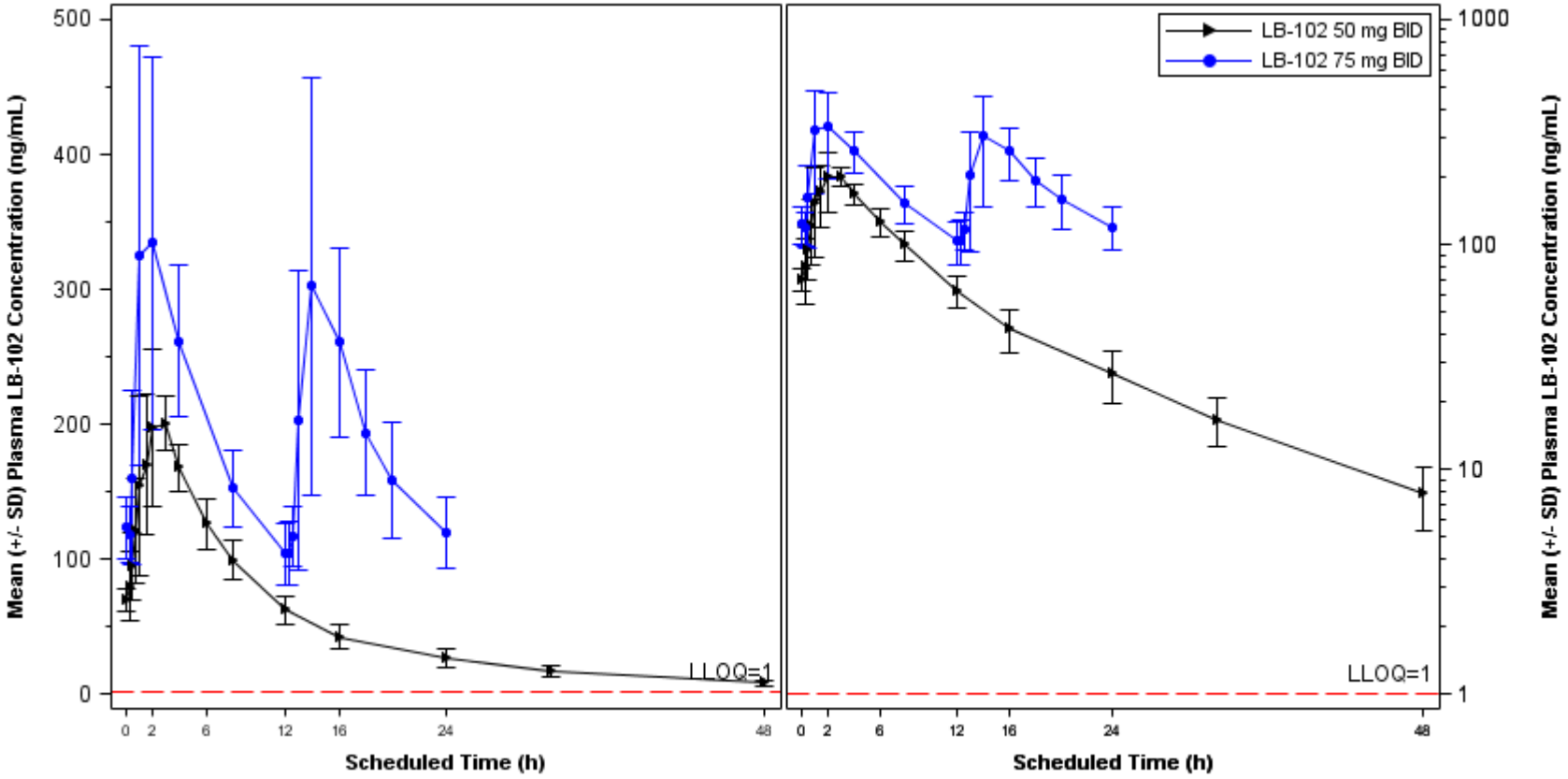


Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. SD = standard deviation.

Source Data: ADPCMAD; Reference listing(s): 16.2.6.3
Program Name: figmean_mad.sas

SDTM Date: 04AUG2020 16:09
Analysis Date: 25AUG2020 12:09

Figure 14.2.1.4
Plot of Mean (+/-SD) Plasma LB-102 Concentrations after Multiple Dose by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part B (MAD)

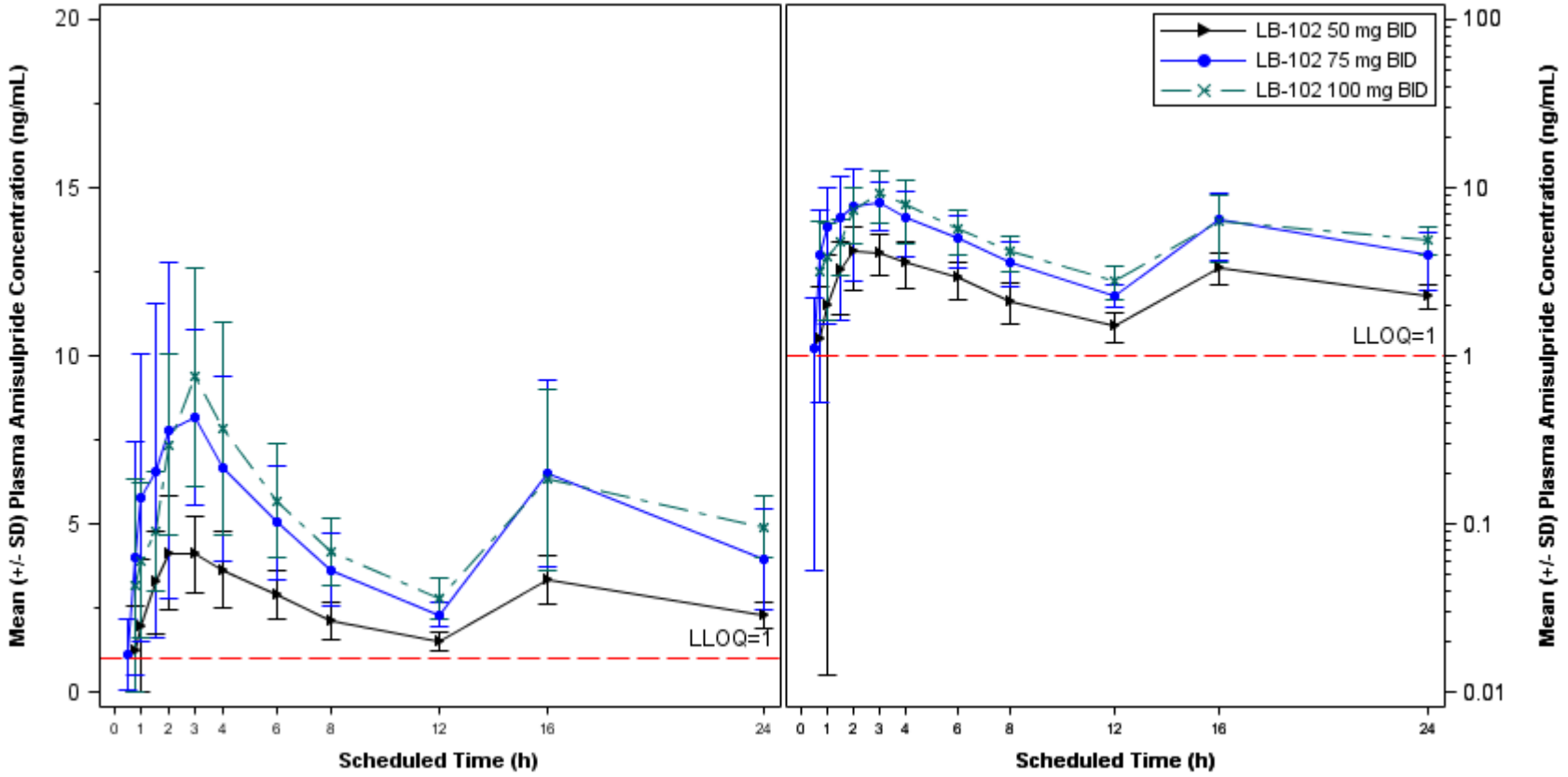


Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. SD = standard deviation.
For Cohort 6 (LB-102 50 mg BID), the PK concentrations of the QD dosing on Day 7 are plotted. For Cohort 8 (LB-102 75 mg BID), the PK concentrations of both doses on Day 6 are plotted.

Source Data: ADPCMAD; Reference listing(s): 16.2.6.3
Program Name: figmean_mad.sas

SDTM Date: 04AUG2020 16:09
Analysis Date: 25AUG2020 12:09

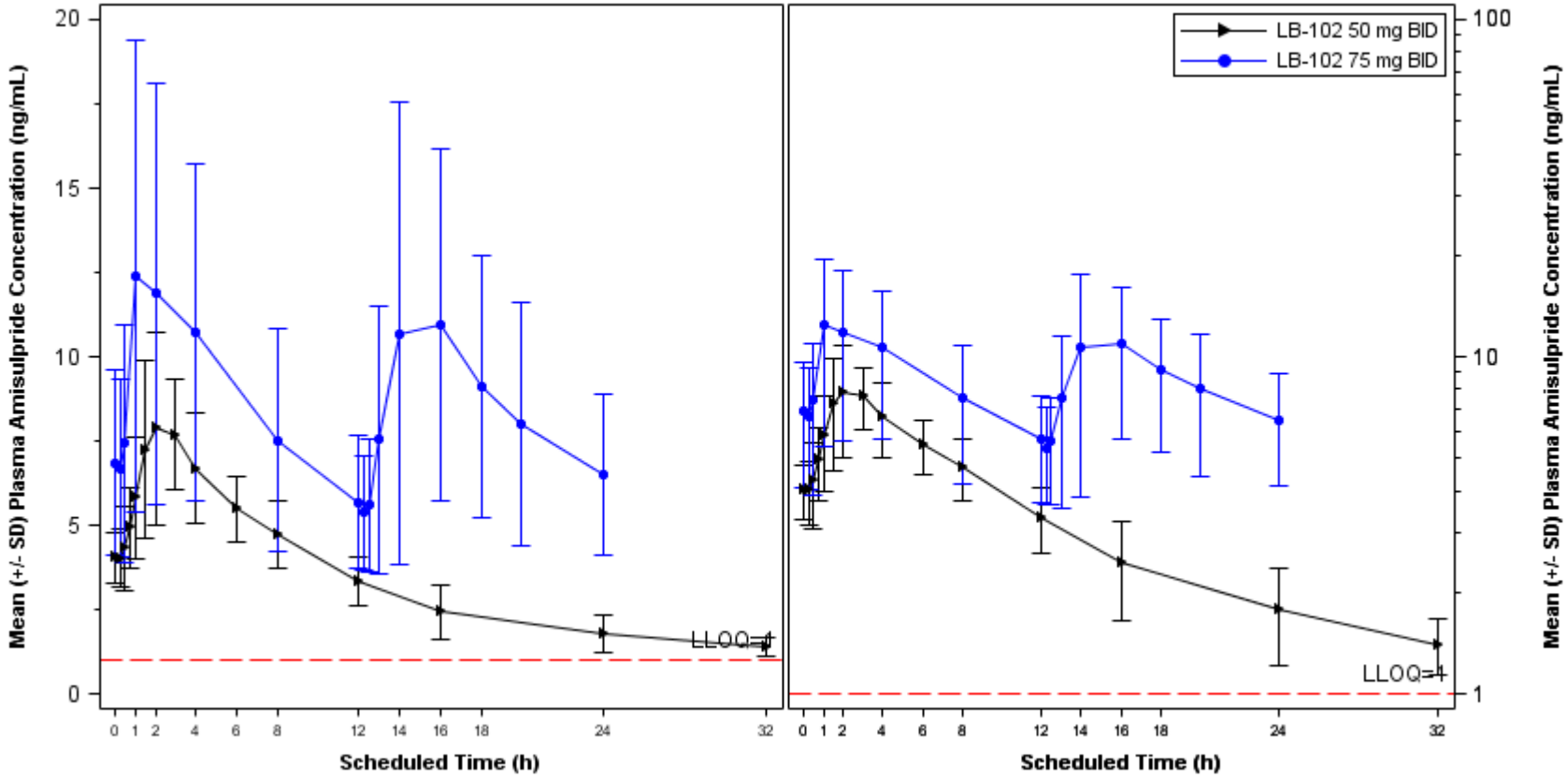
Figure 14.2.1.5
Plot of Mean (+/-SD) Plasma Amisulpride Concentrations on Day 1 by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part B (MAD)



Note: Lower limit of quantification (LLOQ) of amisulpride = 1 ng/mL. SD = standard deviation.

Source Data: ADPCMAD; Reference listing(s): 16.2.6.3
SDTM Date: 04AUG2020 16:09
Program Name: figmean_mad.sas
Analysis Date: 25AUG2020 12:09

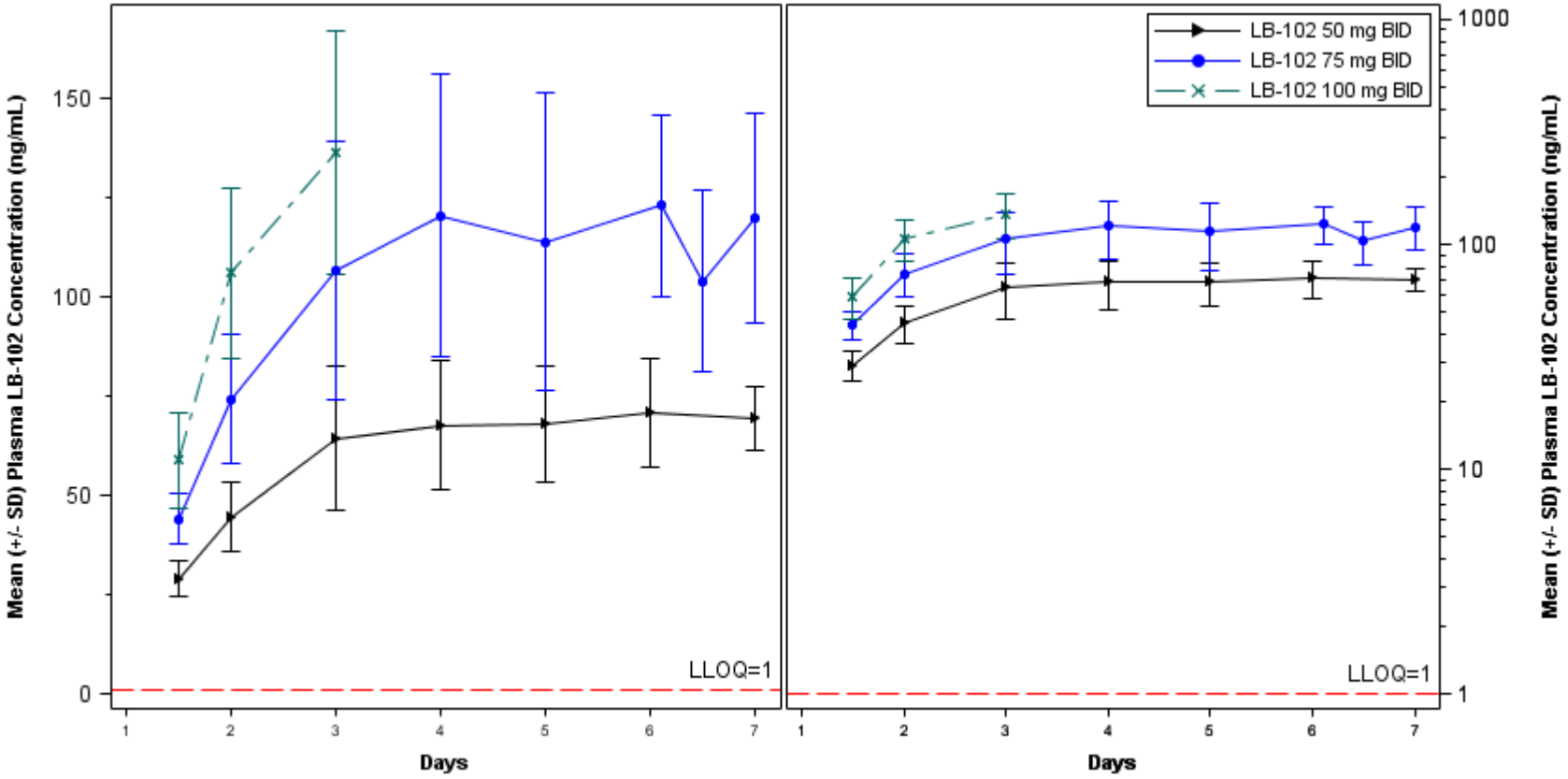
Figure 14.2.1.6
Plot of Mean (+/-SD) Plasma Amisulpride Concentrations after Multiple Dose by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part B (MAD)



Note: Lower limit of quantification (LLOQ) of amisulpride = 1 ng/mL. SD = standard deviation.
For Cohort 6 (LB-102 50 mg BID), the PK concentrations of the QD dosing on Day 7 are plotted. For Cohort 8 (LB-102 75 mg BID), the PK concentrations of both doses on Day 6 are plotted.

Source Data: ADPCMAD; Reference listing(s): 16.2.6.3 SDTM Date: 04AUG2020 16:09
Program Name: figmean_mad.sas Analysis Date: 25AUG2020 12:09

Figure 14.2.1.7
Plot of Mean (+/-SD) Plasma Trough LB-102 Concentrations by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part B (MAD)

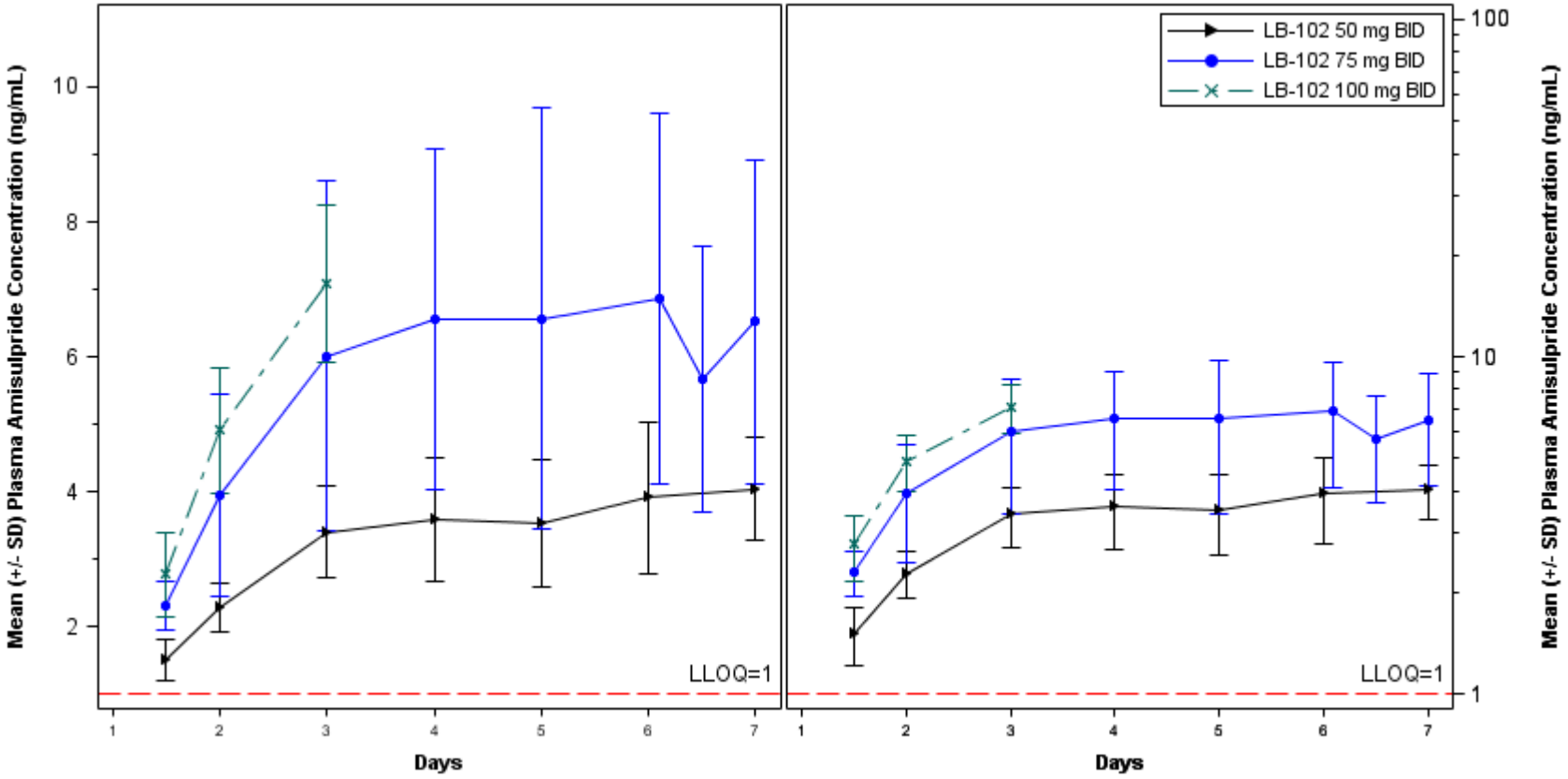


Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. SD = standard deviation.
All predose concentrations except that for the first dose on Day 1 are plotted as trough concentration.

Source Data: ADPCMAD; Reference listing(s): 16.2.6.3
Program Name: figmeanCtrough_mad.sas

SDTM Date: 04AUG2020 16:09
Analysis Date: 25AUG2020 11:51

Figure 14.2.1.8
Plot of Mean (+/-SD) Plasma Trough Amisulpride Concentrations by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part B (MAD)

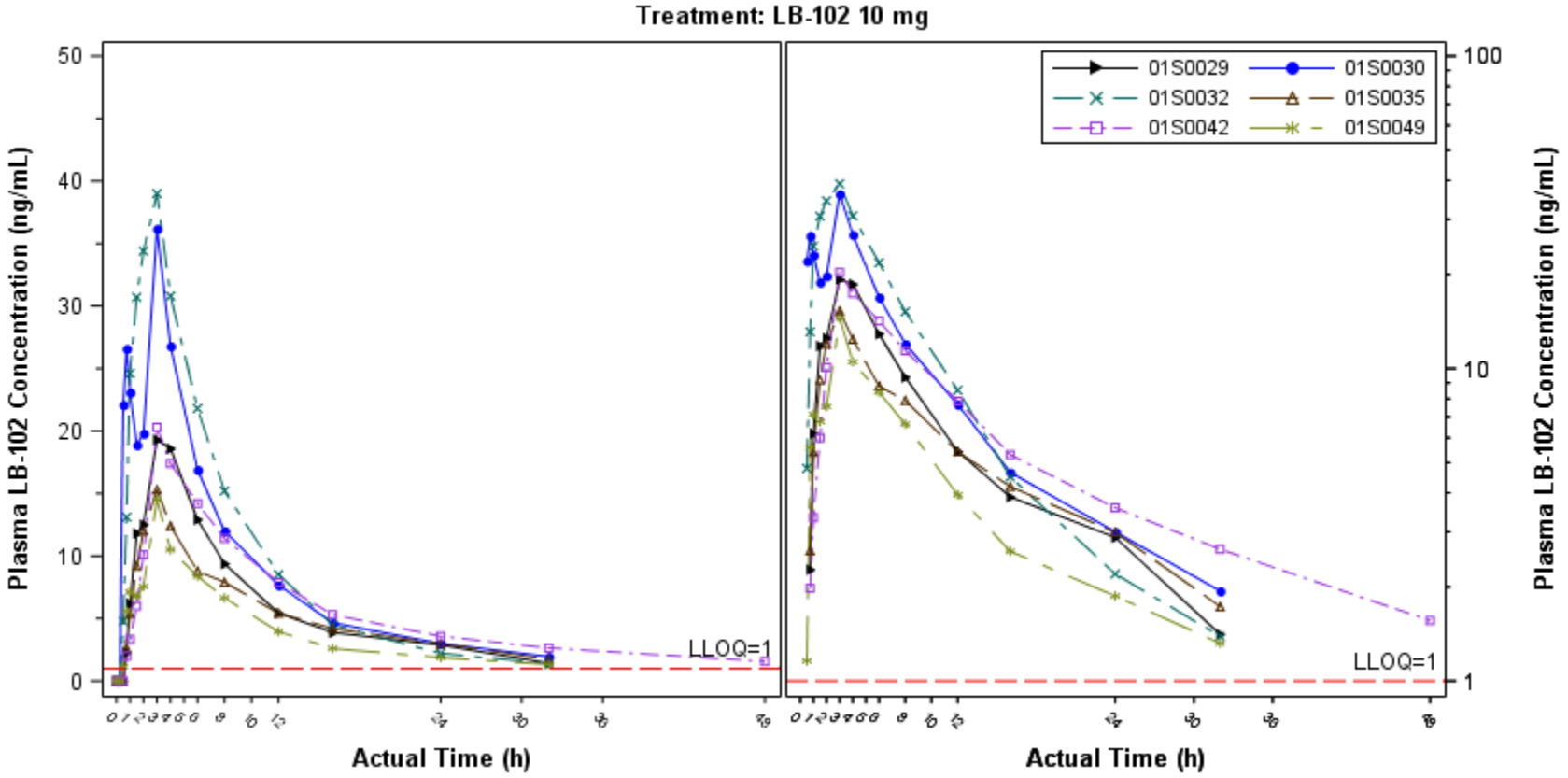


Note: Lower limit of quantification (LLOQ) of amisulpride = 1 ng/mL. SD = standard deviation.
All predose concentrations except that for the first dose on Day 1 are plotted as trough concentration.

Source Data: ADPCMAD; Reference listing(s): 16.2.6.3
Program Name: figmeanCtrough_mad.sas

SDTM Date: 04AUG2020 16:09
Analysis Date: 25AUG2020 11:51

Figure 14.2.2.1
Spaghetti Plot of Individual Plasma LB-102 Concentrations by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part A (SAD)

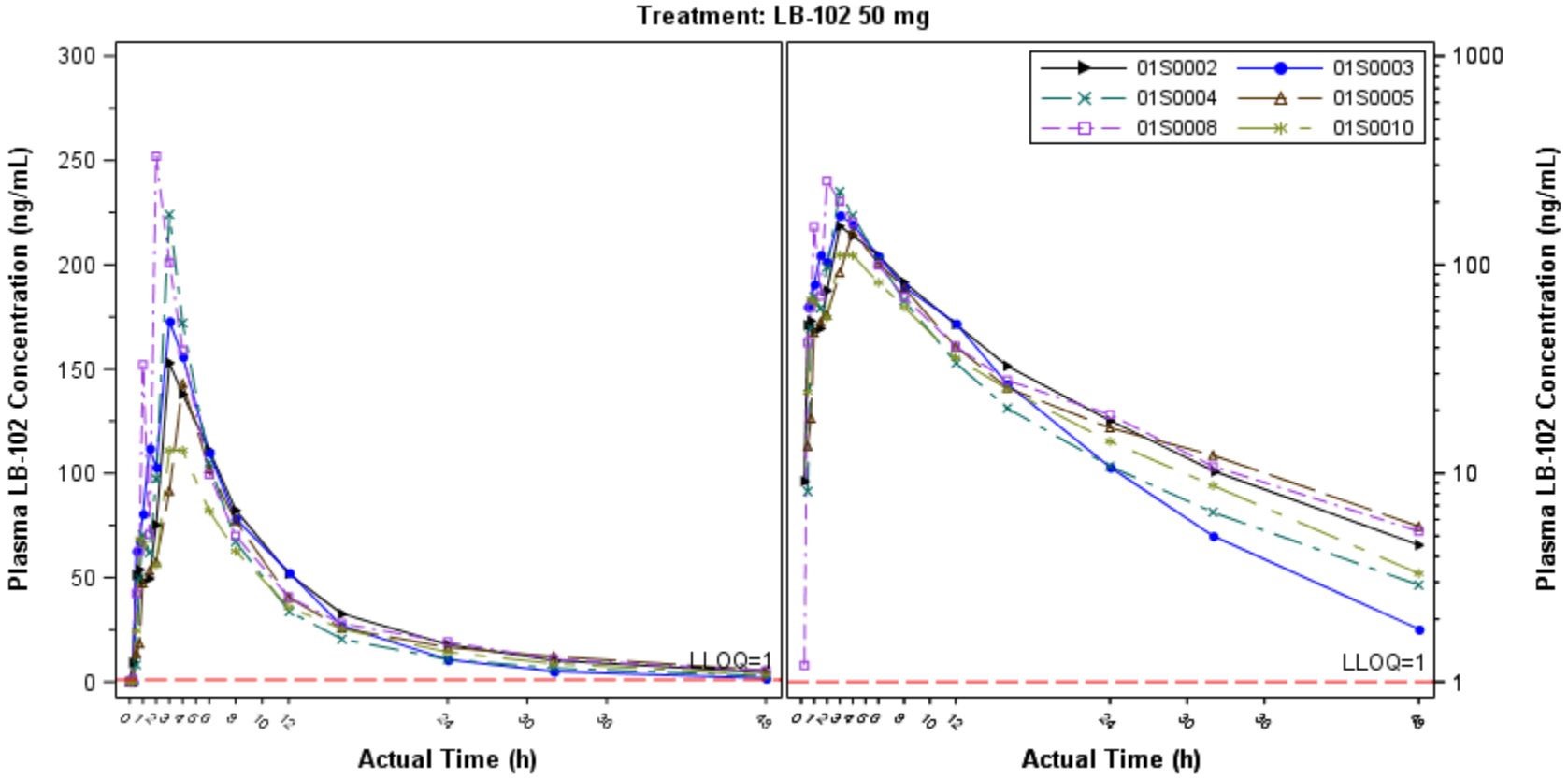


Note: Lower limit of quantification (LLOQ) for LB-102 = 1 ng/mL. SD = standard deviation.

Source Data: ADPC; Reference listing(s): 16.2.6.2
Program Name: Figure.sas

SDTM Date: 04AUG2020 16:09
Analysis Date: 20AUG2020 18:00

Figure 14.2.2.1
Spaghetti Plot of Individual Plasma LB-102 Concentrations by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part A (SAD)

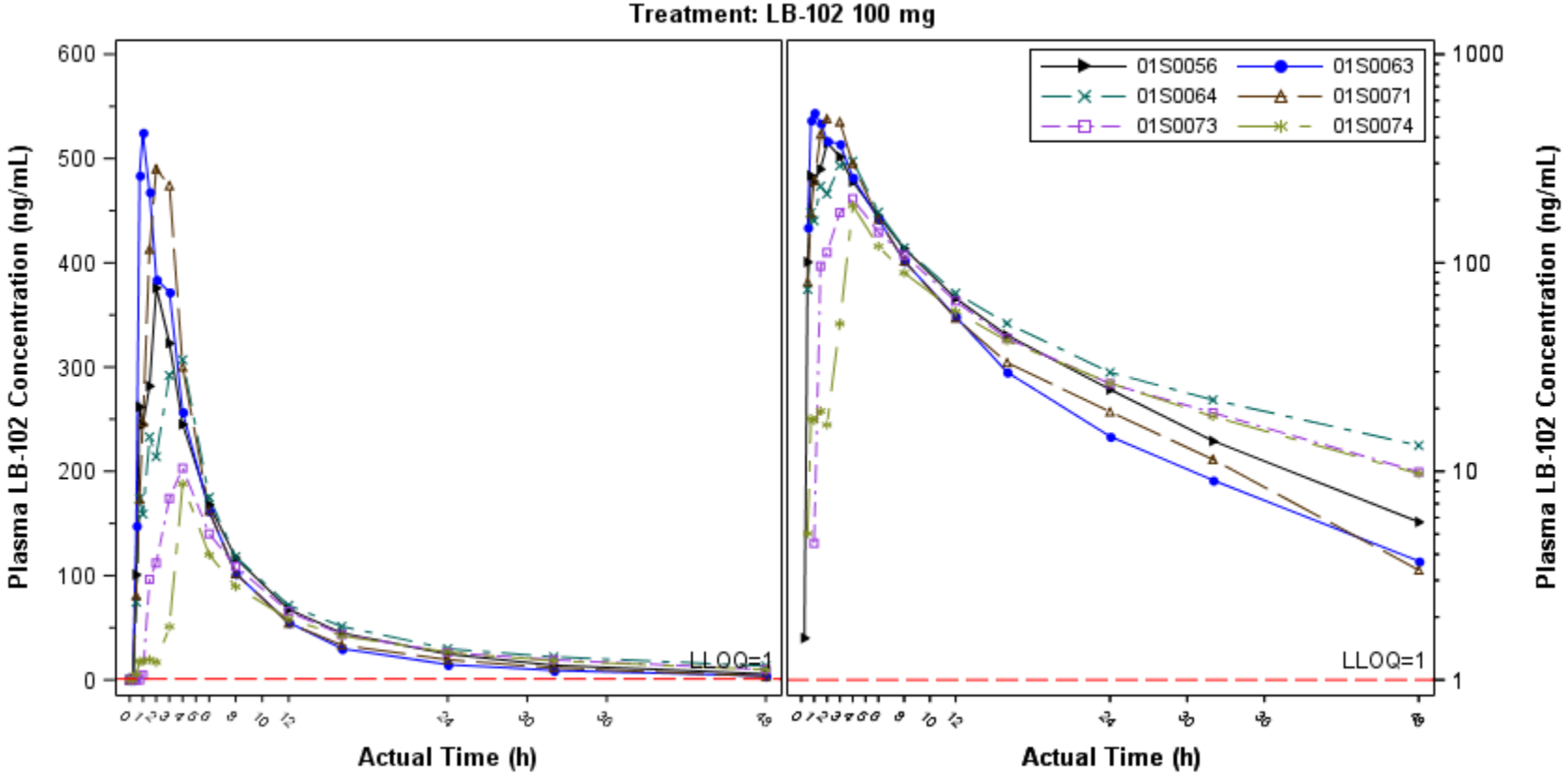


Note: Lower limit of quantification (LLOQ) for LB-102 = 1 ng/mL. SD = standard deviation.

Source Data: ADPC; Reference listing(s): 16.2.6.2
Program Name: Figure.sas

SDTM Date: 04AUG2020 16:09
Analysis Date: 20AUG2020 18:00

Figure 14.2.2.1
Spaghetti Plot of Individual Plasma LB-102 Concentrations by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part A (SAD)

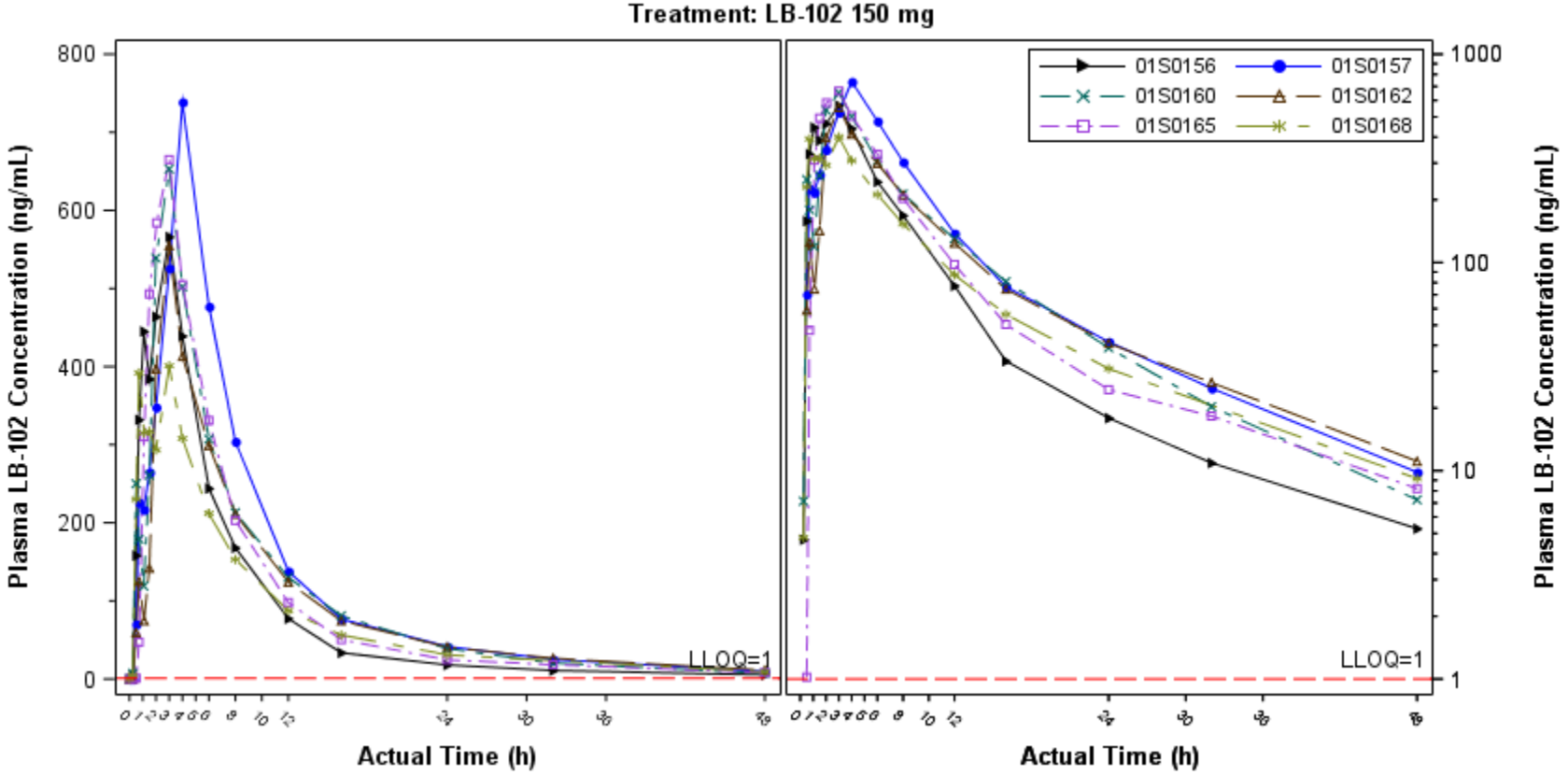


Note: Lower limit of quantification (LLOQ) for LB-102 = 1 ng/mL. SD = standard deviation.

Source Data: ADPC; Reference listing(s): 16.2.6.2
Program Name: Figure.sas

SDTM Date: 04AUG2020 16:09
Analysis Date: 20AUG2020 18:00

Figure 14.2.2.1
Spaghetti Plot of Individual Plasma LB-102 Concentrations by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part A (SAD)

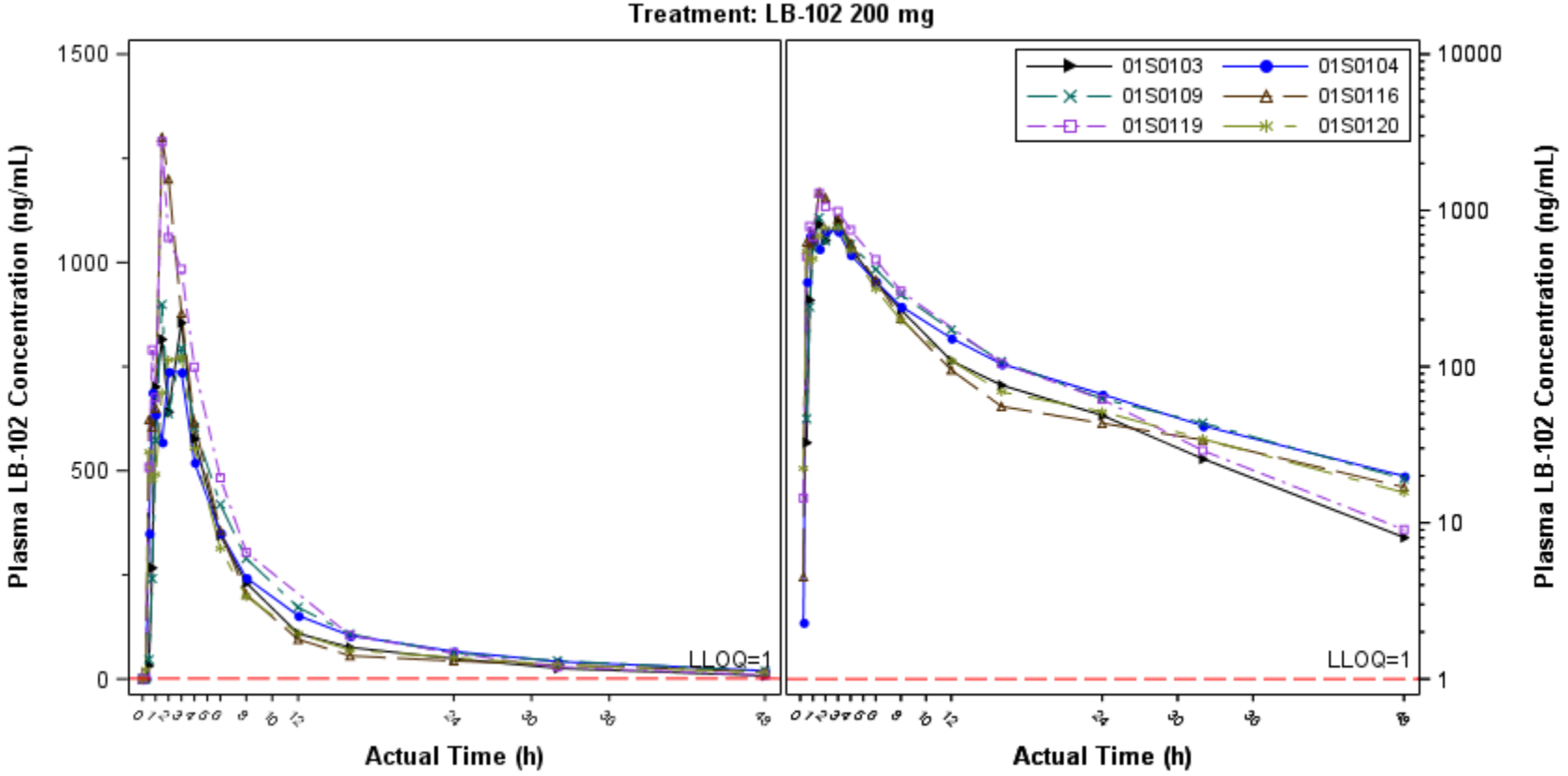


Note: Lower limit of quantification (LLOQ) for LB-102 = 1 ng/mL. SD = standard deviation.

Source Data: ADPC; Reference listing(s): 16.2.6.2
Program Name: Figure.sas

SDTM Date: 04AUG2020 16:09
Analysis Date: 20AUG2020 18:00

Figure 14.2.2.1
Spaghetti Plot of Individual Plasma LB-102 Concentrations by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part A (SAD)

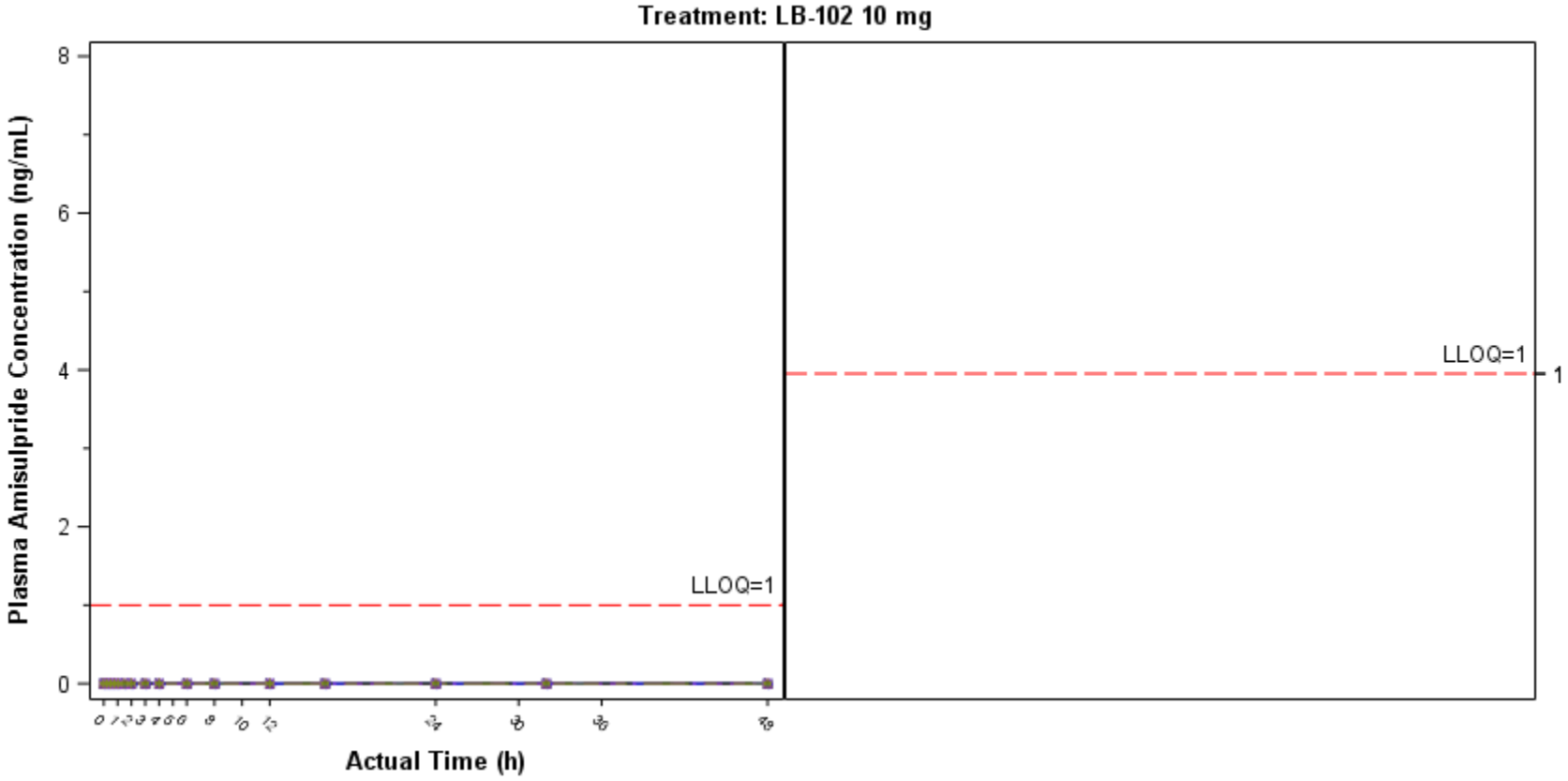


Note: Lower limit of quantification (LLOQ) for LB-102 = 1 ng/mL. SD = standard deviation.

Source Data: ADPC; Reference listing(s): 16.2.6.2
Program Name: Figure.sas

SDTM Date: 04AUG2020 16:09
Analysis Date: 20AUG2020 18:00

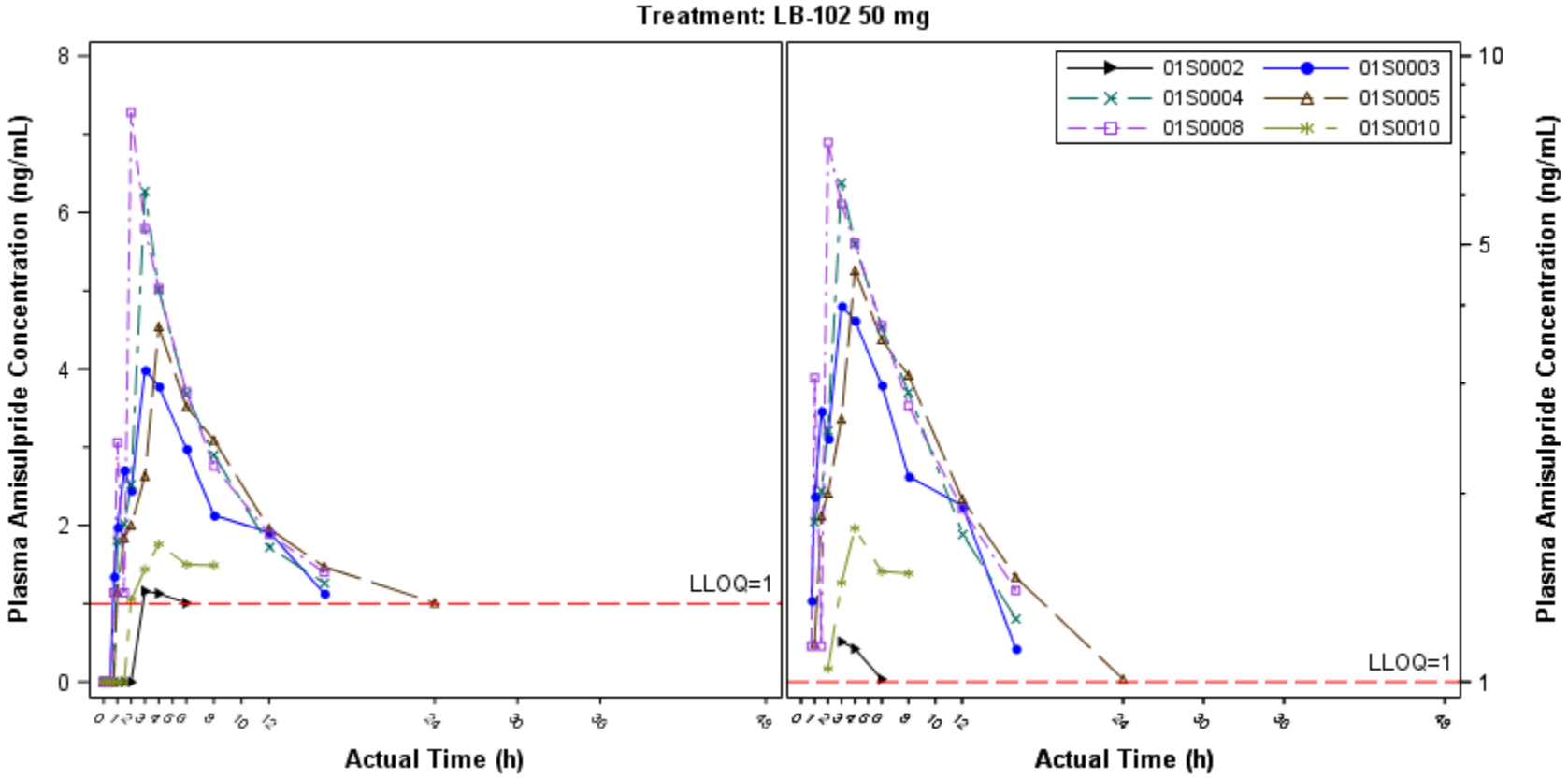
Figure 14.2.2.2
Spaghetti Plot of Individual Plasma Amisulpride Concentrations by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part A (SAD)



Note: Lower limit of quantification (LLOQ) for Amisulpride = 1 ng/mL. SD = standard deviation.

Source Data: ADPC; Reference listing(s): 16.2.6.2 SDTM Date: 04AUG2020 16:09
Program Name: Figure.sas Analysis Date: 20AUG2020 18:00

Figure 14.2.2.2
Spaghetti Plot of Individual Plasma Amisulpride Concentrations by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part A (SAD)

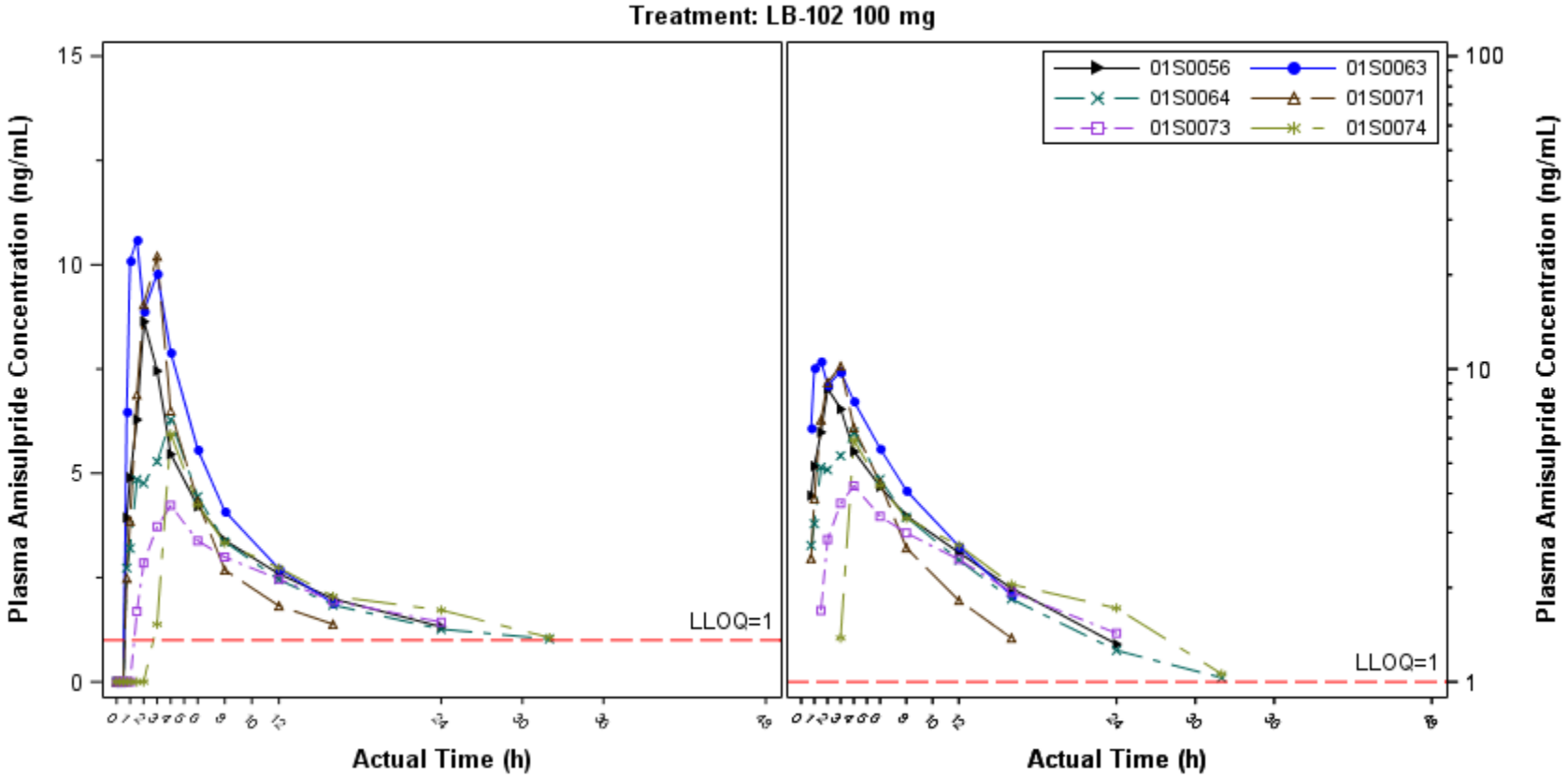


Note: Lower limit of quantification (LLOQ) for Amisulpride = 1 ng/mL. SD = standard deviation.

Source Data: ADPC; Reference listing(s): 16.2.6.2
Program Name: Figure.sas

SDTM Date: 04AUG2020 16:09
Analysis Date: 20AUG2020 18:00

Figure 14.2.2.2
Spaghetti Plot of Individual Plasma Amisulpride Concentrations by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part A (SAD)

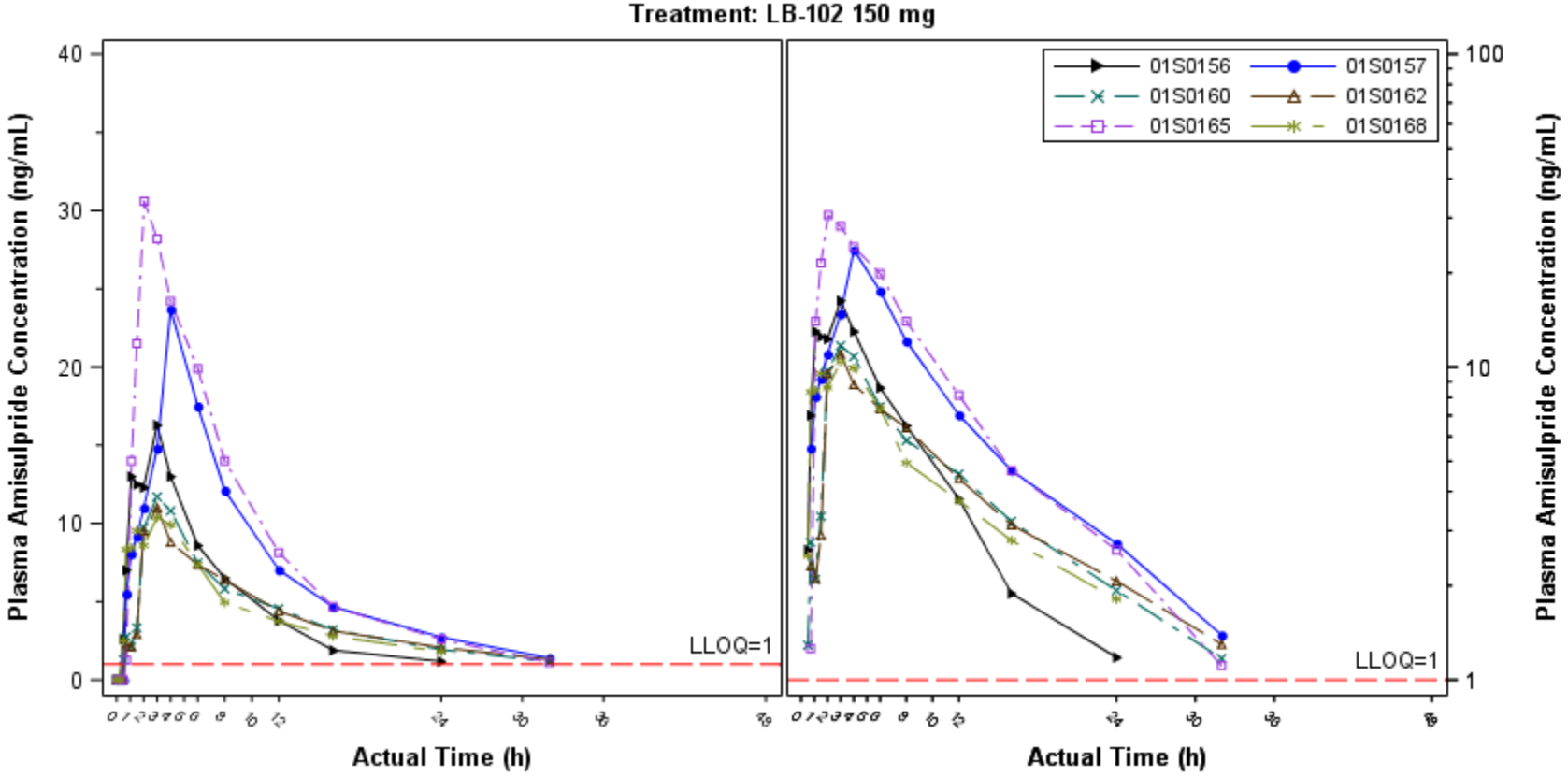


Note: Lower limit of quantification (LLOQ) for Amisulpride = 1 ng/mL. SD = standard deviation.

Source Data: ADPC; Reference listing(s): 16.2.6.2
Program Name: Figure.sas

SDTM Date: 04AUG2020 16:09
Analysis Date: 20AUG2020 18:00

Figure 14.2.2.2
Spaghetti Plot of Individual Plasma Amisulpride Concentrations by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part A (SAD)

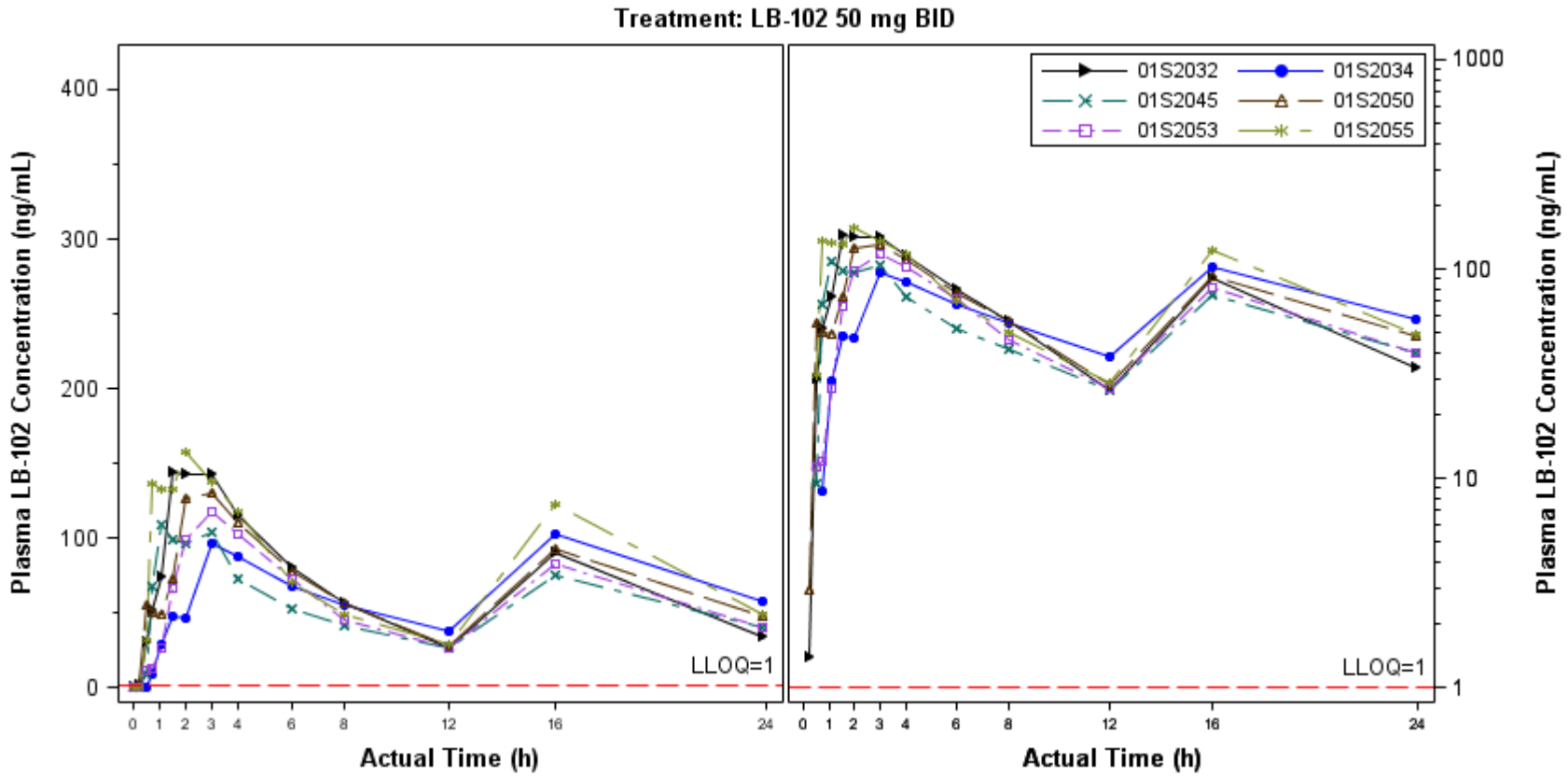


Note: Lower limit of quantification (LLOQ) for Amisulpride = 1 ng/mL. SD = standard deviation.

Source Data: ADPC; Reference listing(s): 16.2.6.2
Program Name: Figure.sas

SDTM Date: 04AUG2020 16:09
Analysis Date: 20AUG2020 18:00

Figure 14.2.2.3
Spaghetti Plot of Individual Plasma LB-102 Concentrations on Day 1 by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part B (MAD)

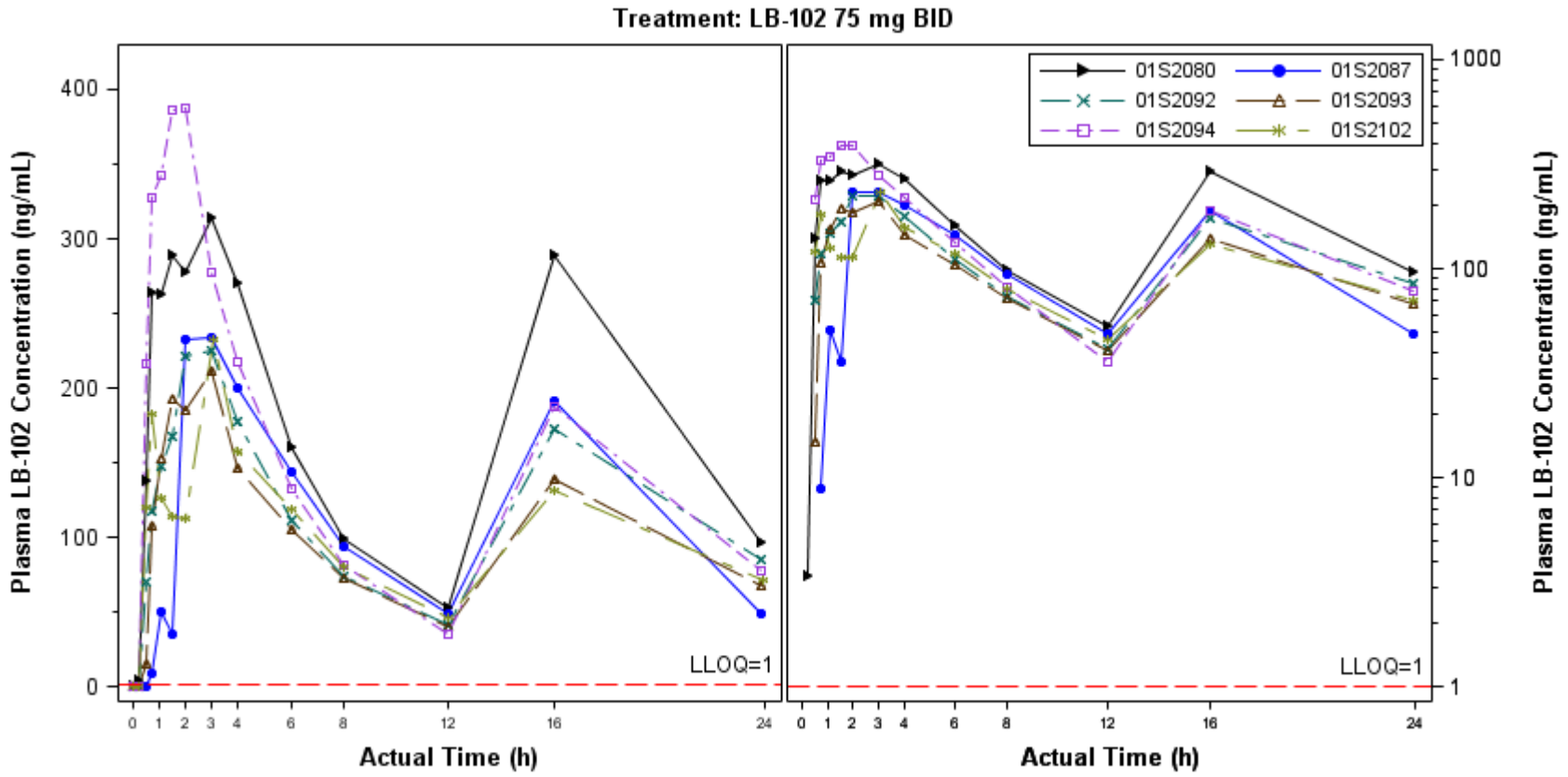


Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL.

Source Data: ADPCMAD; Reference listing(s): 16.2.6.3
Program Name: figSpagh_mad.sas

SDTM Date: 04AUG2020 16:09
Analysis Date: 25AUG2020 14:27

Figure 14.2.2.3
Spaghetti Plot of Individual Plasma LB-102 Concentrations on Day 1 by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part B (MAD)

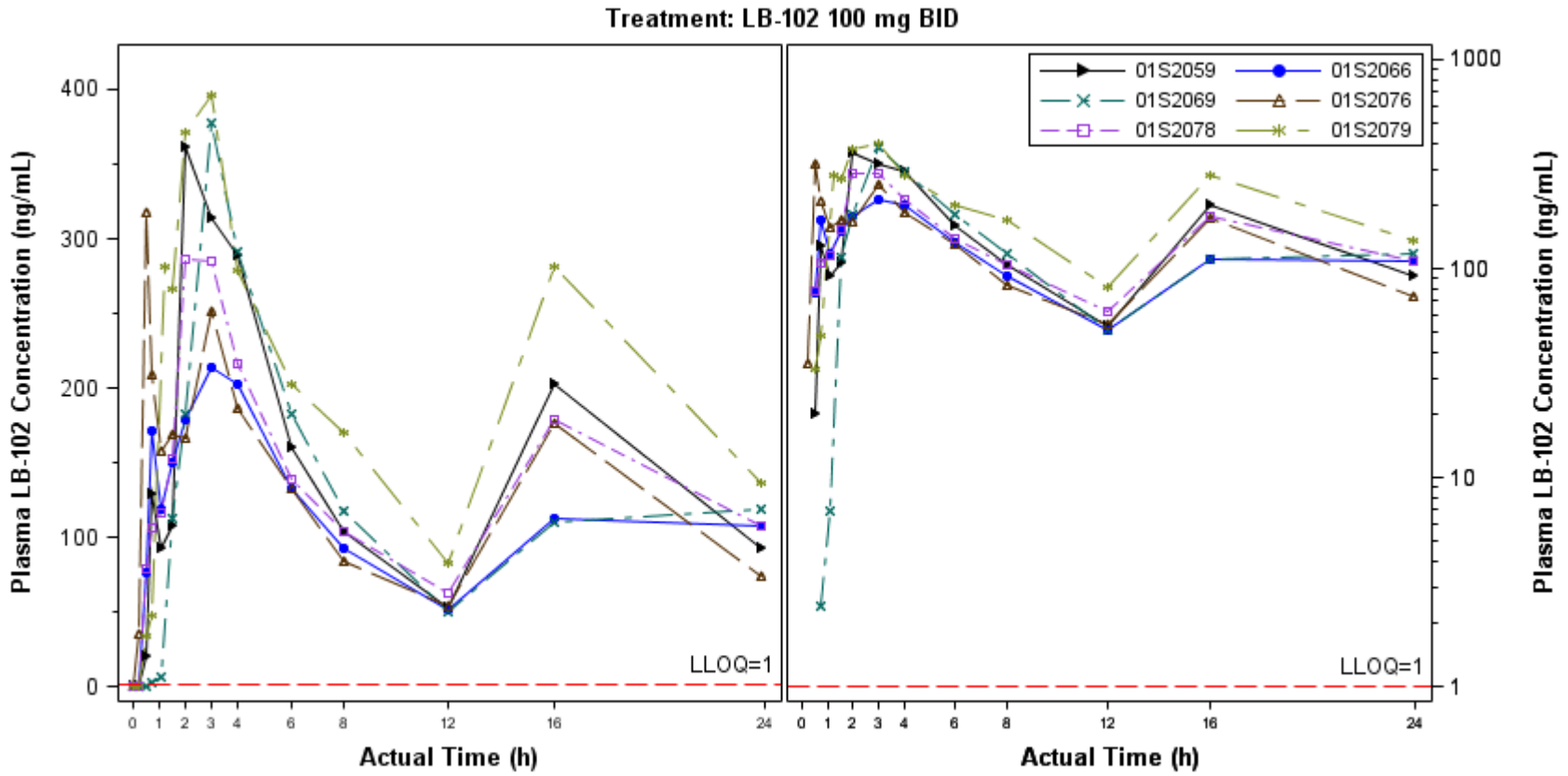


Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL.

Source Data: ADPCMAD; Reference listing(s): 16.2.6.3
Program Name: figSpagh_mad.sas

SDTM Date: 04AUG2020 16:09
Analysis Date: 25AUG2020 14:27

Figure 14.2.2.3
Spaghetti Plot of Individual Plasma LB-102 Concentrations on Day 1 by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part B (MAD)

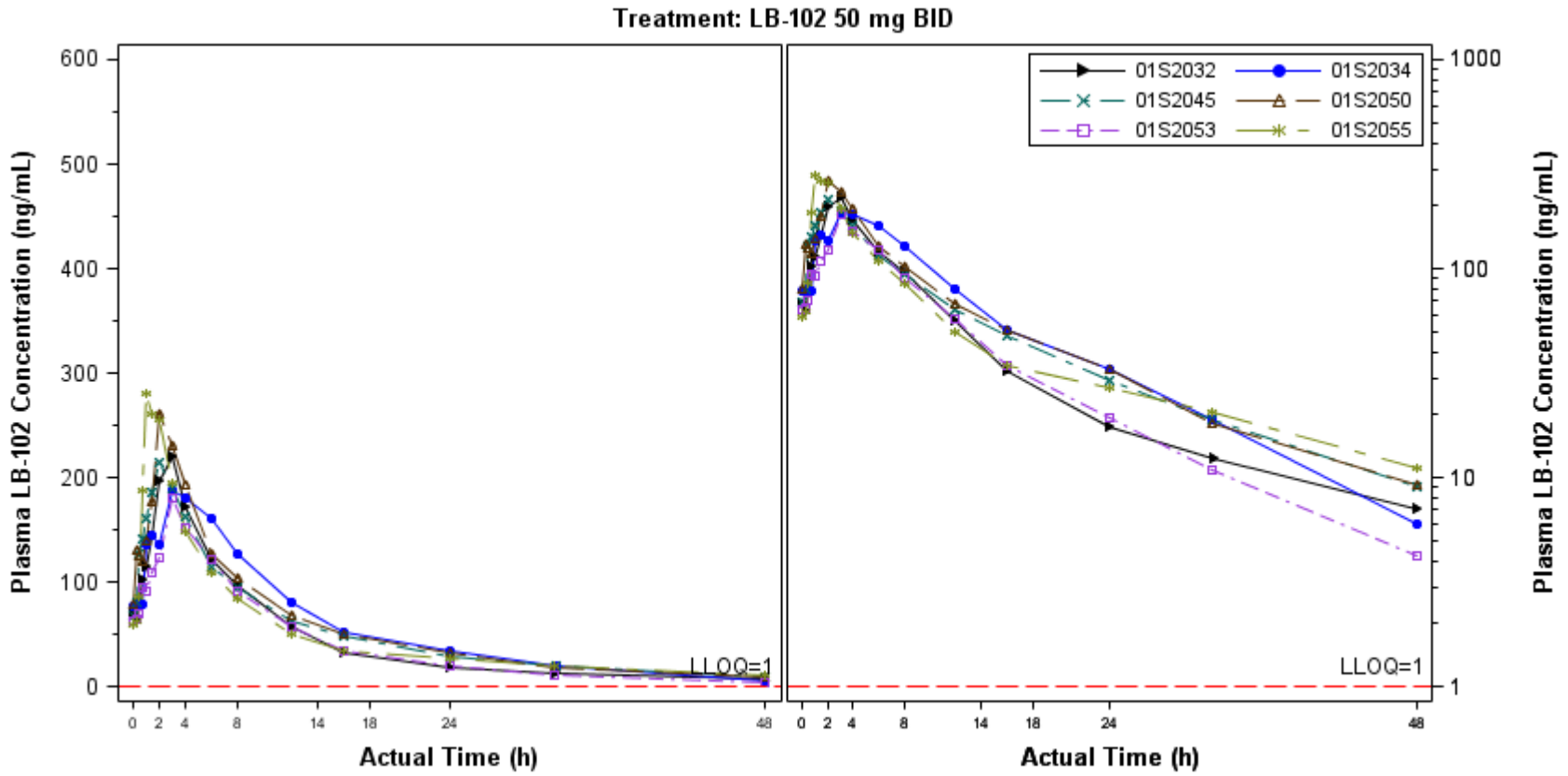


Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL.

Source Data: ADPCMAD; Reference listing(s): 16.2.6.3
Program Name: figSpagh_mad.sas

SDTM Date: 04AUG2020 16:09
Analysis Date: 25AUG2020 14:27

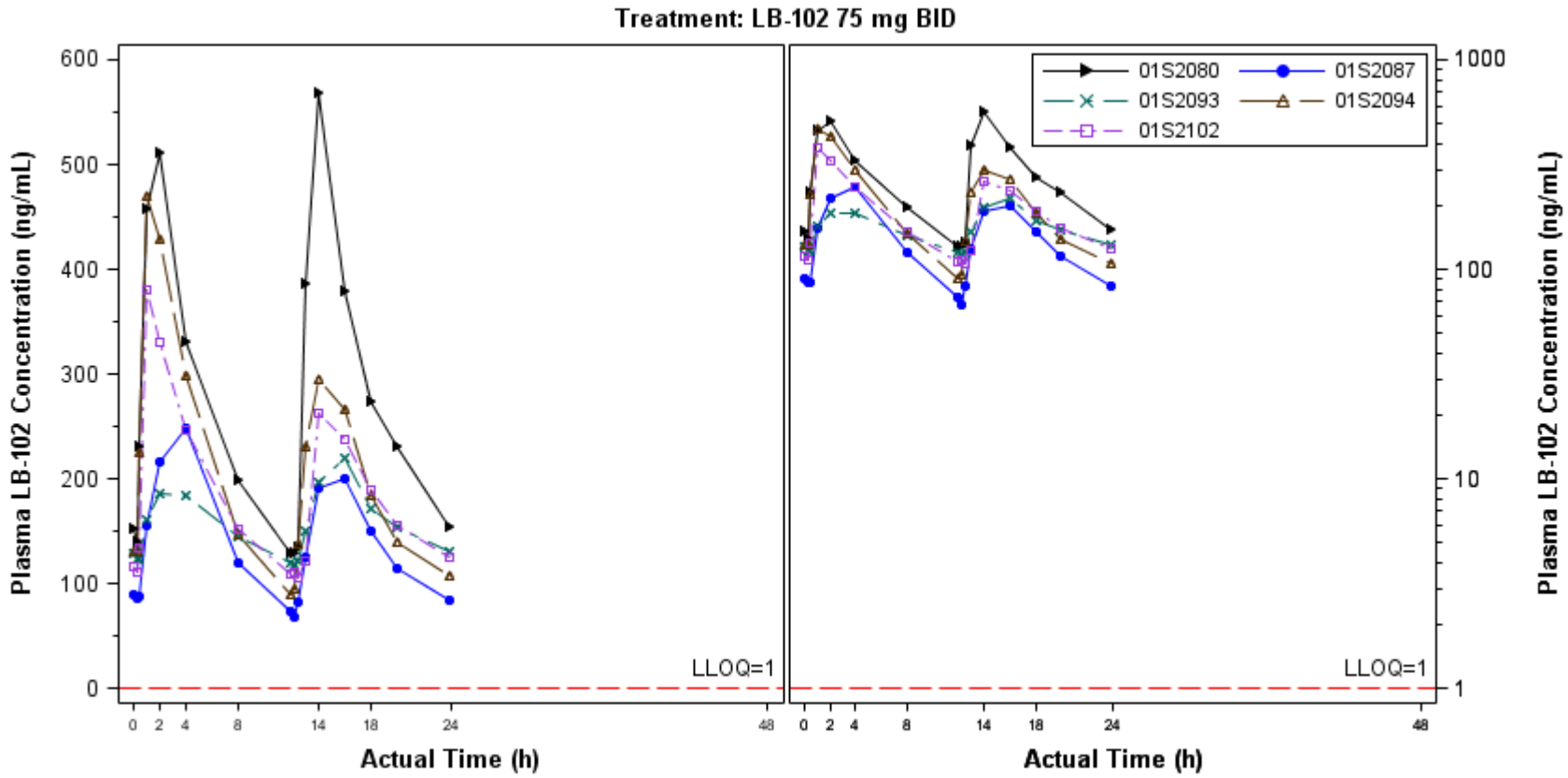
Figure 14.2.2.4
Spaghetti Plot of Individual Plasma LB-102 Concentrations after Multiple Dose by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part B (MAD)



Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. SD = standard deviation.
For Cohort 6 (LB-102 50 mg BID), the PK concentrations of the QD dosing on Day 7 are plotted. For Cohort 8 (LB-102 75 mg BID), the PK concentrations of both doses on Day 6 are plotted.

Source Data: ADPCMAD; Reference listing(s): 16.2.6.3
SDTM Date: 04AUG2020 16:09
Program Name: figSpagh_mad.sas
Analysis Date: 25AUG2020 14:27

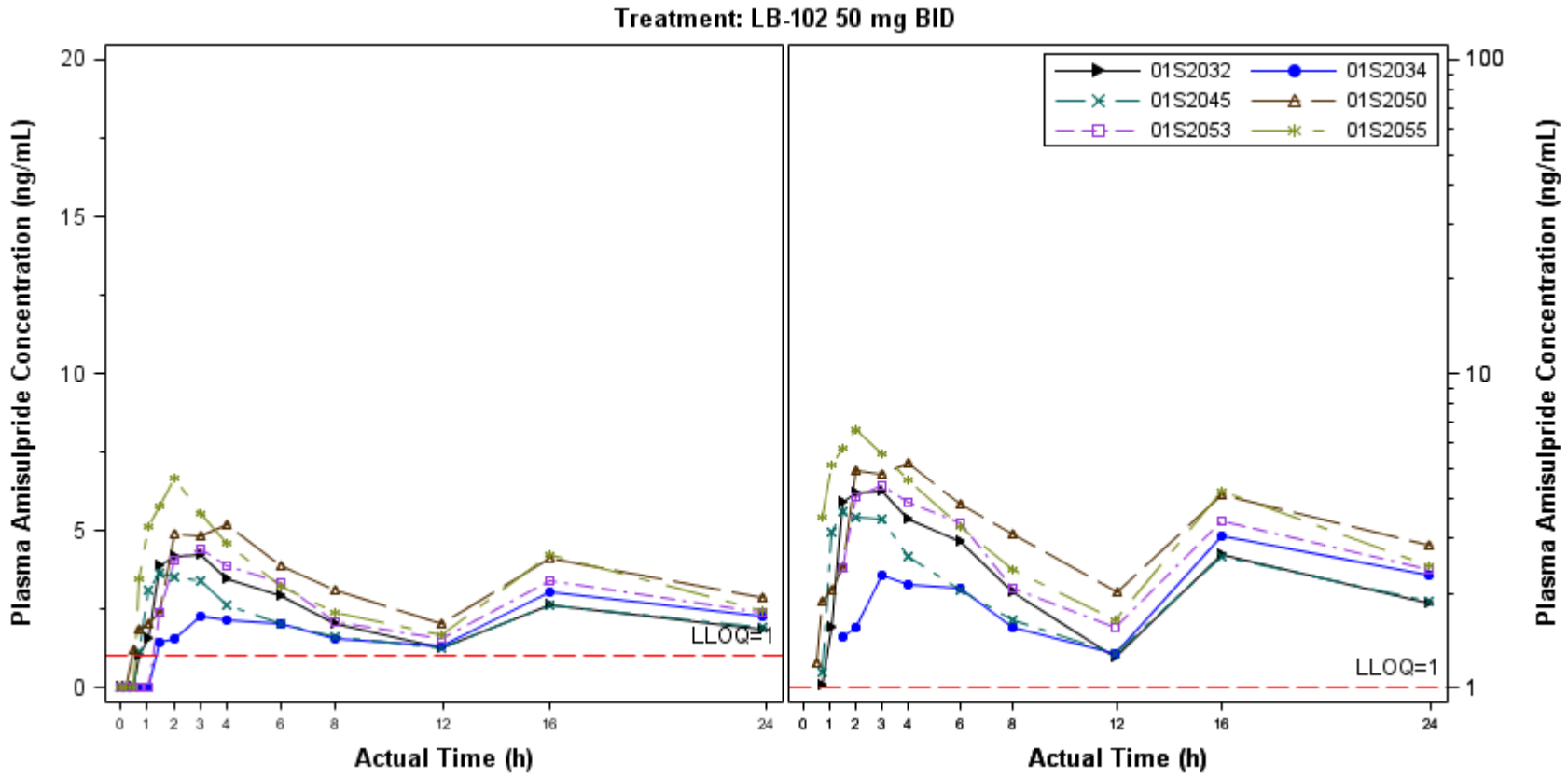
Figure 14.2.2.4
Spaghetti Plot of Individual Plasma LB-102 Concentrations after Multiple Dose by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part B (MAD)



Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. SD = standard deviation.
For Cohort 6 (LB-102 50 mg BID), the PK concentrations of the QD dosing on Day 7 are plotted. For Cohort 8 (LB-102 75 mg BID), the PK concentrations of both doses on Day 6 are plotted.

Source Data: ADPCMAD; Reference listing(s): 16.2.6.3 SDTM Date: 04AUG2020 16:09
Program Name: figSpagh_mad.sas Analysis Date: 25AUG2020 14:27

Figure 14.2.2.5
Spaghetti Plot of Individual Plasma Amisulpride Concentrations on Day 1 by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part B (MAD)

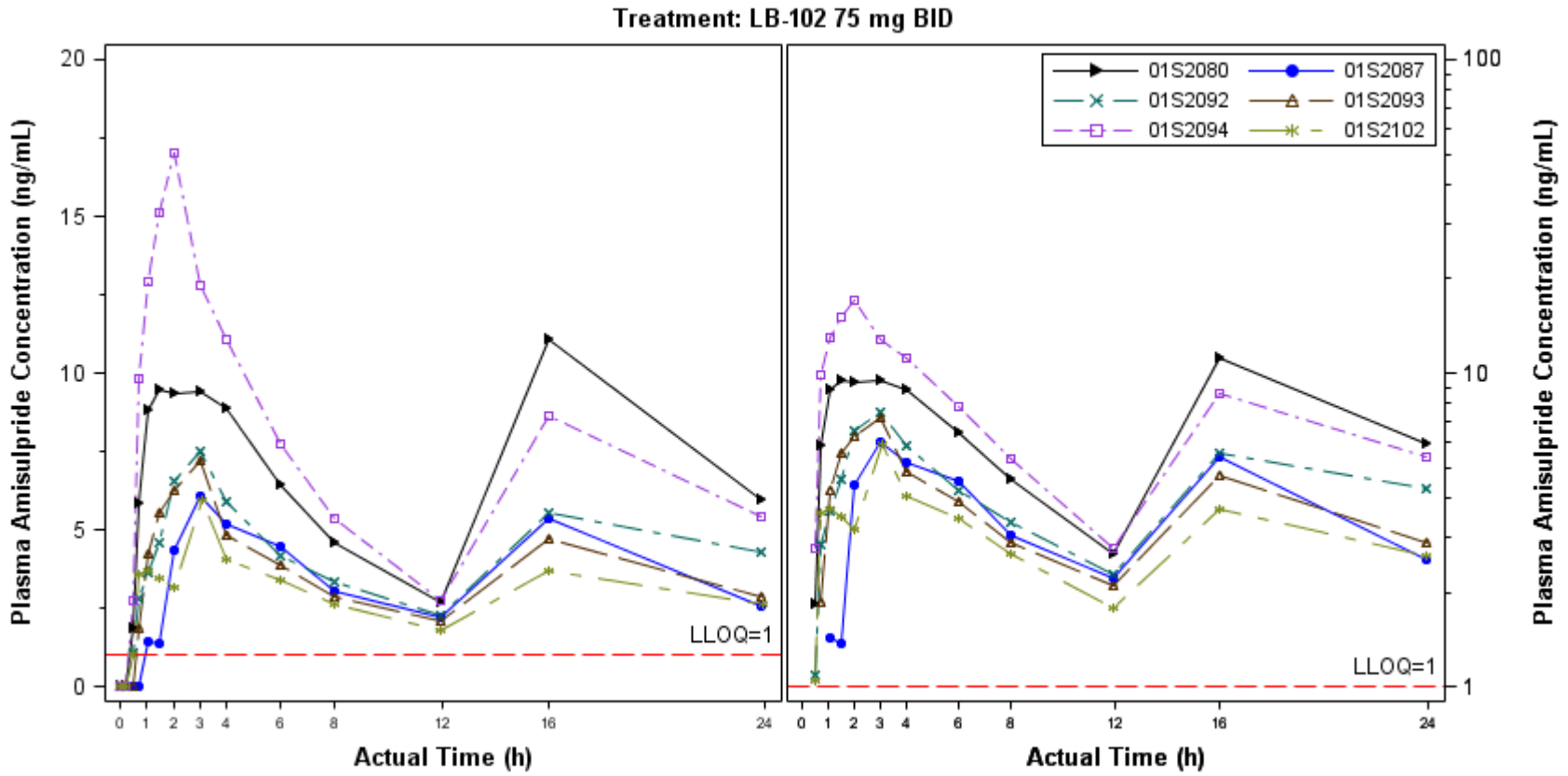


Note: Lower limit of quantification (LLOQ) of amisulpride = 1 ng/mL.

Source Data: ADPCMAD; Reference listing(s): 16.2.6.3
Program Name: figSpagh_mad.sas

SDTM Date: 04AUG2020 16:09
Analysis Date: 25AUG2020 14:27

Figure 14.2.2.5
Spaghetti Plot of Individual Plasma Amisulpride Concentrations on Day 1 by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part B (MAD)

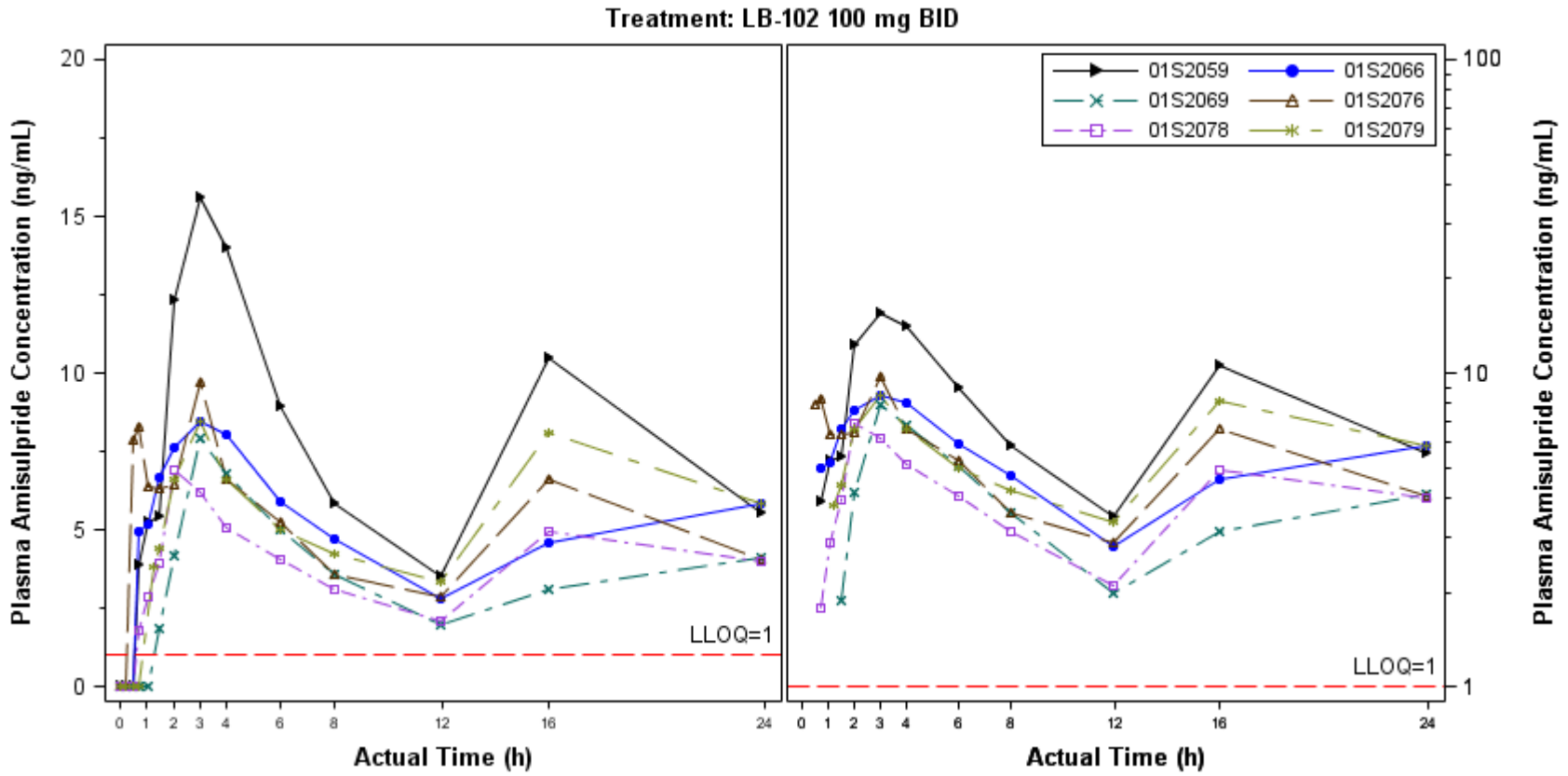


Note: Lower limit of quantification (LLOQ) of amisulpride = 1 ng/mL.

Source Data: ADPCMAD; Reference listing(s): 16.2.6.3
Program Name: figSpagh_mad.sas

SDTM Date: 04AUG2020 16:09
Analysis Date: 25AUG2020 14:27

Figure 14.2.2.5
Spaghetti Plot of Individual Plasma Amisulpride Concentrations on Day 1 by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part B (MAD)

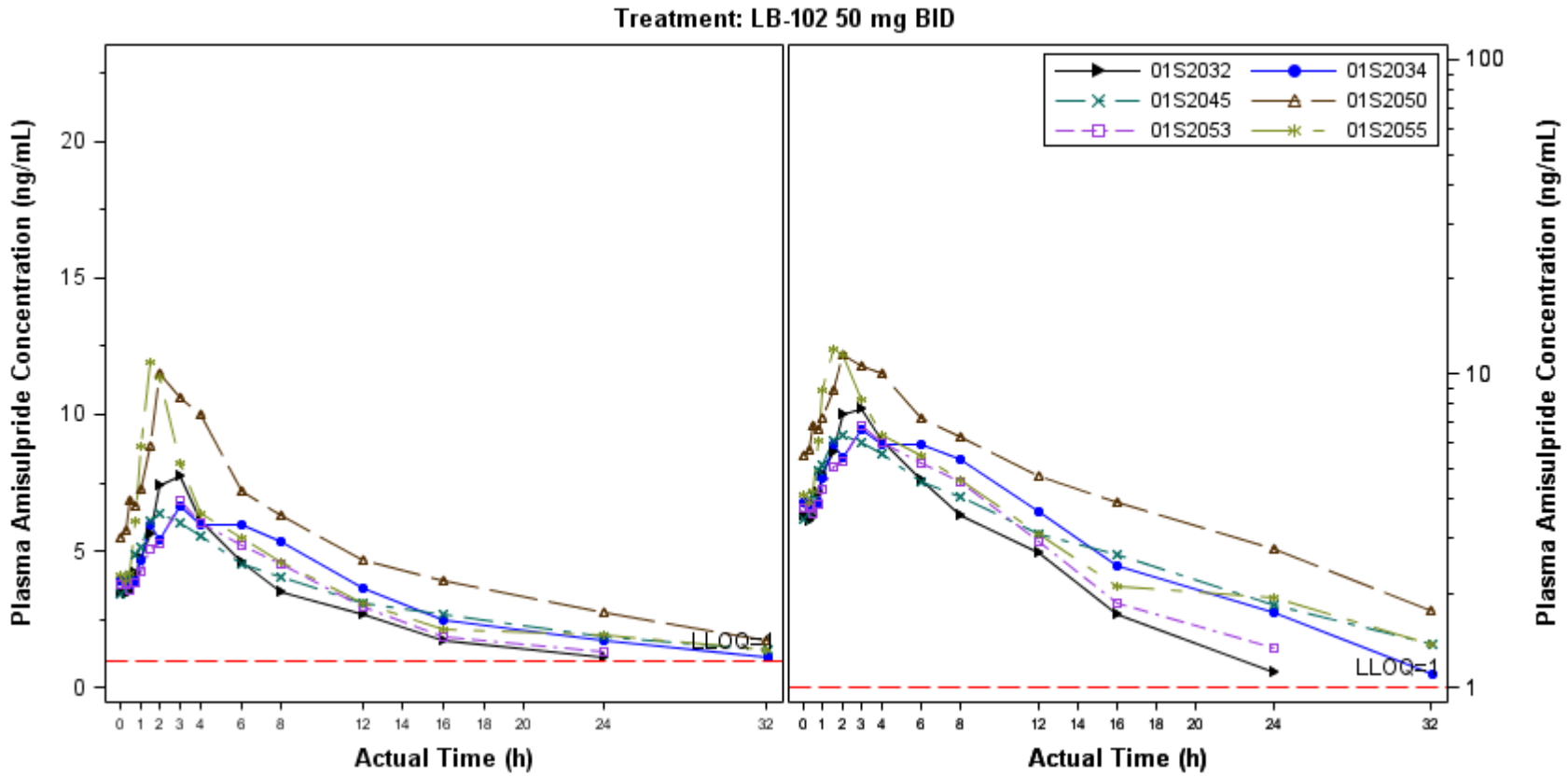


Note: Lower limit of quantification (LLOQ) of amisulpride = 1 ng/mL.

Source Data: ADPCMAD; Reference listing(s): 16.2.6.3
Program Name: figSpagh_mad.sas

SDTM Date: 04AUG2020 16:09
Analysis Date: 25AUG2020 14:27

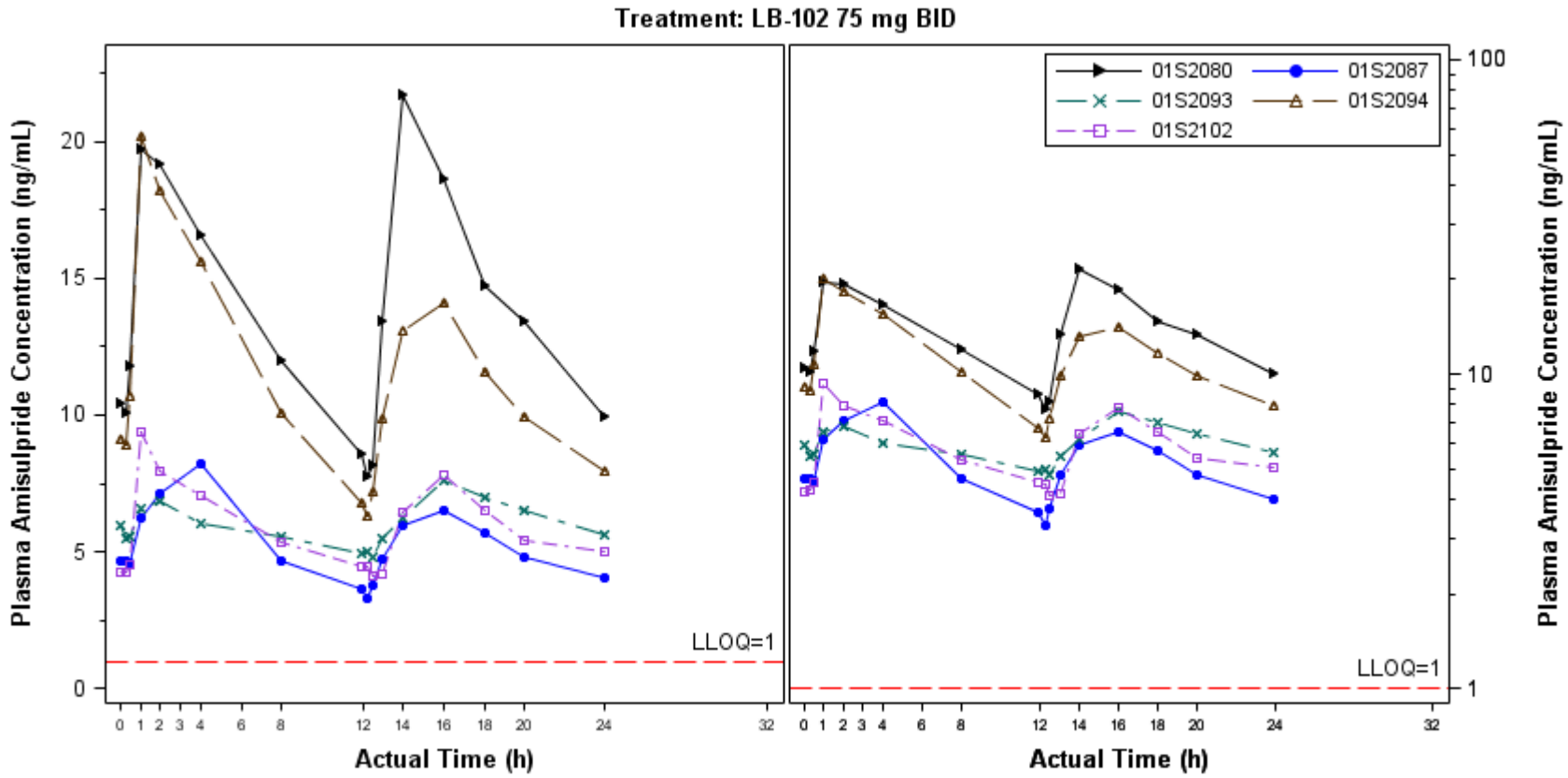
Figure 14.2.2.6
Spaghetti Plot of Individual Plasma Amisulpride Concentrations after Multiple Dose by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part B (MAD)



Note: Lower limit of quantification (LLOQ) of amisulpride = 1 ng/mL. SD = standard deviation.
For Cohort 6 (LB-102 50 mg BID), the PK concentrations of the QD dosing on Day 7 are plotted. For Cohort 8 (LB-102 75 mg BID), the PK concentrations of both doses on Day 6 are plotted.

Source Data: ADPCMAD; Reference listing(s): 16.2.6.3 SDTM Date: 04AUG2020 16:09
Program Name: figSpagh_mad.sas Analysis Date: 25AUG2020 14:27

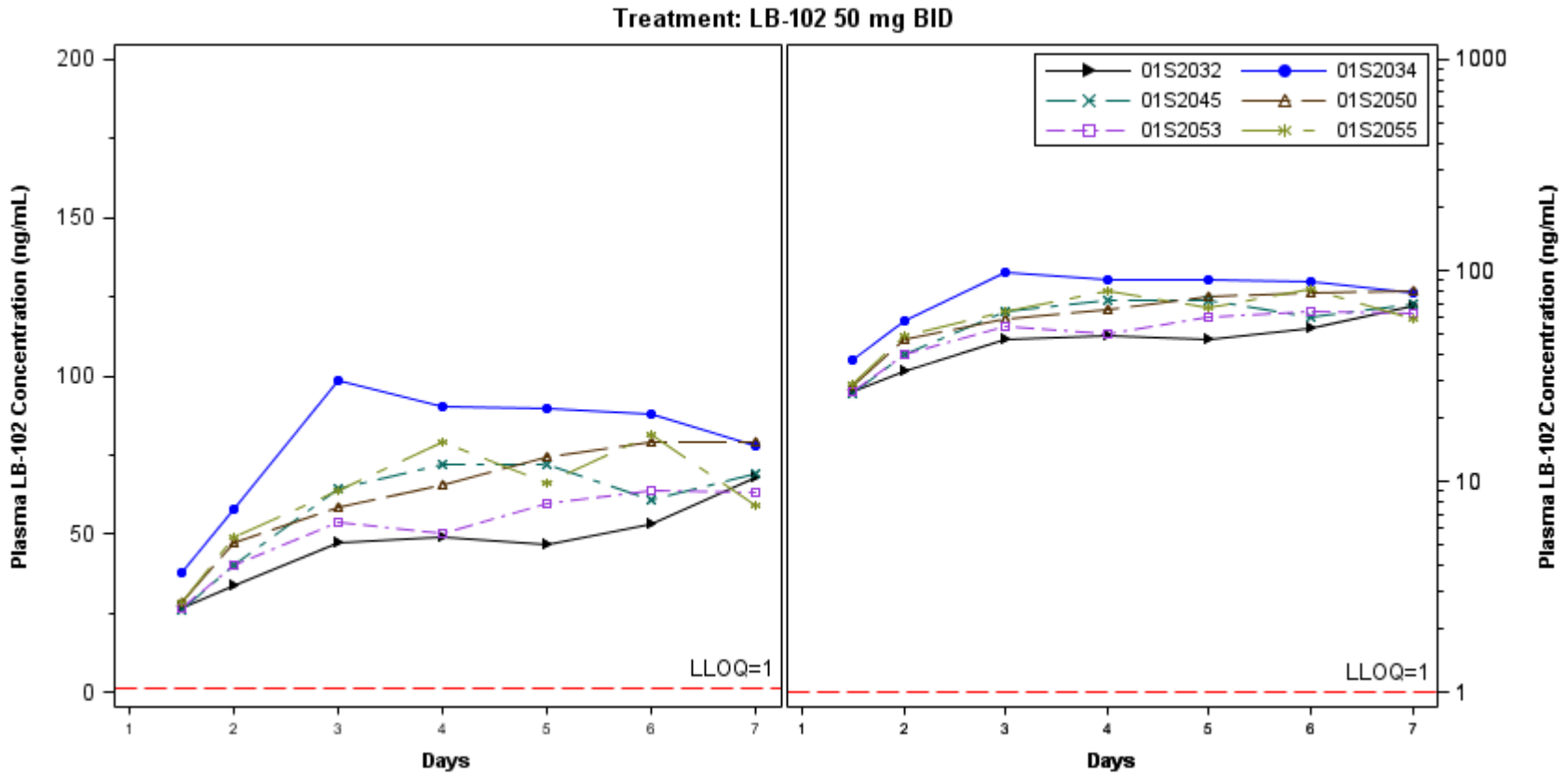
Figure 14.2.2.6
Spaghetti Plot of Individual Plasma Amisulpride Concentrations after Multiple Dose by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part B (MAD)



Note: Lower limit of quantification (LLOQ) of amisulpride = 1 ng/mL. SD = standard deviation.
For Cohort 6 (LB-102 50 mg BID), the PK concentrations of the QD dosing on Day 7 are plotted. For Cohort 8 (LB-102 75 mg BID), the PK concentrations of both doses on Day 6 are plotted.

Source Data: ADPCMAD; Reference listing(s): 16.2.6.3 SDTM Date: 04AUG2020 16:09
Program Name: figSpagh_mad.sas Analysis Date: 25AUG2020 14:27

Figure 14.2.2.7
Spaghetti Plot of Individual Plasma Trough LB-102 Concentrations after Multiple Dose by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part B (MAD)

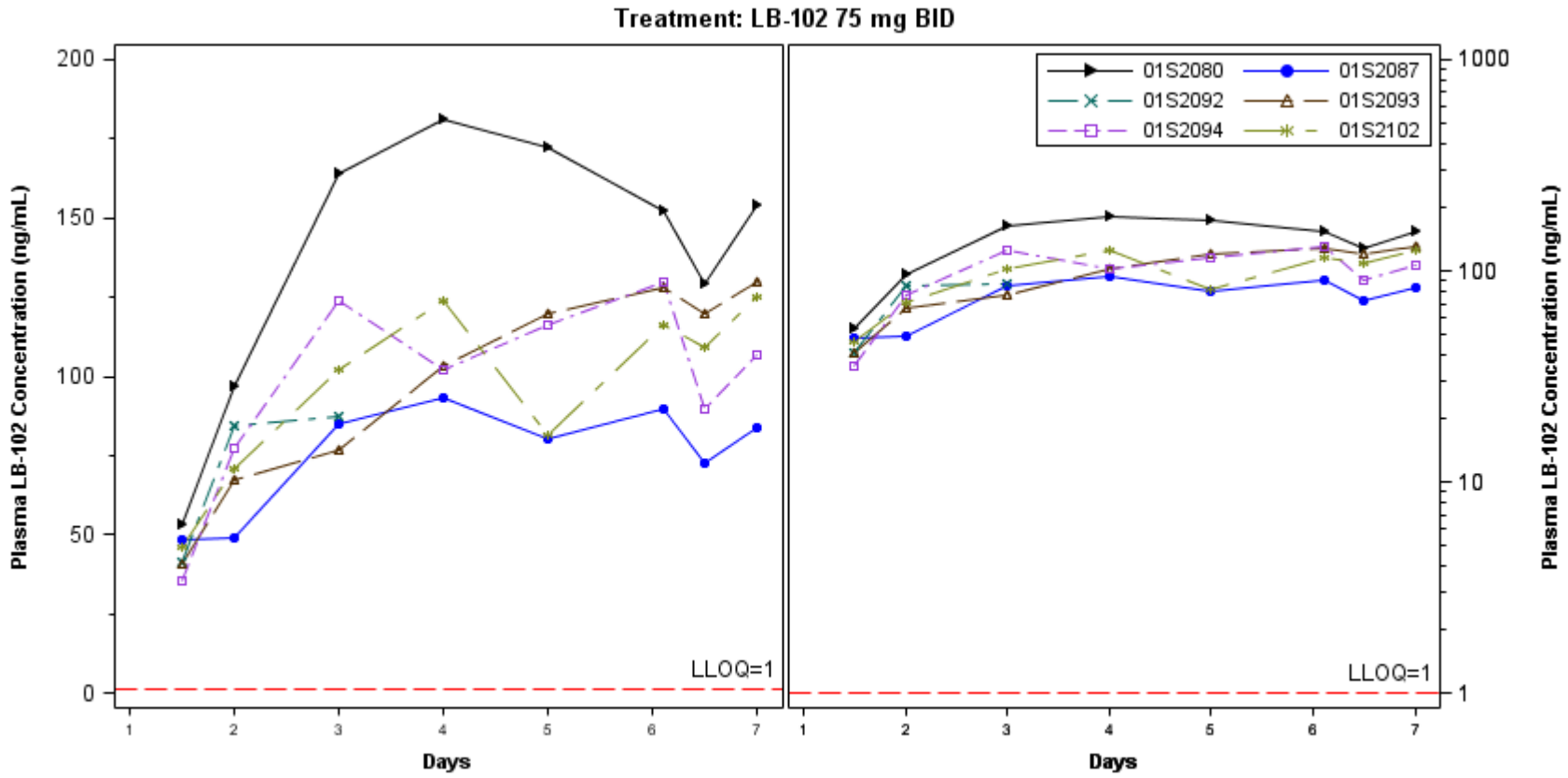


Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL.
All predose concentrations except that for the first dose on Day 1 are plotted as trough concentration.

Source Data: ADPCMAD; Reference listing(s): 16.2.6.3
Program Name: figSpaghCtrough_mad.sas

SDTM Date: 04AUG2020 16:09
Analysis Date: 25AUG2020 16:25

Figure 14.2.2.7
Spaghetti Plot of Individual Plasma Trough LB-102 Concentrations after Multiple Dose by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part B (MAD)

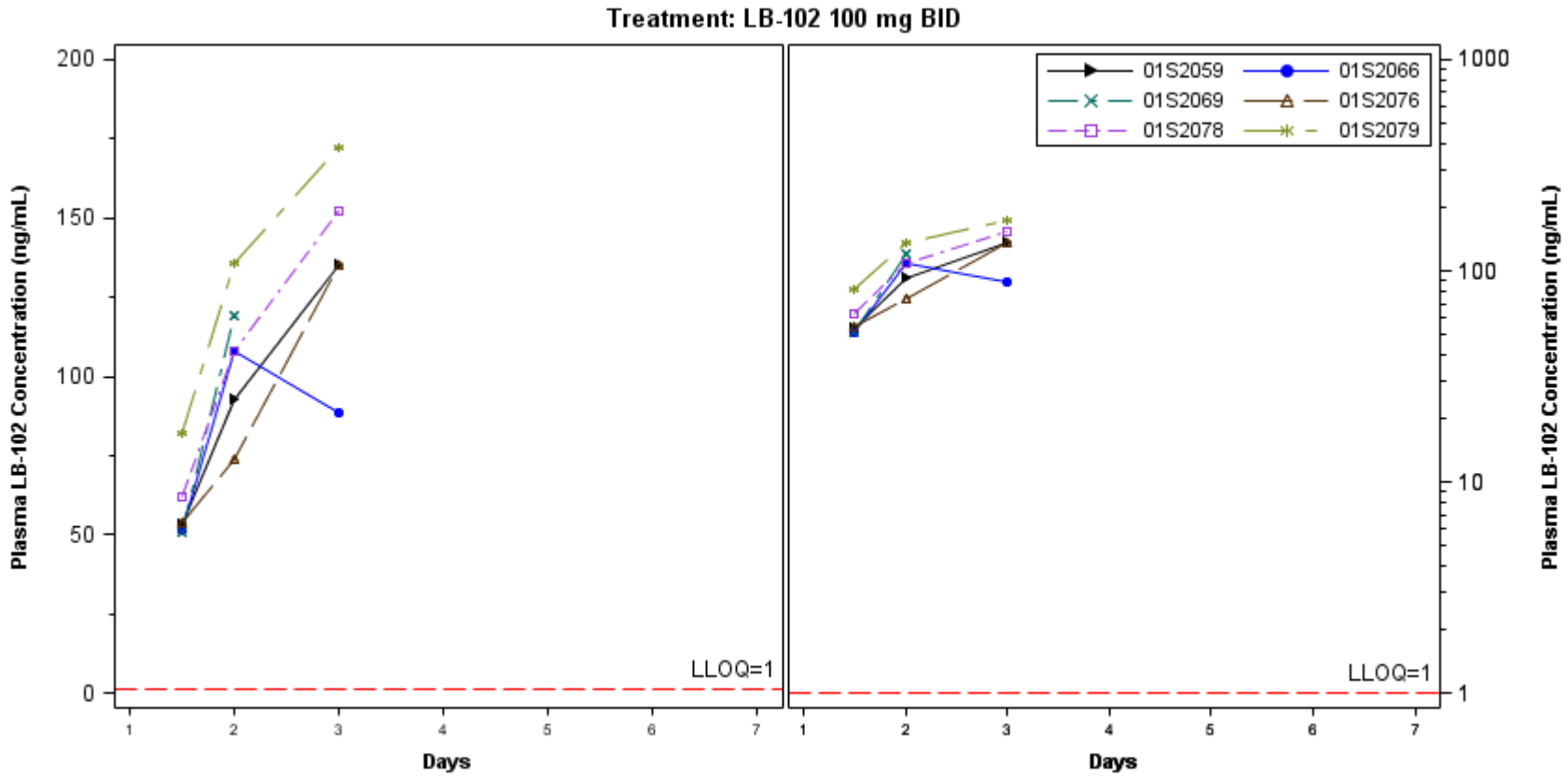


Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL.
All predose concentrations except that for the first dose on Day 1 are plotted as trough concentration.

Source Data: ADPCMAD; Reference listing(s): 16.2.6.3
Program Name: figSpaghCtrough_mad.sas

SDTM Date: 04AUG2020 16:09
Analysis Date: 25AUG2020 16:25

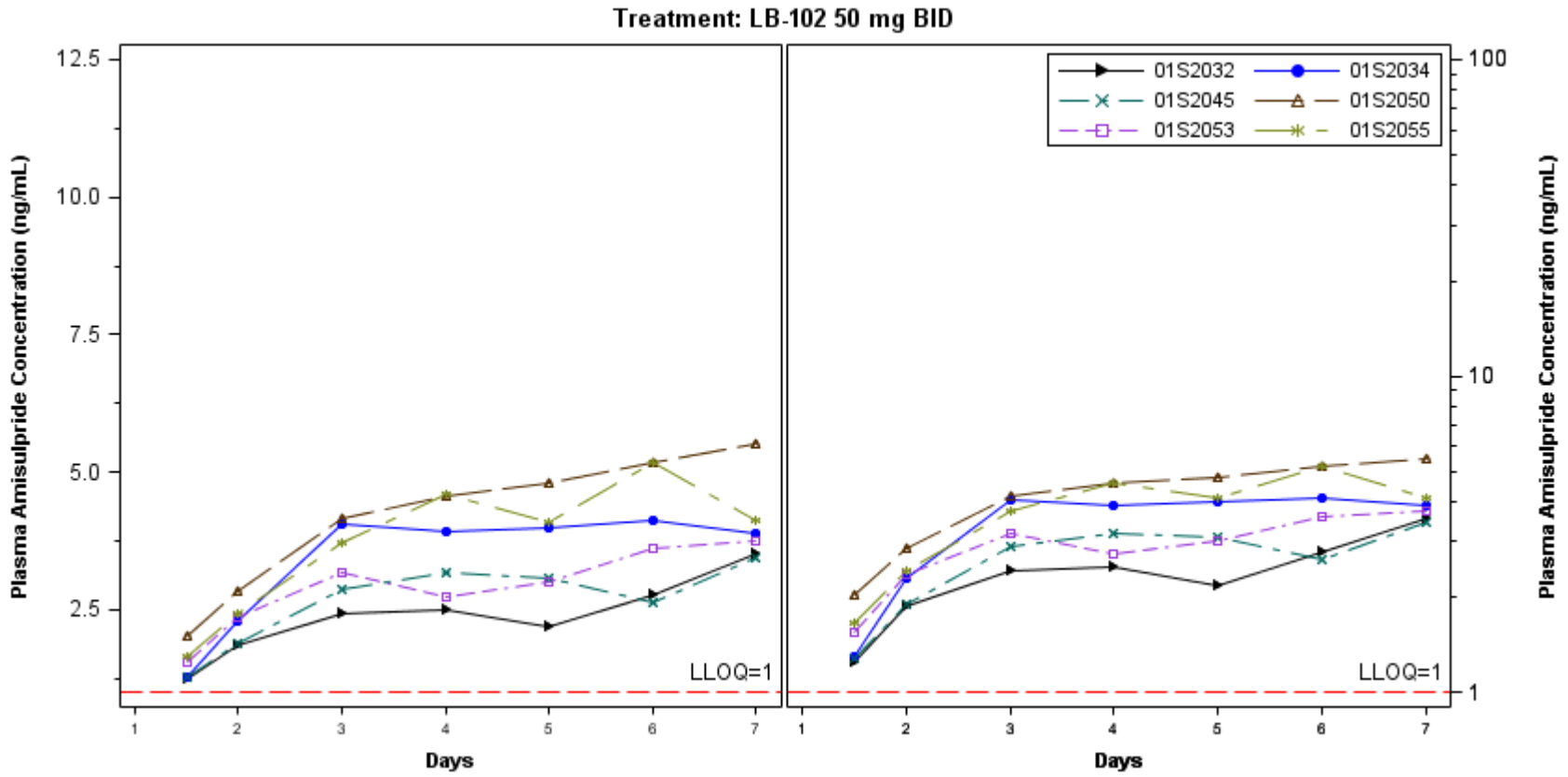
Figure 14.2.2.7
Spaghetti Plot of Individual Plasma Trough LB-102 Concentrations after Multiple Dose by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part B (MAD)



Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL.
All predose concentrations except that for the first dose on Day 1 are plotted as trough concentration.

Source Data: ADPCMAD; Reference listing(s): 16.2.6.3 SDTM Date: 04AUG2020 16:09
Program Name: figSpaghCtrough_mad.sas Analysis Date: 25AUG2020 16:25

Figure 14.2.2.8
Spaghetti Plot of Individual Plasma Trough Amisulpride Concentrations by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part B (MAD)

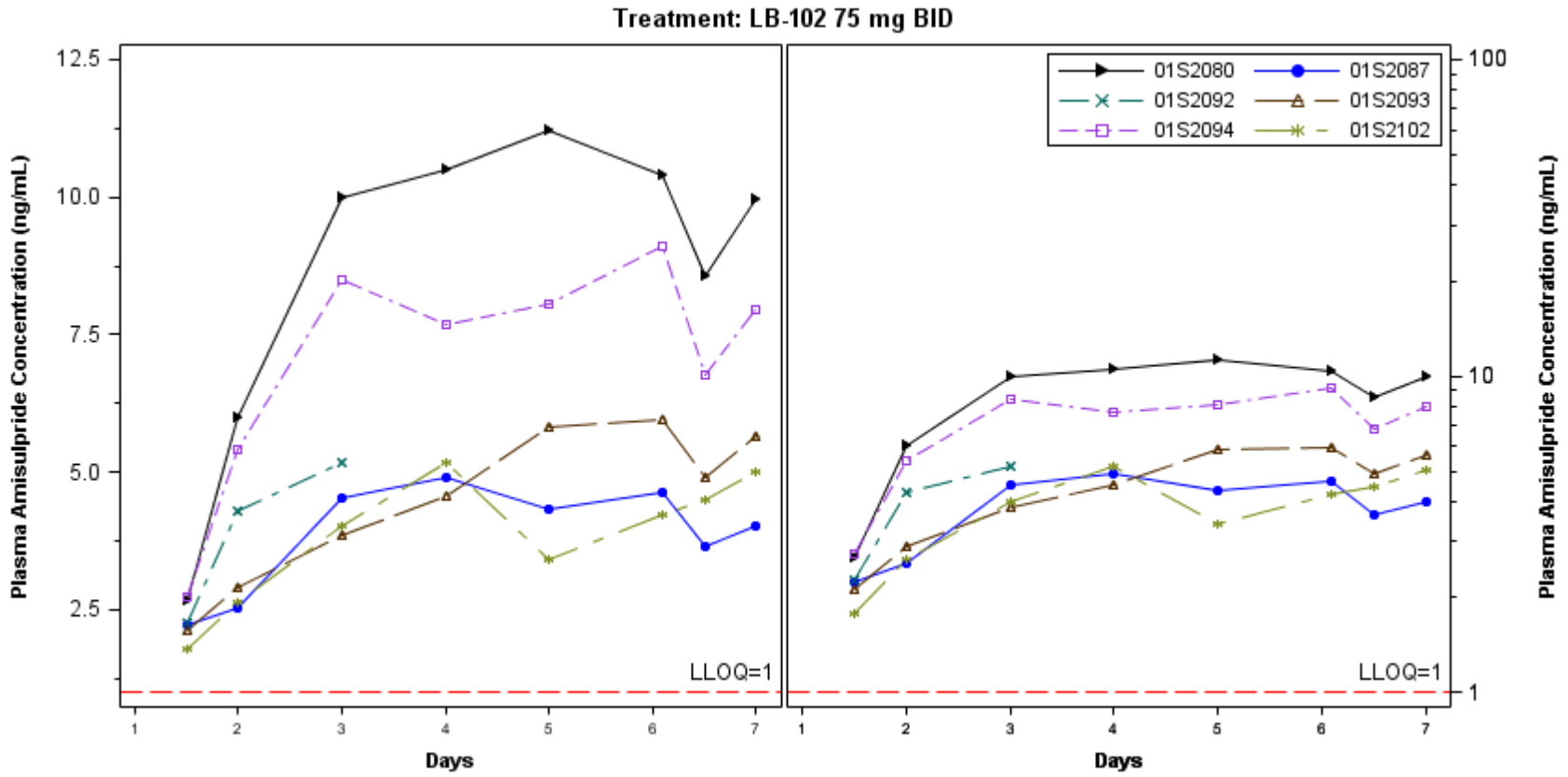


Note: Lower limit of quantification (LLOQ) of amisulpride = 1 ng/mL.
All predose concentrations except that for the first dose on Day 1 are plotted as trough concentration.

Source Data: ADPCMAD; Reference listing(s): 16.2.6.3
Program Name: figSpaghCtrough_mad.sas

SDTM Date: 04AUG2020 16:09
Analysis Date: 25AUG2020 16:25

Figure 14.2.2.8
Spaghetti Plot of Individual Plasma Trough Amisulpride Concentrations by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part B (MAD)

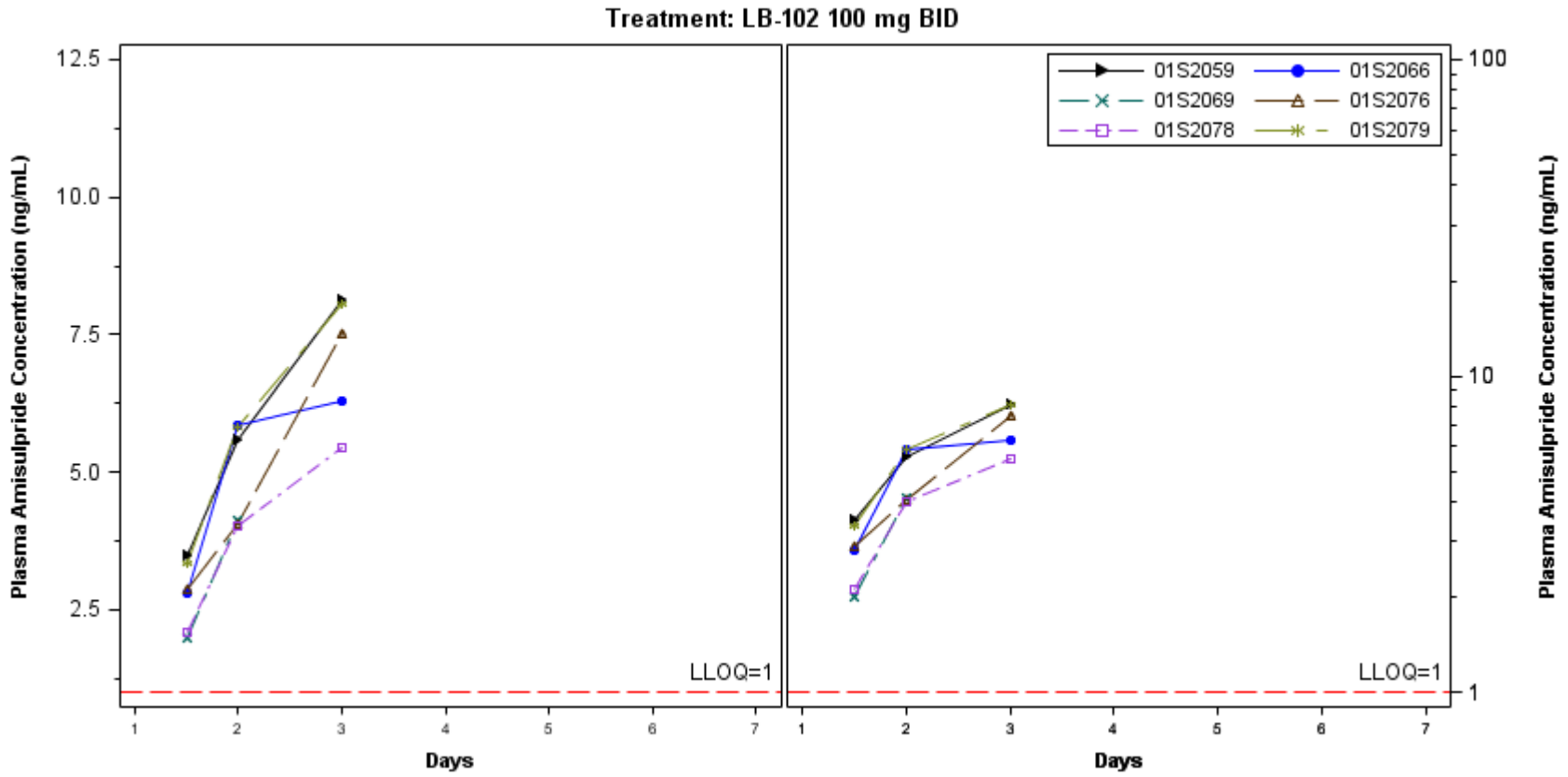


Note: Lower limit of quantification (LLOQ) of amisulpride = 1 ng/mL.
All predose concentrations except that for the first dose on Day 1 are plotted as trough concentration.

Source Data: ADPCMAD; Reference listing(s): 16.2.6.3
Program Name: figSpaghCtrough_mad.sas

SDTM Date: 04AUG2020 16:09
Analysis Date: 25AUG2020 16:25

Figure 14.2.2.8
Spaghetti Plot of Individual Plasma Trough Amisulpride Concentrations by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part B (MAD)

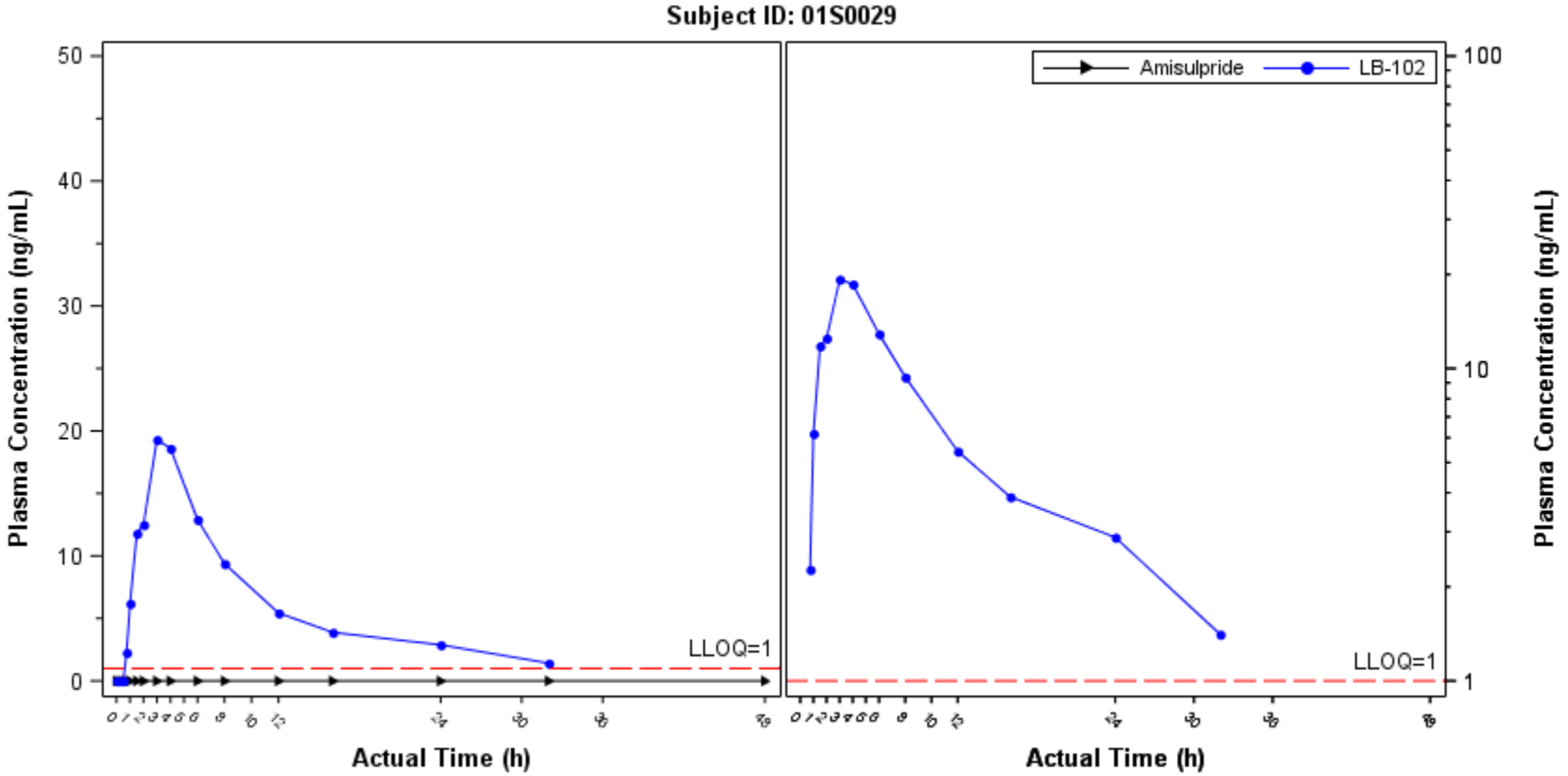


Note: Lower limit of quantification (LLOQ) of amisulpride = 1 ng/mL.
All predose concentrations except that for the first dose on Day 1 are plotted as trough concentration.

Source Data: ADPCMAD; Reference listing(s): 16.2.6.3
Program Name: figSpaghCtrough_mad.sas

SDTM Date: 04AUG2020 16:09
Analysis Date: 25AUG2020 16:25

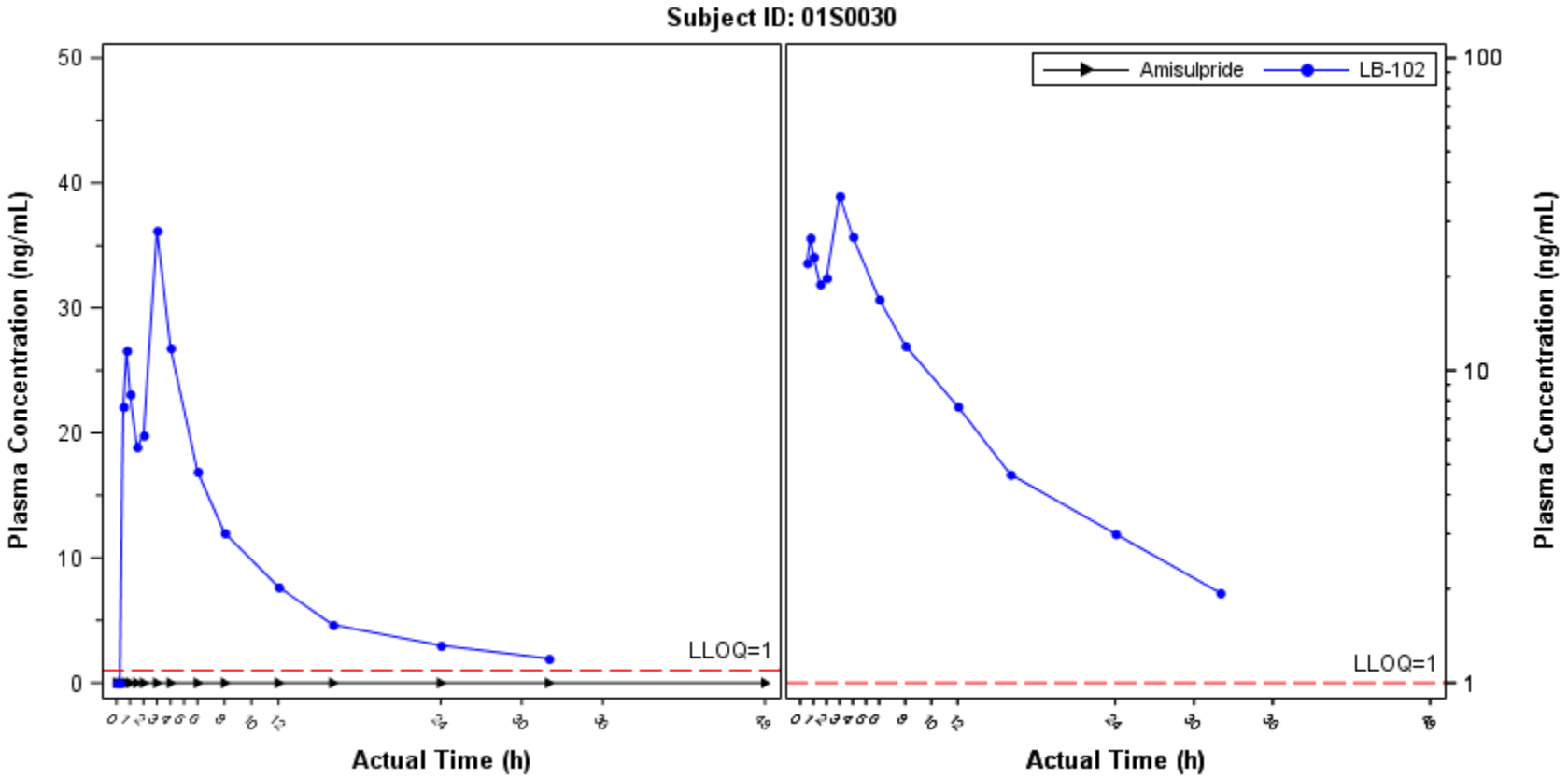
Figure 14.2.3.1
Plot of Individual Plasma Concentrations of LB-102 and Amisulpride by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part A (SAD)
LB-102 10 mg



Note: Lower limit of quantification (LLOQ) for LB-102 = 1 ng/mL. LLOQ for amisulpride = 1 ng/mL.
SD = standard deviation.

Source Data: ADPC; Reference listing(s): 16.2.6.2 SDTM Date: 04AUG2020 16:09
Program Name: Figure.sas Analysis Date: 20AUG2020 18:00

Figure 14.2.3.1
Plot of Individual Plasma Concentrations of LB-102 and Amisulpride by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part A (SAD)
LB-102 10 mg

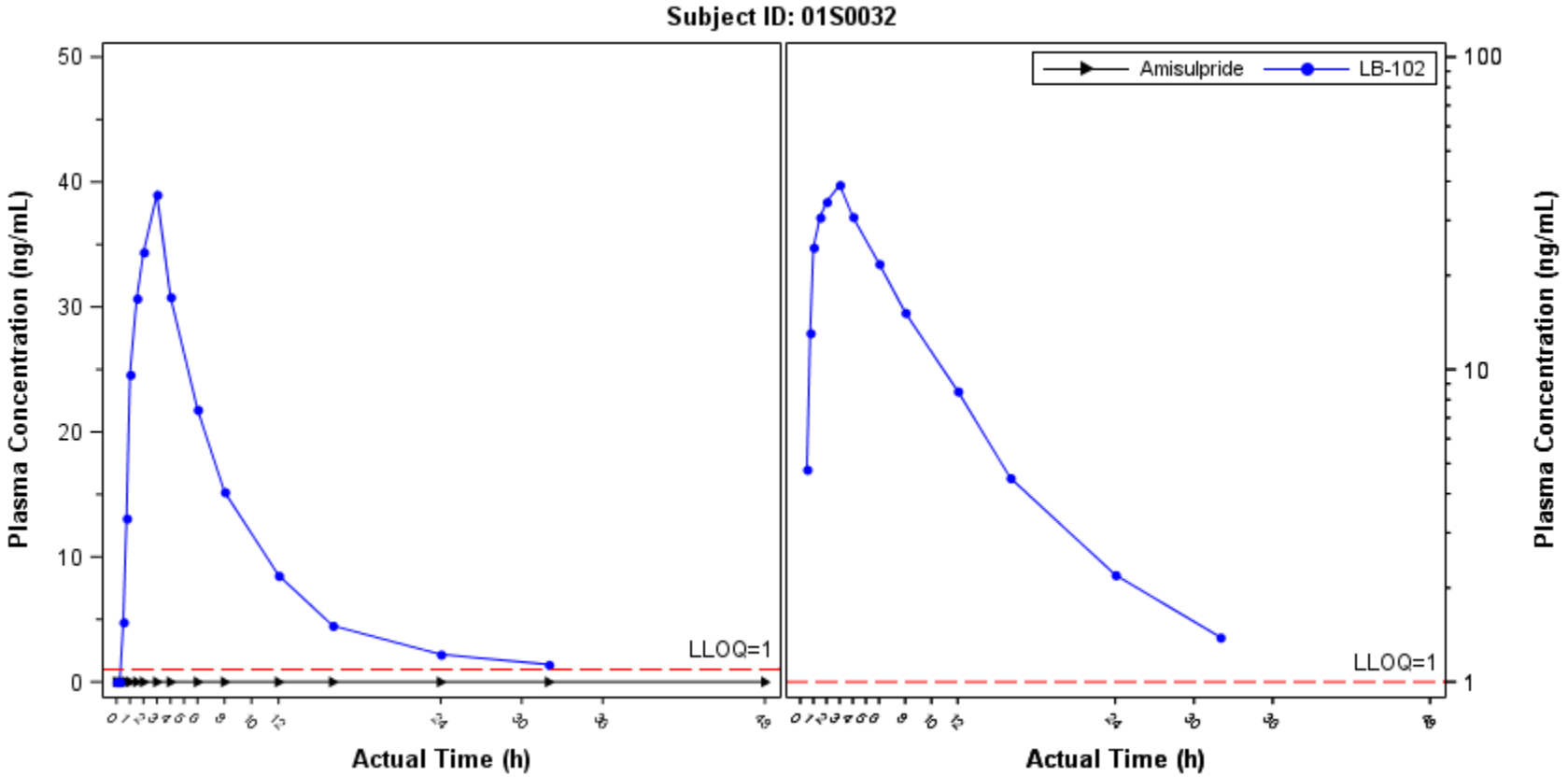


Note: Lower limit of quantification (LLOQ) for LB-102 = 1 ng/mL. LLOQ for amisulpride = 1 ng/mL.
SD = standard deviation.

Source Data: ADPC; Reference listing(s): 16.2.6.2
Program Name: Figure.sas

SDTM Date: 04AUG2020 16:09
Analysis Date: 20AUG2020 18:00

Figure 14.2.3.1
Plot of Individual Plasma Concentrations of LB-102 and Amisulpride by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part A (SAD)
LB-102 10 mg

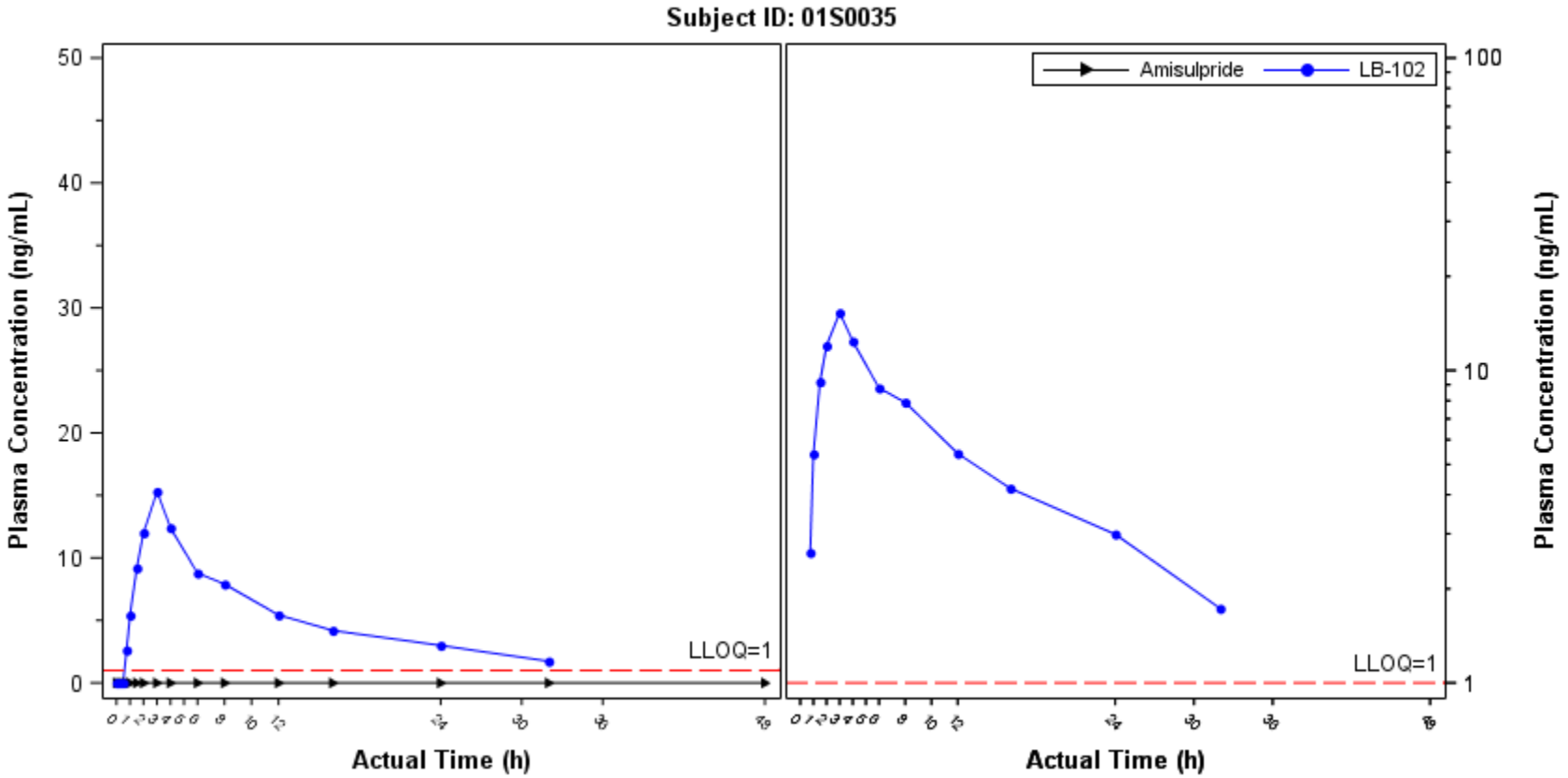


Note: Lower limit of quantification (LLOQ) for LB-102 = 1 ng/mL. LLOQ for amisulpride = 1 ng/mL.
SD = standard deviation.

Source Data: ADPC; Reference listing(s): 16.2.6.2
Program Name: Figure.sas

SDTM Date: 04AUG2020 16:09
Analysis Date: 20AUG2020 18:00

Figure 14.2.3.1
Plot of Individual Plasma Concentrations of LB-102 and Amisulpride by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part A (SAD)
LB-102 10 mg

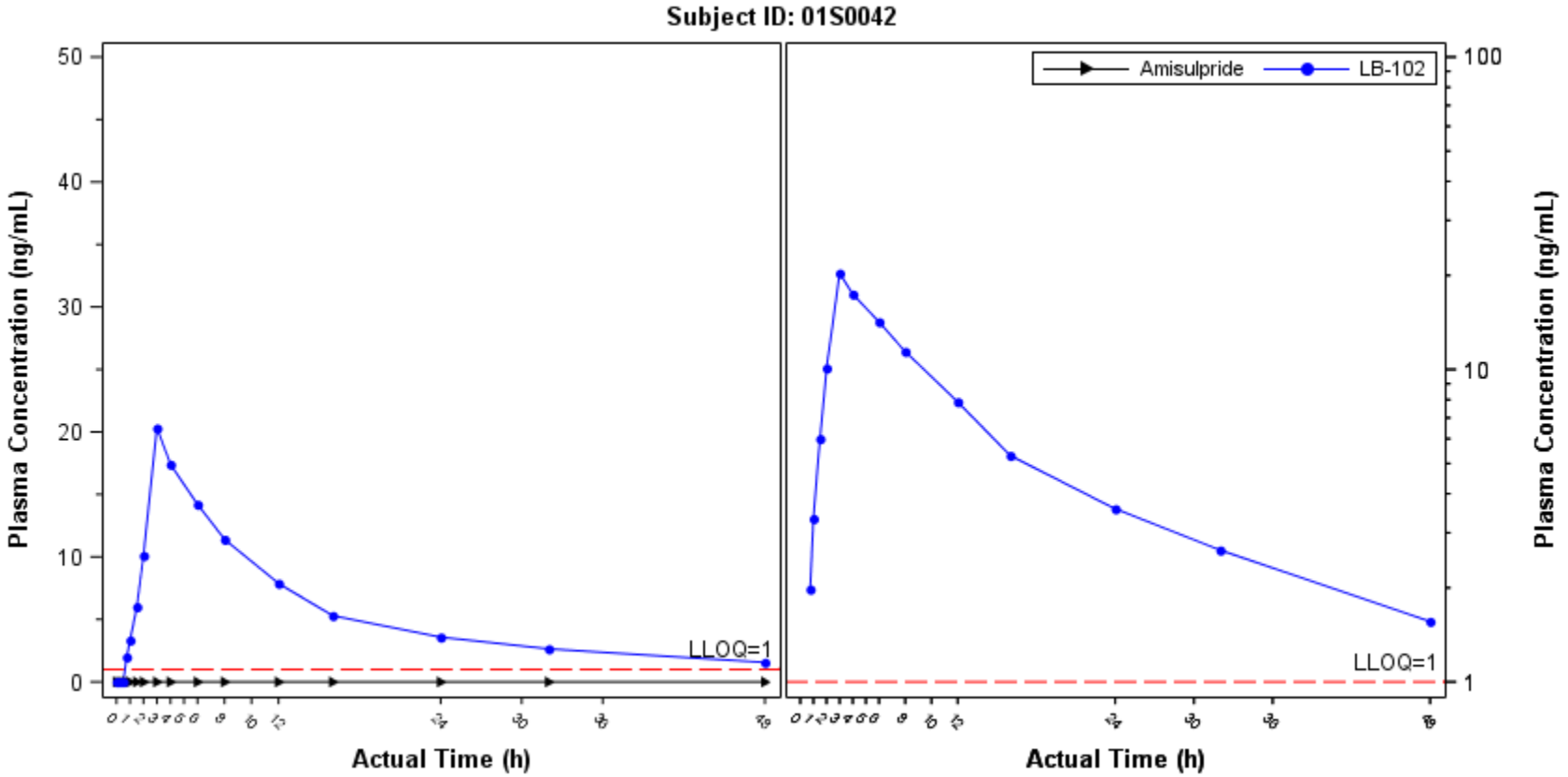


Note: Lower limit of quantification (LLOQ) for LB-102 = 1 ng/mL. LLOQ for amisulpride = 1 ng/mL.
SD = standard deviation.

Source Data: ADPC; Reference listing(s): 16.2.6.2
Program Name: Figure.sas

SDTM Date: 04AUG2020 16:09
Analysis Date: 20AUG2020 18:00

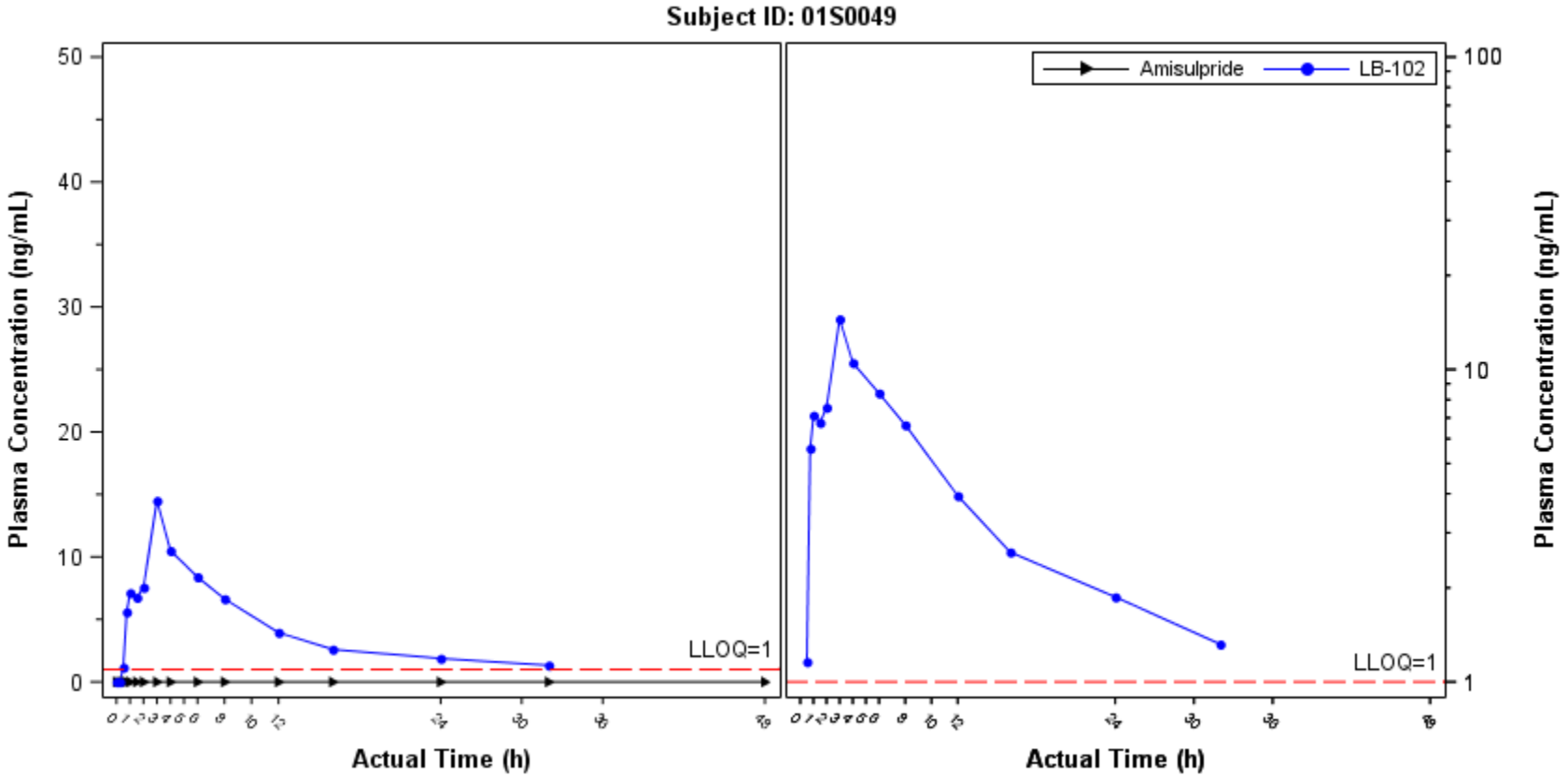
Figure 14.2.3.1
Plot of Individual Plasma Concentrations of LB-102 and Amisulpride by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part A (SAD)
LB-102 10 mg



Note: Lower limit of quantification (LLOQ) for LB-102 = 1 ng/mL. LLOQ for amisulpride = 1 ng/mL.
SD = standard deviation.

Source Data: ADPC; Reference listing(s): 16.2.6.2 SDTM Date: 04AUG2020 16:09
Program Name: Figure.sas Analysis Date: 20AUG2020 18:00

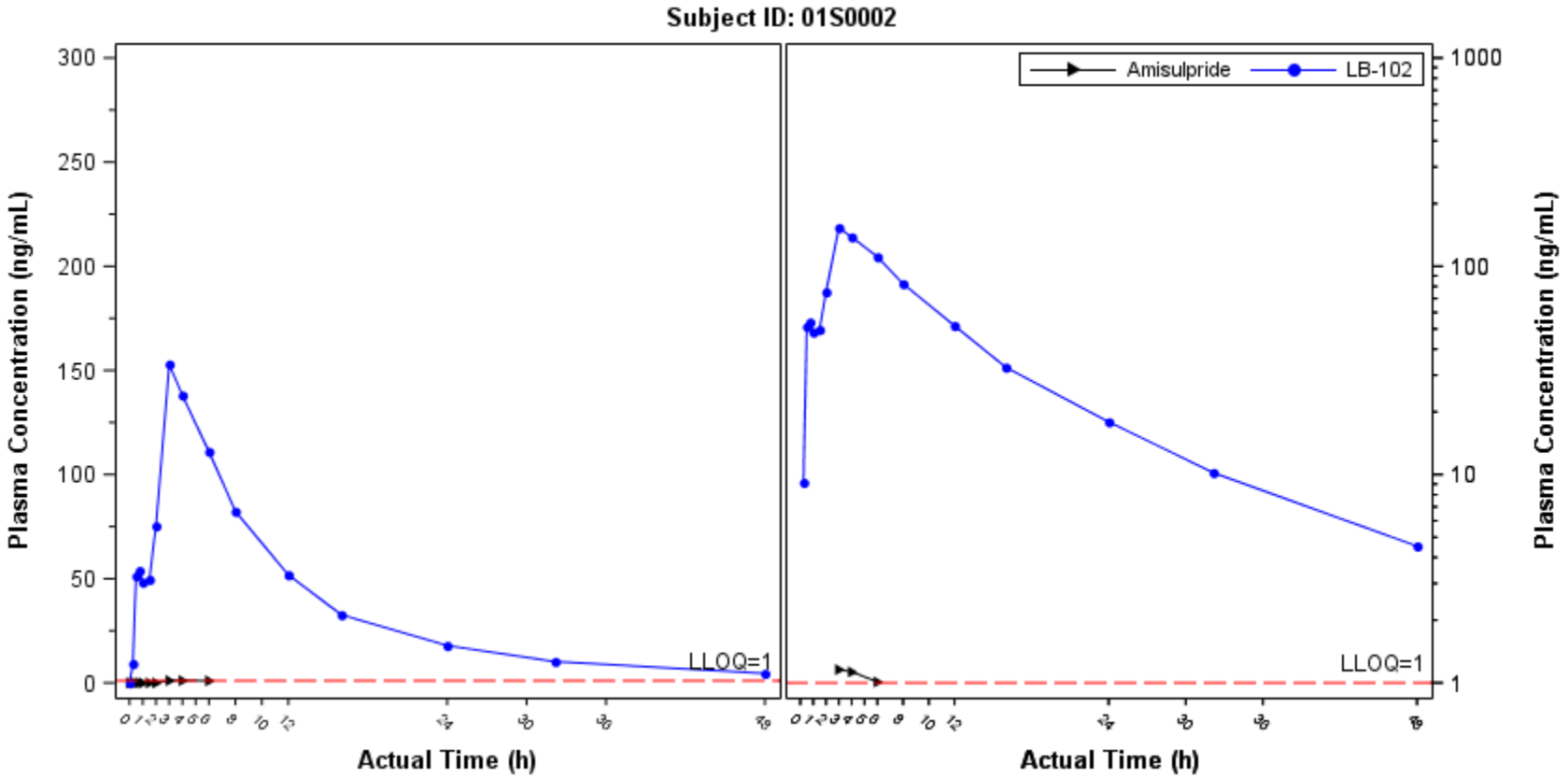
Figure 14.2.3.1
Plot of Individual Plasma Concentrations of LB-102 and Amisulpride by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part A (SAD)
LB-102 10 mg



Note: Lower limit of quantification (LLOQ) for LB-102 = 1 ng/mL. LLOQ for amisulpride = 1 ng/mL.
SD = standard deviation.

Source Data: ADPC; Reference listing(s): 16.2.6.2 SDTM Date: 04AUG2020 16:09
Program Name: Figure.sas Analysis Date: 20AUG2020 18:00

Figure 14.2.3.2
Plot of Individual Plasma Concentrations of LB-102 and Amisulpride by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part A (SAD)
LB-102 50 mg

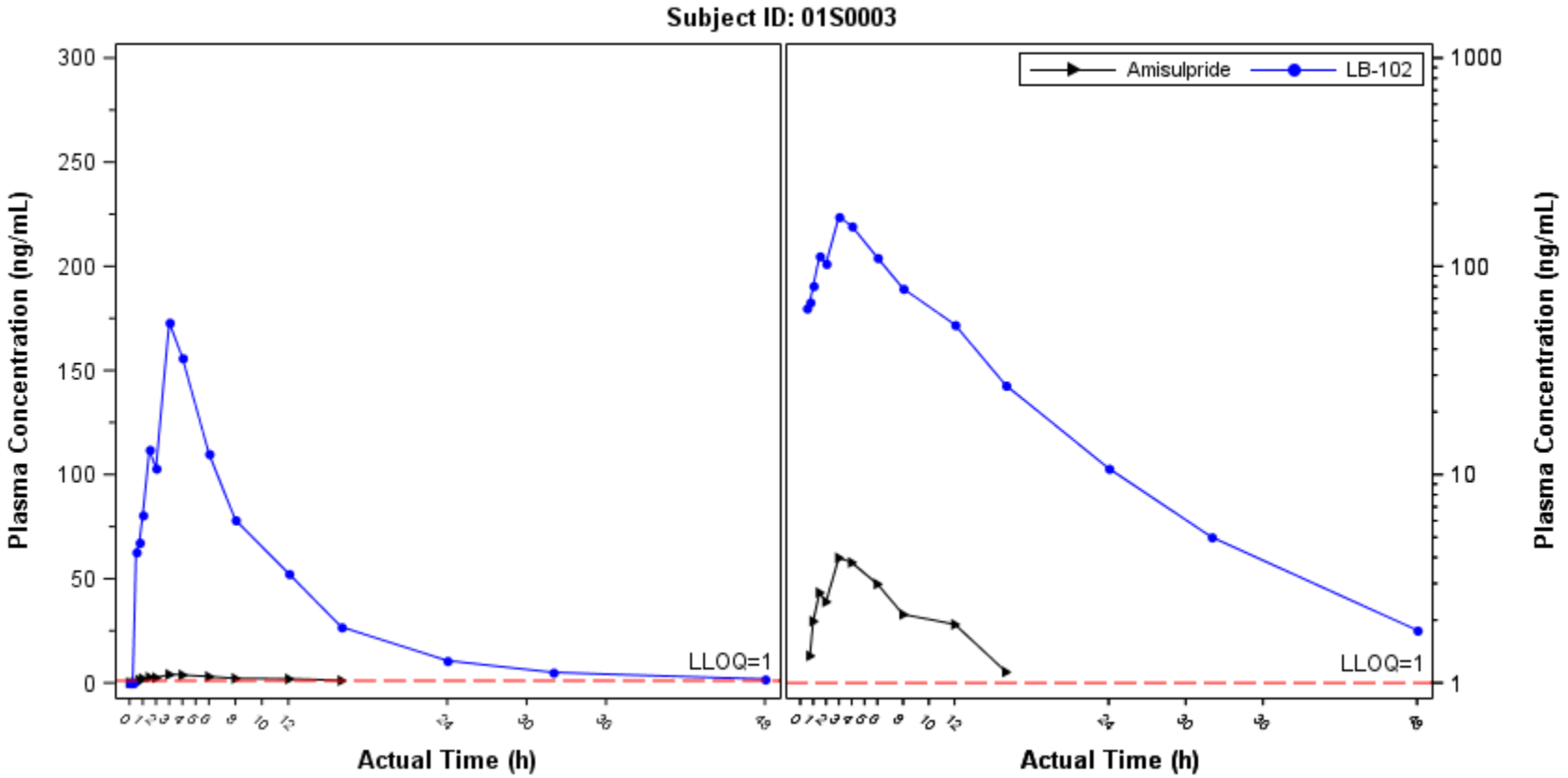


Note: Lower limit of quantification (LLOQ) for LB-102 = 1 ng/mL. LLOQ for amisulpride = 1 ng/mL.
SD = standard deviation.

Source Data: ADPC; Reference listing(s): 16.2.6.2
Program Name: Figure.sas

SDTM Date: 04AUG2020 16:09
Analysis Date: 20AUG2020 18:00

Figure 14.2.3.2
Plot of Individual Plasma Concentrations of LB-102 and Amisulpride by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part A (SAD)
LB-102 50 mg

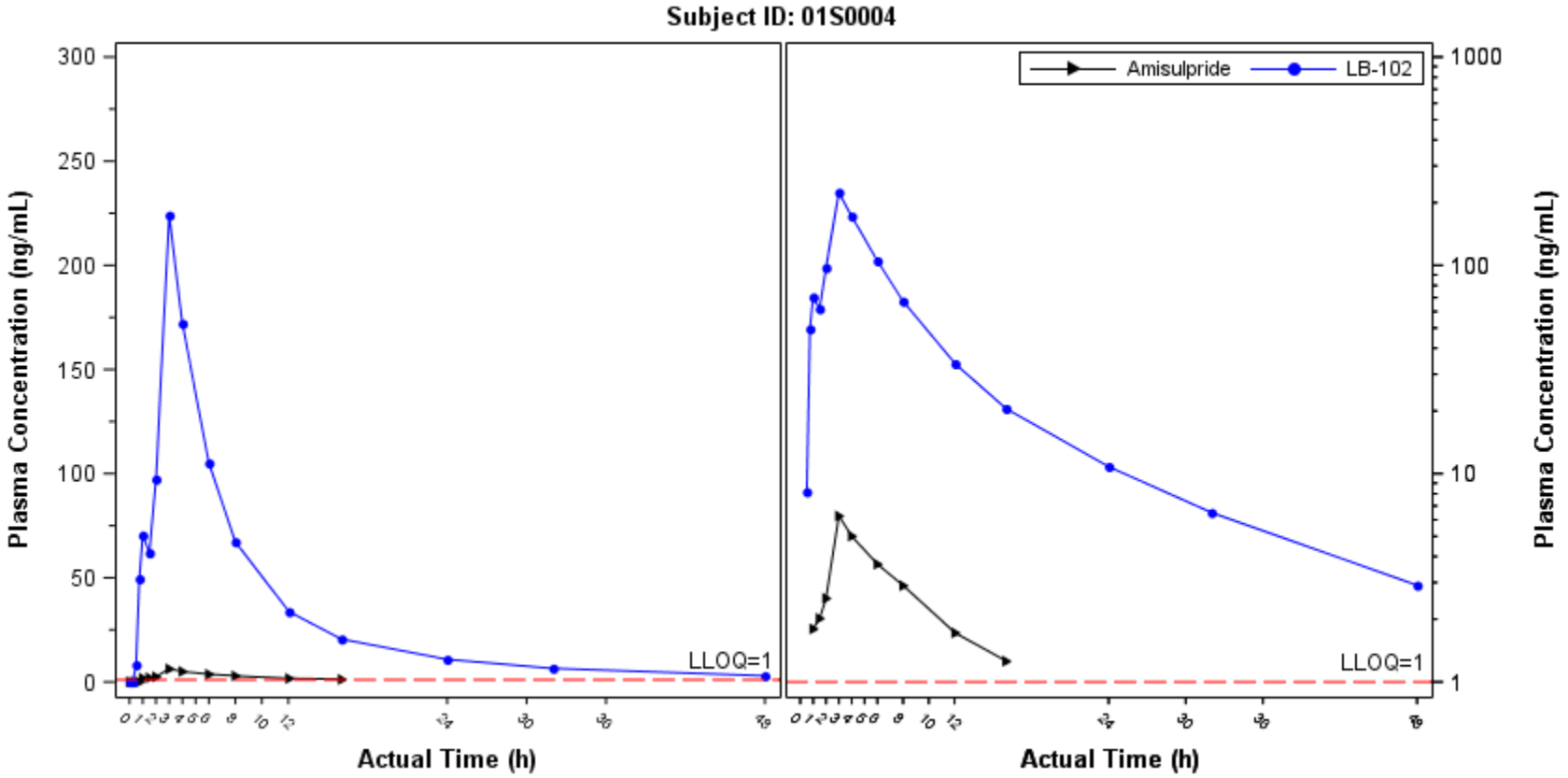


Note: Lower limit of quantification (LLOQ) for LB-102 = 1 ng/mL. LLOQ for amisulpride = 1 ng/mL.
SD = standard deviation.

Source Data: ADPC; Reference listing(s): 16.2.6.2
Program Name: Figure.sas

SDTM Date: 04AUG2020 16:09
Analysis Date: 20AUG2020 18:00

Figure 14.2.3.2
Plot of Individual Plasma Concentrations of LB-102 and Amisulpride by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part A (SAD)
LB-102 50 mg

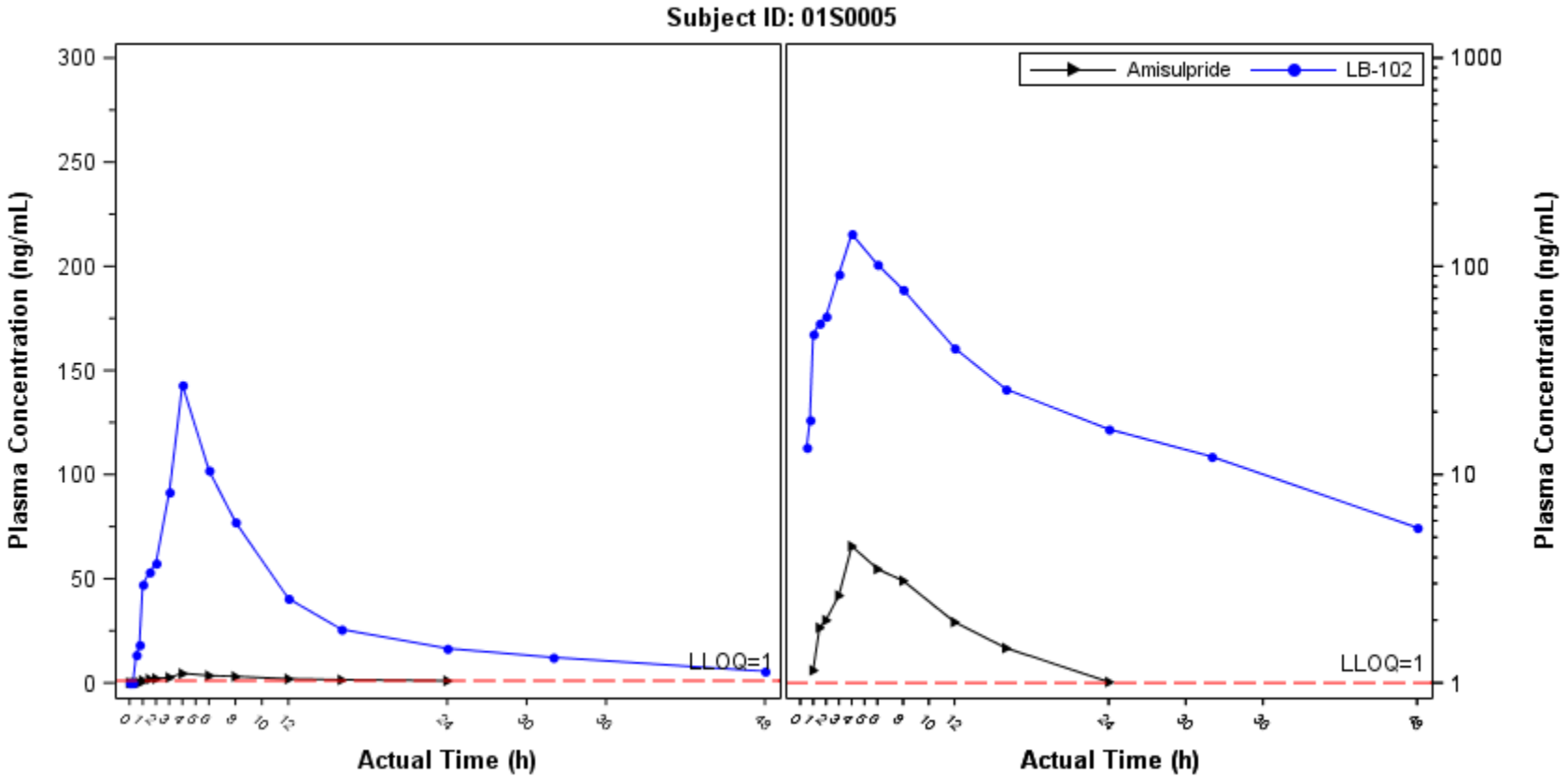


Note: Lower limit of quantification (LLOQ) for LB-102 = 1 ng/mL. LLOQ for amisulpride = 1 ng/mL.
SD = standard deviation.

Source Data: ADPC; Reference listing(s): 16.2.6.2
Program Name: Figure.sas

SDTM Date: 04AUG2020 16:09
Analysis Date: 20AUG2020 18:00

Figure 14.2.3.2
Plot of Individual Plasma Concentrations of LB-102 and Amisulpride by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part A (SAD)
LB-102 50 mg

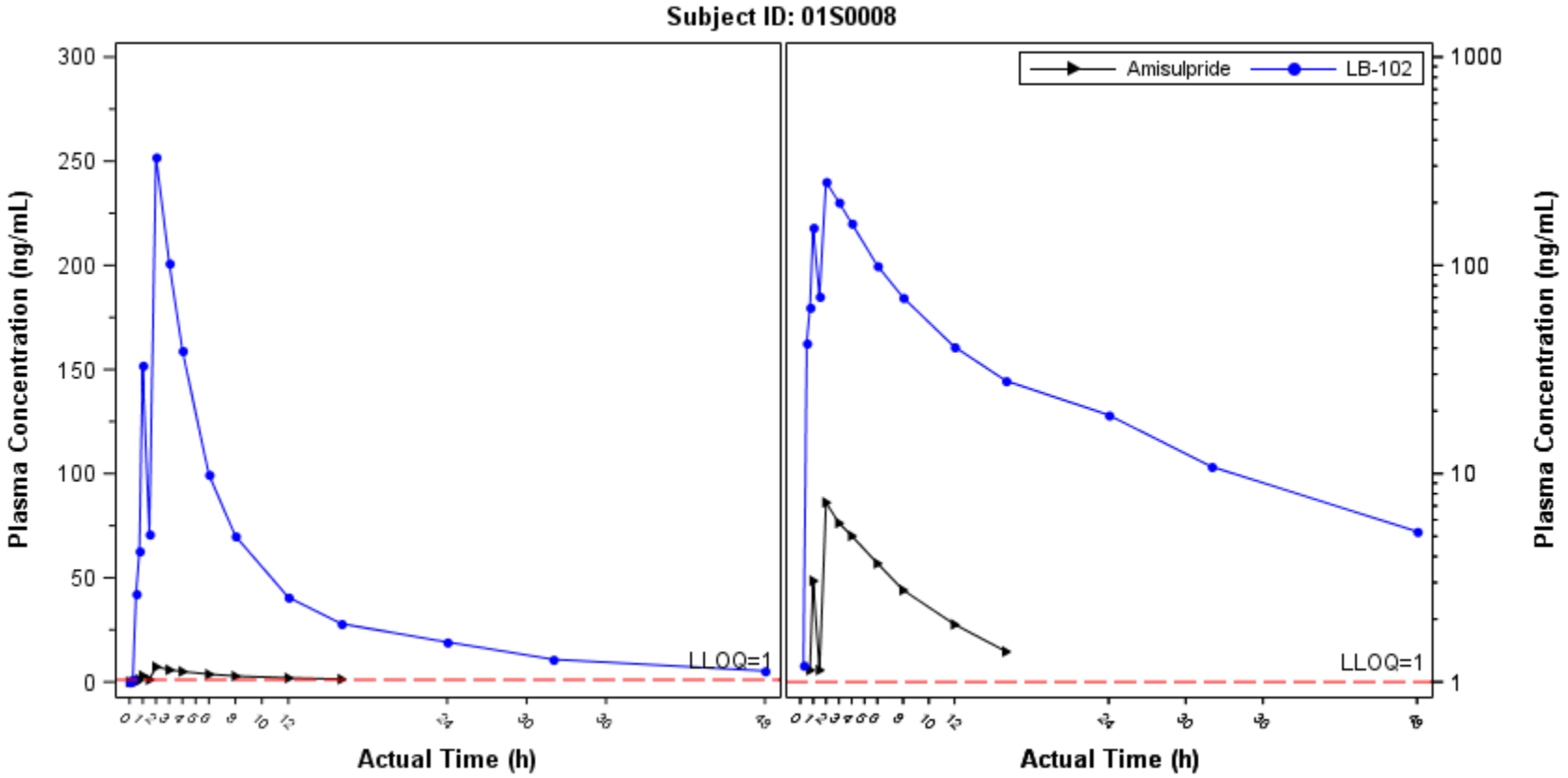


Note: Lower limit of quantification (LLOQ) for LB-102 = 1 ng/mL. LLOQ for amisulpride = 1 ng/mL.
SD = standard deviation.

Source Data: ADPC; Reference listing(s): 16.2.6.2
Program Name: Figure.sas

SDTM Date: 04AUG2020 16:09
Analysis Date: 20AUG2020 18:00

Figure 14.2.3.2
Plot of Individual Plasma Concentrations of LB-102 and Amisulpride by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part A (SAD)
LB-102 50 mg

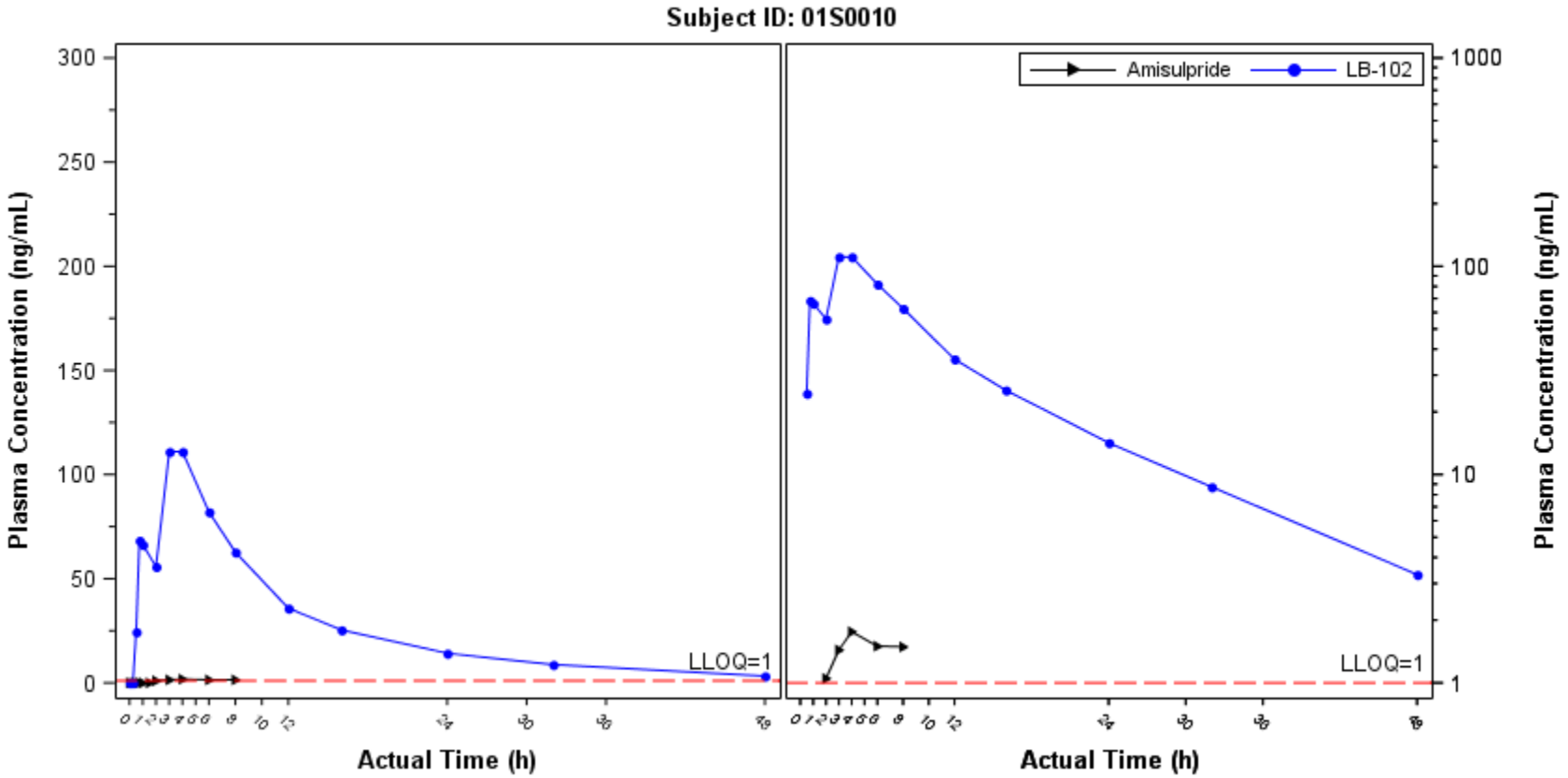


Note: Lower limit of quantification (LLOQ) for LB-102 = 1 ng/mL. LLOQ for amisulpride = 1 ng/mL.
SD = standard deviation.

Source Data: ADPC; Reference listing(s): 16.2.6.2
Program Name: Figure.sas

SDTM Date: 04AUG2020 16:09
Analysis Date: 20AUG2020 18:00

Figure 14.2.3.2
Plot of Individual Plasma Concentrations of LB-102 and Amisulpride by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part A (SAD)
LB-102 50 mg

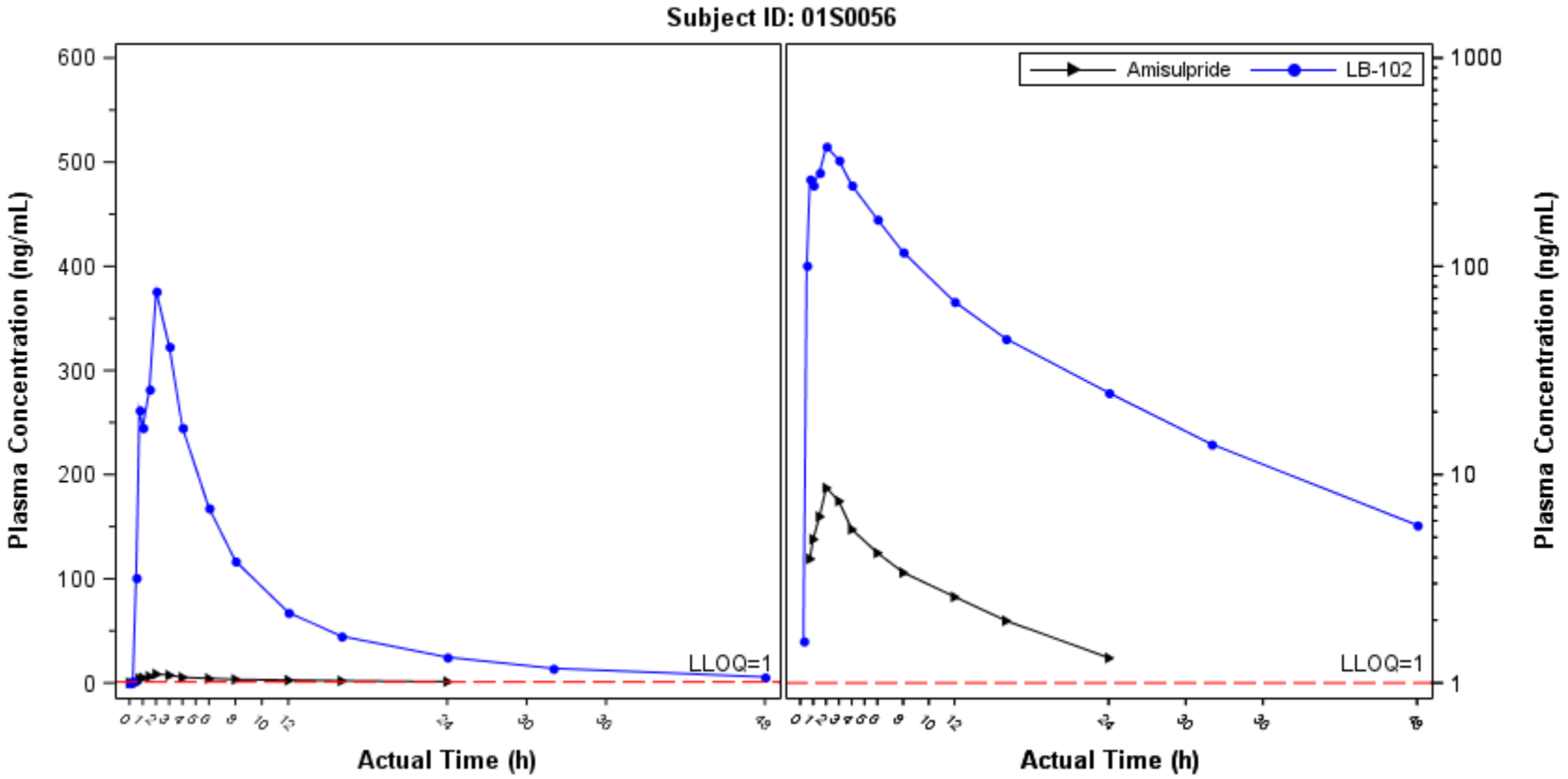


Note: Lower limit of quantification (LLOQ) for LB-102 = 1 ng/mL. LLOQ for amisulpride = 1 ng/mL.
SD = standard deviation.

Source Data: ADPC; Reference listing(s): 16.2.6.2
Program Name: Figure.sas

SDTM Date: 04AUG2020 16:09
Analysis Date: 20AUG2020 18:00

Figure 14.2.3.3
Plot of Individual Plasma Concentrations of LB-102 and Amisulpride by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part A (SAD)
LB-102 100 mg

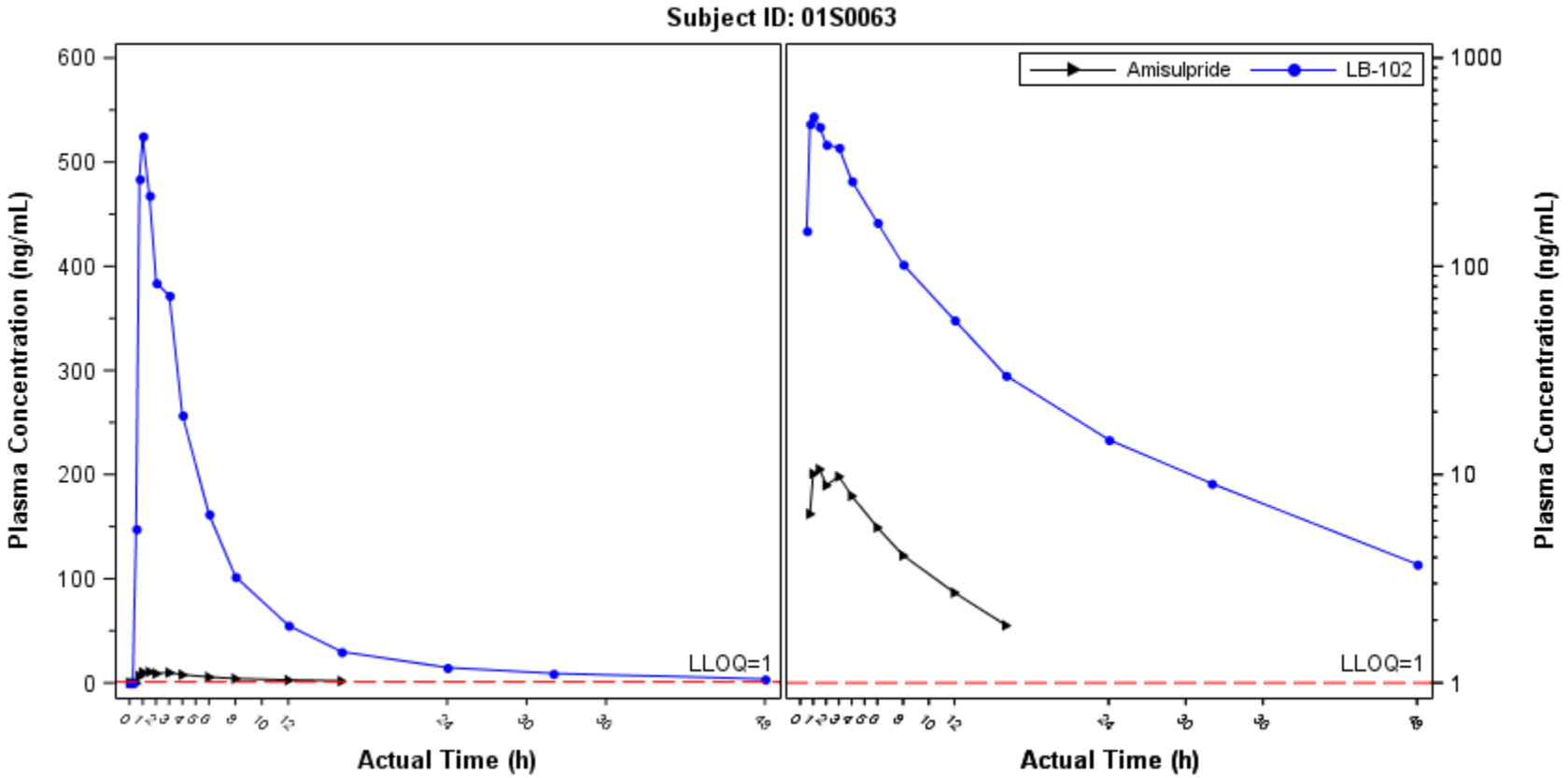


Note: Lower limit of quantification (LLOQ) for LB-102 = 1 ng/mL. LLOQ for amisulpride = 1 ng/mL.
SD = standard deviation.

Source Data: ADPC; Reference listing(s): 16.2.6.2
Program Name: Figure.sas

SDTM Date: 04AUG2020 16:09
Analysis Date: 20AUG2020 18:00

Figure 14.2.3.3
Plot of Individual Plasma Concentrations of LB-102 and Amisulpride by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part A (SAD)
LB-102 100 mg

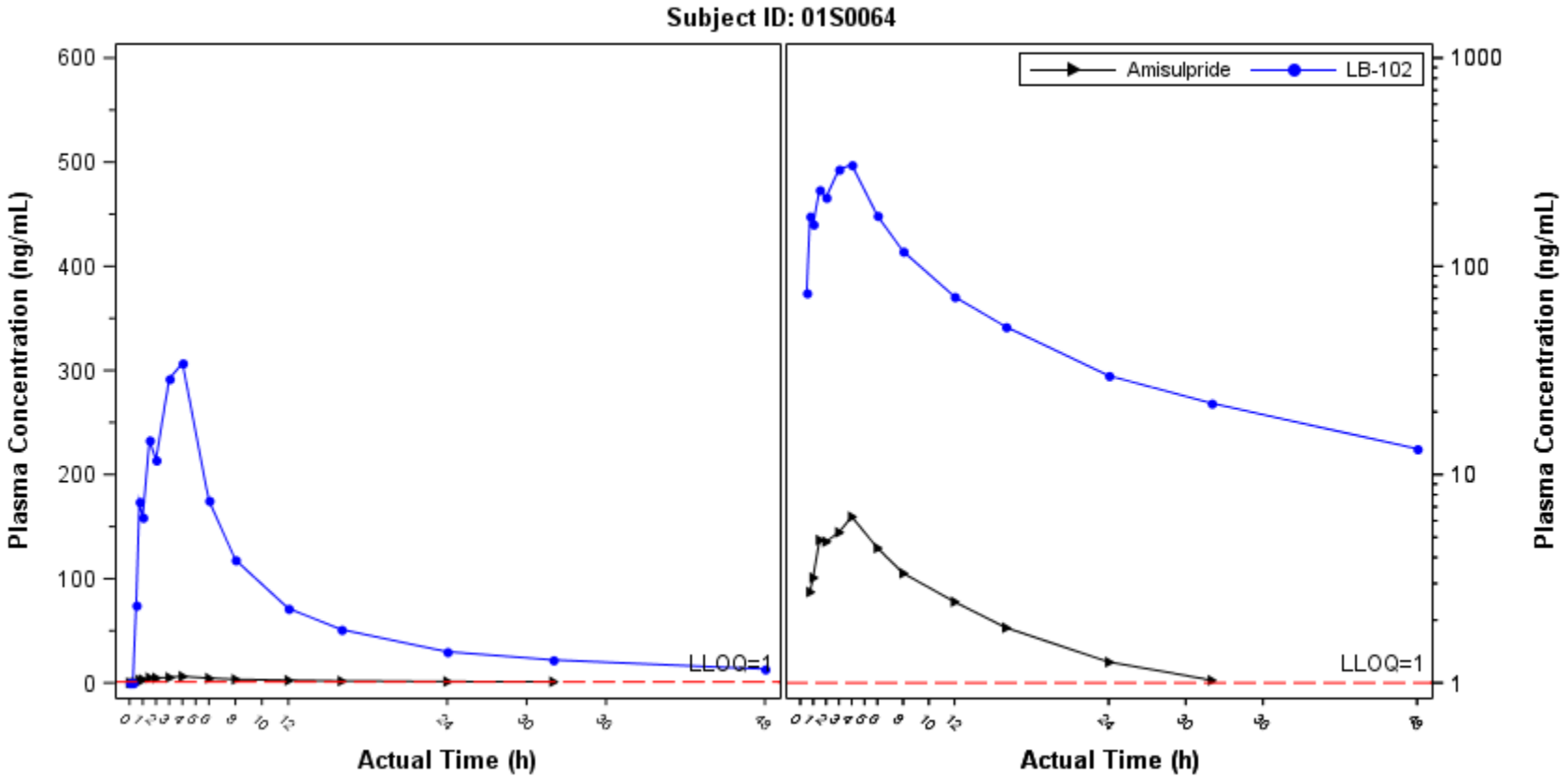


Note: Lower limit of quantification (LLOQ) for LB-102 = 1 ng/mL. LLOQ for amisulpride = 1 ng/mL.
SD = standard deviation.

Source Data: ADPC; Reference listing(s): 16.2.6.2
Program Name: Figure.sas

SDTM Date: 04AUG2020 16:09
Analysis Date: 20AUG2020 18:00

Figure 14.2.3.3
Plot of Individual Plasma Concentrations of LB-102 and Amisulpride by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part A (SAD)
LB-102 100 mg

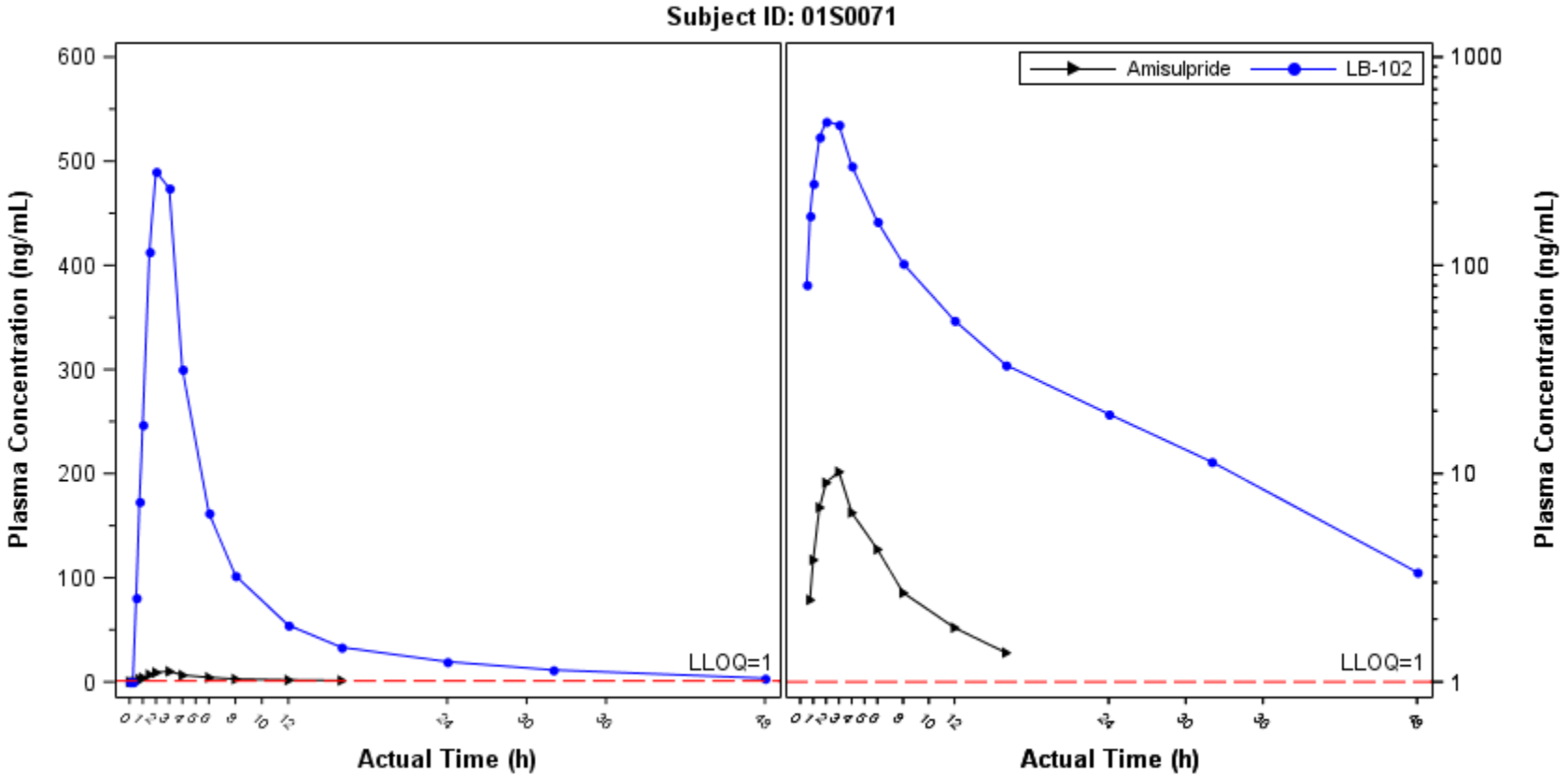


Note: Lower limit of quantification (LLOQ) for LB-102 = 1 ng/mL. LLOQ for amisulpride = 1 ng/mL.
SD = standard deviation.

Source Data: ADPC; Reference listing(s): 16.2.6.2
Program Name: Figure.sas

SDTM Date: 04AUG2020 16:09
Analysis Date: 20AUG2020 18:00

Figure 14.2.3.3
Plot of Individual Plasma Concentrations of LB-102 and Amisulpride by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part A (SAD)
LB-102 100 mg

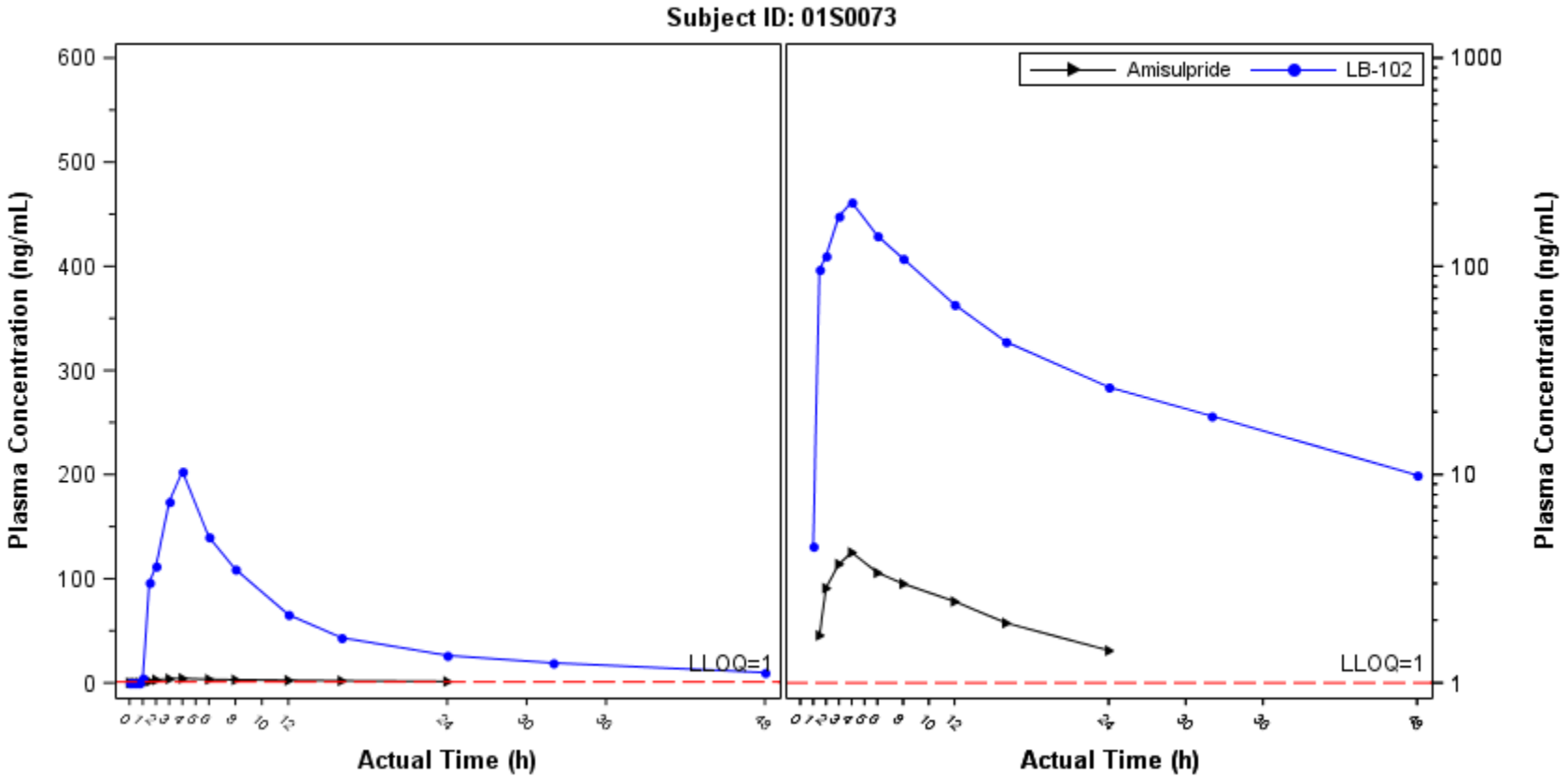


Note: Lower limit of quantification (LLOQ) for LB-102 = 1 ng/mL. LLOQ for amisulpride = 1 ng/mL.
SD = standard deviation.

Source Data: ADPC; Reference listing(s): 16.2.6.2
Program Name: Figure.sas

SDTM Date: 04AUG2020 16:09
Analysis Date: 20AUG2020 18:00

Figure 14.2.3.3
Plot of Individual Plasma Concentrations of LB-102 and Amisulpride by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part A (SAD)
LB-102 100 mg

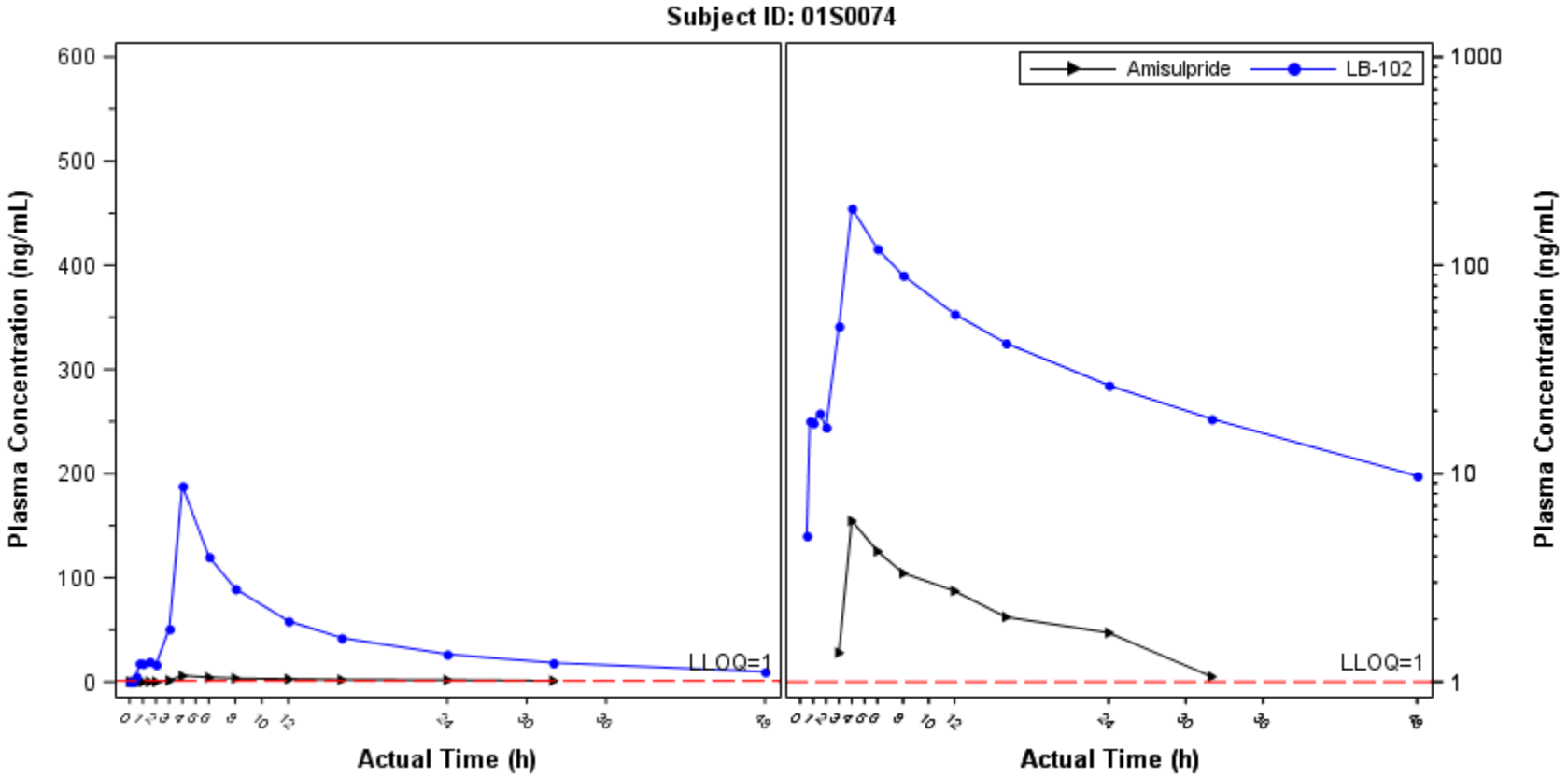


Note: Lower limit of quantification (LLOQ) for LB-102 = 1 ng/mL. LLOQ for amisulpride = 1 ng/mL.
SD = standard deviation.

Source Data: ADPC; Reference listing(s): 16.2.6.2
Program Name: Figure.sas

SDTM Date: 04AUG2020 16:09
Analysis Date: 20AUG2020 18:00

Figure 14.2.3.3
Plot of Individual Plasma Concentrations of LB-102 and Amisulpride by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part A (SAD)
LB-102 100 mg

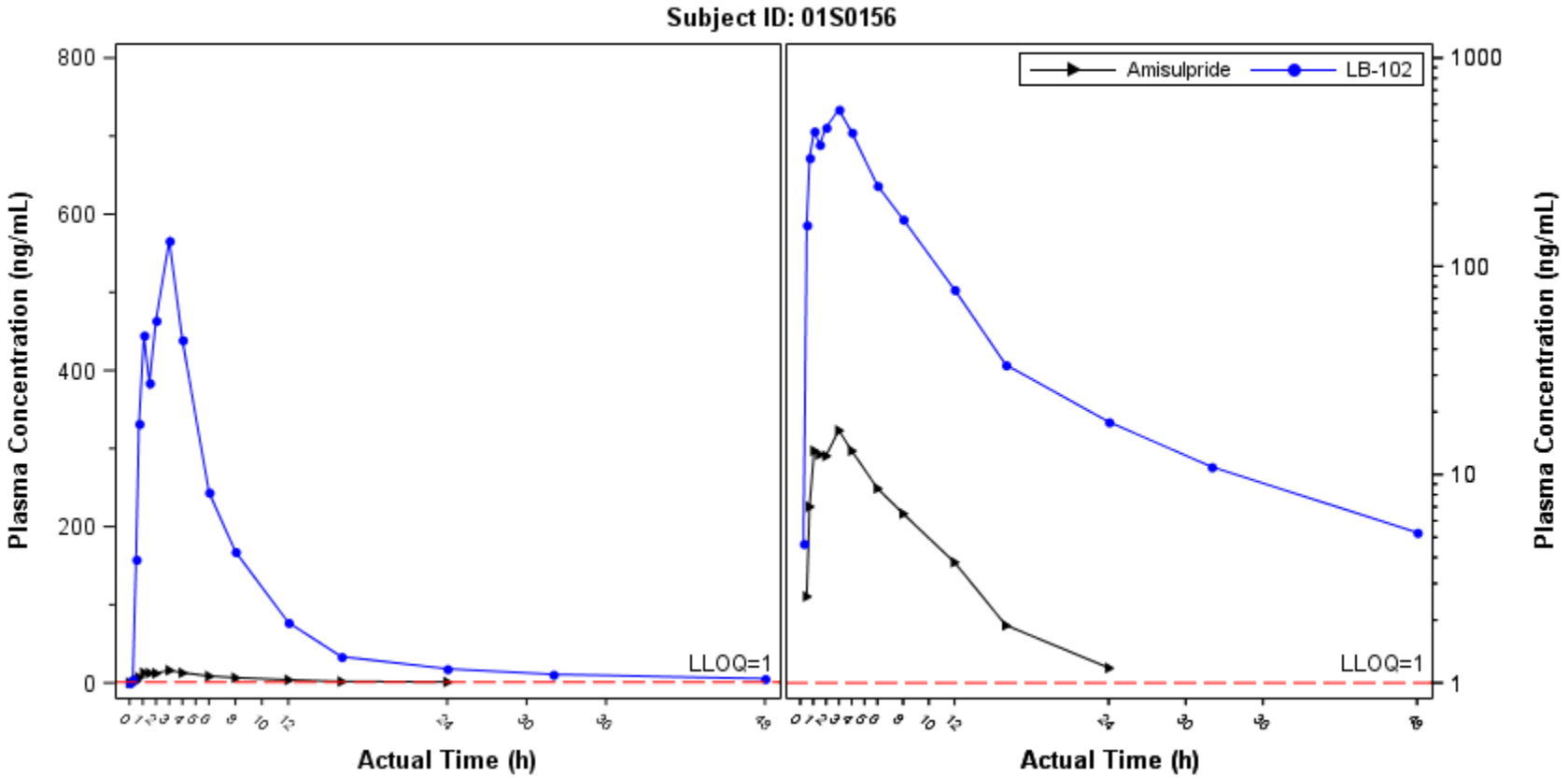


Note: Lower limit of quantification (LLOQ) for LB-102 = 1 ng/mL. LLOQ for amisulpride = 1 ng/mL.
SD = standard deviation.

Source Data: ADPC; Reference listing(s): 16.2.6.2
Program Name: Figure.sas

SDTM Date: 04AUG2020 16:09
Analysis Date: 20AUG2020 18:00

Figure 14.2.3.4
Plot of Individual Plasma Concentrations of LB-102 and Amisulpride by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part A (SAD)
LB-102 150 mg

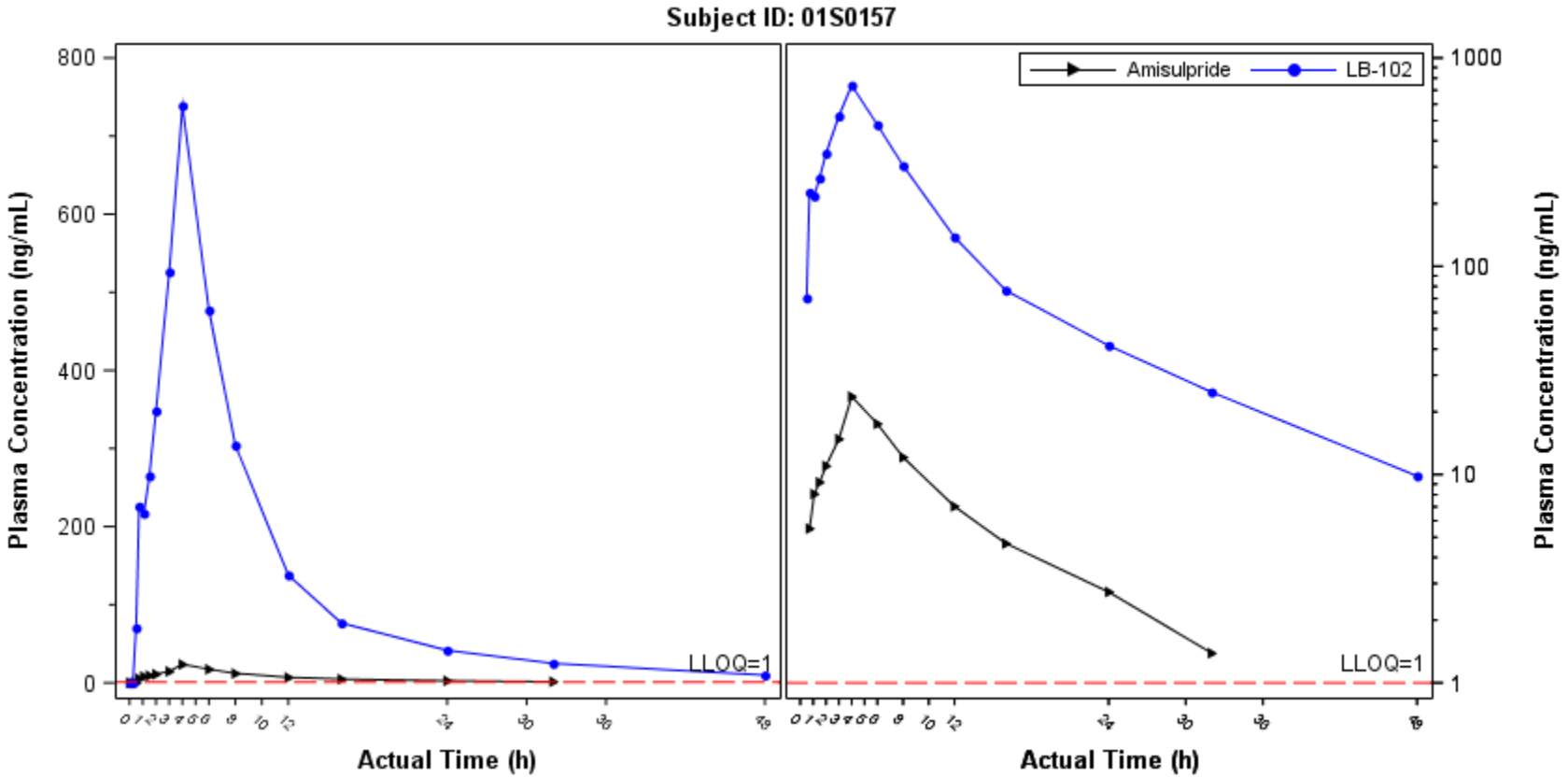


Note: Lower limit of quantification (LLOQ) for LB-102 = 1 ng/mL. LLOQ for amisulpride = 1 ng/mL.
SD = standard deviation.

Source Data: ADPC; Reference listing(s): 16.2.6.2
Program Name: Figure.sas

SDTM Date: 04AUG2020 16:09
Analysis Date: 20AUG2020 18:00

Figure 14.2.3.4
Plot of Individual Plasma Concentrations of LB-102 and Amisulpride by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part A (SAD)
LB-102 150 mg

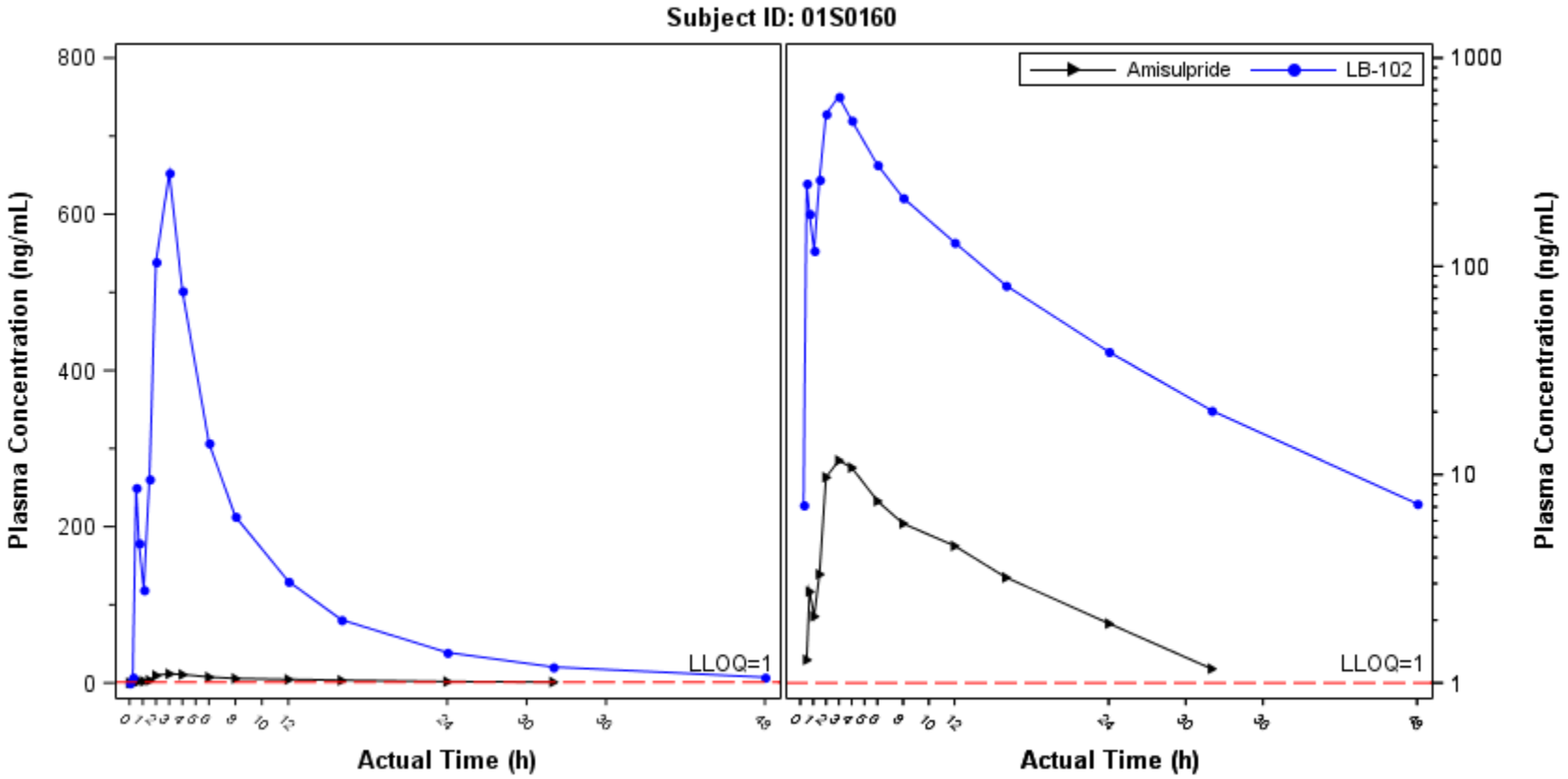


Note: Lower limit of quantification (LLOQ) for LB-102 = 1 ng/mL. LLOQ for amisulpride = 1 ng/mL.
SD = standard deviation.

Source Data: ADPC; Reference listing(s): 16.2.6.2
Program Name: Figure.sas

SDTM Date: 04AUG2020 16:09
Analysis Date: 20AUG2020 18:00

Figure 14.2.3.4
Plot of Individual Plasma Concentrations of LB-102 and Amisulpride by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part A (SAD)
LB-102 150 mg

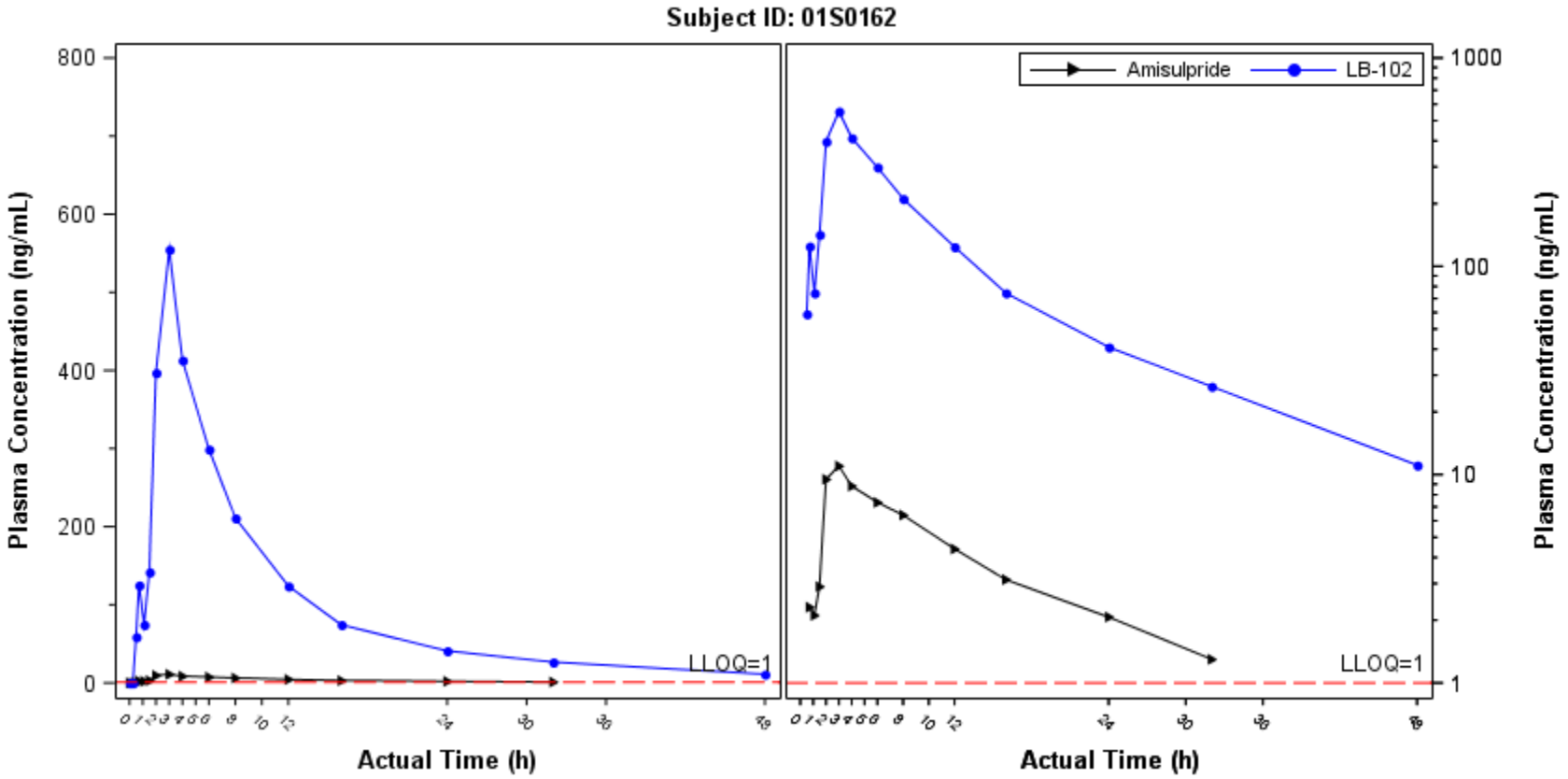


Note: Lower limit of quantification (LLOQ) for LB-102 = 1 ng/mL. LLOQ for amisulpride = 1 ng/mL.
SD = standard deviation.

Source Data: ADPC; Reference listing(s): 16.2.6.2
Program Name: Figure.sas

SDTM Date: 04AUG2020 16:09
Analysis Date: 20AUG2020 18:00

Figure 14.2.3.4
Plot of Individual Plasma Concentrations of LB-102 and Amisulpride by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part A (SAD)
LB-102 150 mg

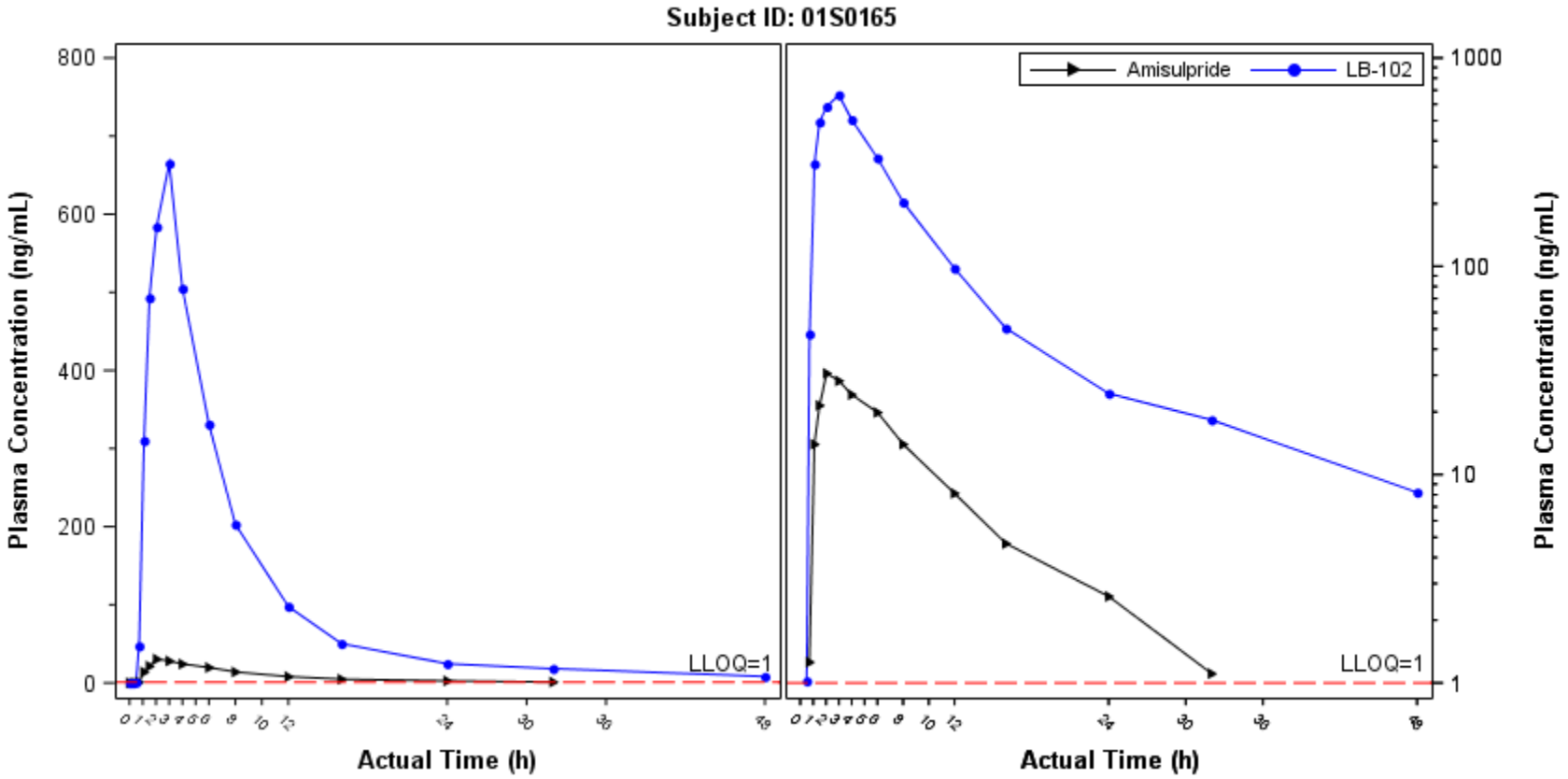


Note: Lower limit of quantification (LLOQ) for LB-102 = 1 ng/mL. LLOQ for amisulpride = 1 ng/mL.
SD = standard deviation.

Source Data: ADPC; Reference listing(s): 16.2.6.2
Program Name: Figure.sas

SDTM Date: 04AUG2020 16:09
Analysis Date: 20AUG2020 18:00

Figure 14.2.3.4
Plot of Individual Plasma Concentrations of LB-102 and Amisulpride by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part A (SAD)
LB-102 150 mg

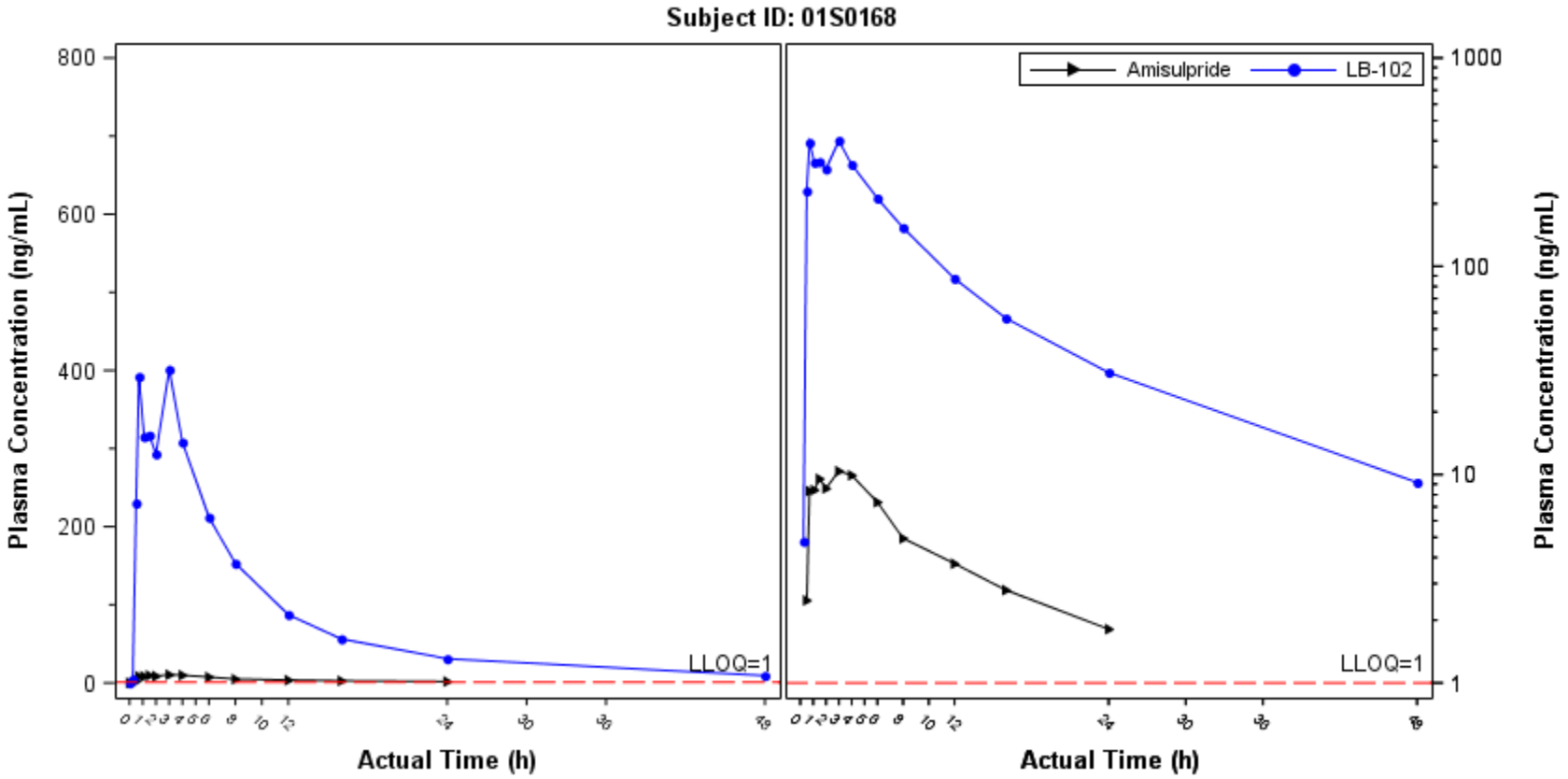


Note: Lower limit of quantification (LLOQ) for LB-102 = 1 ng/mL. LLOQ for amisulpride = 1 ng/mL.
SD = standard deviation.

Source Data: ADPC; Reference listing(s): 16.2.6.2
Program Name: Figure.sas

SDTM Date: 04AUG2020 16:09
Analysis Date: 20AUG2020 18:00

Figure 14.2.3.4
Plot of Individual Plasma Concentrations of LB-102 and Amisulpride by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part A (SAD)
LB-102 150 mg

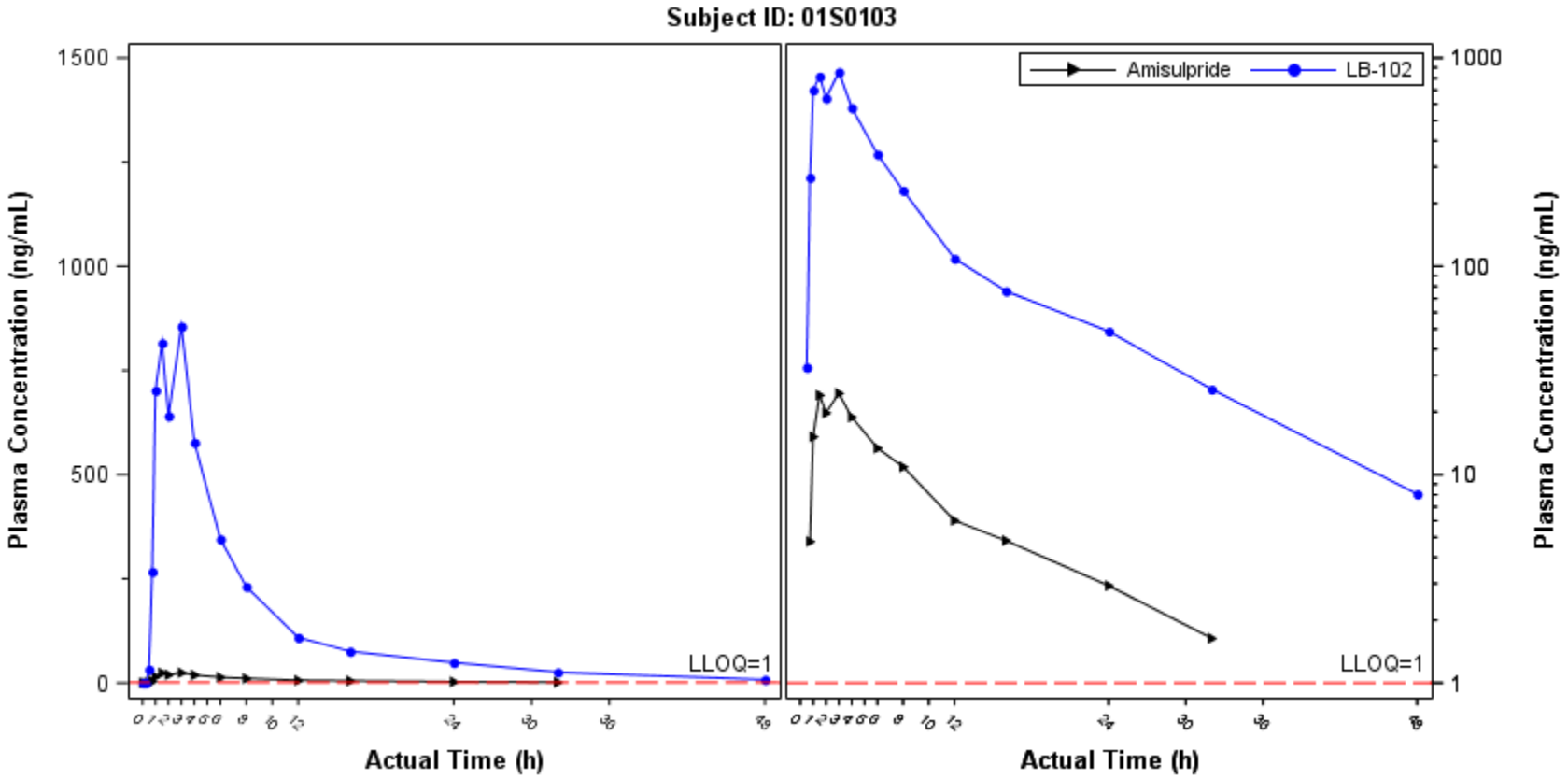


Note: Lower limit of quantification (LLOQ) for LB-102 = 1 ng/mL. LLOQ for amisulpride = 1 ng/mL.
SD = standard deviation.

Source Data: ADPC; Reference listing(s): 16.2.6.2
Program Name: Figure.sas

SDTM Date: 04AUG2020 16:09
Analysis Date: 20AUG2020 18:00

Figure 14.2.3.5
Plot of Individual Plasma Concentrations of LB-102 and Amisulpride by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part A (SAD)
LB-102 200 mg

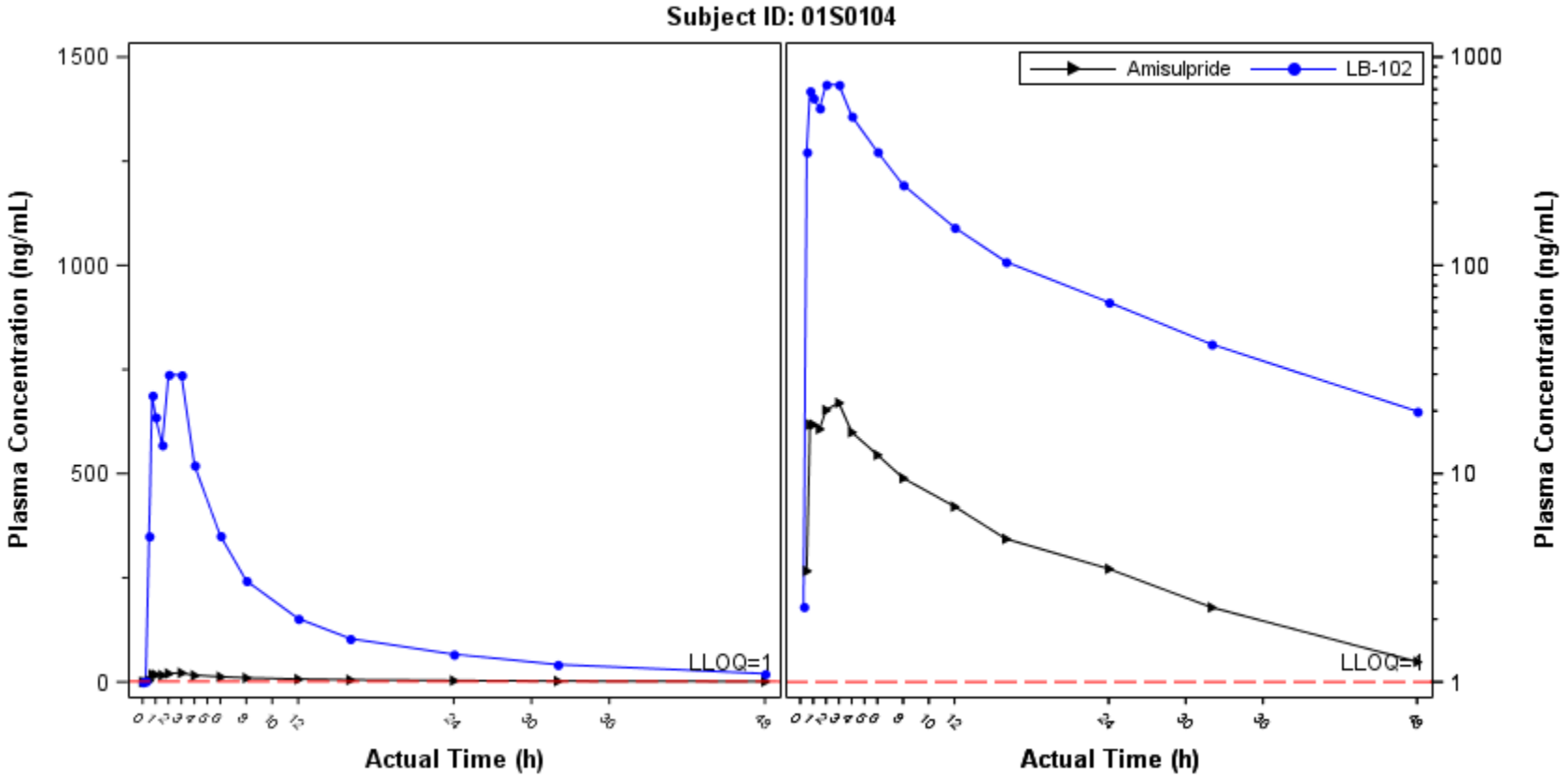


Note: Lower limit of quantification (LLOQ) for LB-102 = 1 ng/mL. LLOQ for amisulpride = 1 ng/mL.
SD = standard deviation.

Source Data: ADPC; Reference listing(s): 16.2.6.2
Program Name: Figure.sas

SDTM Date: 04AUG2020 16:09
Analysis Date: 20AUG2020 18:00

Figure 14.2.3.5
Plot of Individual Plasma Concentrations of LB-102 and Amisulpride by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part A (SAD)
LB-102 200 mg

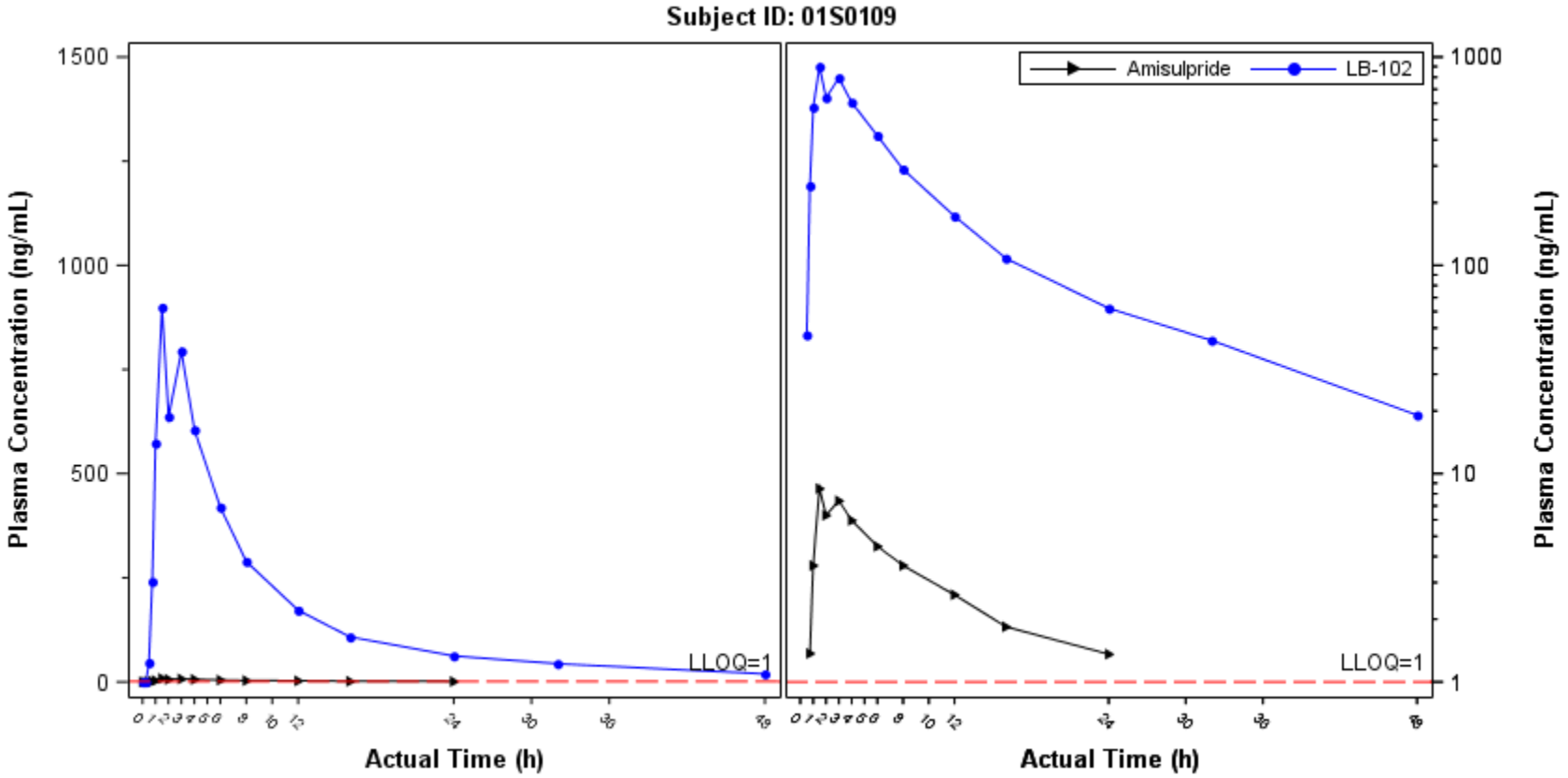


Note: Lower limit of quantification (LLOQ) for LB-102 = 1 ng/mL. LLOQ for amisulpride = 1 ng/mL.
SD = standard deviation.

Source Data: ADPC; Reference listing(s): 16.2.6.2
Program Name: Figure.sas

SDTM Date: 04AUG2020 16:09
Analysis Date: 20AUG2020 18:00

Figure 14.2.3.5
Plot of Individual Plasma Concentrations of LB-102 and Amisulpride by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part A (SAD)
LB-102 200 mg

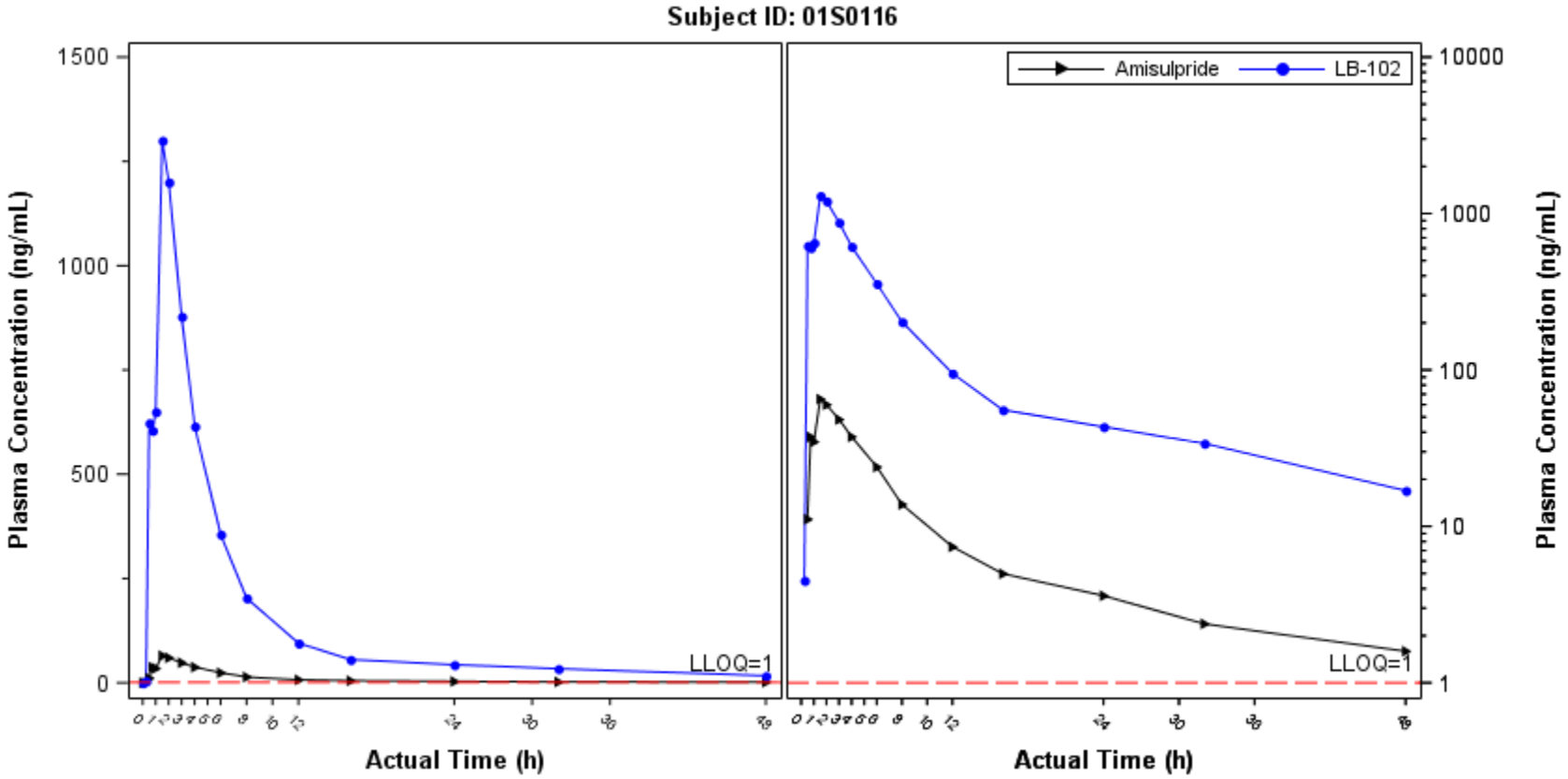


Note: Lower limit of quantification (LLOQ) for LB-102 = 1 ng/mL. LLOQ for amisulpride = 1 ng/mL.
SD = standard deviation.

Source Data: ADPC; Reference listing(s): 16.2.6.2
Program Name: Figure.sas

SDTM Date: 04AUG2020 16:09
Analysis Date: 20AUG2020 18:00

Figure 14.2.3.5
Plot of Individual Plasma Concentrations of LB-102 and Amisulpride by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part A (SAD)
LB-102 200 mg

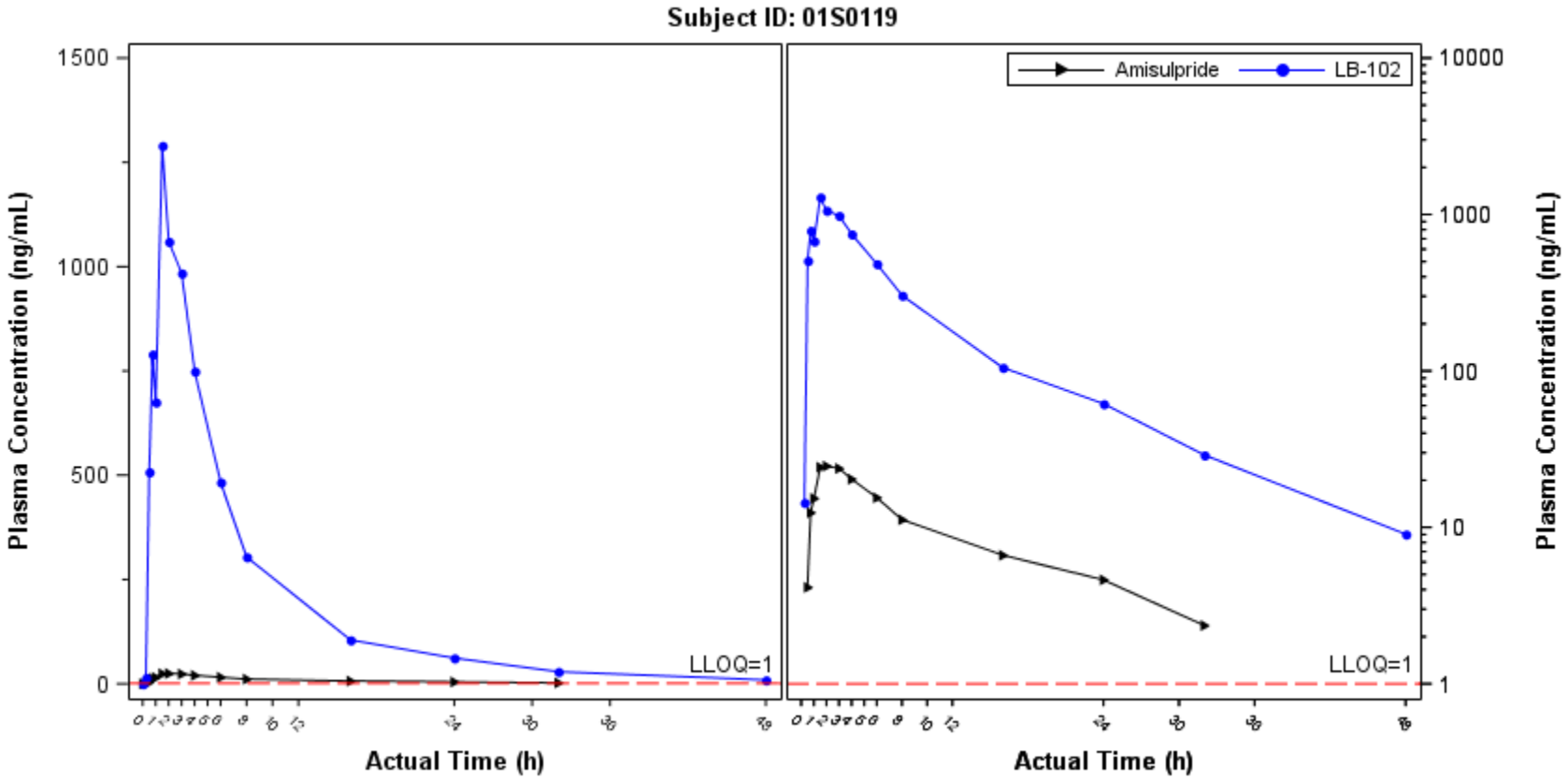


Note: Lower limit of quantification (LLOQ) for LB-102 = 1 ng/mL. LLOQ for amisulpride = 1 ng/mL.
SD = standard deviation.

Source Data: ADPC; Reference listing(s): 16.2.6.2
Program Name: Figure.sas

SDTM Date: 04AUG2020 16:09
Analysis Date: 20AUG2020 18:00

Figure 14.2.3.5
Plot of Individual Plasma Concentrations of LB-102 and Amisulpride by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part A (SAD)
LB-102 200 mg

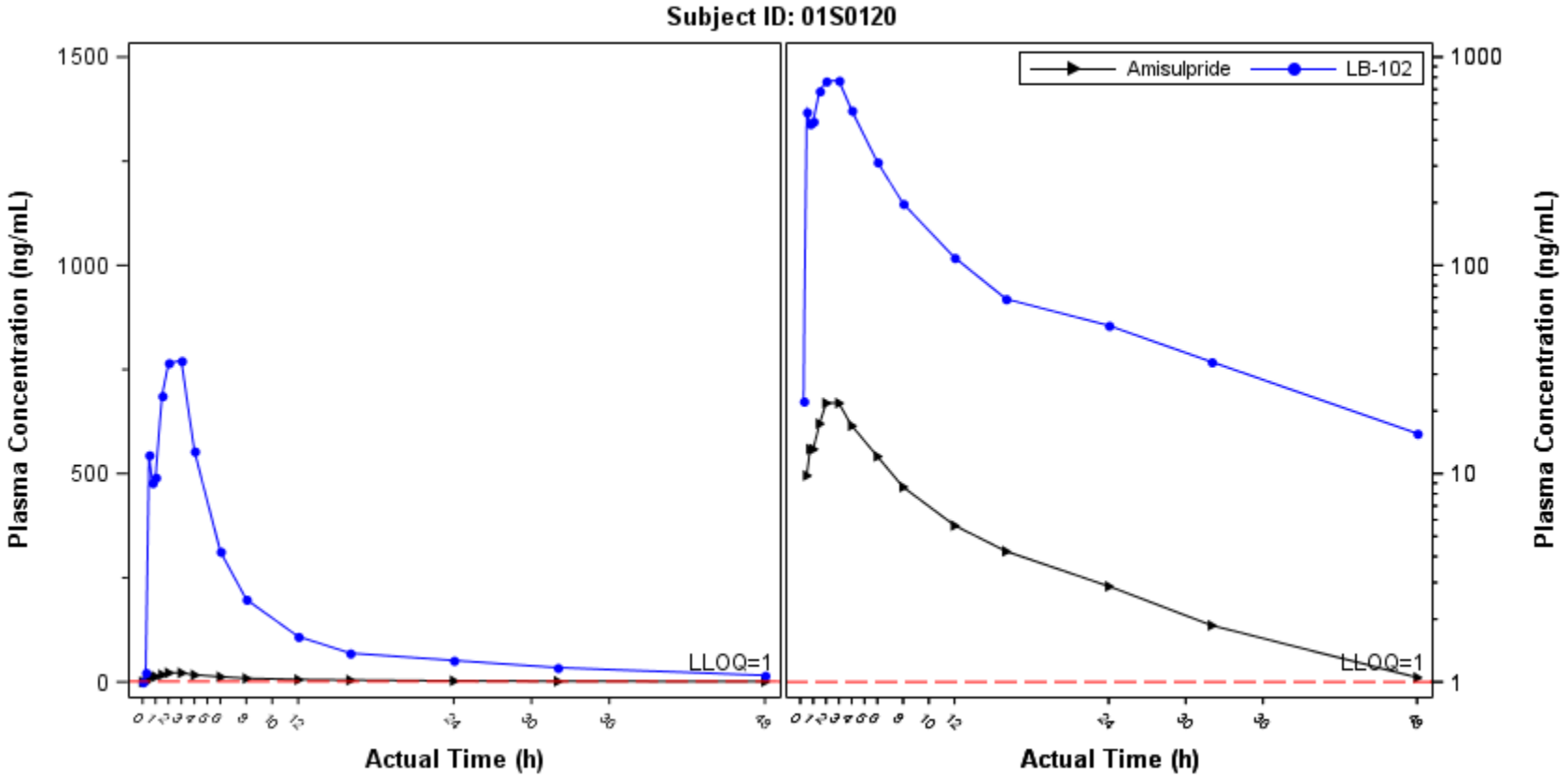


Note: Lower limit of quantification (LLOQ) for LB-102 = 1 ng/mL. LLOQ for amisulpride = 1 ng/mL.
SD = standard deviation.

Source Data: ADPC; Reference listing(s): 16.2.6.2
Program Name: Figure.sas

SDTM Date: 04AUG2020 16:09
Analysis Date: 20AUG2020 18:00

Figure 14.2.3.5
Plot of Individual Plasma Concentrations of LB-102 and Amisulpride by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part A (SAD)
LB-102 200 mg

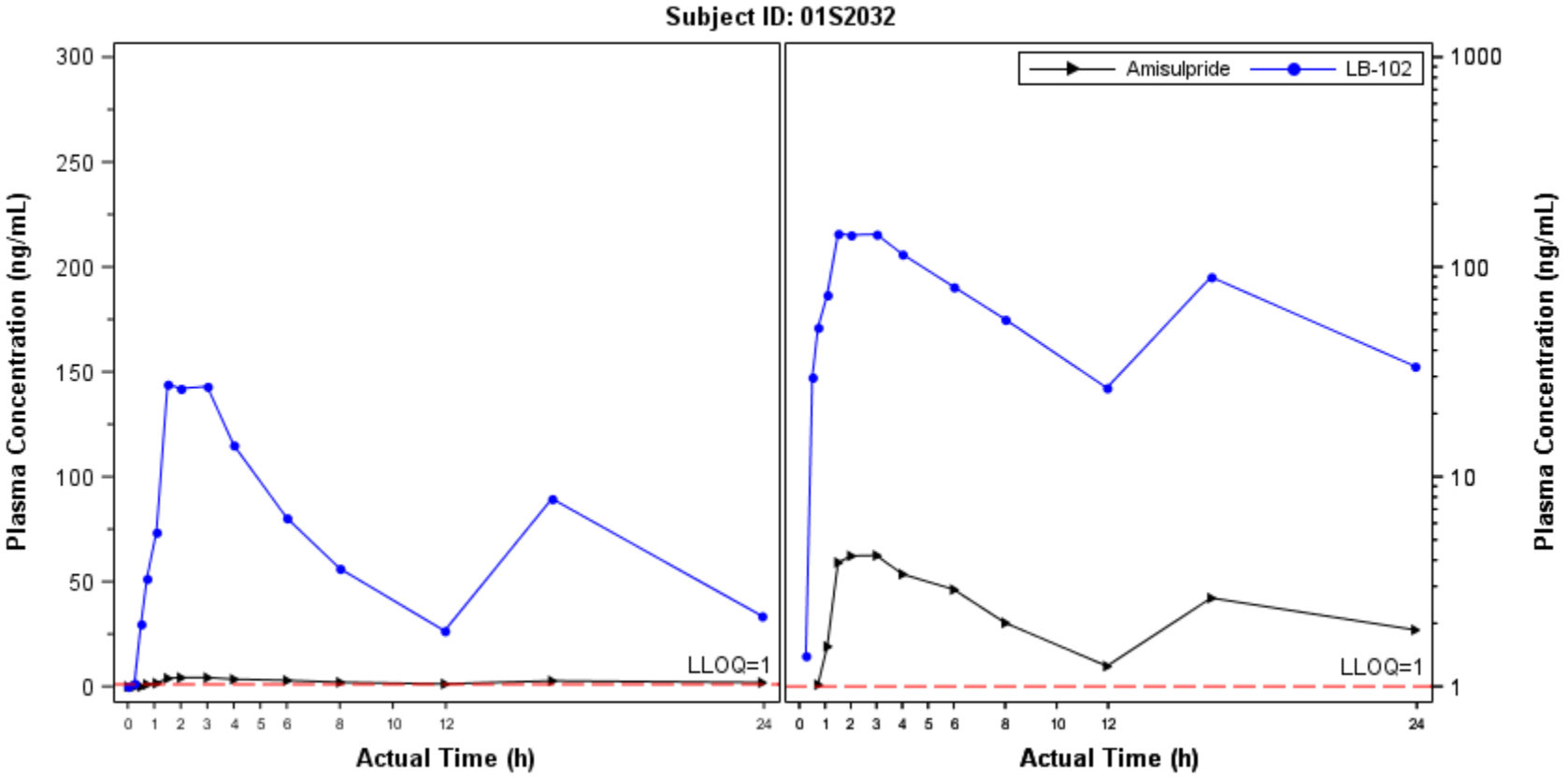


Note: Lower limit of quantification (LLOQ) for LB-102 = 1 ng/mL. LLOQ for amisulpride = 1 ng/mL.
SD = standard deviation.

Source Data: ADPC; Reference listing(s): 16.2.6.2
Program Name: Figure.sas

SDTM Date: 04AUG2020 16:09
Analysis Date: 20AUG2020 18:00

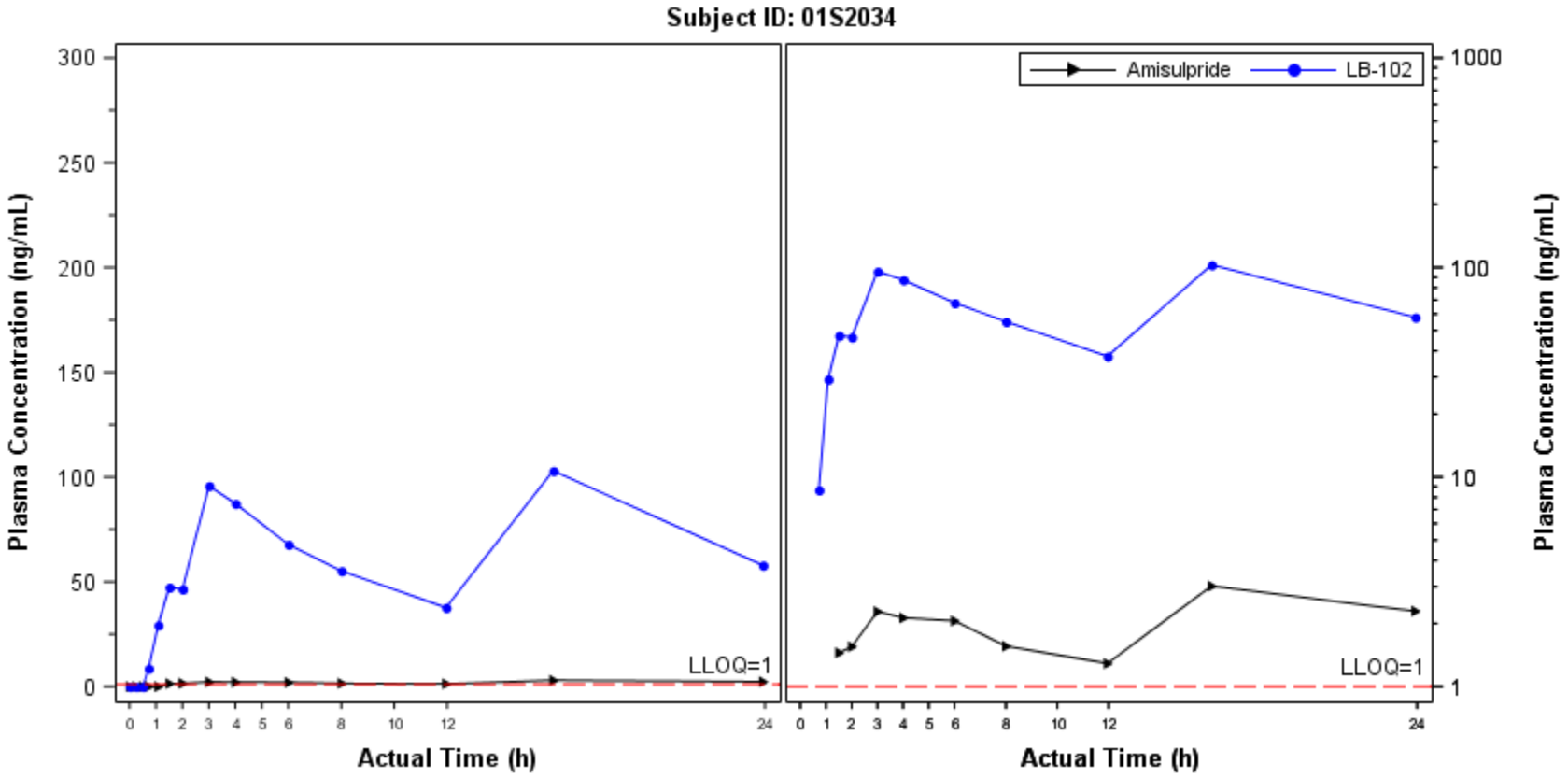
Figure 14.2.4.1
Plot of Individual Plasma Concentrations of LB-102 and Amisulpride on Day 1 by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part B (MAD)
LB-102 50 mg BID



Note: Lower limit of quantification (LLOQ) for LB-102 = 1 ng/mL. LLOQ for amisulpride = 1 ng/mL.

Source Data: ADPC; Reference listing(s): 16.2.6.2
SDTM Date: 04AUG2020 16:09
Program Name: Figure_Ind_mad.sas
Analysis Date: 25AUG2020 11:36

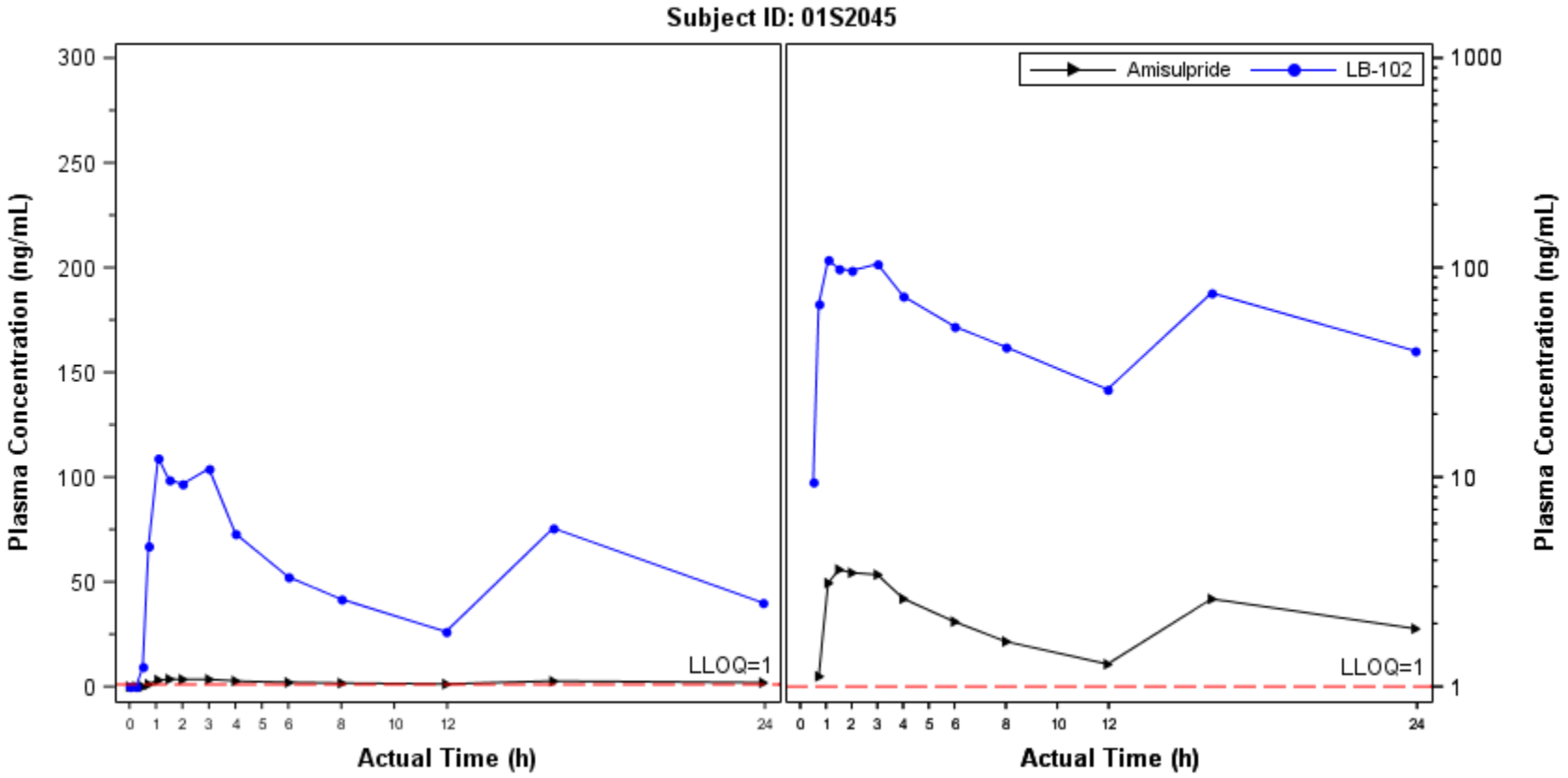
Figure 14.2.4.1
Plot of Individual Plasma Concentrations of LB-102 and Amisulpride on Day 1 by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part B (MAD)
LB-102 50 mg BID



Note: Lower limit of quantification (LLOQ) for LB-102 = 1 ng/mL. LLOQ for amisulpride = 1 ng/mL.

Source Data: ADPC; Reference listing(s): 16.2.6.2
SDTM Date: 04AUG2020 16:09
Program Name: Figure_Ind_mad.sas
Analysis Date: 25AUG2020 11:36

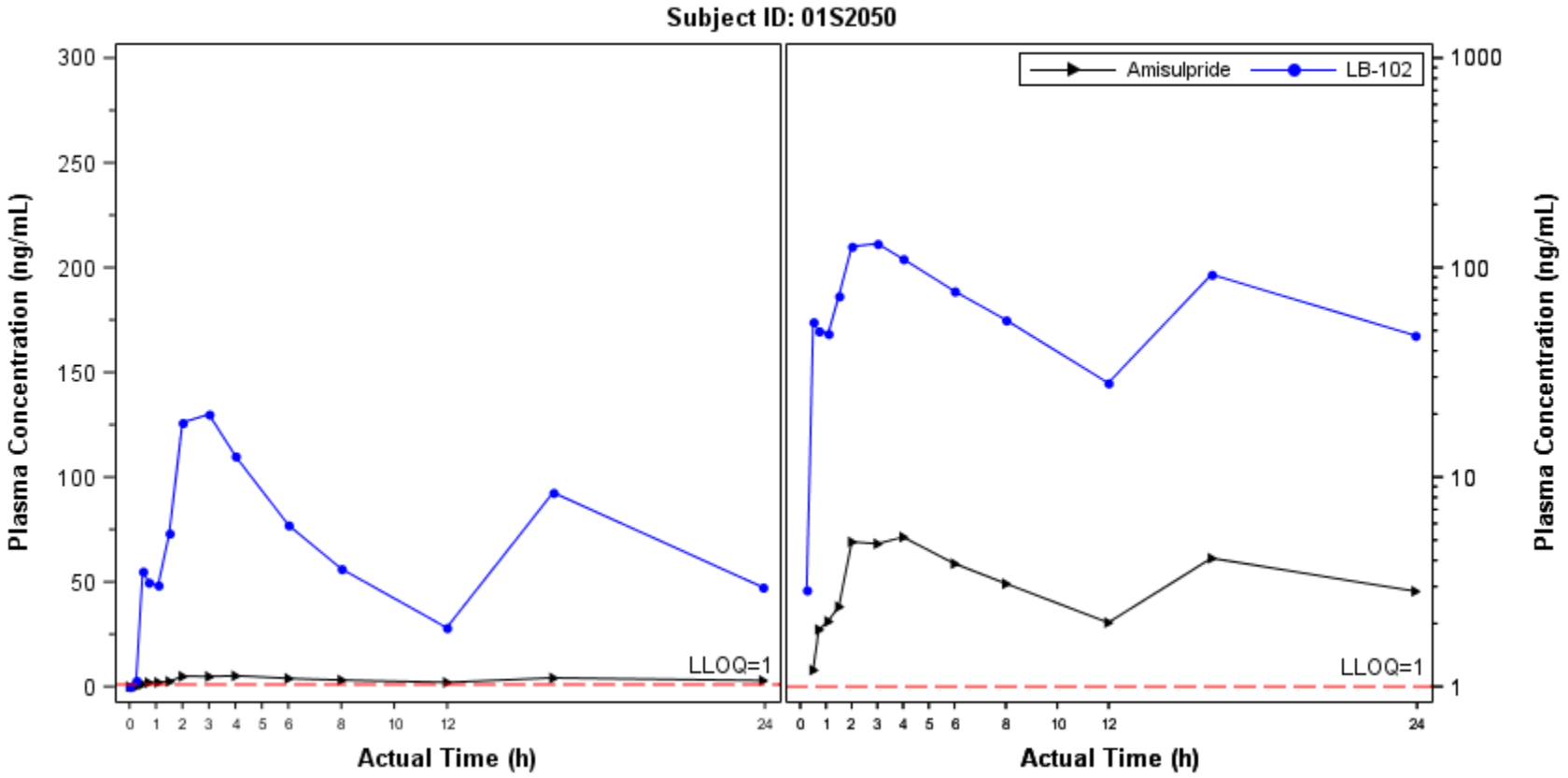
Figure 14.2.4.1
Plot of Individual Plasma Concentrations of LB-102 and Amisulpride on Day 1 by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part B (MAD)
LB-102 50 mg BID



Note: Lower limit of quantification (LLOQ) for LB-102 = 1 ng/mL. LLOQ for amisulpride = 1 ng/mL.

Source Data: ADPC; Reference listing(s): 16.2.6.2
SDTM Date: 04AUG2020 16:09
Program Name: Figure_Ind_mad.sas
Analysis Date: 25AUG2020 11:36

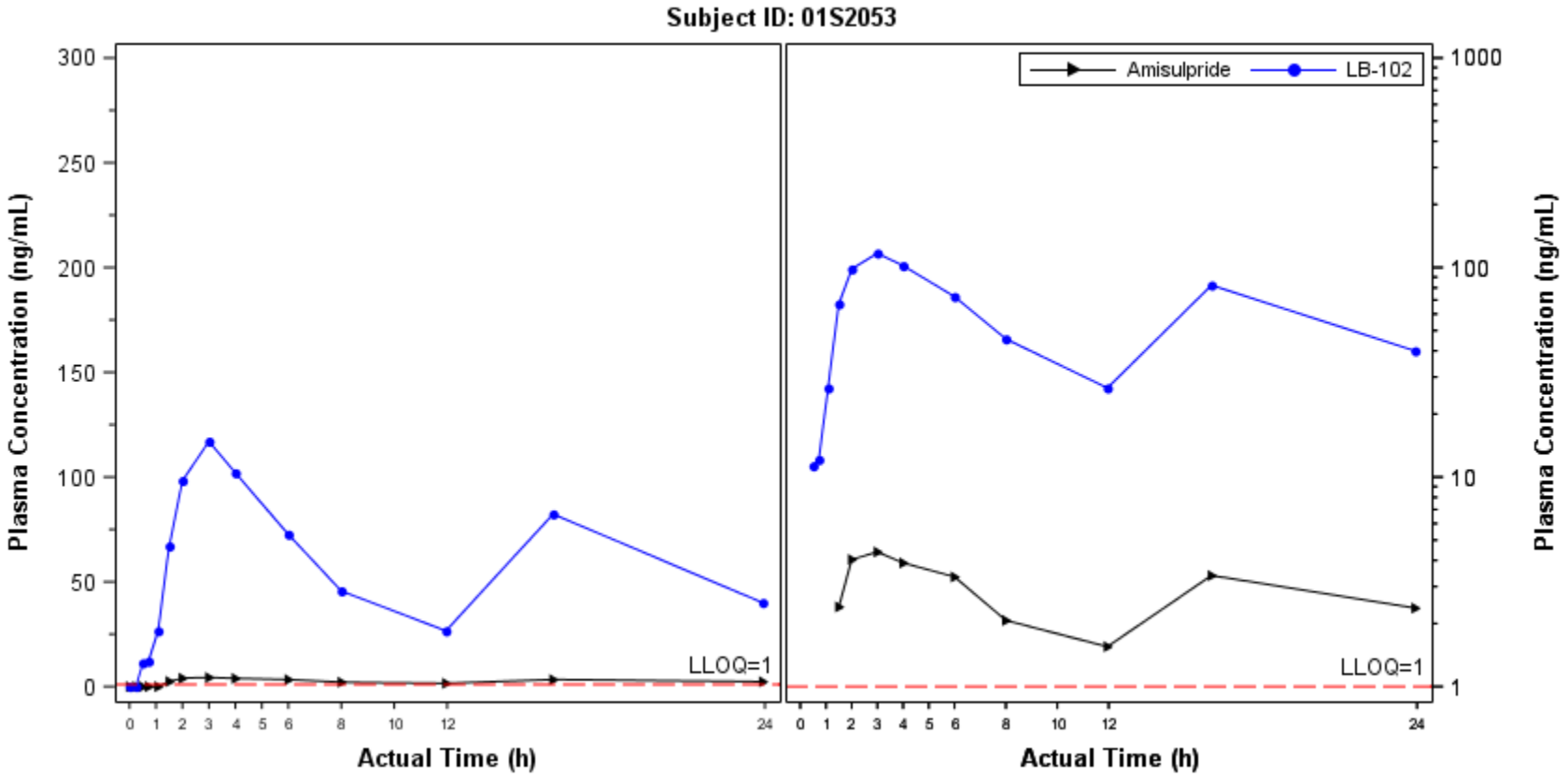
Figure 14.2.4.1
Plot of Individual Plasma Concentrations of LB-102 and Amisulpride on Day 1 by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part B (MAD)
LB-102 50 mg BID



Note: Lower limit of quantification (LLOQ) for LB-102 = 1 ng/mL. LLOQ for amisulpride = 1 ng/mL.

Source Data: ADPC; Reference listing(s): 16.2.6.2
SDTM Date: 04AUG2020 16:09
Program Name: Figure_Ind_mad.sas
Analysis Date: 25AUG2020 11:36

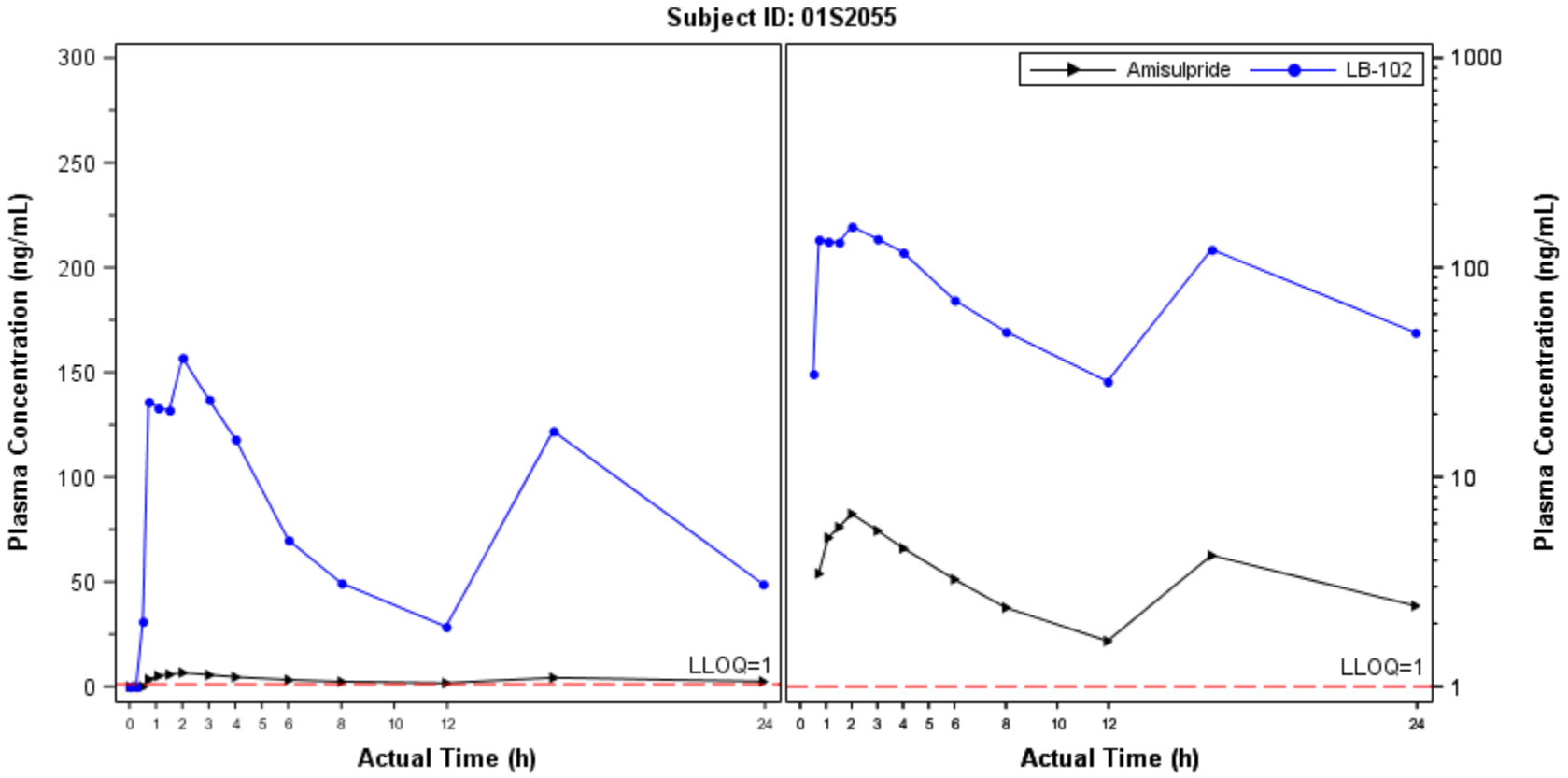
Figure 14.2.4.1
Plot of Individual Plasma Concentrations of LB-102 and Amisulpride on Day 1 by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part B (MAD)
LB-102 50 mg BID



Note: Lower limit of quantification (LLOQ) for LB-102 = 1 ng/mL. LLOQ for amisulpride = 1 ng/mL.

Source Data: ADPC; Reference listing(s): 16.2.6.2
SDTM Date: 04AUG2020 16:09
Program Name: Figure_Ind_mad.sas
Analysis Date: 25AUG2020 11:36

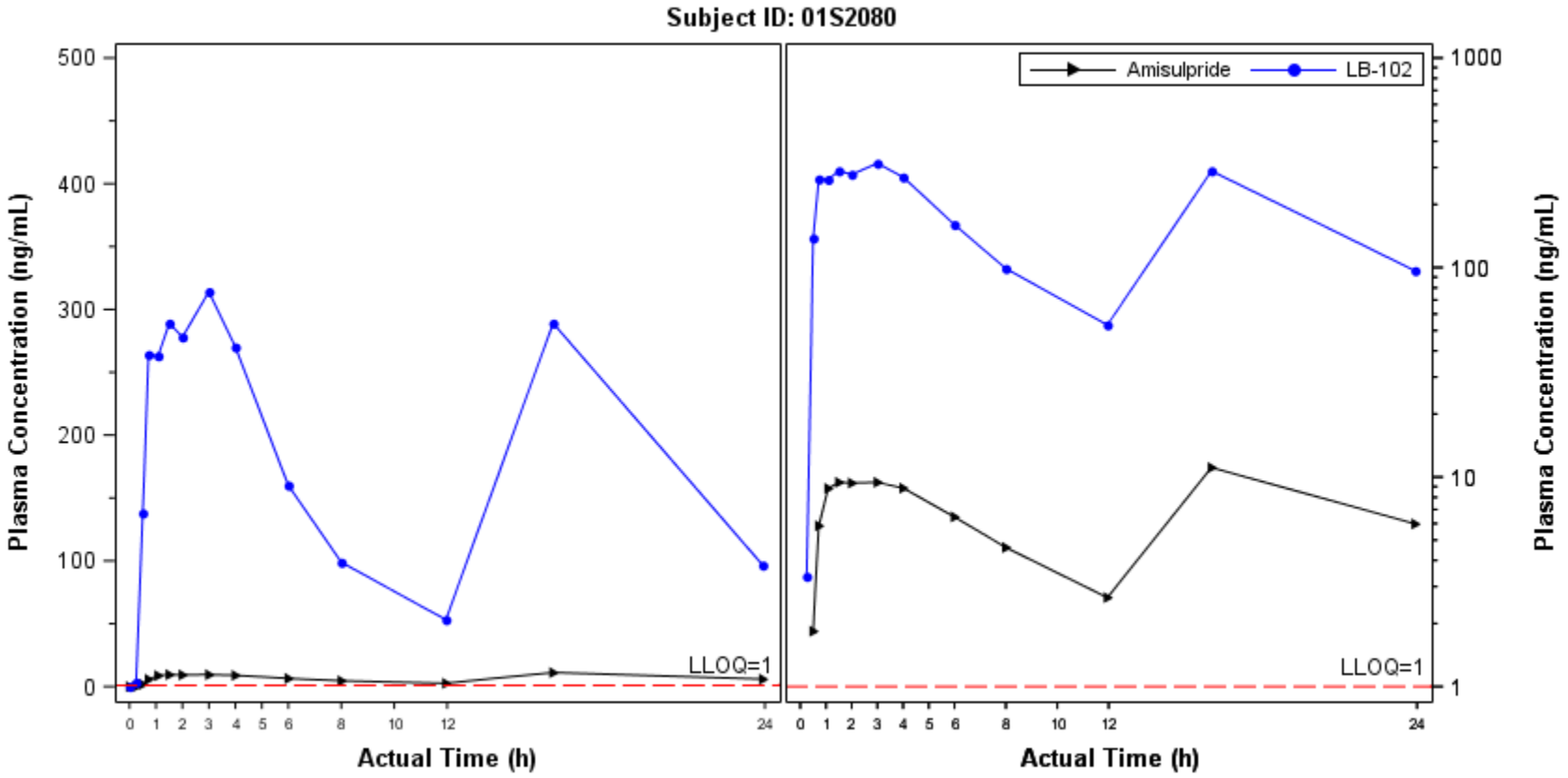
Figure 14.2.4.1
Plot of Individual Plasma Concentrations of LB-102 and Amisulpride on Day 1 by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part B (MAD)
LB-102 50 mg BID



Note: Lower limit of quantification (LLOQ) for LB-102 = 1 ng/mL. LLOQ for amisulpride = 1 ng/mL.

Source Data: ADPC; Reference listing(s): 16.2.6.2
SDTM Date: 04AUG2020 16:09
Program Name: Figure_Ind_mad.sas
Analysis Date: 25AUG2020 11:36

Figure 14.2.4.2
Plot of Individual Plasma Concentrations of LB-102 and Amisulpride on Day 1 by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part B (MAD)
LB-102 75 mg BID

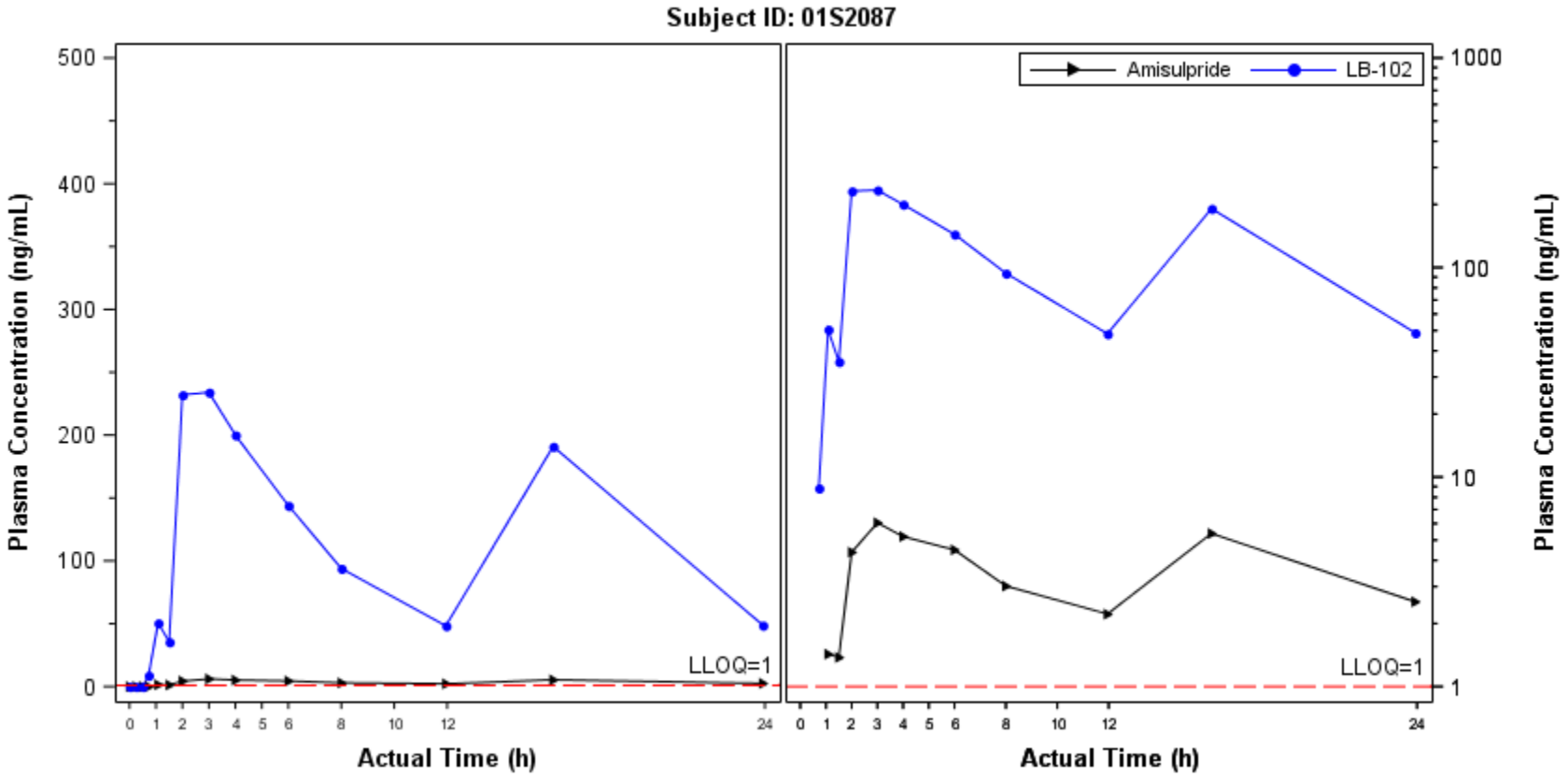


Note: Lower limit of quantification (LLOQ) for LB-102 = 1 ng/mL. LLOQ for amisulpride = 1 ng/mL.

Source Data: ADPC; Reference listing(s): 16.2.6.2
Program Name: Figure_Ind_mad.sas

SDTM Date: 04AUG2020 16:09
Analysis Date: 25AUG2020 11:36

Figure 14.2.4.2
Plot of Individual Plasma Concentrations of LB-102 and Amisulpride on Day 1 by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part B (MAD)
LB-102 75 mg BID

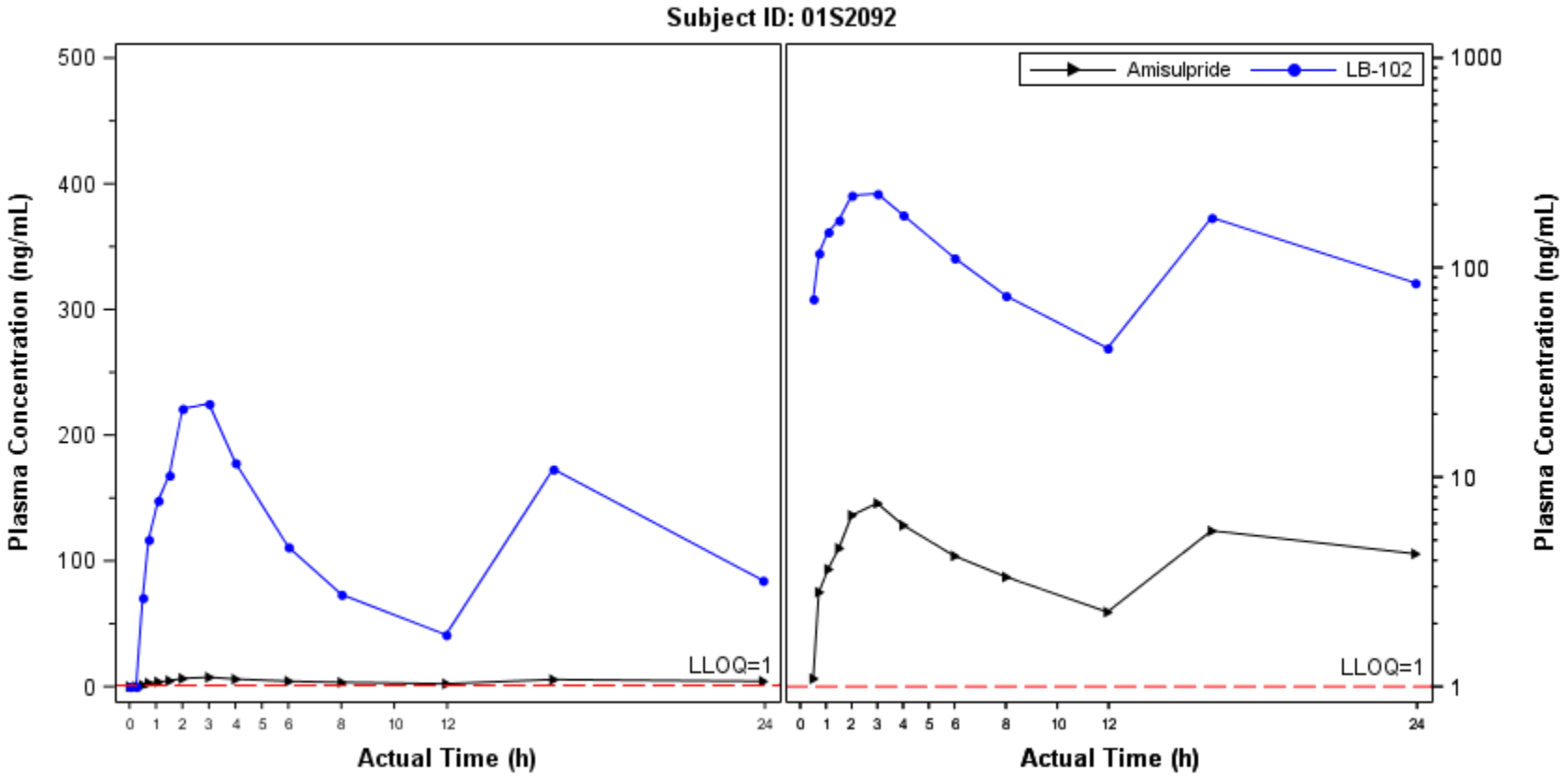


Note: Lower limit of quantification (LLOQ) for LB-102 = 1 ng/mL. LLOQ for amisulpride = 1 ng/mL.

Source Data: ADPC; Reference listing(s): 16.2.6.2
Program Name: Figure_Ind_mad.sas

SDTM Date: 04AUG2020 16:09
Analysis Date: 25AUG2020 11:36

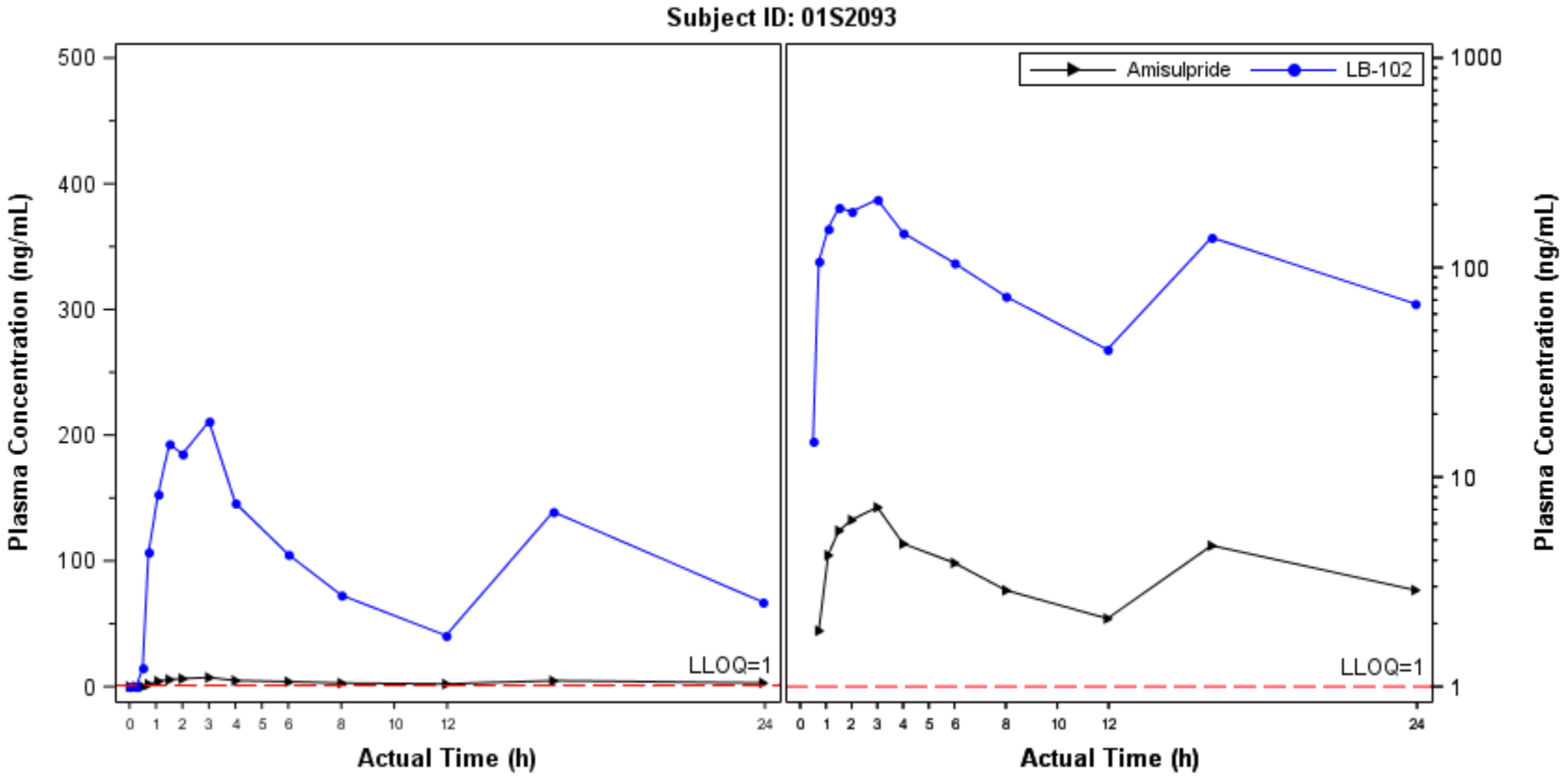
Figure 14.2.4.2
Plot of Individual Plasma Concentrations of LB-102 and Amisulpride on Day 1 by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part B (MAD)
LB-102 75 mg BID



Note: Lower limit of quantification (LLOQ) for LB-102 = 1 ng/mL. LLOQ for amisulpride = 1 ng/mL.

Source Data: ADPC; Reference listing(s): 16.2.6.2
SDTM Date: 04AUG2020 16:09
Program Name: Figure_Ind_mad.sas
Analysis Date: 25AUG2020 11:36

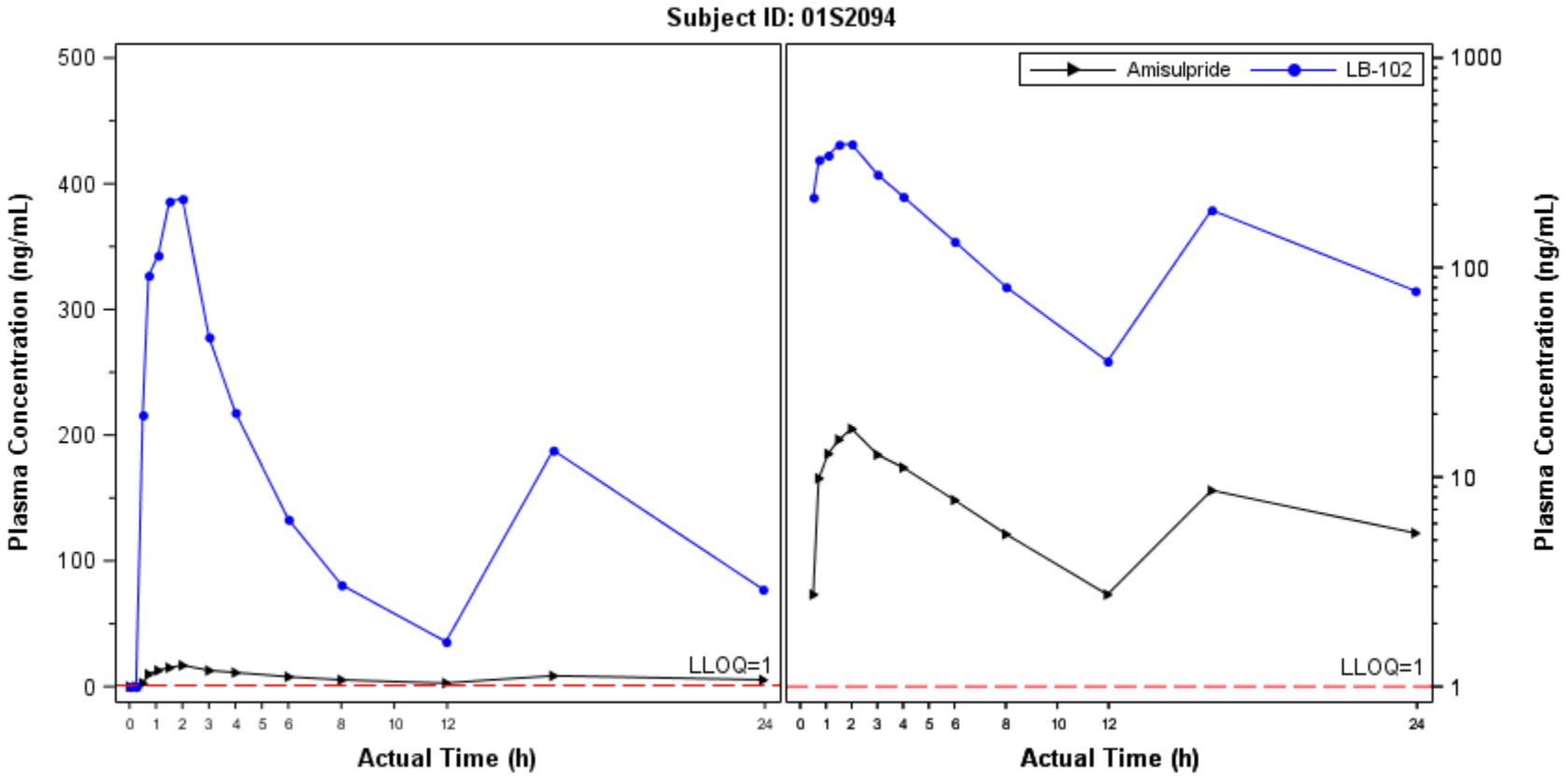
Figure 14.2.4.2
Plot of Individual Plasma Concentrations of LB-102 and Amisulpride on Day 1 by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part B (MAD)
LB-102 75 mg BID



Note: Lower limit of quantification (LLOQ) for LB-102 = 1 ng/mL. LLOQ for amisulpride = 1 ng/mL.

Source Data: ADPC; Reference listing(s): 16.2.6.2
SDTM Date: 04AUG2020 16:09
Program Name: Figure_Ind_mad.sas
Analysis Date: 25AUG2020 11:36

Figure 14.2.4.2
Plot of Individual Plasma Concentrations of LB-102 and Amisulpride on Day 1 by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part B (MAD)
LB-102 75 mg BID

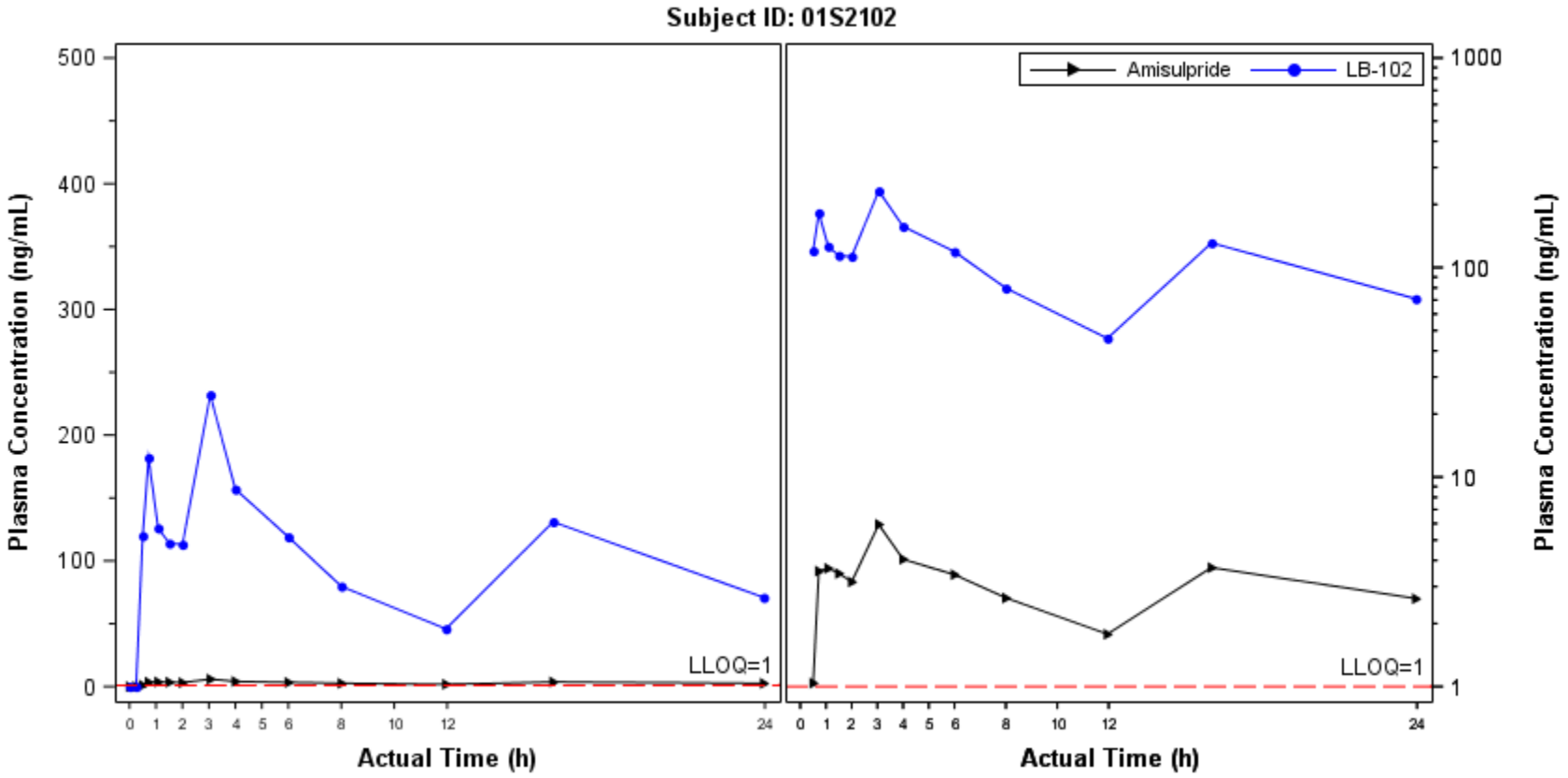


Note: Lower limit of quantification (LLOQ) for LB-102 = 1 ng/mL. LLOQ for amisulpride = 1 ng/mL.

Source Data: ADPC; Reference listing(s): 16.2.6.2
Program Name: Figure_Ind_mad.sas

SDTM Date: 04AUG2020 16:09
Analysis Date: 25AUG2020 11:36

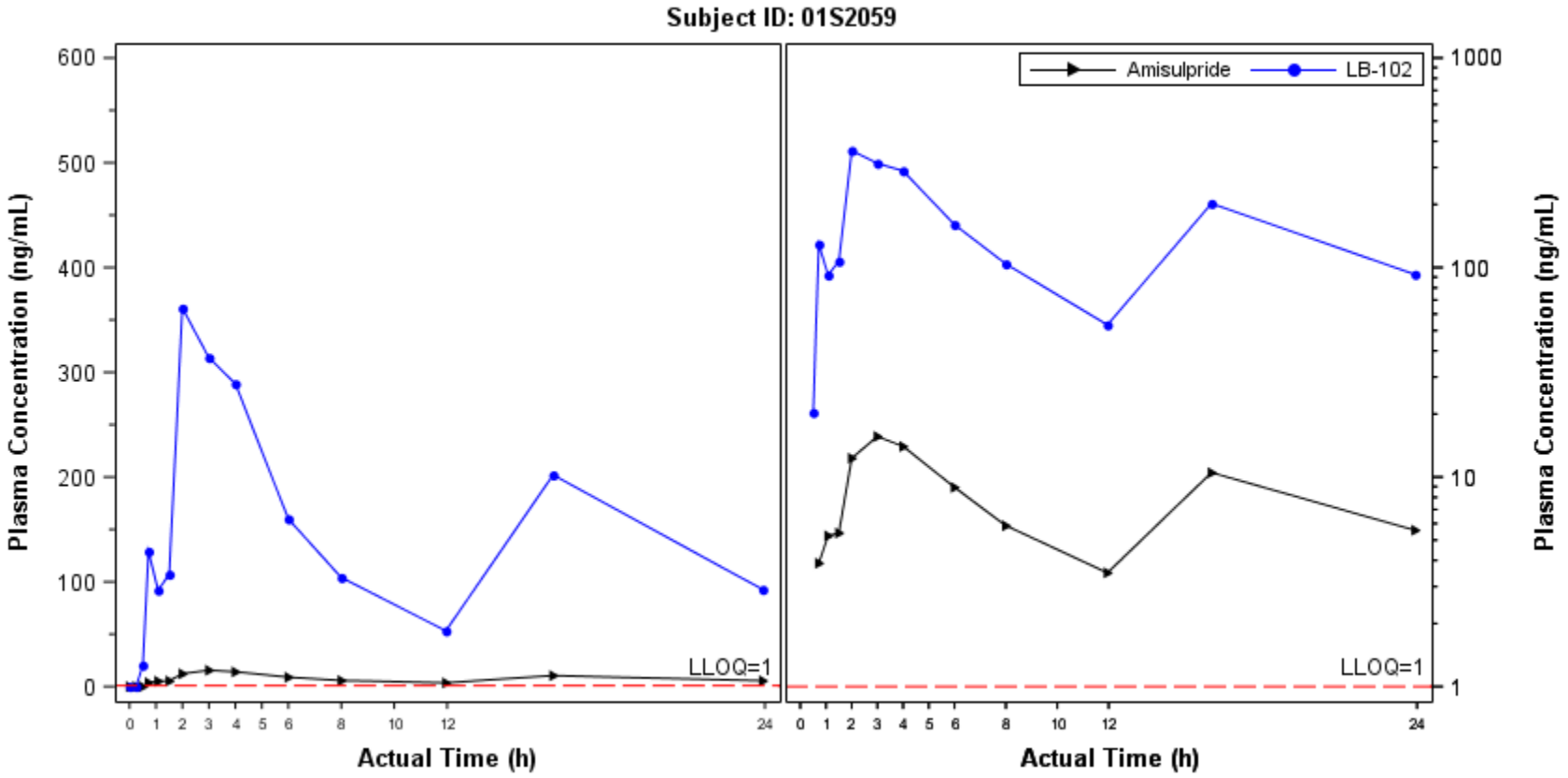
Figure 14.2.4.2
Plot of Individual Plasma Concentrations of LB-102 and Amisulpride on Day 1 by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part B (MAD)
LB-102 75 mg BID



Note: Lower limit of quantification (LLOQ) for LB-102 = 1 ng/mL. LLOQ for amisulpride = 1 ng/mL.

Source Data: ADPC; Reference listing(s): 16.2.6.2 SDTM Date: 04AUG2020 16:09
Program Name: Figure_Ind_mad.sas Analysis Date: 25AUG2020 11:36

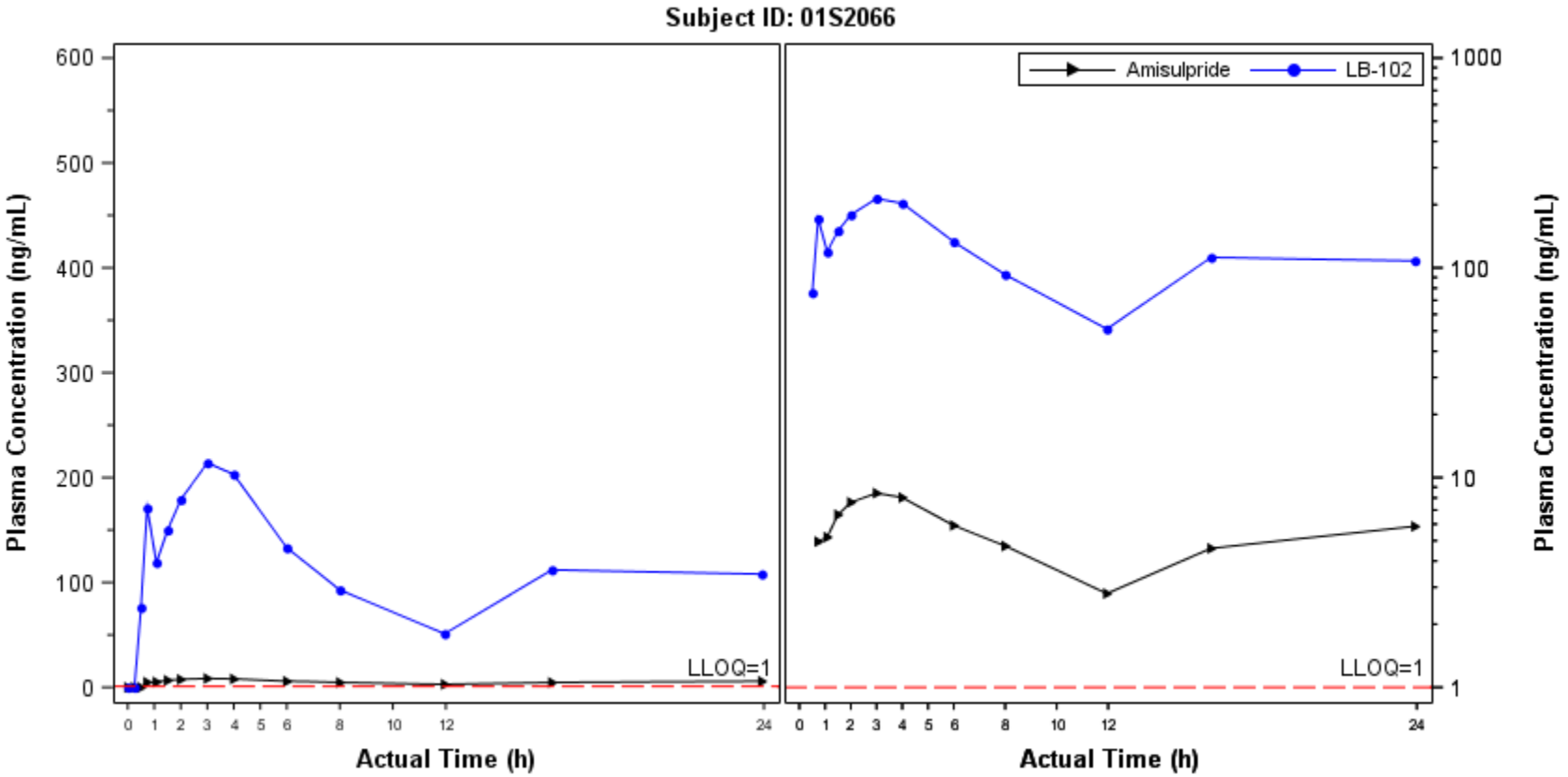
Figure 14.2.4.3
Plot of Individual Plasma Concentrations of LB-102 and Amisulpride on Day 1 by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part B (MAD)
LB-102 100 mg BID



Note: Lower limit of quantification (LLOQ) for LB-102 = 1 ng/mL. LLOQ for amisulpride = 1 ng/mL.

Source Data: ADPC; Reference listing(s): 16.2.6.2
SDTM Date: 04AUG2020 16:09
Program Name: Figure_Ind_mad.sas
Analysis Date: 25AUG2020 11:36

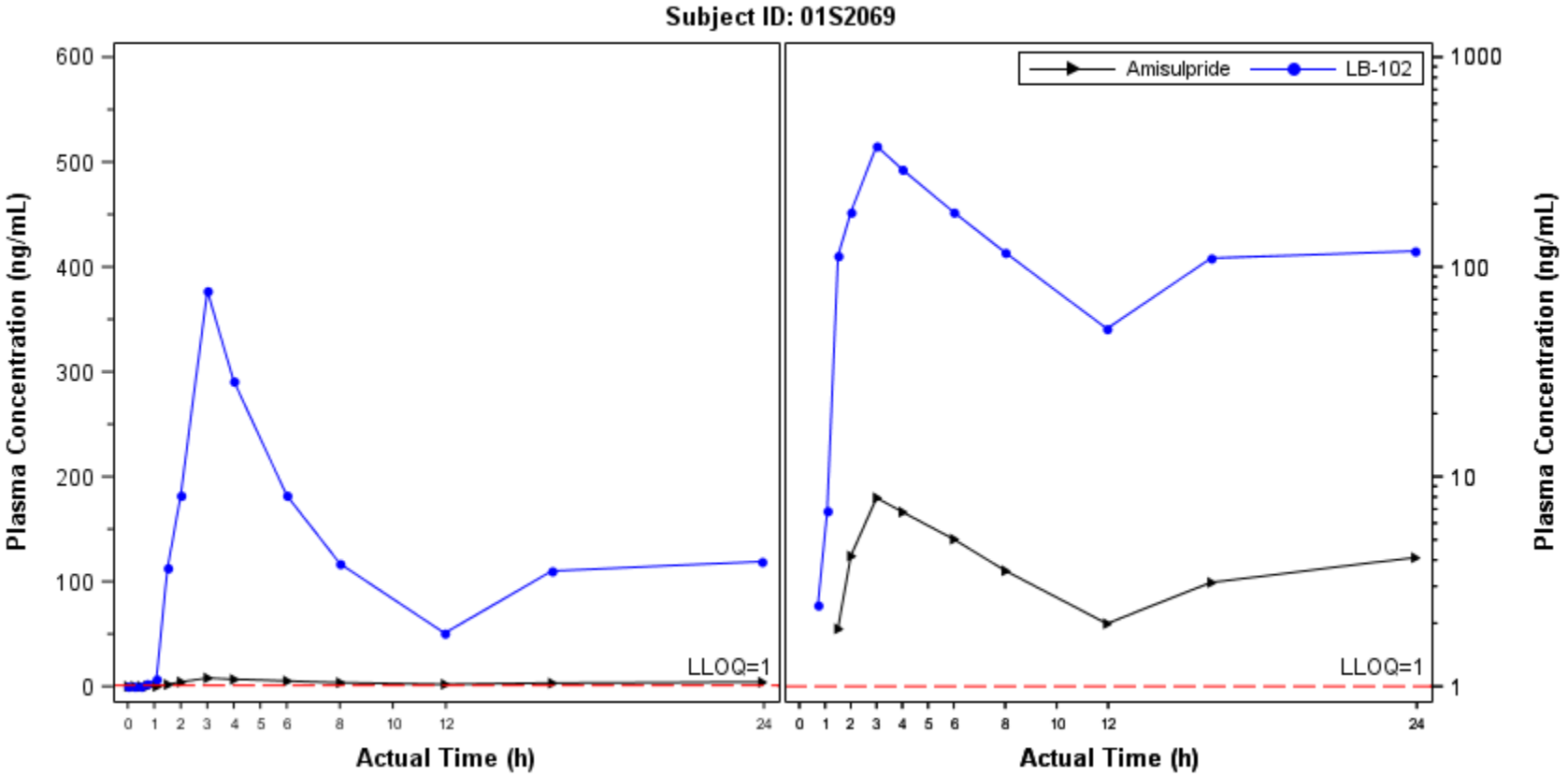
Figure 14.2.4.3
Plot of Individual Plasma Concentrations of LB-102 and Amisulpride on Day 1 by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part B (MAD)
LB-102 100 mg BID



Note: Lower limit of quantification (LLOQ) for LB-102 = 1 ng/mL. LLOQ for amisulpride = 1 ng/mL.

Source Data: ADPC; Reference listing(s): 16.2.6.2
SDTM Date: 04AUG2020 16:09
Program Name: Figure_Ind_mad.sas
Analysis Date: 25AUG2020 11:36

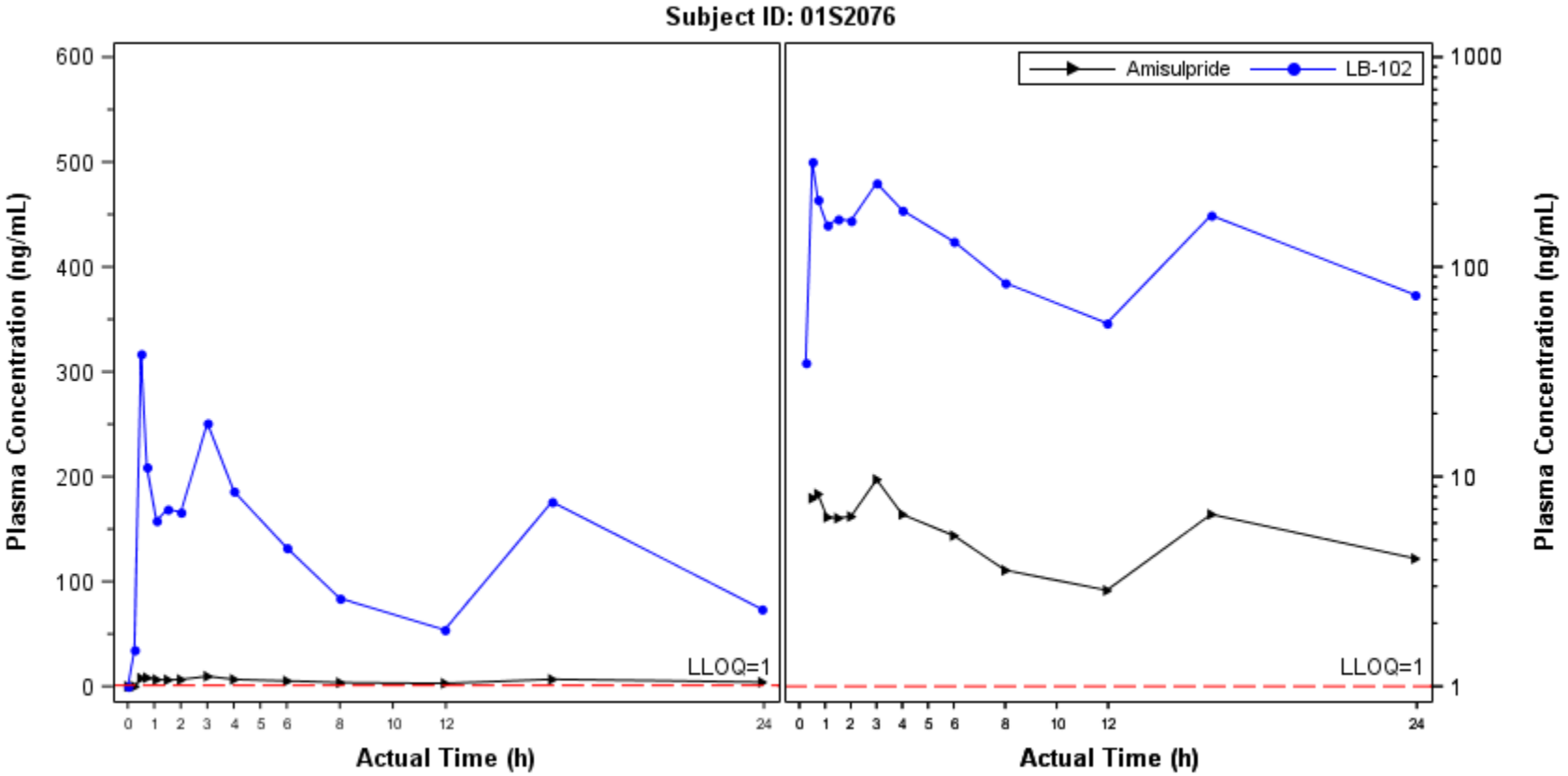
Figure 14.2.4.3
Plot of Individual Plasma Concentrations of LB-102 and Amisulpride on Day 1 by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part B (MAD)
LB-102 100 mg BID



Note: Lower limit of quantification (LLOQ) for LB-102 = 1 ng/mL. LLOQ for amisulpride = 1 ng/mL.

Source Data: ADPC; Reference listing(s): 16.2.6.2
SDTM Date: 04AUG2020 16:09
Program Name: Figure_Ind_mad.sas
Analysis Date: 25AUG2020 11:36

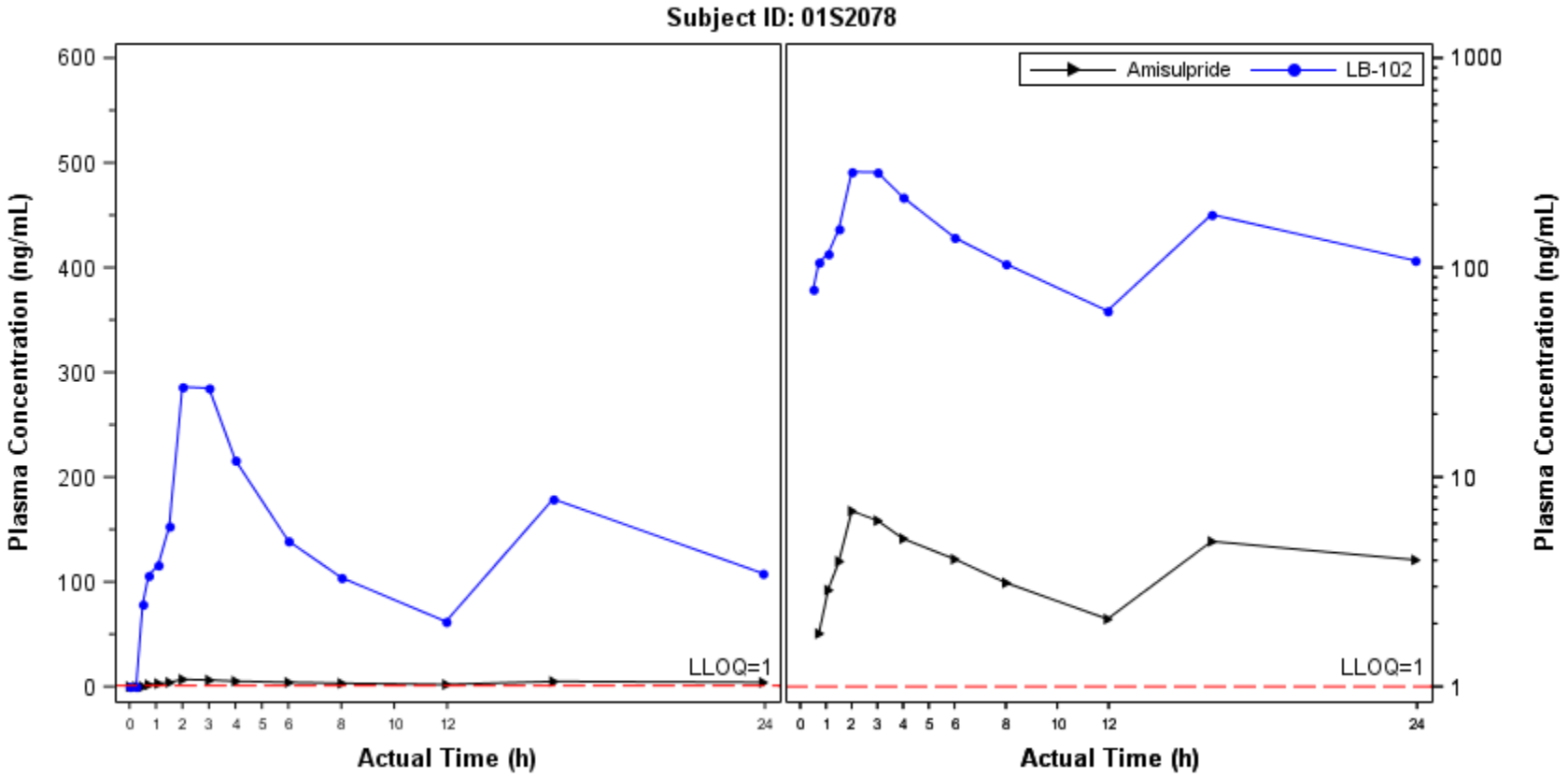
Figure 14.2.4.3
Plot of Individual Plasma Concentrations of LB-102 and Amisulpride on Day 1 by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part B (MAD)
LB-102 100 mg BID



Note: Lower limit of quantification (LLOQ) for LB-102 = 1 ng/mL. LLOQ for amisulpride = 1 ng/mL.

Source Data: ADPC; Reference listing(s): 16.2.6.2
SDTM Date: 04AUG2020 16:09
Program Name: Figure_Ind_mad.sas
Analysis Date: 25AUG2020 11:36

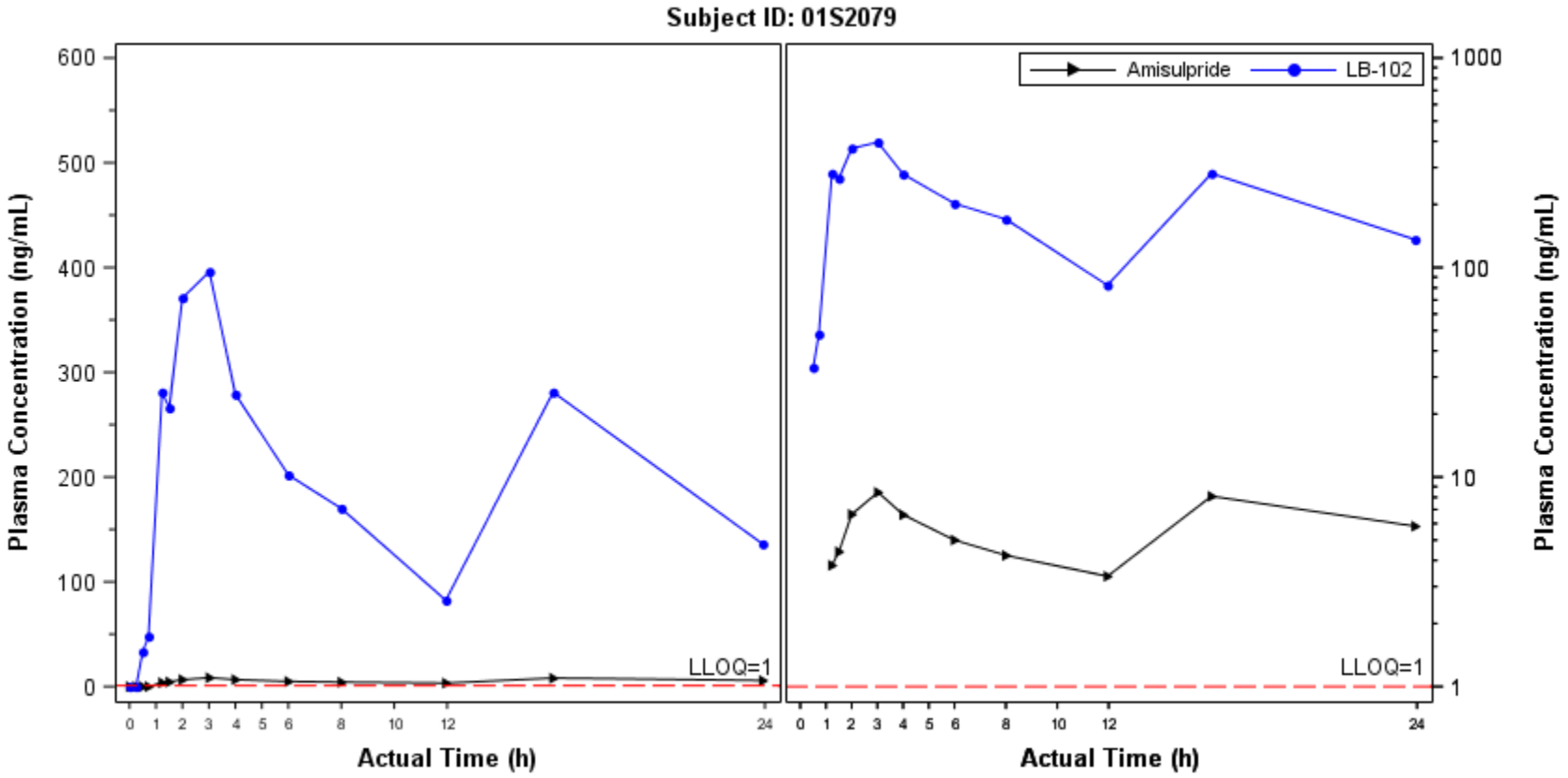
Figure 14.2.4.3
Plot of Individual Plasma Concentrations of LB-102 and Amisulpride on Day 1 by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part B (MAD)
LB-102 100 mg BID



Note: Lower limit of quantification (LLOQ) for LB-102 = 1 ng/mL. LLOQ for amisulpride = 1 ng/mL.

Source Data: ADPC; Reference listing(s): 16.2.6.2
SDTM Date: 04AUG2020 16:09
Program Name: Figure_Ind_mad.sas
Analysis Date: 25AUG2020 11:36

Figure 14.2.4.3
Plot of Individual Plasma Concentrations of LB-102 and Amisulpride on Day 1 by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part B (MAD)
LB-102 100 mg BID

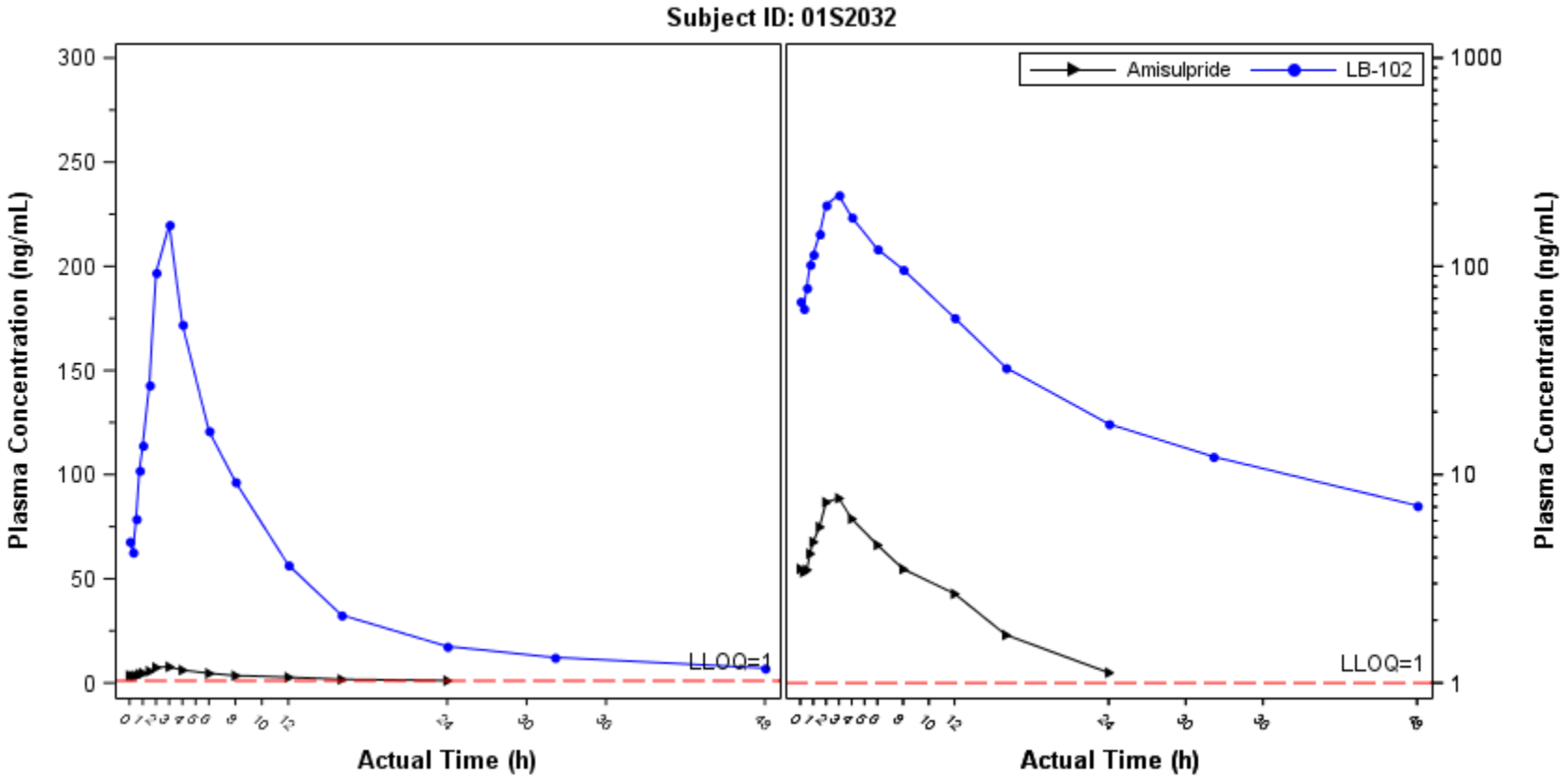


Note: Lower limit of quantification (LLOQ) for LB-102 = 1 ng/mL. LLOQ for amisulpride = 1 ng/mL.

Source Data: ADPC; Reference listing(s): 16.2.6.2
Program Name: Figure_Ind_mad.sas

SDTM Date: 04AUG2020 16:09
Analysis Date: 25AUG2020 11:36

Figure 14.2.4.4
Plot of Individual Plasma Concentrations of LB-102 and Amisulpride after Multiple Dose by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part B (MAD)
LB-102 50 mg BID

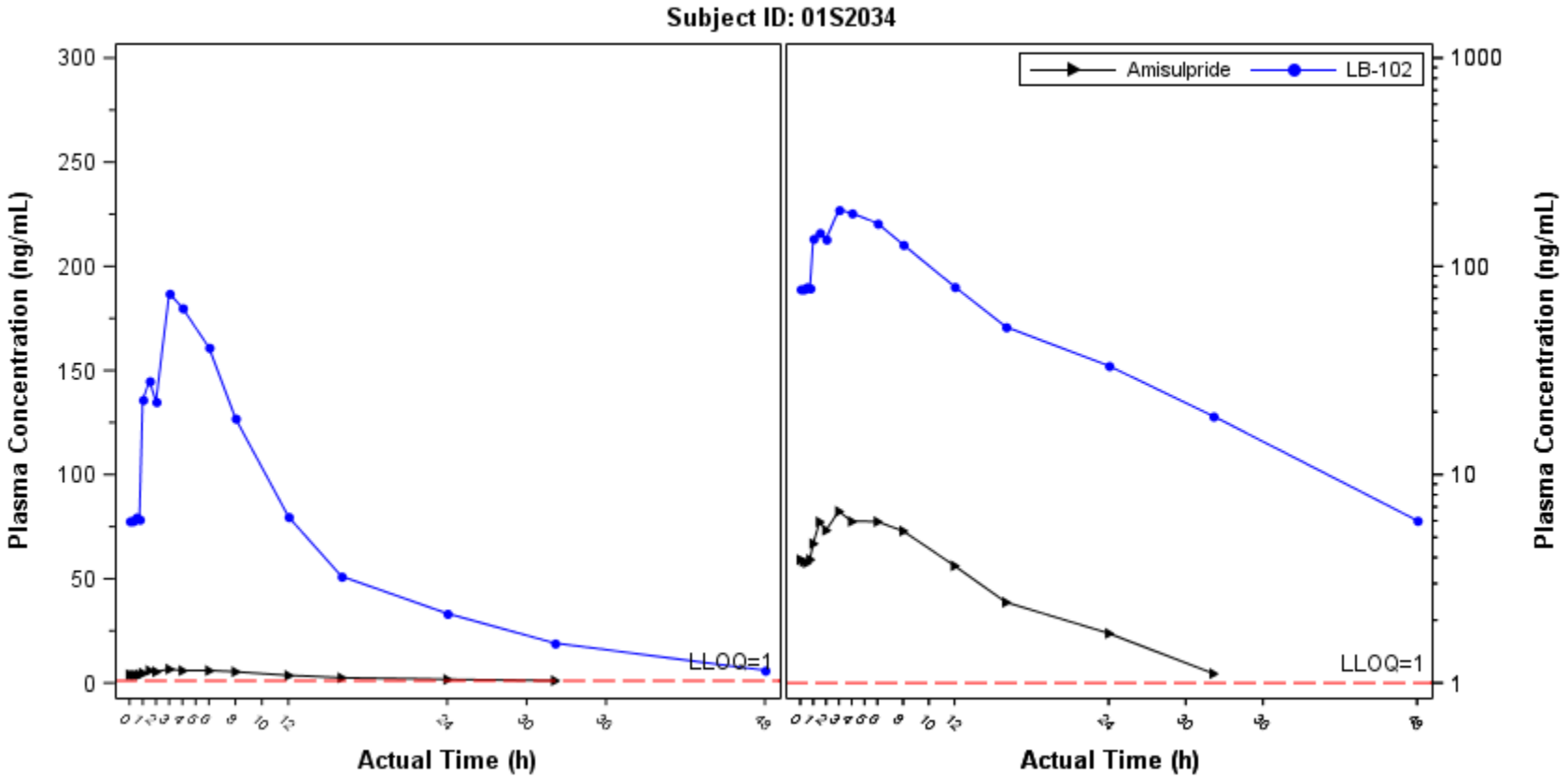


Note: Lower limit of quantification (LLOQ) for LB-102 = 1 ng/mL. LLOQ for amisulpride = 1 ng/mL.
For Cohort 6 (LB-102 50 mg BID), the PK concentrations on Day 7 are plotted.

Source Data: ADPC; Reference listing(s): 16.2.6.2
Program Name: Figure_Ind_mad.sas

SDTM Date: 04AUG2020 16:09
Analysis Date: 25AUG2020 11:36

Figure 14.2.4.4
Plot of Individual Plasma Concentrations of LB-102 and Amisulpride after Multiple Dose by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part B (MAD)
LB-102 50 mg BID

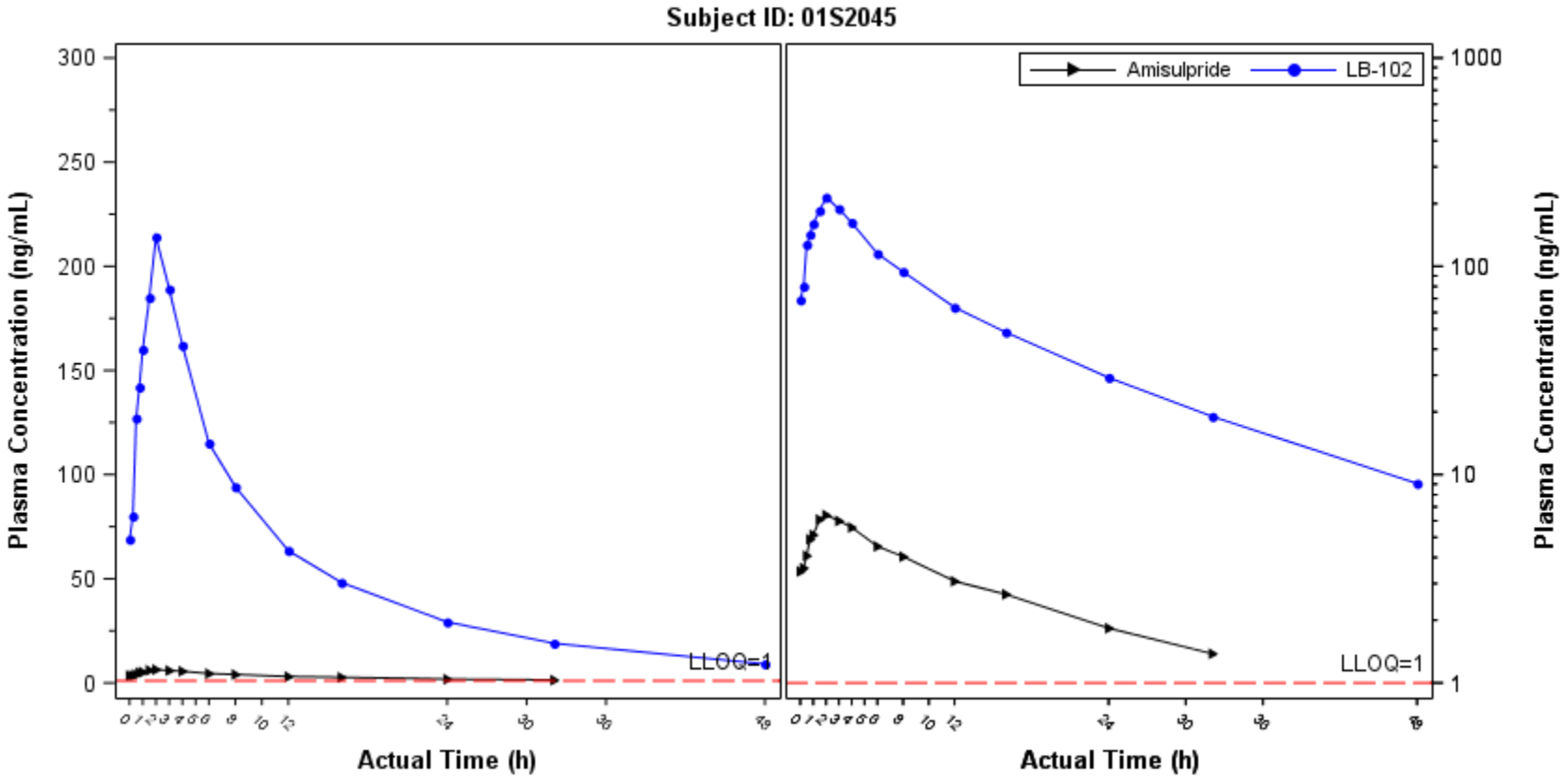


Note: Lower limit of quantification (LLOQ) for LB-102 = 1 ng/mL. LLOQ for amisulpride = 1 ng/mL.
For Cohort 6 (LB-102 50 mg BID), the PK concentrations on Day 7 are plotted.

Source Data: ADPC; Reference listing(s): 16.2.6.2
Program Name: Figure_Ind_mad.sas

SDTM Date: 04AUG2020 16:09
Analysis Date: 25AUG2020 11:36

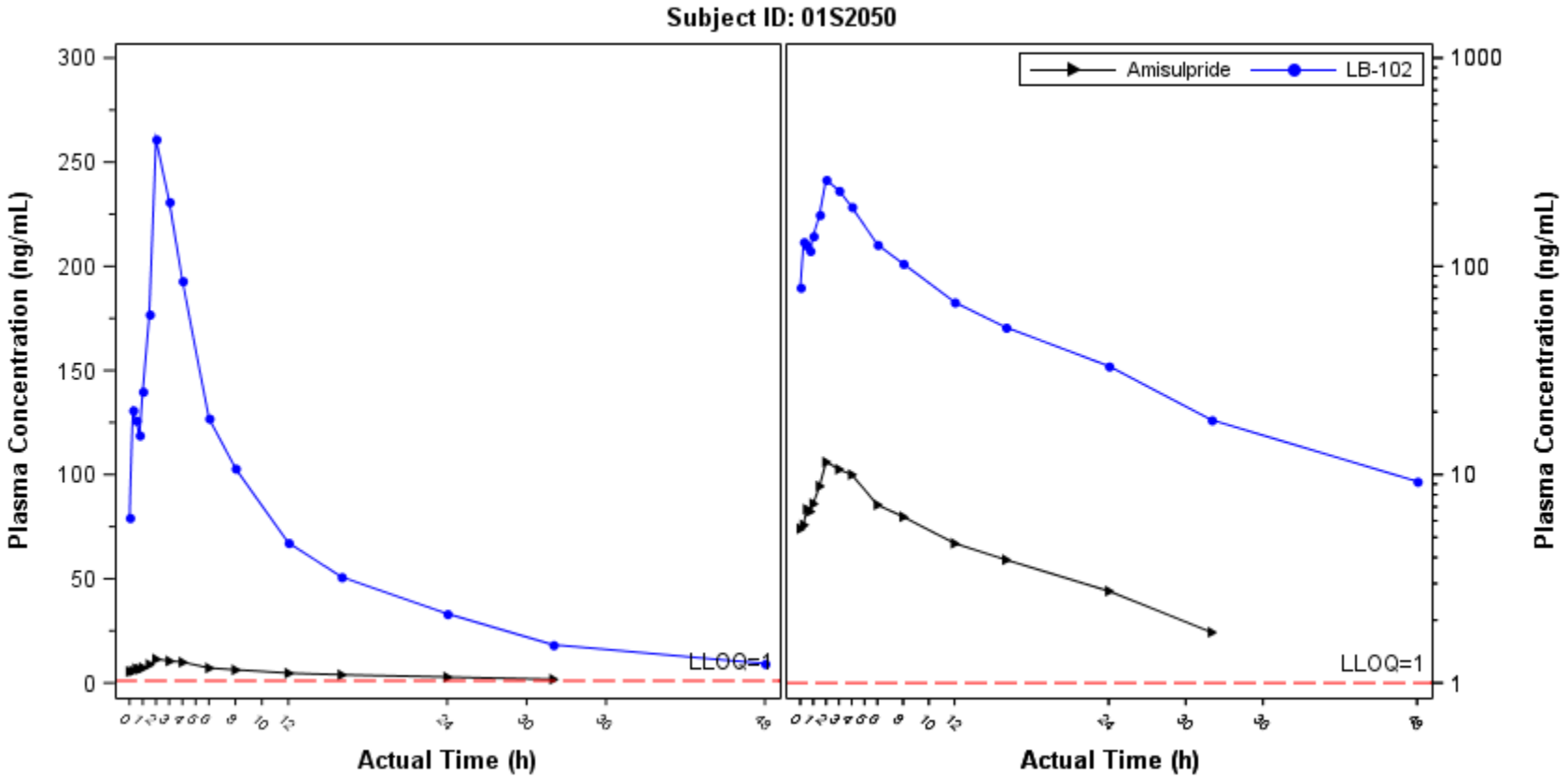
Figure 14.2.4.4
Plot of Individual Plasma Concentrations of LB-102 and Amisulpride after Multiple Dose by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part B (MAD)
LB-102 50 mg BID



Note: Lower limit of quantification (LLOQ) for LB-102 = 1 ng/mL. LLOQ for amisulpride = 1 ng/mL.
For Cohort 6 (LB-102 50 mg BID), the PK concentrations on Day 7 are plotted.

Source Data: ADPC; Reference listing(s): 16.2.6.2 SDTM Date: 04AUG2020 16:09
Program Name: Figure_Ind_mad.sas Analysis Date: 25AUG2020 11:36

Figure 14.2.4.4
Plot of Individual Plasma Concentrations of LB-102 and Amisulpride after Multiple Dose by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part B (MAD)
LB-102 50 mg BID

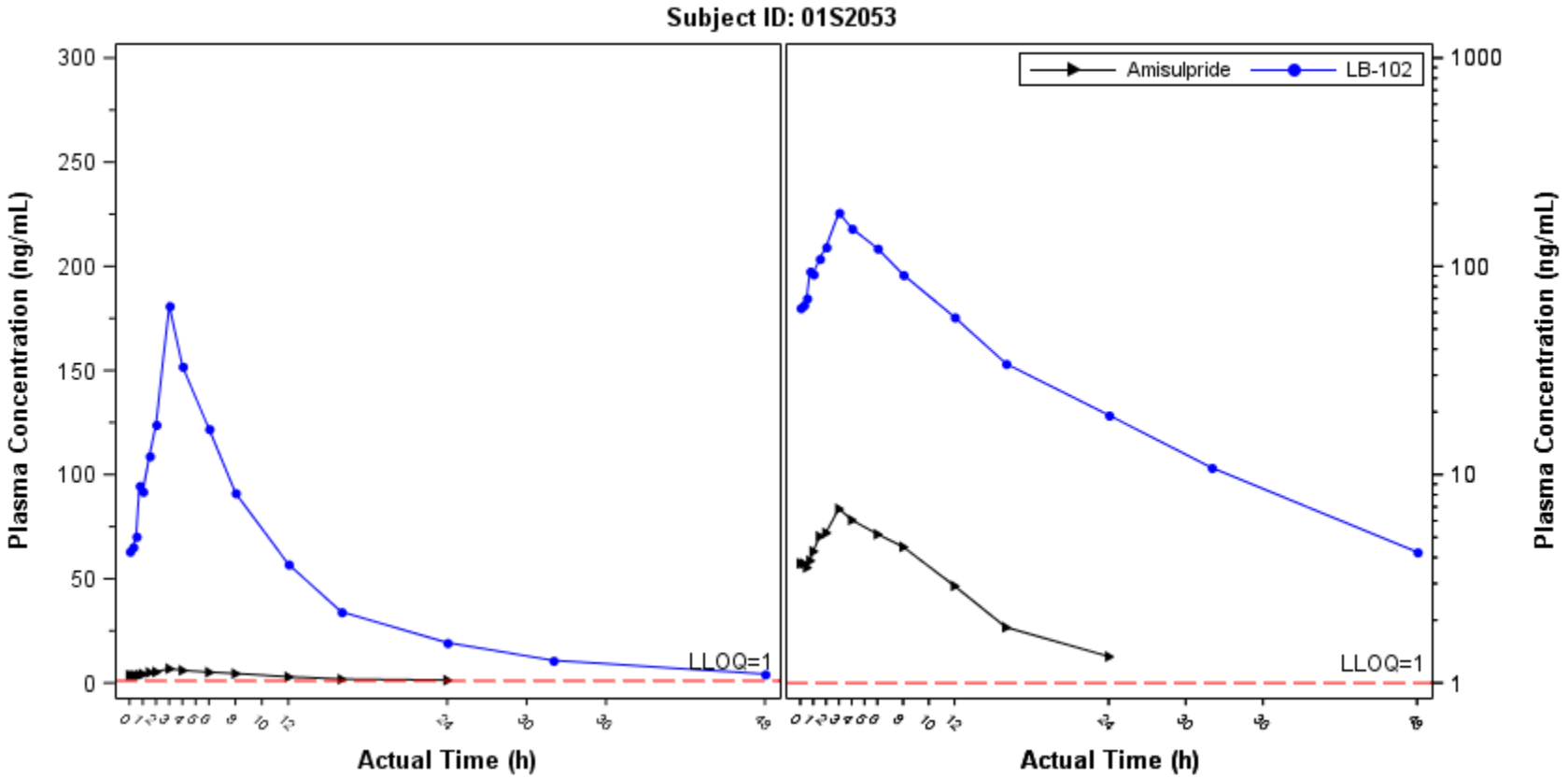


Note: Lower limit of quantification (LLOQ) for LB-102 = 1 ng/mL. LLOQ for amisulpride = 1 ng/mL.
For Cohort 6 (LB-102 50 mg BID), the PK concentrations on Day 7 are plotted.

Source Data: ADPC; Reference listing(s): 16.2.6.2
Program Name: Figure_Ind_mad.sas

SDTM Date: 04AUG2020 16:09
Analysis Date: 25AUG2020 11:36

Figure 14.2.4.4
Plot of Individual Plasma Concentrations of LB-102 and Amisulpride after Multiple Dose by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part B (MAD)
LB-102 50 mg BID

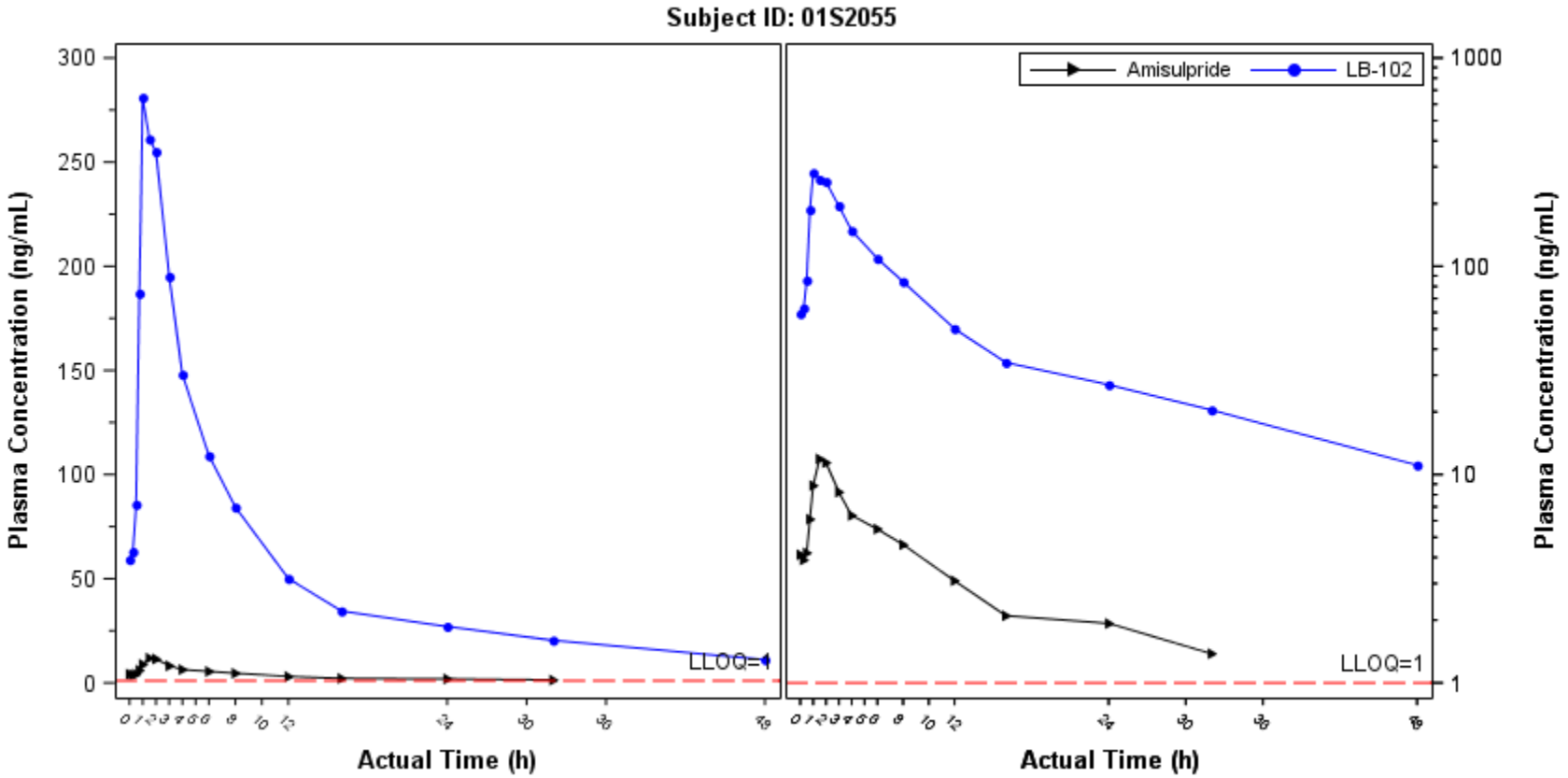


Note: Lower limit of quantification (LLOQ) for LB-102 = 1 ng/mL. LLOQ for amisulpride = 1 ng/mL.
For Cohort 6 (LB-102 50 mg BID), the PK concentrations on Day 7 are plotted.

Source Data: ADPC; Reference listing(s): 16.2.6.2
Program Name: Figure_Ind_mad.sas

SDTM Date: 04AUG2020 16:09
Analysis Date: 25AUG2020 11:36

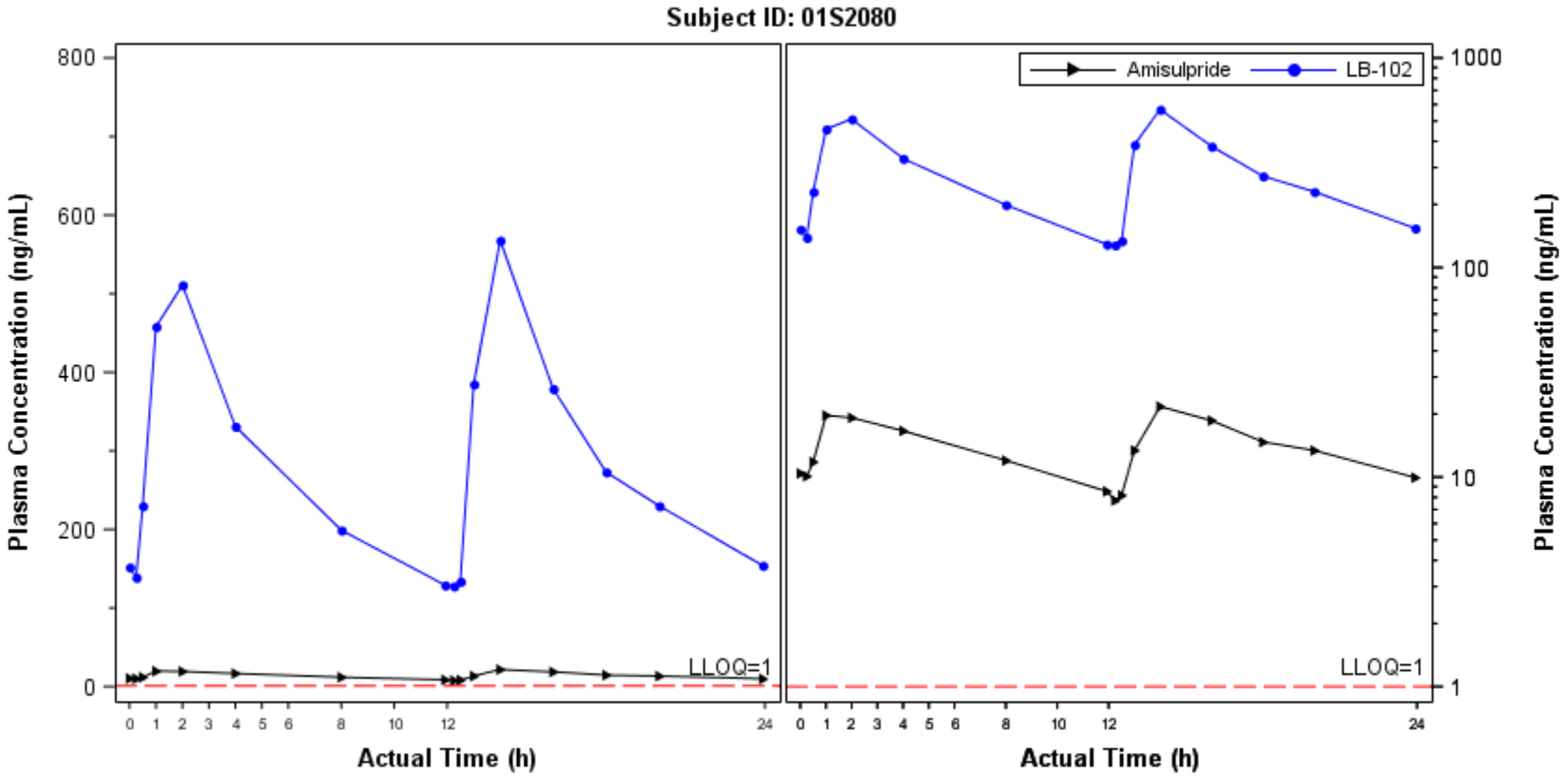
Figure 14.2.4.4
Plot of Individual Plasma Concentrations of LB-102 and Amisulpride after Multiple Dose by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part B (MAD)
LB-102 50 mg BID



Note: Lower limit of quantification (LLOQ) for LB-102 = 1 ng/mL. LLOQ for amisulpride = 1 ng/mL.
For Cohort 6 (LB-102 50 mg BID), the PK concentrations on Day 7 are plotted.

Source Data: ADPC; Reference listing(s): 16.2.6.2 SDTM Date: 04AUG2020 16:09
Program Name: Figure_Ind_mad.sas Analysis Date: 25AUG2020 11:36

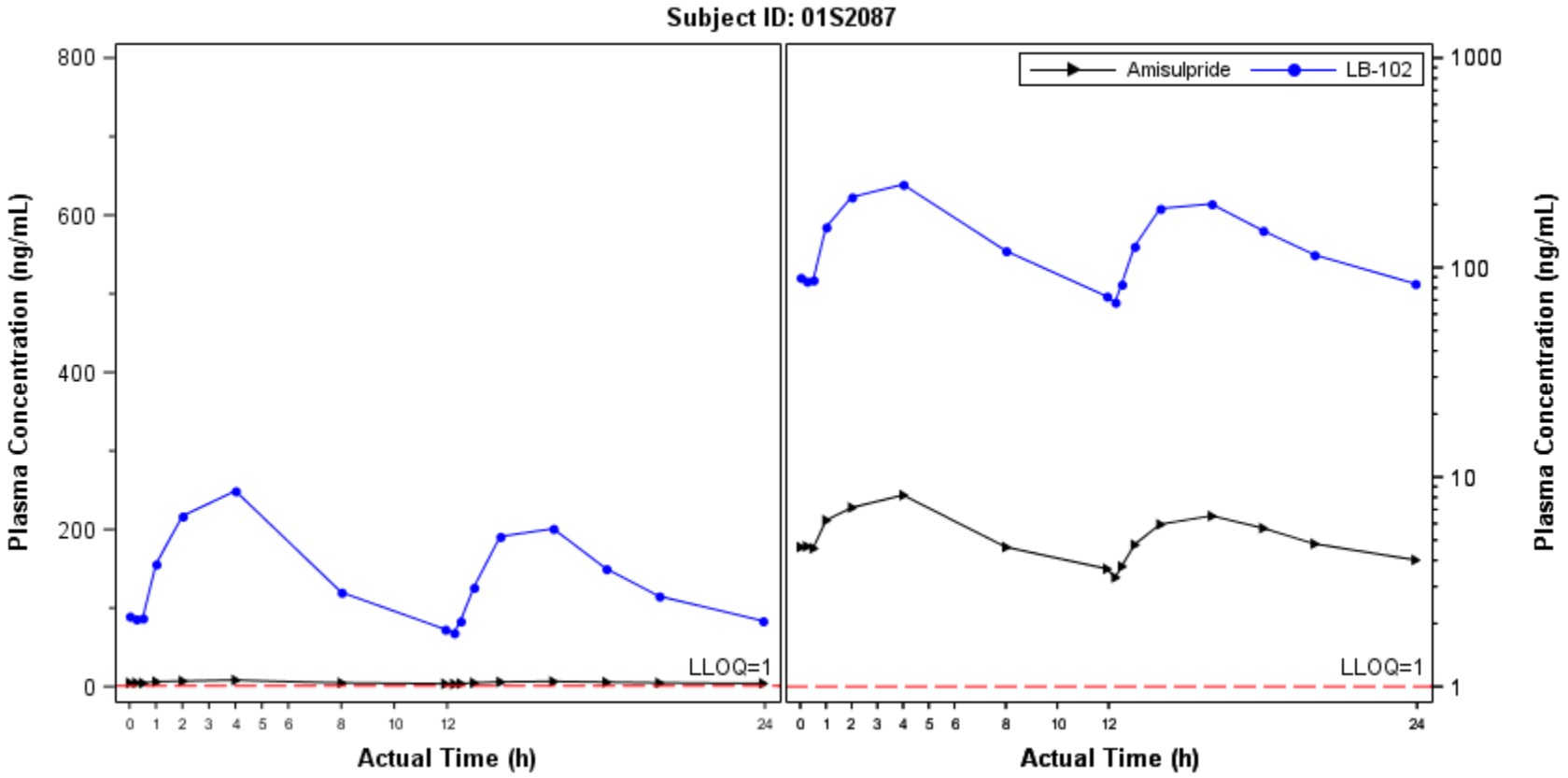
Figure 14.2.4.5
Plot of Individual Plasma Concentrations of LB-102 and Amisulpride after Multiple Dose by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part B (MAD)
LB-102 75 mg BID



Note: Lower limit of quantification (LLOQ) for LB-102 = 1 ng/mL. LLOQ for amisulpride = 1 ng/mL.
For Cohort 8 (LB-102 75 mg BID), the PK concentrations on Day 6 are plotted.

Source Data: ADPC; Reference listing(s): 16.2.6.2
SDTM Date: 04AUG2020 16:09
Program Name: Figure_Ind_mad.sas
Analysis Date: 25AUG2020 15:16

Figure 14.2.4.5
Plot of Individual Plasma Concentrations of LB-102 and Amisulpride after Multiple Dose by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part B (MAD)
LB-102 75 mg BID

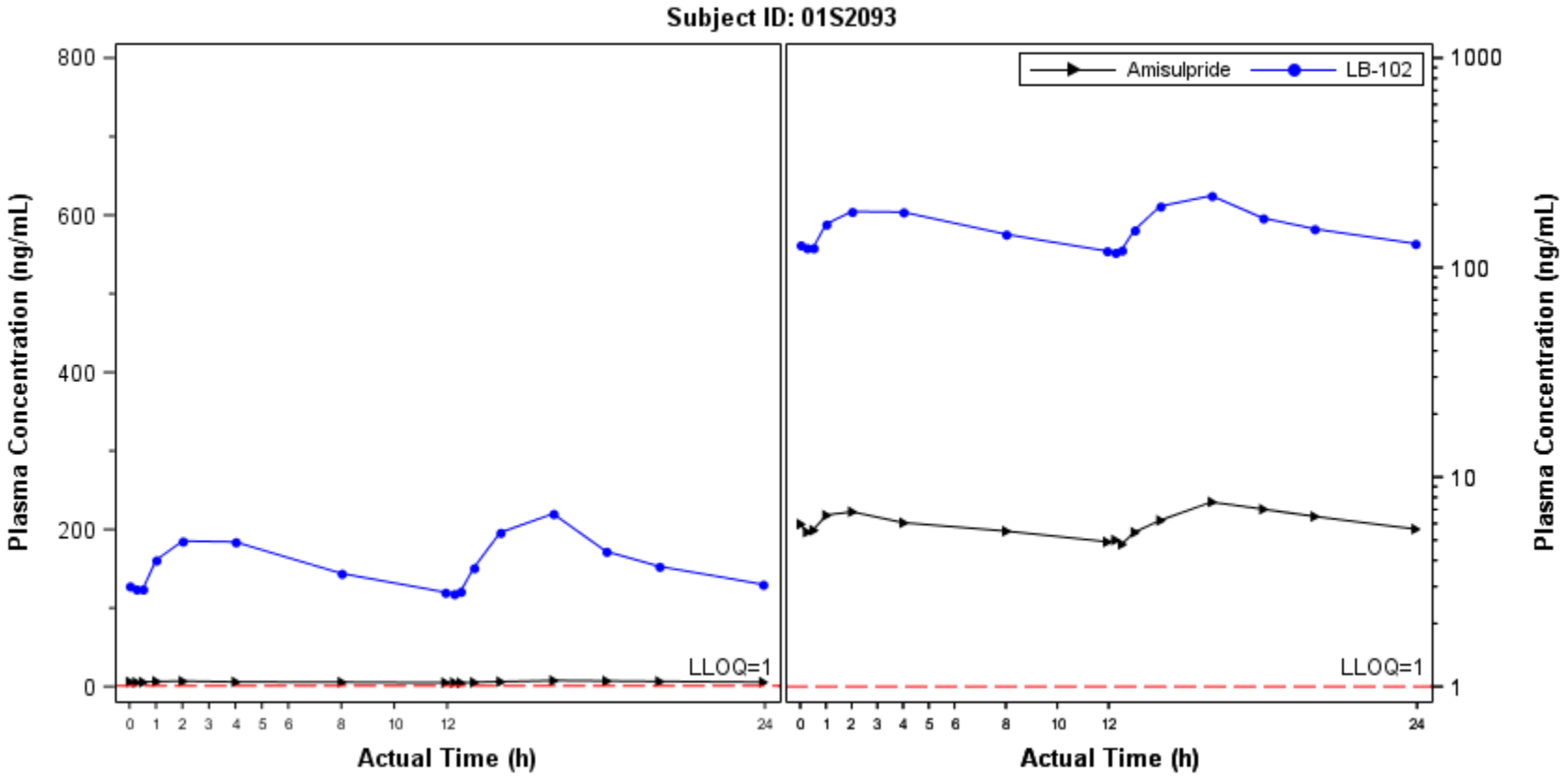


Note: Lower limit of quantification (LLOQ) for LB-102 = 1 ng/mL. LLOQ for amisulpride = 1 ng/mL.
For Cohort 8 (LB-102 75 mg BID), the PK concentrations on Day 6 are plotted.

Source Data: ADPC; Reference listing(s): 16.2.6.2
Program Name: Figure_Ind_mad.sas

SDTM Date: 04AUG2020 16:09
Analysis Date: 25AUG2020 15:16

Figure 14.2.4.5
Plot of Individual Plasma Concentrations of LB-102 and Amisulpride after Multiple Dose by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part B (MAD)
LB-102 75 mg BID

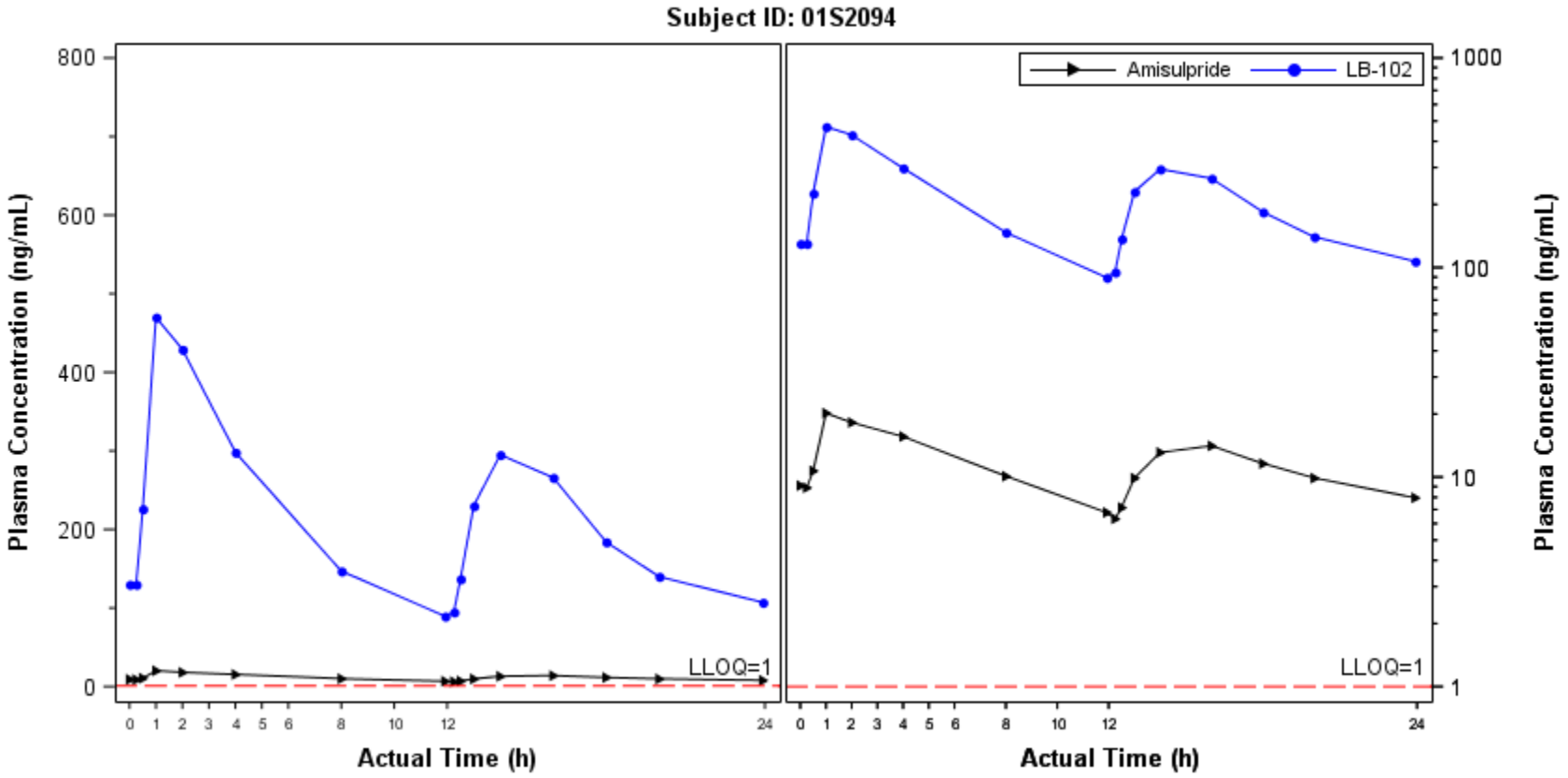


Note: Lower limit of quantification (LLOQ) for LB-102 = 1 ng/mL. LLOQ for amisulpride = 1 ng/mL.
For Cohort 8 (LB-102 75 mg BID), the PK concentrations on Day 6 are plotted.

Source Data: ADPC; Reference listing(s): 16.2.6.2
Program Name: Figure_Ind_mad.sas

SDTM Date: 04AUG2020 16:09
Analysis Date: 25AUG2020 15:16

Figure 14.2.4.5
Plot of Individual Plasma Concentrations of LB-102 and Amisulpride after Multiple Dose by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part B (MAD)
LB-102 75 mg BID

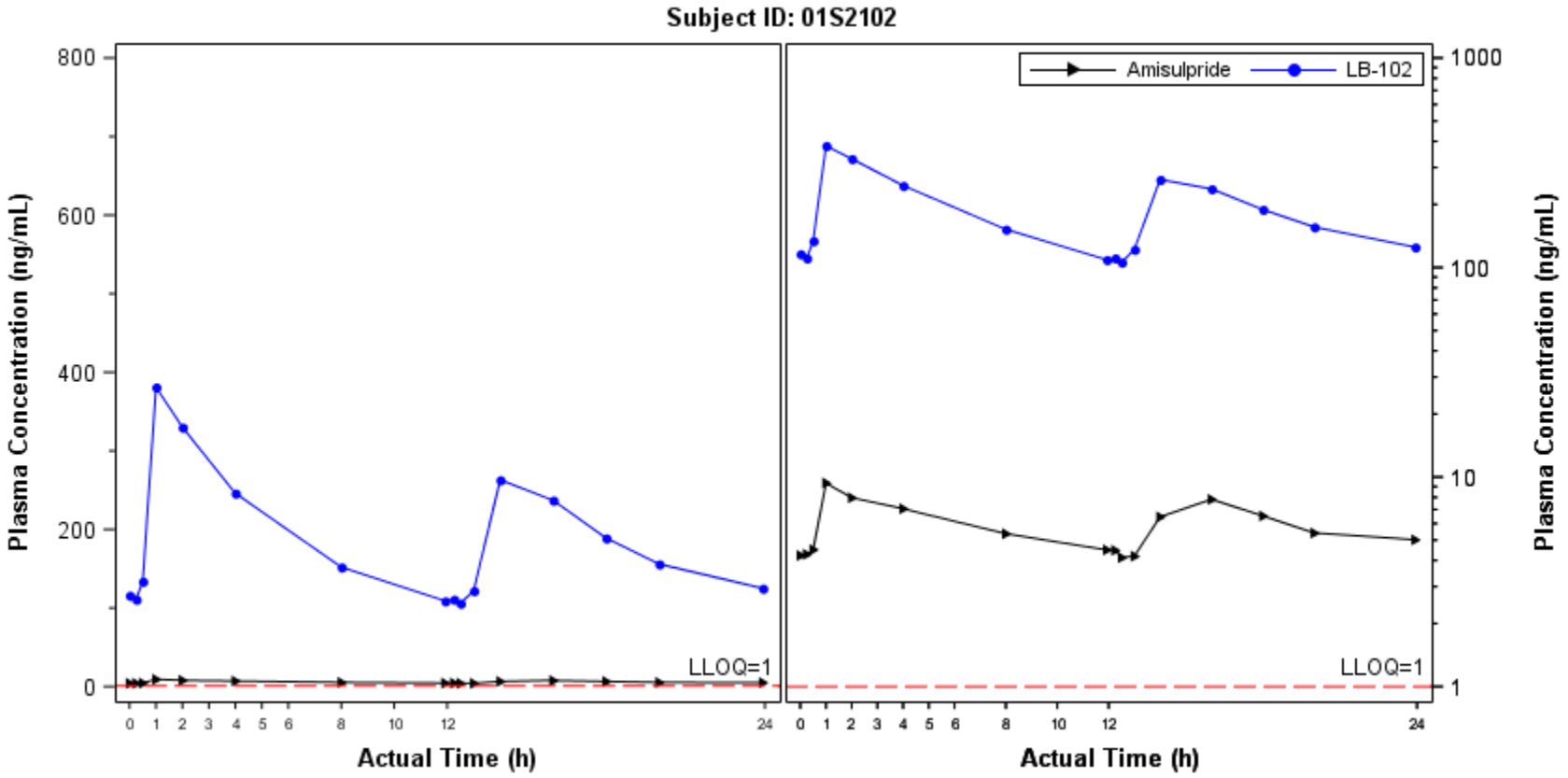


Note: Lower limit of quantification (LLOQ) for LB-102 = 1 ng/mL. LLOQ for amisulpride = 1 ng/mL.
For Cohort 8 (LB-102 75 mg BID), the PK concentrations on Day 6 are plotted.

Source Data: ADPC; Reference listing(s): 16.2.6.2
Program Name: Figure_Ind_mad.sas

SDTM Date: 04AUG2020 16:09
Analysis Date: 25AUG2020 15:16

Figure 14.2.4.5
Plot of Individual Plasma Concentrations of LB-102 and Amisulpride after Multiple Dose by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part B (MAD)
LB-102 75 mg BID

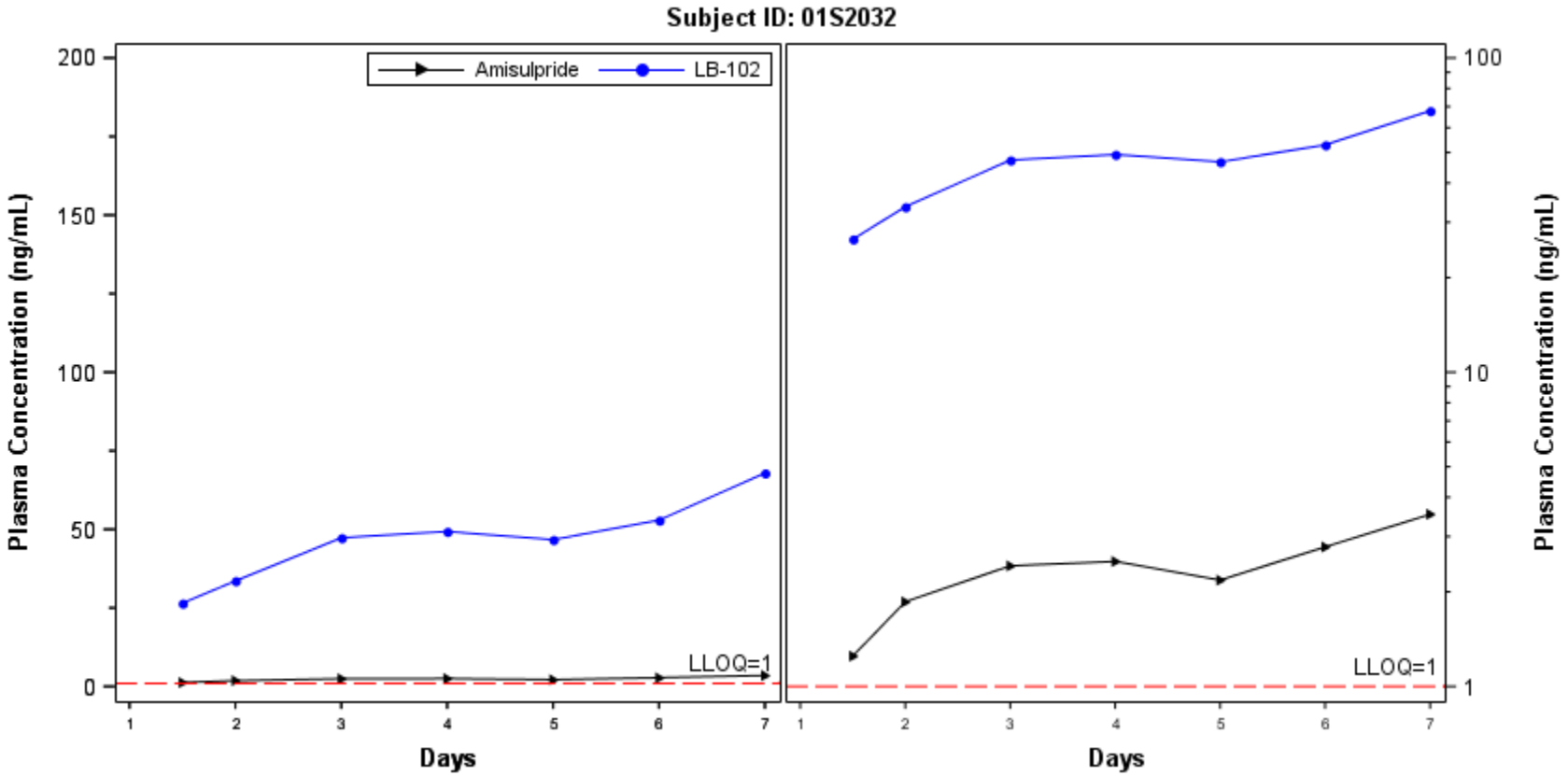


Note: Lower limit of quantification (LLOQ) for LB-102 = 1 ng/mL. LLOQ for amisulpride = 1 ng/mL.
For Cohort 8 (LB-102 75 mg BID), the PK concentrations on Day 6 are plotted.

Source Data: ADPC; Reference listing(s): 16.2.6.2
Program Name: Figure_Ind_mad.sas

SDTM Date: 04AUG2020 16:09
Analysis Date: 25AUG2020 15:16

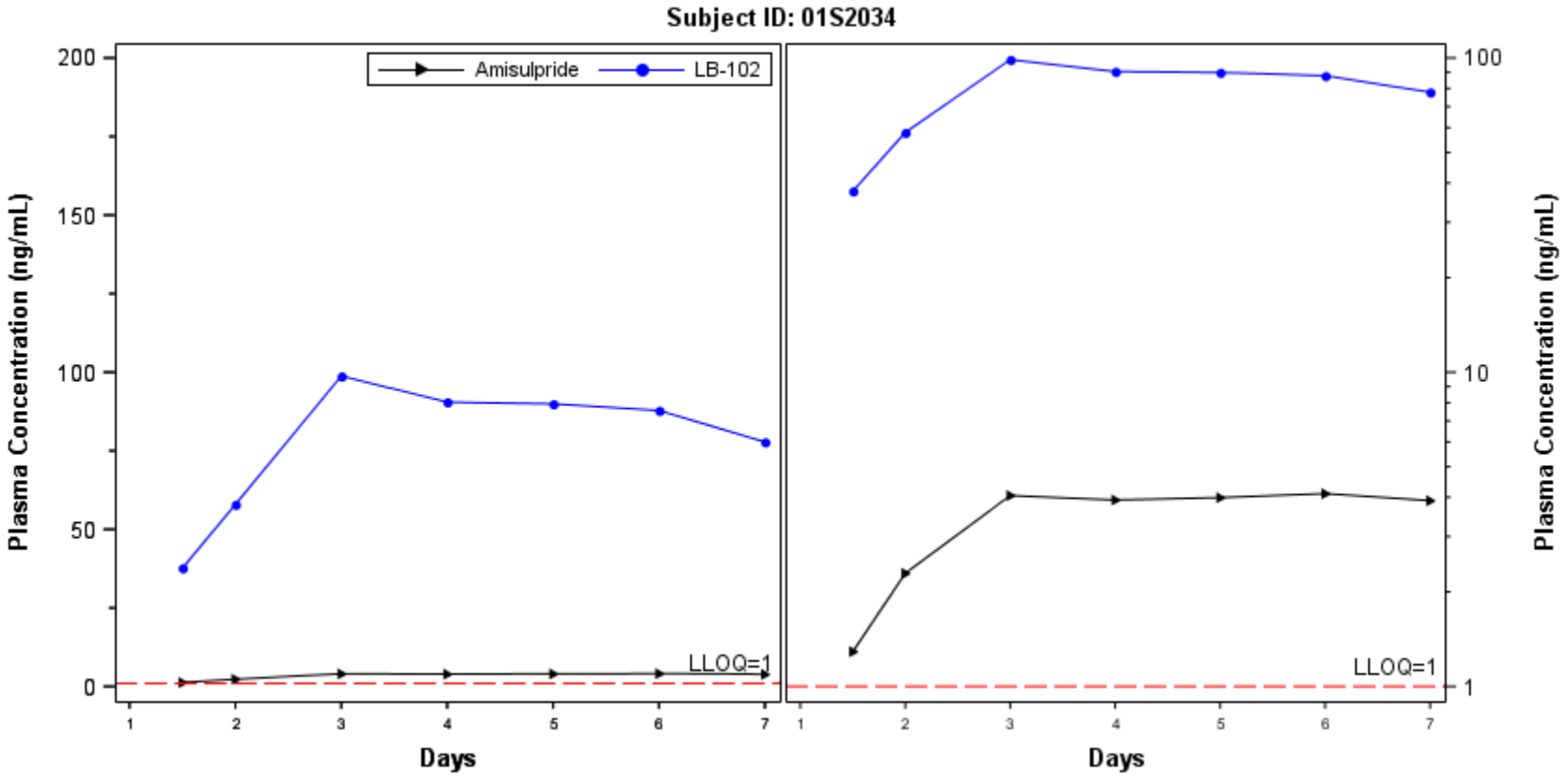
Figure 14.2.4.6
Plot of Individual Plasma Trough Concentrations of LB-102 and Amisulpride by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part B (MAD)
LB-102 50 mg BID



Note: Lower limit of quantification (LLOQ) for LB-102 = 1 ng/mL. LLOQ for amisulpride = 1 ng/mL.
All predose concentrations except that for the first dose on Day 1 are plotted as trough concentration.

Source Data: ADPC; Reference listing(s): 16.2.6.2
SDTM Date: 04AUG2020 16:09
Program Name: Figure_Ind_mad.sas
Analysis Date: 25AUG2020 15:16

Figure 14.2.4.6
Plot of Individual Plasma Trough Concentrations of LB-102 and Amisulpride by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part B (MAD)
LB-102 50 mg BID

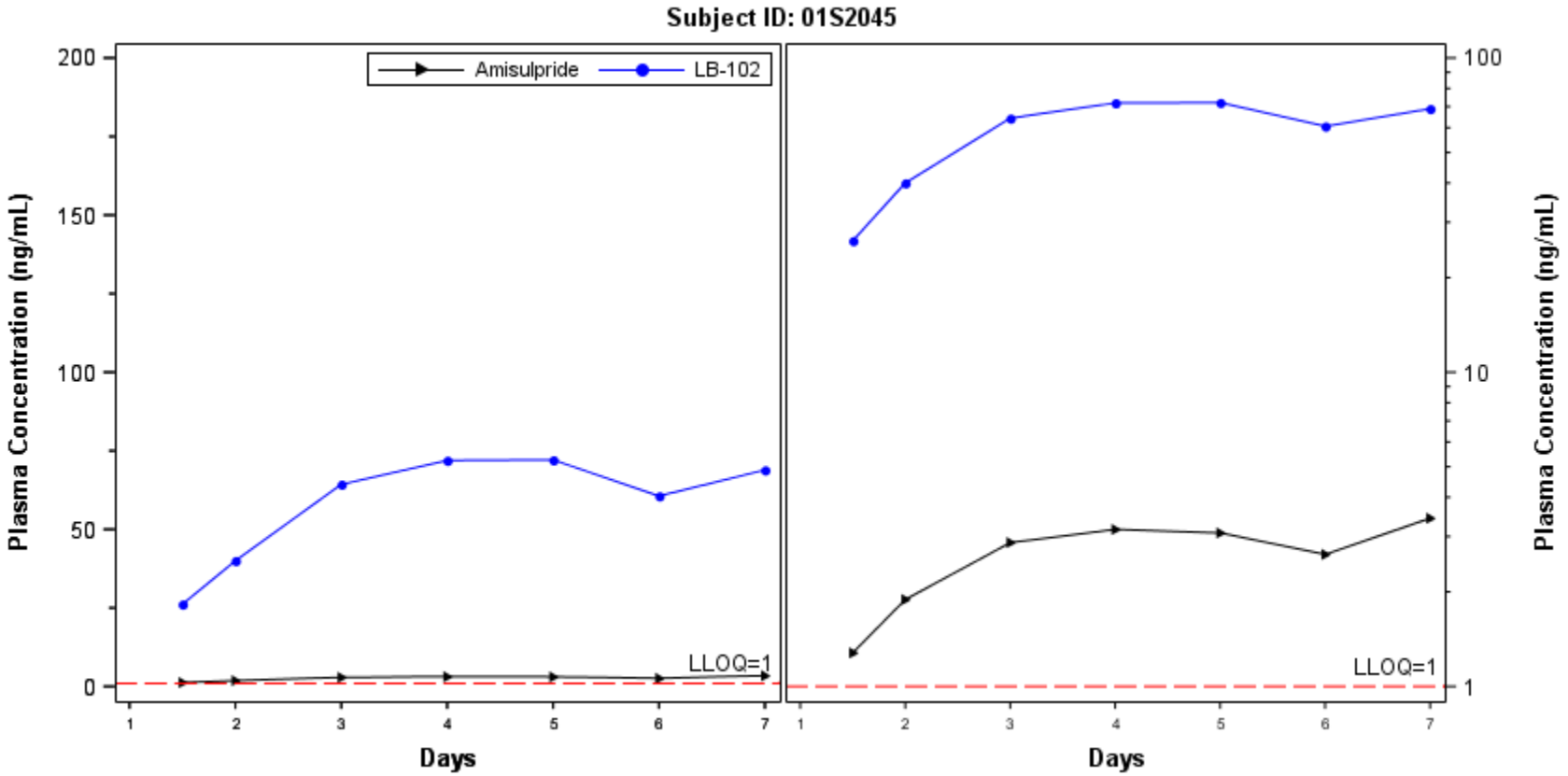


Note: Lower limit of quantification (LLOQ) for LB-102 = 1 ng/mL. LLOQ for amisulpride = 1 ng/mL.
All predose concentrations except that for the first dose on Day 1 are plotted as trough concentration.

Source Data: ADPC; Reference listing(s): 16.2.6.2
Program Name: Figure_Ind_mad.sas

SDTM Date: 04AUG2020 16:09
Analysis Date: 25AUG2020 15:16

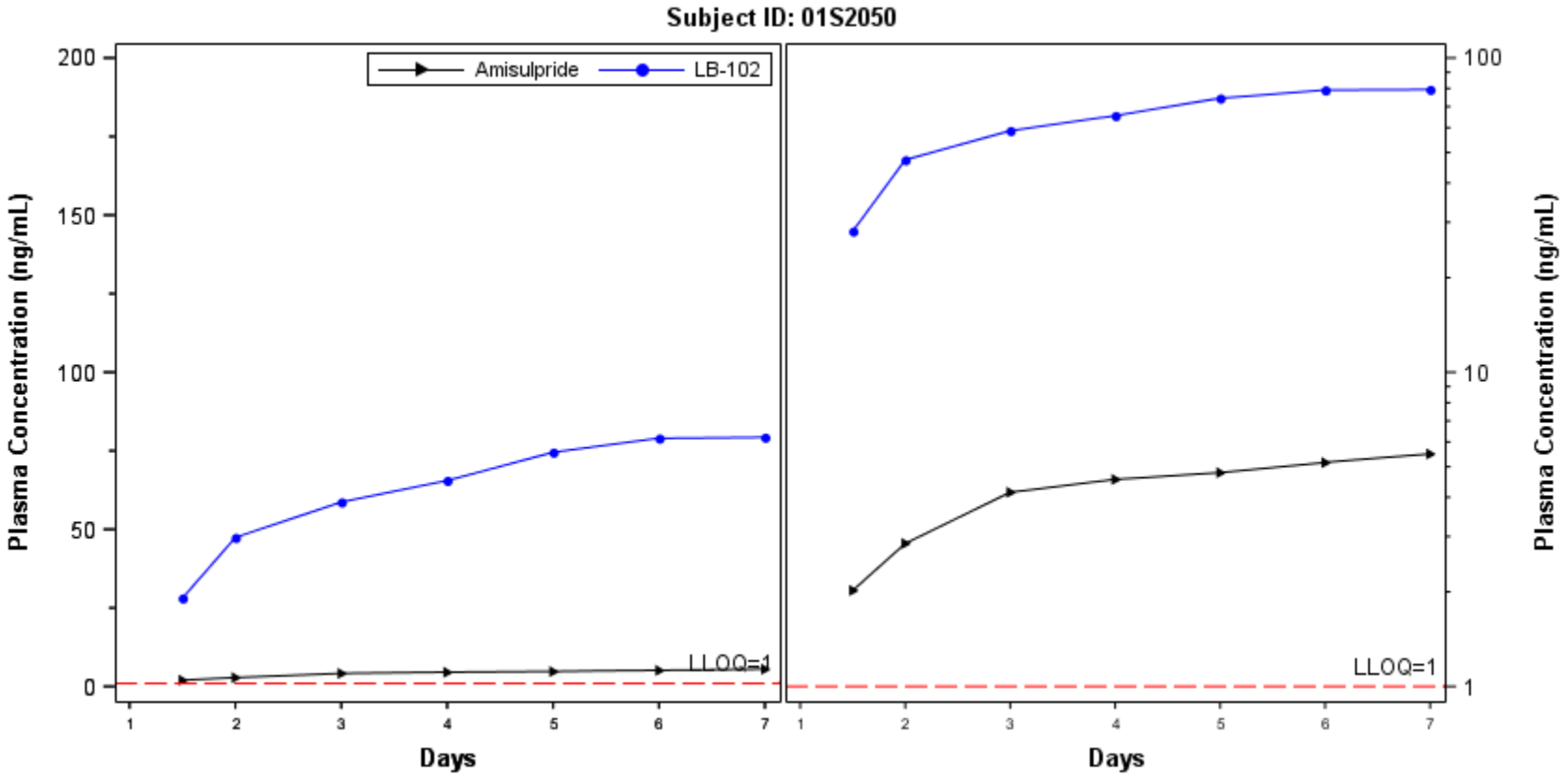
Figure 14.2.4.6
Plot of Individual Plasma Trough Concentrations of LB-102 and Amisulpride by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part B (MAD)
LB-102 50 mg BID



Note: Lower limit of quantification (LLOQ) for LB-102 = 1 ng/mL. LLOQ for amisulpride = 1 ng/mL.
All predose concentrations except that for the first dose on Day 1 are plotted as trough concentration.

Source Data: ADPC; Reference listing(s): 16.2.6.2
SDTM Date: 04AUG2020 16:09
Program Name: Figure_Ind_mad.sas
Analysis Date: 25AUG2020 15:16

Figure 14.2.4.6
Plot of Individual Plasma Trough Concentrations of LB-102 and Amisulpride by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part B (MAD)
LB-102 50 mg BID

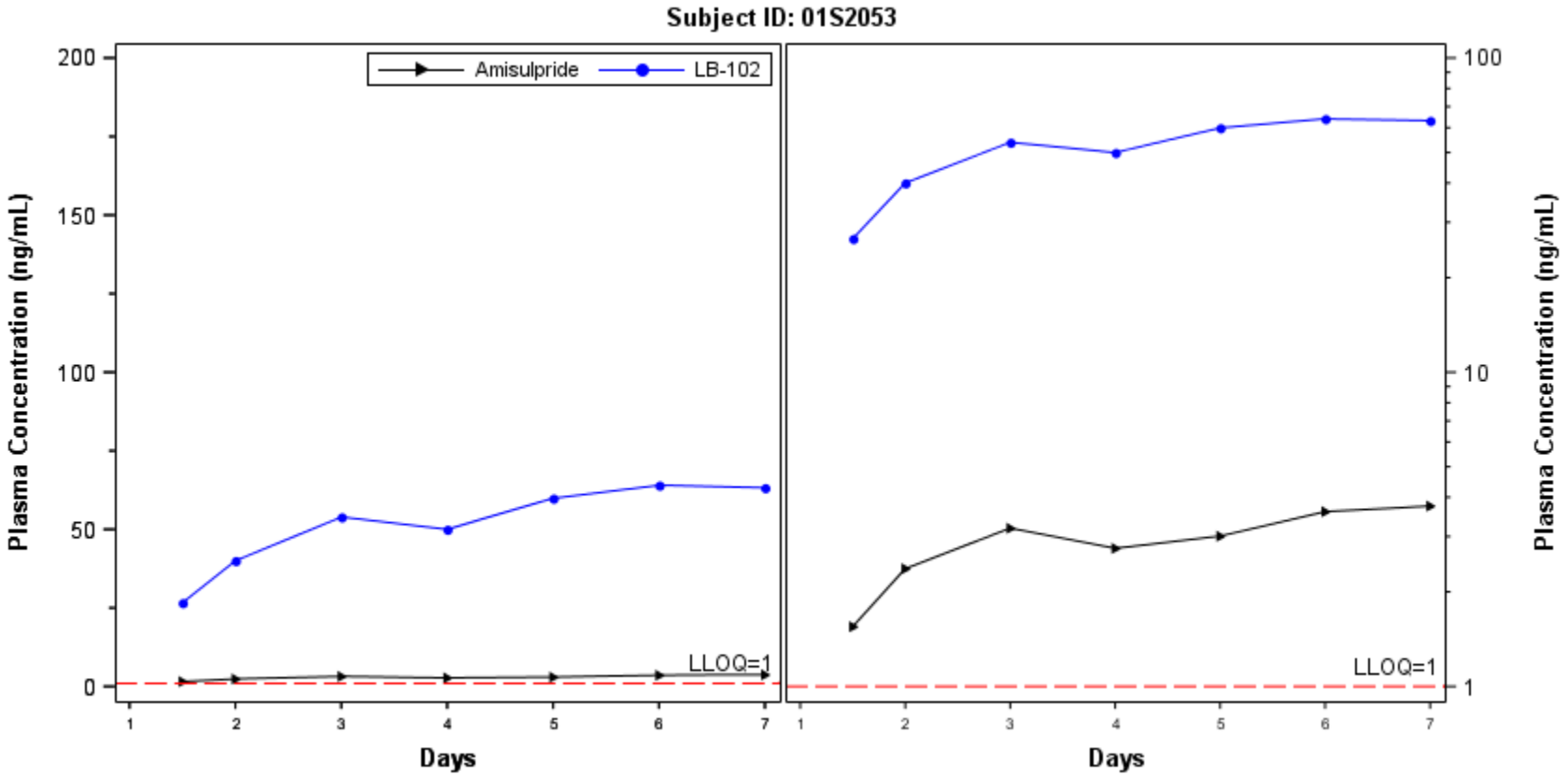


Note: Lower limit of quantification (LLOQ) for LB-102 = 1 ng/mL. LLOQ for amisulpride = 1 ng/mL.
All predose concentrations except that for the first dose on Day 1 are plotted as trough concentration.

Source Data: ADPC; Reference listing(s): 16.2.6.2
Program Name: Figure_Ind_mad.sas

SDTM Date: 04AUG2020 16:09
Analysis Date: 25AUG2020 15:16

Figure 14.2.4.6
Plot of Individual Plasma Trough Concentrations of LB-102 and Amisulpride by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part B (MAD)
LB-102 50 mg BID

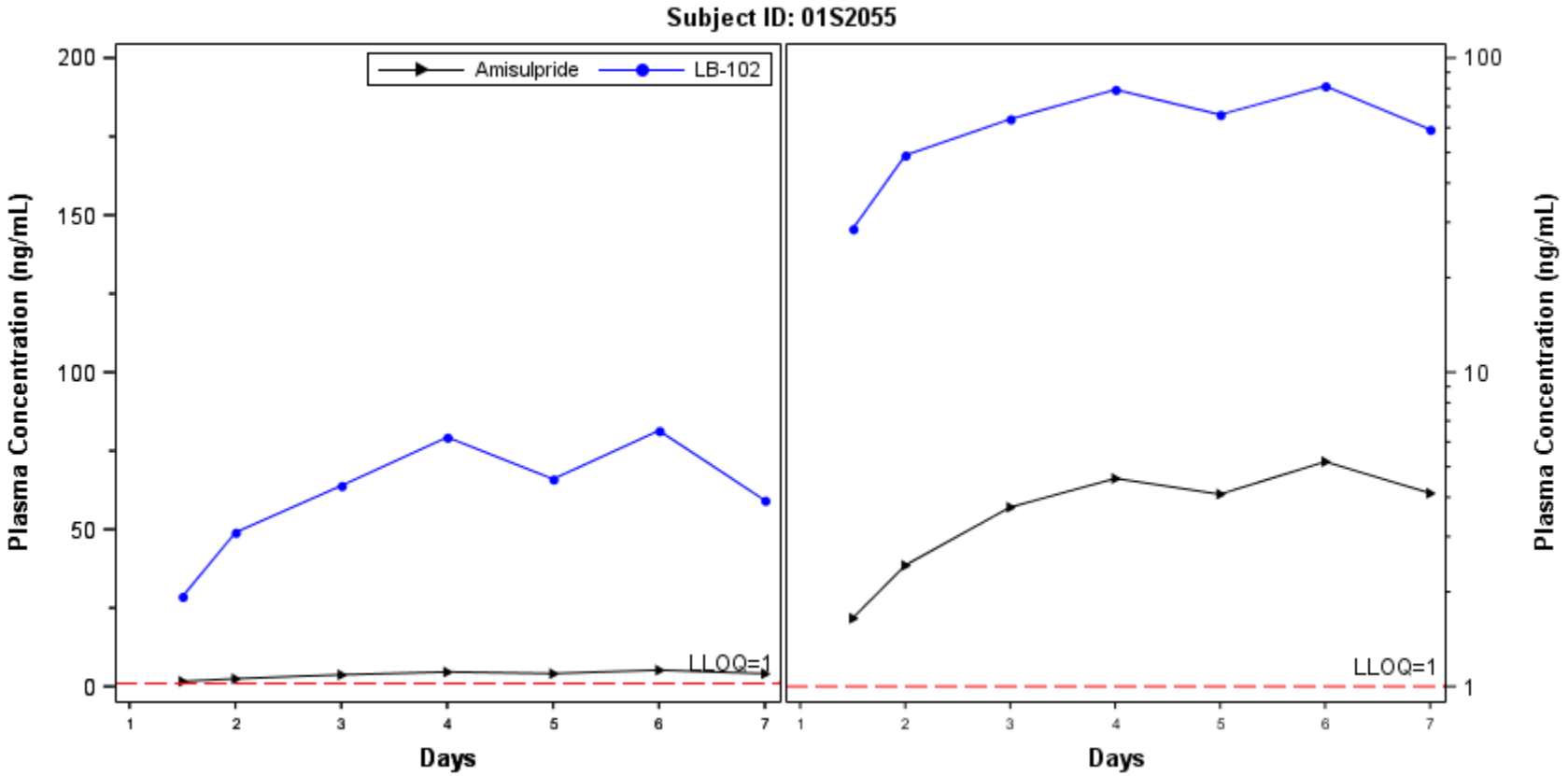


Note: Lower limit of quantification (LLOQ) for LB-102 = 1 ng/mL. LLOQ for amisulpride = 1 ng/mL.
All predose concentrations except that for the first dose on Day 1 are plotted as trough concentration.

Source Data: ADPC; Reference listing(s): 16.2.6.2
Program Name: Figure_Ind_mad.sas

SDTM Date: 04AUG2020 16:09
Analysis Date: 25AUG2020 15:16

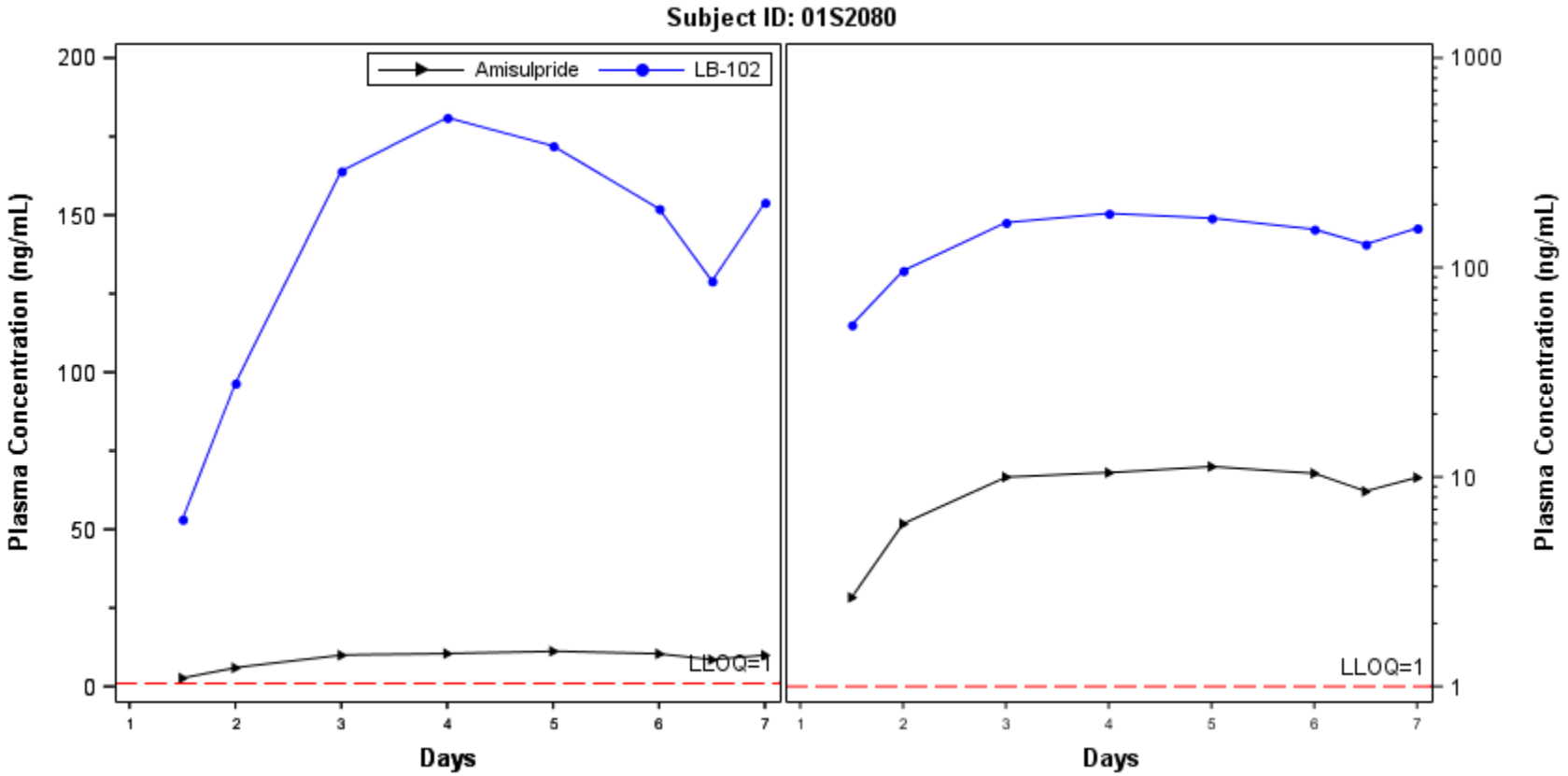
Figure 14.2.4.6
Plot of Individual Plasma Trough Concentrations of LB-102 and Amisulpride by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part B (MAD)
LB-102 50 mg BID



Note: Lower limit of quantification (LLOQ) for LB-102 = 1 ng/mL. LLOQ for amisulpride = 1 ng/mL.
All predose concentrations except that for the first dose on Day 1 are plotted as trough concentration.

Source Data: ADPC; Reference listing(s): 16.2.6.2 SDTM Date: 04AUG2020 16:09
Program Name: Figure_Ind_mad.sas Analysis Date: 25AUG2020 15:16

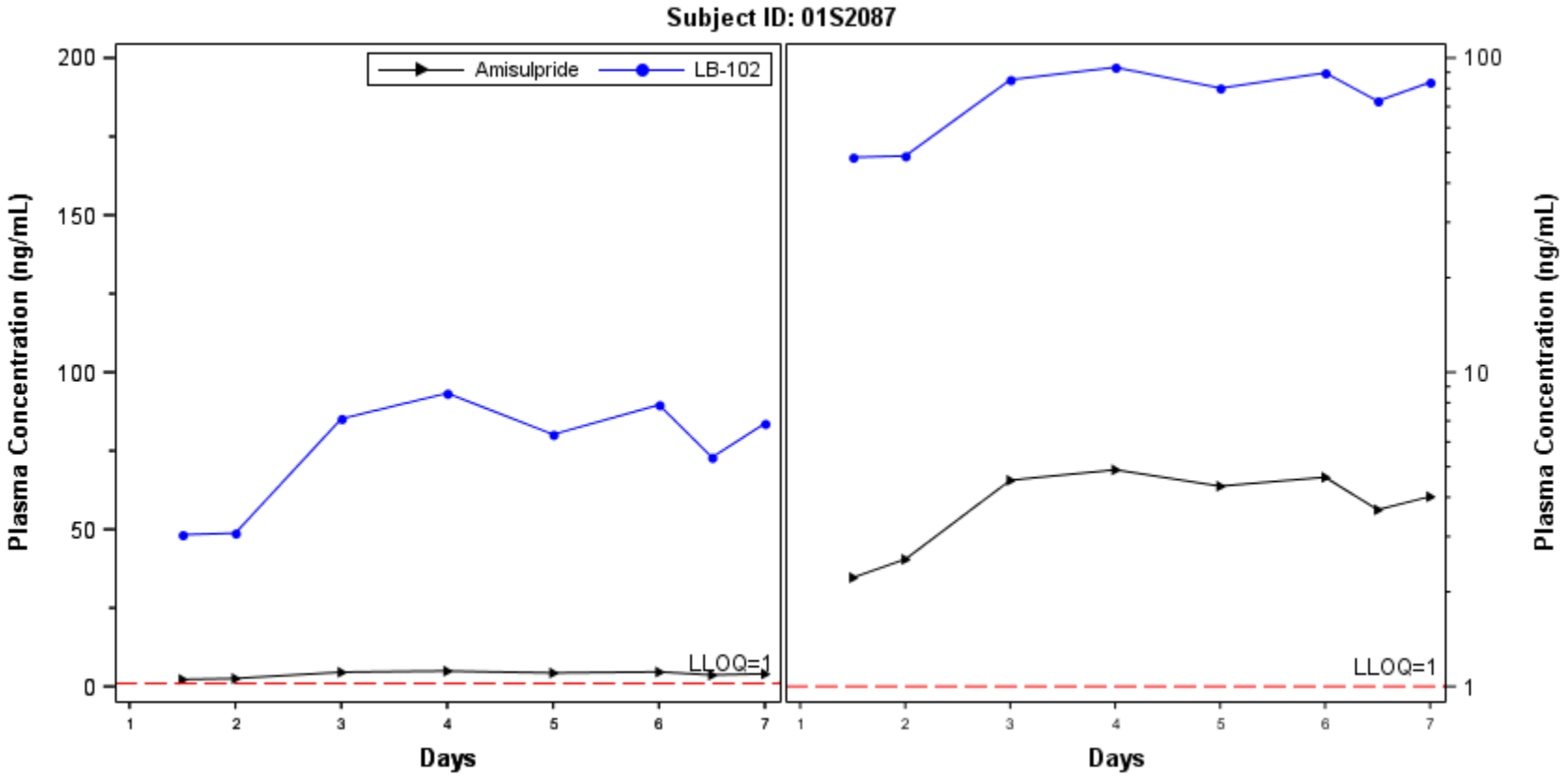
Figure 14.2.4.7
Plot of Individual Plasma Trough Concentrations of LB-102 and Amisulpride by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part B (MAD)
LB-102 75 mg BID



Note: Lower limit of quantification (LLOQ) for LB-102 = 1 ng/mL. LLOQ for amisulpride = 1 ng/mL.
All predose concentrations except that for the first dose on Day 1 are plotted as trough concentration.

Source Data: ADPC; Reference listing(s): 16.2.6.2 SDTM Date: 04AUG2020 16:09
Program Name: Figure_Ind_mad.sas Analysis Date: 25AUG2020 15:16

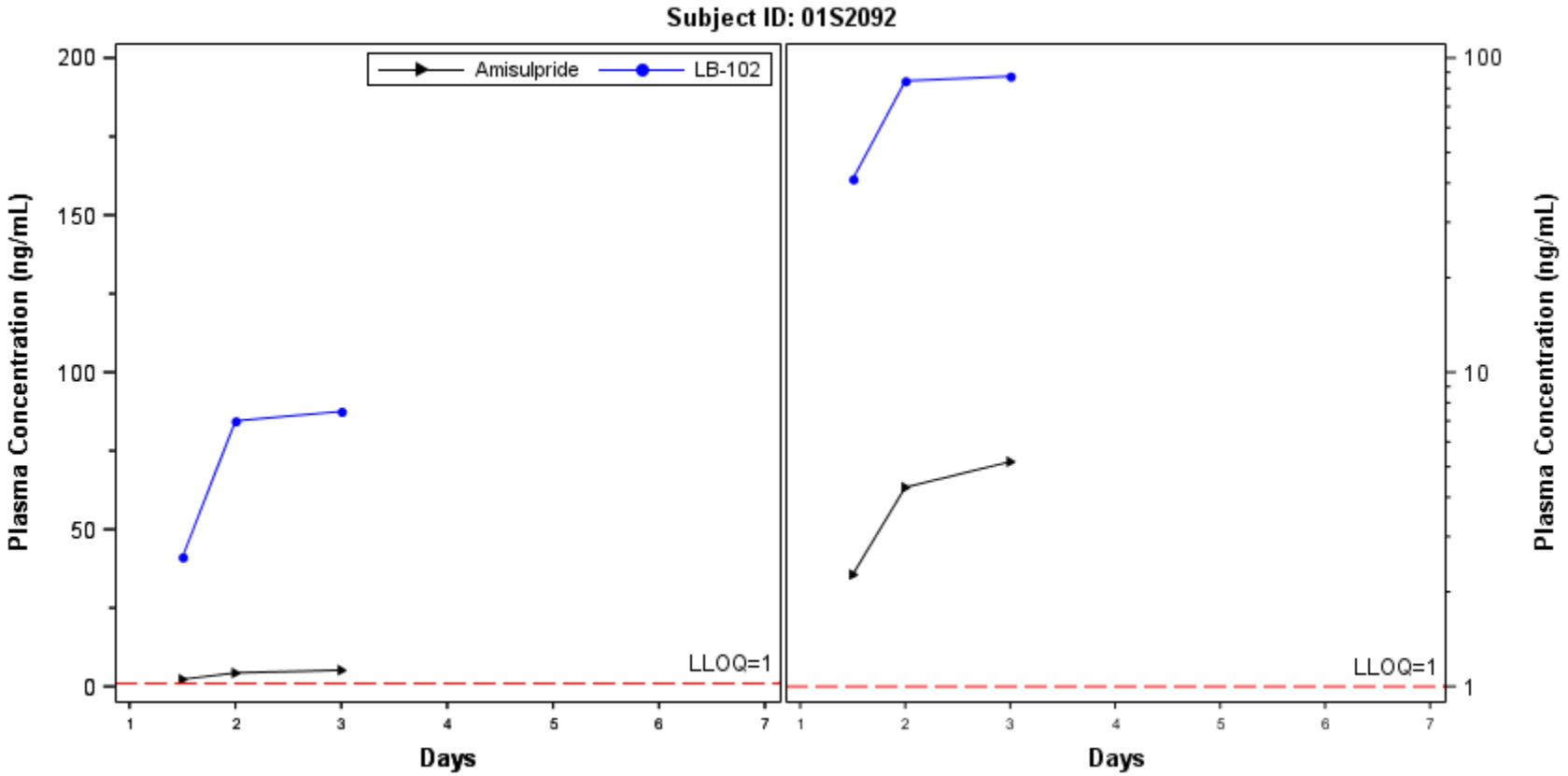
Figure 14.2.4.7
Plot of Individual Plasma Trough Concentrations of LB-102 and Amisulpride by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part B (MAD)
LB-102 75 mg BID



Note: Lower limit of quantification (LLOQ) for LB-102 = 1 ng/mL. LLOQ for amisulpride = 1 ng/mL.
All predose concentrations except that for the first dose on Day 1 are plotted as trough concentration.

Source Data: ADPC; Reference listing(s): 16.2.6.2
SDTM Date: 04AUG2020 16:09
Program Name: Figure_Ind_mad.sas
Analysis Date: 25AUG2020 15:16

Figure 14.2.4.7
Plot of Individual Plasma Trough Concentrations of LB-102 and Amisulpride by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part B (MAD)
LB-102 75 mg BID

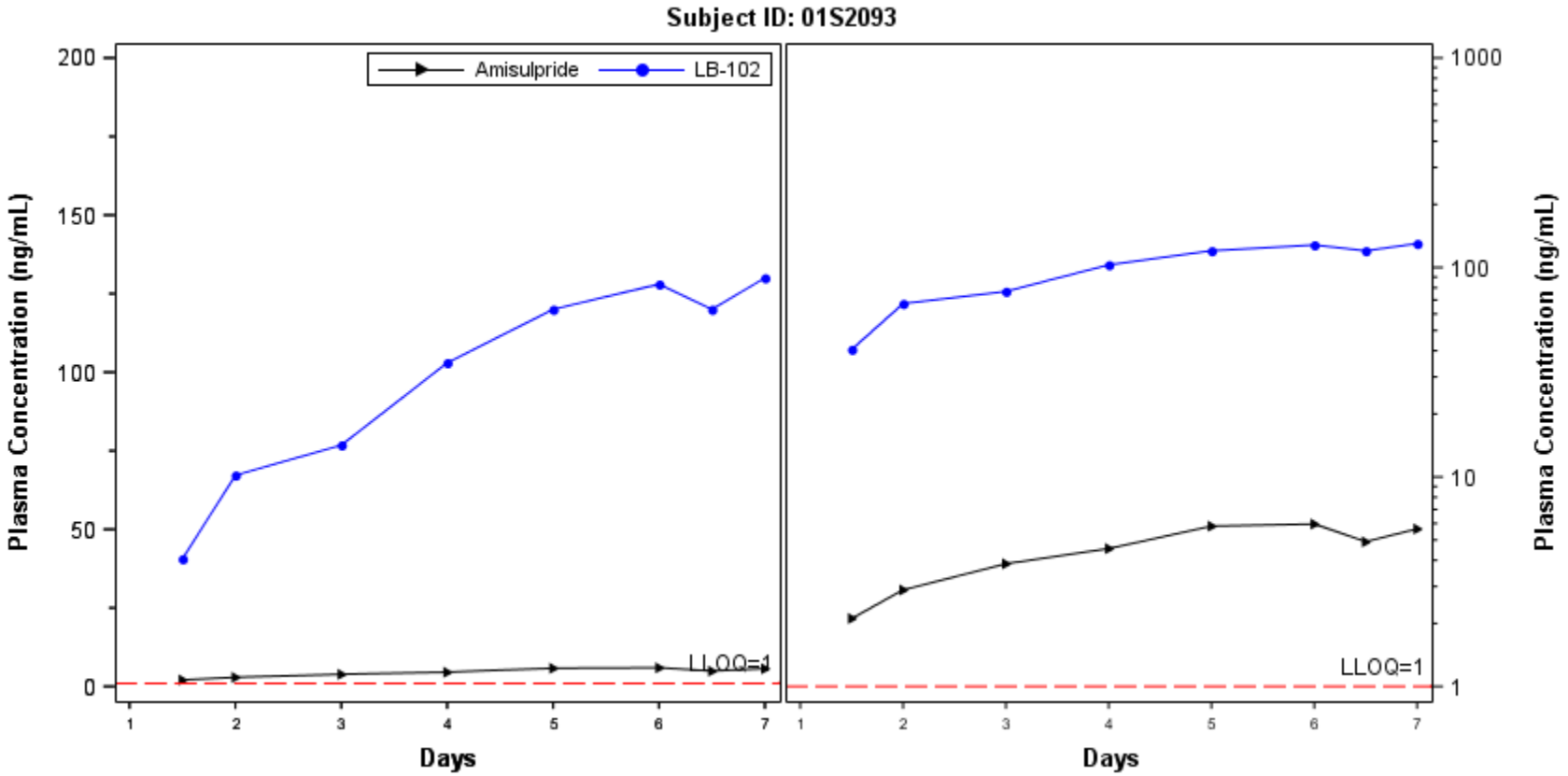


Note: Lower limit of quantification (LLOQ) for LB-102 = 1 ng/mL. LLOQ for amisulpride = 1 ng/mL.
All predose concentrations except that for the first dose on Day 1 are plotted as trough concentration.

Source Data: ADPC; Reference listing(s): 16.2.6.2
Program Name: Figure_Ind_mad.sas

SDTM Date: 04AUG2020 16:09
Analysis Date: 25AUG2020 15:16

Figure 14.2.4.7
Plot of Individual Plasma Trough Concentrations of LB-102 and Amisulpride by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part B (MAD)
LB-102 75 mg BID

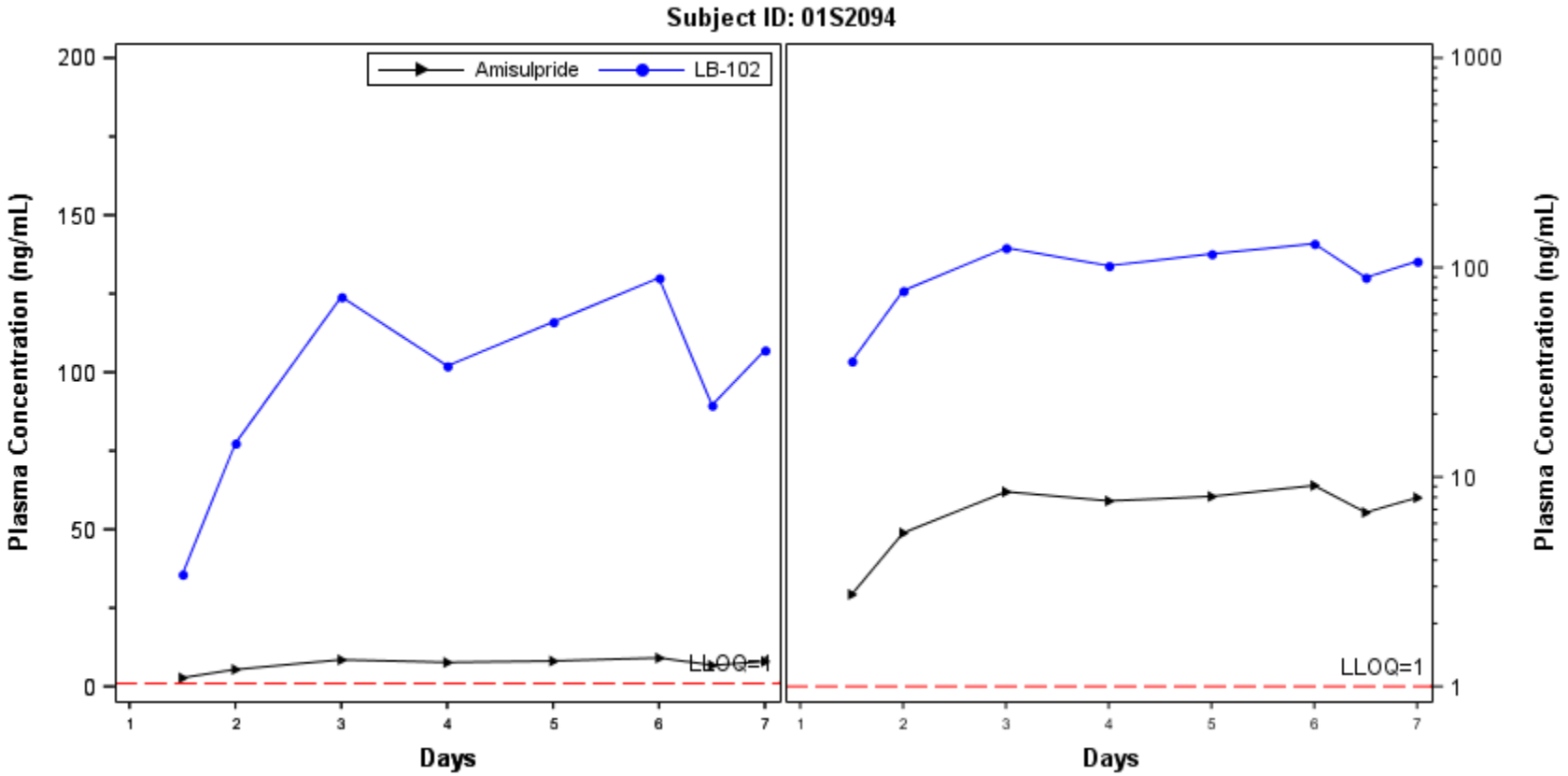


Note: Lower limit of quantification (LLOQ) for LB-102 = 1 ng/mL. LLOQ for amisulpride = 1 ng/mL.
All predose concentrations except that for the first dose on Day 1 are plotted as trough concentration.

Source Data: ADPC; Reference listing(s): 16.2.6.2
Program Name: Figure_Ind_mad.sas

SDTM Date: 04AUG2020 16:09
Analysis Date: 25AUG2020 15:16

Figure 14.2.4.7
Plot of Individual Plasma Trough Concentrations of LB-102 and Amisulpride by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part B (MAD)
LB-102 75 mg BID

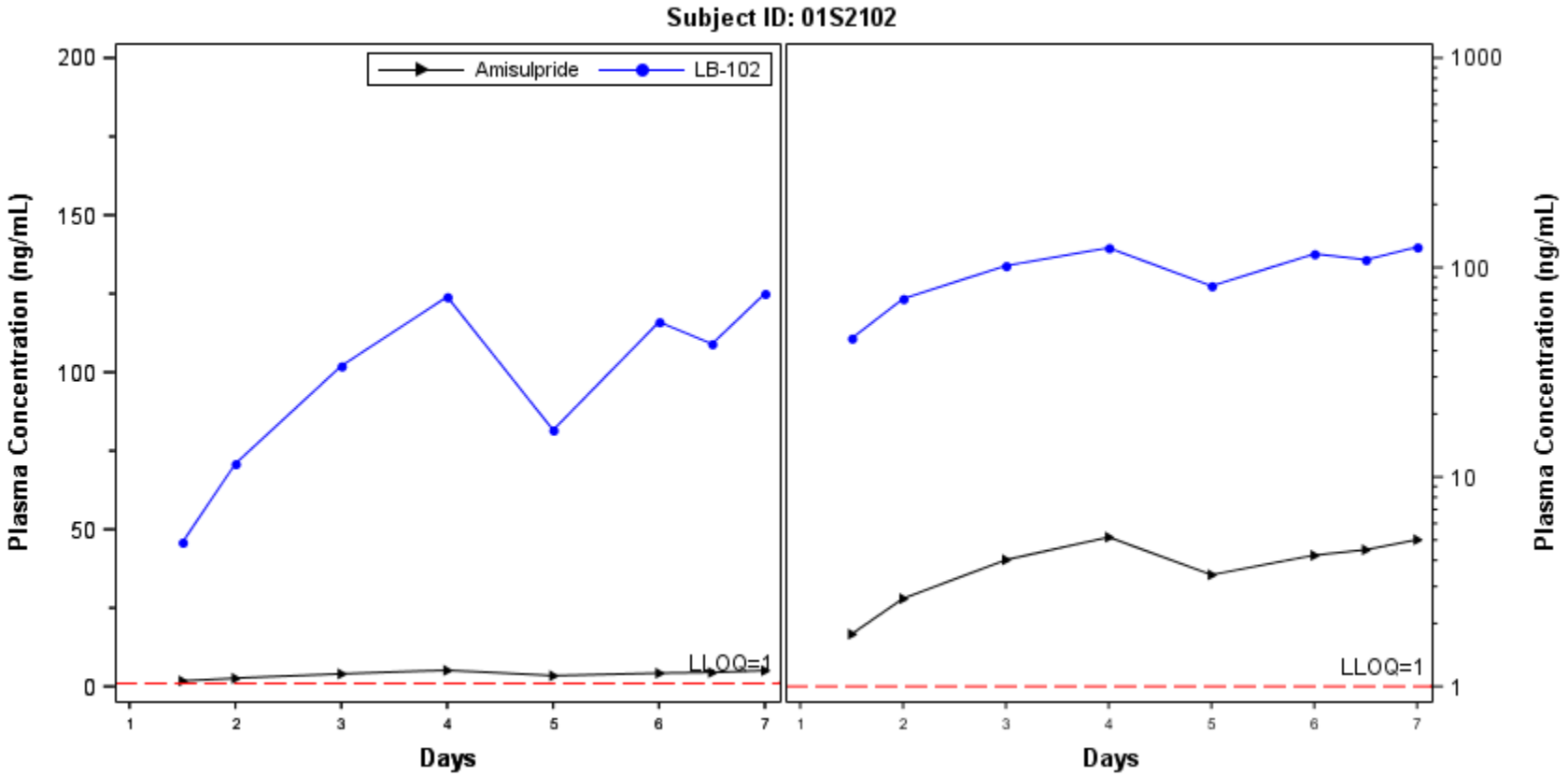


Note: Lower limit of quantification (LLOQ) for LB-102 = 1 ng/mL. LLOQ for amisulpride = 1 ng/mL.
All predose concentrations except that for the first dose on Day 1 are plotted as trough concentration.

Source Data: ADPC; Reference listing(s): 16.2.6.2
Program Name: Figure_Ind_mad.sas

SDTM Date: 04AUG2020 16:09
Analysis Date: 25AUG2020 15:16

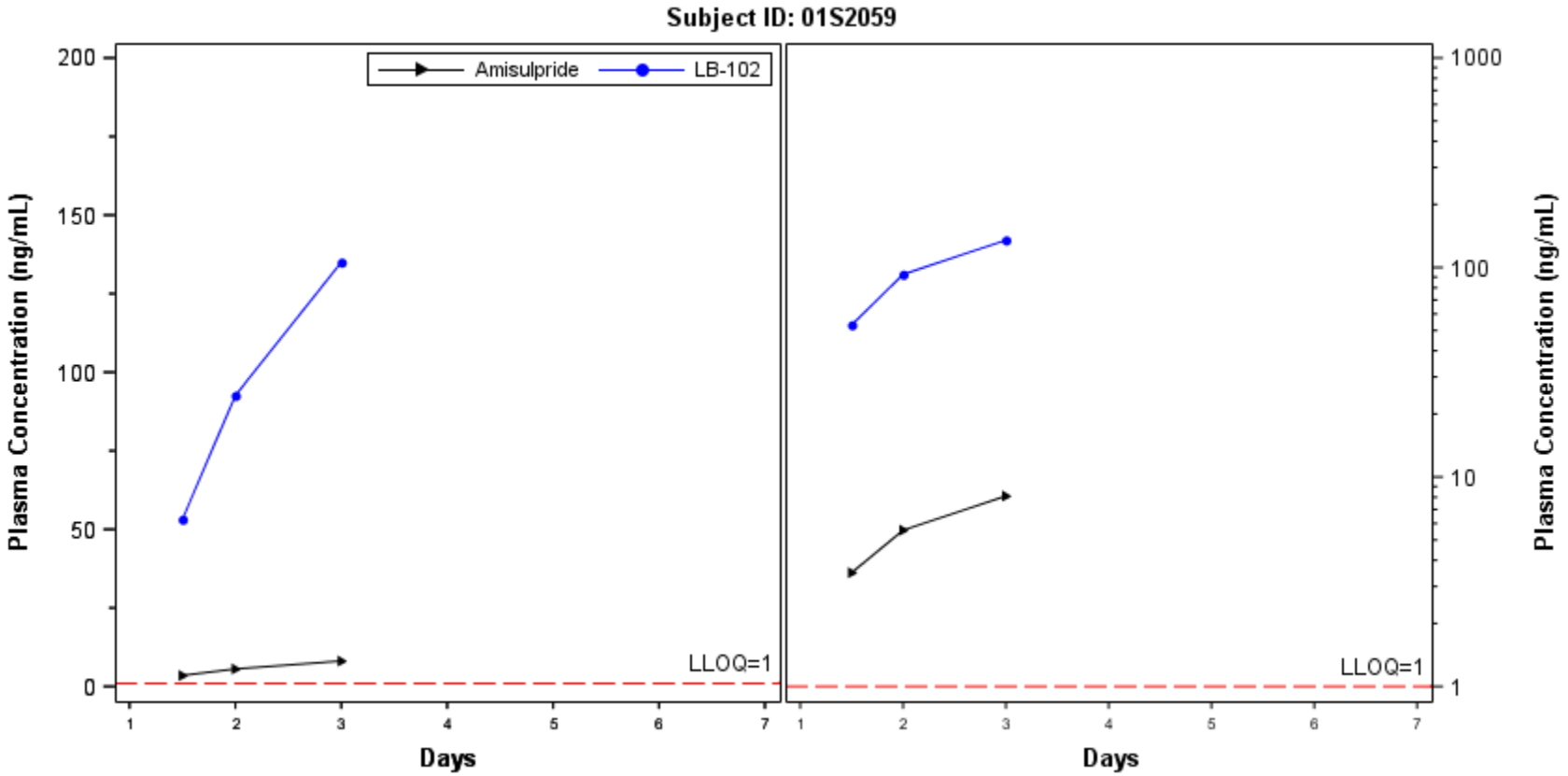
Figure 14.2.4.7
Plot of Individual Plasma Trough Concentrations of LB-102 and Amisulpride by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part B (MAD)
LB-102 75 mg BID



Note: Lower limit of quantification (LLOQ) for LB-102 = 1 ng/mL. LLOQ for amisulpride = 1 ng/mL.
All predose concentrations except that for the first dose on Day 1 are plotted as trough concentration.

Source Data: ADPC; Reference listing(s): 16.2.6.2 SDTM Date: 04AUG2020 16:09
Program Name: Figure_Ind_mad.sas Analysis Date: 25AUG2020 15:16

Figure 14.2.4.8
Plot of Individual Plasma Trough Concentrations of LB-102 and Amisulpride by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part B (MAD)
LB-102 100 mg BID

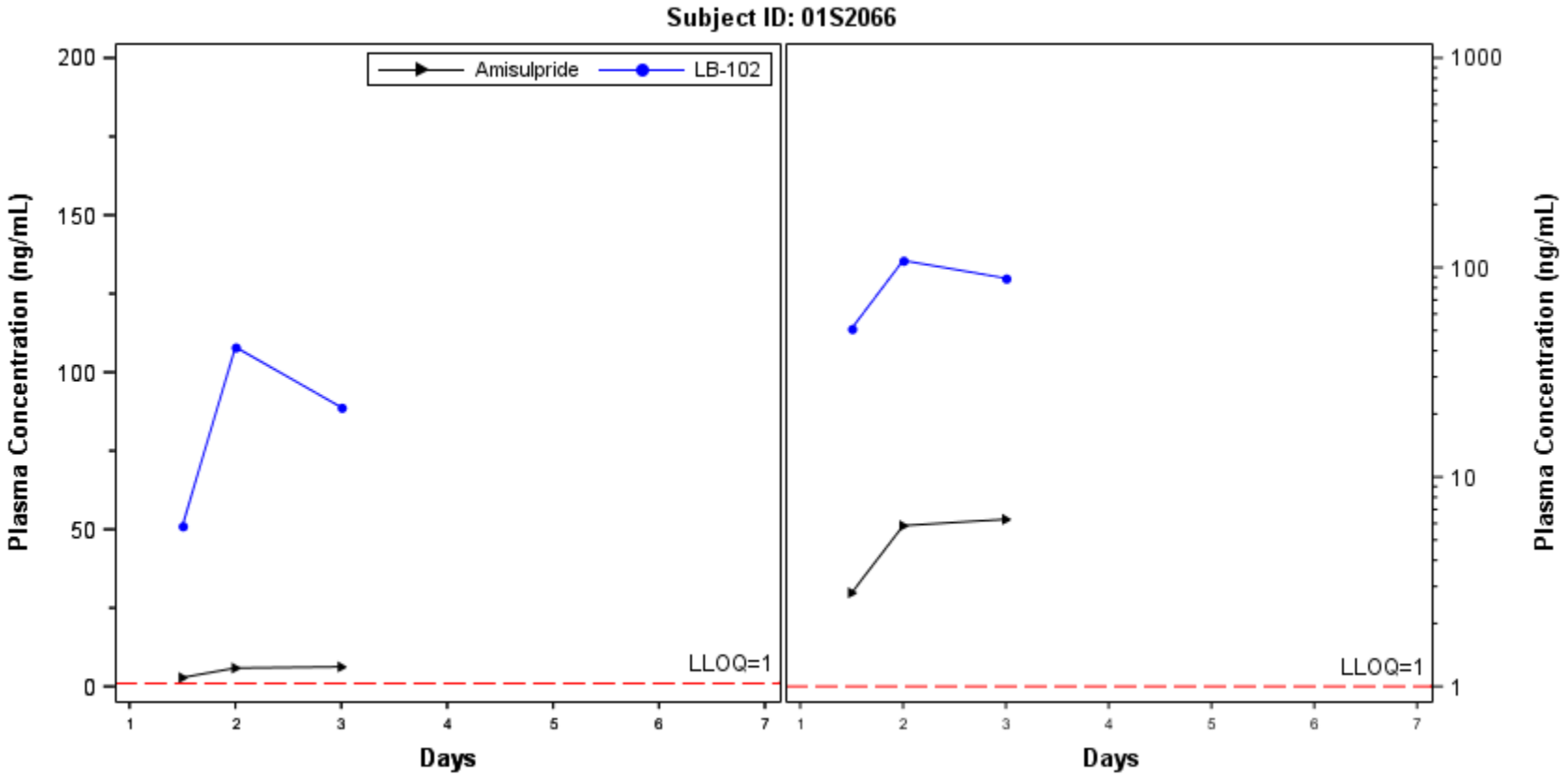


Note: Lower limit of quantification (LLOQ) for LB-102 = 1 ng/mL. LLOQ for amisulpride = 1 ng/mL.
All predose concentrations except that for the first dose on Day 1 are plotted as trough concentration.

Source Data: ADPC; Reference listing(s): 16.2.6.2
Program Name: Figure_Ind_mad.sas

SDTM Date: 04AUG2020 16:09
Analysis Date: 25AUG2020 15:16

Figure 14.2.4.8
Plot of Individual Plasma Trough Concentrations of LB-102 and Amisulpride by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part B (MAD)
LB-102 100 mg BID

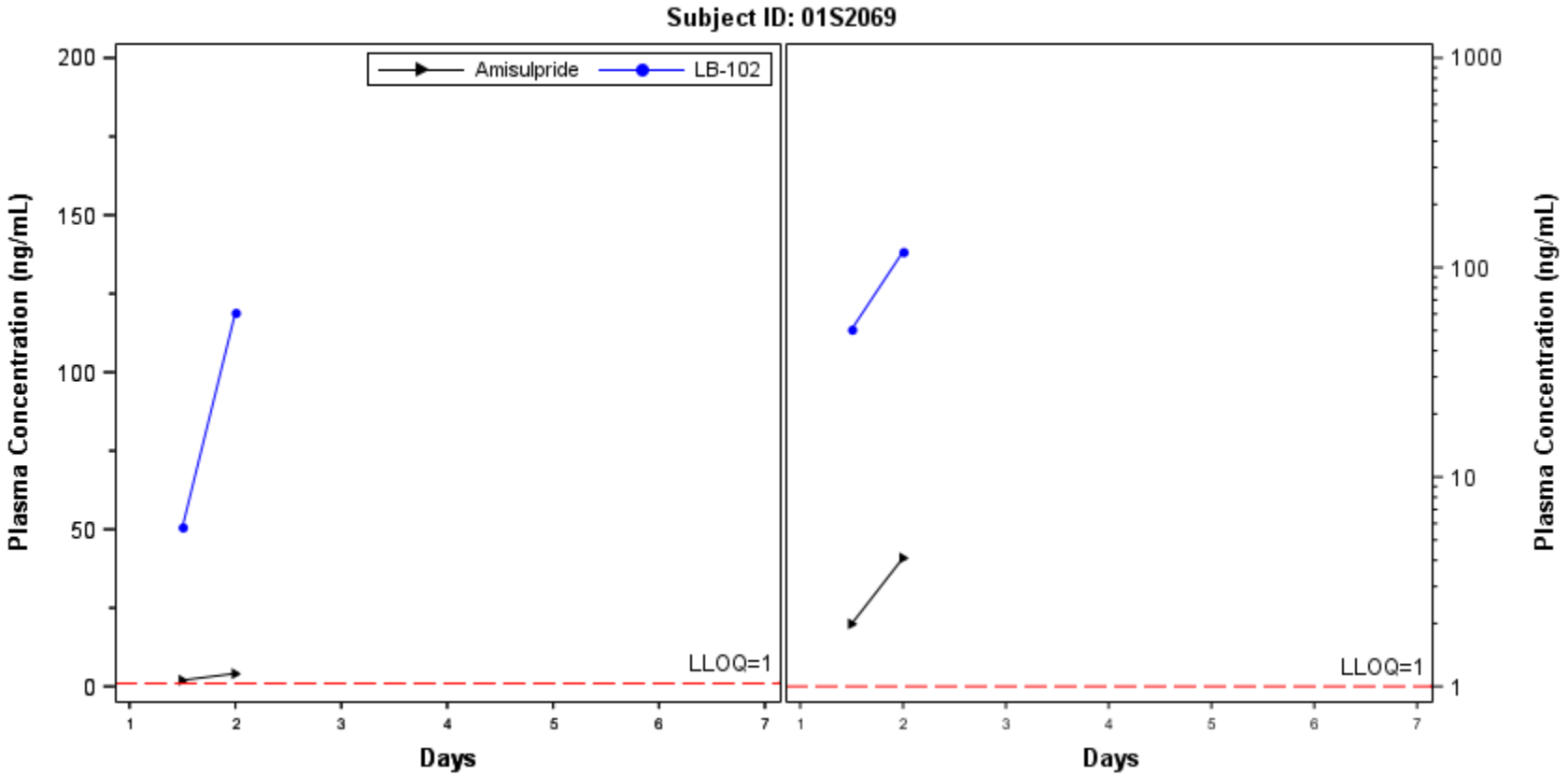


Note: Lower limit of quantification (LLOQ) for LB-102 = 1 ng/mL. LLOQ for amisulpride = 1 ng/mL.
All predose concentrations except that for the first dose on Day 1 are plotted as trough concentration.

Source Data: ADPC; Reference listing(s): 16.2.6.2
Program Name: Figure_Ind_mad.sas

SDTM Date: 04AUG2020 16:09
Analysis Date: 25AUG2020 15:16

Figure 14.2.4.8
Plot of Individual Plasma Trough Concentrations of LB-102 and Amisulpride by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part B (MAD)
LB-102 100 mg BID

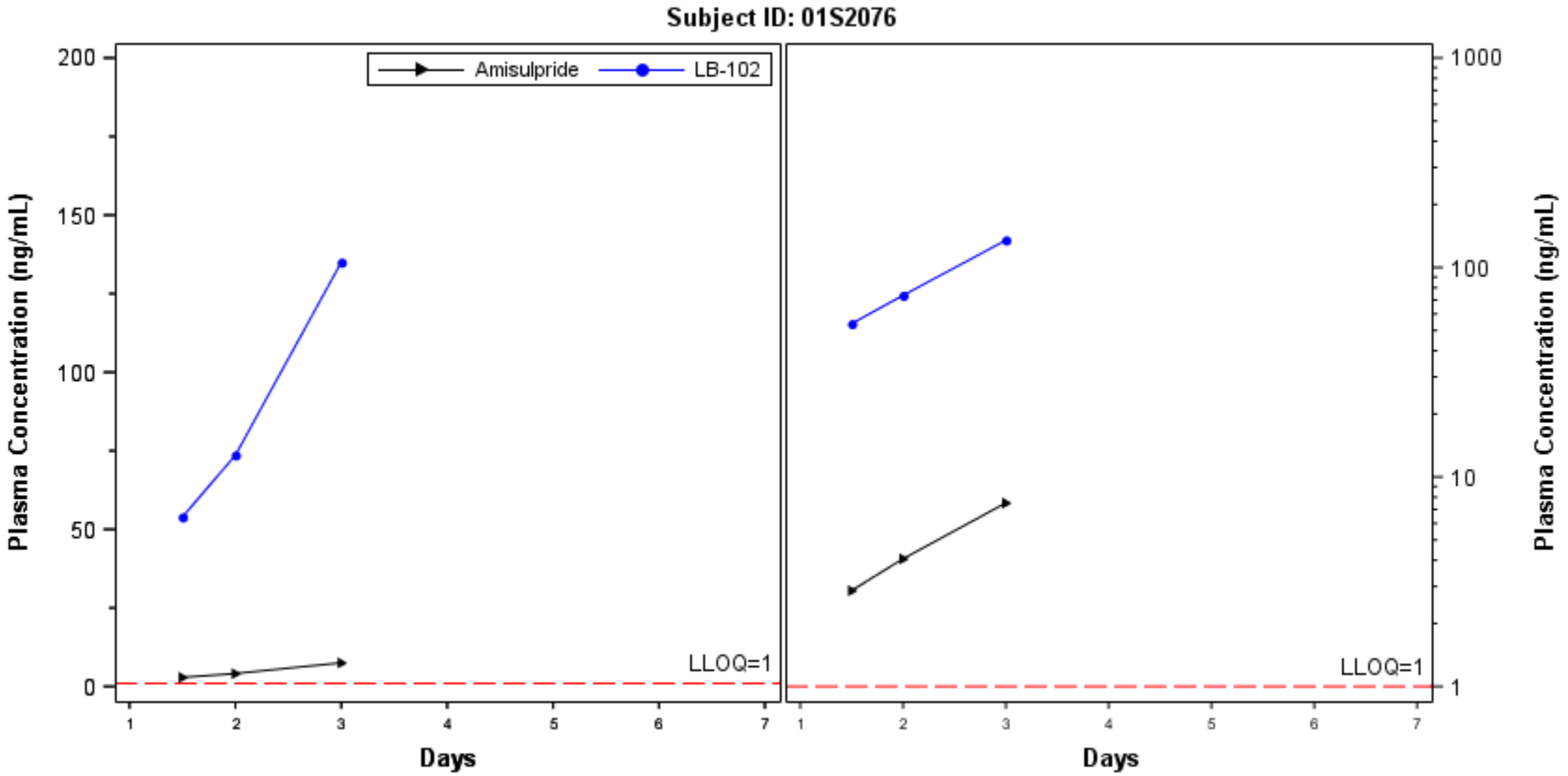


Note: Lower limit of quantification (LLOQ) for LB-102 = 1 ng/mL. LLOQ for amisulpride = 1 ng/mL.
All predose concentrations except that for the first dose on Day 1 are plotted as trough concentration.

Source Data: ADPC; Reference listing(s): 16.2.6.2
Program Name: Figure_Ind_mad.sas

SDTM Date: 04AUG2020 16:09
Analysis Date: 25AUG2020 15:16

Figure 14.2.4.8
Plot of Individual Plasma Trough Concentrations of LB-102 and Amisulpride by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part B (MAD)
LB-102 100 mg BID

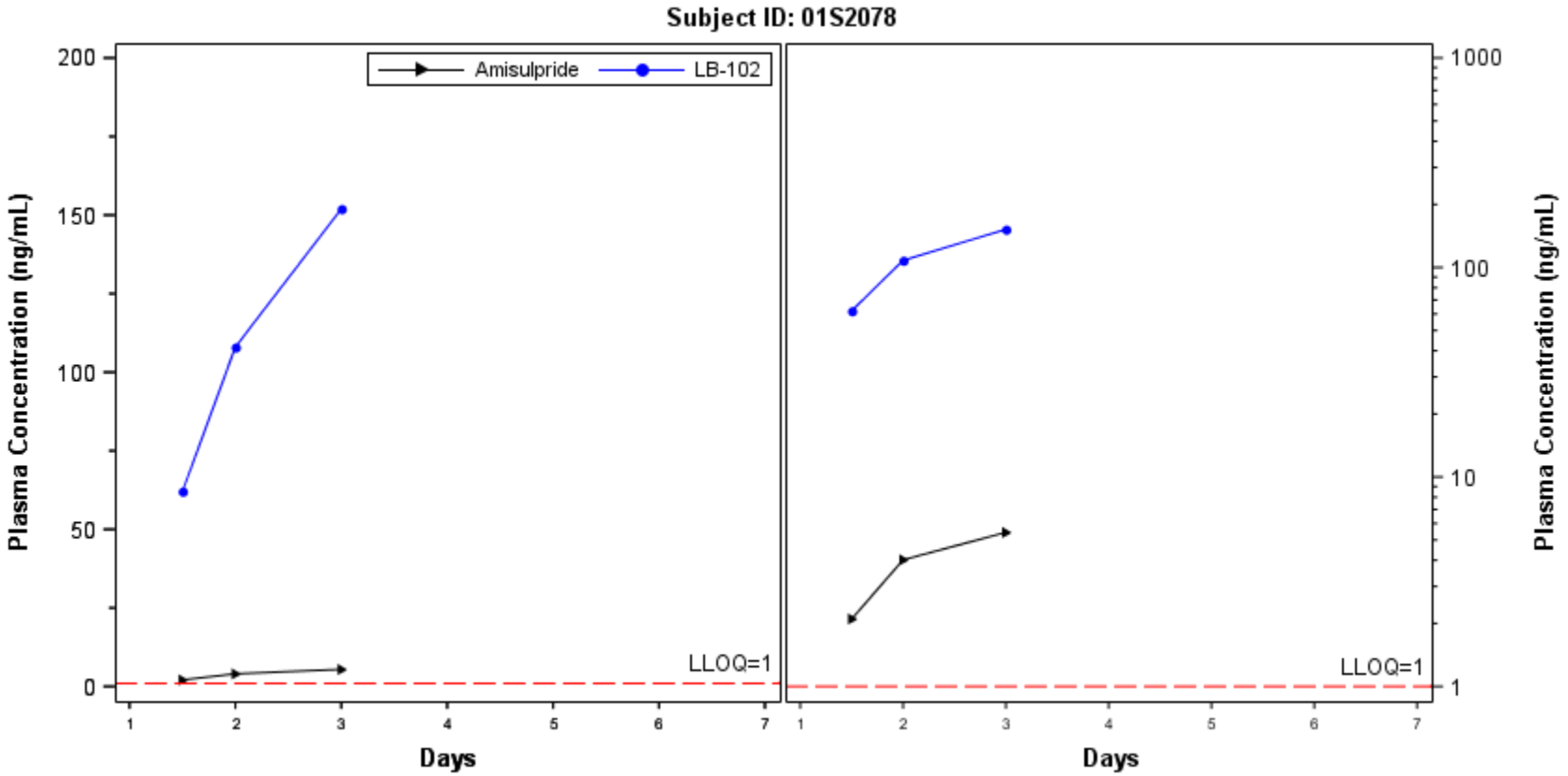


Note: Lower limit of quantification (LLOQ) for LB-102 = 1 ng/mL. LLOQ for amisulpride = 1 ng/mL.
All predose concentrations except that for the first dose on Day 1 are plotted as trough concentration.

Source Data: ADPC; Reference listing(s): 16.2.6.2
Program Name: Figure_Ind_mad.sas

SDTM Date: 04AUG2020 16:09
Analysis Date: 25AUG2020 15:16

Figure 14.2.4.8
Plot of Individual Plasma Trough Concentrations of LB-102 and Amisulpride by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part B (MAD)
LB-102 100 mg BID

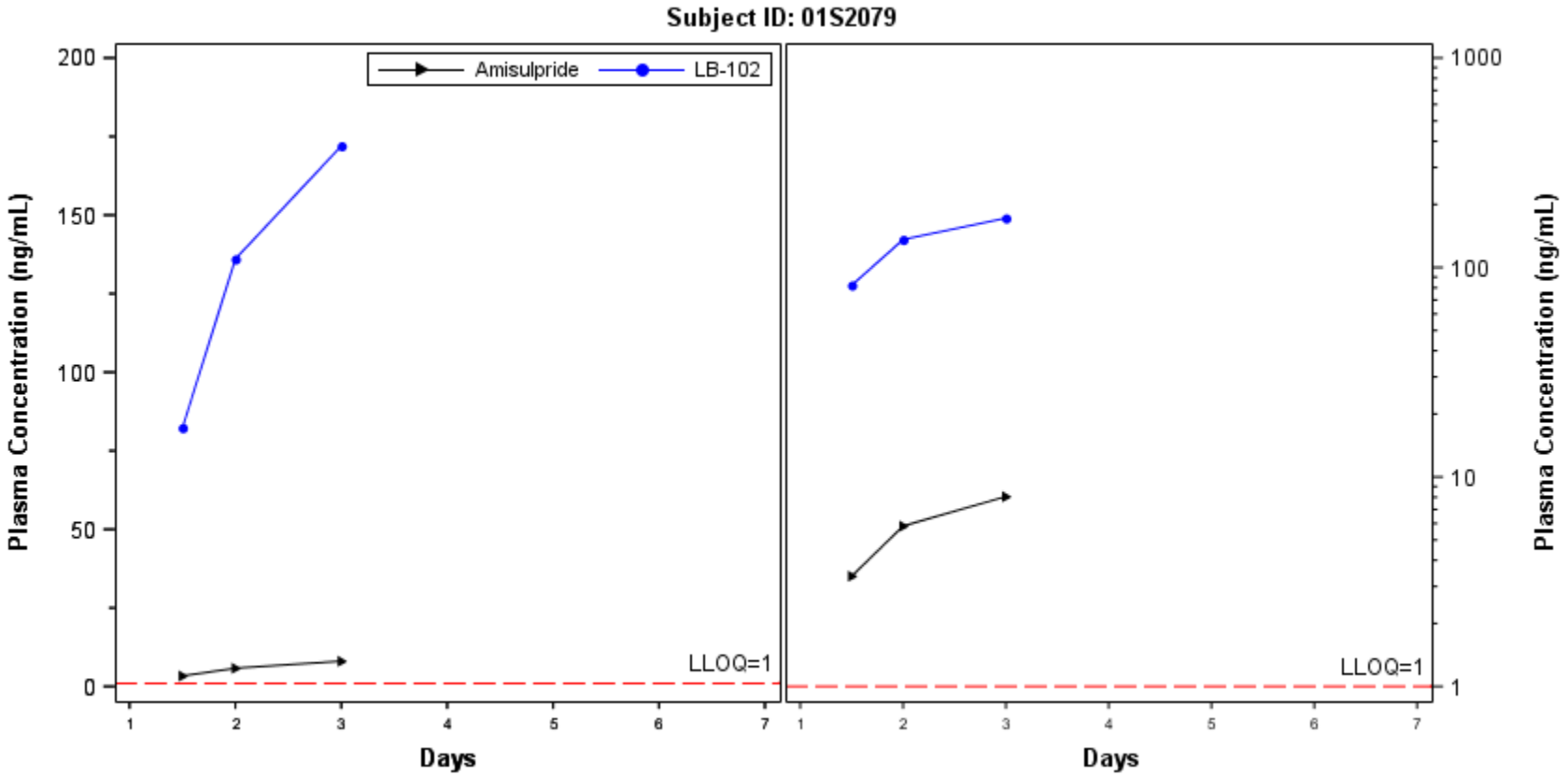


Note: Lower limit of quantification (LLOQ) for LB-102 = 1 ng/mL. LLOQ for amisulpride = 1 ng/mL.
All predose concentrations except that for the first dose on Day 1 are plotted as trough concentration.

Source Data: ADPC; Reference listing(s): 16.2.6.2
Program Name: Figure_Ind_mad.sas

SDTM Date: 04AUG2020 16:09
Analysis Date: 25AUG2020 15:16

Figure 14.2.4.8
Plot of Individual Plasma Trough Concentrations of LB-102 and Amisulpride by Treatment on Linear and Semi-log Scale
Pharmacokinetic Population: Part B (MAD)
LB-102 100 mg BID



Note: Lower limit of quantification (LLOQ) for LB-102 = 1 ng/mL. LLOQ for amisulpride = 1 ng/mL.
All predose concentrations except that for the first dose on Day 1 are plotted as trough concentration.

Source Data: ADPC; Reference listing(s): 16.2.6.2 SDTM Date: 04AUG2020 16:09
Program Name: Figure_Ind_mad.sas Analysis Date: 25AUG2020 15:16

12.2 Data Listing

Listing 16.2.6.1	Pharmacokinetic Sample Collection Pharmacokinetic Population
Listing 16.2.6.2	Plasma Concentration-Time Profiles by Treatment Pharmacokinetic Population: Part A (SAD)
Listing 16.2.6.3	Plasma Concentration-Time Profiles by Treatment Pharmacokinetic Population: Part B (MAD)

Listing 16.2.6.1
Pharmacokinetic Sample Collection
Pharmacokinetic Population

Treatment Subject	Visit	Scheduled Time Point	Date/Time of Sampling	Not Done?/Reason
Part A: LB-102 10 mg				
01S0029	Day 1	PRE DOSE	2020-02-04/08:27	
		15 MINS	2020-02-04/08:47	
		30 MINS	2020-02-04/09:02	
		45 MINS	2020-02-04/09:17	
		1 HOUR	2020-02-04/09:32	
		1.5 HOURS	2020-02-04/10:02	
		2 HOURS	2020-02-04/10:32	
		3 HOURS	2020-02-04/11:32	
		4 HOURS	2020-02-04/12:32	
		6 HOURS	2020-02-04/14:32	
		8 HOURS	2020-02-04/16:32	
		12 HOURS	2020-02-04/20:32	
		16 HOURS	2020-02-05/00:32	
	Day 2	24 HOURS	2020-02-05/08:32	
		32 HOURS	2020-02-05/16:32	
	Day 3	48 HOURS	2020-02-06/08:32	
01S0030	Day 1	PRE DOSE	2020-02-04/08:29	
		15 MINS	2020-02-04/08:49	
		30 MINS	2020-02-04/09:04	
		45 MINS	2020-02-04/09:19	
		1 HOUR	2020-02-04/09:34	
		1.5 HOURS	2020-02-04/10:04	
		2 HOURS	2020-02-04/10:34	
		3 HOURS	2020-02-04/11:34	

Listing 16.2.6.1
Pharmacokinetic Sample Collection
Pharmacokinetic Population

Treatment Subject	Visit	Scheduled Time Point	Date/Time of Sampling	Not Done?/Reason
Part A: LB-102 10 mg				
01S0030	Day 1	4 HOURS	2020-02-04/12:34	
		6 HOURS	2020-02-04/14:34	
		8 HOURS	2020-02-04/16:34	
		12 HOURS	2020-02-04/20:34	
		16 HOURS	2020-02-05/00:34	
	Day 2	24 HOURS	2020-02-05/08:34	
		32 HOURS	2020-02-05/16:34	
	Day 3	48 HOURS	2020-02-06/08:34	
01S0032	Day 1	PRE DOSE	2020-02-04/08:31	
		15 MINS	2020-02-04/08:51	
		30 MINS	2020-02-04/09:06	
		45 MINS	2020-02-04/09:21	
		1 HOUR	2020-02-04/09:36	
		1.5 HOURS	2020-02-04/10:06	
		2 HOURS	2020-02-04/10:36	
		3 HOURS	2020-02-04/11:36	
		4 HOURS	2020-02-04/12:36	
		6 HOURS	2020-02-04/14:36	
		8 HOURS	2020-02-04/16:36	
		12 HOURS	2020-02-04/20:36	
		16 HOURS	2020-02-05/00:36	
	Day 2	24 HOURS	2020-02-05/08:36	
		32 HOURS	2020-02-05/16:36	

Listing 16.2.6.1
Pharmacokinetic Sample Collection
Pharmacokinetic Population

Treatment Subject	Visit	Scheduled Time Point	Date/Time of Sampling	Not Done?/Reason
Part A: LB-102 10 mg				
01S0032	Day 3	48 HOURS	2020-02-06/08:36	
01S0035	Day 1	PRE DOSE	2020-02-04/08:33	
		15 MINS	2020-02-04/08:53	
		30 MINS	2020-02-04/09:08	
		45 MINS	2020-02-04/09:23	
		1 HOUR	2020-02-04/09:38	
		1.5 HOURS	2020-02-04/10:08	
		2 HOURS	2020-02-04/10:38	
		3 HOURS	2020-02-04/11:38	
		4 HOURS	2020-02-04/12:38	
		6 HOURS	2020-02-04/14:38	
		8 HOURS	2020-02-04/16:38	
		12 HOURS	2020-02-04/20:38	
		16 HOURS	2020-02-05/00:38	
	Day 2	24 HOURS	2020-02-05/08:38	
		32 HOURS	2020-02-05/16:38	
	Day 3	48 HOURS	2020-02-06/08:38	
01S0042	Day 1	PRE DOSE	2020-02-04/08:39	
		15 MINS	2020-02-04/08:59	
		30 MINS	2020-02-04/09:14	
		45 MINS	2020-02-04/09:29	
		1 HOUR	2020-02-04/09:44	

Listing 16.2.6.1
Pharmacokinetic Sample Collection
Pharmacokinetic Population

Treatment Subject	Visit	Scheduled Time Point	Date/Time of Sampling	Not Done?/Reason
Part A: LB-102 10 mg				
01S0042	Day 1	1.5 HOURS	2020-02-04/10:14	
		2 HOURS	2020-02-04/10:44	
		3 HOURS	2020-02-04/11:44	
		4 HOURS	2020-02-04/12:44	
		6 HOURS	2020-02-04/14:44	
		8 HOURS	2020-02-04/16:44	
		12 HOURS	2020-02-04/20:44	
		16 HOURS	2020-02-05/00:44	
	Day 2	24 HOURS	2020-02-05/08:44	
		32 HOURS	2020-02-05/16:44	
	Day 3	48 HOURS	2020-02-06/08:44	
01S0049	Day 1	PRE DOSE	2020-02-04/08:37	
		15 MINS	2020-02-04/08:57	
		30 MINS	2020-02-04/09:12	
		45 MINS	2020-02-04/09:27	
		1 HOUR	2020-02-04/09:42	
		1.5 HOURS	2020-02-04/10:12	
		2 HOURS	2020-02-04/10:42	
		3 HOURS	2020-02-04/11:42	
		4 HOURS	2020-02-04/12:42	
		6 HOURS	2020-02-04/14:42	
		8 HOURS	2020-02-04/16:42	
		12 HOURS	2020-02-04/20:42	
		16 HOURS	2020-02-05/00:42	

Listing 16.2.6.1
Pharmacokinetic Sample Collection
Pharmacokinetic Population

Treatment Subject	Visit	Scheduled Time Point	Date/Time of Sampling	Not Done?/Reason
Part A: LB-102 10 mg				
01S0049	Day 2	24 HOURS	2020-02-05/08:42	
		32 HOURS	2020-02-05/16:42	
	Day 3	48 HOURS	2020-02-06/08:42	
Part A: LB-102 50 mg				
01S0002	Day 1	PRE DOSE	2020-01-21/07:27	
		15 MINS	2020-01-21/07:47	
		30 MINS	2020-01-21/08:02	
		45 MINS	2020-01-21/08:17	
		1 HOUR	2020-01-21/08:32	
		1.5 HOURS	2020-01-21/09:02	
		2 HOURS	2020-01-21/09:32	
		3 HOURS	2020-01-21/10:32	
		4 HOURS	2020-01-21/11:32	
		6 HOURS	2020-01-21/13:32	
		8 HOURS	2020-01-21/15:32	
		12 HOURS	2020-01-21/19:32	
		16 HOURS	2020-01-21/23:32	
	Day 2	24 HOURS	2020-01-22/07:32	
		32 HOURS	2020-01-22/15:41	
	Day 3	48 HOURS	2020-01-23/07:32	
01S0003	Day 1	PRE DOSE	2020-01-22/07:29	
		15 MINS	2020-01-22/07:49	

Listing 16.2.6.1
Pharmacokinetic Sample Collection
Pharmacokinetic Population

Treatment / Subject	Visit	Scheduled Time Point	Date/Time of Sampling	Not Done?/Reason
Part A: LB-102 50 mg				
01S0003	Day 1	30 MINS	2020-01-22/08:04	
		45 MINS	2020-01-22/08:19	
		1 HOUR	2020-01-22/08:34	
		1.5 HOURS	2020-01-22/09:04	
		2 HOURS	2020-01-22/09:34	
		3 HOURS	2020-01-22/10:34	
		4 HOURS	2020-01-22/11:34	
		6 HOURS	2020-01-22/13:34	
		8 HOURS	2020-01-22/15:34	
		12 HOURS	2020-01-22/19:36	
		16 HOURS	2020-01-22/23:34	
	Day 2	24 HOURS	2020-01-23/07:34	
		32 HOURS	2020-01-23/15:34	
	Day 3	48 HOURS	2020-01-24/07:34	
01S0004	Day 1	PRE DOSE	2020-01-22/07:31	
		15 MINS	2020-01-22/07:51	
		30 MINS	2020-01-22/08:06	
		45 MINS	2020-01-22/08:21	
		1 HOUR	2020-01-22/08:36	
		1.5 HOURS	2020-01-22/09:06	
		2 HOURS	2020-01-22/09:36	
		3 HOURS	2020-01-22/10:36	
		4 HOURS	2020-01-22/11:36	
		6 HOURS	2020-01-22/13:36	

Listing 16.2.6.1
Pharmacokinetic Sample Collection
Pharmacokinetic Population

Treatment Subject	Visit	Scheduled Time Point	Date/Time of Sampling	Not Done?/Reason
Part A: LB-102 50 mg				
01S0004	Day 1	8 HOURS	2020-01-22/15:36	
		12 HOURS	2020-01-22/19:39	
		16 HOURS	2020-01-22/23:37	
	Day 2	24 HOURS	2020-01-23/07:36	
		32 HOURS	2020-01-23/15:36	
	Day 3	48 HOURS	2020-01-24/07:36	
01S0005	Day 1	PRE DOSE	2020-01-22/07:33	
		15 MINS	2020-01-22/07:53	
		30 MINS	2020-01-22/08:08	
		45 MINS	2020-01-22/08:23	
		1 HOUR	2020-01-22/08:38	
		1.5 HOURS	2020-01-22/09:08	
		2 HOURS	2020-01-22/09:38	
		3 HOURS	2020-01-22/10:38	
		4 HOURS	2020-01-22/11:38	
		6 HOURS	2020-01-22/13:38	
		8 HOURS	2020-01-22/15:38	
		12 HOURS	2020-01-22/19:38	
		16 HOURS	2020-01-22/23:38	
	Day 2	24 HOURS	2020-01-23/07:38	
		32 HOURS	2020-01-23/15:38	
	Day 3	48 HOURS	2020-01-24/07:38	

Listing 16.2.6.1
Pharmacokinetic Sample Collection
Pharmacokinetic Population

Treatment Subject	Visit	Scheduled Time Point	Date/Time of Sampling	Not Done?/Reason
Part A: LB-102 50 mg				
01S0008	Day 1	PRE DOSE	2020-01-22/07:37	
		15 MINS	2020-01-22/07:57	
		30 MINS	2020-01-22/08:12	
		45 MINS	2020-01-22/08:27	
		1 HOUR	2020-01-22/08:42	
		1.5 HOURS	2020-01-22/09:12	
		2 HOURS	2020-01-22/09:42	
		3 HOURS	2020-01-22/10:42	
		4 HOURS	2020-01-22/11:42	
		6 HOURS	2020-01-22/13:42	
		8 HOURS	2020-01-22/15:42	
		12 HOURS	2020-01-22/19:42	
		16 HOURS	2020-01-22/23:42	
	Day 2	24 HOURS	2020-01-23/07:42	
		32 HOURS	2020-01-23/15:42	
	Day 3	48 HOURS	2020-01-24/07:42	
01S0010	Day 1	PRE DOSE	2020-01-22/07:39	
		15 MINS	2020-01-22/07:59	
		30 MINS	2020-01-22/08:14	
		45 MINS	2020-01-22/08:29	
		1 HOUR	2020-01-22/08:44	
		1.5 HOURS	2020-01-22/09:14	
		2 HOURS	2020-01-22/09:44	
		3 HOURS	2020-01-22/10:44	
		4 HOURS	2020-01-22/11:44	

Listing 16.2.6.1
Pharmacokinetic Sample Collection
Pharmacokinetic Population

Treatment Subject	Visit	Scheduled Time Point	Date/Time of Sampling	Not Done?/Reason
Part A: LB-102 50 mg				
01S0010	Day 1	6 HOURS	2020-01-22/13:44	
		8 HOURS	2020-01-22/15:44	
		12 HOURS	2020-01-22/19:44	
		16 HOURS	2020-01-22/23:44	
	Day 2	24 HOURS	2020-01-23/07:44	
		32 HOURS	2020-01-23/15:44	
	Day 3	48 HOURS	2020-01-24/07:44	
Part A: LB-102 100 mg				
01S0056	Day 1	PRE DOSE	2020-02-18/07:25	
		15 MINS	2020-02-18/07:45	
		30 MINS	2020-02-18/08:00	
		45 MINS	2020-02-18/08:15	
		1 HOUR	2020-02-18/08:30	
		1.5 HOURS	2020-02-18/09:00	
		2 HOURS	2020-02-18/09:31	
		3 HOURS	2020-02-18/10:30	
		4 HOURS	2020-02-18/11:30	
		6 HOURS	2020-02-18/13:30	
		8 HOURS	2020-02-18/15:30	
		12 HOURS	2020-02-18/19:30	
		16 HOURS	2020-02-18/23:30	
	Day 2	24 HOURS	2020-02-19/07:30	
		32 HOURS	2020-02-19/15:30	
	Day 3	48 HOURS	2020-02-20/07:30	

Listing 16.2.6.1
Pharmacokinetic Sample Collection
Pharmacokinetic Population

Treatment Subject	Visit	Scheduled Time Point	Date/Time of Sampling	Not Done?/Reason
Part A: LB-102 100 mg				
01S0063	Day 1	PRE DOSE	2020-02-18/07:27	
		15 MINS	2020-02-18/07:47	
		30 MINS	2020-02-18/08:02	
		45 MINS	2020-02-18/08:17	
		1 HOUR	2020-02-18/08:32	
		1.5 HOURS	2020-02-18/09:02	
		2 HOURS	2020-02-18/09:33	
		3 HOURS	2020-02-18/10:32	
		4 HOURS	2020-02-18/11:32	
		6 HOURS	2020-02-18/13:32	
		8 HOURS	2020-02-18/15:32	
		12 HOURS	2020-02-18/19:32	
		16 HOURS	2020-02-18/23:32	
	Day 2	24 HOURS	2020-02-19/07:32	
		32 HOURS	2020-02-19/15:32	
	Day 3	48 HOURS	2020-02-20/07:32	
01S0064	Day 1	PRE DOSE	2020-02-18/07:29	
		15 MINS	2020-02-18/07:49	
		30 MINS	2020-02-18/08:04	
		45 MINS	2020-02-18/08:19	
		1 HOUR	2020-02-18/08:34	
		1.5 HOURS	2020-02-18/09:04	
		2 HOURS	2020-02-18/09:34	
		3 HOURS	2020-02-18/10:34	
		4 HOURS	2020-02-18/11:34	

Listing 16.2.6.1
Pharmacokinetic Sample Collection
Pharmacokinetic Population

Treatment Subject	Visit	Scheduled Time Point	Date/Time of Sampling	Not Done?/Reason
Part A: LB-102 100 mg				
01S0064	Day 1	6 HOURS	2020-02-18/13:34	
		8 HOURS	2020-02-18/15:34	
		12 HOURS	2020-02-18/19:34	
		16 HOURS	2020-02-18/23:34	
	Day 2	24 HOURS	2020-02-19/07:34	
		32 HOURS	2020-02-19/15:34	
	Day 3	48 HOURS	2020-02-20/07:34	
01S0071	Day 1	PRE DOSE	2020-02-18/07:33	
		15 MINS	2020-02-18/07:53	
		30 MINS	2020-02-18/08:08	
		45 MINS	2020-02-18/08:23	
		1 HOUR	2020-02-18/08:38	
		1.5 HOURS	2020-02-18/09:08	
		2 HOURS	2020-02-18/09:38	
		3 HOURS	2020-02-18/10:38	
		4 HOURS	2020-02-18/11:38	
		6 HOURS	2020-02-18/13:38	
		8 HOURS	2020-02-18/15:38	
		12 HOURS	2020-02-18/19:38	
		16 HOURS	2020-02-18/23:38	
	Day 2	24 HOURS	2020-02-19/07:38	
		32 HOURS	2020-02-19/15:38	
	Day 3	48 HOURS	2020-02-20/07:38	

Listing 16.2.6.1
Pharmacokinetic Sample Collection
Pharmacokinetic Population

Treatment / Subject	Visit	Scheduled Time Point	Date/Time of Sampling	Not Done?/Reason
Part A: LB-102 100 mg				
01S0073	Day 1	PRE DOSE	2020-02-18/07:35	
		15 MINS	2020-02-18/07:55	
		30 MINS	2020-02-18/08:10	
		45 MINS	2020-02-18/08:25	
		1 HOUR	2020-02-18/08:40	
		1.5 HOURS	2020-02-18/09:10	
		2 HOURS	2020-02-18/09:40	
		3 HOURS	2020-02-18/10:40	
		4 HOURS	2020-02-18/11:40	
		6 HOURS	2020-02-18/13:40	
		8 HOURS	2020-02-18/15:40	
		12 HOURS	2020-02-18/19:40	
		16 HOURS	2020-02-18/23:40	
	Day 2	24 HOURS	2020-02-19/07:40	
		32 HOURS	2020-02-19/15:40	
	Day 3	48 HOURS	2020-02-20/07:40	
01S0074	Day 1	PRE DOSE	2020-02-18/07:37	
		15 MINS	2020-02-18/07:57	
		30 MINS	2020-02-18/08:12	
		45 MINS	2020-02-18/08:27	
		1 HOUR	2020-02-18/08:42	
		1.5 HOURS	2020-02-18/09:12	
		2 HOURS	2020-02-18/09:42	
		3 HOURS	2020-02-18/10:42	
		4 HOURS	2020-02-18/11:42	

Listing 16.2.6.1
Pharmacokinetic Sample Collection
Pharmacokinetic Population

Treatment Subject	Visit	Scheduled Time Point	Date/Time of Sampling	Not Done?/Reason
Part A: LB-102 100 mg				
01S0074	Day 1	6 HOURS	2020-02-18/13:42	
		8 HOURS	2020-02-18/15:42	
		12 HOURS	2020-02-18/19:42	
		16 HOURS	2020-02-18/23:42	
	Day 2	24 HOURS	2020-02-19/07:42	
		32 HOURS	2020-02-19/15:42	
	Day 3	48 HOURS	2020-02-20/07:42	
Part A: LB-102 150 mg				
01S0156	Day 1	PRE DOSE	2020-04-18/07:27	
		15 MINS	2020-04-18/07:47	
		30 MINS	2020-04-18/08:02	
		45 MINS	2020-04-18/08:15	
		1 HOUR	2020-04-18/08:37	
		1.5 HOURS	2020-04-18/09:02	
		2 HOURS	2020-04-18/09:32	
		3 HOURS	2020-04-18/10:32	
		4 HOURS	2020-04-18/11:32	
		6 HOURS	2020-04-18/13:32	
		8 HOURS	2020-04-18/15:32	
		12 HOURS	2020-04-18/19:32	
		16 HOURS	2020-04-18/23:32	
	Day 2	24 HOURS	2020-04-19/07:32	
		32 HOURS	2020-04-19/15:32	
	Day 3	48 HOURS	2020-04-20/07:32	

Listing 16.2.6.1
Pharmacokinetic Sample Collection
Pharmacokinetic Population

Treatment Subject	Visit	Scheduled Time Point	Date/Time of Sampling	Not Done?/Reason
Part A: LB-102 150 mg				
01S0156	Day 8		2020-04-25/08:12	
	Day 15		2020-05-02/07:58	
01S0157	Day 1	PRE DOSE	2020-04-18/07:29	
		15 MINS	2020-04-18/07:49	
		30 MINS	2020-04-18/08:04	
		45 MINS	2020-04-18/08:17	
		1 HOUR	2020-04-18/08:39	
		1.5 HOURS	2020-04-18/09:04	
		2 HOURS	2020-04-18/09:34	
		3 HOURS	2020-04-18/10:34	
		4 HOURS	2020-04-18/11:34	
		6 HOURS	2020-04-18/13:34	
		8 HOURS	2020-04-18/15:34	
		12 HOURS	2020-04-18/19:34	
		16 HOURS	2020-04-18/23:34	
	Day 2	24 HOURS	2020-04-19/07:34	
		32 HOURS	2020-04-19/15:34	
	Day 3	48 HOURS	2020-04-20/07:34	
	Day 8		2020-04-25/08:50	
	Day 15		2020-05-02/08:12	

Listing 16.2.6.1
Pharmacokinetic Sample Collection
Pharmacokinetic Population

Treatment Subject	Visit	Scheduled Time Point	Date/Time of Sampling	Not Done?/Reason
Part A: LB-102 150 mg				
01S0160	Day 1	PRE DOSE	2020-04-18/07:31	
		15 MINS	2020-04-18/07:51	
		30 MINS	2020-04-18/08:06	
		45 MINS	2020-04-18/08:19	
		1 HOUR	2020-04-18/08:41	
		1.5 HOURS	2020-04-18/09:06	
		2 HOURS	2020-04-18/09:36	
		3 HOURS	2020-04-18/10:36	
		4 HOURS	2020-04-18/11:36	
		6 HOURS	2020-04-18/13:36	
		8 HOURS	2020-04-18/15:36	
		12 HOURS	2020-04-18/19:36	
		16 HOURS	2020-04-18/23:36	
	Day 2	24 HOURS	2020-04-19/07:36	
		32 HOURS	2020-04-19/15:36	
	Day 3	48 HOURS	2020-04-20/07:36	
	Day 8		2020-04-25/08:24	
	Day 15		2020-05-02/08:41	
01S0162	Day 1	PRE DOSE	2020-04-18/07:33	
		15 MINS	2020-04-18/07:53	
		30 MINS	2020-04-18/08:08	
		45 MINS	2020-04-18/08:21	

Listing 16.2.6.1
Pharmacokinetic Sample Collection
Pharmacokinetic Population

Treatment Subject	Visit	Scheduled Time Point	Date/Time of Sampling	Not Done?/Reason
Part A: LB-102 150 mg				
01S0162	Day 1	1 HOUR	2020-04-18/08:44	
		1.5 HOURS	2020-04-18/09:08	
		2 HOURS	2020-04-18/09:38	
		3 HOURS	2020-04-18/10:38	
		4 HOURS	2020-04-18/11:38	
		6 HOURS	2020-04-18/13:38	
		8 HOURS	2020-04-18/15:38	
		12 HOURS	2020-04-18/19:38	
		16 HOURS	2020-04-18/23:38	
	Day 2	24 HOURS	2020-04-19/07:38	
		32 HOURS	2020-04-19/15:38	
	Day 3	48 HOURS	2020-04-20/07:38	
	Day 8		2020-04-25/08:19	
	Day 15		2020-05-02/08:32	
01S0165	Day 1	PRE DOSE	2020-04-18/07:35	
		15 MINS	2020-04-18/07:56	
		30 MINS	2020-04-18/08:10	
		45 MINS	2020-04-18/08:23	
		1 HOUR	2020-04-18/08:46	
		1.5 HOURS	2020-04-18/09:10	
		2 HOURS	2020-04-18/09:43	
		3 HOURS	2020-04-18/10:40	
		4 HOURS	2020-04-18/11:40	

Listing 16.2.6.1
Pharmacokinetic Sample Collection
Pharmacokinetic Population

Treatment Subject	Visit	Scheduled Time Point	Date/Time of Sampling	Not Done?/Reason
Part A: LB-102 150 mg				
01S0165	Day 1	6 HOURS	2020-04-18/13:40	
		8 HOURS	2020-04-18/15:40	
		12 HOURS	2020-04-18/19:40	
		16 HOURS	2020-04-18/23:40	
	Day 2	24 HOURS	2020-04-19/07:40	
		32 HOURS	2020-04-19/15:40	
	Day 3	48 HOURS	2020-04-20/07:40	
	Day 8		2020-04-25/08:16	
	Day 15		2020-05-02/08:03	
01S0168	Day 1	PRE DOSE	2020-04-18/07:37	
		15 MINS	2020-04-18/07:57	
		30 MINS	2020-04-18/08:12	
		45 MINS	2020-04-18/08:25	
		1 HOUR	2020-04-18/08:48	
		1.5 HOURS	2020-04-18/09:12	
		2 HOURS	2020-04-18/09:42	
		3 HOURS	2020-04-18/10:42	
		4 HOURS	2020-04-18/11:42	
		6 HOURS	2020-04-18/13:42	
		8 HOURS	2020-04-18/15:42	
		12 HOURS	2020-04-18/19:42	
		16 HOURS	2020-04-18/23:42	

Listing 16.2.6.1
Pharmacokinetic Sample Collection
Pharmacokinetic Population

Treatment Subject	Visit	Scheduled Time Point	Date/Time of Sampling	Not Done?/Reason
Part A: LB-102 150 mg				
01S0168	Day 2	24 HOURS	2020-04-19/07:42	
		32 HOURS	2020-04-19/15:42	
	Day 3	48 HOURS	2020-04-20/07:42	
	Day 8		2020-04-25/08:28	
	Day 15		2020-05-02/08:06	
Part A: LB-102 200 mg				
01S0103	Day 1	PRE DOSE	2020-03-03/07:31	
		15 MINS	2020-03-03/07:51	
		30 MINS	2020-03-03/08:06	
		45 MINS	2020-03-03/08:21	
		1 HOUR	2020-03-03/08:36	
		1.5 HOURS	2020-03-03/09:06	
		2 HOURS	2020-03-03/09:36	
		3 HOURS	2020-03-03/10:36	
		4 HOURS	2020-03-03/11:36	
		6 HOURS	2020-03-03/13:36	
		8 HOURS	2020-03-03/15:36	
		12 HOURS	2020-03-03/19:36	
		16 HOURS	2020-03-03/23:36	
	Day 2	24 HOURS	2020-03-04/07:36	
		32 HOURS	2020-03-04/15:36	
	Day 3	48 HOURS	2020-03-05/07:36	

Listing 16.2.6.1
Pharmacokinetic Sample Collection
Pharmacokinetic Population

Treatment Subject	Visit	Scheduled Time Point	Date/Time of Sampling	Not Done?/Reason
Part A: LB-102 200 mg				
01S0104	Day 1	PRE DOSE	2020-03-03/07:33	
		15 MINS	2020-03-03/07:53	
		30 MINS	2020-03-03/08:08	
		45 MINS	2020-03-03/08:23	
		1 HOUR	2020-03-03/08:38	
		1.5 HOURS	2020-03-03/09:08	
		2 HOURS	2020-03-03/09:38	
		3 HOURS	2020-03-03/10:38	
		4 HOURS	2020-03-03/11:38	
		6 HOURS	2020-03-03/13:38	
		8 HOURS	2020-03-03/15:38	
		12 HOURS	2020-03-03/19:38	
		16 HOURS	2020-03-03/23:38	
	Day 2	24 HOURS	2020-03-04/07:38	
		32 HOURS	2020-03-04/15:38	
	Day 3	48 HOURS	2020-03-05/07:38	
01S0109	Day 1	PRE DOSE	2020-03-03/07:35	
		15 MINS	2020-03-03/07:55	
		30 MINS	2020-03-03/08:10	
		45 MINS	2020-03-03/08:25	
		1 HOUR	2020-03-03/08:40	
		1.5 HOURS	2020-03-03/09:10	
		2 HOURS	2020-03-03/09:40	
		3 HOURS	2020-03-03/10:40	

Listing 16.2.6.1
Pharmacokinetic Sample Collection
Pharmacokinetic Population

Treatment Subject	Visit	Scheduled Time Point	Date/Time of Sampling	Not Done?/Reason
Part A: LB-102 200 mg				
01S0109	Day 1	4 HOURS	2020-03-03/11:40	
		6 HOURS	2020-03-03/13:40	
		8 HOURS	2020-03-03/15:40	
		12 HOURS	2020-03-03/19:40	
		16 HOURS	2020-03-03/23:40	
	Day 2	24 HOURS	2020-03-04/07:40	
		32 HOURS	2020-03-04/15:40	
	Day 3	48 HOURS	2020-03-05/07:40	
01S0116	Day 1	PRE DOSE	2020-03-03/07:39	
		15 MINS	2020-03-03/07:57	
		30 MINS	2020-03-03/08:12	
		45 MINS	2020-03-03/08:27	
		1 HOUR	2020-03-03/08:42	
		1.5 HOURS	2020-03-03/09:12	
		2 HOURS	2020-03-03/09:42	
		3 HOURS	2020-03-03/10:42	
		4 HOURS	2020-03-03/11:42	
		6 HOURS	2020-03-03/13:42	
		8 HOURS	2020-03-03/15:42	
		12 HOURS	2020-03-03/19:42	
		16 HOURS	2020-03-03/23:42	
	Day 2	24 HOURS	2020-03-04/07:42	
		32 HOURS	2020-03-04/15:42	

Listing 16.2.6.1
Pharmacokinetic Sample Collection
Pharmacokinetic Population

Treatment Subject	Visit	Scheduled Time Point	Date/Time of Sampling	Not Done?/Reason
Part A: LB-102 200 mg				
01S0116	Day 3	48 HOURS	2020-03-05/07:42	
01S0119	Day 1	PRE DOSE	2020-03-03/07:29	
		15 MINS	2020-03-03/07:49	
		30 MINS	2020-03-03/08:04	
		45 MINS	2020-03-03/08:19	
		1 HOUR	2020-03-03/08:34	
		1.5 HOURS	2020-03-03/09:04	
		2 HOURS	2020-03-03/09:34	
		3 HOURS	2020-03-03/10:34	
		4 HOURS	2020-03-03/11:34	
		6 HOURS	2020-03-03/13:34	
		8 HOURS	2020-03-03/15:34	
		12 HOURS		Not Done/subjectt in Emergency room with AE
		16 HOURS	2020-03-03/23:34	
	Day 2	24 HOURS	2020-03-04/07:34	
		32 HOURS	2020-03-04/15:34	
	Day 3	48 HOURS	2020-03-05/07:34	
01S0120	Day 1	PRE DOSE	2020-03-03/07:41	
		15 MINS	2020-03-03/08:01	
		30 MINS	2020-03-03/08:16	
		45 MINS	2020-03-03/08:31	
		1 HOUR	2020-03-03/08:46	

Listing 16.2.6.1
Pharmacokinetic Sample Collection
Pharmacokinetic Population

Treatment Subject	Visit	Scheduled Time Point	Date/Time of Sampling	Not Done?/Reason
Part A: LB-102 200 mg				
01S0120	Day 1	1.5 HOURS	2020-03-03/09:16	
		2 HOURS	2020-03-03/09:46	
		3 HOURS	2020-03-03/10:46	
		4 HOURS	2020-03-03/11:46	
		6 HOURS	2020-03-03/13:46	
		8 HOURS	2020-03-03/15:46	
		12 HOURS	2020-03-03/19:46	
		16 HOURS	2020-03-03/23:46	
	Day 2	24 HOURS	2020-03-04/07:46	
		32 HOURS	2020-03-04/15:46	
	Day 3	48 HOURS	2020-03-05/07:46	
Part B: LB-102 50 mg BID				
01S2032	Day 1	PRE DOSE	2020-05-12/07:25	
		15 MINS	2020-05-12/07:45	
		30 MINS	2020-05-12/08:00	
		45 MINS	2020-05-12/08:13	
		1 HOUR	2020-05-12/08:35	
		1.5 HOURS	2020-05-12/09:00	
		2 HOURS	2020-05-12/09:30	
		3 HOURS	2020-05-12/10:30	
		4 HOURS	2020-05-12/11:30	
		6 HOURS	2020-05-12/13:30	
		8 HOURS	2020-05-12/15:30	
		12 HOURS	2020-05-12/19:27	
		16 HOURS	2020-05-12/23:30	

Listing 16.2.6.1
Pharmacokinetic Sample Collection
Pharmacokinetic Population

Treatment Subject	Visit	Scheduled Time Point	Date/Time of Sampling	Not Done?/Reason
Part B: LB-102 50 mg BID				
01S2032	Day 2	PRE DOSE	2020-05-13/07:25	
	Day 3	PRE DOSE	2020-05-14/07:25	
	Day 4	PRE DOSE	2020-05-15/07:25	
	Day 5	PRE DOSE	2020-05-16/07:25	
	Day 6	PRE DOSE	2020-05-17/07:25	
	Day 7	PRE DOSE	2020-05-18/07:25	
		15 MINS	2020-05-18/07:45	
		30 MINS	2020-05-18/08:00	
		45 MINS	2020-05-18/08:15	
		1 HOUR	2020-05-18/08:30	
		1.5 HOURS	2020-05-18/09:00	
		2 HOURS	2020-05-18/09:30	
		3 HOURS	2020-05-18/10:30	
		4 HOURS	2020-05-18/11:30	
		6 HOURS	2020-05-18/13:30	
		8 HOURS	2020-05-18/15:30	
		12 HOURS	2020-05-18/19:30	
		16 HOURS	2020-05-18/23:30	
	Day 8	24 HOURS	2020-05-19/07:30	
		32 HOURS	2020-05-19/15:38	
	Day 9	48 HOURS	2020-05-20/07:30	

Listing 16.2.6.1
Pharmacokinetic Sample Collection
Pharmacokinetic Population

Treatment Subject	Visit	Scheduled Time Point	Date/Time of Sampling	Not Done?/Reason
Part B: LB-102 50 mg BID				
01S2034	Day 1	PRE DOSE	2020-05-12/07:27	
		15 MINS	2020-05-12/07:47	
		30 MINS	2020-05-12/08:02	
		45 MINS	2020-05-12/08:15	
		1 HOUR	2020-05-12/08:37	
		1.5 HOURS	2020-05-12/09:02	
		2 HOURS	2020-05-12/09:32	
		3 HOURS	2020-05-12/10:32	
		4 HOURS	2020-05-12/11:32	
		6 HOURS	2020-05-12/13:32	
		8 HOURS	2020-05-12/15:32	
		12 HOURS	2020-05-12/19:29	
		16 HOURS	2020-05-12/23:32	
	Day 2	PRE DOSE	2020-05-13/07:27	
	Day 3	PRE DOSE	2020-05-14/07:27	
	Day 4	PRE DOSE	2020-05-15/07:27	
	Day 5	PRE DOSE	2020-05-16/07:27	
	Day 6	PRE DOSE	2020-05-17/07:27	
	Day 7	PRE DOSE	2020-05-18/07:27	
		15 MINS	2020-05-18/07:47	
		30 MINS	2020-05-18/08:02	
		45 MINS	2020-05-18/08:17	

Listing 16.2.6.1
Pharmacokinetic Sample Collection
Pharmacokinetic Population

Treatment Subject	Visit	Scheduled Time Point	Date/Time of Sampling	Not Done?/Reason
Part B: LB-102 50 mg BID				
01S2034	Day 7	1 HOUR	2020-05-18/08:32	
		1.5 HOURS	2020-05-18/09:02	
		2 HOURS	2020-05-18/09:32	
		3 HOURS	2020-05-18/10:32	
		4 HOURS	2020-05-18/11:32	
		6 HOURS	2020-05-18/13:32	
		8 HOURS	2020-05-18/15:32	
		12 HOURS	2020-05-18/19:32	
		16 HOURS	2020-05-18/23:32	
	Day 8	24 HOURS	2020-05-19/07:32	
		32 HOURS	2020-05-19/15:39	
	Day 9	48 HOURS	2020-05-20/07:32	
01S2045	Day 1	PRE DOSE	2020-05-12/07:31	
		15 MINS	2020-05-12/07:51	
		30 MINS	2020-05-12/08:06	
		45 MINS	2020-05-12/08:19	
		1 HOUR	2020-05-12/08:41	
		1.5 HOURS	2020-05-12/09:06	
		2 HOURS	2020-05-12/09:36	
		3 HOURS	2020-05-12/10:36	
		4 HOURS	2020-05-12/11:36	
		6 HOURS	2020-05-12/13:36	
		8 HOURS	2020-05-12/15:36	
		12 HOURS	2020-05-12/19:33	

Listing 16.2.6.1
Pharmacokinetic Sample Collection
Pharmacokinetic Population

Treatment Subject	Visit	Scheduled Time Point	Date/Time of Sampling	Not Done?/Reason
Part B: LB-102 50 mg BID				
01S2045	Day 1	16 HOURS	2020-05-12/23:36	
	Day 2	PRE DOSE	2020-05-13/07:31	
	Day 3	PRE DOSE	2020-05-14/07:31	
	Day 4	PRE DOSE	2020-05-15/07:31	
	Day 5	PRE DOSE	2020-05-16/07:31	
	Day 6	PRE DOSE	2020-05-17/07:31	
	Day 7	PRE DOSE	2020-05-18/07:31	
		15 MINS	2020-05-18/07:51	
		30 MINS	2020-05-18/08:06	
		45 MINS	2020-05-18/08:21	
		1 HOUR	2020-05-18/08:36	
		1.5 HOURS	2020-05-18/09:06	
		2 HOURS	2020-05-18/09:36	
		3 HOURS	2020-05-18/10:36	
		4 HOURS	2020-05-18/11:36	
		6 HOURS	2020-05-18/13:36	
		8 HOURS	2020-05-18/15:36	
		12 HOURS	2020-05-18/19:36	
		16 HOURS	2020-05-18/23:36	
	Day 8	24 HOURS	2020-05-19/07:36	
		32 HOURS	2020-05-19/15:40	

Listing 16.2.6.1
Pharmacokinetic Sample Collection
Pharmacokinetic Population

Treatment Subject	Visit	Scheduled Time Point	Date/Time of Sampling	Not Done?/Reason
Part B: LB-102 50 mg BID				
01S2045	Day 9	48 HOURS	2020-05-20/07:36	
01S2050	Day 1	PRE DOSE	2020-05-12/07:37	
		15 MINS	2020-05-12/07:57	
		30 MINS	2020-05-12/08:12	
		45 MINS	2020-05-12/08:25	
		1 HOUR	2020-05-12/08:47	
		1.5 HOURS	2020-05-12/09:12	
		2 HOURS	2020-05-12/09:42	
		3 HOURS	2020-05-12/10:42	
		4 HOURS	2020-05-12/11:42	
		6 HOURS	2020-05-12/13:42	
		8 HOURS	2020-05-12/15:42	
		12 HOURS	2020-05-12/19:41	
		16 HOURS	2020-05-12/23:42	
	Day 2	PRE DOSE	2020-05-13/07:37	
	Day 3	PRE DOSE	2020-05-14/07:37	
	Day 4	PRE DOSE	2020-05-15/07:37	
	Day 5	PRE DOSE	2020-05-16/07:37	
	Day 6	PRE DOSE	2020-05-17/07:37	
	Day 7	PRE DOSE	2020-05-18/07:37	

Listing 16.2.6.1
Pharmacokinetic Sample Collection
Pharmacokinetic Population

Treatment Subject	Visit	Scheduled Time Point	Date/Time of Sampling	Not Done?/Reason
Part B: LB-102 50 mg BID				
01S2050	Day 7	15 MINS	2020-05-18/07:57	
		30 MINS	2020-05-18/08:12	
		45 MINS	2020-05-18/08:27	
		1 HOUR	2020-05-18/08:42	
		1.5 HOURS	2020-05-18/09:12	
		2 HOURS	2020-05-18/09:42	
		3 HOURS	2020-05-18/10:42	
		4 HOURS	2020-05-18/11:42	
		6 HOURS	2020-05-18/13:42	
		8 HOURS	2020-05-18/15:42	
		12 HOURS	2020-05-18/19:42	
		16 HOURS	2020-05-18/23:42	
	Day 8	24 HOURS	2020-05-19/07:42	
		32 HOURS	2020-05-19/15:42	
	Day 9	48 HOURS	2020-05-20/07:42	
01S2053	Day 1	PRE DOSE	2020-05-12/07:39	
		15 MINS	2020-05-12/07:59	
		30 MINS	2020-05-12/08:14	
		45 MINS	2020-05-12/08:27	
		1 HOUR	2020-05-12/08:49	
		1.5 HOURS	2020-05-12/09:14	
		2 HOURS	2020-05-12/09:44	
		3 HOURS	2020-05-12/10:44	
		4 HOURS	2020-05-12/11:44	

Listing 16.2.6.1
Pharmacokinetic Sample Collection
Pharmacokinetic Population

Treatment Subject	Visit	Scheduled Time Point	Date/Time of Sampling	Not Done?/Reason
Part B: LB-102 50 mg BID				
01S2053	Day 1	6 HOURS	2020-05-12/13:44	
		8 HOURS	2020-05-12/15:44	
		12 HOURS	2020-05-12/19:41	
		16 HOURS	2020-05-12/23:44	
	Day 2	PRE DOSE	2020-05-13/07:39	
	Day 3	PRE DOSE	2020-05-14/07:39	
	Day 4	PRE DOSE	2020-05-15/07:39	
	Day 5	PRE DOSE	2020-05-16/07:39	
	Day 6	PRE DOSE	2020-05-17/07:39	
	Day 7	PRE DOSE	2020-05-18/07:39	
		15 MINS	2020-05-18/07:59	
		30 MINS	2020-05-18/08:14	
		45 MINS	2020-05-18/08:29	
		1 HOUR	2020-05-18/08:44	
		1.5 HOURS	2020-05-18/09:14	
		2 HOURS	2020-05-18/09:44	
		3 HOURS	2020-05-18/10:44	
		4 HOURS	2020-05-18/11:44	
		6 HOURS	2020-05-18/13:44	
		8 HOURS	2020-05-18/15:44	
		12 HOURS	2020-05-18/19:44	
		16 HOURS	2020-05-18/23:44	

Listing 16.2.6.1
Pharmacokinetic Sample Collection
Pharmacokinetic Population

Treatment Subject	Visit	Scheduled Time Point	Date/Time of Sampling	Not Done?/Reason
Part B: LB-102 50 mg BID				
01S2053	Day 8	24 HOURS	2020-05-19/07:44	
		32 HOURS	2020-05-19/15:44	
	Day 9	48 HOURS	2020-05-20/07:44	
01S2055	Day 1	PRE DOSE	2020-05-12/07:41	
		15 MINS	2020-05-12/08:01	
		30 MINS	2020-05-12/08:16	
		45 MINS	2020-05-12/08:29	
		1 HOUR	2020-05-12/08:51	
		1.5 HOURS	2020-05-12/09:16	
		2 HOURS	2020-05-12/09:46	
		3 HOURS	2020-05-12/10:46	
		4 HOURS	2020-05-12/11:46	
		6 HOURS	2020-05-12/13:46	
		8 HOURS	2020-05-12/15:46	
		12 HOURS	2020-05-12/19:43	
		16 HOURS	2020-05-12/23:46	
	Day 2	PRE DOSE	2020-05-13/07:41	
	Day 3	PRE DOSE	2020-05-14/07:41	
	Day 4	PRE DOSE	2020-05-15/07:41	
	Day 5	PRE DOSE	2020-05-16/07:41	

Listing 16.2.6.1
Pharmacokinetic Sample Collection
Pharmacokinetic Population

Treatment Subject	Visit	Scheduled Time Point	Date/Time of Sampling	Not Done?/Reason
Part B: LB-102 50 mg BID				
01S2055	Day 6	PRE DOSE	2020-05-17/07:41	
	Day 7	PRE DOSE	2020-05-18/07:41	
		15 MINS	2020-05-18/08:01	
		30 MINS	2020-05-18/08:16	
		45 MINS	2020-05-18/08:31	
		1 HOUR	2020-05-18/08:46	
		1.5 HOURS	2020-05-18/09:16	
		2 HOURS	2020-05-18/09:46	
		3 HOURS	2020-05-18/10:46	
		4 HOURS	2020-05-18/11:46	
		6 HOURS	2020-05-18/13:46	
		8 HOURS	2020-05-18/15:46	
		12 HOURS	2020-05-18/19:46	
		16 HOURS	2020-05-18/23:46	
	Day 8	24 HOURS	2020-05-19/07:46	
		32 HOURS	2020-05-19/15:46	
	Day 9	48 HOURS	2020-05-20/07:46	
Part B: LB-102 75 mg BID				
01S2080	Day 1	PRE DOSE	2020-06-23/07:25	
		15 MINS	2020-06-23/07:45	
		30 MINS	2020-06-23/08:00	
		45 MINS	2020-06-23/08:13	
		1 HOUR	2020-06-23/08:35	
		1.5 HOURS	2020-06-23/09:00	

Listing 16.2.6.1
Pharmacokinetic Sample Collection
Pharmacokinetic Population

Treatment Subject	Visit	Scheduled Time Point	Date/Time of Sampling	Not Done?/Reason
Part B: LB-102 75 mg BID				
01S2080	Day 1	2 HOURS	2020-06-23/09:30	
		3 HOURS	2020-06-23/10:30	
		4 HOURS	2020-06-23/11:30	
		6 HOURS	2020-06-23/13:30	
		8 HOURS	2020-06-23/15:30	
		12 HOURS	2020-06-23/19:27	
		16 HOURS	2020-06-23/23:30	
	Day 2	PRE DOSE	2020-06-24/07:25	
	Day 3	PRE DOSE	2020-06-25/07:25	
	Day 4	PRE DOSE	2020-06-26/07:25	
	Day 5	PRE DOSE	2020-06-27/07:25	
	Day 6	PRE DOSE	2020-06-28/07:25	
		15 MINS	2020-06-28/07:45	
		30 MINS	2020-06-28/08:00	
		1 HOUR	2020-06-28/08:30	
		2 HOURS	2020-06-28/09:30	
		4 HOURS	2020-06-28/11:30	
		8 HOURS	2020-06-28/15:30	
		12 HOURS	2020-06-28/19:25	
		12.25 HOURS	2020-06-28/19:45	
		12.5 HOURS	2020-06-28/20:00	
		13 HOURS	2020-06-28/20:30	
		14 HOURS	2020-06-28/21:30	

Listing 16.2.6.1
Pharmacokinetic Sample Collection
Pharmacokinetic Population

Treatment Subject	Visit	Scheduled Time Point	Date/Time of Sampling	Not Done?/Reason
Part B: LB-102 75 mg BID				
01S2080	Day 6	16 HOURS	2020-06-28/23:30	
		18 HOURS	2020-06-29/01:30	
		20 HOURS	2020-06-29/03:30	
	Day 7	PRE DOSE	2020-06-29/07:25	
	Day 8	24 HOURS	2020-06-30/07:30	
		32 HOURS	2020-06-30/15:30	
	Day 9	48 HOURS	2020-07-01/07:30	
01S2087	Day 1	PRE DOSE	2020-06-23/07:31	
		15 MINS	2020-06-23/07:51	
		30 MINS	2020-06-23/08:06	
		45 MINS	2020-06-23/08:19	
		1 HOUR	2020-06-23/08:41	
		1.5 HOURS	2020-06-23/09:06	
		2 HOURS	2020-06-23/09:36	
		3 HOURS	2020-06-23/10:36	
		4 HOURS	2020-06-23/11:36	
		6 HOURS	2020-06-23/13:36	
		8 HOURS	2020-06-23/15:36	
		12 HOURS	2020-06-23/19:33	
		16 HOURS	2020-06-23/23:36	
	Day 2	PRE DOSE	2020-06-24/07:31	

Listing 16.2.6.1
Pharmacokinetic Sample Collection
Pharmacokinetic Population

Treatment Subject	Visit	Scheduled Time Point	Date/Time of Sampling	Not Done?/Reason
Part B: LB-102 75 mg BID				
01S2087	Day 3	PRE DOSE	2020-06-25/07:31	
	Day 4	PRE DOSE	2020-06-26/07:31	
	Day 5	PRE DOSE	2020-06-27/07:31	
	Day 6	PRE DOSE	2020-06-28/07:31	
		15 MINS	2020-06-28/07:51	
		30 MINS	2020-06-28/08:06	
		1 HOUR	2020-06-28/08:36	
		2 HOURS	2020-06-28/09:36	
		4 HOURS	2020-06-28/11:36	
		8 HOURS	2020-06-28/15:36	
		12 HOURS	2020-06-28/19:31	
		12.25 HOURS	2020-06-28/19:51	
		12.5 HOURS	2020-06-28/20:06	
		13 HOURS	2020-06-28/20:36	
		14 HOURS	2020-06-28/21:36	
		16 HOURS	2020-06-28/23:36	
		18 HOURS	2020-06-29/01:36	
		20 HOURS	2020-06-29/03:36	
	Day 7	PRE DOSE	2020-06-29/07:31	
	Day 8	24 HOURS	2020-06-30/07:36	
		32 HOURS	2020-06-30/15:36	
	Day 9	48 HOURS	2020-07-01/07:36	

Listing 16.2.6.1
Pharmacokinetic Sample Collection
Pharmacokinetic Population

Treatment Subject	Visit	Scheduled Time Point	Date/Time of Sampling	Not Done?/Reason
Part B: LB-102 75 mg BID				
01S2092	Day 1	PRE DOSE	2020-06-23/07:33	
		15 MINS	2020-06-23/07:53	
		30 MINS	2020-06-23/08:08	
		45 MINS	2020-06-23/08:21	
		1 HOUR	2020-06-23/08:43	
		1.5 HOURS	2020-06-23/09:08	
		2 HOURS	2020-06-23/09:38	
		3 HOURS	2020-06-23/10:38	
		4 HOURS	2020-06-23/11:38	
		6 HOURS	2020-06-23/13:38	
		8 HOURS	2020-06-23/15:38	
		12 HOURS	2020-06-23/19:35	
		16 HOURS	2020-06-23/23:38	
	Day 2	PRE DOSE	2020-06-24/07:33	
	Day 3	PRE DOSE	2020-06-25/07:33	
	Day 4	PRE DOSE	2020-06-26/07:33	
01S2093	Day 1	PRE DOSE	2020-06-23/07:35	
		15 MINS	2020-06-23/07:55	
		30 MINS	2020-06-23/08:10	
		45 MINS	2020-06-23/08:23	
		1 HOUR	2020-06-23/08:45	
		1.5 HOURS	2020-06-23/09:10	
		2 HOURS	2020-06-23/09:40	

Listing 16.2.6.1
Pharmacokinetic Sample Collection
Pharmacokinetic Population

Treatment Subject	Visit	Scheduled Time Point	Date/Time of Sampling	Not Done?/Reason
Part B: LB-102 75 mg BID				
01S2093	Day 1	3 HOURS	2020-06-23/10:40	
		4 HOURS	2020-06-23/11:40	
		6 HOURS	2020-06-23/13:40	
		8 HOURS	2020-06-23/15:40	
		12 HOURS	2020-06-23/19:37	
		16 HOURS	2020-06-23/23:40	
	Day 2	PRE DOSE	2020-06-24/07:35	
	Day 3	PRE DOSE	2020-06-25/07:35	
	Day 4	PRE DOSE	2020-06-26/07:35	
	Day 5	PRE DOSE	2020-06-27/07:35	
	Day 6	PRE DOSE	2020-06-28/07:35	
		15 MINS	2020-06-28/07:55	
		30 MINS	2020-06-28/08:10	
		1 HOUR	2020-06-28/08:40	
		2 HOURS	2020-06-28/09:40	
		4 HOURS	2020-06-28/11:40	
		8 HOURS	2020-06-28/15:40	
		12 HOURS	2020-06-28/19:35	
		12.25 HOURS	2020-06-28/19:55	
		12.5 HOURS	2020-06-28/20:10	
		13 HOURS	2020-06-28/20:40	
		14 HOURS	2020-06-28/21:40	
		16 HOURS	2020-06-28/23:40	
		18 HOURS	2020-06-29/01:40	

Listing 16.2.6.1
Pharmacokinetic Sample Collection
Pharmacokinetic Population

Treatment Subject	Visit	Scheduled Time Point	Date/Time of Sampling	Not Done?/Reason
Part B: LB-102 75 mg BID				
01S2093	Day 6	20 HOURS	2020-06-29/03:40	
	Day 7	PRE DOSE	2020-06-29/07:35	
	Day 8	24 HOURS	2020-06-30/07:40	
		32 HOURS	2020-06-30/15:40	
	Day 9	48 HOURS	2020-07-01/07:40	
01S2094	Day 1	PRE DOSE	2020-06-23/07:37	
		15 MINS	2020-06-23/07:57	
		30 MINS	2020-06-23/08:12	
		45 MINS	2020-06-23/08:25	
		1 HOUR	2020-06-23/08:47	
		1.5 HOURS	2020-06-23/09:12	
		2 HOURS	2020-06-23/09:42	
		3 HOURS	2020-06-23/10:42	
		4 HOURS	2020-06-23/11:42	
		6 HOURS	2020-06-23/13:42	
		8 HOURS	2020-06-23/15:42	
		12 HOURS	2020-06-23/19:39	
		16 HOURS	2020-06-23/23:42	
	Day 2	PRE DOSE	2020-06-24/07:37	
	Day 3	PRE DOSE	2020-06-25/07:37	

Listing 16.2.6.1
Pharmacokinetic Sample Collection
Pharmacokinetic Population

Treatment Subject	Visit	Scheduled Time Point	Date/Time of Sampling	Not Done?/Reason
Part B: LB-102 75 mg BID				
01S2094	Day 4	PRE DOSE	2020-06-26/07:37	
	Day 5	PRE DOSE	2020-06-27/07:37	
	Day 6	PRE DOSE	2020-06-28/07:37	
		15 MINS	2020-06-28/07:57	
		30 MINS	2020-06-28/08:12	
		1 HOUR	2020-06-28/08:42	
		2 HOURS	2020-06-28/09:42	
		4 HOURS	2020-06-28/11:42	
		8 HOURS	2020-06-28/15:42	
		12 HOURS	2020-06-28/19:37	
		12.25 HOURS	2020-06-28/19:57	
		12.5 HOURS	2020-06-28/20:12	
		13 HOURS	2020-06-28/20:42	
		14 HOURS	2020-06-28/21:42	
		16 HOURS	2020-06-28/23:42	
		18 HOURS	2020-06-29/01:42	
		20 HOURS	2020-06-29/03:42	
	Day 7	PRE DOSE	2020-06-29/07:37	
	Day 8	24 HOURS	2020-06-30/07:42	
		32 HOURS	2020-06-30/15:42	
	Day 9	48 HOURS	2020-07-01/07:42	

Listing 16.2.6.1
Pharmacokinetic Sample Collection
Pharmacokinetic Population

Treatment Subject	Visit	Scheduled Time Point	Date/Time of Sampling	Not Done?/Reason
Part B: LB-102 75 mg BID				
01S2102	Day 1	PRE DOSE	2020-06-23/07:27	
		15 MINS	2020-06-23/07:47	
		30 MINS	2020-06-23/08:02	
		45 MINS	2020-06-23/08:15	
		1 HOUR	2020-06-23/08:37	
		1.5 HOURS	2020-06-23/09:02	
		2 HOURS	2020-06-23/09:32	
		3 HOURS	2020-06-23/10:35	
		4 HOURS	2020-06-23/11:32	
		6 HOURS	2020-06-23/13:32	
		8 HOURS	2020-06-23/15:32	
		12 HOURS	2020-06-23/19:29	
		16 HOURS	2020-06-23/23:32	
	Day 2	PRE DOSE	2020-06-24/07:29	
	Day 3	PRE DOSE	2020-06-25/07:27	
	Day 4	PRE DOSE	2020-06-26/07:27	
	Day 5	PRE DOSE	2020-06-27/07:27	
	Day 6	PRE DOSE	2020-06-28/07:27	
		15 MINS	2020-06-28/07:47	
		30 MINS	2020-06-28/08:02	
		1 HOUR	2020-06-28/08:32	
		2 HOURS	2020-06-28/09:32	
		4 HOURS	2020-06-28/11:32	

Listing 16.2.6.1
Pharmacokinetic Sample Collection
Pharmacokinetic Population

Treatment Subject	Visit	Scheduled Time Point	Date/Time of Sampling	Not Done?/Reason
Part B: LB-102 75 mg BID				
01S2102	Day 6	8 HOURS	2020-06-28/15:32	
		12 HOURS	2020-06-28/19:27	
		12.25 HOURS	2020-06-28/19:47	
		12.5 HOURS	2020-06-28/20:02	
		13 HOURS	2020-06-28/20:32	
		14 HOURS	2020-06-28/21:32	
		16 HOURS	2020-06-28/23:32	
		18 HOURS	2020-06-29/01:32	
		20 HOURS	2020-06-29/03:32	
	Day 7	PRE DOSE	2020-06-29/07:27	
	Day 8	24 HOURS	2020-06-30/07:32	
		32 HOURS	2020-06-30/15:32	
	Day 9	48 HOURS	2020-07-01/07:32	
Part B: LB-102 100 mg BID				
01S2059	Day 1	PRE DOSE	2020-06-02/07:25	
		15 MINS	2020-06-02/07:45	
		30 MINS	2020-06-02/08:00	
		45 MINS	2020-06-02/08:13	
		1 HOUR	2020-06-02/08:35	
		1.5 HOURS	2020-06-02/09:00	
		2 HOURS	2020-06-02/09:30	
		3 HOURS	2020-06-02/10:30	
		4 HOURS	2020-06-02/11:30	
		6 HOURS	2020-06-02/13:30	

Listing 16.2.6.1
Pharmacokinetic Sample Collection
Pharmacokinetic Population

Treatment Subject	Visit	Scheduled Time Point	Date/Time of Sampling	Not Done?/Reason
Part B: LB-102 100 mg BID				
01S2059	Day 1	8 HOURS	2020-06-02/15:30	
		12 HOURS	2020-06-02/19:27	
		16 HOURS	2020-06-02/23:30	
	Day 2	PRE DOSE	2020-06-03/07:25	
	Day 3	PRE DOSE	2020-06-04/07:25	
	Day 4	PRE DOSE	2020-06-05/07:25	
	Day 5	PRE DOSE	2020-06-06/07:25	
01S2066	Day 1	PRE DOSE	2020-06-02/07:31	
		15 MINS	2020-06-02/07:51	
		30 MINS	2020-06-02/08:06	
		45 MINS	2020-06-02/08:20	
		1 HOUR	2020-06-02/08:41	
		1.5 HOURS	2020-06-02/09:06	
		2 HOURS	2020-06-02/09:36	
		3 HOURS	2020-06-02/10:36	
		4 HOURS	2020-06-02/11:36	
		6 HOURS	2020-06-02/13:36	
		8 HOURS	2020-06-02/15:36	
		12 HOURS	2020-06-02/19:33	
		16 HOURS	2020-06-02/23:36	
	Day 2	PRE DOSE	2020-06-03/07:31	

Listing 16.2.6.1
Pharmacokinetic Sample Collection
Pharmacokinetic Population

Treatment Subject	Visit	Scheduled Time Point	Date/Time of Sampling	Not Done?/Reason
Part B: LB-102 100 mg BID				
01S2066	Day 3	PRE DOSE	2020-06-04/07:31	
	Day 4	PRE DOSE	2020-06-05/07:31	
	Day 5	PRE DOSE	2020-06-06/07:31	
01S2069	Day 1	PRE DOSE	2020-06-02/07:35	
		15 MINS	2020-06-02/07:55	
		30 MINS	2020-06-02/08:10	
		45 MINS	2020-06-02/08:23	
		1 HOUR	2020-06-02/08:45	
		1.5 HOURS	2020-06-02/09:10	
		2 HOURS	2020-06-02/09:40	
		3 HOURS	2020-06-02/10:40	
		4 HOURS	2020-06-02/11:40	
		6 HOURS	2020-06-02/13:40	
		8 HOURS	2020-06-02/15:40	
		12 HOURS	2020-06-02/19:37	
		16 HOURS	2020-06-02/23:40	
	Day 2	PRE DOSE	2020-06-03/07:35	
	Day 3	PRE DOSE	2020-06-04/07:48	
01S2076	Day 1	PRE DOSE	2020-06-02/07:47	
		15 MINS	2020-06-02/08:03	

Listing 16.2.6.1
Pharmacokinetic Sample Collection
Pharmacokinetic Population

Treatment Subject	Visit	Scheduled Time Point	Date/Time of Sampling	Not Done?/Reason
Part B: LB-102 100 mg BID				
01S2076	Day 1	30 MINS	2020-06-02/08:18	
		45 MINS	2020-06-02/08:31	
		1 HOUR	2020-06-02/08:53	
		1.5 HOURS	2020-06-02/09:18	
		2 HOURS	2020-06-02/09:48	
		3 HOURS	2020-06-02/10:48	
		4 HOURS	2020-06-02/11:48	
		6 HOURS	2020-06-02/13:48	
		8 HOURS	2020-06-02/15:48	
		12 HOURS	2020-06-02/19:45	
		16 HOURS	2020-06-02/23:48	
	Day 2	PRE DOSE	2020-06-03/07:43	
	Day 3	PRE DOSE	2020-06-04/07:43	
01S2078	Day 1	PRE DOSE	2020-06-02/07:33	
		15 MINS	2020-06-02/07:53	
		30 MINS	2020-06-02/08:08	
		45 MINS	2020-06-02/08:21	
		1 HOUR	2020-06-02/08:43	
		1.5 HOURS	2020-06-02/09:08	
		2 HOURS	2020-06-02/09:38	
		3 HOURS	2020-06-02/10:38	
		4 HOURS	2020-06-02/11:38	
		6 HOURS	2020-06-02/13:38	
		8 HOURS	2020-06-02/15:38	

Listing 16.2.6.1
Pharmacokinetic Sample Collection
Pharmacokinetic Population

Treatment Subject	Visit	Scheduled Time Point	Date/Time of Sampling	Not Done?/Reason
Part B: LB-102 100 mg BID				
01S2078	Day 1	12 HOURS	2020-06-02/19:35	
		16 HOURS	2020-06-02/23:38	
	Day 2	PRE DOSE	2020-06-03/07:33	
	Day 3	PRE DOSE	2020-06-04/07:33	
	Day 4	PRE DOSE	2020-06-05/07:33	
	Day 5	PRE DOSE	2020-06-06/07:33	
01S2079	Day 1	PRE DOSE	2020-06-02/07:30	
		15 MINS	2020-06-02/07:47	
		30 MINS	2020-06-02/08:02	
		45 MINS	2020-06-02/08:15	
		1 HOUR	2020-06-02/08:46	
		1.5 HOURS	2020-06-02/09:02	
		2 HOURS	2020-06-02/09:32	
		3 HOURS	2020-06-02/10:33	
		4 HOURS	2020-06-02/11:32	
		6 HOURS	2020-06-02/13:32	
		8 HOURS	2020-06-02/15:32	
		12 HOURS	2020-06-02/19:29	
		16 HOURS	2020-06-02/23:32	
	Day 2	PRE DOSE	2020-06-03/07:27	
	Day 3	PRE DOSE	2020-06-04/07:27	

Listing 16.2.6.2
Plasma Concentration-Time Profiles by Treatment
Pharmacokinetic Population: Part A (SAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
LB-102 (ng/mL)									
LB-102 10 mg									
01S0029									
Day 1	2020-02-04/08:32	PRE DOSE	2020-02-04/08:27	0	0	BLQ	0	0	
		15 MINS	2020-02-04/08:47	0.25	0	BLQ	0	0	
		30 MINS	2020-02-04/09:02	0.5	0	BLQ	0	0	
		45 MINS	2020-02-04/09:17	0.75	0	2.27	2.27	2.27	
		1 HOUR	2020-02-04/09:32	1	0	6.19	6.19	6.19	
		1.5 HOURS	2020-02-04/10:02	1.5	0	11.8	11.8	11.8	
		2 HOURS	2020-02-04/10:32	2	0	12.5	12.5	12.5	
		3 HOURS	2020-02-04/11:32	3	0	19.3	19.3	19.3	
		4 HOURS	2020-02-04/12:32	4	0	18.6	18.6	18.6	
		6 HOURS	2020-02-04/14:32	6	0	12.9	12.9	12.9	
		8 HOURS	2020-02-04/16:32	8	0	9.38	9.38	9.38	
		12 HOURS	2020-02-04/20:32	12	0	5.43	5.43	5.43	+
		16 HOURS	2020-02-05/00:32	16	0	3.88	3.88	3.88	+
Day 2		24 HOURS	2020-02-05/08:32	24	0	2.88	2.88	2.88	+
		32 HOURS	2020-02-05/16:32	32	0	1.41	1.41	1.41	+
Day 3		48 HOURS	2020-02-06/08:32	48	0	BLQ	0		

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.2
Plasma Concentration-Time Profiles by Treatment
Pharmacokinetic Population: Part A (SAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
LB-102 (ng/mL)									
LB-102 10 mg									
01S0030									
Day 1	2020-02-04/08:34	PRE DOSE	2020-02-04/08:29	0	0	BLQ	0	0	
		15 MINS	2020-02-04/08:49	0.25	0	BLQ	0	0	
		30 MINS	2020-02-04/09:04	0.5	0	22.1	22.1	22.1	
		45 MINS	2020-02-04/09:19	0.75	0	26.6	26.6	26.6	
		1 HOUR	2020-02-04/09:34	1	0	23.1	23.1	23.1	
		1.5 HOURS	2020-02-04/10:04	1.5	0	18.9	18.9	18.9	
		2 HOURS	2020-02-04/10:34	2	0	19.8	19.8	19.8	
		3 HOURS	2020-02-04/11:34	3	0	36.2	36.2	36.2	
		4 HOURS	2020-02-04/12:34	4	0	26.8	26.8	26.8	
		6 HOURS	2020-02-04/14:34	6	0	16.9	16.9	16.9	
		8 HOURS	2020-02-04/16:34	8	0	12.0	12	12	
		12 HOURS	2020-02-04/20:34	12	0	7.67	7.67	7.67	
		16 HOURS	2020-02-05/00:34	16	0	4.65	4.65	4.65	+
Day 2		24 HOURS	2020-02-05/08:34	24	0	3.00	3	3	+
		32 HOURS	2020-02-05/16:34	32	0	1.94	1.94	1.94	+
Day 3		48 HOURS	2020-02-06/08:34	48	0	BLQ	0		

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.2
Plasma Concentration-Time Profiles by Treatment
Pharmacokinetic Population: Part A (SAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
LB-102 (ng/mL)									
LB-102 10 mg									
01S0032									
Day 1	2020-02-04/08:36	PRE DOSE	2020-02-04/08:31	0	0	BLQ	0	0	
		15 MINS	2020-02-04/08:51	0.25	0	BLQ	0	0	
		30 MINS	2020-02-04/09:06	0.5	0	4.79	4.79	4.79	
		45 MINS	2020-02-04/09:21	0.75	0	13.1	13.1	13.1	
		1 HOUR	2020-02-04/09:36	1	0	24.6	24.6	24.6	
		1.5 HOURS	2020-02-04/10:06	1.5	0	30.7	30.7	30.7	
		2 HOURS	2020-02-04/10:36	2	0	34.4	34.4	34.4	
		3 HOURS	2020-02-04/11:36	3	0	39.0	39	39	
		4 HOURS	2020-02-04/12:36	4	0	30.8	30.8	30.8	
		6 HOURS	2020-02-04/14:36	6	0	21.8	21.8	21.8	
		8 HOURS	2020-02-04/16:36	8	0	15.2	15.2	15.2	
		12 HOURS	2020-02-04/20:36	12	0	8.52	8.52	8.52	
		16 HOURS	2020-02-05/00:36	16	0	4.50	4.5	4.5	+
Day 2		24 HOURS	2020-02-05/08:36	24	0	2.20	2.2	2.2	+
		32 HOURS	2020-02-05/16:36	32	0	1.39	1.39	1.39	+
Day 3		48 HOURS	2020-02-06/08:36	48	0	BLQ	0		

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.2
Plasma Concentration-Time Profiles by Treatment
Pharmacokinetic Population: Part A (SAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
LB-102 (ng/mL)									
LB-102 10 mg									
01S0035									
Day 1	2020-02-04/08:38	PRE DOSE	2020-02-04/08:33	0	0	BLQ	0	0	
		15 MINS	2020-02-04/08:53	0.25	0	BLQ	0	0	
		30 MINS	2020-02-04/09:08	0.5	0	BLQ	0	0	
		45 MINS	2020-02-04/09:23	0.75	0	2.61	2.61	2.61	
		1 HOUR	2020-02-04/09:38	1	0	5.40	5.4	5.4	
		1.5 HOURS	2020-02-04/10:08	1.5	0	9.19	9.19	9.19	
		2 HOURS	2020-02-04/10:38	2	0	12.0	12	12	
		3 HOURS	2020-02-04/11:38	3	0	15.3	15.3	15.3	
		4 HOURS	2020-02-04/12:38	4	0	12.4	12.4	12.4	
		6 HOURS	2020-02-04/14:38	6	0	8.78	8.78	8.78	
		8 HOURS	2020-02-04/16:38	8	0	7.90	7.9	7.9	
		12 HOURS	2020-02-04/20:38	12	0	5.42	5.42	5.42	+
		16 HOURS	2020-02-05/00:38	16	0	4.19	4.19	4.19	+
Day 2		24 HOURS	2020-02-05/08:38	24	0	2.99	2.99	2.99	+
		32 HOURS	2020-02-05/16:38	32	0	1.73	1.73	1.73	+
Day 3		48 HOURS	2020-02-06/08:38	48	0	BLQ	0		

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.2
Plasma Concentration-Time Profiles by Treatment
Pharmacokinetic Population: Part A (SAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
LB-102 (ng/mL)									
LB-102 10 mg									
01S0042									
Day 1	2020-02-04/08:44	PRE DOSE	2020-02-04/08:39	0	0	BLQ	0	0	
		15 MINS	2020-02-04/08:59	0.25	0	BLQ	0	0	
		30 MINS	2020-02-04/09:14	0.5	0	BLQ	0	0	
		45 MINS	2020-02-04/09:29	0.75	0	1.98	1.98	1.98	
		1 HOUR	2020-02-04/09:44	1	0	3.33	3.33	3.33	
		1.5 HOURS	2020-02-04/10:14	1.5	0	6.00	6	6	
		2 HOURS	2020-02-04/10:44	2	0	10.1	10.1	10.1	
		3 HOURS	2020-02-04/11:44	3	0	20.3	20.3	20.3	
		4 HOURS	2020-02-04/12:44	4	0	17.4	17.4	17.4	
		6 HOURS	2020-02-04/14:44	6	0	14.2	14.2	14.2	
		8 HOURS	2020-02-04/16:44	8	0	11.4	11.4	11.4	
		12 HOURS	2020-02-04/20:44	12	0	7.87	7.87	7.87	
		16 HOURS	2020-02-05/00:44	16	0	5.30	5.3	5.3	
Day 2		24 HOURS	2020-02-05/08:44	24	0	3.58	3.58	3.58	+
		32 HOURS	2020-02-05/16:44	32	0	2.64	2.64	2.64	+
Day 3		48 HOURS	2020-02-06/08:44	48	0	1.56	1.56	1.56	+

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.2
Plasma Concentration-Time Profiles by Treatment
Pharmacokinetic Population: Part A (SAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
LB-102 (ng/mL)									
LB-102 10 mg									
01S0049									
Day 1	2020-02-04/08:42	PRE DOSE	2020-02-04/08:37	0	0	BLQ	0	0	
		15 MINS	2020-02-04/08:57	0.25	0	BLQ	0	0	
		30 MINS	2020-02-04/09:12	0.5	0	1.16	1.16	1.16	
		45 MINS	2020-02-04/09:27	0.75	0	5.59	5.59	5.59	
		1 HOUR	2020-02-04/09:42	1	0	7.13	7.13	7.13	
		1.5 HOURS	2020-02-04/10:12	1.5	0	6.76	6.76	6.76	
		2 HOURS	2020-02-04/10:42	2	0	7.56	7.56	7.56	
		3 HOURS	2020-02-04/11:42	3	0	14.5	14.5	14.5	
		4 HOURS	2020-02-04/12:42	4	0	10.5	10.5	10.5	
		6 HOURS	2020-02-04/14:42	6	0	8.39	8.39	8.39	
		8 HOURS	2020-02-04/16:42	8	0	6.64	6.64	6.64	
		12 HOURS	2020-02-04/20:42	12	0	3.94	3.94	3.94	
		16 HOURS	2020-02-05/00:42	16	0	2.60	2.6	2.6	+
Day 2		24 HOURS	2020-02-05/08:42	24	0	1.87	1.87	1.87	+
		32 HOURS	2020-02-05/16:42	32	0	1.32	1.32	1.32	+
Day 3		48 HOURS	2020-02-06/08:42	48	0	BLQ	0		

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.2
Plasma Concentration-Time Profiles by Treatment
Pharmacokinetic Population: Part A (SAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
LB-102 (ng/mL)									
LB-102 50 mg									
01S0002									
Day 1	2020-01-21/07:32	PRE DOSE	2020-01-21/07:27	0	0	BLQ	0	0	
		15 MINS	2020-01-21/07:47	0.25	0	9.16	9.16	9.16	
		30 MINS	2020-01-21/08:02	0.5	0	51.3	51.3	51.3	
		45 MINS	2020-01-21/08:17	0.75	0	53.9	53.9	53.9	
		1 HOUR	2020-01-21/08:32	1	0	48.3	48.3	48.3	
		1.5 HOURS	2020-01-21/09:02	1.5	0	49.6	49.6	49.6	
		2 HOURS	2020-01-21/09:32	2	0	75.3	75.3	75.3	
		3 HOURS	2020-01-21/10:32	3	0	153	153	153	
		4 HOURS	2020-01-21/11:32	4	0	138	138	138	
		6 HOURS	2020-01-21/13:32	6	0	111	111	111	
		8 HOURS	2020-01-21/15:32	8	0	82.3	82.3	82.3	
		12 HOURS	2020-01-21/19:32	12	0	51.8	51.8	51.8	
		16 HOURS	2020-01-21/23:32	16	0	32.7	32.7	32.7	+
Day 2		24 HOURS	2020-01-22/07:32	24	0	17.9	17.9	17.9	+
		32 HOURS	2020-01-22/15:41	32.15	0.15	10.2	10.2	10.2	+
Day 3		48 HOURS	2020-01-23/07:32	48	0	4.53	4.53	4.53	+

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.2
Plasma Concentration-Time Profiles by Treatment
Pharmacokinetic Population: Part A (SAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
LB-102 (ng/mL)									
LB-102 50 mg									
01S0003									
Day 1	2020-01-22/07:34	PRE DOSE	2020-01-22/07:29	0	0	BLQ	0	0	
		15 MINS	2020-01-22/07:49	0.25	0	BLQ	0	0	
		30 MINS	2020-01-22/08:04	0.5	0	62.9	62.9	62.9	
		45 MINS	2020-01-22/08:19	0.75	0	67.4	67.4	67.4	
		1 HOUR	2020-01-22/08:34	1	0	80.6	80.6	80.6	
		1.5 HOURS	2020-01-22/09:04	1.5	0	112	112	112	
		2 HOURS	2020-01-22/09:34	2	0	103	103	103	
		3 HOURS	2020-01-22/10:34	3	0	173	173	173	
		4 HOURS	2020-01-22/11:34	4	0	156	156	156	
		6 HOURS	2020-01-22/13:34	6	0	110	110	110	
		8 HOURS	2020-01-22/15:34	8	0	78.2	78.2	78.2	
		12 HOURS	2020-01-22/19:36	12.03	0.03	52.4	52.4	52.4	
		16 HOURS	2020-01-22/23:34	16	0	26.8	26.8	26.8	
Day 2		24 HOURS	2020-01-23/07:34	24	0	10.7	10.7	10.7	+
		32 HOURS	2020-01-23/15:34	32	0	5.01	5.01	5.01	+
Day 3		48 HOURS	2020-01-24/07:34	48	0	1.79	1.79	1.79	+

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.2
Plasma Concentration-Time Profiles by Treatment
Pharmacokinetic Population: Part A (SAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
LB-102 (ng/mL)									
LB-102 50 mg									
01S0004									
Day 1	2020-01-22/07:36	PRE DOSE	2020-01-22/07:31	0	0	BLQ	0	0	
		15 MINS	2020-01-22/07:51	0.25	0	BLQ	0	0	
		30 MINS	2020-01-22/08:06	0.5	0	8.18	8.18	8.18	
		45 MINS	2020-01-22/08:21	0.75	0	49.5	49.5	49.5	
		1 HOUR	2020-01-22/08:36	1	0	70.4	70.4	70.4	
		1.5 HOURS	2020-01-22/09:06	1.5	0	61.9	61.9	61.9	
		2 HOURS	2020-01-22/09:36	2	0	97.3	97.3	97.3	
		3 HOURS	2020-01-22/10:36	3	0	224	224	224	
		4 HOURS	2020-01-22/11:36	4	0	172	172	172	
		6 HOURS	2020-01-22/13:36	6	0	105	105	105	
		8 HOURS	2020-01-22/15:36	8	0	67.2	67.2	67.2	
		12 HOURS	2020-01-22/19:39	12.05	0.05	33.7	33.7	33.7	
		16 HOURS	2020-01-22/23:37	16.02	0.02	20.5	20.5	20.5	+
Day 2		24 HOURS	2020-01-23/07:36	24	0	10.8	10.8	10.8	+
		32 HOURS	2020-01-23/15:36	32	0	6.50	6.5	6.5	+
Day 3		48 HOURS	2020-01-24/07:36	48	0	2.91	2.91	2.91	+

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.2
Plasma Concentration-Time Profiles by Treatment
Pharmacokinetic Population: Part A (SAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
LB-102 (ng/mL)									
LB-102 50 mg									
01S0005									
Day 1	2020-01-22/07:38	PRE DOSE	2020-01-22/07:33	0	0	BLQ	0	0	
		15 MINS	2020-01-22/07:53	0.25	0	BLQ	0	0	
		30 MINS	2020-01-22/08:08	0.5	0	13.5	13.5	13.5	
		45 MINS	2020-01-22/08:23	0.75	0	18.3	18.3	18.3	
		1 HOUR	2020-01-22/08:38	1	0	47.2	47.2	47.2	
		1.5 HOURS	2020-01-22/09:08	1.5	0	53.2	53.2	53.2	
		2 HOURS	2020-01-22/09:38	2	0	57.5	57.5	57.5	
		3 HOURS	2020-01-22/10:38	3	0	91.6	91.6	91.6	
		4 HOURS	2020-01-22/11:38	4	0	143	143	143	
		6 HOURS	2020-01-22/13:38	6	0	102	102	102	
		8 HOURS	2020-01-22/15:38	8	0	77.2	77.2	77.2	
		12 HOURS	2020-01-22/19:38	12	0	40.5	40.5	40.5	
		16 HOURS	2020-01-22/23:38	16	0	25.7	25.7	25.7	+
Day 2		24 HOURS	2020-01-23/07:38	24	0	16.5	16.5	16.5	+
		32 HOURS	2020-01-23/15:38	32	0	12.2	12.2	12.2	+
Day 3		48 HOURS	2020-01-24/07:38	48	0	5.56	5.56	5.56	+

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.2
Plasma Concentration-Time Profiles by Treatment
Pharmacokinetic Population: Part A (SAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
LB-102 (ng/mL)									
LB-102 50 mg									
01S0008									
Day 1	2020-01-22/07:42	PRE DOSE	2020-01-22/07:37	0	0	BLQ	0	0	
		15 MINS	2020-01-22/07:57	0.25	0	1.20	1.2	1.2	
		30 MINS	2020-01-22/08:12	0.5	0	42.3	42.3	42.3	
		45 MINS	2020-01-22/08:27	0.75	0	62.8	62.8	62.8	
		1 HOUR	2020-01-22/08:42	1	0	152	152	152	
		1.5 HOURS	2020-01-22/09:12	1.5	0	70.9	70.9	70.9	
		2 HOURS	2020-01-22/09:42	2	0	252	252	252	
		3 HOURS	2020-01-22/10:42	3	0	201	201	201	
		4 HOURS	2020-01-22/11:42	4	0	159	159	159	
		6 HOURS	2020-01-22/13:42	6	0	99.5	99.5	99.5	
		8 HOURS	2020-01-22/15:42	8	0	70.0	70	70	
		12 HOURS	2020-01-22/19:42	12	0	40.6	40.6	40.6	
		16 HOURS	2020-01-22/23:42	16	0	27.9	27.9	27.9	+
Day 2		24 HOURS	2020-01-23/07:42	24	0	19.1	19.1	19.1	+
		32 HOURS	2020-01-23/15:42	32	0	10.8	10.8	10.8	+
Day 3		48 HOURS	2020-01-24/07:42	48	0	5.27	5.27	5.27	+

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.2
Plasma Concentration-Time Profiles by Treatment
Pharmacokinetic Population: Part A (SAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
LB-102 (ng/mL)									
LB-102 50 mg									
01S0010									
Day 1	2020-01-22/07:44	PRE DOSE	2020-01-22/07:39	0	0	BLQ	0	0	
		15 MINS	2020-01-22/07:59	0.25	0	BLQ	0	0	
		30 MINS	2020-01-22/08:14	0.5	0	24.5	24.5	24.5	
		45 MINS	2020-01-22/08:29	0.75	0	68.3	68.3	68.3	
		1 HOUR	2020-01-22/08:44	1	0	66.3	66.3	66.3	
		1.5 HOURS	2020-01-22/09:14	1.5	0	BLQ	0		
		2 HOURS	2020-01-22/09:44	2	0	55.8	55.8	55.8	
		3 HOURS	2020-01-22/10:44	3	0	111	111	111	
		4 HOURS	2020-01-22/11:44	4	0	111	111	111	
		6 HOURS	2020-01-22/13:44	6	0	82.0	82	82	
		8 HOURS	2020-01-22/15:44	8	0	62.7	62.7	62.7	
		12 HOURS	2020-01-22/19:44	12	0	35.8	35.8	35.8	
		16 HOURS	2020-01-22/23:44	16	0	25.4	25.4	25.4	
Day 2		24 HOURS	2020-01-23/07:44	24	0	14.2	14.2	14.2	+
		32 HOURS	2020-01-23/15:44	32	0	8.73	8.73	8.73	+
Day 3		48 HOURS	2020-01-24/07:44	48	0	3.31	3.31	3.31	+

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.2
Plasma Concentration-Time Profiles by Treatment
Pharmacokinetic Population: Part A (SAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
LB-102 (ng/mL)									
LB-102 100 mg									
01S0056									
Day 1	2020-02-18/07:30	PRE DOSE	2020-02-18/07:25	0	0	BLQ	0	0	
		15 MINS	2020-02-18/07:45	0.25	0	1.59	1.59	1.59	
		30 MINS	2020-02-18/08:00	0.5	0	101	101	101	
		45 MINS	2020-02-18/08:15	0.75	0	262	262	262	
		1 HOUR	2020-02-18/08:30	1	0	245	245	245	
		1.5 HOURS	2020-02-18/09:00	1.5	0	282	282	282	
		2 HOURS	2020-02-18/09:31	2.02	0.02	376	376	376	
		3 HOURS	2020-02-18/10:30	3	0	323	323	323	
		4 HOURS	2020-02-18/11:30	4	0	245	245	245	
		6 HOURS	2020-02-18/13:30	6	0	168	168	168	
		8 HOURS	2020-02-18/15:30	8	0	117	117	117	
		12 HOURS	2020-02-18/19:30	12	0	67.6	67.6	67.6	
		16 HOURS	2020-02-18/23:30	16	0	44.9	44.9	44.9	
Day 2		24 HOURS	2020-02-19/07:30	24	0	24.7	24.7	24.7	+
		32 HOURS	2020-02-19/15:30	32	0	14.0	14	14	+
Day 3		48 HOURS	2020-02-20/07:30	48	0	5.72	5.72	5.72	+

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.2
Plasma Concentration-Time Profiles by Treatment
Pharmacokinetic Population: Part A (SAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
LB-102 (ng/mL)									
LB-102 100 mg									
01S0063									
Day 1	2020-02-18/07:32	PRE DOSE	2020-02-18/07:27	0	0	BLQ	0	0	
		15 MINS	2020-02-18/07:47	0.25	0	BLQ	0	0	
		30 MINS	2020-02-18/08:02	0.5	0	148	148	148	
		45 MINS	2020-02-18/08:17	0.75	0	484	484	484	
		1 HOUR	2020-02-18/08:32	1	0	525	525	525	
		1.5 HOURS	2020-02-18/09:02	1.5	0	468	468	468	
		2 HOURS	2020-02-18/09:33	2.02	0.02	384	384	384	
		3 HOURS	2020-02-18/10:32	3	0	372	372	372	
		4 HOURS	2020-02-18/11:32	4	0	257	257	257	
		6 HOURS	2020-02-18/13:32	6	0	162	162	162	
		8 HOURS	2020-02-18/15:32	8	0	102	102	102	
		12 HOURS	2020-02-18/19:32	12	0	55.2	55.2	55.2	
		16 HOURS	2020-02-18/23:32	16	0	29.9	29.9	29.9	
Day 2		24 HOURS	2020-02-19/07:32	24	0	14.7	14.7	14.7	+
		32 HOURS	2020-02-19/15:32	32	0	9.07	9.07	9.07	+
Day 3		48 HOURS	2020-02-20/07:32	48	0	3.71	3.71	3.71	+

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.2
Plasma Concentration-Time Profiles by Treatment
Pharmacokinetic Population: Part A (SAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
LB-102 (ng/mL)									
LB-102 100 mg									
01S0064									
Day 1	2020-02-18/07:34	PRE DOSE	2020-02-18/07:29	0	0	BLQ	0	0	
		15 MINS	2020-02-18/07:49	0.25	0	BLQ	0	0	
		30 MINS	2020-02-18/08:04	0.5	0	74.5	74.5	74.5	
		45 MINS	2020-02-18/08:19	0.75	0	174	174	174	
		1 HOUR	2020-02-18/08:34	1	0	159	159	159	
		1.5 HOURS	2020-02-18/09:04	1.5	0	233	233	233	
		2 HOURS	2020-02-18/09:34	2	0	214	214	214	
		3 HOURS	2020-02-18/10:34	3	0	292	292	292	
		4 HOURS	2020-02-18/11:34	4	0	307	307	307	
		6 HOURS	2020-02-18/13:34	6	0	175	175	175	
		8 HOURS	2020-02-18/15:34	8	0	118	118	118	
		12 HOURS	2020-02-18/19:34	12	0	71.4	71.4	71.4	
		16 HOURS	2020-02-18/23:34	16	0	51.2	51.2	51.2	
Day 2		24 HOURS	2020-02-19/07:34	24	0	29.8	29.8	29.8	+
		32 HOURS	2020-02-19/15:34	32	0	22.0	22	22	+
Day 3		48 HOURS	2020-02-20/07:34	48	0	13.3	13.3	13.3	+

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.2
Plasma Concentration-Time Profiles by Treatment
Pharmacokinetic Population: Part A (SAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
LB-102 (ng/mL)									
LB-102 100 mg									
01S0071									
Day 1	2020-02-18/07:38	PRE DOSE	2020-02-18/07:33	0	0	BLQ	0	0	
		15 MINS	2020-02-18/07:53	0.25	0	BLQ	0	0	
		30 MINS	2020-02-18/08:08	0.5	0	80.7	80.7	80.7	
		45 MINS	2020-02-18/08:23	0.75	0	173	173	173	
		1 HOUR	2020-02-18/08:38	1	0	247	247	247	
		1.5 HOURS	2020-02-18/09:08	1.5	0	413	413	413	
		2 HOURS	2020-02-18/09:38	2	0	490	490	490	
		3 HOURS	2020-02-18/10:38	3	0	474	474	474	
		4 HOURS	2020-02-18/11:38	4	0	300	300	300	
		6 HOURS	2020-02-18/13:38	6	0	162	162	162	
		8 HOURS	2020-02-18/15:38	8	0	102	102	102	
		12 HOURS	2020-02-18/19:38	12	0	54.3	54.3	54.3	
		16 HOURS	2020-02-18/23:38	16	0	33.2	33.2	33.2	+
Day 2		24 HOURS	2020-02-19/07:38	24	0	19.3	19.3	19.3	+
		32 HOURS	2020-02-19/15:38	32	0	11.4	11.4	11.4	+
Day 3		48 HOURS	2020-02-20/07:38	48	0	3.36	3.36	3.36	+

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.2
Plasma Concentration-Time Profiles by Treatment
Pharmacokinetic Population: Part A (SAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
LB-102 (ng/mL)									
LB-102 100 mg									
01S0073									
Day 1	2020-02-18/07:40	PRE DOSE	2020-02-18/07:35	0	0	BLQ	0	0	
		15 MINS	2020-02-18/07:55	0.25	0	BLQ	0	0	
		30 MINS	2020-02-18/08:10	0.5	0	BLQ	0	0	
		45 MINS	2020-02-18/08:25	0.75	0	BLQ	0	0	
		1 HOUR	2020-02-18/08:40	1	0	4.52	4.52	4.52	
		1.5 HOURS	2020-02-18/09:10	1.5	0	96.4	96.4	96.4	
		2 HOURS	2020-02-18/09:40	2	0	112	112	112	
		3 HOURS	2020-02-18/10:40	3	0	174	174	174	
		4 HOURS	2020-02-18/11:40	4	0	203	203	203	
		6 HOURS	2020-02-18/13:40	6	0	140	140	140	
		8 HOURS	2020-02-18/15:40	8	0	109	109	109	
		12 HOURS	2020-02-18/19:40	12	0	65.5	65.5	65.5	
		16 HOURS	2020-02-18/23:40	16	0	43.4	43.4	43.4	+
Day 2		24 HOURS	2020-02-19/07:40	24	0	26.3	26.3	26.3	+
		32 HOURS	2020-02-19/15:40	32	0	19.1	19.1	19.1	+
Day 3		48 HOURS	2020-02-20/07:40	48	0	9.93	9.93	9.93	+

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.2
Plasma Concentration-Time Profiles by Treatment
Pharmacokinetic Population: Part A (SAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
LB-102 (ng/mL)									
LB-102 100 mg									
01S0074									
Day 1	2020-02-18/07:42	PRE DOSE	2020-02-18/07:37	0	0	BLQ	0	0	
		15 MINS	2020-02-18/07:57	0.25	0	BLQ	0	0	
		30 MINS	2020-02-18/08:12	0.5	0	5.03	5.03	5.03	
		45 MINS	2020-02-18/08:27	0.75	0	17.9	17.9	17.9	
		1 HOUR	2020-02-18/08:42	1	0	17.5	17.5	17.5	
		1.5 HOURS	2020-02-18/09:12	1.5	0	19.5	19.5	19.5	
		2 HOURS	2020-02-18/09:42	2	0	16.7	16.7	16.7	
		3 HOURS	2020-02-18/10:42	3	0	51.0	51	51	
		4 HOURS	2020-02-18/11:42	4	0	188	188	188	
		6 HOURS	2020-02-18/13:42	6	0	120	120	120	
		8 HOURS	2020-02-18/15:42	8	0	89.4	89.4	89.4	
		12 HOURS	2020-02-18/19:42	12	0	58.4	58.4	58.4	
		16 HOURS	2020-02-18/23:42	16	0	42.3	42.3	42.3	+
Day 2		24 HOURS	2020-02-19/07:42	24	0	26.5	26.5	26.5	+
		32 HOURS	2020-02-19/15:42	32	0	18.3	18.3	18.3	+
Day 3		48 HOURS	2020-02-20/07:42	48	0	9.74	9.74	9.74	+

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.2
Plasma Concentration-Time Profiles by Treatment
Pharmacokinetic Population: Part A (SAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
LB-102 (ng/mL)									
LB-102 150 mg									
01S0156									
Day 1	2020-04-18/07:32	PRE DOSE	2020-04-18/07:27	0	0	BLQ	0	0	
		15 MINS	2020-04-18/07:47	0.25	0	4.66	4.66	4.66	
		30 MINS	2020-04-18/08:02	0.5	0	158	158	158	
		45 MINS	2020-04-18/08:15	0.72	-0.03	332	332	332	
		1 HOUR	2020-04-18/08:37	1.08	0.08	445	445	445	
		1.5 HOURS	2020-04-18/09:02	1.5	0	384	384	384	
		2 HOURS	2020-04-18/09:32	2	0	464	464	464	
		3 HOURS	2020-04-18/10:32	3	0	566	566	566	
		4 HOURS	2020-04-18/11:32	4	0	439	439	439	
		6 HOURS	2020-04-18/13:32	6	0	244	244	244	
		8 HOURS	2020-04-18/15:32	8	0	168	168	168	
		12 HOURS	2020-04-18/19:32	12	0	77.2	77.2	77.2	
		16 HOURS	2020-04-18/23:32	16	0	33.6	33.6	33.6	+
Day 2		24 HOURS	2020-04-19/07:32	24	0	17.9	17.9	17.9	+
		32 HOURS	2020-04-19/15:32	32	0	10.9	10.9	10.9	+
Day 3		48 HOURS	2020-04-20/07:32	48	0	5.27	5.27	5.27	+
Day 8		168 HOURS	2020-04-25/08:12	168.67	0.67	BLQ	0		
Day 15		336 HOURS	2020-05-02/07:58	336.43	0.43	BLQ	0		

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.2
Plasma Concentration-Time Profiles by Treatment
Pharmacokinetic Population: Part A (SAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
LB-102 (ng/mL)									
LB-102 150 mg									
01S0157									
Day 1	2020-04-18/07:34	PRE DOSE	2020-04-18/07:29	0	0	BLQ	0	0	
		15 MINS	2020-04-18/07:49	0.25	0	BLQ	0	0	
		30 MINS	2020-04-18/08:04	0.5	0	70.3	70.3	70.3	
		45 MINS	2020-04-18/08:17	0.72	-0.03	226	226	226	
		1 HOUR	2020-04-18/08:39	1.08	0.08	217	217	217	
		1.5 HOURS	2020-04-18/09:04	1.5	0	265	265	265	
		2 HOURS	2020-04-18/09:34	2	0	348	348	348	
		3 HOURS	2020-04-18/10:34	3	0	526	526	526	
		4 HOURS	2020-04-18/11:34	4	0	739	739	739	
		6 HOURS	2020-04-18/13:34	6	0	477	477	477	
		8 HOURS	2020-04-18/15:34	8	0	304	304	304	
		12 HOURS	2020-04-18/19:34	12	0	138	138	138	
		16 HOURS	2020-04-18/23:34	16	0	76.6	76.6	76.6	+
Day 2		24 HOURS	2020-04-19/07:34	24	0	41.6	41.6	41.6	+
		32 HOURS	2020-04-19/15:34	32	0	24.9	24.9	24.9	+
Day 3		48 HOURS	2020-04-20/07:34	48	0	9.84	9.84	9.84	+
Day 8		168 HOURS	2020-04-25/08:50	169.27	1.27	BLQ	0		
Day 15		336 HOURS	2020-05-02/08:12	336.63	0.63	BLQ	0		

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.2
Plasma Concentration-Time Profiles by Treatment
Pharmacokinetic Population: Part A (SAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
LB-102 (ng/mL)									
LB-102 150 mg									
01S0160									
Day 1	2020-04-18/07:36	PRE DOSE	2020-04-18/07:31	0	0	BLQ	0	0	
		15 MINS	2020-04-18/07:51	0.25	0	7.14	7.14	7.14	
		30 MINS	2020-04-18/08:06	0.5	0	250	250	250	
		45 MINS	2020-04-18/08:19	0.72	-0.03	179	179	179	
		1 HOUR	2020-04-18/08:41	1.08	0.08	119	119	119	
		1.5 HOURS	2020-04-18/09:06	1.5	0	261	261	261	
		2 HOURS	2020-04-18/09:36	2	0	539	539	539	
		3 HOURS	2020-04-18/10:36	3	0	653	653	653	
		4 HOURS	2020-04-18/11:36	4	0	502	502	502	
		6 HOURS	2020-04-18/13:36	6	0	307	307	307	
		8 HOURS	2020-04-18/15:36	8	0	213	213	213	
		12 HOURS	2020-04-18/19:36	12	0	130	130	130	
		16 HOURS	2020-04-18/23:36	16	0	80.9	80.9	80.9	+
Day 2		24 HOURS	2020-04-19/07:36	24	0	38.9	38.9	38.9	+
		32 HOURS	2020-04-19/15:36	32	0	20.3	20.3	20.3	+
Day 3		48 HOURS	2020-04-20/07:36	48	0	7.25	7.25	7.25	+
Day 8		168 HOURS	2020-04-25/08:24	168.8	0.8	BLQ	0		
Day 15		336 HOURS	2020-05-02/08:41	337.08	1.08	BLQ	0		

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.2
Plasma Concentration-Time Profiles by Treatment
Pharmacokinetic Population: Part A (SAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
LB-102 (ng/mL)									
LB-102 150 mg									
01S0162									
Day 1	2020-04-18/07:38	PRE DOSE	2020-04-18/07:33	0	0	BLQ	0	0	
		15 MINS	2020-04-18/07:53	0.25	0	BLQ	0	0	
		30 MINS	2020-04-18/08:08	0.5	0	59.0	59	59	
		45 MINS	2020-04-18/08:21	0.72	-0.03	125	125	125	
		1 HOUR	2020-04-18/08:44	1.1	0.1	74.4	74.4	74.4	
		1.5 HOURS	2020-04-18/09:08	1.5	0	142	142	142	
		2 HOURS	2020-04-18/09:38	2	0	397	397	397	
		3 HOURS	2020-04-18/10:38	3	0	555	555	555	
		4 HOURS	2020-04-18/11:38	4	0	413	413	413	
		6 HOURS	2020-04-18/13:38	6	0	299	299	299	
		8 HOURS	2020-04-18/15:38	8	0	211	211	211	
		12 HOURS	2020-04-18/19:38	12	0	124	124	124	
		16 HOURS	2020-04-18/23:38	16	0	74.4	74.4	74.4	+
Day 2		24 HOURS	2020-04-19/07:38	24	0	40.9	40.9	40.9	+
		32 HOURS	2020-04-19/15:38	32	0	26.5	26.5	26.5	+
Day 3		48 HOURS	2020-04-20/07:38	48	0	11.1	11.1	11.1	+
Day 8		168 HOURS	2020-04-25/08:19	168.68	0.68	BLQ	0		
Day 15		336 HOURS	2020-05-02/08:32	336.9	0.9	BLQ	0		

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.2
Plasma Concentration-Time Profiles by Treatment
Pharmacokinetic Population: Part A (SAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
LB-102 (ng/mL)									
LB-102 150 mg									
01S0165									
Day 1	2020-04-18/07:40	PRE DOSE	2020-04-18/07:35	0	0	BLQ	0	0	
		15 MINS	2020-04-18/07:56	0.27	0.02	BLQ	0	0	
		30 MINS	2020-04-18/08:10	0.5	0	1.02	1.02	1.02	
		45 MINS	2020-04-18/08:23	0.72	-0.03	47.2	47.2	47.2	
		1 HOUR	2020-04-18/08:46	1.1	0.1	310	310	310	
		1.5 HOURS	2020-04-18/09:10	1.5	0	493	493	493	
		2 HOURS	2020-04-18/09:43	2.05	0.05	584	584	584	
		3 HOURS	2020-04-18/10:40	3	0	665	665	665	
		4 HOURS	2020-04-18/11:40	4	0	505	505	505	
		6 HOURS	2020-04-18/13:40	6	0	331	331	331	
		8 HOURS	2020-04-18/15:40	8	0	203	203	203	
		12 HOURS	2020-04-18/19:40	12	0	97.8	97.8	97.8	
		16 HOURS	2020-04-18/23:40	16	0	50.4	50.4	50.4	
Day 2		24 HOURS	2020-04-19/07:40	24	0	24.5	24.5	24.5	+
		32 HOURS	2020-04-19/15:40	32	0	18.3	18.3	18.3	+
Day 3		48 HOURS	2020-04-20/07:40	48	0	8.21	8.21	8.21	+
Day 8		168 HOURS	2020-04-25/08:16	168.6	0.6	BLQ	0		
Day 15		336 HOURS	2020-05-02/08:03	336.38	0.38	BLQ	0		

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.2
Plasma Concentration-Time Profiles by Treatment
Pharmacokinetic Population: Part A (SAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
LB-102 (ng/mL)									
LB-102 150 mg									
01S0168									
Day 1	2020-04-18/07:42	PRE DOSE	2020-04-18/07:37	0	0	BLQ	0	0	
		15 MINS	2020-04-18/07:57	0.25	0	4.77	4.77	4.77	
		30 MINS	2020-04-18/08:12	0.5	0	230	230	230	
		45 MINS	2020-04-18/08:25	0.72	-0.03	392	392	392	
		1 HOUR	2020-04-18/08:48	1.1	0.1	315	315	315	
		1.5 HOURS	2020-04-18/09:12	1.5	0	317	317	317	
		2 HOURS	2020-04-18/09:42	2	0	293	293	293	
		3 HOURS	2020-04-18/10:42	3	0	401	401	401	
		4 HOURS	2020-04-18/11:42	4	0	308	308	308	
		6 HOURS	2020-04-18/13:42	6	0	212	212	212	
		8 HOURS	2020-04-18/15:42	8	0	153	153	153	
		12 HOURS	2020-04-18/19:42	12	0	87.3	87.3	87.3	
		16 HOURS	2020-04-18/23:42	16	0	56.3	56.3	56.3	+
Day 2		24 HOURS	2020-04-19/07:42	24	0	30.9	30.9	30.9	+
		32 HOURS	2020-04-19/15:42	32	0	BLQ	0		+
Day 3		48 HOURS	2020-04-20/07:42	48	0	9.17	9.17	9.17	+
Day 8		168 HOURS	2020-04-25/08:28	168.77	0.77	BLQ	0		
Day 15		336 HOURS	2020-05-02/08:06	336.4	0.4	BLQ	0		

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.2
Plasma Concentration-Time Profiles by Treatment
Pharmacokinetic Population: Part A (SAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
LB-102 (ng/mL)									
LB-102 200 mg									
01S0103									
Day 1	2020-03-03/07:36	PRE DOSE	2020-03-03/07:31	0	0	BLQ	0	0	
		15 MINS	2020-03-03/07:51	0.25	0	BLQ	0	0	
		30 MINS	2020-03-03/08:06	0.5	0	32.7	32.7	32.7	
		45 MINS	2020-03-03/08:21	0.75	0	267	267	267	
		1 HOUR	2020-03-03/08:36	1	0	702	702	702	
		1.5 HOURS	2020-03-03/09:06	1.5	0	816	816	816	
		2 HOURS	2020-03-03/09:36	2	0	641	641	641	
		3 HOURS	2020-03-03/10:36	3	0	856	856	856	
		4 HOURS	2020-03-03/11:36	4	0	577	577	577	
		6 HOURS	2020-03-03/13:36	6	0	345	345	345	
		8 HOURS	2020-03-03/15:36	8	0	231	231	231	
		12 HOURS	2020-03-03/19:36	12	0	109	109	109	
		16 HOURS	2020-03-03/23:36	16	0	76.0	76	76	
Day 2		24 HOURS	2020-03-04/07:36	24	0	48.7	48.7	48.7	+
		32 HOURS	2020-03-04/15:36	32	0	25.7	25.7	25.7	+
Day 3		48 HOURS	2020-03-05/07:36	48	0	8.07	8.07	8.07	+

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.2
Plasma Concentration-Time Profiles by Treatment
Pharmacokinetic Population: Part A (SAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
LB-102 (ng/mL)									
LB-102 200 mg									
01S0104									
Day 1	2020-03-03/07:38	PRE DOSE	2020-03-03/07:33	0	0	BLQ	0	0	
		15 MINS	2020-03-03/07:53	0.25	0	2.30	2.3	2.3	
		30 MINS	2020-03-03/08:08	0.5	0	350	350	350	
		45 MINS	2020-03-03/08:23	0.75	0	688	688	688	
		1 HOUR	2020-03-03/08:38	1	0	636	636	636	
		1.5 HOURS	2020-03-03/09:08	1.5	0	569	569	569	
		2 HOURS	2020-03-03/09:38	2	0	738	738	738	
		3 HOURS	2020-03-03/10:38	3	0	737	737	737	
		4 HOURS	2020-03-03/11:38	4	0	520	520	520	
		6 HOURS	2020-03-03/13:38	6	0	351	351	351	
		8 HOURS	2020-03-03/15:38	8	0	243	243	243	
		12 HOURS	2020-03-03/19:38	12	0	152	152	152	
		16 HOURS	2020-03-03/23:38	16	0	104	104	104	+
Day 2		24 HOURS	2020-03-04/07:38	24	0	66.5	66.5	66.5	+
		32 HOURS	2020-03-04/15:38	32	0	41.8	41.8	41.8	+
Day 3		48 HOURS	2020-03-05/07:38	48	0	19.9	19.9	19.9	+

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.2
Plasma Concentration-Time Profiles by Treatment
Pharmacokinetic Population: Part A (SAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
LB-102 (ng/mL)									
LB-102 200 mg									
01S0109									
Day 1	2020-03-03/07:40	PRE DOSE	2020-03-03/07:35	0	0	BLQ	0	0	
		15 MINS	2020-03-03/07:55	0.25	0	BLQ	0	0	
		30 MINS	2020-03-03/08:10	0.5	0	46.3	46.3	46.3	
		45 MINS	2020-03-03/08:25	0.75	0	241	241	241	
		1 HOUR	2020-03-03/08:40	1	0	573	573	573	
		1.5 HOURS	2020-03-03/09:10	1.5	0	899	899	899	
		2 HOURS	2020-03-03/09:40	2	0	637	637	637	
		3 HOURS	2020-03-03/10:40	3	0	794	794	794	
		4 HOURS	2020-03-03/11:40	4	0	605	605	605	
		6 HOURS	2020-03-03/13:40	6	0	419	419	419	
		8 HOURS	2020-03-03/15:40	8	0	289	289	289	
		12 HOURS	2020-03-03/19:40	12	0	172	172	172	
		16 HOURS	2020-03-03/23:40	16	0	108	108	108	+
Day 2		24 HOURS	2020-03-04/07:40	24	0	62.2	62.2	62.2	+
		32 HOURS	2020-03-04/15:40	32	0	43.6	43.6	43.6	+
Day 3		48 HOURS	2020-03-05/07:40	48	0	19.1	19.1	19.1	+

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.2
Plasma Concentration-Time Profiles by Treatment
Pharmacokinetic Population: Part A (SAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
LB-102 (ng/mL)									
LB-102 200 mg									
01S0116									
Day 1	2020-03-03/07:42	PRE DOSE	2020-03-03/07:39	0	0	BLQ	0	0	
		15 MINS	2020-03-03/07:57	0.25	0	4.51	4.51	4.51	
		30 MINS	2020-03-03/08:12	0.5	0	623	623	623	
		45 MINS	2020-03-03/08:27	0.75	0	605	605	605	
		1 HOUR	2020-03-03/08:42	1	0	650	650	650	
		1.5 HOURS	2020-03-03/09:12	1.5	0	1300	1300	1300	
		2 HOURS	2020-03-03/09:42	2	0	1200	1200	1200	
		3 HOURS	2020-03-03/10:42	3	0	878	878	878	
		4 HOURS	2020-03-03/11:42	4	0	615	615	615	
		6 HOURS	2020-03-03/13:42	6	0	356	356	356	
		8 HOURS	2020-03-03/15:42	8	0	203	203	203	
		12 HOURS	2020-03-03/19:42	12	0	95.1	95.1	95.1	
		16 HOURS	2020-03-03/23:42	16	0	55.6	55.6	55.6	+
Day 2		24 HOURS	2020-03-04/07:42	24	0	43.3	43.3	43.3	+
		32 HOURS	2020-03-04/15:42	32	0	33.9	33.9	33.9	+
Day 3		48 HOURS	2020-03-05/07:42	48	0	16.9	16.9	16.9	+

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.2
Plasma Concentration-Time Profiles by Treatment
Pharmacokinetic Population: Part A (SAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
LB-102 (ng/mL)									
LB-102 200 mg									
01S0119									
Day 1	2020-03-03/07:34	PRE DOSE	2020-03-03/07:29	0	0	BLQ	0	0	
		15 MINS	2020-03-03/07:49	0.25	0	14.4	14.4	14.4	
		30 MINS	2020-03-03/08:04	0.5	0	508	508	508	
		45 MINS	2020-03-03/08:19	0.75	0	790	790	790	
		1 HOUR	2020-03-03/08:34	1	0	675	675	675	
		1.5 HOURS	2020-03-03/09:04	1.5	0	1290	1290	1290	
		2 HOURS	2020-03-03/09:34	2	0	1060	1060	1060	
		3 HOURS	2020-03-03/10:34	3	0	984	984	984	
		4 HOURS	2020-03-03/11:34	4	0	749	749	749	
		6 HOURS	2020-03-03/13:34	6	0	483	483	483	
		8 HOURS	2020-03-03/15:34	8	0	304	304	304	
		16 HOURS	2020-03-03/23:34	16	0	105	105	105	+
Day 2		24 HOURS	2020-03-04/07:34	24	0	61.7	61.7	61.7	+
		32 HOURS	2020-03-04/15:34	32	0	29.0	29	29	+
Day 3		48 HOURS	2020-03-05/07:34	48	0	9.04	9.04	9.04	+

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.2
Plasma Concentration-Time Profiles by Treatment
Pharmacokinetic Population: Part A (SAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
LB-102 (ng/mL)									
LB-102 200 mg									
01S0120									
Day 1	2020-03-03/07:46	PRE DOSE	2020-03-03/07:41	0	0	BLQ	0	0	
		15 MINS	2020-03-03/08:01	0.25	0	22.3	22.3	22.3	
		30 MINS	2020-03-03/08:16	0.5	0	545	545	545	
		45 MINS	2020-03-03/08:31	0.75	0	478	478	478	
		1 HOUR	2020-03-03/08:46	1	0	491	491	491	
		1.5 HOURS	2020-03-03/09:16	1.5	0	687	687	687	
		2 HOURS	2020-03-03/09:46	2	0	766	766	766	
		3 HOURS	2020-03-03/10:46	3	0	771	771	771	
		4 HOURS	2020-03-03/11:46	4	0	554	554	554	
		6 HOURS	2020-03-03/13:46	6	0	313	313	313	
		8 HOURS	2020-03-03/15:46	8	0	198	198	198	
		12 HOURS	2020-03-03/19:46	12	0	109	109	109	
		16 HOURS	2020-03-03/23:46	16	0	69.0	69	69	+
Day 2		24 HOURS	2020-03-04/07:46	24	0	51.4	51.4	51.4	+
		32 HOURS	2020-03-04/15:46	32	0	34.4	34.4	34.4	+
Day 3		48 HOURS	2020-03-05/07:46	48	0	15.6	15.6	15.6	+

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.2
Plasma Concentration-Time Profiles by Treatment
Pharmacokinetic Population: Part A (SAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
Amisulpride (ng/mL)									
LB-102 10 mg									
01S0029									
Day 1	2020-02-04/08:32	PRE DOSE	2020-02-04/08:27	0	0	BLQ	0	0	
		15 MINS	2020-02-04/08:47	0.25	0	BLQ	0	0	
		30 MINS	2020-02-04/09:02	0.5	0	BLQ	0	0	
		45 MINS	2020-02-04/09:17	0.75	0	BLQ	0	0	
		1 HOUR	2020-02-04/09:32	1	0	BLQ	0	0	
		1.5 HOURS	2020-02-04/10:02	1.5	0	BLQ	0	0	
		2 HOURS	2020-02-04/10:32	2	0	BLQ	0	0	
		3 HOURS	2020-02-04/11:32	3	0	BLQ	0	0	
		4 HOURS	2020-02-04/12:32	4	0	BLQ	0	0	
		6 HOURS	2020-02-04/14:32	6	0	BLQ	0	0	
		8 HOURS	2020-02-04/16:32	8	0	BLQ	0	0	
		12 HOURS	2020-02-04/20:32	12	0	BLQ	0	0	
		16 HOURS	2020-02-05/00:32	16	0	BLQ	0	0	
Day 2		24 HOURS	2020-02-05/08:32	24	0	BLQ	0	0	
		32 HOURS	2020-02-05/16:32	32	0	BLQ	0	0	
Day 3		48 HOURS	2020-02-06/08:32	48	0	BLQ	0	0	

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.2
Plasma Concentration-Time Profiles by Treatment
Pharmacokinetic Population: Part A (SAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
Amisulpride (ng/mL)									
LB-102 10 mg									
01S0030									
Day 1	2020-02-04/08:34	PRE DOSE	2020-02-04/08:29	0	0	BLQ	0	0	
		15 MINS	2020-02-04/08:49	0.25	0	BLQ	0	0	
		30 MINS	2020-02-04/09:04	0.5	0	BLQ	0	0	
		45 MINS	2020-02-04/09:19	0.75	0	BLQ	0	0	
		1 HOUR	2020-02-04/09:34	1	0	BLQ	0	0	
		1.5 HOURS	2020-02-04/10:04	1.5	0	BLQ	0	0	
		2 HOURS	2020-02-04/10:34	2	0	BLQ	0	0	
		3 HOURS	2020-02-04/11:34	3	0	BLQ	0	0	
		4 HOURS	2020-02-04/12:34	4	0	BLQ	0	0	
		6 HOURS	2020-02-04/14:34	6	0	BLQ	0	0	
		8 HOURS	2020-02-04/16:34	8	0	BLQ	0	0	
		12 HOURS	2020-02-04/20:34	12	0	BLQ	0	0	
		16 HOURS	2020-02-05/00:34	16	0	BLQ	0	0	
Day 2		24 HOURS	2020-02-05/08:34	24	0	BLQ	0	0	
		32 HOURS	2020-02-05/16:34	32	0	BLQ	0	0	
Day 3		48 HOURS	2020-02-06/08:34	48	0	BLQ	0	0	

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.2
Plasma Concentration-Time Profiles by Treatment
Pharmacokinetic Population: Part A (SAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
Amisulpride (ng/mL)									
LB-102 10 mg									
01S0032									
Day 1	2020-02-04/08:36	PRE DOSE	2020-02-04/08:31	0	0	BLQ	0	0	
		15 MINS	2020-02-04/08:51	0.25	0	BLQ	0	0	
		30 MINS	2020-02-04/09:06	0.5	0	BLQ	0	0	
		45 MINS	2020-02-04/09:21	0.75	0	BLQ	0	0	
		1 HOUR	2020-02-04/09:36	1	0	BLQ	0	0	
		1.5 HOURS	2020-02-04/10:06	1.5	0	BLQ	0	0	
		2 HOURS	2020-02-04/10:36	2	0	BLQ	0	0	
		3 HOURS	2020-02-04/11:36	3	0	BLQ	0	0	
		4 HOURS	2020-02-04/12:36	4	0	BLQ	0	0	
		6 HOURS	2020-02-04/14:36	6	0	BLQ	0	0	
		8 HOURS	2020-02-04/16:36	8	0	BLQ	0	0	
		12 HOURS	2020-02-04/20:36	12	0	BLQ	0	0	
		16 HOURS	2020-02-05/00:36	16	0	BLQ	0	0	
Day 2		24 HOURS	2020-02-05/08:36	24	0	BLQ	0	0	
		32 HOURS	2020-02-05/16:36	32	0	BLQ	0	0	
Day 3		48 HOURS	2020-02-06/08:36	48	0	BLQ	0	0	

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.2
Plasma Concentration-Time Profiles by Treatment
Pharmacokinetic Population: Part A (SAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
Amisulpride (ng/mL)									
LB-102 10 mg									
01S0035									
Day 1	2020-02-04/08:38	PRE DOSE	2020-02-04/08:33	0	0	BLQ	0	0	
		15 MINS	2020-02-04/08:53	0.25	0	BLQ	0	0	
		30 MINS	2020-02-04/09:08	0.5	0	BLQ	0	0	
		45 MINS	2020-02-04/09:23	0.75	0	BLQ	0	0	
		1 HOUR	2020-02-04/09:38	1	0	BLQ	0	0	
		1.5 HOURS	2020-02-04/10:08	1.5	0	BLQ	0	0	
		2 HOURS	2020-02-04/10:38	2	0	BLQ	0	0	
		3 HOURS	2020-02-04/11:38	3	0	BLQ	0	0	
		4 HOURS	2020-02-04/12:38	4	0	BLQ	0	0	
		6 HOURS	2020-02-04/14:38	6	0	BLQ	0	0	
		8 HOURS	2020-02-04/16:38	8	0	BLQ	0	0	
		12 HOURS	2020-02-04/20:38	12	0	BLQ	0	0	
		16 HOURS	2020-02-05/00:38	16	0	BLQ	0	0	
Day 2		24 HOURS	2020-02-05/08:38	24	0	BLQ	0	0	
		32 HOURS	2020-02-05/16:38	32	0	BLQ	0	0	
Day 3		48 HOURS	2020-02-06/08:38	48	0	BLQ	0	0	

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.2
Plasma Concentration-Time Profiles by Treatment
Pharmacokinetic Population: Part A (SAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
Amisulpride (ng/mL)									
LB-102 10 mg									
01S0042									
Day 1	2020-02-04/08:44	PRE DOSE	2020-02-04/08:39	0	0	BLQ	0	0	
		15 MINS	2020-02-04/08:59	0.25	0	BLQ	0	0	
		30 MINS	2020-02-04/09:14	0.5	0	BLQ	0	0	
		45 MINS	2020-02-04/09:29	0.75	0	BLQ	0	0	
		1 HOUR	2020-02-04/09:44	1	0	BLQ	0	0	
		1.5 HOURS	2020-02-04/10:14	1.5	0	BLQ	0	0	
		2 HOURS	2020-02-04/10:44	2	0	BLQ	0	0	
		3 HOURS	2020-02-04/11:44	3	0	BLQ	0	0	
		4 HOURS	2020-02-04/12:44	4	0	BLQ	0	0	
		6 HOURS	2020-02-04/14:44	6	0	BLQ	0	0	
		8 HOURS	2020-02-04/16:44	8	0	BLQ	0	0	
		12 HOURS	2020-02-04/20:44	12	0	BLQ	0	0	
		16 HOURS	2020-02-05/00:44	16	0	BLQ	0	0	
Day 2		24 HOURS	2020-02-05/08:44	24	0	BLQ	0	0	
		32 HOURS	2020-02-05/16:44	32	0	BLQ	0	0	
Day 3		48 HOURS	2020-02-06/08:44	48	0	BLQ	0	0	

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.2
Plasma Concentration-Time Profiles by Treatment
Pharmacokinetic Population: Part A (SAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
Amisulpride (ng/mL)									
LB-102 10 mg									
01S0049									
Day 1	2020-02-04/08:42	PRE DOSE	2020-02-04/08:37	0	0	BLQ	0	0	
		15 MINS	2020-02-04/08:57	0.25	0	BLQ	0	0	
		30 MINS	2020-02-04/09:12	0.5	0	BLQ	0	0	
		45 MINS	2020-02-04/09:27	0.75	0	BLQ	0	0	
		1 HOUR	2020-02-04/09:42	1	0	BLQ	0	0	
		1.5 HOURS	2020-02-04/10:12	1.5	0	BLQ	0	0	
		2 HOURS	2020-02-04/10:42	2	0	BLQ	0	0	
		3 HOURS	2020-02-04/11:42	3	0	BLQ	0	0	
		4 HOURS	2020-02-04/12:42	4	0	BLQ	0	0	
		6 HOURS	2020-02-04/14:42	6	0	BLQ	0	0	
		8 HOURS	2020-02-04/16:42	8	0	BLQ	0	0	
		12 HOURS	2020-02-04/20:42	12	0	BLQ	0	0	
		16 HOURS	2020-02-05/00:42	16	0	BLQ	0	0	
Day 2		24 HOURS	2020-02-05/08:42	24	0	BLQ	0	0	
		32 HOURS	2020-02-05/16:42	32	0	BLQ	0	0	
Day 3		48 HOURS	2020-02-06/08:42	48	0	BLQ	0	0	

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.2
Plasma Concentration-Time Profiles by Treatment
Pharmacokinetic Population: Part A (SAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
Amisulpride (ng/mL)									
LB-102 50 mg									
01S0002									
Day 1	2020-01-21/07:32	PRE DOSE	2020-01-21/07:27	0	0	BLQ	0	0	
		15 MINS	2020-01-21/07:47	0.25	0	BLQ	0	0	
		30 MINS	2020-01-21/08:02	0.5	0	BLQ	0	0	
		45 MINS	2020-01-21/08:17	0.75	0	BLQ	0	0	
		1 HOUR	2020-01-21/08:32	1	0	BLQ	0	0	
		1.5 HOURS	2020-01-21/09:02	1.5	0	BLQ	0	0	
		2 HOURS	2020-01-21/09:32	2	0	BLQ	0	0	
		3 HOURS	2020-01-21/10:32	3	0	1.16	1.16	1.16	
		4 HOURS	2020-01-21/11:32	4	0	1.13	1.13	1.13	
		6 HOURS	2020-01-21/13:32	6	0	1.01	1.01	1.01	
		8 HOURS	2020-01-21/15:32	8	0	BLQ	0		
		12 HOURS	2020-01-21/19:32	12	0	BLQ	0		
		16 HOURS	2020-01-21/23:32	16	0	BLQ	0		
Day 2		24 HOURS	2020-01-22/07:32	24	0	BLQ	0		
		32 HOURS	2020-01-22/15:41	32.15	0.15	BLQ	0		
Day 3		48 HOURS	2020-01-23/07:32	48	0	BLQ	0		

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.2
Plasma Concentration-Time Profiles by Treatment
Pharmacokinetic Population: Part A (SAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
Amisulpride (ng/mL)									
LB-102 50 mg									
01S0003									
Day 1	2020-01-22/07:34	PRE DOSE	2020-01-22/07:29	0	0	BLQ	0	0	
		15 MINS	2020-01-22/07:49	0.25	0	BLQ	0	0	
		30 MINS	2020-01-22/08:04	0.5	0	BLQ	0	0	
		45 MINS	2020-01-22/08:19	0.75	0	1.35	1.35	1.35	
		1 HOUR	2020-01-22/08:34	1	0	1.98	1.98	1.98	
		1.5 HOURS	2020-01-22/09:04	1.5	0	2.71	2.71	2.71	
		2 HOURS	2020-01-22/09:34	2	0	2.45	2.45	2.45	
		3 HOURS	2020-01-22/10:34	3	0	3.99	3.99	3.99	
		4 HOURS	2020-01-22/11:34	4	0	3.78	3.78	3.78	
		6 HOURS	2020-01-22/13:34	6	0	2.98	2.98	2.98	+
		8 HOURS	2020-01-22/15:34	8	0	2.13	2.13	2.13	+
		12 HOURS	2020-01-22/19:36	12.03	0.03	1.91	1.91	1.91	+
		16 HOURS	2020-01-22/23:34	16	0	1.13	1.13	1.13	+
Day 2		24 HOURS	2020-01-23/07:34	24	0	BLQ	0		
		32 HOURS	2020-01-23/15:34	32	0	BLQ	0		
Day 3		48 HOURS	2020-01-24/07:34	48	0	BLQ	0		

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.2
Plasma Concentration-Time Profiles by Treatment
Pharmacokinetic Population: Part A (SAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
Amisulpride (ng/mL)									
LB-102 50 mg									
01S0004									
Day 1	2020-01-22/07:36	PRE DOSE	2020-01-22/07:31	0	0	BLQ	0	0	
		15 MINS	2020-01-22/07:51	0.25	0	BLQ	0	0	
		30 MINS	2020-01-22/08:06	0.5	0	BLQ	0	0	
		45 MINS	2020-01-22/08:21	0.75	0	BLQ	0	0	
		1 HOUR	2020-01-22/08:36	1	0	1.80	1.8	1.8	
		1.5 HOURS	2020-01-22/09:06	1.5	0	2.02	2.02	2.02	
		2 HOURS	2020-01-22/09:36	2	0	2.52	2.52	2.52	
		3 HOURS	2020-01-22/10:36	3	0	6.27	6.27	6.27	
		4 HOURS	2020-01-22/11:36	4	0	5.01	5.01	5.01	
		6 HOURS	2020-01-22/13:36	6	0	3.68	3.68	3.68	+
		8 HOURS	2020-01-22/15:36	8	0	2.90	2.9	2.9	+
		12 HOURS	2020-01-22/19:39	12.05	0.05	1.72	1.72	1.72	+
		16 HOURS	2020-01-22/23:37	16.02	0.02	1.26	1.26	1.26	+
Day 2		24 HOURS	2020-01-23/07:36	24	0	BLQ	0		
		32 HOURS	2020-01-23/15:36	32	0	BLQ	0		
Day 3		48 HOURS	2020-01-24/07:36	48	0	BLQ	0		

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.2
Plasma Concentration-Time Profiles by Treatment
Pharmacokinetic Population: Part A (SAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
Amisulpride (ng/mL)									
LB-102 50 mg									
01S0005									
Day 1	2020-01-22/07:38	PRE DOSE	2020-01-22/07:33	0	0	BLQ	0	0	
		15 MINS	2020-01-22/07:53	0.25	0	BLQ	0	0	
		30 MINS	2020-01-22/08:08	0.5	0	BLQ	0	0	
		45 MINS	2020-01-22/08:23	0.75	0	BLQ	0	0	
		1 HOUR	2020-01-22/08:38	1	0	1.15	1.15	1.15	
		1.5 HOURS	2020-01-22/09:08	1.5	0	1.84	1.84	1.84	
		2 HOURS	2020-01-22/09:38	2	0	2.00	2	2	
		3 HOURS	2020-01-22/10:38	3	0	2.63	2.63	2.63	
		4 HOURS	2020-01-22/11:38	4	0	4.54	4.54	4.54	
		6 HOURS	2020-01-22/13:38	6	0	3.52	3.52	3.52	
		8 HOURS	2020-01-22/15:38	8	0	3.09	3.09	3.09	
		12 HOURS	2020-01-22/19:38	12	0	1.96	1.96	1.96	+
		16 HOURS	2020-01-22/23:38	16	0	1.47	1.47	1.47	+
Day 2		24 HOURS	2020-01-23/07:38	24	0	1.01	1.01	1.01	+
		32 HOURS	2020-01-23/15:38	32	0	BLQ	0		
Day 3		48 HOURS	2020-01-24/07:38	48	0	BLQ	0		

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.2
Plasma Concentration-Time Profiles by Treatment
Pharmacokinetic Population: Part A (SAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
Amisulpride (ng/mL)									
LB-102 50 mg									
01S0008									
Day 1	2020-01-22/07:42	PRE DOSE	2020-01-22/07:37	0	0	BLQ	0	0	
		15 MINS	2020-01-22/07:57	0.25	0	BLQ	0	0	
		30 MINS	2020-01-22/08:12	0.5	0	BLQ	0	0	
		45 MINS	2020-01-22/08:27	0.75	0	1.14	1.14	1.14	
		1 HOUR	2020-01-22/08:42	1	0	3.06	3.06	3.06	
		1.5 HOURS	2020-01-22/09:12	1.5	0	1.14	1.14	1.14	
		2 HOURS	2020-01-22/09:42	2	0	7.28	7.28	7.28	
		3 HOURS	2020-01-22/10:42	3	0	5.80	5.8	5.8	
		4 HOURS	2020-01-22/11:42	4	0	5.03	5.03	5.03	
		6 HOURS	2020-01-22/13:42	6	0	3.71	3.71	3.71	
		8 HOURS	2020-01-22/15:42	8	0	2.76	2.76	2.76	+
		12 HOURS	2020-01-22/19:42	12	0	1.89	1.89	1.89	+
		16 HOURS	2020-01-22/23:42	16	0	1.40	1.4	1.4	+
Day 2		24 HOURS	2020-01-23/07:42	24	0	BLQ	0		
		32 HOURS	2020-01-23/15:42	32	0	BLQ	0		
Day 3		48 HOURS	2020-01-24/07:42	48	0	BLQ	0		

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.2
Plasma Concentration-Time Profiles by Treatment
Pharmacokinetic Population: Part A (SAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
Amisulpride (ng/mL)									
LB-102 50 mg									
01S0010									
Day 1	2020-01-22/07:44	PRE DOSE	2020-01-22/07:39	0	0	BLQ	0	0	
		15 MINS	2020-01-22/07:59	0.25	0	BLQ	0	0	
		30 MINS	2020-01-22/08:14	0.5	0	BLQ	0	0	
		45 MINS	2020-01-22/08:29	0.75	0	BLQ	0	0	
		1 HOUR	2020-01-22/08:44	1	0	BLQ	0	0	
		1.5 HOURS	2020-01-22/09:14	1.5	0	BLQ	0	0	
		2 HOURS	2020-01-22/09:44	2	0	1.05	1.05	1.05	
		3 HOURS	2020-01-22/10:44	3	0	1.44	1.44	1.44	
		4 HOURS	2020-01-22/11:44	4	0	1.76	1.76	1.76	
		6 HOURS	2020-01-22/13:44	6	0	1.50	1.5	1.5	
		8 HOURS	2020-01-22/15:44	8	0	1.49	1.49	1.49	
		12 HOURS	2020-01-22/19:44	12	0	BLQ	0		
		16 HOURS	2020-01-22/23:44	16	0	BLQ	0		
Day 2		24 HOURS	2020-01-23/07:44	24	0	BLQ	0		
		32 HOURS	2020-01-23/15:44	32	0	BLQ	0		
Day 3		48 HOURS	2020-01-24/07:44	48	0	BLQ	0		

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.2
Plasma Concentration-Time Profiles by Treatment
Pharmacokinetic Population: Part A (SAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
Amisulpride (ng/mL)									
LB-102 100 mg									
01S0056									
Day 1	2020-02-18/07:30	PRE DOSE	2020-02-18/07:25	0	0	BLQ	0	0	
		15 MINS	2020-02-18/07:45	0.25	0	BLQ	0	0	
		30 MINS	2020-02-18/08:00	0.5	0	BLQ	0	0	
		45 MINS	2020-02-18/08:15	0.75	0	3.94	3.94	3.94	
		1 HOUR	2020-02-18/08:30	1	0	4.90	4.9	4.9	
		1.5 HOURS	2020-02-18/09:00	1.5	0	6.29	6.29	6.29	
		2 HOURS	2020-02-18/09:31	2.02	0.02	8.64	8.64	8.64	
		3 HOURS	2020-02-18/10:30	3	0	7.46	7.46	7.46	
		4 HOURS	2020-02-18/11:30	4	0	5.46	5.46	5.46	
		6 HOURS	2020-02-18/13:30	6	0	4.21	4.21	4.21	
		8 HOURS	2020-02-18/15:30	8	0	3.39	3.39	3.39	+
		12 HOURS	2020-02-18/19:30	12	0	2.59	2.59	2.59	+
		16 HOURS	2020-02-18/23:30	16	0	1.99	1.99	1.99	+
Day 2		24 HOURS	2020-02-19/07:30	24	0	1.32	1.32	1.32	+
		32 HOURS	2020-02-19/15:30	32	0	BLQ	0		
Day 3		48 HOURS	2020-02-20/07:30	48	0	BLQ	0		

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.2
Plasma Concentration-Time Profiles by Treatment
Pharmacokinetic Population: Part A (SAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
Amisulpride (ng/mL)									
LB-102 100 mg									
01S0063									
Day 1	2020-02-18/07:32	PRE DOSE	2020-02-18/07:27	0	0	BLQ	0	0	
		15 MINS	2020-02-18/07:47	0.25	0	BLQ	0	0	
		30 MINS	2020-02-18/08:02	0.5	0	BLQ	0	0	
		45 MINS	2020-02-18/08:17	0.75	0	6.48	6.48	6.48	
		1 HOUR	2020-02-18/08:32	1	0	10.1	10.1	10.1	
		1.5 HOURS	2020-02-18/09:02	1.5	0	10.6	10.6	10.6	
		2 HOURS	2020-02-18/09:33	2.02	0.02	8.89	8.89	8.89	
		3 HOURS	2020-02-18/10:32	3	0	9.79	9.79	9.79	
		4 HOURS	2020-02-18/11:32	4	0	7.90	7.9	7.9	
		6 HOURS	2020-02-18/13:32	6	0	5.57	5.57	5.57	
		8 HOURS	2020-02-18/15:32	8	0	4.09	4.09	4.09	+
		12 HOURS	2020-02-18/19:32	12	0	2.71	2.71	2.71	+
		16 HOURS	2020-02-18/23:32	16	0	1.89	1.89	1.89	+
Day 2		24 HOURS	2020-02-19/07:32	24	0	BLQ	0		
		32 HOURS	2020-02-19/15:32	32	0	BLQ	0		
Day 3		48 HOURS	2020-02-20/07:32	48	0	BLQ	0		

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.2
Plasma Concentration-Time Profiles by Treatment
Pharmacokinetic Population: Part A (SAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
Amisulpride (ng/mL)									
LB-102 100 mg									
01S0064									
Day 1	2020-02-18/07:34	PRE DOSE	2020-02-18/07:29	0	0	BLQ	0	0	
		15 MINS	2020-02-18/07:49	0.25	0	BLQ	0	0	
		30 MINS	2020-02-18/08:04	0.5	0	BLQ	0	0	
		45 MINS	2020-02-18/08:19	0.75	0	2.73	2.73	2.73	
		1 HOUR	2020-02-18/08:34	1	0	3.20	3.2	3.2	
		1.5 HOURS	2020-02-18/09:04	1.5	0	4.85	4.85	4.85	
		2 HOURS	2020-02-18/09:34	2	0	4.76	4.76	4.76	
		3 HOURS	2020-02-18/10:34	3	0	5.28	5.28	5.28	
		4 HOURS	2020-02-18/11:34	4	0	6.28	6.28	6.28	
		6 HOURS	2020-02-18/13:34	6	0	4.44	4.44	4.44	
		8 HOURS	2020-02-18/15:34	8	0	3.36	3.36	3.36	
		12 HOURS	2020-02-18/19:34	12	0	2.45	2.45	2.45	
		16 HOURS	2020-02-18/23:34	16	0	1.84	1.84	1.84	+
Day 2		24 HOURS	2020-02-19/07:34	24	0	1.26	1.26	1.26	+
		32 HOURS	2020-02-19/15:34	32	0	1.03	1.03	1.03	+
Day 3		48 HOURS	2020-02-20/07:34	48	0	BLQ	0		

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.2
Plasma Concentration-Time Profiles by Treatment
Pharmacokinetic Population: Part A (SAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
Amisulpride (ng/mL)									
LB-102 100 mg									
01S0071									
Day 1	2020-02-18/07:38	PRE DOSE	2020-02-18/07:33	0	0	BLQ	0	0	
		15 MINS	2020-02-18/07:53	0.25	0	BLQ	0	0	
		30 MINS	2020-02-18/08:08	0.5	0	BLQ	0	0	
		45 MINS	2020-02-18/08:23	0.75	0	2.48	2.48	2.48	
		1 HOUR	2020-02-18/08:38	1	0	3.85	3.85	3.85	
		1.5 HOURS	2020-02-18/09:08	1.5	0	6.88	6.88	6.88	
		2 HOURS	2020-02-18/09:38	2	0	9.04	9.04	9.04	
		3 HOURS	2020-02-18/10:38	3	0	10.2	10.2	10.2	
		4 HOURS	2020-02-18/11:38	4	0	6.49	6.49	6.49	
		6 HOURS	2020-02-18/13:38	6	0	4.33	4.33	4.33	
		8 HOURS	2020-02-18/15:38	8	0	2.68	2.68	2.68	+
		12 HOURS	2020-02-18/19:38	12	0	1.82	1.82	1.82	+
		16 HOURS	2020-02-18/23:38	16	0	1.38	1.38	1.38	+
Day 2		24 HOURS	2020-02-19/07:38	24	0	BLQ	0		
		32 HOURS	2020-02-19/15:38	32	0	BLQ	0		
Day 3		48 HOURS	2020-02-20/07:38	48	0	BLQ	0		

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.2
Plasma Concentration-Time Profiles by Treatment
Pharmacokinetic Population: Part A (SAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
Amisulpride (ng/mL)									
LB-102 100 mg									
01S0073									
Day 1	2020-02-18/07:40	PRE DOSE	2020-02-18/07:35	0	0	BLQ	0	0	
		15 MINS	2020-02-18/07:55	0.25	0	BLQ	0	0	
		30 MINS	2020-02-18/08:10	0.5	0	BLQ	0	0	
		45 MINS	2020-02-18/08:25	0.75	0	BLQ	0	0	
		1 HOUR	2020-02-18/08:40	1	0	BLQ	0	0	
		1.5 HOURS	2020-02-18/09:10	1.5	0	1.69	1.69	1.69	
		2 HOURS	2020-02-18/09:40	2	0	2.85	2.85	2.85	
		3 HOURS	2020-02-18/10:40	3	0	3.72	3.72	3.72	
		4 HOURS	2020-02-18/11:40	4	0	4.23	4.23	4.23	
		6 HOURS	2020-02-18/13:40	6	0	3.38	3.38	3.38	
		8 HOURS	2020-02-18/15:40	8	0	2.99	2.99	2.99	
		12 HOURS	2020-02-18/19:40	12	0	2.46	2.46	2.46	+
		16 HOURS	2020-02-18/23:40	16	0	1.94	1.94	1.94	+
Day 2		24 HOURS	2020-02-19/07:40	24	0	1.43	1.43	1.43	+
		32 HOURS	2020-02-19/15:40	32	0	BLQ	0		
Day 3		48 HOURS	2020-02-20/07:40	48	0	BLQ	0		

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.2
Plasma Concentration-Time Profiles by Treatment
Pharmacokinetic Population: Part A (SAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
Amisulpride (ng/mL)									
LB-102 100 mg									
01S0074									
Day 1	2020-02-18/07:42	PRE DOSE	2020-02-18/07:37	0	0	BLQ	0	0	
		15 MINS	2020-02-18/07:57	0.25	0	BLQ	0	0	
		30 MINS	2020-02-18/08:12	0.5	0	BLQ	0	0	
		45 MINS	2020-02-18/08:27	0.75	0	BLQ	0	0	
		1 HOUR	2020-02-18/08:42	1	0	BLQ	0	0	
		1.5 HOURS	2020-02-18/09:12	1.5	0	BLQ	0	0	
		2 HOURS	2020-02-18/09:42	2	0	BLQ	0	0	
		3 HOURS	2020-02-18/10:42	3	0	1.38	1.38	1.38	
		4 HOURS	2020-02-18/11:42	4	0	5.94	5.94	5.94	
		6 HOURS	2020-02-18/13:42	6	0	4.24	4.24	4.24	
		8 HOURS	2020-02-18/15:42	8	0	3.33	3.33	3.33	
		12 HOURS	2020-02-18/19:42	12	0	2.73	2.73	2.73	+
		16 HOURS	2020-02-18/23:42	16	0	2.05	2.05	2.05	+
Day 2		24 HOURS	2020-02-19/07:42	24	0	1.72	1.72	1.72	+
		32 HOURS	2020-02-19/15:42	32	0	1.06	1.06	1.06	+
Day 3		48 HOURS	2020-02-20/07:42	48	0	BLQ	0		

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.2
Plasma Concentration-Time Profiles by Treatment
Pharmacokinetic Population: Part A (SAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
Amisulpride (ng/mL)									
LB-102 150 mg									
01S0156									
Day 1	2020-04-18/07:32	PRE DOSE	2020-04-18/07:27	0	0	BLQ	0	0	
		15 MINS	2020-04-18/07:47	0.25	0	BLQ	0	0	
		30 MINS	2020-04-18/08:02	0.5	0	2.60	2.6	2.6	
		45 MINS	2020-04-18/08:15	0.72	-0.03	7.01	7.01	7.01	
		1 HOUR	2020-04-18/08:37	1.08	0.08	13.0	13	13	
		1.5 HOURS	2020-04-18/09:02	1.5	0	12.5	12.5	12.5	
		2 HOURS	2020-04-18/09:32	2	0	12.3	12.3	12.3	
		3 HOURS	2020-04-18/10:32	3	0	16.3	16.3	16.3	
		4 HOURS	2020-04-18/11:32	4	0	13.0	13	13	
		6 HOURS	2020-04-18/13:32	6	0	8.59	8.59	8.59	
		8 HOURS	2020-04-18/15:32	8	0	6.49	6.49	6.49	+
		12 HOURS	2020-04-18/19:32	12	0	3.79	3.79	3.79	+
		16 HOURS	2020-04-18/23:32	16	0	1.89	1.89	1.89	+
Day 2		24 HOURS	2020-04-19/07:32	24	0	1.18	1.18	1.18	+
		32 HOURS	2020-04-19/15:32	32	0	BLQ	0		
Day 3		48 HOURS	2020-04-20/07:32	48	0	BLQ	0		
Day 8		168 HOURS	2020-04-25/08:12	168.67	0.67	BLQ	0		
Day 15		336 HOURS	2020-05-02/07:58	336.43	0.43	BLQ	0		

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.2
Plasma Concentration-Time Profiles by Treatment
Pharmacokinetic Population: Part A (SAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
Amisulpride (ng/mL)									
LB-102 150 mg									
01S0157									
Day 1	2020-04-18/07:34	PRE DOSE	2020-04-18/07:29	0	0	BLQ	0	0	
		15 MINS	2020-04-18/07:49	0.25	0	BLQ	0	0	
		30 MINS	2020-04-18/08:04	0.5	0	BLQ	0	0	
		45 MINS	2020-04-18/08:17	0.72	-0.03	5.50	5.5	5.5	
		1 HOUR	2020-04-18/08:39	1.08	0.08	8.06	8.06	8.06	
		1.5 HOURS	2020-04-18/09:04	1.5	0	9.18	9.18	9.18	
		2 HOURS	2020-04-18/09:34	2	0	11.0	11	11	
		3 HOURS	2020-04-18/10:34	3	0	14.8	14.8	14.8	
		4 HOURS	2020-04-18/11:34	4	0	23.7	23.7	23.7	
		6 HOURS	2020-04-18/13:34	6	0	17.5	17.5	17.5	
		8 HOURS	2020-04-18/15:34	8	0	12.1	12.1	12.1	
		12 HOURS	2020-04-18/19:34	12	0	7.03	7.03	7.03	+
		16 HOURS	2020-04-18/23:34	16	0	4.67	4.67	4.67	+
Day 2		24 HOURS	2020-04-19/07:34	24	0	2.73	2.73	2.73	+
		32 HOURS	2020-04-19/15:34	32	0	1.39	1.39	1.39	+
Day 3		48 HOURS	2020-04-20/07:34	48	0	BLQ	0		
Day 8		168 HOURS	2020-04-25/08:50	169.27	1.27	BLQ	0		
Day 15		336 HOURS	2020-05-02/08:12	336.63	0.63	BLQ	0		

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.2
Plasma Concentration-Time Profiles by Treatment
Pharmacokinetic Population: Part A (SAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
Amisulpride (ng/mL)									
LB-102 150 mg									
01S0160									
Day 1	2020-04-18/07:36	PRE DOSE	2020-04-18/07:31	0	0	BLQ	0	0	
		15 MINS	2020-04-18/07:51	0.25	0	BLQ	0	0	
		30 MINS	2020-04-18/08:06	0.5	0	1.29	1.29	1.29	
		45 MINS	2020-04-18/08:19	0.72	-0.03	2.75	2.75	2.75	
		1 HOUR	2020-04-18/08:41	1.08	0.08	2.09	2.09	2.09	
		1.5 HOURS	2020-04-18/09:06	1.5	0	3.33	3.33	3.33	
		2 HOURS	2020-04-18/09:36	2	0	9.72	9.72	9.72	
		3 HOURS	2020-04-18/10:36	3	0	11.7	11.7	11.7	
		4 HOURS	2020-04-18/11:36	4	0	10.8	10.8	10.8	
		6 HOURS	2020-04-18/13:36	6	0	7.47	7.47	7.47	
		8 HOURS	2020-04-18/15:36	8	0	5.82	5.82	5.82	
		12 HOURS	2020-04-18/19:36	12	0	4.55	4.55	4.55	+
		16 HOURS	2020-04-18/23:36	16	0	3.21	3.21	3.21	+
Day 2		24 HOURS	2020-04-19/07:36	24	0	1.93	1.93	1.93	+
		32 HOURS	2020-04-19/15:36	32	0	1.17	1.17	1.17	+
Day 3		48 HOURS	2020-04-20/07:36	48	0	BLQ	0		
Day 8		168 HOURS	2020-04-25/08:24	168.8	0.8	BLQ	0		
Day 15		336 HOURS	2020-05-02/08:41	337.08	1.08	BLQ	0		

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.2
Plasma Concentration-Time Profiles by Treatment
Pharmacokinetic Population: Part A (SAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
Amisulpride (ng/mL)									
LB-102 150 mg									
01S0162									
Day 1	2020-04-18/07:38	PRE DOSE	2020-04-18/07:33	0	0	BLQ	0	0	
		15 MINS	2020-04-18/07:53	0.25	0	BLQ	0	0	
		30 MINS	2020-04-18/08:08	0.5	0	BLQ	0	0	
		45 MINS	2020-04-18/08:21	0.72	-0.03	2.31	2.31	2.31	
		1 HOUR	2020-04-18/08:44	1.1	0.1	2.11	2.11	2.11	
		1.5 HOURS	2020-04-18/09:08	1.5	0	2.90	2.9	2.9	
		2 HOURS	2020-04-18/09:38	2	0	9.50	9.5	9.5	
		3 HOURS	2020-04-18/10:38	3	0	11.0	11	11	
		4 HOURS	2020-04-18/11:38	4	0	8.80	8.8	8.8	
		6 HOURS	2020-04-18/13:38	6	0	7.36	7.36	7.36	
		8 HOURS	2020-04-18/15:38	8	0	6.39	6.39	6.39	
		12 HOURS	2020-04-18/19:38	12	0	4.40	4.4	4.4	+
		16 HOURS	2020-04-18/23:38	16	0	3.13	3.13	3.13	+
Day 2		24 HOURS	2020-04-19/07:38	24	0	2.07	2.07	2.07	+
		32 HOURS	2020-04-19/15:38	32	0	1.30	1.3	1.3	+
Day 3		48 HOURS	2020-04-20/07:38	48	0	BLQ	0		
Day 8		168 HOURS	2020-04-25/08:19	168.68	0.68	BLQ	0		
Day 15		336 HOURS	2020-05-02/08:32	336.9	0.9	BLQ	0		

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.2
Plasma Concentration-Time Profiles by Treatment
Pharmacokinetic Population: Part A (SAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
Amisulpride (ng/mL)									
LB-102 150 mg									
01S0165									
Day 1	2020-04-18/07:40	PRE DOSE	2020-04-18/07:35	0	0	BLQ	0	0	
		15 MINS	2020-04-18/07:56	0.27	0.02	BLQ	0	0	
		30 MINS	2020-04-18/08:10	0.5	0	BLQ	0	0	
		45 MINS	2020-04-18/08:23	0.72	-0.03	1.26	1.26	1.26	
		1 HOUR	2020-04-18/08:46	1.1	0.1	14.0	14	14	
		1.5 HOURS	2020-04-18/09:10	1.5	0	21.5	21.5	21.5	
		2 HOURS	2020-04-18/09:43	2.05	0.05	30.6	30.6	30.6	
		3 HOURS	2020-04-18/10:40	3	0	28.2	28.2	28.2	
		4 HOURS	2020-04-18/11:40	4	0	24.2	24.2	24.2	
		6 HOURS	2020-04-18/13:40	6	0	19.9	19.9	19.9	
		8 HOURS	2020-04-18/15:40	8	0	14.0	14	14	
		12 HOURS	2020-04-18/19:40	12	0	8.13	8.13	8.13	+
		16 HOURS	2020-04-18/23:40	16	0	4.67	4.67	4.67	+
Day 2		24 HOURS	2020-04-19/07:40	24	0	2.60	2.6	2.6	+
		32 HOURS	2020-04-19/15:40	32	0	1.11	1.11	1.11	+
Day 3		48 HOURS	2020-04-20/07:40	48	0	BLQ	0		
Day 8		168 HOURS	2020-04-25/08:16	168.6	0.6	BLQ	0		
Day 15		336 HOURS	2020-05-02/08:03	336.38	0.38	BLQ	0		

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.2
Plasma Concentration-Time Profiles by Treatment
Pharmacokinetic Population: Part A (SAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
Amisulpride (ng/mL)									
LB-102 150 mg									
01S0168									
Day 1	2020-04-18/07:42	PRE DOSE	2020-04-18/07:37	0	0	BLQ	0	0	
		15 MINS	2020-04-18/07:57	0.25	0	BLQ	0	0	
		30 MINS	2020-04-18/08:12	0.5	0	2.49	2.49	2.49	
		45 MINS	2020-04-18/08:25	0.72	-0.03	8.34	8.34	8.34	
		1 HOUR	2020-04-18/08:48	1.1	0.1	8.44	8.44	8.44	
		1.5 HOURS	2020-04-18/09:12	1.5	0	9.55	9.55	9.55	
		2 HOURS	2020-04-18/09:42	2	0	8.59	8.59	8.59	
		3 HOURS	2020-04-18/10:42	3	0	10.4	10.4	10.4	
		4 HOURS	2020-04-18/11:42	4	0	9.92	9.92	9.92	
		6 HOURS	2020-04-18/13:42	6	0	7.37	7.37	7.37	
		8 HOURS	2020-04-18/15:42	8	0	4.94	4.94	4.94	+
		12 HOURS	2020-04-18/19:42	12	0	3.74	3.74	3.74	+
		16 HOURS	2020-04-18/23:42	16	0	2.79	2.79	2.79	+
Day 2		24 HOURS	2020-04-19/07:42	24	0	1.81	1.81	1.81	+
		32 HOURS	2020-04-19/15:42	32	0	BLQ	0		
Day 3		48 HOURS	2020-04-20/07:42	48	0	BLQ	0		
Day 8		168 HOURS	2020-04-25/08:28	168.77	0.77	BLQ	0		
Day 15		336 HOURS	2020-05-02/08:06	336.4	0.4	BLQ	0		

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.2
Plasma Concentration-Time Profiles by Treatment
Pharmacokinetic Population: Part A (SAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
Amisulpride (ng/mL)									
LB-102 200 mg									
01S0103									
Day 1	2020-03-03/07:36	PRE DOSE	2020-03-03/07:31	0	0	BLQ	0	0	
		15 MINS	2020-03-03/07:51	0.25	0	BLQ	0	0	
		30 MINS	2020-03-03/08:06	0.5	0	BLQ	0	0	
		45 MINS	2020-03-03/08:21	0.75	0	4.78	4.78	4.78	
		1 HOUR	2020-03-03/08:36	1	0	15.2	15.2	15.2	
		1.5 HOURS	2020-03-03/09:06	1.5	0	24.1	24.1	24.1	
		2 HOURS	2020-03-03/09:36	2	0	19.8	19.8	19.8	
		3 HOURS	2020-03-03/10:36	3	0	24.6	24.6	24.6	
		4 HOURS	2020-03-03/11:36	4	0	18.9	18.9	18.9	
		6 HOURS	2020-03-03/13:36	6	0	13.4	13.4	13.4	
		8 HOURS	2020-03-03/15:36	8	0	10.9	10.9	10.9	
		12 HOURS	2020-03-03/19:36	12	0	6.02	6.02	6.02	+
		16 HOURS	2020-03-03/23:36	16	0	4.82	4.82	4.82	+
Day 2		24 HOURS	2020-03-04/07:36	24	0	2.93	2.93	2.93	+
		32 HOURS	2020-03-04/15:36	32	0	1.64	1.64	1.64	+
Day 3		48 HOURS	2020-03-05/07:36	48	0	BLQ	0		

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.2
Plasma Concentration-Time Profiles by Treatment
Pharmacokinetic Population: Part A (SAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
Amisulpride (ng/mL)									
LB-102 200 mg									
01S0104									
Day 1	2020-03-03/07:38	PRE DOSE	2020-03-03/07:33	0	0	BLQ	0	0	
		15 MINS	2020-03-03/07:53	0.25	0	BLQ	0	0	
		30 MINS	2020-03-03/08:08	0.5	0	3.41	3.41	3.41	
		45 MINS	2020-03-03/08:23	0.75	0	17.2	17.2	17.2	
		1 HOUR	2020-03-03/08:38	1	0	17.2	17.2	17.2	
		1.5 HOURS	2020-03-03/09:08	1.5	0	16.4	16.4	16.4	
		2 HOURS	2020-03-03/09:38	2	0	20.2	20.2	20.2	
		3 HOURS	2020-03-03/10:38	3	0	21.9	21.9	21.9	
		4 HOURS	2020-03-03/11:38	4	0	15.8	15.8	15.8	
		6 HOURS	2020-03-03/13:38	6	0	12.3	12.3	12.3	
		8 HOURS	2020-03-03/15:38	8	0	9.51	9.51	9.51	
		12 HOURS	2020-03-03/19:38	12	0	6.95	6.95	6.95	
		16 HOURS	2020-03-03/23:38	16	0	4.86	4.86	4.86	+
Day 2		24 HOURS	2020-03-04/07:38	24	0	3.49	3.49	3.49	+
		32 HOURS	2020-03-04/15:38	32	0	2.28	2.28	2.28	+
Day 3		48 HOURS	2020-03-05/07:38	48	0	1.25	1.25	1.25	+

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.2
Plasma Concentration-Time Profiles by Treatment
Pharmacokinetic Population: Part A (SAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
Amisulpride (ng/mL)									
LB-102 200 mg									
01S0109									
Day 1	2020-03-03/07:40	PRE DOSE	2020-03-03/07:35	0	0	BLQ	0	0	
		15 MINS	2020-03-03/07:55	0.25	0	BLQ	0	0	
		30 MINS	2020-03-03/08:10	0.5	0	BLQ	0	0	
		45 MINS	2020-03-03/08:25	0.75	0	1.37	1.37	1.37	
		1 HOUR	2020-03-03/08:40	1	0	3.62	3.62	3.62	
		1.5 HOURS	2020-03-03/09:10	1.5	0	8.48	8.48	8.48	
		2 HOURS	2020-03-03/09:40	2	0	6.32	6.32	6.32	
		3 HOURS	2020-03-03/10:40	3	0	7.41	7.41	7.41	
		4 HOURS	2020-03-03/11:40	4	0	5.96	5.96	5.96	
		6 HOURS	2020-03-03/13:40	6	0	4.48	4.48	4.48	
		8 HOURS	2020-03-03/15:40	8	0	3.62	3.62	3.62	
		12 HOURS	2020-03-03/19:40	12	0	2.62	2.62	2.62	+
		16 HOURS	2020-03-03/23:40	16	0	1.84	1.84	1.84	+
Day 2		24 HOURS	2020-03-04/07:40	24	0	1.36	1.36	1.36	+
		32 HOURS	2020-03-04/15:40	32	0	BLQ	0		
Day 3		48 HOURS	2020-03-05/07:40	48	0	BLQ	0		

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.2
Plasma Concentration-Time Profiles by Treatment
Pharmacokinetic Population: Part A (SAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
Amisulpride (ng/mL)									
LB-102 200 mg									
01S0116									
Day 1	2020-03-03/07:42	PRE DOSE	2020-03-03/07:39	0	0	BLQ	0	0	
		15 MINS	2020-03-03/07:57	0.25	0	BLQ	0	0	
		30 MINS	2020-03-03/08:12	0.5	0	11.1	11.1	11.1	
		45 MINS	2020-03-03/08:27	0.75	0	37.2	37.2	37.2	
		1 HOUR	2020-03-03/08:42	1	0	34.8	34.8	34.8	
		1.5 HOURS	2020-03-03/09:12	1.5	0	65.1	65.1	65.1	
		2 HOURS	2020-03-03/09:42	2	0	59.9	59.9	59.9	
		3 HOURS	2020-03-03/10:42	3	0	48.3	48.3	48.3	
		4 HOURS	2020-03-03/11:42	4	0	37.4	37.4	37.4	
		6 HOURS	2020-03-03/13:42	6	0	24.0	24	24	
		8 HOURS	2020-03-03/15:42	8	0	13.8	13.8	13.8	
		12 HOURS	2020-03-03/19:42	12	0	7.41	7.41	7.41	
		16 HOURS	2020-03-03/23:42	16	0	4.98	4.98	4.98	+
Day 2		24 HOURS	2020-03-04/07:42	24	0	3.60	3.6	3.6	+
		32 HOURS	2020-03-04/15:42	32	0	2.38	2.38	2.38	+
Day 3		48 HOURS	2020-03-05/07:42	48	0	1.59	1.59	1.59	+

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.2
Plasma Concentration-Time Profiles by Treatment
Pharmacokinetic Population: Part A (SAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
Amisulpride (ng/mL)									
LB-102 200 mg									
01S0119									
Day 1	2020-03-03/07:34	PRE DOSE	2020-03-03/07:29	0	0	BLQ	0	0	
		15 MINS	2020-03-03/07:49	0.25	0	BLQ	0	0	
		30 MINS	2020-03-03/08:04	0.5	0	4.14	4.14	4.14	
		45 MINS	2020-03-03/08:19	0.75	0	12.4	12.4	12.4	
		1 HOUR	2020-03-03/08:34	1	0	15.3	15.3	15.3	
		1.5 HOURS	2020-03-03/09:04	1.5	0	24.2	24.2	24.2	
		2 HOURS	2020-03-03/09:34	2	0	24.6	24.6	24.6	
		3 HOURS	2020-03-03/10:34	3	0	23.8	23.8	23.8	
		4 HOURS	2020-03-03/11:34	4	0	20.3	20.3	20.3	
		6 HOURS	2020-03-03/13:34	6	0	15.5	15.5	15.5	
		8 HOURS	2020-03-03/15:34	8	0	11.2	11.2	11.2	+
		16 HOURS	2020-03-03/23:34	16	0	6.64	6.64	6.64	+
Day 2		24 HOURS	2020-03-04/07:34	24	0	4.61	4.61	4.61	+
		32 HOURS	2020-03-04/15:34	32	0	2.36	2.36	2.36	+
Day 3		48 HOURS	2020-03-05/07:34	48	0	BLQ	0		

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.2
Plasma Concentration-Time Profiles by Treatment
Pharmacokinetic Population: Part A (SAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
Amisulpride (ng/mL)									
LB-102 200 mg									
01S0120									
Day 1	2020-03-03/07:46	PRE DOSE	2020-03-03/07:41	0	0	BLQ	0	0	
		15 MINS	2020-03-03/08:01	0.25	0	BLQ	0	0	
		30 MINS	2020-03-03/08:16	0.5	0	9.80	9.8	9.8	
		45 MINS	2020-03-03/08:31	0.75	0	13.1	13.1	13.1	
		1 HOUR	2020-03-03/08:46	1	0	13.1	13.1	13.1	
		1.5 HOURS	2020-03-03/09:16	1.5	0	17.4	17.4	17.4	
		2 HOURS	2020-03-03/09:46	2	0	21.8	21.8	21.8	
		3 HOURS	2020-03-03/10:46	3	0	21.8	21.8	21.8	
		4 HOURS	2020-03-03/11:46	4	0	17.0	17	17	
		6 HOURS	2020-03-03/13:46	6	0	12.1	12.1	12.1	
		8 HOURS	2020-03-03/15:46	8	0	8.62	8.62	8.62	
		12 HOURS	2020-03-03/19:46	12	0	5.64	5.64	5.64	
		16 HOURS	2020-03-03/23:46	16	0	4.24	4.24	4.24	+
Day 2		24 HOURS	2020-03-04/07:46	24	0	2.88	2.88	2.88	+
		32 HOURS	2020-03-04/15:46	32	0	1.87	1.87	1.87	+
Day 3		48 HOURS	2020-03-05/07:46	48	0	1.05	1.05	1.05	+

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.3
Plasma Concentration-Time Profiles by Treatment
PK Concentration Population: Part B (MAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
LB-102 (ng/mL)									
LB-102 50 mg BID									
01S2032									
Day 1 Dose 1	2020-05-12/07:30	PRE DOSE	2020-05-12/07:25	0	0	BLQ	0	0	
		0.25 HOUR	2020-05-12/07:45	0.25	0	1.40	1.4	1.4	
		0.5 HOUR	2020-05-12/08:00	0.5	0	29.8	29.8	29.8	
		0.75 HOUR	2020-05-12/08:13	0.72	-0.03	51.4	51.4	51.4	
		1 HOUR	2020-05-12/08:35	1.08	0.08	73.5	73.5	73.5	
		1.5 HOURS	2020-05-12/09:00	1.5	0	144	144	144	
		2 HOURS	2020-05-12/09:30	2	0	142	142	142	
		3 HOURS	2020-05-12/10:30	3	0	143	143	143	
		4 HOURS	2020-05-12/11:30	4	0	115	115	115	
		6 HOURS	2020-05-12/13:30	6	0	80.3	80.3	80.3	+
		8 HOURS	2020-05-12/15:30	8	0	56.2	56.2	56.2	+
		12 HOURS	2020-05-12/19:27	11.95	-0.05	26.5	26.5	26.5	+

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Source Data: ADPCMAD SDTM Date: 04AUG2020 16:09
Program Name: List_mad.sas Analysis Date: 24AUG2020 10:23

Listing 16.2.6.3
Plasma Concentration-Time Profiles by Treatment
PK Concentration Population: Part B (MAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
LB-102 (ng/mL)									
LB-102 50 mg BID									
01S2032									
Day 1 Dose 2	2020-05-12/19:30	PRE DOSE	2020-05-12/19:27	0	0	26.5	26.5	26.5	
		4 HOURS	2020-05-12/23:30	4	0	89.5	89.5	89.5	
		12 HOURS	2020-05-13/07:25	11.92	-0.08	33.6	33.6	33.6	
Day 2	2020-05-13/07:30	PRE DOSE	2020-05-13/07:25	0	0	33.6	33.6	33.6	
Day 3	2020-05-14/07:30	PRE DOSE	2020-05-14/07:25	0	0	47.3	47.3	47.3	
Day 4	2020-05-15/07:30	PRE DOSE	2020-05-15/07:25	0	0	49.3	49.3	49.3	
Day 5	2020-05-16/07:30	PRE DOSE	2020-05-16/07:25	0	0	46.7	46.7	46.7	

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Source Data: ADPCMAD SDTM Date: 04AUG2020 16:09
Program Name: List_mad.sas Analysis Date: 24AUG2020 10:23

Listing 16.2.6.3
Plasma Concentration-Time Profiles by Treatment
PK Concentration Population: Part B (MAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
LB-102 (ng/mL)									
LB-102 50 mg BID									
01S2032									
Day 6	2020-05-17/07:30	PRE DOSE	2020-05-17/07:25	0	0	52.9	52.9	52.9	
Day 7	2020-05-18/07:30	PRE DOSE	2020-05-18/07:25	0	0	67.9	67.9	67.9	
		0.25 HOUR	2020-05-18/07:45	0.25	0	62.7	62.7	62.7	
		0.5 HOUR	2020-05-18/08:00	0.5	0	78.8	78.8	78.8	
		0.75 HOUR	2020-05-18/08:15	0.75	0	102	102	102	
		1 HOUR	2020-05-18/08:30	1	0	114	114	114	
		1.5 HOURS	2020-05-18/09:00	1.5	0	143	143	143	
		2 HOURS	2020-05-18/09:30	2	0	197	197	197	
		3 HOURS	2020-05-18/10:30	3	0	220	220	220	
		4 HOURS	2020-05-18/11:30	4	0	172	172	172	
		6 HOURS	2020-05-18/13:30	6	0	121	121	121	
		8 HOURS	2020-05-18/15:30	8	0	96.5	96.5	96.5	
		12 HOURS	2020-05-18/19:30	12	0	56.6	56.6	56.6	
		16 HOURS	2020-05-18/23:30	16	0	32.6	32.6	32.6	
		24 HOURS	2020-05-19/07:30	24	0	17.5	17.5	17.5	+
		32 HOURS	2020-05-19/15:38	32.13	0.13	12.2	12.2	12.2	+
		48 HOURS	2020-05-20/07:30	48	0	7.10	7.1	7.1	+

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.3
Plasma Concentration-Time Profiles by Treatment
PK Concentration Population: Part B (MAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
LB-102 (ng/mL)									
LB-102 50 mg BID									
01S2034									
Day 1 Dose 1	2020-05-12/07:32	PRE DOSE	2020-05-12/07:27	0	0	BLQ	0	0	
		0.25 HOUR	2020-05-12/07:47	0.25	0	BLQ	0	0	
		0.5 HOUR	2020-05-12/08:02	0.5	0	BLQ	0	0	
		0.75 HOUR	2020-05-12/08:15	0.72	-0.03	8.68	8.68	8.68	
		1 HOUR	2020-05-12/08:37	1.08	0.08	29.3	29.3	29.3	
		1.5 HOURS	2020-05-12/09:02	1.5	0	47.4	47.4	47.4	
		2 HOURS	2020-05-12/09:32	2	0	46.5	46.5	46.5	
		3 HOURS	2020-05-12/10:32	3	0	95.8	95.8	95.8	
		4 HOURS	2020-05-12/11:32	4	0	87.3	87.3	87.3	
		6 HOURS	2020-05-12/13:32	6	0	67.8	67.8	67.8	+
		8 HOURS	2020-05-12/15:32	8	0	55.2	55.2	55.2	+
		12 HOURS	2020-05-12/19:29	11.95	-0.05	37.7	37.7	37.7	+

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Source Data: ADPCMAD SDTM Date: 04AUG2020 16:09
Program Name: List_mad.sas Analysis Date: 24AUG2020 10:23

Listing 16.2.6.3
Plasma Concentration-Time Profiles by Treatment
PK Concentration Population: Part B (MAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
LB-102 (ng/mL)									
LB-102 50 mg BID									
01S2034									
Day 1 Dose 2	2020-05-12/19:32	PRE DOSE	2020-05-12/19:29	0	0	37.7	37.7	37.7	
		4 HOURS	2020-05-12/23:32	4	0	103	103	103	
		12 HOURS	2020-05-13/07:27	11.92	-0.08	57.9	57.9	57.9	
Day 2	2020-05-13/07:32	PRE DOSE	2020-05-13/07:27	0	0	57.9	57.9	57.9	
Day 3	2020-05-14/07:32	PRE DOSE	2020-05-14/07:27	0	0	98.8	98.8	98.8	
Day 4	2020-05-15/07:32	PRE DOSE	2020-05-15/07:27	0	0	90.5	90.5	90.5	
Day 5	2020-05-16/07:32	PRE DOSE	2020-05-16/07:27	0	0	89.9	89.9	89.9	

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Source Data: ADPCMAD SDTM Date: 04AUG2020 16:09
Program Name: List_mad.sas Analysis Date: 24AUG2020 10:23

Listing 16.2.6.3
Plasma Concentration-Time Profiles by Treatment
PK Concentration Population: Part B (MAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
LB-102 (ng/mL)									
LB-102 50 mg BID									
01S2034									
Day 6	2020-05-17/07:32	PRE DOSE	2020-05-17/07:27	0	0	87.8	87.8	87.8	
Day 7	2020-05-18/07:32	PRE DOSE	2020-05-18/07:27	0	0	77.8	77.8	77.8	
		0.25 HOUR	2020-05-18/07:47	0.25	0	77.9	77.9	77.9	
		0.5 HOUR	2020-05-18/08:02	0.5	0	79.6	79.6	79.6	
		0.75 HOUR	2020-05-18/08:17	0.75	0	78.6	78.6	78.6	
		1 HOUR	2020-05-18/08:32	1	0	136	136	136	
		1.5 HOURS	2020-05-18/09:02	1.5	0	145	145	145	
		2 HOURS	2020-05-18/09:32	2	0	135	135	135	
		3 HOURS	2020-05-18/10:32	3	0	187	187	187	
		4 HOURS	2020-05-18/11:32	4	0	180	180	180	
		6 HOURS	2020-05-18/13:32	6	0	161	161	161	
		8 HOURS	2020-05-18/15:32	8	0	127	127	127	
		12 HOURS	2020-05-18/19:32	12	0	79.8	79.8	79.8	
		16 HOURS	2020-05-18/23:32	16	0	51.2	51.2	51.2	
		24 HOURS	2020-05-19/07:32	24	0	33.3	33.3	33.3	+
		32 HOURS	2020-05-19/15:39	32.12	0.12	19.1	19.1	19.1	+
		48 HOURS	2020-05-20/07:32	48	0	6.02	6.02	6.02	+

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.3
Plasma Concentration-Time Profiles by Treatment
PK Concentration Population: Part B (MAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
LB-102 (ng/mL)									
LB-102 50 mg BID									
01S2045									
Day 1 Dose 1	2020-05-12/07:36	PRE DOSE	2020-05-12/07:31	0	0	BLQ	0	0	
		0.25 HOUR	2020-05-12/07:51	0.25	0	BLQ	0	0	
		0.5 HOUR	2020-05-12/08:06	0.5	0	9.46	9.46	9.46	
		0.75 HOUR	2020-05-12/08:19	0.72	-0.03	67.1	67.1	67.1	
		1 HOUR	2020-05-12/08:41	1.08	0.08	109	109	109	
		1.5 HOURS	2020-05-12/09:06	1.5	0	98.6	98.6	98.6	
		2 HOURS	2020-05-12/09:36	2	0	96.7	96.7	96.7	
		3 HOURS	2020-05-12/10:36	3	0	104	104	104	
		4 HOURS	2020-05-12/11:36	4	0	73.0	73	73	
		6 HOURS	2020-05-12/13:36	6	0	52.3	52.3	52.3	+
		8 HOURS	2020-05-12/15:36	8	0	41.7	41.7	41.7	+
		12 HOURS	2020-05-12/19:33	11.95	-0.05	26.2	26.2	26.2	+

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.3
Plasma Concentration-Time Profiles by Treatment
PK Concentration Population: Part B (MAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
LB-102 (ng/mL)									
LB-102 50 mg BID									
01S2045									
Day 1 Dose 2	2020-05-12/19:36	PRE DOSE	2020-05-12/19:33	0	0	26.2	26.2	26.2	
		4 HOURS	2020-05-12/23:36	4	0	75.6	75.6	75.6	
		12 HOURS	2020-05-13/07:31	11.92	-0.08	40.0	40	40	
Day 2	2020-05-13/07:36	PRE DOSE	2020-05-13/07:31	0	0	40.0	40	40	
Day 3	2020-05-14/07:36	PRE DOSE	2020-05-14/07:31	0	0	64.3	64.3	64.3	
Day 4	2020-05-15/07:36	PRE DOSE	2020-05-15/07:31	0	0	71.9	71.9	71.9	
Day 5	2020-05-16/07:36	PRE DOSE	2020-05-16/07:31	0	0	72.1	72.1	72.1	

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Source Data: ADPCMAD SDTM Date: 04AUG2020 16:09
Program Name: List_mad.sas Analysis Date: 24AUG2020 10:23

Listing 16.2.6.3
Plasma Concentration-Time Profiles by Treatment
PK Concentration Population: Part B (MAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
LB-102 (ng/mL)									
LB-102 50 mg BID									
01S2045									
Day 6	2020-05-17/07:36	PRE DOSE	2020-05-17/07:31	0	0	60.6	60.6	60.6	
Day 7	2020-05-18/07:36	PRE DOSE	2020-05-18/07:31	0	0	68.9	68.9	68.9	
		0.25 HOUR	2020-05-18/07:51	0.25	0	80.0	80	80	
		0.5 HOUR	2020-05-18/08:06	0.5	0	127	127	127	
		0.75 HOUR	2020-05-18/08:21	0.75	0	142	142	142	
		1 HOUR	2020-05-18/08:36	1	0	160	160	160	
		1.5 HOURS	2020-05-18/09:06	1.5	0	185	185	185	
		2 HOURS	2020-05-18/09:36	2	0	214	214	214	
		3 HOURS	2020-05-18/10:36	3	0	189	189	189	
		4 HOURS	2020-05-18/11:36	4	0	162	162	162	
		6 HOURS	2020-05-18/13:36	6	0	115	115	115	
		8 HOURS	2020-05-18/15:36	8	0	94.1	94.1	94.1	
		12 HOURS	2020-05-18/19:36	12	0	63.5	63.5	63.5	
		16 HOURS	2020-05-18/23:36	16	0	48.2	48.2	48.2	
		24 HOURS	2020-05-19/07:36	24	0	29.2	29.2	29.2	+
		32 HOURS	2020-05-19/15:40	32.07	0.07	19.0	19	19	+
		48 HOURS	2020-05-20/07:36	48	0	9.06	9.06	9.06	+

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.3
Plasma Concentration-Time Profiles by Treatment
PK Concentration Population: Part B (MAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
LB-102 (ng/mL)									
LB-102 50 mg BID									
01S2050									
Day 1 Dose 1	2020-05-12/07:42	PRE DOSE	2020-05-12/07:37	0	0	BLQ	0	0	
		0.25 HOUR	2020-05-12/07:57	0.25	0	2.89	2.89	2.89	
		0.5 HOUR	2020-05-12/08:12	0.5	0	55.0	55	55	
		0.75 HOUR	2020-05-12/08:25	0.72	-0.03	49.8	49.8	49.8	
		1 HOUR	2020-05-12/08:47	1.08	0.08	48.4	48.4	48.4	
		1.5 HOURS	2020-05-12/09:12	1.5	0	73.2	73.2	73.2	
		2 HOURS	2020-05-12/09:42	2	0	126	126	126	
		3 HOURS	2020-05-12/10:42	3	0	130	130	130	
		4 HOURS	2020-05-12/11:42	4	0	110	110	110	
		6 HOURS	2020-05-12/13:42	6	0	77.1	77.1	77.1	+
		8 HOURS	2020-05-12/15:42	8	0	56.2	56.2	56.2	+
		12 HOURS	2020-05-12/19:41	11.98	-0.02	28.1	28.1	28.1	+

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Source Data: ADPCMAD SDTM Date: 04AUG2020 16:09
Program Name: List_mad.sas Analysis Date: 24AUG2020 10:23

Listing 16.2.6.3
Plasma Concentration-Time Profiles by Treatment
PK Concentration Population: Part B (MAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
LB-102 (ng/mL)									
LB-102 50 mg BID									
01S2050									
Day 1 Dose 2	2020-05-12/19:42	PRE DOSE	2020-05-12/19:41	0	0	28.1	28.1	28.1	
		4 HOURS	2020-05-12/23:42	4	0	92.6	92.6	92.6	
		12 HOURS	2020-05-13/07:37	11.92	-0.08	47.4	47.4	47.4	
Day 2	2020-05-13/07:40	PRE DOSE	2020-05-13/07:37	0	0	47.4	47.4	47.4	
Day 3	2020-05-14/07:42	PRE DOSE	2020-05-14/07:37	0	0	58.7	58.7	58.7	
Day 4	2020-05-15/07:42	PRE DOSE	2020-05-15/07:37	0	0	65.5	65.5	65.5	
Day 5	2020-05-16/07:42	PRE DOSE	2020-05-16/07:37	0	0	74.5	74.5	74.5	

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Source Data: ADPCMAD SDTM Date: 04AUG2020 16:09
Program Name: List_mad.sas Analysis Date: 24AUG2020 10:23

Listing 16.2.6.3
Plasma Concentration-Time Profiles by Treatment
PK Concentration Population: Part B (MAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
LB-102 (ng/mL)									
LB-102 50 mg BID									
01S2050									
Day 6	2020-05-17/07:42	PRE DOSE	2020-05-17/07:37	0	0	79.0	79	79	
Day 7	2020-05-18/07:42	PRE DOSE	2020-05-18/07:37	0	0	79.3	79.3	79.3	
		0.25 HOUR	2020-05-18/07:57	0.25	0	131	131	131	
		0.5 HOUR	2020-05-18/08:12	0.5	0	126	126	126	
		0.75 HOUR	2020-05-18/08:27	0.75	0	119	119	119	
		1 HOUR	2020-05-18/08:42	1	0	140	140	140	
		1.5 HOURS	2020-05-18/09:12	1.5	0	177	177	177	
		2 HOURS	2020-05-18/09:42	2	0	261	261	261	
		3 HOURS	2020-05-18/10:42	3	0	231	231	231	
		4 HOURS	2020-05-18/11:42	4	0	193	193	193	
		6 HOURS	2020-05-18/13:42	6	0	127	127	127	
		8 HOURS	2020-05-18/15:42	8	0	103	103	103	
		12 HOURS	2020-05-18/19:42	12	0	67.3	67.3	67.3	
		16 HOURS	2020-05-18/23:42	16	0	50.9	50.9	50.9	
		24 HOURS	2020-05-19/07:42	24	0	33.2	33.2	33.2	+
		32 HOURS	2020-05-19/15:42	32	0	18.3	18.3	18.3	+
		48 HOURS	2020-05-20/07:42	48	0	9.27	9.27	9.27	+

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.3
Plasma Concentration-Time Profiles by Treatment
PK Concentration Population: Part B (MAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
LB-102 (ng/mL)									
LB-102 50 mg BID									
01S2053									
Day 1 Dose 1	2020-05-12/07:44	PRE DOSE	2020-05-12/07:39	0	0	BLQ	0	0	
		0.25 HOUR	2020-05-12/07:59	0.25	0	BLQ	0	0	
		0.5 HOUR	2020-05-12/08:14	0.5	0	11.3	11.3	11.3	
		0.75 HOUR	2020-05-12/08:27	0.72	-0.03	12.1	12.1	12.1	
		1 HOUR	2020-05-12/08:49	1.08	0.08	26.6	26.6	26.6	
		1.5 HOURS	2020-05-12/09:14	1.5	0	67.0	67	67	
		2 HOURS	2020-05-12/09:44	2	0	98.3	98.3	98.3	
		3 HOURS	2020-05-12/10:44	3	0	117	117	117	
		4 HOURS	2020-05-12/11:44	4	0	102	102	102	
		6 HOURS	2020-05-12/13:44	6	0	72.6	72.6	72.6	+
		8 HOURS	2020-05-12/15:44	8	0	45.6	45.6	45.6	+
		12 HOURS	2020-05-12/19:41	11.95	-0.05	26.6	26.6	26.6	+

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.3
Plasma Concentration-Time Profiles by Treatment
PK Concentration Population: Part B (MAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
LB-102 (ng/mL)									
LB-102 50 mg BID									
01S2053									
Day 1 Dose 2	2020-05-12/19:44	PRE DOSE	2020-05-12/19:41	0	0	26.6	26.6	26.6	
		4 HOURS	2020-05-12/23:44	4	0	82.3	82.3	82.3	
		12 HOURS	2020-05-13/07:39	11.92	-0.08	40.0	40	40	
Day 2	2020-05-13/07:42	PRE DOSE	2020-05-13/07:39	0	0	40.0	40	40	
Day 3	2020-05-14/07:44	PRE DOSE	2020-05-14/07:39	0	0	53.9	53.9	53.9	
Day 4	2020-05-15/07:44	PRE DOSE	2020-05-15/07:39	0	0	50.0	50	50	
Day 5	2020-05-16/07:44	PRE DOSE	2020-05-16/07:39	0	0	59.9	59.9	59.9	

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.3
Plasma Concentration-Time Profiles by Treatment
PK Concentration Population: Part B (MAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
LB-102 (ng/mL)									
LB-102 50 mg BID									
01S2053									
Day 6	2020-05-17/07:44	PRE DOSE	2020-05-17/07:39	0	0	64.0	64	64	
Day 7	2020-05-18/07:44	PRE DOSE	2020-05-18/07:39	0	0	63.2	63.2	63.2	
		0.25 HOUR	2020-05-18/07:59	0.25	0	65.3	65.3	65.3	
		0.5 HOUR	2020-05-18/08:14	0.5	0	70.4	70.4	70.4	
		0.75 HOUR	2020-05-18/08:29	0.75	0	94.7	94.7	94.7	
		1 HOUR	2020-05-18/08:44	1	0	91.9	91.9	91.9	
		1.5 HOURS	2020-05-18/09:14	1.5	0	109	109	109	
		2 HOURS	2020-05-18/09:44	2	0	124	124	124	
		3 HOURS	2020-05-18/10:44	3	0	181	181	181	
		4 HOURS	2020-05-18/11:44	4	0	152	152	152	
		6 HOURS	2020-05-18/13:44	6	0	122	122	122	
		8 HOURS	2020-05-18/15:44	8	0	91.2	91.2	91.2	
		12 HOURS	2020-05-18/19:44	12	0	57.0	57	57	
		16 HOURS	2020-05-18/23:44	16	0	34.1	34.1	34.1	
		24 HOURS	2020-05-19/07:44	24	0	19.3	19.3	19.3	+
		32 HOURS	2020-05-19/15:44	32	0	10.8	10.8	10.8	+
		48 HOURS	2020-05-20/07:44	48	0	4.25	4.25	4.25	+

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.3
Plasma Concentration-Time Profiles by Treatment
PK Concentration Population: Part B (MAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
LB-102 (ng/mL)									
LB-102 50 mg BID									
01S2055									
Day 1 Dose 1	2020-05-12/07:46	PRE DOSE	2020-05-12/07:41	0	0	BLQ	0	0	
		0.25 HOUR	2020-05-12/08:01	0.25	0	BLQ	0	0	
		0.5 HOUR	2020-05-12/08:16	0.5	0	31.1	31.1	31.1	
		0.75 HOUR	2020-05-12/08:29	0.72	-0.03	136	136	136	
		1 HOUR	2020-05-12/08:51	1.08	0.08	133	133	133	
		1.5 HOURS	2020-05-12/09:16	1.5	0	132	132	132	
		2 HOURS	2020-05-12/09:46	2	0	157	157	157	
		3 HOURS	2020-05-12/10:46	3	0	137	137	137	
		4 HOURS	2020-05-12/11:46	4	0	118	118	118	
		6 HOURS	2020-05-12/13:46	6	0	69.9	69.9	69.9	+
		8 HOURS	2020-05-12/15:46	8	0	49.4	49.4	49.4	+
		12 HOURS	2020-05-12/19:43	11.95	-0.05	28.6	28.6	28.6	+

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Source Data: ADPCMAD SDTM Date: 04AUG2020 16:09
Program Name: List_mad.sas Analysis Date: 24AUG2020 10:23

Listing 16.2.6.3
Plasma Concentration-Time Profiles by Treatment
PK Concentration Population: Part B (MAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
LB-102 (ng/mL)									
LB-102 50 mg BID									
01S2055									
Day 1 Dose 2	2020-05-12/19:46	PRE DOSE	2020-05-12/19:43	0	0	28.6	28.6	28.6	
		4 HOURS	2020-05-12/23:46	4	0	122	122	122	
		12 HOURS	2020-05-13/07:41	11.92	-0.08	49.0	49	49	
Day 2	2020-05-13/07:46	PRE DOSE	2020-05-13/07:41	0	0	49.0	49	49	
Day 3	2020-05-14/07:46	PRE DOSE	2020-05-14/07:41	0	0	63.9	63.9	63.9	
Day 4	2020-05-15/07:46	PRE DOSE	2020-05-15/07:41	0	0	79.3	79.3	79.3	
Day 5	2020-05-16/07:46	PRE DOSE	2020-05-16/07:41	0	0	66.0	66	66	

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Source Data: ADPCMAD SDTM Date: 04AUG2020 16:09
Program Name: List_mad.sas Analysis Date: 24AUG2020 10:23

Listing 16.2.6.3
Plasma Concentration-Time Profiles by Treatment
PK Concentration Population: Part B (MAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
LB-102 (ng/mL)									
LB-102 50 mg BID									
01S2055									
Day 6	2020-05-17/07:46	PRE DOSE	2020-05-17/07:41	0	0	81.4	81.4	81.4	
Day 7	2020-05-18/07:46	PRE DOSE	2020-05-18/07:41	0	0	59.2	59.2	59.2	
		0.25 HOUR	2020-05-18/08:01	0.25	0	63.0	63	63	
		0.5 HOUR	2020-05-18/08:16	0.5	0	85.6	85.6	85.6	
		0.75 HOUR	2020-05-18/08:31	0.75	0	187	187	187	
		1 HOUR	2020-05-18/08:46	1	0	281	281	281	
		1.5 HOURS	2020-05-18/09:16	1.5	0	261	261	261	
		2 HOURS	2020-05-18/09:46	2	0	255	255	255	
		3 HOURS	2020-05-18/10:46	3	0	195	195	195	
		4 HOURS	2020-05-18/11:46	4	0	148	148	148	
		6 HOURS	2020-05-18/13:46	6	0	109	109	109	
		8 HOURS	2020-05-18/15:46	8	0	84.3	84.3	84.3	
		12 HOURS	2020-05-18/19:46	12	0	50.1	50.1	50.1	
		16 HOURS	2020-05-18/23:46	16	0	34.5	34.5	34.5	
		24 HOURS	2020-05-19/07:46	24	0	27.0	27	27	+
		32 HOURS	2020-05-19/15:46	32	0	20.4	20.4	20.4	+
		48 HOURS	2020-05-20/07:46	48	0	11.1	11.1	11.1	+

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.3
Plasma Concentration-Time Profiles by Treatment
PK Concentration Population: Part B (MAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
LB-102 (ng/mL)									
LB-102 75 mg BID									
01S2080									
Day 1 Dose 1	2020-06-23/07:30	PRE DOSE	2020-06-23/07:25	0	0	BLQ	0	0	
		0.25 HOUR	2020-06-23/07:45	0.25	0	3.35	3.35	3.35	
		0.5 HOUR	2020-06-23/08:00	0.5	0	138	138	138	
		0.75 HOUR	2020-06-23/08:13	0.72	-0.03	264	264	264	
		1 HOUR	2020-06-23/08:35	1.08	0.08	263	263	263	
		1.5 HOURS	2020-06-23/09:00	1.5	0	289	289	289	
		2 HOURS	2020-06-23/09:30	2	0	278	278	278	
		3 HOURS	2020-06-23/10:30	3	0	314	314	314	
		4 HOURS	2020-06-23/11:30	4	0	270	270	270	
		6 HOURS	2020-06-23/13:30	6	0	160	160	160	+
		8 HOURS	2020-06-23/15:30	8	0	98.8	98.8	98.8	+
		12 HOURS	2020-06-23/19:27	11.95	-0.05	53.2	53.2	53.2	+

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.3
Plasma Concentration-Time Profiles by Treatment
PK Concentration Population: Part B (MAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
LB-102 (ng/mL)									
LB-102 75 mg BID									
01S2080									
Day 1 Dose 2	2020-06-23/19:30	PRE DOSE	2020-06-23/19:27	0	0	53.2	53.2	53.2	
		4 HOURS	2020-06-23/23:30	4	0	289	289	289	
		12 HOURS	2020-06-24/07:25	11.92	-0.08	96.5	96.5	96.5	
Day 2	2020-06-24/07:30	PRE DOSE	2020-06-24/07:25	0	0	96.5	96.5	96.5	
Day 3	2020-06-25/07:30	PRE DOSE	2020-06-25/07:25	0	0	164	164	164	
Day 4	2020-06-26/07:30	PRE DOSE	2020-06-26/07:25	0	0	181	181	181	
Day 5	2020-06-27/07:30	PRE DOSE	2020-06-27/07:25	0	0	172	172	172	

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Source Data: ADPCMAD SDTM Date: 04AUG2020 16:09
Program Name: List_mad.sas Analysis Date: 24AUG2020 10:23

Listing 16.2.6.3
Plasma Concentration-Time Profiles by Treatment
PK Concentration Population: Part B (MAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
LB-102 (ng/mL)									
LB-102 75 mg BID									
01S2080									
Day 6 Dose 1	2020-06-28/07:30	PRE DOSE	2020-06-28/07:25	0	0	152	152	152	
		0.25 HOUR	2020-06-28/07:45	0.25	0	139	139	139	
		0.5 HOUR	2020-06-28/08:00	0.5	0	230	230	230	
		1 HOUR	2020-06-28/08:30	1	0	458	458	458	
		2 HOURS	2020-06-28/09:30	2	0	511	511	511	
		4 HOURS	2020-06-28/11:30	4	0	331	331	331	
		8 HOURS	2020-06-28/15:30	8	0	199	199	199	
		12 HOURS	2020-06-28/19:25	11.92	-0.08	129	129	129	
Day 6 Dose 2	2020-06-28/19:30	PRE DOSE	2020-06-28/19:25	0	0	129	129	129	
		0.25 HOUR	2020-06-28/19:45	0.25	0	128	128	128	
		0.5 HOUR	2020-06-28/20:00	0.5	0	134	134	134	
		1 HOUR	2020-06-28/20:30	1	0	385	385	385	
		2 HOURS	2020-06-28/21:30	2	0	568	568	568	
		4 HOURS	2020-06-28/23:30	4	0	379	379	379	
		6 HOURS	2020-06-29/01:30	6	0	273	273	273	+
		8 HOURS	2020-06-29/03:30	8	0	230	230	230	+
		12 HOURS	2020-06-29/07:25	11.92	-0.08	154	154	154	+

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.3
Plasma Concentration-Time Profiles by Treatment
PK Concentration Population: Part B (MAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
LB-102 (ng/mL)									
LB-102 75 mg BID									
01S2080									
Day 7	2020-06-29/07:30	PRE DOSE	2020-06-29/07:25	0	0	154	154	154	
		24 HOURS	2020-06-30/07:30	24	0	62.0	62	62	
		32 HOURS	2020-06-30/15:30	32	0	38.2	38.2	38.2	
		48 HOURS	2020-07-01/07:30	48	0	21.4	21.4	21.4	
01S2087									
Day 1 Dose 1	2020-06-23/07:36	PRE DOSE	2020-06-23/07:31	0	0	BLQ	0	0	
		0.25 HOUR	2020-06-23/07:51	0.25	0	BLQ	0	0	
		0.5 HOUR	2020-06-23/08:06	0.5	0	BLQ	0	0	
		0.75 HOUR	2020-06-23/08:19	0.72	-0.03	8.86	8.86	8.86	
		1 HOUR	2020-06-23/08:41	1.08	0.08	50.6	50.6	50.6	
		1.5 HOURS	2020-06-23/09:06	1.5	0	35.5	35.5	35.5	
		2 HOURS	2020-06-23/09:36	2	0	232	232	232	
		3 HOURS	2020-06-23/10:36	3	0	234	234	234	
		4 HOURS	2020-06-23/11:36	4	0	200	200	200	
		6 HOURS	2020-06-23/13:36	6	0	144	144	144	+
		8 HOURS	2020-06-23/15:36	8	0	93.9	93.9	93.9	+
		12 HOURS	2020-06-23/19:33	11.95	-0.05	48.3	48.3	48.3	+

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.3
Plasma Concentration-Time Profiles by Treatment
PK Concentration Population: Part B (MAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
LB-102 (ng/mL)									
LB-102 75 mg BID									
01S2087									
Day 1 Dose 2	2020-06-23/19:36	PRE DOSE	2020-06-23/19:33	0	0	48.3	48.3	48.3	
		4 HOURS	2020-06-23/23:36	4	0	191	191	191	
		12 HOURS	2020-06-24/07:31	11.92	-0.08	48.8	48.8	48.8	
Day 2	2020-06-24/07:36	PRE DOSE	2020-06-24/07:31	0	0	48.8	48.8	48.8	
Day 3	2020-06-25/07:36	PRE DOSE	2020-06-25/07:31	0	0	85.2	85.2	85.2	
Day 4	2020-06-26/07:36	PRE DOSE	2020-06-26/07:31	0	0	93.3	93.3	93.3	
Day 5	2020-06-27/07:36	PRE DOSE	2020-06-27/07:31	0	0	80.2	80.2	80.2	

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Source Data: ADPCMAD SDTM Date: 04AUG2020 16:09
Program Name: List_mad.sas Analysis Date: 24AUG2020 10:23

Listing 16.2.6.3
Plasma Concentration-Time Profiles by Treatment
PK Concentration Population: Part B (MAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
LB-102 (ng/mL)									
LB-102 75 mg BID									
01S2087									
Day 6 Dose 1	2020-06-28/07:36	PRE DOSE	2020-06-28/07:31	0	0	89.6	89.6	89.6	
		0.25 HOUR	2020-06-28/07:51	0.25	0	86.0	86	86	
		0.5 HOUR	2020-06-28/08:06	0.5	0	87.2	87.2	87.2	
		1 HOUR	2020-06-28/08:36	1	0	156	156	156	
		2 HOURS	2020-06-28/09:36	2	0	217	217	217	
		4 HOURS	2020-06-28/11:36	4	0	249	249	249	
		8 HOURS	2020-06-28/15:36	8	0	120	120	120	
		12 HOURS	2020-06-28/19:31	11.92	-0.08	72.9	72.9	72.9	
Day 6 Dose 2	2020-06-28/19:36	PRE DOSE	2020-06-28/19:31	0	0	72.9	72.9	72.9	
		0.25 HOUR	2020-06-28/19:51	0.25	0	68.3	68.3	68.3	
		0.5 HOUR	2020-06-28/20:06	0.5	0	83.2	83.2	83.2	
		1 HOUR	2020-06-28/20:36	1	0	126	126	126	
		2 HOURS	2020-06-28/21:36	2	0	191	191	191	
		4 HOURS	2020-06-28/23:36	4	0	201	201	201	
		6 HOURS	2020-06-29/01:36	6	0	150	150	150	+
		8 HOURS	2020-06-29/03:36	8	0	115	115	115	+
		12 HOURS	2020-06-29/07:31	11.92	-0.08	83.7	83.7	83.7	+

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.3
Plasma Concentration-Time Profiles by Treatment
PK Concentration Population: Part B (MAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
LB-102 (ng/mL)									
LB-102 75 mg BID									
01S2087									
Day 7	2020-06-29/07:36	PRE DOSE	2020-06-29/07:31	0	0	83.7	83.7	83.7	
		24 HOURS	2020-06-30/07:36	24	0	31.9	31.9	31.9	
		32 HOURS	2020-06-30/15:36	32	0	19.4	19.4	19.4	
		48 HOURS	2020-07-01/07:36	48	0	6.30	6.3	6.3	
01S2092									
Day 1 Dose 1	2020-06-23/07:38	PRE DOSE	2020-06-23/07:33	0	0	BLQ	0	0	
		0.25 HOUR	2020-06-23/07:53	0.25	0	BLQ	0	0	
		0.5 HOUR	2020-06-23/08:08	0.5	0	70.7	70.7	70.7	
		0.75 HOUR	2020-06-23/08:21	0.72	-0.03	117	117	117	
		1 HOUR	2020-06-23/08:43	1.08	0.08	148	148	148	
		1.5 HOURS	2020-06-23/09:08	1.5	0	168	168	168	
		2 HOURS	2020-06-23/09:38	2	0	221	221	221	
		3 HOURS	2020-06-23/10:38	3	0	225	225	225	
		4 HOURS	2020-06-23/11:38	4	0	178	178	178	
		6 HOURS	2020-06-23/13:38	6	0	111	111	111	+
		8 HOURS	2020-06-23/15:38	8	0	73.3	73.3	73.3	+
		12 HOURS	2020-06-23/19:35	11.95	-0.05	41.2	41.2	41.2	+

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.3
Plasma Concentration-Time Profiles by Treatment
PK Concentration Population: Part B (MAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
LB-102 (ng/mL)									
LB-102 75 mg BID									
01S2092									
Day 1 Dose 2	2020-06-23/19:38	PRE DOSE	2020-06-23/19:35	0	0	41.2	41.2	41.2	
		4 HOURS	2020-06-23/23:38	4	0	173	173	173	
		12 HOURS	2020-06-24/07:33	11.92	-0.08	84.5	84.5	84.5	
Day 2	2020-06-24/07:38	PRE DOSE	2020-06-24/07:33	0	0	84.5	84.5	84.5	
Day 3	2020-06-25/07:38	PRE DOSE	2020-06-25/07:33	0	0	87.5	87.5	87.5	
Day 4		PRE DOSE	2020-06-26/07:33			51.0	51	51	
01S2093									
Day 1 Dose 1	2020-06-23/07:40	PRE DOSE	2020-06-23/07:35	0	0	BLQ	0	0	
		0.25 HOUR	2020-06-23/07:55	0.25	0	BLQ	0	0	
		0.5 HOUR	2020-06-23/08:10	0.5	0	14.8	14.8	14.8	
		0.75 HOUR	2020-06-23/08:23	0.72	-0.03	107	107	107	
		1 HOUR	2020-06-23/08:45	1.08	0.08	153	153	153	
		1.5 HOURS	2020-06-23/09:10	1.5	0	193	193	193	
		2 HOURS	2020-06-23/09:40	2	0	185	185	185	
		3 HOURS	2020-06-23/10:40	3	0	211	211	211	
		4 HOURS	2020-06-23/11:40	4	0	146	146	146	
		6 HOURS	2020-06-23/13:40	6	0	105	105	105	+
		8 HOURS	2020-06-23/15:40	8	0	72.7	72.7	72.7	+
		12 HOURS	2020-06-23/19:37	11.95	-0.05	40.6	40.6	40.6	+

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.3
Plasma Concentration-Time Profiles by Treatment
PK Concentration Population: Part B (MAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
LB-102 (ng/mL)									
LB-102 75 mg BID									
01S2093									
Day 1 Dose 2	2020-06-23/19:40	PRE DOSE	2020-06-23/19:37	0	0	40.6	40.6	40.6	
		4 HOURS	2020-06-23/23:40	4	0	139	139	139	
		12 HOURS	2020-06-24/07:35	11.92	-0.08	67.2	67.2	67.2	
Day 2	2020-06-24/07:40	PRE DOSE	2020-06-24/07:35	0	0	67.2	67.2	67.2	
Day 3	2020-06-25/07:40	PRE DOSE	2020-06-25/07:35	0	0	76.8	76.8	76.8	
Day 4	2020-06-26/07:40	PRE DOSE	2020-06-26/07:35	0	0	103	103	103	
Day 5	2020-06-27/07:40	PRE DOSE	2020-06-27/07:35	0	0	120	120	120	

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Source Data: ADPCMAD SDTM Date: 04AUG2020 16:09
Program Name: List_mad.sas Analysis Date: 24AUG2020 10:23

Listing 16.2.6.3
Plasma Concentration-Time Profiles by Treatment
PK Concentration Population: Part B (MAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
LB-102 (ng/mL)									
LB-102 75 mg BID									
01S2093									
Day 6 Dose 1	2020-06-28/07:40	PRE DOSE	2020-06-28/07:35	0	0	128	128	128	
		0.25 HOUR	2020-06-28/07:55	0.25	0	124	124	124	
		0.5 HOUR	2020-06-28/08:10	0.5	0	124	124	124	
		1 HOUR	2020-06-28/08:40	1	0	161	161	161	
		2 HOURS	2020-06-28/09:40	2	0	185	185	185	
		4 HOURS	2020-06-28/11:40	4	0	184	184	184	
		8 HOURS	2020-06-28/15:40	8	0	144	144	144	
		12 HOURS	2020-06-28/19:35	11.92	-0.08	120	120	120	
Day 6 Dose 2	2020-06-28/19:40	PRE DOSE	2020-06-28/19:35	0	0	120	120	120	
		0.25 HOUR	2020-06-28/19:55	0.25	0	118	118	118	
		0.5 HOUR	2020-06-28/20:10	0.5	0	121	121	121	
		1 HOUR	2020-06-28/20:40	1	0	151	151	151	
		2 HOURS	2020-06-28/21:40	2	0	196	196	196	
		4 HOURS	2020-06-28/23:40	4	0	220	220	220	
		6 HOURS	2020-06-29/01:40	6	0	172	172	172	+
		8 HOURS	2020-06-29/03:40	8	0	153	153	153	+
		12 HOURS	2020-06-29/07:35	11.92	-0.08	130	130	130	+

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.3
Plasma Concentration-Time Profiles by Treatment
PK Concentration Population: Part B (MAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
LB-102 (ng/mL)									
LB-102 75 mg BID									
01S2093									
Day 7	2020-06-29/07:40	PRE DOSE	2020-06-29/07:35	0	0	130	130	130	
		24 HOURS	2020-06-30/07:40	24	0	85.0	85	85	
		32 HOURS	2020-06-30/15:40	32	0	60.6	60.6	60.6	
		48 HOURS	2020-07-01/07:40	48	0	23.3	23.3	23.3	
01S2094									
Day 1 Dose 1	2020-06-23/07:42	PRE DOSE	2020-06-23/07:37	0	0	BLQ	0	0	
		0.25 HOUR	2020-06-23/07:57	0.25	0	BLQ	0	0	
		0.5 HOUR	2020-06-23/08:12	0.5	0	216	216	216	
		0.75 HOUR	2020-06-23/08:25	0.72	-0.03	327	327	327	
		1 HOUR	2020-06-23/08:47	1.08	0.08	343	343	343	
		1.5 HOURS	2020-06-23/09:12	1.5	0	386	386	386	
		2 HOURS	2020-06-23/09:42	2	0	388	388	388	
		3 HOURS	2020-06-23/10:42	3	0	278	278	278	
		4 HOURS	2020-06-23/11:42	4	0	218	218	218	
		6 HOURS	2020-06-23/13:42	6	0	133	133	133	+
		8 HOURS	2020-06-23/15:42	8	0	80.9	80.9	80.9	+
		12 HOURS	2020-06-23/19:39	11.95	-0.05	35.7	35.7	35.7	+

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.3
Plasma Concentration-Time Profiles by Treatment
PK Concentration Population: Part B (MAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
LB-102 (ng/mL)									
LB-102 75 mg BID									
01S2094									
Day 1 Dose 2	2020-06-23/19:42	PRE DOSE	2020-06-23/19:39	0	0	35.7	35.7	35.7	
		4 HOURS	2020-06-23/23:42	4	0	188	188	188	
		12 HOURS	2020-06-24/07:37	11.92	-0.08	77.4	77.4	77.4	
Day 2	2020-06-24/07:42	PRE DOSE	2020-06-24/07:37	0	0	77.4	77.4	77.4	
Day 3	2020-06-25/07:42	PRE DOSE	2020-06-25/07:37	0	0	124	124	124	
Day 4	2020-06-26/07:42	PRE DOSE	2020-06-26/07:37	0	0	102	102	102	
Day 5	2020-06-27/07:42	PRE DOSE	2020-06-27/07:37	0	0	116	116	116	

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.3
Plasma Concentration-Time Profiles by Treatment
PK Concentration Population: Part B (MAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
LB-102 (ng/mL)									
LB-102 75 mg BID									
01S2094									
Day 6 Dose 1	2020-06-28/07:42	PRE DOSE	2020-06-28/07:37	0	0	130	130	130	
		0.25 HOUR	2020-06-28/07:57	0.25	0	130	130	130	
		0.5 HOUR	2020-06-28/08:12	0.5	0	226	226	226	
		1 HOUR	2020-06-28/08:42	1	0	470	470	470	
		2 HOURS	2020-06-28/09:42	2	0	429	429	429	
		4 HOURS	2020-06-28/11:42	4	0	298	298	298	
		8 HOURS	2020-06-28/15:42	8	0	147	147	147	
		12 HOURS	2020-06-28/19:37	11.92	-0.08	89.5	89.5	89.5	
Day 6 Dose 2	2020-06-28/19:42	PRE DOSE	2020-06-28/19:37	0	0	89.5	89.5	89.5	
		0.25 HOUR	2020-06-28/19:57	0.25	0	95.0	95	95	
		0.5 HOUR	2020-06-28/20:12	0.5	0	137	137	137	
		1 HOUR	2020-06-28/20:42	1	0	230	230	230	
		2 HOURS	2020-06-28/21:42	2	0	295	295	295	
		4 HOURS	2020-06-28/23:42	4	0	266	266	266	
		6 HOURS	2020-06-29/01:42	6	0	184	184	184	+
		8 HOURS	2020-06-29/03:42	8	0	140	140	140	+
		12 HOURS	2020-06-29/07:37	11.92	-0.08	107	107	107	+

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.3
Plasma Concentration-Time Profiles by Treatment
PK Concentration Population: Part B (MAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
LB-102 (ng/mL)									
LB-102 75 mg BID									
01S2094									
Day 7	2020-06-29/07:42	PRE DOSE	2020-06-29/07:37	0	0	107	107	107	
		24 HOURS	2020-06-30/07:42	24	0	52.3	52.3	52.3	
		32 HOURS	2020-06-30/15:42	32	0	39.4	39.4	39.4	
		48 HOURS	2020-07-01/07:42	48	0	20.5	20.5	20.5	
01S2102									
Day 1 Dose 1	2020-06-23/07:32	PRE DOSE	2020-06-23/07:27	0	0	BLQ	0	0	
		0.25 HOUR	2020-06-23/07:47	0.25	0	BLQ	0	0	
		0.5 HOUR	2020-06-23/08:02	0.5	0	120	120	120	
		0.75 HOUR	2020-06-23/08:15	0.72	-0.03	182	182	182	
		1 HOUR	2020-06-23/08:37	1.08	0.08	126	126	126	
		1.5 HOURS	2020-06-23/09:02	1.5	0	114	114	114	
		2 HOURS	2020-06-23/09:32	2	0	113	113	113	
		3 HOURS	2020-06-23/10:35	3.05	0.05	232	232	232	
		4 HOURS	2020-06-23/11:32	4	0	157	157	157	
		6 HOURS	2020-06-23/13:32	6	0	119	119	119	+
		8 HOURS	2020-06-23/15:32	8	0	79.7	79.7	79.7	+
		12 HOURS	2020-06-23/19:29	11.95	-0.05	45.9	45.9	45.9	+

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.3
Plasma Concentration-Time Profiles by Treatment
PK Concentration Population: Part B (MAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
LB-102 (ng/mL)									
LB-102 75 mg BID									
01S2102									
Day 1 Dose 2	2020-06-23/19:32	PRE DOSE	2020-06-23/19:29	0	0	45.9	45.9	45.9	
		4 HOURS	2020-06-23/23:32	4	0	131	131	131	
		12 HOURS	2020-06-24/07:29	11.95	-0.05	70.9	70.9	70.9	
Day 2	2020-06-24/07:32	PRE DOSE	2020-06-24/07:29	0	0	70.9	70.9	70.9	
Day 3	2020-06-25/07:32	PRE DOSE	2020-06-25/07:27	0	0	102	102	102	
Day 4	2020-06-26/07:32	PRE DOSE	2020-06-26/07:27	0	0	124	124	124	
Day 5	2020-06-27/07:32	PRE DOSE	2020-06-27/07:27	0	0	81.6	81.6	81.6	

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Source Data: ADPCMAD SDTM Date: 04AUG2020 16:09
Program Name: List_mad.sas Analysis Date: 24AUG2020 10:23

Listing 16.2.6.3
Plasma Concentration-Time Profiles by Treatment
PK Concentration Population: Part B (MAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
LB-102 (ng/mL)									
LB-102 75 mg BID									
01S2102									
Day 6 Dose 1	2020-06-28/07:32	PRE DOSE	2020-06-28/07:27	0	0	116	116	116	
		0.25 HOUR	2020-06-28/07:47	0.25	0	111	111	111	
		0.5 HOUR	2020-06-28/08:02	0.5	0	134	134	134	
		1 HOUR	2020-06-28/08:32	1	0	381	381	381	
		2 HOURS	2020-06-28/09:32	2	0	330	330	330	
		4 HOURS	2020-06-28/11:32	4	0	246	246	246	
		8 HOURS	2020-06-28/15:32	8	0	152	152	152	
		12 HOURS	2020-06-28/19:27	11.92	-0.08	109	109	109	
Day 6 Dose 2	2020-06-28/19:32	PRE DOSE	2020-06-28/19:27	0	0	109	109	109	
		0.25 HOUR	2020-06-28/19:47	0.25	0	111	111	111	
		0.5 HOUR	2020-06-28/20:02	0.5	0	106	106	106	
		1 HOUR	2020-06-28/20:32	1	0	122	122	122	
		2 HOURS	2020-06-28/21:32	2	0	263	263	263	
		4 HOURS	2020-06-28/23:32	4	0	237	237	237	
		6 HOURS	2020-06-29/01:32	6	0	189	189	189	+
		8 HOURS	2020-06-29/03:32	8	0	156	156	156	+
		12 HOURS	2020-06-29/07:27	11.92	-0.08	125	125	125	+

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.3
Plasma Concentration-Time Profiles by Treatment
PK Concentration Population: Part B (MAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
LB-102 (ng/mL)									
LB-102 75 mg BID									
01S2102									
Day 7	2020-06-29/07:32	PRE DOSE	2020-06-29/07:27	0	0	125	125	125	
		24 HOURS	2020-06-30/07:32	24	0	59.4	59.4	59.4	
		32 HOURS	2020-06-30/15:32	32	0	35.1	35.1	35.1	
		48 HOURS	2020-07-01/07:32	48	0	14.8	14.8	14.8	
LB-102 100 mg BID									
01S2059									
Day 1 Dose 1	2020-06-02/07:30	PRE DOSE	2020-06-02/07:25	0	0	BLQ	0	0	
		0.25 HOUR	2020-06-02/07:45	0.25	0	BLQ	0	0	
		0.5 HOUR	2020-06-02/08:00	0.5	0	20.3	20.3	20.3	
		0.75 HOUR	2020-06-02/08:13	0.72	-0.03	129	129	129	
		1 HOUR	2020-06-02/08:35	1.08	0.08	92.0	92	92	
		1.5 HOURS	2020-06-02/09:00	1.5	0	107	107	107	
		2 HOURS	2020-06-02/09:30	2	0	361	361	361	
		3 HOURS	2020-06-02/10:30	3	0	314	314	314	
		4 HOURS	2020-06-02/11:30	4	0	289	289	289	
		6 HOURS	2020-06-02/13:30	6	0	160	160	160	+
		8 HOURS	2020-06-02/15:30	8	0	104	104	104	+
		12 HOURS	2020-06-02/19:27	11.95	-0.05	53.2	53.2	53.2	+

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.3
Plasma Concentration-Time Profiles by Treatment
PK Concentration Population: Part B (MAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
LB-102 (ng/mL)									
LB-102 100 mg BID									
01S2059									
Day 1 Dose 2	2020-06-02/19:30	PRE DOSE	2020-06-02/19:27	0	0	53.2	53.2	53.2	
		4 HOURS	2020-06-02/23:30	4	0	202	202	202	
		12 HOURS	2020-06-03/07:25	11.92	-0.08	92.6	92.6	92.6	
Day 2	2020-06-03/07:30	PRE DOSE	2020-06-03/07:25	0	0	92.6	92.6	92.6	
Day 3	2020-06-04/07:30	PRE DOSE	2020-06-04/07:25	0	0	135	135	135	
Day 4		PRE DOSE	2020-06-05/07:25			46.7	46.7	46.7	
Day 5		PRE DOSE	2020-06-06/07:25			7.00	7	7	

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.3
Plasma Concentration-Time Profiles by Treatment
PK Concentration Population: Part B (MAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
LB-102 (ng/mL)									
LB-102 100 mg BID									
01S2066									
Day 1 Dose 1	2020-06-02/07:36	PRE DOSE	2020-06-02/07:31	0	0	BLQ	0	0	
		0.25 HOUR	2020-06-02/07:51	0.25	0	BLQ	0	0	
		0.5 HOUR	2020-06-02/08:06	0.5	0	76.1	76.1	76.1	
		0.75 HOUR	2020-06-02/08:20	0.73	-0.02	171	171	171	
		1 HOUR	2020-06-02/08:41	1.08	0.08	119	119	119	
		1.5 HOURS	2020-06-02/09:06	1.5	0	150	150	150	
		2 HOURS	2020-06-02/09:36	2	0	179	179	179	
		3 HOURS	2020-06-02/10:36	3	0	214	214	214	
		4 HOURS	2020-06-02/11:36	4	0	203	203	203	
		6 HOURS	2020-06-02/13:36	6	0	133	133	133	+
		8 HOURS	2020-06-02/15:36	8	0	92.8	92.8	92.8	+
		12 HOURS	2020-06-02/19:33	11.95	-0.05	51.1	51.1	51.1	+

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Source Data: ADPCMAD SDTM Date: 04AUG2020 16:09
Program Name: List_mad.sas Analysis Date: 24AUG2020 10:23

Listing 16.2.6.3
Plasma Concentration-Time Profiles by Treatment
PK Concentration Population: Part B (MAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
LB-102 (ng/mL)									
LB-102 100 mg BID									
01S2066									
Day 1 Dose 2	2020-06-02/19:36	PRE DOSE	2020-06-02/19:33	0	0	51.1	51.1	51.1	
		4 HOURS	2020-06-02/23:36	4	0	112	112	112	
		12 HOURS	2020-06-03/07:31	11.92	-0.08	108	108	108	
Day 2	2020-06-03/07:36	PRE DOSE	2020-06-03/07:31	0	0	108	108	108	
Day 3	2020-06-04/07:36	PRE DOSE	2020-06-04/07:31	0	0	88.8	88.8	88.8	
Day 4		PRE DOSE	2020-06-05/07:31			37.7	37.7	37.7	
Day 5		PRE DOSE	2020-06-06/07:31			6.76	6.76	6.76	

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.3
Plasma Concentration-Time Profiles by Treatment
PK Concentration Population: Part B (MAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
LB-102 (ng/mL)									
LB-102 100 mg BID									
01S2069									
Day 1 Dose 1	2020-06-02/07:40	PRE DOSE	2020-06-02/07:35	0	0	BLQ	0	0	
		0.25 HOUR	2020-06-02/07:55	0.25	0	BLQ	0	0	
		0.5 HOUR	2020-06-02/08:10	0.5	0	BLQ	0	0	
		0.75 HOUR	2020-06-02/08:23	0.72	-0.03	2.44	2.44	2.44	
		1 HOUR	2020-06-02/08:45	1.08	0.08	6.87	6.87	6.87	
		1.5 HOURS	2020-06-02/09:10	1.5	0	113	113	113	
		2 HOURS	2020-06-02/09:40	2	0	182	182	182	
		3 HOURS	2020-06-02/10:40	3	0	377	377	377	
		4 HOURS	2020-06-02/11:40	4	0	291	291	291	
		6 HOURS	2020-06-02/13:40	6	0	182	182	182	+
		8 HOURS	2020-06-02/15:40	8	0	117	117	117	+
		12 HOURS	2020-06-02/19:37	11.95	-0.05	50.7	50.7	50.7	+

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Source Data: ADPCMAD SDTM Date: 04AUG2020 16:09
Program Name: List_mad.sas Analysis Date: 24AUG2020 10:23

Listing 16.2.6.3
Plasma Concentration-Time Profiles by Treatment
PK Concentration Population: Part B (MAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
LB-102 (ng/mL)									
LB-102 100 mg BID									
01S2069									
Day 1 Dose 2	2020-06-02/19:40	PRE DOSE	2020-06-02/19:37	0	0	50.7	50.7	50.7	
		4 HOURS	2020-06-02/23:40	4	0	110	110	110	
		12 HOURS	2020-06-03/07:35	11.92	-0.08	119	119	119	
Day 2	2020-06-03/07:40	PRE DOSE	2020-06-03/07:35	0	0	119	119	119	
Day 3		PRE DOSE	2020-06-04/07:48			43.4	43.4	43.4	
01S2076									
Day 1 Dose 1	2020-06-02/07:48	PRE DOSE	2020-06-02/07:47	0	0	BLQ	0	0	
		0.25 HOUR	2020-06-02/08:03	0.25	0	34.9	34.9	34.9	
		0.5 HOUR	2020-06-02/08:18	0.5	0	317	317	317	
		0.75 HOUR	2020-06-02/08:31	0.72	-0.03	209	209	209	
		1 HOUR	2020-06-02/08:53	1.08	0.08	158	158	158	
		1.5 HOURS	2020-06-02/09:18	1.5	0	169	169	169	
		2 HOURS	2020-06-02/09:48	2	0	166	166	166	
		3 HOURS	2020-06-02/10:48	3	0	251	251	251	
		4 HOURS	2020-06-02/11:48	4	0	186	186	186	
		6 HOURS	2020-06-02/13:48	6	0	132	132	132	+
		8 HOURS	2020-06-02/15:48	8	0	83.9	83.9	83.9	+
		12 HOURS	2020-06-02/19:45	11.95	-0.05	53.9	53.9	53.9	+

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.3
Plasma Concentration-Time Profiles by Treatment
PK Concentration Population: Part B (MAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
LB-102 (ng/mL)									
LB-102 100 mg BID									
01S2076									
Day 1 Dose 2	2020-06-02/19:48	PRE DOSE	2020-06-02/19:45	0	0	53.9	53.9	53.9	
		4 HOURS	2020-06-02/23:48	4	0	176	176	176	
		12 HOURS	2020-06-03/07:43	11.92	-0.08	73.6	73.6	73.6	
Day 2	2020-06-03/07:48	PRE DOSE	2020-06-03/07:43	0	0	73.6	73.6	73.6	
Day 3	2020-06-04/07:48	PRE DOSE	2020-06-04/07:43	0	0	135	135	135	
01S2078									
Day 1 Dose 1	2020-06-02/07:38	PRE DOSE	2020-06-02/07:33	0	0	BLQ	0	0	
		0.25 HOUR	2020-06-02/07:53	0.25	0	BLQ	0	0	
		0.5 HOUR	2020-06-02/08:08	0.5	0	78.6	78.6	78.6	
		0.75 HOUR	2020-06-02/08:21	0.72	-0.03	106	106	106	
		1 HOUR	2020-06-02/08:43	1.08	0.08	116	116	116	
		1.5 HOURS	2020-06-02/09:08	1.5	0	153	153	153	
		2 HOURS	2020-06-02/09:38	2	0	286	286	286	
		3 HOURS	2020-06-02/10:38	3	0	285	285	285	
		4 HOURS	2020-06-02/11:38	4	0	216	216	216	
		6 HOURS	2020-06-02/13:38	6	0	139	139	139	+
		8 HOURS	2020-06-02/15:38	8	0	104	104	104	+
		12 HOURS	2020-06-02/19:35	11.95	-0.05	62.1	62.1	62.1	+

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.3
Plasma Concentration-Time Profiles by Treatment
PK Concentration Population: Part B (MAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
LB-102 (ng/mL)									
LB-102 100 mg BID									
01S2078									
Day 1 Dose 2	2020-06-02/19:38	PRE DOSE	2020-06-02/19:35	0	0	62.1	62.1	62.1	
		4 HOURS	2020-06-02/23:38	4	0	179	179	179	
		12 HOURS	2020-06-03/07:33	11.92	-0.08	108	108	108	
Day 2	2020-06-03/07:38	PRE DOSE	2020-06-03/07:33	0	0	108	108	108	
Day 3	2020-06-04/07:38	PRE DOSE	2020-06-04/07:33	0	0	152	152	152	
Day 4		PRE DOSE	2020-06-05/07:33			87.1	87.1	87.1	
Day 5		PRE DOSE	2020-06-06/07:33			40.0	40	40	

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.3
Plasma Concentration-Time Profiles by Treatment
PK Concentration Population: Part B (MAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
LB-102 (ng/mL)									
LB-102 100 mg BID									
01S2079									
Day 1 Dose 1	2020-06-02/07:32	PRE DOSE	2020-06-02/07:30	0	0	BLQ	0	0	
		0.25 HOUR	2020-06-02/07:47	0.25	0	BLQ	0	0	
		0.5 HOUR	2020-06-02/08:02	0.5	0	33.3	33.3	33.3	
		0.75 HOUR	2020-06-02/08:15	0.72	-0.03	48.0	48	48	
		1 HOUR	2020-06-02/08:46	1.23	0.23	281	281	281	
		1.5 HOURS	2020-06-02/09:02	1.5	0	266	266	266	
		2 HOURS	2020-06-02/09:32	2	0	371	371	371	
		3 HOURS	2020-06-02/10:33	3.02	0.02	396	396	396	
		4 HOURS	2020-06-02/11:32	4	0	279	279	279	
		6 HOURS	2020-06-02/13:32	6	0	202	202	202	+
		8 HOURS	2020-06-02/15:32	8	0	170	170	170	+
		12 HOURS	2020-06-02/19:29	11.95	-0.05	82.3	82.3	82.3	+

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Source Data: ADPCMAD SDTM Date: 04AUG2020 16:09
Program Name: List_mad.sas Analysis Date: 24AUG2020 10:23

Listing 16.2.6.3
Plasma Concentration-Time Profiles by Treatment
PK Concentration Population: Part B (MAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
LB-102 (ng/mL)									
LB-102 100 mg BID									
01S2079									
Day 1 Dose 2	2020-06-02/19:32	PRE DOSE	2020-06-02/19:29	0	0	82.3	82.3	82.3	
		4 HOURS	2020-06-02/23:32	4	0	281	281	281	
		12 HOURS	2020-06-03/07:27	11.92	-0.08	136	136	136	
Day 2	2020-06-03/07:32	PRE DOSE	2020-06-03/07:27	0	0	136	136	136	
Day 3	2020-06-04/07:32	PRE DOSE	2020-06-04/07:27	0	0	172	172	172	
Amisulpride (ng/mL)									
LB-102 50 mg BID									
01S2032									
Day 1 Dose 1	2020-05-12/07:30	PRE DOSE	2020-05-12/07:25	0	0	BLQ	0	0	
		0.25 HOUR	2020-05-12/07:45	0.25	0	BLQ	0	0	
		0.5 HOUR	2020-05-12/08:00	0.5	0	BLQ	0	0	
		0.75 HOUR	2020-05-12/08:13	0.72	-0.03	1.02	1.02	1.02	
		1 HOUR	2020-05-12/08:35	1.08	0.08	1.55	1.55	1.55	
		1.5 HOURS	2020-05-12/09:00	1.5	0	3.90	3.9	3.9	
		2 HOURS	2020-05-12/09:30	2	0	4.19	4.19	4.19	
		3 HOURS	2020-05-12/10:30	3	0	4.21	4.21	4.21	
		4 HOURS	2020-05-12/11:30	4	0	3.43	3.43	3.43	
		6 HOURS	2020-05-12/13:30	6	0	2.90	2.9	2.9	+
		8 HOURS	2020-05-12/15:30	8	0	2.01	2.01	2.01	+
		12 HOURS	2020-05-12/19:27	11.95	-0.05	1.25	1.25	1.25	+

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.3
Plasma Concentration-Time Profiles by Treatment
PK Concentration Population: Part B (MAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
Amisulpride (ng/mL)									
LB-102 50 mg BID									
01S2032									
Day 1 Dose 2	2020-05-12/19:30	PRE DOSE	2020-05-12/19:27	0	0	1.25	1.25	1.25	
		4 HOURS	2020-05-12/23:30	4	0	2.64	2.64	2.64	
		12 HOURS	2020-05-13/07:25	11.92	-0.08	1.86	1.86	1.86	
Day 2	2020-05-13/07:30	PRE DOSE	2020-05-13/07:25	0	0	1.86	1.86	1.86	
Day 3	2020-05-14/07:30	PRE DOSE	2020-05-14/07:25	0	0	2.42	2.42	2.42	
Day 4	2020-05-15/07:30	PRE DOSE	2020-05-15/07:25	0	0	2.50	2.5	2.5	
Day 5	2020-05-16/07:30	PRE DOSE	2020-05-16/07:25	0	0	2.18	2.18	2.18	

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Source Data: ADPCMAD SDTM Date: 04AUG2020 16:09
Program Name: List_mad.sas Analysis Date: 24AUG2020 10:23

Listing 16.2.6.3
Plasma Concentration-Time Profiles by Treatment
PK Concentration Population: Part B (MAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
Amisulpride (ng/mL)									
LB-102 50 mg BID									
01S2032									
Day 6	2020-05-17/07:30	PRE DOSE	2020-05-17/07:25	0	0	2.78	2.78	2.78	
Day 7	2020-05-18/07:30	PRE DOSE	2020-05-18/07:25	0	0	3.53	3.53	3.53	
		0.25 HOUR	2020-05-18/07:45	0.25	0	3.40	3.4	3.4	
		0.5 HOUR	2020-05-18/08:00	0.5	0	3.49	3.49	3.49	
		0.75 HOUR	2020-05-18/08:15	0.75	0	4.17	4.17	4.17	
		1 HOUR	2020-05-18/08:30	1	0	4.75	4.75	4.75	
		1.5 HOURS	2020-05-18/09:00	1.5	0	5.61	5.61	5.61	
		2 HOURS	2020-05-18/09:30	2	0	7.38	7.38	7.38	
		3 HOURS	2020-05-18/10:30	3	0	7.71	7.71	7.71	
		4 HOURS	2020-05-18/11:30	4	0	6.13	6.13	6.13	
		6 HOURS	2020-05-18/13:30	6	0	4.59	4.59	4.59	
		8 HOURS	2020-05-18/15:30	8	0	3.52	3.52	3.52	
		12 HOURS	2020-05-18/19:30	12	0	2.68	2.68	2.68	+
		16 HOURS	2020-05-18/23:30	16	0	1.70	1.7	1.7	+
		24 HOURS	2020-05-19/07:30	24	0	1.12	1.12	1.12	+
		32 HOURS	2020-05-19/15:38	32.13	0.13	BLQ	0		
		48 HOURS	2020-05-20/07:30	48	0	BLQ	0		

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.3
Plasma Concentration-Time Profiles by Treatment
PK Concentration Population: Part B (MAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
Amisulpride (ng/mL)									
LB-102 50 mg BID									
01S2034									
Day 1 Dose 1	2020-05-12/07:32	PRE DOSE	2020-05-12/07:27	0	0	BLQ	0	0	
		0.25 HOUR	2020-05-12/07:47	0.25	0	BLQ	0	0	
		0.5 HOUR	2020-05-12/08:02	0.5	0	BLQ	0	0	
		0.75 HOUR	2020-05-12/08:15	0.72	-0.03	BLQ	0	0	
		1 HOUR	2020-05-12/08:37	1.08	0.08	BLQ	0	0	
		1.5 HOURS	2020-05-12/09:02	1.5	0	1.45	1.45	1.45	
		2 HOURS	2020-05-12/09:32	2	0	1.55	1.55	1.55	
		3 HOURS	2020-05-12/10:32	3	0	2.28	2.28	2.28	
		4 HOURS	2020-05-12/11:32	4	0	2.13	2.13	2.13	
		6 HOURS	2020-05-12/13:32	6	0	2.06	2.06	2.06	+
		8 HOURS	2020-05-12/15:32	8	0	1.56	1.56	1.56	+
		12 HOURS	2020-05-12/19:29	11.95	-0.05	1.29	1.29	1.29	+

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Source Data: ADPCMAD
SDTM Date: 04AUG2020 16:09
Program Name: List_mad.sas
Analysis Date: 24AUG2020 10:23

Listing 16.2.6.3
Plasma Concentration-Time Profiles by Treatment
PK Concentration Population: Part B (MAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
Amisulpride (ng/mL)									
LB-102 50 mg BID									
01S2034									
Day 1 Dose 2	2020-05-12/19:32	PRE DOSE	2020-05-12/19:29	0	0	1.29	1.29	1.29	
		4 HOURS	2020-05-12/23:32	4	0	3.02	3.02	3.02	
		12 HOURS	2020-05-13/07:27	11.92	-0.08	2.29	2.29	2.29	
Day 2	2020-05-13/07:32	PRE DOSE	2020-05-13/07:27	0	0	2.29	2.29	2.29	
Day 3	2020-05-14/07:32	PRE DOSE	2020-05-14/07:27	0	0	4.05	4.05	4.05	
Day 4	2020-05-15/07:32	PRE DOSE	2020-05-15/07:27	0	0	3.92	3.92	3.92	
Day 5	2020-05-16/07:32	PRE DOSE	2020-05-16/07:27	0	0	3.99	3.99	3.99	

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Source Data: ADPCMAD SDTM Date: 04AUG2020 16:09
Program Name: List_mad.sas Analysis Date: 24AUG2020 10:23

Listing 16.2.6.3
Plasma Concentration-Time Profiles by Treatment
PK Concentration Population: Part B (MAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
Amisulpride (ng/mL)									
LB-102 50 mg BID									
01S2034									
Day 6	2020-05-17/07:32	PRE DOSE	2020-05-17/07:27	0	0	4.11	4.11	4.11	
Day 7	2020-05-18/07:32	PRE DOSE	2020-05-18/07:27	0	0	3.90	3.9	3.9	
		0.25 HOUR	2020-05-18/07:47	0.25	0	3.82	3.82	3.82	
		0.5 HOUR	2020-05-18/08:02	0.5	0	3.77	3.77	3.77	
		0.75 HOUR	2020-05-18/08:17	0.75	0	3.91	3.91	3.91	
		1 HOUR	2020-05-18/08:32	1	0	4.67	4.67	4.67	
		1.5 HOURS	2020-05-18/09:02	1.5	0	5.93	5.93	5.93	
		2 HOURS	2020-05-18/09:32	2	0	5.41	5.41	5.41	
		3 HOURS	2020-05-18/10:32	3	0	6.67	6.67	6.67	
		4 HOURS	2020-05-18/11:32	4	0	5.96	5.96	5.96	
		6 HOURS	2020-05-18/13:32	6	0	5.95	5.95	5.95	
		8 HOURS	2020-05-18/15:32	8	0	5.36	5.36	5.36	
		12 HOURS	2020-05-18/19:32	12	0	3.65	3.65	3.65	
		16 HOURS	2020-05-18/23:32	16	0	2.44	2.44	2.44	+
		24 HOURS	2020-05-19/07:32	24	0	1.73	1.73	1.73	+
		32 HOURS	2020-05-19/15:39	32.12	0.12	1.11	1.11	1.11	+
		48 HOURS	2020-05-20/07:32	48	0	BLQ	0		

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.3
Plasma Concentration-Time Profiles by Treatment
PK Concentration Population: Part B (MAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
Amisulpride (ng/mL)									
LB-102 50 mg BID									
01S2045									
Day 1 Dose 1	2020-05-12/07:36	PRE DOSE	2020-05-12/07:31	0	0	BLQ	0	0	
		0.25 HOUR	2020-05-12/07:51	0.25	0	BLQ	0	0	
		0.5 HOUR	2020-05-12/08:06	0.5	0	BLQ	0	0	
		0.75 HOUR	2020-05-12/08:19	0.72	-0.03	1.12	1.12	1.12	
		1 HOUR	2020-05-12/08:41	1.08	0.08	3.12	3.12	3.12	
		1.5 HOURS	2020-05-12/09:06	1.5	0	3.62	3.62	3.62	
		2 HOURS	2020-05-12/09:36	2	0	3.49	3.49	3.49	
		3 HOURS	2020-05-12/10:36	3	0	3.42	3.42	3.42	
		4 HOURS	2020-05-12/11:36	4	0	2.63	2.63	2.63	
		6 HOURS	2020-05-12/13:36	6	0	2.04	2.04	2.04	+
		8 HOURS	2020-05-12/15:36	8	0	1.64	1.64	1.64	+
		12 HOURS	2020-05-12/19:33	11.95	-0.05	1.28	1.28	1.28	+

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Source Data: ADPCMAD SDTM Date: 04AUG2020 16:09
Program Name: List_mad.sas Analysis Date: 24AUG2020 10:23

Listing 16.2.6.3
Plasma Concentration-Time Profiles by Treatment
PK Concentration Population: Part B (MAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
Amisulpride (ng/mL)									
LB-102 50 mg BID									
01S2045									
Day 1 Dose 2	2020-05-12/19:36	PRE DOSE	2020-05-12/19:33	0	0	1.28	1.28	1.28	
		4 HOURS	2020-05-12/23:36	4	0	2.62	2.62	2.62	
		12 HOURS	2020-05-13/07:31	11.92	-0.08	1.89	1.89	1.89	
Day 2	2020-05-13/07:36	PRE DOSE	2020-05-13/07:31	0	0	1.89	1.89	1.89	
Day 3	2020-05-14/07:36	PRE DOSE	2020-05-14/07:31	0	0	2.87	2.87	2.87	
Day 4	2020-05-15/07:36	PRE DOSE	2020-05-15/07:31	0	0	3.16	3.16	3.16	
Day 5	2020-05-16/07:36	PRE DOSE	2020-05-16/07:31	0	0	3.08	3.08	3.08	

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Source Data: ADPCMAD SDTM Date: 04AUG2020 16:09
Program Name: List_mad.sas Analysis Date: 24AUG2020 10:23

Listing 16.2.6.3
Plasma Concentration-Time Profiles by Treatment
PK Concentration Population: Part B (MAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
Amisulpride (ng/mL)									
LB-102 50 mg BID									
01S2045									
Day 6	2020-05-17/07:36	PRE DOSE	2020-05-17/07:31	0	0	2.63	2.63	2.63	
Day 7	2020-05-18/07:36	PRE DOSE	2020-05-18/07:31	0	0	3.43	3.43	3.43	
		0.25 HOUR	2020-05-18/07:51	0.25	0	3.56	3.56	3.56	
		0.5 HOUR	2020-05-18/08:06	0.5	0	4.08	4.08	4.08	
		0.75 HOUR	2020-05-18/08:21	0.75	0	4.89	4.89	4.89	
		1 HOUR	2020-05-18/08:36	1	0	5.13	5.13	5.13	
		1.5 HOURS	2020-05-18/09:06	1.5	0	6.09	6.09	6.09	
		2 HOURS	2020-05-18/09:36	2	0	6.39	6.39	6.39	
		3 HOURS	2020-05-18/10:36	3	0	6.00	6	6	
		4 HOURS	2020-05-18/11:36	4	0	5.58	5.58	5.58	
		6 HOURS	2020-05-18/13:36	6	0	4.52	4.52	4.52	
		8 HOURS	2020-05-18/15:36	8	0	4.04	4.04	4.04	
		12 HOURS	2020-05-18/19:36	12	0	3.08	3.08	3.08	
		16 HOURS	2020-05-18/23:36	16	0	2.66	2.66	2.66	+
		24 HOURS	2020-05-19/07:36	24	0	1.83	1.83	1.83	+
		32 HOURS	2020-05-19/15:40	32.07	0.07	1.38	1.38	1.38	+
		48 HOURS	2020-05-20/07:36	48	0	BLQ	0		

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.3
Plasma Concentration-Time Profiles by Treatment
PK Concentration Population: Part B (MAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
Amisulpride (ng/mL)									
LB-102 50 mg BID									
01S2050									
Day 1 Dose 1	2020-05-12/07:42	PRE DOSE	2020-05-12/07:37	0	0	BLQ	0	0	
		0.25 HOUR	2020-05-12/07:57	0.25	0	BLQ	0	0	
		0.5 HOUR	2020-05-12/08:12	0.5	0	1.20	1.2	1.2	
		0.75 HOUR	2020-05-12/08:25	0.72	-0.03	1.87	1.87	1.87	
		1 HOUR	2020-05-12/08:47	1.08	0.08	2.05	2.05	2.05	
		1.5 HOURS	2020-05-12/09:12	1.5	0	2.41	2.41	2.41	
		2 HOURS	2020-05-12/09:42	2	0	4.90	4.9	4.9	
		3 HOURS	2020-05-12/10:42	3	0	4.80	4.8	4.8	
		4 HOURS	2020-05-12/11:42	4	0	5.17	5.17	5.17	
		6 HOURS	2020-05-12/13:42	6	0	3.86	3.86	3.86	+
		8 HOURS	2020-05-12/15:42	8	0	3.10	3.1	3.1	+
		12 HOURS	2020-05-12/19:41	11.98	-0.02	2.02	2.02	2.02	+

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Source Data: ADPCMAD
SDTM Date: 04AUG2020 16:09
Program Name: List_mad.sas
Analysis Date: 24AUG2020 10:23

Listing 16.2.6.3
Plasma Concentration-Time Profiles by Treatment
PK Concentration Population: Part B (MAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
Amisulpride (ng/mL)									
LB-102 50 mg BID									
01S2050									
Day 1 Dose 2	2020-05-12/19:42	PRE DOSE	2020-05-12/19:41	0	0	2.02	2.02	2.02	
		4 HOURS	2020-05-12/23:42	4	0	4.10	4.1	4.1	
		12 HOURS	2020-05-13/07:37	11.92	-0.08	2.85	2.85	2.85	
Day 2	2020-05-13/07:40	PRE DOSE	2020-05-13/07:37	0	0	2.85	2.85	2.85	
Day 3	2020-05-14/07:42	PRE DOSE	2020-05-14/07:37	0	0	4.15	4.15	4.15	
Day 4	2020-05-15/07:42	PRE DOSE	2020-05-15/07:37	0	0	4.56	4.56	4.56	
Day 5	2020-05-16/07:42	PRE DOSE	2020-05-16/07:37	0	0	4.79	4.79	4.79	

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Source Data: ADPCMAD SDTM Date: 04AUG2020 16:09
Program Name: List_mad.sas Analysis Date: 24AUG2020 10:23

Listing 16.2.6.3
Plasma Concentration-Time Profiles by Treatment
PK Concentration Population: Part B (MAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
Amisulpride (ng/mL)									
LB-102 50 mg BID									
01S2050									
Day 6	2020-05-17/07:42	PRE DOSE	2020-05-17/07:37	0	0	5.16	5.16	5.16	
Day 7	2020-05-18/07:42	PRE DOSE	2020-05-18/07:37	0	0	5.50	5.5	5.5	
		0.25 HOUR	2020-05-18/07:57	0.25	0	5.74	5.74	5.74	
		0.5 HOUR	2020-05-18/08:12	0.5	0	6.83	6.83	6.83	
		0.75 HOUR	2020-05-18/08:27	0.75	0	6.66	6.66	6.66	
		1 HOUR	2020-05-18/08:42	1	0	7.25	7.25	7.25	
		1.5 HOURS	2020-05-18/09:12	1.5	0	8.82	8.82	8.82	
		2 HOURS	2020-05-18/09:42	2	0	11.5	11.5	11.5	
		3 HOURS	2020-05-18/10:42	3	0	10.6	10.6	10.6	
		4 HOURS	2020-05-18/11:42	4	0	9.99	9.99	9.99	
		6 HOURS	2020-05-18/13:42	6	0	7.16	7.16	7.16	
		8 HOURS	2020-05-18/15:42	8	0	6.28	6.28	6.28	
		12 HOURS	2020-05-18/19:42	12	0	4.68	4.68	4.68	
		16 HOURS	2020-05-18/23:42	16	0	3.90	3.9	3.9	+
		24 HOURS	2020-05-19/07:42	24	0	2.76	2.76	2.76	+
		32 HOURS	2020-05-19/15:42	32	0	1.75	1.75	1.75	+
		48 HOURS	2020-05-20/07:42	48	0	BLQ	0		

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.3
Plasma Concentration-Time Profiles by Treatment
PK Concentration Population: Part B (MAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
Amisulpride (ng/mL)									
LB-102 50 mg BID									
01S2053									
Day 1 Dose 1	2020-05-12/07:44	PRE DOSE	2020-05-12/07:39	0	0	BLQ	0	0	
		0.25 HOUR	2020-05-12/07:59	0.25	0	BLQ	0	0	
		0.5 HOUR	2020-05-12/08:14	0.5	0	BLQ	0	0	
		0.75 HOUR	2020-05-12/08:27	0.72	-0.03	BLQ	0	0	
		1 HOUR	2020-05-12/08:49	1.08	0.08	BLQ	0	0	
		1.5 HOURS	2020-05-12/09:14	1.5	0	2.40	2.4	2.4	
		2 HOURS	2020-05-12/09:44	2	0	4.04	4.04	4.04	
		3 HOURS	2020-05-12/10:44	3	0	4.39	4.39	4.39	
		4 HOURS	2020-05-12/11:44	4	0	3.89	3.89	3.89	+
		6 HOURS	2020-05-12/13:44	6	0	3.34	3.34	3.34	+
		8 HOURS	2020-05-12/15:44	8	0	2.07	2.07	2.07	+
		12 HOURS	2020-05-12/19:41	11.95	-0.05	1.55	1.55	1.55	+

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Source Data: ADPCMAD
SDTM Date: 04AUG2020 16:09
Program Name: List_mad.sas
Analysis Date: 24AUG2020 10:23

Listing 16.2.6.3
Plasma Concentration-Time Profiles by Treatment
PK Concentration Population: Part B (MAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
Amisulpride (ng/mL)									
LB-102 50 mg BID									
01S2053									
Day 1 Dose 2	2020-05-12/19:44	PRE DOSE	2020-05-12/19:41	0	0	1.55	1.55	1.55	
		4 HOURS	2020-05-12/23:44	4	0	3.39	3.39	3.39	
		12 HOURS	2020-05-13/07:39	11.92	-0.08	2.37	2.37	2.37	
Day 2	2020-05-13/07:42	PRE DOSE	2020-05-13/07:39	0	0	2.37	2.37	2.37	
Day 3	2020-05-14/07:44	PRE DOSE	2020-05-14/07:39	0	0	3.19	3.19	3.19	
Day 4	2020-05-15/07:44	PRE DOSE	2020-05-15/07:39	0	0	2.75	2.75	2.75	
Day 5	2020-05-16/07:44	PRE DOSE	2020-05-16/07:39	0	0	3.01	3.01	3.01	

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Source Data: ADPCMAD SDTM Date: 04AUG2020 16:09
Program Name: List_mad.sas Analysis Date: 24AUG2020 10:23

Listing 16.2.6.3
Plasma Concentration-Time Profiles by Treatment
PK Concentration Population: Part B (MAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
Amisulpride (ng/mL)									
LB-102 50 mg BID									
01S2053									
Day 6	2020-05-17/07:44	PRE DOSE	2020-05-17/07:39	0	0	3.60	3.6	3.6	
Day 7	2020-05-18/07:44	PRE DOSE	2020-05-18/07:39	0	0	3.75	3.75	3.75	
		0.25 HOUR	2020-05-18/07:59	0.25	0	3.75	3.75	3.75	
		0.5 HOUR	2020-05-18/08:14	0.5	0	3.58	3.58	3.58	
		0.75 HOUR	2020-05-18/08:29	0.75	0	3.86	3.86	3.86	
		1 HOUR	2020-05-18/08:44	1	0	4.28	4.28	4.28	
		1.5 HOURS	2020-05-18/09:14	1.5	0	5.06	5.06	5.06	
		2 HOURS	2020-05-18/09:44	2	0	5.25	5.25	5.25	
		3 HOURS	2020-05-18/10:44	3	0	6.86	6.86	6.86	
		4 HOURS	2020-05-18/11:44	4	0	6.05	6.05	6.05	
		6 HOURS	2020-05-18/13:44	6	0	5.18	5.18	5.18	
		8 HOURS	2020-05-18/15:44	8	0	4.50	4.5	4.5	
		12 HOURS	2020-05-18/19:44	12	0	2.92	2.92	2.92	+
		16 HOURS	2020-05-18/23:44	16	0	1.85	1.85	1.85	+
		24 HOURS	2020-05-19/07:44	24	0	1.34	1.34	1.34	+
		32 HOURS	2020-05-19/15:44	32	0	BLQ	0		
		48 HOURS	2020-05-20/07:44	48	0	BLQ	0		

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.3
Plasma Concentration-Time Profiles by Treatment
PK Concentration Population: Part B (MAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
Amisulpride (ng/mL)									
LB-102 50 mg BID									
01S2055									
Day 1 Dose 1	2020-05-12/07:46	PRE DOSE	2020-05-12/07:41	0	0	BLQ	0	0	
		0.25 HOUR	2020-05-12/08:01	0.25	0	BLQ	0	0	
		0.5 HOUR	2020-05-12/08:16	0.5	0	BLQ	0	0	
		0.75 HOUR	2020-05-12/08:29	0.72	-0.03	3.47	3.47	3.47	
		1 HOUR	2020-05-12/08:51	1.08	0.08	5.13	5.13	5.13	
		1.5 HOURS	2020-05-12/09:16	1.5	0	5.77	5.77	5.77	
		2 HOURS	2020-05-12/09:46	2	0	6.67	6.67	6.67	
		3 HOURS	2020-05-12/10:46	3	0	5.55	5.55	5.55	
		4 HOURS	2020-05-12/11:46	4	0	4.58	4.58	4.58	
		6 HOURS	2020-05-12/13:46	6	0	3.25	3.25	3.25	+
		8 HOURS	2020-05-12/15:46	8	0	2.38	2.38	2.38	+
		12 HOURS	2020-05-12/19:43	11.95	-0.05	1.65	1.65	1.65	+

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Source Data: ADPCMAD SDTM Date: 04AUG2020 16:09
Program Name: List_mad.sas Analysis Date: 24AUG2020 10:23

Listing 16.2.6.3
Plasma Concentration-Time Profiles by Treatment
PK Concentration Population: Part B (MAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
Amisulpride (ng/mL)									
LB-102 50 mg BID									
01S2055									
Day 1 Dose 2	2020-05-12/19:46	PRE DOSE	2020-05-12/19:43	0	0	1.65	1.65	1.65	
		4 HOURS	2020-05-12/23:46	4	0	4.23	4.23	4.23	
		12 HOURS	2020-05-13/07:41	11.92	-0.08	2.43	2.43	2.43	
Day 2	2020-05-13/07:46	PRE DOSE	2020-05-13/07:41	0	0	2.43	2.43	2.43	
Day 3	2020-05-14/07:46	PRE DOSE	2020-05-14/07:41	0	0	3.72	3.72	3.72	
Day 4	2020-05-15/07:46	PRE DOSE	2020-05-15/07:41	0	0	4.59	4.59	4.59	
Day 5	2020-05-16/07:46	PRE DOSE	2020-05-16/07:41	0	0	4.09	4.09	4.09	

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Source Data: ADPCMAD SDTM Date: 04AUG2020 16:09
Program Name: List_mad.sas Analysis Date: 24AUG2020 10:23

Listing 16.2.6.3
Plasma Concentration-Time Profiles by Treatment
PK Concentration Population: Part B (MAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
Amisulpride (ng/mL)									
LB-102 50 mg BID									
01S2055									
Day 6	2020-05-17/07:46	PRE DOSE	2020-05-17/07:41	0	0	5.19	5.19	5.19	
Day 7	2020-05-18/07:46	PRE DOSE	2020-05-18/07:41	0	0	4.12	4.12	4.12	
		0.25 HOUR	2020-05-18/08:01	0.25	0	3.89	3.89	3.89	
		0.5 HOUR	2020-05-18/08:16	0.5	0	4.21	4.21	4.21	
		0.75 HOUR	2020-05-18/08:31	0.75	0	6.11	6.11	6.11	
		1 HOUR	2020-05-18/08:46	1	0	8.85	8.85	8.85	
		1.5 HOURS	2020-05-18/09:16	1.5	0	11.9	11.9	11.9	
		2 HOURS	2020-05-18/09:46	2	0	11.4	11.4	11.4	
		3 HOURS	2020-05-18/10:46	3	0	8.24	8.24	8.24	
		4 HOURS	2020-05-18/11:46	4	0	6.36	6.36	6.36	
		6 HOURS	2020-05-18/13:46	6	0	5.47	5.47	5.47	
		8 HOURS	2020-05-18/15:46	8	0	4.61	4.61	4.61	
		12 HOURS	2020-05-18/19:46	12	0	3.09	3.09	3.09	+
		16 HOURS	2020-05-18/23:46	16	0	2.10	2.1	2.1	+
		24 HOURS	2020-05-19/07:46	24	0	1.93	1.93	1.93	+
		32 HOURS	2020-05-19/15:46	32	0	1.38	1.38	1.38	+
		48 HOURS	2020-05-20/07:46	48	0	BLQ	0		

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.3
Plasma Concentration-Time Profiles by Treatment
PK Concentration Population: Part B (MAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
Amisulpride (ng/mL)									
LB-102 75 mg BID									
01S2080									
Day 1 Dose 1	2020-06-23/07:30	PRE DOSE	2020-06-23/07:25	0	0	BLQ	0	0	
		0.25 HOUR	2020-06-23/07:45	0.25	0	BLQ	0	0	
		0.5 HOUR	2020-06-23/08:00	0.5	0	1.84	1.84	1.84	
		0.75 HOUR	2020-06-23/08:13	0.72	-0.03	5.85	5.85	5.85	
		1 HOUR	2020-06-23/08:35	1.08	0.08	8.83	8.83	8.83	
		1.5 HOURS	2020-06-23/09:00	1.5	0	9.44	9.44	9.44	
		2 HOURS	2020-06-23/09:30	2	0	9.37	9.37	9.37	
		3 HOURS	2020-06-23/10:30	3	0	9.43	9.43	9.43	
		4 HOURS	2020-06-23/11:30	4	0	8.86	8.86	8.86	
		6 HOURS	2020-06-23/13:30	6	0	6.45	6.45	6.45	+
		8 HOURS	2020-06-23/15:30	8	0	4.61	4.61	4.61	+
		12 HOURS	2020-06-23/19:27	11.95	-0.05	2.66	2.66	2.66	+

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Source Data: ADPCMAD SDTM Date: 04AUG2020 16:09
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Listing 16.2.6.3
Plasma Concentration-Time Profiles by Treatment
PK Concentration Population: Part B (MAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
Amisulpride (ng/mL)									
LB-102 75 mg BID									
01S2080									
Day 1 Dose 2	2020-06-23/19:30	PRE DOSE	2020-06-23/19:27	0	0	2.66	2.66	2.66	
		4 HOURS	2020-06-23/23:30	4	0	11.1	11.1	11.1	
		12 HOURS	2020-06-24/07:25	11.92	-0.08	5.98	5.98	5.98	
Day 2	2020-06-24/07:30	PRE DOSE	2020-06-24/07:25	0	0	5.98	5.98	5.98	
Day 3	2020-06-25/07:30	PRE DOSE	2020-06-25/07:25	0	0	9.98	9.98	9.98	
Day 4	2020-06-26/07:30	PRE DOSE	2020-06-26/07:25	0	0	10.5	10.5	10.5	
Day 5	2020-06-27/07:30	PRE DOSE	2020-06-27/07:25	0	0	11.2	11.2	11.2	

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Source Data: ADPCMAD SDTM Date: 04AUG2020 16:09
Program Name: List_mad.sas Analysis Date: 24AUG2020 10:23

Listing 16.2.6.3
Plasma Concentration-Time Profiles by Treatment
PK Concentration Population: Part B (MAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
Amisulpride (ng/mL)									
LB-102 75 mg BID									
01S2080									
Day 6 Dose 1	2020-06-28/07:30	PRE DOSE	2020-06-28/07:25	0	0	10.4	10.4	10.4	
		0.25 HOUR	2020-06-28/07:45	0.25	0	10.1	10.1	10.1	
		0.5 HOUR	2020-06-28/08:00	0.5	0	11.8	11.8	11.8	
		1 HOUR	2020-06-28/08:30	1	0	19.7	19.7	19.7	
		2 HOURS	2020-06-28/09:30	2	0	19.2	19.2	19.2	
		4 HOURS	2020-06-28/11:30	4	0	16.6	16.6	16.6	
		8 HOURS	2020-06-28/15:30	8	0	12.0	12	12	
		12 HOURS	2020-06-28/19:25	11.92	-0.08	8.55	8.55	8.55	
Day 6 Dose 2	2020-06-28/19:30	PRE DOSE	2020-06-28/19:25	0	0	8.55	8.55	8.55	
		0.25 HOUR	2020-06-28/19:45	0.25	0	7.73	7.73	7.73	
		0.5 HOUR	2020-06-28/20:00	0.5	0	8.18	8.18	8.18	
		1 HOUR	2020-06-28/20:30	1	0	13.4	13.4	13.4	
		2 HOURS	2020-06-28/21:30	2	0	21.7	21.7	21.7	
		4 HOURS	2020-06-28/23:30	4	0	18.6	18.6	18.6	
		6 HOURS	2020-06-29/01:30	6	0	14.7	14.7	14.7	+
		8 HOURS	2020-06-29/03:30	8	0	13.4	13.4	13.4	+
		12 HOURS	2020-06-29/07:25	11.92	-0.08	9.94	9.94	9.94	+

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.3
Plasma Concentration-Time Profiles by Treatment
PK Concentration Population: Part B (MAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
Amisulpride (ng/mL)									
LB-102 75 mg BID									
01S2080									
Day 7	2020-06-29/07:30	PRE DOSE	2020-06-29/07:25	0	0	9.94	9.94	9.94	
		24 HOURS	2020-06-30/07:30	24	0	4.66	4.66	4.66	
		32 HOURS	2020-06-30/15:30	32	0	2.74	2.74	2.74	
		48 HOURS	2020-07-01/07:30	48	0	1.90	1.9	1.9	
01S2087									
Day 1 Dose 1	2020-06-23/07:36	PRE DOSE	2020-06-23/07:31	0	0	BLQ	0	0	
		0.25 HOUR	2020-06-23/07:51	0.25	0	BLQ	0	0	
		0.5 HOUR	2020-06-23/08:06	0.5	0	BLQ	0	0	
		0.75 HOUR	2020-06-23/08:19	0.72	-0.03	BLQ	0	0	
		1 HOUR	2020-06-23/08:41	1.08	0.08	1.43	1.43	1.43	
		1.5 HOURS	2020-06-23/09:06	1.5	0	1.38	1.38	1.38	
		2 HOURS	2020-06-23/09:36	2	0	4.38	4.38	4.38	
		3 HOURS	2020-06-23/10:36	3	0	6.05	6.05	6.05	
		4 HOURS	2020-06-23/11:36	4	0	5.20	5.2	5.2	
		6 HOURS	2020-06-23/13:36	6	0	4.49	4.49	4.49	+
		8 HOURS	2020-06-23/15:36	8	0	3.02	3.02	3.02	+
		12 HOURS	2020-06-23/19:33	11.95	-0.05	2.22	2.22	2.22	+

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.3
Plasma Concentration-Time Profiles by Treatment
PK Concentration Population: Part B (MAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
Amisulpride (ng/mL)									
LB-102 75 mg BID									
01S2087									
Day 1 Dose 2	2020-06-23/19:36	PRE DOSE	2020-06-23/19:33	0	0	2.22	2.22	2.22	
		4 HOURS	2020-06-23/23:36	4	0	5.38	5.38	5.38	
		12 HOURS	2020-06-24/07:31	11.92	-0.08	2.54	2.54	2.54	
Day 2	2020-06-24/07:36	PRE DOSE	2020-06-24/07:31	0	0	2.54	2.54	2.54	
Day 3	2020-06-25/07:36	PRE DOSE	2020-06-25/07:31	0	0	4.53	4.53	4.53	
Day 4	2020-06-26/07:36	PRE DOSE	2020-06-26/07:31	0	0	4.89	4.89	4.89	
Day 5	2020-06-27/07:36	PRE DOSE	2020-06-27/07:31	0	0	4.34	4.34	4.34	

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Source Data: ADPCMAD SDTM Date: 04AUG2020 16:09
Program Name: List_mad.sas Analysis Date: 24AUG2020 10:23

Listing 16.2.6.3
Plasma Concentration-Time Profiles by Treatment
PK Concentration Population: Part B (MAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
Amisulpride (ng/mL)									
LB-102 75 mg BID									
01S2087									
Day 6 Dose 1	2020-06-28/07:36	PRE DOSE	2020-06-28/07:31	0	0	4.63	4.63	4.63	
		0.25 HOUR	2020-06-28/07:51	0.25	0	4.67	4.67	4.67	
		0.5 HOUR	2020-06-28/08:06	0.5	0	4.57	4.57	4.57	
		1 HOUR	2020-06-28/08:36	1	0	6.22	6.22	6.22	
		2 HOURS	2020-06-28/09:36	2	0	7.15	7.15	7.15	
		4 HOURS	2020-06-28/11:36	4	0	8.20	8.2	8.2	
		8 HOURS	2020-06-28/15:36	8	0	4.63	4.63	4.63	
		12 HOURS	2020-06-28/19:31	11.92	-0.08	3.65	3.65	3.65	
Day 6 Dose 2	2020-06-28/19:36	PRE DOSE	2020-06-28/19:31	0	0	3.65	3.65	3.65	
		0.25 HOUR	2020-06-28/19:51	0.25	0	3.32	3.32	3.32	
		0.5 HOUR	2020-06-28/20:06	0.5	0	3.74	3.74	3.74	
		1 HOUR	2020-06-28/20:36	1	0	4.76	4.76	4.76	
		2 HOURS	2020-06-28/21:36	2	0	5.95	5.95	5.95	
		4 HOURS	2020-06-28/23:36	4	0	6.53	6.53	6.53	
		6 HOURS	2020-06-29/01:36	6	0	5.71	5.71	5.71	+
		8 HOURS	2020-06-29/03:36	8	0	4.80	4.8	4.8	+
		12 HOURS	2020-06-29/07:31	11.92	-0.08	4.02	4.02	4.02	+

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.3
Plasma Concentration-Time Profiles by Treatment
PK Concentration Population: Part B (MAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
Amisulpride (ng/mL)									
LB-102 75 mg BID									
01S2087									
Day 7	2020-06-29/07:36	PRE DOSE	2020-06-29/07:31	0	0	4.02	4.02	4.02	
		24 HOURS	2020-06-30/07:36	24	0	2.24	2.24	2.24	
		32 HOURS	2020-06-30/15:36	32	0	1.22	1.22	1.22	
		48 HOURS	2020-07-01/07:36	48	0	BLQ	0		
01S2092									
Day 1 Dose 1	2020-06-23/07:38	PRE DOSE	2020-06-23/07:33	0	0	BLQ	0	0	
		0.25 HOUR	2020-06-23/07:53	0.25	0	BLQ	0	0	
		0.5 HOUR	2020-06-23/08:08	0.5	0	1.09	1.09	1.09	
		0.75 HOUR	2020-06-23/08:21	0.72	-0.03	2.82	2.82	2.82	
		1 HOUR	2020-06-23/08:43	1.08	0.08	3.63	3.63	3.63	
		1.5 HOURS	2020-06-23/09:08	1.5	0	4.57	4.57	4.57	
		2 HOURS	2020-06-23/09:38	2	0	6.57	6.57	6.57	
		3 HOURS	2020-06-23/10:38	3	0	7.50	7.5	7.5	
		4 HOURS	2020-06-23/11:38	4	0	5.89	5.89	5.89	
		6 HOURS	2020-06-23/13:38	6	0	4.20	4.2	4.2	+
		8 HOURS	2020-06-23/15:38	8	0	3.34	3.34	3.34	+
		12 HOURS	2020-06-23/19:35	11.95	-0.05	2.27	2.27	2.27	+

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.3
Plasma Concentration-Time Profiles by Treatment
PK Concentration Population: Part B (MAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
Amisulpride (ng/mL)									
LB-102 75 mg BID									
01S2092									
Day 1 Dose 2	2020-06-23/19:38	PRE DOSE	2020-06-23/19:35	0	0	2.27	2.27	2.27	
		4 HOURS	2020-06-23/23:38	4	0	5.54	5.54	5.54	
		12 HOURS	2020-06-24/07:33	11.92	-0.08	4.30	4.3	4.3	
Day 2	2020-06-24/07:38	PRE DOSE	2020-06-24/07:33	0	0	4.30	4.3	4.3	
Day 3	2020-06-25/07:38	PRE DOSE	2020-06-25/07:33	0	0	5.19	5.19	5.19	
Day 4		PRE DOSE	2020-06-26/07:33			3.49	3.49	3.49	
01S2093									
Day 1 Dose 1	2020-06-23/07:40	PRE DOSE	2020-06-23/07:35	0	0	BLQ	0	0	
		0.25 HOUR	2020-06-23/07:55	0.25	0	BLQ	0	0	
		0.5 HOUR	2020-06-23/08:10	0.5	0	BLQ	0	0	
		0.75 HOUR	2020-06-23/08:23	0.72	-0.03	1.85	1.85	1.85	
		1 HOUR	2020-06-23/08:45	1.08	0.08	4.24	4.24	4.24	
		1.5 HOURS	2020-06-23/09:10	1.5	0	5.55	5.55	5.55	
		2 HOURS	2020-06-23/09:40	2	0	6.25	6.25	6.25	
		3 HOURS	2020-06-23/10:40	3	0	7.18	7.18	7.18	
		4 HOURS	2020-06-23/11:40	4	0	4.81	4.81	4.81	
		6 HOURS	2020-06-23/13:40	6	0	3.89	3.89	3.89	+
		8 HOURS	2020-06-23/15:40	8	0	2.88	2.88	2.88	+
		12 HOURS	2020-06-23/19:37	11.95	-0.05	2.11	2.11	2.11	+

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.3
Plasma Concentration-Time Profiles by Treatment
PK Concentration Population: Part B (MAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
Amisulpride (ng/mL)									
LB-102 75 mg BID									
01S2093									
Day 1 Dose 2	2020-06-23/19:40	PRE DOSE	2020-06-23/19:37	0	0	2.11	2.11	2.11	
		4 HOURS	2020-06-23/23:40	4	0	4.71	4.71	4.71	
		12 HOURS	2020-06-24/07:35	11.92	-0.08	2.89	2.89	2.89	
Day 2	2020-06-24/07:40	PRE DOSE	2020-06-24/07:35	0	0	2.89	2.89	2.89	
Day 3	2020-06-25/07:40	PRE DOSE	2020-06-25/07:35	0	0	3.85	3.85	3.85	
Day 4	2020-06-26/07:40	PRE DOSE	2020-06-26/07:35	0	0	4.55	4.55	4.55	
Day 5	2020-06-27/07:40	PRE DOSE	2020-06-27/07:35	0	0	5.83	5.83	5.83	

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Source Data: ADPCMAD SDTM Date: 04AUG2020 16:09
Program Name: List_mad.sas Analysis Date: 24AUG2020 10:23

Listing 16.2.6.3
Plasma Concentration-Time Profiles by Treatment
PK Concentration Population: Part B (MAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
Amisulpride (ng/mL)									
LB-102 75 mg BID									
01S2093									
Day 6 Dose 1	2020-06-28/07:40	PRE DOSE	2020-06-28/07:35	0	0	5.96	5.96	5.96	
		0.25 HOUR	2020-06-28/07:55	0.25	0	5.46	5.46	5.46	
		0.5 HOUR	2020-06-28/08:10	0.5	0	5.58	5.58	5.58	
		1 HOUR	2020-06-28/08:40	1	0	6.57	6.57	6.57	
		2 HOURS	2020-06-28/09:40	2	0	6.83	6.83	6.83	
		4 HOURS	2020-06-28/11:40	4	0	6.05	6.05	6.05	
		8 HOURS	2020-06-28/15:40	8	0	5.52	5.52	5.52	
		12 HOURS	2020-06-28/19:35	11.92	-0.08	4.91	4.91	4.91	
Day 6 Dose 2	2020-06-28/19:40	PRE DOSE	2020-06-28/19:35	0	0	4.91	4.91	4.91	
		0.25 HOUR	2020-06-28/19:55	0.25	0	5.01	5.01	5.01	
		0.5 HOUR	2020-06-28/20:10	0.5	0	4.78	4.78	4.78	
		1 HOUR	2020-06-28/20:40	1	0	5.45	5.45	5.45	
		2 HOURS	2020-06-28/21:40	2	0	6.21	6.21	6.21	
		4 HOURS	2020-06-28/23:40	4	0	7.60	7.6	7.6	
		6 HOURS	2020-06-29/01:40	6	0	7.02	7.02	7.02	+
		8 HOURS	2020-06-29/03:40	8	0	6.49	6.49	6.49	+
		12 HOURS	2020-06-29/07:35	11.92	-0.08	5.65	5.65	5.65	+

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.3
Plasma Concentration-Time Profiles by Treatment
PK Concentration Population: Part B (MAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
Amisulpride (ng/mL)									
LB-102 75 mg BID									
01S2093									
Day 7	2020-06-29/07:40	PRE DOSE	2020-06-29/07:35	0	0	5.65	5.65	5.65	
		24 HOURS	2020-06-30/07:40	24	0	4.19	4.19	4.19	
		32 HOURS	2020-06-30/15:40	32	0	2.68	2.68	2.68	
		48 HOURS	2020-07-01/07:40	48	0	1.34	1.34	1.34	
01S2094									
Day 1 Dose 1	2020-06-23/07:42	PRE DOSE	2020-06-23/07:37	0	0	BLQ	0	0	
		0.25 HOUR	2020-06-23/07:57	0.25	0	BLQ	0	0	
		0.5 HOUR	2020-06-23/08:12	0.5	0	2.75	2.75	2.75	
		0.75 HOUR	2020-06-23/08:25	0.72	-0.03	9.85	9.85	9.85	
		1 HOUR	2020-06-23/08:47	1.08	0.08	12.9	12.9	12.9	
		1.5 HOURS	2020-06-23/09:12	1.5	0	15.1	15.1	15.1	
		2 HOURS	2020-06-23/09:42	2	0	17.0	17	17	
		3 HOURS	2020-06-23/10:42	3	0	12.8	12.8	12.8	
		4 HOURS	2020-06-23/11:42	4	0	11.1	11.1	11.1	
		6 HOURS	2020-06-23/13:42	6	0	7.77	7.77	7.77	+
		8 HOURS	2020-06-23/15:42	8	0	5.34	5.34	5.34	+
		12 HOURS	2020-06-23/19:39	11.95	-0.05	2.75	2.75	2.75	+

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.3
Plasma Concentration-Time Profiles by Treatment
PK Concentration Population: Part B (MAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
Amisulpride (ng/mL)									
LB-102 75 mg BID									
01S2094									
Day 1 Dose 2	2020-06-23/19:42	PRE DOSE	2020-06-23/19:39	0	0	2.75	2.75	2.75	
		4 HOURS	2020-06-23/23:42	4	0	8.64	8.64	8.64	
		12 HOURS	2020-06-24/07:37	11.92	-0.08	5.40	5.4	5.4	
Day 2	2020-06-24/07:42	PRE DOSE	2020-06-24/07:37	0	0	5.40	5.4	5.4	
Day 3	2020-06-25/07:42	PRE DOSE	2020-06-25/07:37	0	0	8.50	8.5	8.5	
Day 4	2020-06-26/07:42	PRE DOSE	2020-06-26/07:37	0	0	7.68	7.68	7.68	
Day 5	2020-06-27/07:42	PRE DOSE	2020-06-27/07:37	0	0	8.07	8.07	8.07	

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Source Data: ADPCMAD SDTM Date: 04AUG2020 16:09
Program Name: List_mad.sas Analysis Date: 24AUG2020 10:23

Listing 16.2.6.3
Plasma Concentration-Time Profiles by Treatment
PK Concentration Population: Part B (MAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
Amisulpride (ng/mL)									
LB-102 75 mg BID									
01S2094									
Day 6 Dose 1	2020-06-28/07:42	PRE DOSE	2020-06-28/07:37	0	0	9.10	9.1	9.1	
		0.25 HOUR	2020-06-28/07:57	0.25	0	8.90	8.9	8.9	
		0.5 HOUR	2020-06-28/08:12	0.5	0	10.7	10.7	10.7	
		1 HOUR	2020-06-28/08:42	1	0	20.2	20.2	20.2	
		2 HOURS	2020-06-28/09:42	2	0	18.2	18.2	18.2	
		4 HOURS	2020-06-28/11:42	4	0	15.6	15.6	15.6	
		8 HOURS	2020-06-28/15:42	8	0	10.1	10.1	10.1	
		12 HOURS	2020-06-28/19:37	11.92	-0.08	6.77	6.77	6.77	
Day 6 Dose 2	2020-06-28/19:42	PRE DOSE	2020-06-28/19:37	0	0	6.77	6.77	6.77	
		0.25 HOUR	2020-06-28/19:57	0.25	0	6.32	6.32	6.32	
		0.5 HOUR	2020-06-28/20:12	0.5	0	7.16	7.16	7.16	
		1 HOUR	2020-06-28/20:42	1	0	9.89	9.89	9.89	
		2 HOURS	2020-06-28/21:42	2	0	13.1	13.1	13.1	
		4 HOURS	2020-06-28/23:42	4	0	14.1	14.1	14.1	
		6 HOURS	2020-06-29/01:42	6	0	11.6	11.6	11.6	+
		8 HOURS	2020-06-29/03:42	8	0	9.90	9.9	9.9	+
		12 HOURS	2020-06-29/07:37	11.92	-0.08	7.96	7.96	7.96	+

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.3
Plasma Concentration-Time Profiles by Treatment
PK Concentration Population: Part B (MAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
Amisulpride (ng/mL)									
LB-102 75 mg BID									
01S2094									
Day 7	2020-06-29/07:42	PRE DOSE	2020-06-29/07:37	0	0	7.96	7.96	7.96	
		24 HOURS	2020-06-30/07:42	24	0	4.52	4.52	4.52	
		32 HOURS	2020-06-30/15:42	32	0	3.41	3.41	3.41	
		48 HOURS	2020-07-01/07:42	48	0	1.89	1.89	1.89	
01S2102									
Day 1 Dose 1	2020-06-23/07:32	PRE DOSE	2020-06-23/07:27	0	0	BLQ	0	0	
		0.25 HOUR	2020-06-23/07:47	0.25	0	BLQ	0	0	
		0.5 HOUR	2020-06-23/08:02	0.5	0	1.04	1.04	1.04	
		0.75 HOUR	2020-06-23/08:15	0.72	-0.03	3.56	3.56	3.56	
		1 HOUR	2020-06-23/08:37	1.08	0.08	3.67	3.67	3.67	
		1.5 HOURS	2020-06-23/09:02	1.5	0	3.47	3.47	3.47	
		2 HOURS	2020-06-23/09:32	2	0	3.16	3.16	3.16	
		3 HOURS	2020-06-23/10:35	3.05	0.05	5.94	5.94	5.94	
		4 HOURS	2020-06-23/11:32	4	0	4.05	4.05	4.05	
		6 HOURS	2020-06-23/13:32	6	0	3.42	3.42	3.42	+
		8 HOURS	2020-06-23/15:32	8	0	2.65	2.65	2.65	+
		12 HOURS	2020-06-23/19:29	11.95	-0.05	1.78	1.78	1.78	+

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.3
Plasma Concentration-Time Profiles by Treatment
PK Concentration Population: Part B (MAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
Amisulpride (ng/mL)									
LB-102 75 mg BID									
01S2102									
Day 1 Dose 2	2020-06-23/19:32	PRE DOSE	2020-06-23/19:29	0	0	1.78	1.78	1.78	
		4 HOURS	2020-06-23/23:32	4	0	3.70	3.7	3.7	
		12 HOURS	2020-06-24/07:29	11.95	-0.05	2.63	2.63	2.63	
Day 2	2020-06-24/07:32	PRE DOSE	2020-06-24/07:29	0	0	2.63	2.63	2.63	
Day 3	2020-06-25/07:32	PRE DOSE	2020-06-25/07:27	0	0	4.02	4.02	4.02	
Day 4	2020-06-26/07:32	PRE DOSE	2020-06-26/07:27	0	0	5.16	5.16	5.16	
Day 5	2020-06-27/07:32	PRE DOSE	2020-06-27/07:27	0	0	3.41	3.41	3.41	

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Source Data: ADPCMAD
SDTM Date: 04AUG2020 16:09
Program Name: List_mad.sas
Analysis Date: 24AUG2020 10:23

Listing 16.2.6.3
Plasma Concentration-Time Profiles by Treatment
PK Concentration Population: Part B (MAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
Amisulpride (ng/mL)									
LB-102 75 mg BID									
01S2102									
Day 6 Dose 1	2020-06-28/07:32	PRE DOSE	2020-06-28/07:27	0	0	4.23	4.23	4.23	
		0.25 HOUR	2020-06-28/07:47	0.25	0	4.28	4.28	4.28	
		0.5 HOUR	2020-06-28/08:02	0.5	0	4.50	4.5	4.5	
		1 HOUR	2020-06-28/08:32	1	0	9.36	9.36	9.36	
		2 HOURS	2020-06-28/09:32	2	0	7.96	7.96	7.96	
		4 HOURS	2020-06-28/11:32	4	0	7.06	7.06	7.06	
		8 HOURS	2020-06-28/15:32	8	0	5.36	5.36	5.36	
		12 HOURS	2020-06-28/19:27	11.92	-0.08	4.49	4.49	4.49	
Day 6 Dose 2	2020-06-28/19:32	PRE DOSE	2020-06-28/19:27	0	0	4.49	4.49	4.49	
		0.25 HOUR	2020-06-28/19:47	0.25	0	4.47	4.47	4.47	
		0.5 HOUR	2020-06-28/20:02	0.5	0	4.13	4.13	4.13	
		1 HOUR	2020-06-28/20:32	1	0	4.19	4.19	4.19	
		2 HOURS	2020-06-28/21:32	2	0	6.46	6.46	6.46	
		4 HOURS	2020-06-28/23:32	4	0	7.83	7.83	7.83	
		6 HOURS	2020-06-29/01:32	6	0	6.52	6.52	6.52	+
		8 HOURS	2020-06-29/03:32	8	0	5.41	5.41	5.41	+
		12 HOURS	2020-06-29/07:27	11.92	-0.08	5.02	5.02	5.02	+

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.3
Plasma Concentration-Time Profiles by Treatment
PK Concentration Population: Part B (MAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
Amisulpride (ng/mL)									
LB-102 75 mg BID									
01S2102									
Day 7	2020-06-29/07:32	PRE DOSE	2020-06-29/07:27	0	0	5.02	5.02	5.02	
		24 HOURS	2020-06-30/07:32	24	0	3.02	3.02	3.02	
		32 HOURS	2020-06-30/15:32	32	0	1.85	1.85	1.85	
		48 HOURS	2020-07-01/07:32	48	0	BLQ	0		
LB-102 100 mg BID									
01S2059									
Day 1 Dose 1	2020-06-02/07:30	PRE DOSE	2020-06-02/07:25	0	0	BLQ	0	0	
		0.25 HOUR	2020-06-02/07:45	0.25	0	BLQ	0	0	
		0.5 HOUR	2020-06-02/08:00	0.5	0	BLQ	0	0	
		0.75 HOUR	2020-06-02/08:13	0.72	-0.03	3.88	3.88	3.88	
		1 HOUR	2020-06-02/08:35	1.08	0.08	5.24	5.24	5.24	
		1.5 HOURS	2020-06-02/09:00	1.5	0	5.41	5.41	5.41	
		2 HOURS	2020-06-02/09:30	2	0	12.3	12.3	12.3	
		3 HOURS	2020-06-02/10:30	3	0	15.6	15.6	15.6	
		4 HOURS	2020-06-02/11:30	4	0	14.0	14	14	
		6 HOURS	2020-06-02/13:30	6	0	8.93	8.93	8.93	+
		8 HOURS	2020-06-02/15:30	8	0	5.86	5.86	5.86	+
		12 HOURS	2020-06-02/19:27	11.95	-0.05	3.49	3.49	3.49	+

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.3
Plasma Concentration-Time Profiles by Treatment
PK Concentration Population: Part B (MAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
Amisulpride (ng/mL)									
LB-102 100 mg BID									
01S2059									
Day 1 Dose 2	2020-06-02/19:30	PRE DOSE	2020-06-02/19:27	0	0	3.49	3.49	3.49	
		4 HOURS	2020-06-02/23:30	4	0	10.5	10.5	10.5	
		12 HOURS	2020-06-03/07:25	11.92	-0.08	5.57	5.57	5.57	
Day 2	2020-06-03/07:30	PRE DOSE	2020-06-03/07:25	0	0	5.57	5.57	5.57	
Day 3	2020-06-04/07:30	PRE DOSE	2020-06-04/07:25	0	0	8.11	8.11	8.11	
Day 4		PRE DOSE	2020-06-05/07:25			3.94	3.94	3.94	
Day 5		PRE DOSE	2020-06-06/07:25			BLQ	1	1	

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.3
Plasma Concentration-Time Profiles by Treatment
PK Concentration Population: Part B (MAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
Amisulpride (ng/mL)									
LB-102 100 mg BID									
01S2066									
Day 1 Dose 1	2020-06-02/07:36	PRE DOSE	2020-06-02/07:31	0	0	BLQ	0	0	
		0.25 HOUR	2020-06-02/07:51	0.25	0	BLQ	0	0	
		0.5 HOUR	2020-06-02/08:06	0.5	0	BLQ	0	0	
		0.75 HOUR	2020-06-02/08:20	0.73	-0.02	4.96	4.96	4.96	
		1 HOUR	2020-06-02/08:41	1.08	0.08	5.20	5.2	5.2	
		1.5 HOURS	2020-06-02/09:06	1.5	0	6.66	6.66	6.66	
		2 HOURS	2020-06-02/09:36	2	0	7.62	7.62	7.62	
		3 HOURS	2020-06-02/10:36	3	0	8.44	8.44	8.44	
		4 HOURS	2020-06-02/11:36	4	0	8.03	8.03	8.03	
		6 HOURS	2020-06-02/13:36	6	0	5.91	5.91	5.91	+
		8 HOURS	2020-06-02/15:36	8	0	4.72	4.72	4.72	+
		12 HOURS	2020-06-02/19:33	11.95	-0.05	2.80	2.8	2.8	+

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.3
Plasma Concentration-Time Profiles by Treatment
PK Concentration Population: Part B (MAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
Amisulpride (ng/mL)									
LB-102 100 mg BID									
01S2066									
Day 1 Dose 2	2020-06-02/19:36	PRE DOSE	2020-06-02/19:33	0	0	2.80	2.8	2.8	
		4 HOURS	2020-06-02/23:36	4	0	4.60	4.6	4.6	
		12 HOURS	2020-06-03/07:31	11.92	-0.08	5.85	5.85	5.85	
Day 2	2020-06-03/07:36	PRE DOSE	2020-06-03/07:31	0	0	5.85	5.85	5.85	
Day 3	2020-06-04/07:36	PRE DOSE	2020-06-04/07:31	0	0	6.28	6.28	6.28	
Day 4		PRE DOSE	2020-06-05/07:31			3.15	3.15	3.15	
Day 5		PRE DOSE	2020-06-06/07:31			BLQ	1	1	

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.3
Plasma Concentration-Time Profiles by Treatment
PK Concentration Population: Part B (MAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
Amisulpride (ng/mL)									
LB-102 100 mg BID									
01S2069									
Day 1 Dose 1	2020-06-02/07:40	PRE DOSE	2020-06-02/07:35	0	0	BLQ	0	0	
		0.25 HOUR	2020-06-02/07:55	0.25	0	BLQ	0	0	
		0.5 HOUR	2020-06-02/08:10	0.5	0	BLQ	0	0	
		0.75 HOUR	2020-06-02/08:23	0.72	-0.03	BLQ	0	0	
		1 HOUR	2020-06-02/08:45	1.08	0.08	BLQ	0	0	
		1.5 HOURS	2020-06-02/09:10	1.5	0	1.88	1.88	1.88	
		2 HOURS	2020-06-02/09:40	2	0	4.18	4.18	4.18	
		3 HOURS	2020-06-02/10:40	3	0	7.92	7.92	7.92	
		4 HOURS	2020-06-02/11:40	4	0	6.78	6.78	6.78	
		6 HOURS	2020-06-02/13:40	6	0	5.03	5.03	5.03	+
		8 HOURS	2020-06-02/15:40	8	0	3.56	3.56	3.56	+
		12 HOURS	2020-06-02/19:37	11.95	-0.05	1.99	1.99	1.99	+

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.3
Plasma Concentration-Time Profiles by Treatment
PK Concentration Population: Part B (MAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
Amisulpride (ng/mL)									
LB-102 100 mg BID									
01S2069									
Day 1 Dose 2	2020-06-02/19:40	PRE DOSE	2020-06-02/19:37	0	0	1.99	1.99	1.99	
		4 HOURS	2020-06-02/23:40	4	0	3.13	3.13	3.13	
		12 HOURS	2020-06-03/07:35	11.92	-0.08	4.11	4.11	4.11	
Day 2	2020-06-03/07:40	PRE DOSE	2020-06-03/07:35	0	0	4.11	4.11	4.11	
Day 3		PRE DOSE	2020-06-04/07:48			2.08	2.08	2.08	
01S2076									
Day 1 Dose 1	2020-06-02/07:48	PRE DOSE	2020-06-02/07:47	0	0	BLQ	0	0	
		0.25 HOUR	2020-06-02/08:03	0.25	0	BLQ	0	0	
		0.5 HOUR	2020-06-02/08:18	0.5	0	7.88	7.88	7.88	
		0.75 HOUR	2020-06-02/08:31	0.72	-0.03	8.26	8.26	8.26	
		1 HOUR	2020-06-02/08:53	1.08	0.08	6.40	6.4	6.4	
		1.5 HOURS	2020-06-02/09:18	1.5	0	6.34	6.34	6.34	
		2 HOURS	2020-06-02/09:48	2	0	6.45	6.45	6.45	
		3 HOURS	2020-06-02/10:48	3	0	9.68	9.68	9.68	
		4 HOURS	2020-06-02/11:48	4	0	6.60	6.6	6.6	+
		6 HOURS	2020-06-02/13:48	6	0	5.23	5.23	5.23	+
		8 HOURS	2020-06-02/15:48	8	0	3.58	3.58	3.58	+
		12 HOURS	2020-06-02/19:45	11.95	-0.05	2.87	2.87	2.87	+

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.3
Plasma Concentration-Time Profiles by Treatment
PK Concentration Population: Part B (MAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
Amisulpride (ng/mL)									
LB-102 100 mg BID									
01S2076									
Day 1 Dose 2	2020-06-02/19:48	PRE DOSE	2020-06-02/19:45	0	0	2.87	2.87	2.87	
		4 HOURS	2020-06-02/23:48	4	0	6.61	6.61	6.61	
		12 HOURS	2020-06-03/07:43	11.92	-0.08	4.07	4.07	4.07	
Day 2	2020-06-03/07:48	PRE DOSE	2020-06-03/07:43	0	0	4.07	4.07	4.07	
Day 3	2020-06-04/07:48	PRE DOSE	2020-06-04/07:43	0	0	7.52	7.52	7.52	
01S2078									
Day 1 Dose 1	2020-06-02/07:38	PRE DOSE	2020-06-02/07:33	0	0	BLQ	0	0	
		0.25 HOUR	2020-06-02/07:53	0.25	0	BLQ	0	0	
		0.5 HOUR	2020-06-02/08:08	0.5	0	BLQ	0	0	
		0.75 HOUR	2020-06-02/08:21	0.72	-0.03	1.79	1.79	1.79	
		1 HOUR	2020-06-02/08:43	1.08	0.08	2.89	2.89	2.89	
		1.5 HOURS	2020-06-02/09:08	1.5	0	3.96	3.96	3.96	
		2 HOURS	2020-06-02/09:38	2	0	6.89	6.89	6.89	
		3 HOURS	2020-06-02/10:38	3	0	6.20	6.2	6.2	
		4 HOURS	2020-06-02/11:38	4	0	5.08	5.08	5.08	
		6 HOURS	2020-06-02/13:38	6	0	4.06	4.06	4.06	+
		8 HOURS	2020-06-02/15:38	8	0	3.13	3.13	3.13	+
		12 HOURS	2020-06-02/19:35	11.95	-0.05	2.10	2.1	2.1	+

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.3
Plasma Concentration-Time Profiles by Treatment
PK Concentration Population: Part B (MAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
Amisulpride (ng/mL)									
LB-102 100 mg BID									
01S2078									
Day 1 Dose 2	2020-06-02/19:38	PRE DOSE	2020-06-02/19:35	0	0	2.10	2.1	2.1	
		4 HOURS	2020-06-02/23:38	4	0	4.93	4.93	4.93	
		12 HOURS	2020-06-03/07:33	11.92	-0.08	4.02	4.02	4.02	
Day 2	2020-06-03/07:38	PRE DOSE	2020-06-03/07:33	0	0	4.02	4.02	4.02	
Day 3	2020-06-04/07:38	PRE DOSE	2020-06-04/07:33	0	0	5.44	5.44	5.44	
Day 4		PRE DOSE	2020-06-05/07:33			4.24	4.24	4.24	
Day 5		PRE DOSE	2020-06-06/07:33			2.12	2.12	2.12	

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Listing 16.2.6.3
Plasma Concentration-Time Profiles by Treatment
PK Concentration Population: Part B (MAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
Amisulpride (ng/mL)									
LB-102 100 mg BID									
01S2079									
Day 1 Dose 1	2020-06-02/07:32	PRE DOSE	2020-06-02/07:30	0	0	BLQ	0	0	
		0.25 HOUR	2020-06-02/07:47	0.25	0	BLQ	0	0	
		0.5 HOUR	2020-06-02/08:02	0.5	0	BLQ	0	0	
		0.75 HOUR	2020-06-02/08:15	0.72	-0.03	BLQ	0	0	
		1 HOUR	2020-06-02/08:46	1.23	0.23	3.79	3.79	3.79	
		1.5 HOURS	2020-06-02/09:02	1.5	0	4.40	4.4	4.4	
		2 HOURS	2020-06-02/09:32	2	0	6.64	6.64	6.64	
		3 HOURS	2020-06-02/10:33	3.02	0.02	8.46	8.46	8.46	
		4 HOURS	2020-06-02/11:32	4	0	6.61	6.61	6.61	
		6 HOURS	2020-06-02/13:32	6	0	5.00	5	5	+
		8 HOURS	2020-06-02/15:32	8	0	4.23	4.23	4.23	+
		12 HOURS	2020-06-02/19:29	11.95	-0.05	3.36	3.36	3.36	+

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Source Data: ADPCMAD SDTM Date: 04AUG2020 16:09
Program Name: List_mad.sas Analysis Date: 24AUG2020 10:23

Listing 16.2.6.3
Plasma Concentration-Time Profiles by Treatment
PK Concentration Population: Part B (MAD)

Analyte (Unit) / Treatment / Subject / Visit	Dose Date/Time	Scheduled Time point	Sampling Date/Time	Actual Time Point (hr)[1]	Deviation (hr)[2]	Concentration Reported	Concentration Imputed[3]	Concentration Imputed[4]	Terminal Phase[5]
Amisulpride (ng/mL)									
LB-102 100 mg BID									
01S2079									
Day 1 Dose 2	2020-06-02/19:32	PRE DOSE	2020-06-02/19:29	0	0	3.36	3.36	3.36	
		4 HOURS	2020-06-02/23:32	4	0	8.10	8.1	8.1	
		12 HOURS	2020-06-03/07:27	11.92	-0.08	5.83	5.83	5.83	
Day 2	2020-06-03/07:32	PRE DOSE	2020-06-03/07:27	0	0	5.83	5.83	5.83	
Day 3	2020-06-04/07:32	PRE DOSE	2020-06-04/07:27	0	0	8.06	8.06	8.06	

Note: Lower limit of quantification (LLOQ) of LB-102 = 1 ng/mL. LLOQ of amisulpride = 1 ng/mL.
[1] Actual time point is relative to reference dosing date/time.
[2] Deviation from the scheduled time point.
[3] Imputed concentration values for concentration summary.
[4] Imputed concentration values for PK parameter calculation and individual concentration data.
[5] Terminal phase flag (+) identifies concentration values which are used in estimating the terminal elimination rate.

Source Data: ADPCMAD SDTM Date: 04AUG2020 16:09
Program Name: List_mad.sas Analysis Date: 24AUG2020 10:23

13 APPENDIX

Pharmacokinetic Analysis Plan

PHARMACOKINETIC ANALYSIS PLAN

Protocol Title:	A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects
Protocol Number:	LB-102-001
Protocol Version/Date:	Version 5/18 May, 2020
Investigational Product:	LB-102
Sponsor:	LB Pharmaceuticals, Inc. 575 Madison Avenue New York, NY 10022 Phone: (646)-588-8175
PKAP Version/Date:	Version 2.0/15 June 2020

SIGNATURE PAGE

Protocol Title: A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Protocol Number: LB-102-001

PKAP Version/Date: Version 2.0 / 15 June 2020

We, the undersigned, have reviewed and approved this Statistical Analysis Plan:

Signature		Date
Liaoliao Li	Electronically signed by: Liaoliao Li Reason: Approved Date: Jun 18, 2020 16:24 CDT	18-Jun-2020
Liaoliao Li, PhD Clinical Pharmacologist Medpace, Inc.		
Jeffrey Vest	Electronically signed by: Jeffrey Vest Reason: Approved Date: Jun 18, 2020 17:05 EDT	18-Jun-2020
Jeffrey Vest, PhD Executive Director, Biostatistics Medpace, Inc.		
A Vaino		6/18/20
Andrew Vaino Chief Scientific Officer LB Pharmaceuticals, Inc.		

VERSION HISTORY

Version	Version Date	Description
1.0	03 March 2020	Original signed version
2.0	15 June 2020	Updated according to Protocol Amendment V5.0

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LIST OF ABBREVIATIONS

Abbreviation	Definition
AE	Adverse Event
API	Active Pharmaceutical Ingredient
AUC	Area under the Plasma Concentration vs Time Curve
BID	Twice Daily
BLQ	Below the Lower Limit of Quantification
CL/F	Apparent Clearance
C_{max}	Maximum Plasma Concentration
C-SSRS	Columbia-Suicide Severity Rating Scale
CI	Confidence interval
CV	Coefficient of variability
ECG	Electrocardiogram
GM	Geometric Mean
λ_z	Terminal Elimination Rate Constant
LLOQ	Lower Limit of Quantification
MAD	Multiple Ascending Doses
NCA	Non-Compartmental Analysis
PK	Pharmacokinetics
REML	Restricted Maximum Likelihood
$t_{1/2}$	Half-life
T_{max}	Time that drug is present at the maximum concentration in serum
QD	Once Daily
SAD	Single Ascending Dose
SD	Standard Deviation

1 INTRODUCTION

The purpose of this Pharmacokinetic (PK) Analysis Plan is to provide a description of the methods to be implemented for the analysis of PK data from the study with protocol number LB-102-001. The PK Analysis Plan will be finalized prior to database lock. Any deviations from the PK Analysis Plan after database lock will be documented in the final PK Report.

For completeness, the safety endpoints are included in this document as well. The analysis of safety endpoints will be planned in a separate document.

2 STUDY OVERVIEW

2.1 Study Objectives

2.1.1 Primary Objective

Part A: Single Ascending Dose (SAD)

- To evaluate the safety and the tolerability of a single oral dose of LB-102 compared to placebo

Part B: Multiple Ascending Doses (MAD)

- To evaluate the safety and the tolerability of multiple oral doses of LB-102 compared to placebo

2.1.2 Secondary Objectives

Part A (SAD)

- To evaluate the PK of a single dose of LB-102

Part B (MAD)

- To evaluate the PK of multiple oral doses of LB-102

2.2 Study Design

2.2.1 Overview

This is a Phase 1, randomized, double-blind, placebo-controlled study designed to evaluate the safety, tolerability, and PK of LB-102 in healthy subjects. The study will consist of two parts: Part A – Single Ascending Dose and Part B – Multiple Ascending Doses. There will be 5 cohorts in Part A and 3 Cohorts in Part B of this study. Each cohort consists of 8 subjects, with 6 subjects assigned to LB-102 treatment and 2 subjects assigned to placebo treatment.

In Parts A and B, eligible subjects will be randomized on Day 1 (pre-dose) to placebo (n=2) or LB-102 (n=6) treatment. Eligible subjects will receive 1 dose on Day 1 (Part A) or 13 doses on Days 1-7 (Part B) of placebo or LB-102. In Cohort 1 (Part A), dosing of the first 2 subjects (1 active and 1 placebo) will commence at least 24 hours prior to the remaining 6 subjects.

Dosing of the remaining subjects in the cohort may proceed if no safety issues are identified for the first 2 subjects. Blood samples for PK and safety assessments will be collected at nominal timepoints described in Appendix A and B. Subjects will be discharged on Day 3 (Part A) or Day 9 (Part B) and return for a Follow-up Visit (Day 8 or Day 15, respectively) for safety review. For Cohort 5 (Part A), subjects will return for an additional Follow-Up Visit.

Part A	
Cohort	**Treatment**
1 (n=8)[a]	LB-102 50 mg (n=6) or Matching Placebo (n=2) QD x 1 day
2 (n=8)[b]	LB-102 10 mg (n=6) or Matching Placebo (n=2) QD x 1 day
3 (n=8)[b]	LB-102 100 mg (n=6) or Matching Placebo (n=2) QD x 1 day
4 (n=8)[b]	LB-102 200 mg (n=6) or Matching Placebo (n=2) QD x 1 day
5 (n=8)[b]	LB-120 150 mg (n=6) or Matching Placebo (n=2) QD x 1 day
Part B	
6 (n=8)	LB-102 (n=6) 50 mg BID (100 mg/day) x 6 days (Days 1-6) and QD x 1 day (Day 7) or Matching Placebo (n=2) BID x 6 days (Days 1-6) and QD x 1 day (Day 7)
7 (n=8)	LB-102 (n=6) Y* mg BID x 6 days (Days 1-6) and QD x 1 day (Day 7) or Matching Placebo (n=2) BID x 6 days (Days 1-6) and QD x 1 day (Day 7)
8 (n=8)	LB-102 (n=6) Y* mg BID x 6 days (Days 1-6) and QD x 1 day (Day 7) or Matching Placebo (n=2) BID x 6 days (Days 1-6) and QD x 1 day (Day 7)

a – In Cohort 1 (Part A), dosing of the first 2 subjects (1 active and 1 placebo) will commence at least 24 hours prior to the remaining 6 subjects.
b – For Cohorts 2-5, the doses may be reduced based on the PK results of Cohort 1.
Y* - Dose will be determined by the SRC depending on the safety profile and clinical observations of the previous Cohort.
QD = Once daily; BID = Twice daily

2.2.2 Randomization and Blinding

Upon confirmation of eligibility, subjects will be randomized to LB-102 or placebo. Study randomization will be computer generated.

This study will be conducted under double-blind conditions so that neither the subject nor the Investigator or study staff members will know the identity of each subject's treatment. LB-102 will be dispensed by an unblinded pharmacist to study staff for administration to the patient.

Treatment assignment for an individual subject should be unblinded only in an emergency, when knowledge of the treatment assignment is urgently needed for the clinical management or welfare of the subject. The Investigator should contact the Medical Monitor or project manager before unblinding, when possible, but priority should be given to treatment of the subject. If unblinding occurs without prior approval, the Investigator should promptly communicate the circumstances leading to the unblinding by telephone and in writing to the Medical Monitor.

Breaking of the blind, other than as described above, will be considered a protocol violation. Any subject whose study drug treatment is unblinded will be discontinued and the date, time, and reason for the unblinding must be documented.

2.2.3 Study Drug

LB Pharmaceuticals, Inc. will provide an adequate supply of active pharmaceutical ingredient (API) for the research site. The Pharmacist at the site will mix the API into the capsules.

LB-102 capsules at each dose level will have matching placebo capsules. All study personnel, sponsor personnel, and vendors will be blinded. Only the unblinded pharmacist will know which study participants are randomized to LB-102 or placebo.

2.2.4 Sample Size Determination

The sample size for the study is based on clinical rather than statistical rationale. No formal sample size calculations were made. Cohorts of 8 subjects (6 active, 2 placebo) are sufficient to characterize the safety, tolerability, and PK profile of LB-102.

2.3 Study Endpoints

2.3.1 Safety Endpoints

The following schedule represents the ideal study schedule. It should be used as guidance for study conduct. In the event there are delays at any visit days that may affect the dates of any subsequent visit, the planned days may vary. The following will be monitored to assess safety:

- AEs
- Hematology, chemistry, urinalysis at:
    - Part A: Screening, Check-in (Day 0), Day 2, and at Follow-up (Day 8).
    - Part B: Screening, Check-in (Day 0), Day 4 prior to first dose, Day 8, and at Follow-up (Day 15).
- Prolactin at:
    - Part A: Screening, Day 3, and Day 8, and Day 15 (For Cohort 5 only).
    - Part B: Screening, Day 4, Day 9, and Day 15.
- Electrocardiogram (ECG)
    - Part A: Screening, Check-in, Day 1 at pre-dose and at 1, 2, 3, 4, 5, 6, 8 and 24 (Day 2) hours (±30 min) post-dose on Day 1. ECG will be measured once at each time point for Cohorts 1-4 and in triplicate for Cohort 5.
    - Part B: Screening, Check-in, Day 1 prior to the first dose and at 1, 2, 3, 4, 5, 6, and 8 hours (±30 min) post first dose on Day 1, prior to first dose on Days 2-7, and Day 8 (24 hours (±30 min) post-dose Day 7). ECG will be measured in triplicate at each time point.
- Physical examination
    - Part A: Screening, Check-in, Day 2, and Follow-up (Day 8).
    - Part B: Screening, Check-in, Days 2, 4 and 8, and Follow-up (Day 15).
- Vital signs (heart rate, respiratory rate, temperature, and blood pressure)
    - Part A: Screening, Check-in, Day 1 at pre-dose and at 0.5, 1, 1.5, 2, 4, 6, 8, 12, 24 (Day 2), and 48 hours (Day 3) post-dose (±30 min), and at Follow-up (Day 8).

- Part B: Screening, Check-in, Day 1 prior to first dose and at 0.5, 1, 1.5, 2, 4, 6, 8 and 12 hours (±30 min) post first dose on Day 1, prior to first dose and 2 hours (±30 min) post first dose on Days 2-7, 24 and 48 hours (±30 min) post Day 7 dose (Day 8 and 9), and at Follow-up.

- Columbia-Suicide Severity Rating Scale (C-SSRS)
  - Part A: Screening, Day 3.
  - Part B: Screening, Day 4, and Day 8.

2.3.2 Pharmacokinetic Endpoints

Plasma PK samples will be obtained at the following nominal time points:

- Part A (SAD)
  - Day 1: pre-dose, 15, 30, and 45 minutes (±5 minutes), and 1, 1.5, 2, 3, 4, 6, 8, 12, and 16 hours (±15 min) post-dose.
  - Days 2-3: 24, 32, and 48 hours (±15 min) post Day 1 dose.
  - Days 8 and 15 (For Cohort 5 only).
- Part B (MAD)
  - Day 1: prior to the first dose, 15, 30, and 45 minutes (±5 minutes), and 1, 1.5, 2, 3, 4, 6, 8, 12, and 16 hours (±15 min) post first dose.
  - Days 2-6: prior to first dose.
  - Day 7: pre-dose, 15, 30, and 45 minutes (±5 minutes), and 1, 1.5, 2, 3, 4, 6, 8, 12, and 16 hours (±15 min) post dose.
  - Days 8-9: 24, 32, and 48 hours (±15 min) post Day 7 dose.

3 STATISTICAL METHODOLOGY

3.1 General Considerations

Data will be summarized descriptively including the number of subjects with data (n), mean, standard deviation (SD), median, minimum, maximum, coefficient of variability (CV%), geometric mean (GM), and GM CV%. The data point with a value of zero will be excluded from the calculation of GM and GM CV%.

3.2 Analysis Populations

The PK Population will include all of the subjects who are randomized and have received at least one dose of LB-102 and have at least one post-dose measurable concentration of LB-102 or its metabolite, amisulpride.

3.3 Pharmacokinetic Analyses

The PK Population will be used for all PK analyses.

Deviation from procedures described in this protocol that impact the quality of data required to meet the objectives of the study will be documented and may result in exclusion of PK data from the analyses for a particular subject. This includes any deviations or events that would invalidate the evaluation of the PK. Examples of deviations and events which could result in exclusion of PK data from the analyses include

emesis after dosing (within the predetermined time), sample processing or assay errors that lead to inaccurate bioanalytical results. Other deviations or events, which do not disqualify data from analyses, may require minor adjustments to calculations. If these occur, data analyses will be adjusted and documented accordingly such that conclusions are not biased. An example of such an event includes, but is not limited to, minor deviations between the actual and scheduled time of sample collection.

3.3.1 Handling Missing Data or Concentration Below the Lower Limit of Quantification

If the actual sampling time is missing, but a valid concentration value has been measured, the concentration value will be flagged and the scheduled time point may be used for the calculation of PK parameters.

In cases of missing pre-dose on Day 1 (Part A or Part B), the missing components will be assumed as zero. In cases of missing pre-dose on Day 7 in Part B, the minimum observed concentration during the dosing interval (dosing on Day 17 until 12 hours after dosing) will be used as pre-dose concentration values. For the other cases, the missing data will not be imputed.

The following rules will be used to handle concentration below the lower limit of quantification (BLQ) for the PK parameter calculation and individual concentration data:

- If one or more BLQ values occur before the first measurable concentration, they will be assigned as zero concentration for single dose (Part A and the first dose of Part B) and as lower limit of quantification (LLOQ) for multiple dose (other than the first dose of Part B).
- If BLQ values occur between measurable concentrations or after the last measurable concentration in a profile, the BLQ should be omitted (set to missing).

The following general rules will be applied for the concentration summary (including tabulation and plotting):

- Mean concentrations at any individual time point will only be calculated if at least half of the subjects have valid values (i.e. quantifiable and not missing) at this time point for each treatment.
- In cases where a mean value is not calculated, due to the above criterion not being met, the mean value will be set to missing for mean plotting purposes.
- BLQ will be set to zero for the calculation of these mean values. The only exception is that the BLQ at pre-dose or before the last quantifiable measurement for multiple dose (other than Part A and the first dose of Part B) will be imputed as LLOQ for multiple dose.

3.3.2 Pharmacokinetic Concentration

<u>Part A (SAD)</u>

Individual plasma concentration of LB-102 and amisulpride will be listed and summarized by treatment at each nominal time points descriptively.

Individual plasma concentration of LB-102 and amisulpride will be plotted on a linear and semi-log scale against actual sampling time points for each treatment. Mean (±SD) plasma concentration of LB-102 and amisulpride will be plotted on a linear and semi-logarithmic scale against nominal time points by treatment.

<u>Part B (MAD)</u>

Individual plasma concentration of LB-102 and amisulpride will be listed and summarized by treatment at each nominal time points descriptively.

Individual plasma concentration of LB-102 and amisulpride will be plotted on a linear and semi-log scale against actual sampling time points for each treatment. Mean (±SD) plasma concentration of LB-102 and amisulpride will be plotted on a linear and semi-logarithmic scale against nominal time points by treatment.

The following figures will be prepared for LB-102 and amisulpride:

- PK profile after the first and second dose (Day 1 including Day 2 pre-dose as Day 1 24 hours post-dose)
- PK profiles after the last dose (Day 7-9)
- Trough (i.e. pre-dose) concentration on Day 2 through Day 7.

For linear plots, zero concentration value(s) before the first measurable concentration will be included in the plot. For semi-logarithmic plots, zero concentration value(s) before the first measurable concentration will be assigned a missing value. A reference line indicating LLOQ will be included in plots.

3.3.3 Pharmacokinetic Parameter

The PK parameters of LB-102 and amisulpride will be derived using non-compartmental and/or compartmental methods as appropriate. No PK parameters will be calculated for subjects with detectable concentrations for 2 or fewer time points.

Part A (SAD)

The following PK parameters of LB-102 and amisulpride will be calculated (as appropriate) using non-compartmental analysis (NCA) method.

Parameters	**Description**
C_{max}	maximum plasma concentration; if the maximum value occurs at more than one time point, C_{max} is defined as the first maximum value
T_{max}	time to C_{max}
λ_z	apparent terminal elimination rate constant
$t_{½}$	apparent elimination half-life; calculated as $\ln(2)/\lambda_z$
AUC_{0-t}	area under the plasma concentration vs time curve (AUC) calculated using linear-up log-down trapezoidal summation from time 0 to the last quantifiable plasma concentration (C_{last})
AUC_{0-24}	AUC from time 0 to 24 hours post-dose; if the concentration at 24 hours post-dose is not available or cannot be predicted for most subjects, the actual time for 24-hour sample will be used in place of the nominal 24 hours
AUC_{0-inf}	AUC from time 0 to infinity
AUC_{extrap}	proportion of AUC_{inf} due to extrapolation (%), calculated as $100*(C_{last}/\lambda_z)/AUC_{0-inf}$
CL/F	apparent clearance; calculated as Dose/AUC_{0-inf} (only for LB-102)

Part B (MAD)

The following PK parameters of LB-102 and amisulpride will be calculated (as appropriate) using NCA method after the first dose. The individual concentration data before the second dose on Day 1 will be used for PK parameter calculation.

Parameters	Description
$C_{max, D1}$	maximum plasma concentration on Day 1; if the maximum value occurs at more than one time point, C_{max} is defined as the first maximum value
$T_{max, D1}$	time to $C_{max, D1}$
$\lambda_{z, D1}$	apparent terminal elimination rate constant on Day 1
$t_{½, D1}$	terminal elimination half-life on Day 1, calculated as $\ln(2)/\lambda_{z, D1}$
$AUC_{0\text{-}12, D1}$	AUC from time 0 to 12 hours post-dose; if the concentration at 12 hours post-dose is not available or cannot be predicted for most subjects, the actual time for 12-hour sample will be used in place of the nominal 12 hours
$AUC_{0\text{-}24, D1}$	AUC from time 0 to 24 hours post-dose
$AUC_{0\text{-}inf, D1}$	AUC from time 0 to infinity on Day 1
$AUC_{extrap, D1}$	proportion of AUC_{inf} due to extrapolation (%) on Day 1, calculated as $100*(C_{last}/\lambda_{z\ D1})/AUC_{0\text{-}inf, D1}$

The following PK parameters of LB-102 and amisulpride will be calculated (as appropriate) using the individual concentration profiles on Day 7-9, or by comparing the PK parameters on Day 1 with Day 7. The NCA method will be used.

Parameters	Description
Tau	dosing interval; Tau=12 hours
$C_{max, D7}$	maximum plasma concentration on Day 7; between dose time and dose time + Tau. If the maximum value occurs at more than one time point, C_{max} is defined as the first maximum value
$T_{max, D7}$	time to $C_{max, D7}$
$\lambda_{z, D7}$	apparent terminal elimination rate constant on Day 7
$t_{½, D7}$	terminal elimination half-life on Day 7, calculated as $\ln(2)/\lambda_{z, D7}$
$AUC_{0\text{-}inf, D7}$	AUC from time 0 to infinity on Day 7
$AUC_{extrap, D7}$	proportion of AUC_{inf} due to extrapolation (%) on Day 7, calculated as $100*(C_{last}/\lambda_{z, D7})/AUC_{inf}$
$AUC_{0\text{-}12, D7}$	AUC over the dosing interval; if the concentration at 12 hours postdose is not available or cannot be predicted for most subjects, the actual time for 24-hour sample will be used in place of the nominal 12 hours
R_{Cmax}	accumulation ratio based on C_{max} after the first dose and last dose, calculated as $C_{max, D7}/C_{max, D1}$
R_{AUC}	accumulation ratio based on AUC after the first dose and last dose, calculated as $AUC_{0\text{-}12, D7}/ AUC_{0\text{-}12, D1}$
LI	Linearity index; calculated as $AUC_{0\text{-}12, D7}/AUC_{0\text{-}inf, D1}$
CLss/F	apparent clearance at steady state; calculated as $Dose/AUC_{0\text{-}12, D7}$ (only for LB-102)

The actual collection times will be used for the calculation of PK parameters. The Linear Up Log Down method (equivalent to the Linear Up/Log Down option in WinNonlin) will be used in the computation of AUCs.

The apparent terminal elimination rate constant (λ_z), will not be presented for subjects who do not exhibit a terminal elimination phase in their concentration-time profiles. In order to estimate λ_z, linear regression of concentration in logarithm scale versus time will be performed using at least 3 data points. Uniform weighting will be selected to perform the regression analysis to estimate λ_z.

Generally, the λ_z will not be assigned if one of the following happens:

1. T_{max} is one of the 3 last data points,

2. The adjusted regression coefficient (R-squared) is less than 0.80,

3. The AUC_{extrap} exceeds 20%,

4. The estimated elimination rate indicates a positive slope, or

5. The terminal elimination phase is not linear (as appears in a semi-logarithmic scale) based on visual inspection.

If the λ_z is not assigned, the values of associated PK parameters (e.g. λ_z, $AUC_{0\text{-}inf}$, CL/F, or $t_{1/2}$) will not be calculated.

PK parameters of LB-102 and amisulpride will be summarized by treatment using descriptive statistics.

3.3.4 Dose Proportionality

Dose proportionality will be assessed using a linear regression, or other acceptable approach.

Part A (SAD)

Dose proportionality will be assessed using power model based on PK Population. The power model is described below as:

$y = \alpha \times Dose^{\beta}$

where y denotes the plasma PK parameters (C_{max}, $AUC_{0\text{-}t}$, $AUC_{0\text{-}inf}$) of LB-102. Dose proportionality implies that $\beta=1$ and will be assessed by estimating β along with its 90% confidence interval. The exponent, β, in the power model will be estimated by regressing the ln-transformed PK parameter on ln-transformed dose. The power model will be fitted by restricted maximum likelihood (REML) using SAS Proc Mixed. Both the intercept and slope will be fitted as fixed effects. The mean slope will be estimated and the corresponding 90% confidence interval (CI) will be calculated.

Part B (MAD)

Dose proportionality will be assessed using power model similarly using PK Population. The plasma PK parameters of LB-102 on Day 1 ($C_{max,\ D1}$, $AUC_{0\text{-}t,\ D1}$, and $AUC_{0\text{-}inf,\ D1}$) and those on Day 7 ($C_{max,\ D7}$ and $AUC_{0\text{-}12,\ D7}$) will be used for the evaluation.

4 CHANGES FROM PROTOCOL-SPECIFIED STATISTICAL ANALYSES

There are no changes from the protocol-specified statistical analyses.

5 GENERAL REPORTING CONVENTIONS

5.1 Statistical Software

The creation of analysis datasets and all analyses will be performed using SAS® version 9.4 or higher. Phoenix WinNonlin version 8.0 or higher will be used in the determination of the PK terminal phase and the calculation of PK parameters. All the PK parameters will also be calculated via SAS® and verified with the Phoenix WinNonlin results.

5.2 Format of Tables, Figures, and Listings

Detailed Programming Specifications will be provided in a separate document.

APPENDIX A: SCHEDULE OF EVENT FOR PART A

	Screening	Check-In	Treatment Evaluation			Follow-Up Visits
Visit	**1**	**2**	**3**			***4 and 5***
Days	**Days -28 to -1**	**Day 0**	**Day 1**	**Day 2**	**Day 3**	**Days 8 *and 15*[9]**
Informed Consent	X					
Inclusion/Exclusion Criteria	X	X				
Medical History	X	X				
Demographics	X					
Randomization			X			
Height, Weight, BMI[1]	X					X ***(Day 8 Only)***
Physical Examination	X	X		X		X ***(Day 8 Only)***
Vital Signs[2]	X	X	X	X	X	X ***(Day 8 Only)***
Laboratory Tests	X	X		X		X ***(Day 8 Only)***
Serum HbA1c	X					
Serum Prolactin	X				X	X
HIV, HBsAg, and HCV Labs	X					
12-Lead ECG[3]	X	X	X	X		
C-SSRS	X				X	
Urine Drug Screening	X	X				
Alcohol Breathalyzer	X	X				
Pregnancy Test[4]	X	X				X ***(Day 8 Only)***
FSH[5]	X					
Plasma PK[6]			X	X	X	***X***
Dose Subjects[7]			X			
Concomitant Medication[8]	X	X	X	X	X	X
Adverse Event Assessment[8]		X	X	X	X	X

Notes to the Schedule of Events for Part A:

BMI = Body Mass Index; C-SSRS = Columbia-Suicide Severity Rating Scale; ECG = Electrocardiogram; FSH = Follicle-Stimulating Hormone; HbA1c = Hemoglobin A1c; HBsAg = Hepatitis B Surface Antigen; HCV = Hepatitis C Virus; HIV = Human Immunodeficiency Virus; PK = Pharmacokinetic

[1] Only Weight will be recorded at Follow-Up, height and BMI will not.

[2] Vital Signs will be measured at Screening, Check-in, Day 1 at pre-dose and 0.5, 1, 1.5, 2, 4, 6, 8, 12, 24, and 48 (±30 min) hours post-dose, and at Follow-up (Day 8).

[3] ECG will be measured at Screening, Check-in, Day 1 at pre-dose and 2, 4, 6, and 24 (±30 min) hours post-dose. ECG will be measured once at each time point for Cohorts 1-4 and in triplicate for Cohort 5.

[4] Serum pregnancy test at Screening and Urine pregnancy test at Day 0 and Day 8 for all females of childbearing potential.
[5] FSH test for postmenopausal women.
[6] Plasma PK samples will be collected on Day 1 at pre-dose, 15, 30, and 45 minutes (±5 minutes), and 1, 1.5, 2, 3, 4, 6, 8, 12, 16, 24, 32, and 48 hours (±15 min) post- dose, and Day 8 and Day 15.
[7] Subjects are required to fast for approximately 12 hours prior to Day 1 dosing.
[8] Concomitant Medication and Adverse Event Assessment will be recorded once per day on the days indicated.
[9] Day 15 Follow-Up Visit is scheduled for Cohort 5, Part A only.

APPENDIX B: SCHEDULE OF EVENT FOR PART B

	Screening	Check-In	Treatment Evaluation			Follow-Up Visit
Visit	**1**	**2**	**3**			**4**
Days	**Days -28 to -1**	**Day 0**	**Day 1**	**Days 2-7**	**Days 8-9**	**Day 15**
Informed Consent	X					
Inclusion/Exclusion Criteria	X	X				
Medical History	X	X				
Demographics	X					
Randomization			X			
Height, Weight, BMI[1]	X					X
Physical Examination	X	X		X (Days 2, 4 only)	X (Day 8 only)	X
Vital Signs[2]	X	X	X	X	X	X
Laboratory Tests	X	X		X (Day 4 only)	X (Day 8 only)	X
Serum HbA1c	X					
Serum Prolactin	X			X (Day 4 only)	X (Day 9 only)	X
HIV, HBsAg, and HCV Labs	X					
12-Lead ECG[3]	X	X	X	X	X (Day 8 only)	
C-SSRS	X			X (Day 4 only)	X (Day 8 only)	
Urine Drug Screening	X	X				
Alcohol Breathalyzer	X	X				
Pregnancy[4]	X	X				X
FSH[5]	X					
Plasma PK[6]			X	X	X	
Dose Subjects[7]			X	X		
Concomitant Medication[8]	X	X	X	X	X	X
Adverse Event Assessment[8]		X	X	X	X	X

Notes to the Schedule of Events for Part B:
BMI = Body Mass Index; C-SSRS = Columbia-Suicide Severity Rating Scale; ECG = Electrocardiogram; FSH = Follicle-Stimulating Hormone; HbA1c = Hemoglobin A1c; HBsAg = Hepatitis B Surface Antigen; HCV = Hepatitis C Virus; HIV = Human Immunodeficiency Virus; PK = Pharmacokinetic
[1] Only Weight will be recorded at Follow-up, height and BMI will not.
[2] Vital Signs will be measured at Screening, Check-in, Day 1 prior to the first dose and at 0.5, 1, 1.5, 2, 4, 6, 8, and 12 (±30 min) hours post first

dose, prior to the first dose and 2 hours (±30 min) post first dose on Days 2-7, 24 and 48 hours (±30 min) post Day 7 dose, and at Follow-up.
[3] ECG will be measured in triplicate at Screening, Check-in, Day 1 prior to the first dose and 1, 2, 3, 4, 5, 6, and 8 hours (±30 min) post first dose, prior to first dose on Days 2-7, and Day 8 (24 hours (±30 min) post Day 7 dose).
[4] Serum pregnancy test at screening and Urine pregnancy test at Day 0 and Day 15 for all females of childbearing potential.
[5] FSH test for postmenopausal women.
[6] Plasma PK samples will be collected on Day 1 prior to the first dose and 15, 30, and 45 minutes (±5 minutes), and 1, 1.5, 2, 3, 4, 6, 8, 12 and 16 hours (±15 min) post first dose, Days 2-6: prior to first dose, Day 7 prior to the first dose and 15, 30, and 45 minutes (±5 minutes), and 1, 1.5, 2, 3, 4, 6, 8, 12, 16, 24, 32, and
48 hours (±15 min) post first dose.
[7]Subjects are required to fast for approximately 12 hours prior to the first Day 1 dose. On Days 1-6, subjects will receive 2 doses per day (8 AM and 8 PM ±1 hour) separated by approximately 12 hours. On Day 7, subjects will receive 1 dose (8 AM ±1 hour).
[8] Concomitant Medication and Adverse Event Assessment will be recorded once per day on the days indicated.