Saudi Public Assessment Report

(Summary Report)

Ascenta®

Type of Application: New Drug Application.

Type of Product: Human Generic Drug.

Active Pharmaceutical Ingredient(s): Tadalafil

ATC code: G04BE08

Dosage Form: Film-coated tablet

Dosage Strength: 20 mg, 5 mg

Pack Size: 4, 30

Shelf life: 24 months

Storage Conditions: Store below 30°C

Reference Product in SA (if applicable): Cialis

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.: 1512200340 - 1212200323

Date of Decision: 18/02/2020

Proposed Indications:

ASCENTA is indicated for the Treatment of erectile dysfunction in adult males. In order for Tadalafil to be effective for the treatment of erectile dysfunction, sexual stimulation is required.

For 5 mg only: Treatment of the signs and symptoms of benign prostatic hyperplasia in adult males.

ASCENTA is not indicated for use by women.

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 Ascenta® 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

- Tadalafil is a white or almost white powder. Tadalafil is practically insoluble in water, freely soluble in Dimethyl Sulphoxide, slightly soluble in Methylene chloride. 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

- The finished drug product is available in two strengths:
    1. 5 mg film coated tablet: (Yellowish, almond shaped, film coated tablet with JS9 on one side and plain on another side).
    2. 20 mg film coated tablet: (Yellowish, almond shaped, film coated tablet with JS1 on one side and plain on another side).
- Each tablet contains 5 mg or 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.
- 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 / PVDC blister.

- 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 Ascenta® (Tadalafil) 20 mg versus Cialis® (Tadalafil) 20 mg Tablets:

For fast study

Pharmacokinetic Parameter	**Point Estimate**	**90% CI**
C_{max}	104.46	95.68 - 114.05
AUC_{0-72}	103.94	97.85 - 110.41

For fed study

Pharmacokinetic Parameter	**Point Estimate**	**90% CI**
C_{max}	101.13	95.23 - 107.40
AUC_{0-72}	95.46	87.60 - 104.02

Based on the results obtained in these studies, Ascenta® (Tadalafil) 20 mg of Julphar Saudi Arabia, is **bioequivalent** to Cialis® (Tadalafil) 20 mg of Spimaco, Saudi Arabia for Eli Lilly and Company, UK, 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