

# Saudi Public Assessment Report

(Summary Report)

**Vasrasti®**

**Type of Application:** New Drug Application.

**Type of Product:** Human Generic Drug.

**Active Pharmaceutical Ingredient(s):** Hydroxychloroquine Sulfate

**ATC code:** P01BA02

**Dosage Form:** Film-coated tablet

**Dosage Strength:** 200 mg

**Pack Size:** 60

**Shelf life:** 24 months

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

**Reference Product in SA (if applicable):** Plaquenil

**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.:** 2101244769

**Date of Decision:**31/08/2023

**Proposed Indications:**

Adults

Treatment of rheumatoid arthritis, discoid and systemic lupus erythematosus, and dermatological conditions caused or aggravated by sunlight.

Paediatric Population

Treatment of juvenile idiopathic arthritis (in combination with other therapies), discoid and systemic lupus erythematosus

## 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 Vasrasti® 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

- Hydroxychloroquine Sulfate is a white or slightly yellowish, crystalline powder. Hydroxychloroquine Sulfate is freely soluble in water, practically insoluble in ethanol (96 per cent) and in methylene chloride. Polymorphism has been observed (Crystalline Form).
- 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 product is available as white to off-white, round shaped, biconvex film-coated tablets debossed JS46 on one side and plain on other side. Each tablet contains 200mg of Hydroxychloroquine Sulfate. 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 Aluminum- Polyvinyl Chloride/ Polyvinylidene chloride – Blisters.
- 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

The clinical pharmacology, efficacy, and safety of Hydroxychloroquine are well known. According to the regulatory requirements, the applicant has provided a suitable biowaiver study and bioequivalence study is not required for this product .

## 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)