الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Saudi Public Assessment Report

(Summary Report)

Exopex ®

Type of Application: New Drug Application.

Type of Product: Human Generic Drug.

Active Pharmaceutical Ingredient(s): Escitalopram

ATC code: N06AB10

Dosage Form: Film-coated tablet

Dosage Strength: 10 mg , 20 mg .

Pack Size: 30

Shelf life: 24 months.

Storage Conditions: Do not store above 30°C.

Reference Product in SA (if applicable): Cipralex®

Marketing Authorization Holder: Al-Taqaddom pharmaceutical Industries

Manufacturer: Al-Taqaddom pharmaceutical Industries

Registration No.: 0410200181, 0410200182

Date of Decision: 04/10/2020

Proposed Indications:

- Treatment of major depressive episodes.

- Treatment of panic disorder with or without agoraphobia.

- Treatment of social anxiety disorder (social phobia).

- Treatment of generalised anxiety disorder.

- Treatment of obsessive-compulsive disorder.

Escitalopram is indicated in adults.

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 Exopex ® 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:

Quality Aspects

Drug Substance

- Escitalopram Oxalate is a Fine, white to slightly yellow color powder. Escitalopram Oxalate is Freely Soluble in Methanol and in Dimethyl sulphoxide; sparingly Soluble in Methanol and in alcohol; very slightly soluble in ethyl acetate and in isopropyl alcohol; insoluble in Heptane. Escitalopram Oxalate does have one chiral centre. Polymorphism has been observed (Form I).
- The drug substance is manufactured by a multiple-step chemical synthesis.
- The structure of Escitalopram Oxalate 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 drug product is available in two strengths:
    1. 10 mg Film Coated tablets: (White to off-white, film coated oval biconvex tablet engraved with (TQ) on one side and bisected on the other side).
    2. 20 mg Film Coated tablets: (White to off-white, film coated oval biconvex tablet engraved with (TQ) on one side and bisected on the other side).
- Each tablet contains 10 mg or 20 mg unit of Escitalopram Oxalate. 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 PVC/PE/PVDC/Aluminium 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 Exopex® (Escitalopram) 20.mg Film coated tablet versus Cipralex® (Escitalopram) 20 mg Film coated tablet:

Pharmacokinetic Parameter	**Point Estimate**	**90% CI**
C_{max}	95.5	89.16-102.23
AUC_{0-t}	95.9	91.95-99.97

Based on the results obtained in this study, Exopex® (Escitalopram) 20.mg Film coated tablet of Hetero Labs Limited, India is **bioequivalent** to Cipralex® (Escitalopram) 20 mg Film coated tablet under Fasting 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