Saudi Public Assessment Report

(Summary Report)

Tadafect®

Type of Application: New Drug Application

Type of Product: Human Generic Drug

Active Ingredient: Tadalafil

ATC code: G04BE08

Dosage Form: Tablets

Dosage Strength: 20 mg

Pack Size: 8 Tablets

Shelf life: 48 Months

Storage Conditions: Do not store above 30°C. Protect from moisture

Reference Product in SA (if applicable): Cialis 20 mg Film-coated tablet

Marketing Authorization Holder: Aurobindo Pharma Saudi Arabia Limited

Manufacturer: Aurobindo Pharma Limited Unit VII

Registration No.: 1704221945

Decision and Decision Date: Approved on 16/10/2021

Proposed Indications: Treatment of erectile dysfunction in adult males. In order for tadalafil to be effective for the treatment of erectile dysfunction, sexual stimulation is required. Tadalafil is not indicated for use by women.

Product Background

This product is considered 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 Tadafect® (Tadalafil) based on a review of quality, safety and efficacy summarized hereinafter:

Quality Aspects

Drug Substance

Tadalafil is non-hygroscopic white or almost white powder. Tadalafil is practically insoluble in water, freely soluble in dimethyl sulfoxide, slightly soluble in methylene chloride. Tadalafil does have chirality. Polymorphism has not been observed.

- The drug substance is manufactured by a multiple-step chemical synthesis.
- The structure of Tadalafil 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

- The finished product is available as Yellow colored, oval shaped, film-coated tablets debossed with '20' on one side and 'TL' on the other side. Each tablet contains 20 mg of Tadalafil. 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. They 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 Clear PVC/PVdC – Aluminium foil.

- 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 Tadafact® (Tadalafil) 20 mg versus Cialis® (Tadalafil) 20 mg:

Pharmacokinetic Parameter	Point Estimate (%)	CI 90%
C_{max} (ng/mL)	101.44	95.18 - 108.11
AUC_{0-t} (ng.hr/mL)	100.82	94.37 - 107.70
$AUC_{0-\infty}$ (ng.hr/mL)	103.38	96.75 - 110.47

Bioequivalence study under fed conditions:
Ratio and 90% Confidence Intervals (CI) of Tadafact® (Tadalafil) 20 mg versus Cialis® (Tadalafil) 20 mg:

Pharmacokinetic Parameter	Point Estimate (%)	CI 90%
C_{max} (ng/mL)	106.03	100.90 - 111.41
AUC_{0-72} (ng.hr/mL)	102.41	98.40 - 106.57

Based on the results obtained in these studies, Tadafact® (Tadalafil) 20 mg of Aurobindo Pharma Limited (Unit VII), India, is **bioequivalent** to Cialis® (Tadalafil) 20 mg of Lilly S.A, Avada del la Industria, Spain, 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