Saudi Public Assessment Report

(Quality Summary Report)

Kerasal®

Type of Application: New Drug Application.

Type of Product: Human Generic Drug.

Active Pharmaceutical Ingredient(s): Salicylic Acid.

ATC code: D01AE12.

Dosage Form: Ointment.

Dosage Strength: 5 %.

Pack Size: 1 Tube.

Shelf life: 24 Months.

Storage Conditions: Store below 30°C.

Reference Product in SA (if applicable): Diprosalic Ointment.

Marketing Authorization Holder: Dallah Pharma Factory.

Manufacturer: Dallah Pharma Factory.

Registration No.: 2806222272.

Decision and Decision Date: Approved on 27/06/2022.

Proposed Indications: For the treatment of hyperkeratosis and scaling conditions such as psoriasis.

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 Kerasal® (SALICYLIC ACID 5 %) is based on a review of the quality, safety and efficacy as summarized hereinafter:

Quality Aspects

Drug Substance

- Salicylic Acid is a white crystalline powder or white or colourless needle-shaped crystals, non-hygroscopic and odourless. Salicylic Acid is slightly soluble in water at 25°C, freely soluble in some organic solvents (acetone, ethanol and diethyl ether) and sparingly soluble in methylene chloride. Salicylic Acid does not have a chiral center. Salicylic acid crystallises in the form of monoclinic crystals, space group P21/A. Polymorphs are not mentioned in the chemical literature.
- The drug substance is manufactured by multiple-step chemical synthesis.
- The structure of Salicylic Acid 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 drug product is available as a Homogenous ointment with a characteristic odour, clear from foreign particles or black spots.
- Each tube contains 5 % w/w of Salicylic Acid. 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 50 ml white plastic tube with a cap in the carton box.
- 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

No bioequivalence study has been performed to support the application and none is needed. The efficacy of salicylic acid is well established.

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