

# Saudi Public Assessment Report

(Summary Report)

**GLOFEL<sup>®</sup>**

**Type of Application:** New drug application.

**Type of Product:** Human generic drug.

**Active Pharmaceutical Ingredient(s):** Tadalafil.

**ATC code:** G04BE09.

**Dosage Form:** Film-coated tablet.

**Dosage Strength:** 5 mg, 20 mg.

**Pack Size:** 4.

**Shelf life:** 36 months.

**Storage Conditions:** Store below 30°C.

**Reference Product in SA (if applicable):** Cilalis 5 mg. Film-Coated Tablets.



**Marketing Authorization Holder:** Global Pharma.

**Manufacturer:** Global Pharma.

**Registration No.:** 2604221982 - 45-444-19.

**Date of Decision:** Approved on 1/01/2020.

**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 5 mg only: Treatment of the signs and symptoms of benign prostatic hyperplasia in adult males. Glocel is not indicated for use by women.

## 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 regulatory pathway regular submission.

**The SFDA approval for brand Glofel® (Tadalafil 5 mg, 20 mg) is based on a review of the quality, safety and efficacy as summarised hereinafter:**

## Quality Aspects

### Drug Substance

- Tadalafil is a white to almost white powder. Tadalafil is practically insoluble in water, freely soluble in dimethyl sulfoxide, slightly soluble in methylene chloride. Tadalafil exhibits stereoisomerism because the molecule has two asymmetric carbon atoms (chiral centres) (R, R configuration/ cis isomer). Polymorphism has been observed. (form A).
- 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. 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 tablet: Mustard yellow coloured, film-coated caplets, embossed with G2 on one side and plain on the other side
  2. 20 mg tablet: Mustard yellow coloured film-coated caplets, embossed with GP70 on one side and plain on the other 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 of (5 mg strength) is packaged in a carton box, containing 2 PVC/EVOH/Aclar blisters, containing 14 tablets in each blister.
- The drug product of (20 mg strength) is packaged in a carton box, containing 1 PVC/EVOH/Aclar blisters or 2 PVC/EVOH/Aclar blisters or 6 PVC/EVOH/Aclar blisters, containing 2 tablets in each 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 (24 months).

## Clinical Aspects

### Bioequivalence Study

#### Bioequivalence study under fasting conditions:

Ratio and 90% Confidence Intervals (CI) of Glofel<sup>®</sup> (Tadalafil) 20 mg versus Cialis<sup>®</sup> (Tadalafil) 20 mg:

Pharmacokinetic Parameter	Point Estimate	90% CI
C <sub>max</sub> (ng/mL)	108.19	101.24 – 115.61
AUC <sub>0-t</sub> (ng/mL)	106.82	100.84 – 113.15
AUC <sub>0-∞</sub> (ng/mL)	108.27	101.7 – 115.24

#### Bioequivalence study under fed conditions:

Ratio and 90% Confidence Intervals (CI) of Glofel<sup>®</sup> (Tadalafil) 20 mg versus Cialis<sup>®</sup> (Tadalafil) 20 mg:

Pharmacokinetic Parameter	Point Estimate	90% CI
C <sub>max</sub> (ng/mL)	103.19	99.66 - 106.84
AUC <sub>0-t</sub> (ng/mL)	99.43	94.58 - 104.53
AUC <sub>0-∞</sub> (ng/mL)	101.00	96.37 - 105.86

Based on the results obtained in these studies, Glofel<sup>®</sup> (Tadalafil) 20 mg of Globalpharma Co LLC, UAE, is **bioequivalent** to Cialis<sup>®</sup> (Tadalafil) 20 mg of Lilly Puerto Rico, 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/>

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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](mailto:Saudi.PAR@sdfa.gov.sa)