# Saudi Public Assessment Report

## (Quality Summary Report)

## Tofibra®

**Type of Application:** New Drug Application

**Type of Product:** Human Generic Drug

**Active Pharmaceutical Ingredient(s):** Tobramycin

**ATC code:** J01GB01

**Dosage Form:** Nebuliser solution

**Dosage Strength:** 300 mg

**Pack Size:** 56 Ampoule

**Shelf life:** 36 Months

**Storage Conditions:** Store in a refrigerator (2°c – 8°c)

**Reference Product in SA (if applicable):** Tobi 60 mg/ml Nebuliser solution

**Marketing Authorization Holder:** Jazeera Pharmaceutical Industries

**Manufacturer:** Holopack (Laufen)

**Registration No.:** 0507222303

**Date of Decision:** Approved on 13/06/2022

**Proposed Indications:** Long-term management of chronic pulmonary infection due to Pseudomonas aeruginosa in cystic fibrosis (CF) patients aged 6 years and older. Consideration should be given to official guidance on the appropriate use of antibacterial agents.

# 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 Tofibra® (Tobramycin 300 mg) is based on a review of the quality, safety and efficacy as summarized hereinafter:**

# Quality Aspects

## Drug Substance

- Tobramycin is a highly hygroscopic white to off-white powder. Tobramycin is freely soluble in water; very slightly soluble in ethanol; practically insoluble in chloroform and ether. The configuration of the asymmetric carbon atoms is checked in Tobramycin by the specific optical rotation. Polymorphism has been observed.
- The drug substance is manufactured by a multiple-step chemical synthesis.
- The structure of Tobramycin 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 a clear and particle-free solution. Each ampoule contains 60 mg/ml of Tobramycin. 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 5 ml single use low-density polyethylene (LDPE) ampoules.

- 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

As the product provides local therapeutic activity (that is not systemic), investigation of bioequivalence is not appropriate for this product. In addition, the product contains 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