

Saudi Public Assessment Report

(Summary Report)

Vesuv[®]

Type of Application: New drug application.

Type of Product: Human generic drug.

Active Pharmaceutical Ingredient(s): Sildenafil.

ATC code: G04BE03.

Dosage Form: film-coated tablets.

Dosage Strength: 100 mg.

Pack Size: 4.

Shelf life: 36 Months.

Storage Conditions: Do not store above 30°C.

Reference Product in SA (if applicable): Viagra 100 mg film-coated tablets.

Marketing Authorization Holder: Oman Pharmaceutical Products.



Manufacturer: Oman Pharmaceutical Products.

Registration No.: 1808222520 – 1808222521.

Date of Decision: Approved on 9/08/2022.

Proposed Indications: Vesuv is indicated in adult men with erectile dysfunction, which is the inability to achieve or maintain a penile erection sufficient for satisfactory sexual performance. In order for Vesuv to be effective, sexual stimulation is required.

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 Vesuv[®] (Sildenafil 100 mg) is based on a review of the quality, safety and efficacy as summarised hereinafter:

Quality Aspects

Drug Substance

- Sildenafil Citrate is a white or almost white, slightly hygroscopic, crystalline powder. Sildenafil Citrate is slightly soluble in water and in methanol, practically insoluble in hexane. Sildenafil Citrate does not have chiral center. Polymorphism has been observed.
- The drug substance (DS) is manufactured by a multiple-step chemical synthesis.
- The structure of Sildenafil Citrate 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 in three strengths:
 1. 25 mg film coated tablets: Blue coloured round, biconvex, coated tablets, with a deep break line and debossed with "S" & "I" on either side of the break-line on one side and "1" debossed on other side.
 2. 50 mg film coated tablets: blue coloured, round shaped biconvex coated tablets with a deep break line and debossed with "S" & "I" on either side of the break-line on one side and "2" debossed on other side.
 3. 100 mg film coated tablets: Blue coloured, round shaped biconvex coated tablets with a deep break line and debossed with "S" & "I" on either side of the break-line on one side and "3" debossed on other side.
- Each tablet contains:
 1. 25 mg of Sildenafil citrate.
 2. 50 mg of Sildenafil citrate.
 3. 100 mg of Sildenafil citrate.

- The composition of the drug products (DP) 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 products 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 products.
- The drug products is packaged in (Aluminum Foil & PVC/PVDC film).
- Appropriate stability data have been generated in the packaging material intended for commercial use and following relevant international guidelines.

Clinical Aspects

Bioequivalence Study

Ratio and 90% Confidence Intervals (CI) of Vesuv[®] (Sildenafil) 100 mg versus Viagra[®] (Sildenafil) 100 mg:

Pharmacokinetic Parameter	Point Estimate	90% CI
C _{max} (ng/ml)	99.56	87.65-113.10
AUC _{0-t} (ng/ml)	96.61	89.52-104.26

Based on the results obtained in this study, Vesuv[®] (Sildenafil) 100 mg of Oman Pharmaceutical Products Co., LLC, Oman, is **bioequivalent** to Viagra[®] (Sildenafil) 100 mg of Pfizer PGM, France, 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