Saudi Public Assessment Report

(Summary Report)

Dapxiga®

Type of Application: New Drug Application.

Type of Product: Human Generic Drug.

Active Pharmaceutical Ingredient(s): Dapagliflozin.

ATC code: A10BK01.

Dosage Form: Tablet.

Dosage Strength: 5 mg – 10 mg.

Pack Size: 30 Blister.

Shelf life: 24 Months.

Storage Conditions: Store below 30°C.

Reference Product in SA (if applicable): Forxiga.

Marketing Authorization Holder: Saudi Amarox.

Manufacturer: Hetero Labs Limited Unit – III.

Registration No.: 2906222285 – 2906222287.

Decision and Decision Date: Approved on 20/06/2022.

Proposed Indications: Dapagliflozin is indicated in adults for the treatment of insufficiently controlled type 2 diabetes mellitus:

- As an adjunct to diet and exercise.
- As a monotherapy when metformin is considered inappropriate due to intolerance.
- In addition to other medicinal products for the treatment of type 2 diabetes.

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 Dapxiga® (DAPAGLIFLOZIN 5 mg – 10 mg) is based on a review of the quality, safety and efficacy as summarized hereinafter:

Quality Aspects

Drug Substance

- Dapagliflozin is a white to off-white powder. Dapagliflozin is soluble in methanol. Dapagliflozin does have five chiral centers. Polymorphism has been observed (Amorphous).
- The drug substance is manufactured by a multiple-step chemical synthesis.
- The structure of Dapagliflozin 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

- Dapxiga drug product is available in two strengths:
    1. 5 mg film-coated tablets: Pink, round, biconvex, film-coated tablets debossed with "D32" on one side and "H" on the other side.
    2. 10 mg film-coated tablets: Pink, round, biconvex, film-coated tablets debossed with "D33" on one side and "H" on the other side.
- Each film-coated tablet contains 5 mg of Dapagliflozin or 10 mg of Dapagliflozin. 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 a carton box, containing 3 Alu/Alu blisters, each blister contain 10 tablets.
- 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

Ratio and 90% Confidence Intervals (CI) of Dapxiga® (Dapagliflozin) 10 mg versus Farxiga® (Dapagliflozin) 10 mg:

Pharmacokinetic Parameter	Point Estimate (%)	CI 90%
C_{max} (ng/mL)	102.28	96.55 – 108.35
AUC_{0-t} (ng/mL)	101.45	99.65 – 103.28
$AUC_{0-\infty}$ (ng/mL)	101.56	99.81 – 103.34

Based on the results obtained in this study, Dapxiga® (Dapagliflozin) 10 mg of Hetero Labs Limited, India, is **bioequivalent** to Farxiga® (Dapagliflozin) 10 mg of AstraZeneca Pharmaceuticals, USA, under fasting Conditions.

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