Saudi Public Assessment Report

(Summary Report)

TAMFREX®

Type of Application: New Drug Application

Type of Product: Human Generic Drug

Active Pharmaceutical Ingredient(s): Tamsulosin Hydrochloride

ATC code: G04CA02

Dosage Form: Prolonged-release capsule

Dosage Strength: 0.4 mg

Pack Size: 30 Blister

Shelf life: 24 Months

Storage Conditions: Store below 30°c

Reference Product in SA (if applicable): Harnal 0.4 mg Prolonged-release capsule

Marketing Authorization Holder: Aurobindo Pharma Saudi Arabia Limited

Manufacturer: Aurobindo Pharma Limited Unit VII

Registration No.: 3105222113

Date of Decision: Approved on 16/05/2022

Proposed Indications: Lower urinary tract symptoms (LUTS) associated with benign prostatic hyperplasia (BPH)

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 TAMFREX® (Tamsulosin Hydrochloride 0.4 mg) is based on a review of the quality, safety and efficacy as summarized hereinafter:

Quality Aspects

Drug Substance

- Tamsulosin Hydrochloride is a white or almost white powder. Tamsulosin Hydrochloride is freely soluble in formic acid, slightly soluble in water, very slightly soluble in anhydrous ethanol. Tamsulosin Hydrochloride does have one chiral center. Polymorphism has not been observed.
- The drug substance is manufactured by a multiple step chemical synthesis.
- The structure of Tamsulosin Hydrochloride 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 olive green opaque/orange opaque size '1EL' hard gelatin capsules imprinted with 'D' on the cap and '53' on the body with black edible ink filled with white to off-white Pellets. Each prolonged-release capsule contains 0.4 mg of Tamsulosin Hydrochloride. 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 a triple laminated PVC/PE/PVdC-Aluminium foil blister pack.

- 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

Bioequivalence study under fasting conditions:
Ratio and 90% Confidence Intervals (CI) of Tamfrex® (Tamsulosin) 0.4 mg versus Omnic® (Tamsulosin) 0.4 mg:

Pharmacokinetic Parameter	Point Estimate	CI 90%
C_{max} (ng/mL)	97.60	81.65 – 108.61
AUC_{0-t} (ng/mL)	95.62	85.52 – 106.92
$AUC_{0-\infty}$ (ng/mL)	95.48	85.30 – 106.88

Bioequivalence study under fed conditions:
Ratio and 90% Confidence Intervals (CI) of Tamfrex® (Tamsulosin) 0.4 mg versus Omnic® (Tamsulosin) 0.4 mg:

Pharmacokinetic Parameter	Point Estimate	CI 90%
C_{max} (ng/mL)	92.51	82.83 – 103.32
AUC_{0-t} (ng/mL)	89.77	82.56 – 97.62
$AUC_{0-\infty}$ (ng/mL)	89.63	82.64 – 97.22

Based on the results obtained in these studies, Tamfrex® (Tamsulosin) 0.4 mg of Aurobindo Pharma Ltd., India, is **bioequivalent** to Omnic® (Tamsulosin) 0.4 mg of AsteUas Pharma S.p.A. Italy, under fasting and fed 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