

# Saudi Public Assessment Report

(Summary Report)

**Blum D<sup>®</sup>**

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

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

**Active Pharmaceutical Ingredient(s):** Colecalciferol (Vitamin D3)

**ATC code:** A11CC05

**Dosage Form:** Oral drops

**Dosage Strength:** 3000 IU/ML

**Pack Size:** 1

**Shelf life:** 24 months.

**Storage Conditions:** Store below 30° C and keep in the original pack to protect from light.

**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.:** 1808245770

**Date of Decision:** 13/08/2024

**Proposed Indications:**

The prevention and treatment of vitamin D deficiency.

As an adjunct to specific therapy for osteoporosis in patients with vitamin D deficiency or at risk of vitamin D insufficiency.

## 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 Blum D® 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

- Cholecalciferol is a clear, colourless to yellow liquid. Cholecalciferol is practically insoluble in water. It is slightly soluble in anhydrous ethanol and is miscible with solvents of fats.
- The structure of Cholecalciferol has been fully elucidated.
- 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 as Clear, colourless solution free from foreign particles. Each bottle contains 3000 IU/ml (Bottle of 20 ml) of Vitamin D3 active (Cholecalciferol) . 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 20 ML Amber glass euro dropper bottle and black TE screw cap with vertical euro dropper.
- 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.

## 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)