

Saudi Public Assessment Report

(Summary Report)

Drolina[®]

Type of Application: New Drug Application.

Type of Product: Human Generic Drug.

Active Pharmaceutical Ingredient(s): Furosemide

ATC code: C03CA01

Dosage Form: Tablet

Dosage Strength: 20 mg, 40 mg

Pack Size: 100

Shelf life: 24 months

Storage Conditions: Store below 30°C

Reference Product in SA (if applicable): Lasix

Marketing Authorization Holder: Alpha Pharma Industry

Note: The Saudi PAR is a final document, which provides information relating to a submission at a particular point in time and will not be updated after publication.

Manufacturer: Alpha Pharma Industry

Registration No.: 2101244770 , 2101244771

Date of Decision: 18/01/2024

Proposed Indications:

DROLINA 20 mg tablets

- Oedema resulting from heart or liver disease
- Oedema due to kidney disease (treatment of the underlying disorder should be the priority in nephrotic syndrome)
- Arterial hypertension

DROLINA 40 mg tablets

- Oedema resulting from heart or liver disease
- Oedema due to kidney disease (treatment of the underlying disorder should be the priority in nephrotic syndrome)
- Oedema due to burns
- Arterial hypertension

Product Background

This product is considered as a human generic drug for Saudi regulatory purposes qualified to follow the SFDA's regulatory Regular pathway.

The SFDA approval for Drolina® is based on a review of the quality, safety and efficacy of the product provided as an e-CTD in accordance with the relevant guidelines, basic product information summarized hereinafter:

Drug Substance

- Furosemide is a white or almost white, crystalline powder. Furosemide is practically insoluble in water, soluble in acetone, sparingly soluble in ethanol (96%), practically insoluble in methylene chloride. It dissolves in dilute solutions of alkali hydroxides. Polymorphism has been observed (Form I).
- The drug substance is manufactured by a multiple-step chemical synthesis.
- The structure of the API has been fully elucidated using several spectroscopic techniques.
- The drug substance specification includes relevant tests for proper quality control. Whereas the control methods are validated according to international guidelines.
- Appropriate stability data have been presented and justify the established re-test period.

Drug Product

- Drolina drug product is available in two strengths:
 1. 20 mg tablet: (White to off-white, round, flat face bevel edge tablets debossed JS55 on one side and plain on other side.).
 2. 40 mg tablet: (White to off-white, round, flat face, bevel edge tablets debossed JS49 on one side and Score line on other side.
- Each Single unit contains Qty unit of API. 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.
- 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 Alu - PVC green Opaque blisters in carton.

- 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 Drolina® (Furosemide) 40 mg versus Lasix® (Furosemide) 40 mg Tablets:

Pharmacokinetic Parameter	Point Estimate	90% CI
C _{max}	96.75	86.57 - 108.11
AUC _{0-t}	100.37	93.76 - 107.45
AUC _{0-∞}	99.79	93.47 - 106.54

Based on the results obtained in this study, Drolina® (Furosemide) 40 mg of Alpha pharma industries, Saudi Arabia, is **bioequivalent** to Lasix® (Furosemide) 40 mg of SANOFI, France 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