Saudi Public Assessment Report

(Quality Summary Report)

Ponizex®

Type of Application: New Drug Application

Type of Product: Human Generic Drug

Active Pharmaceutical Ingredient(s): Pantoprazole

ATC code: A02BC02

Dosage Form: Powder for solution for intravenous injection

Dosage Strength: 40mg

Pack Size: 1 Vial

Shelf life: 24 Months

Storage Conditions: Store below 30°c

Reference Product in SA (if applicable): Pepsolan 40 MG Powder for solution for injection

Marketing Authorization Holder: MS Pharma Saudi (MSPS)

Manufacturer: MS Pharma Saudi

Registration No.: 2305222051

Date of Decision: Approved on 8/11/2021

Proposed Indications:

- Reflux esophagitis
- Gastric and duodenal ulcer
- Zollinger-Ellison-Syndrome and other pathological hypersecretory conditions

Product Background

This product is considered as a human generic drug, for Saudi regulatory purposes. Furthermore, this product is qualified to follow the SFDA's normal submission regulatory pathway.

The SFDA approval for Ponizex® (Pantoprazole 40 mg) is based on a review of the quality, safety and efficacy as summarized hereinafter:

Quality Aspects

Drug Substance

- Pantoprazole sodium sesquihydrate is a white to off-white, crystalline powder. Pantoprazole sodium sesquihydrate is Freely soluble in water, soluble in methanol, practically insoluble in methylene chloride. Pantoprazole sodium sesquihydrate is an optically active compound and is given as a racemic mixture. Polymorphism has been observed.
- The drug substance is manufactured by a multiple-step chemical synthesis.
- The structure of Pantoprazole sodium sesquihydrate has been fully elucidated using several spectroscopic techniques.
- The drug substance specification includes relevant tests for proper quality control. The control methods are validated according to international guidelines.
- Appropriate stability data have been presented and justify the established re-test period.

Drug Product

- The finished product is available as white to almost white powder for solution for injection. Each vial contains 40 mg of pantoprazole sodium sesquihydrate. The composition of the drug product is adequately described, qualitatively and quantitatively. Suitable pharmaceutical development data have been provided for the finished product composition and manufacturing process.
- The manufacturing process is described narratively and in sufficient detail, taking into account pharmaceutical development data. Batch manufacturing formulas and in-process controls are included. Satisfactory validation data pertaining to the commercial manufacturing process are provided.
- The drug product specification covers appropriate parameters for this dosage form which allow for proper control of the finished drug product. The control methods are validated according to international guidelines. Batch data show consistent quality of the drug product.

- The drug product is packaged in 10 ml clear tubular glass vials with bromobutyl rubber stopper and aluminum cap with a flip-off seal.
- Appropriate stability data have been generated in the packaging material intended for commercial use and following relevant international guidelines. The data show good stability of the finished product and support the shelf life.

Clinical Aspects

Bioequivalence Study

A bioequivalence study is not required if the test product is an aqueous intravenous solution containing the same active substance as the reference product.

Product Information

The approved Summary of Product Characteristics (SPC) with the submission can be found in Saudi Drug Information System (SDI) at: https://sdi.sfda.gov.sa/

The date of revision of this text corresponds to that of the Saudi PAR. New information concerning the authorized medicinal product in question will not be incorporated into the Saudi PAR. New findings that could impair the medicinal product's quality, efficacy, or safety are recorded and published at (SDI or Summary Saudi-PAR report).

For inquiry and feedback regarding Saudi PAR, please contact us at Saudi.PAR@sdfa.gov.sa