Analysis Data Reviewer's Guide

Graviti Pharmaceuticals Pvt. Ltd.

Study No.: PANT-126-22

Final v1.0

Date: 14-Sep-2023

Contents

1. Introduction

1.1 Purpose

This document provides context for the analysis datasets and terminology that benefit from additional explanation beyond the Data Definition document (define.xml). In addition, this document provides a summary of ADaM conformance findings.

1.2 Acronyms

Acronym	Translation
T	Test
R	Reference

1.3 Study Data Standards and Dictionary Inventory

Standard or Dictionary	Versions Used
SDTM	SDTM IG **v3.3**
ADaM	ADaM IG **v1.1**
Data Definitions	Define.xml **v2.0**

1.4 Source Data Used for Analysis Dataset Creation

The analysis files for this study were derived from the submitted SDTM files. SDTM files were prepared from CRF data according to version 3.3 of the SDTM IG.

2. Protocol Description

2.1 Protocol Number and Title

Protocol Number: PANT-126-22

Protocol Title: An open label, randomized, balanced, single-dose, two-treatment, two-period, two-sequence, two-way crossover, oral bioequivalence study of Pantoprazole Sodium Delayed-Release Tablets 40 mg of Graviti Pharmaceuticals Pvt. Ltd. with Protonix (pantoprazole sodium) delayed-release tablets 40 mg Distributed by Wyeth Pharmaceuticals LLC, A subsidiary of Pfizer Inc., Philadelphia, PA 19101 in healthy, adult, human subjects under fasting conditions.

Protocol Version: 00 dated 03 Oct 2022.

2.2 Protocol Design in Relation to ADaM Concepts

An open label, randomized, balanced, single-dose, two-treatment, two-period, two-sequence, two-way crossover, oral bioequivalence study in 38 healthy, adult, human subjects (Males and non-pregnant, non-lactating females) under fasting conditions.

3. Analysis Considerations Related to Multiple Analysis Datasets

3.1 Comparison of SDTM and ADaM Content

- Are data for screen failures, including data for run-in screening (for example, SDTM values of ARMCD='SCRNFAIL', or 'NOTASSGN') included in ADaM datasets?

  Screen failures data is not used for analysis in the study.

- Are data taken from an ongoing study?

  Data is not taken from ongoing study.

Additional Content of Interest

- The values of baseline are identical between SDTM domains and ADaM datasets.

3.2 Core Variables

Core variables are those that are represented across all/most analysis datasets.

Variable Name	Variable Description
USUBJID	Unique Subject Identifier
STUDYID	Study Identifier
SUBJID	Subject Identifier for the Study
SITEID	Study Site Identifier
SAFFL	Safety Population Flag
ENRLFL	Enrolled Population Flag
ITTFL	Intent-To-Treat Population Flag
PKFL	PK Population Flag
DISCFL	Discontinuation Flag
COMPLFL	Completers Population Flag
ARMCD	Planned Arm Code
DCSREAS	Discontinuation Reason
ACTARMCD	Actual Arm Code

TRTSEQA	Actual Sequence of Treatments
TRTSEQP	Planned Sequence of Treatments
TRTSEQAN	Actual Sequence of Treatments (N)
TRTSEQPN	Planned Sequence of Treatments (N)
TRT01PN	Planned Treatment for Period 01 (N)
TRT02PN	Planned Treatment for Period 02 (N)
TRT01P	Planned Treatment for Period 01
TRT02P	Planned Treatment for Period 02
TRT01A	Actual Treatment for Period 01
TRT02A	Actual Treatment for Period 02
TRT01AN	Actual Treatment for Period 01 (N)
TRT02AN	Actual Treatment for Period 02 (N)
TR01SDT	Date of First Exposure in Period 01
TR01STM	Time of First Exposure in Period 01
TR01SDTM	Datetime of First Exposure in Period 01
TR01EDT	Date of Last Exposure in Period 01
TR01ETM	Time of Last Exposure in Period 01
TR01EDTM	Datetime of Last Exposure in Period 01
TR02SDT	Date of First Exposure in Period 02
TR02STM	Time of First Exposure in Period 02
TR02SDTM	Datetime of First Exposure in Period 02
TR02EDT	Date of Last Exposure in Period 02
TR02ETM	Time of Last Exposure in Period 02
TR02EDTM	Datetime of Last Exposure in Period 02
TRTSDT	Date of First Exposure to Treatment
TRTSDTM	Datetime of First Exposure to Treatment
TRTEDT	Date of Last Exposure to Treatment
TRTEDTM	Datetime of Last Exposure to Treatment

DTHFL	Subject Death Flag
DTHDTC	Date/Time of Death
WEIGHTBL	Weight (kg) at Baseline
HEIGHTBL	Height (cm) at Baseline
BMIBL	BMI (kg/m^2) at Baseline

3.3 Treatment Variables

ARM versus TRTxxP

- Are the values of ARM equivalent in meaning to values of TRTxxP?

  Yes, for this study the values of ARM (split with '/') and TRT01P/TRT02P are identical. The values of treatment variables are "**Protonix (pantoprazole sodium) delayed-release tablets 40 mg**" and "**Pantoprazole Sodium Delayed-Release Tablets 40 mg".**

ACTARM versus TRTxxA

- If TRTxxA is used, then are the values of ACTARM equivalent in meaning to values of TRTxxA?

  The values of ACTARM (split with '/') in SDTM is identical with the values of TRT01A/ TRT02A for all the subjects except for who were withdrawn from the study at second period had TRT02A.

Use of ADaM Treatment Variables in Analysis

- Are both planned and actual treatment variables used in analyses?

  There are no differences between the planned and the actual arm except for the subject who was withdrawn from the study at second period had TRT02A missing.

3.4 Subject Issues that Require Special Analysis Rules

There were no subjects who required any special analysis rules in this study.

3.5 Use of Visit Windowing, Unscheduled Visits, and Record Selection

- Was windowing used in one or more analysis datasets?

  No windowing rules were used in this study.

- Were unscheduled visits used in any analyses?

  Unscheduled visits were not used for any analysis.

3.6 Imputation/Derivation Methods

If date imputation was performed, were there rules that were used in multiple analysis datasets?

No date imputation was performed.

4. Analysis Data Creation and Processing Issues

4.1 Split Datasets

There were no datasets that were split at the time of submission of the study.

4.2 Data Dependencies

ADSL was used in the creation of all other analysis datasets.

4.3 Intermediate Datasets

- No intermediate analysis datasets were created in this trial.

4.4 Variable Conventions

- For laboratory parameters the values of SDTM LBTESTCD were prefixed with first letter of SDTM.LBSPEC is used for the value of PARAMCD.
- LBSPEC, LBTEST, LBMETHOD and LBSTRESU are concatenated to get PARAM in ADLB dataset.
- VSTEST and VSSTRESU are concatenated to get PARAM in ADVS.
- EGTEST and EGSTRESU are concatenated to get PARAM in ADEG.
- PCSPEC, PCTEST and PCSTRESU are concatenated to get PARAM in ADPC.
- PPTEST and PPSTRESU are concatenated to get PARAM in ADPP.

5. Analysis Dataset Descriptions

5.1 Overview

- Do the analysis datasets support all protocol- and statistical analysis plan-specified objectives?

  Yes, all protocol specified objectives are supported by the analysis datasets.

5.2 Analysis Datasets

Dataset – Dataset Label	Class	Efficacy	Safety	Baseline or other subject characteristics	Primary Objective	Structure
ADSL Subject Level Analysis Dataset	ADSL		X	X		One record per subject
ADPC PK concentrations Analysis Dataset	BDS	X				One or more records per subject per analysis parameter per analysis timepoint
ADPP PK Parameters Analysis Dataset	BDS	X				One or more records per subject per analysis parameter per analysis timepoint
ADVS Vital Signs Analysis Dataset	BDS		X			One or more records per subject per analysis parameter per analysis timepoint
ADLB Laboratory Test Results Analysis Dataset	BDS		X			One or more records per subject per analysis parameter per analysis timepoint
ADEG ECG Test Results Analysis Dataset	BDS		X			One or more records per subject per analysis parameter per analysis timepoint

5.2.1 ADSL – Subject Level Analysis Dataset

- In addition to supporting all analyses, ADSL contains variables to also support baseline characteristics and disposition analyses. The population indicator variables are defined in ADSL and copied into other analysis datasets as needed. All subjects in DM, were included in ADSL.

5.2.2 ADPC – PK concentrations Analysis Dataset

- ADPC contains one record per analysis parameter, per time-point, per subject along with additional ADSL needed variable.

5.2.3 ADPP – PK Parameters Analysis Dataset

- ADPP contains one record per analysis parameter, per visit, per subject along with additional ADSL needed variable.

5.2.4 ADVS – Vital Signs Analysis Dataset

- ADVS contains one record per analysis parameter, per time-point, per subject along with additional ADSL needed variable.

5.2.5 ADLB – Laboratory Test Results Analysis Dataset

- ADLB contains one record per analysis parameter, per visit, per subject along with additional ADSL needed variable.

5.2.6 ADEG – ECG Analysis Dataset

- ADEG contains one record per analysis parameter, per visit, per subject along with additional ADSL needed variable.

6. Data Conformance Summary

6.1 Conformance Inputs

- Were the analysis datasets evaluated for conformance with CDISC ADaM Validation Checks? Yes

If yes: Version of CDISC ADaM Validation Checks: **1.1**

- Specify software used: Pinnacle 21 Community **4.0.1**
- Were the ADaM datasets evaluated in relation to define.xml? **Yes**
- Was define.xml evaluated? **Yes**

6.2 Issues Summary

- No issues were reported in Pinnacle 21 validation report.

7. Submission of Programs

- All programs related to all ADaM datasets were submitted. The submitted programs will execute on a PC environment running Windows and SAS version 9.4. Library definitions will need to be modified to reflect the actual environment where run.
- Only one SAS Macro is used, and it is locally defined within the program used.