PRODUCT SPECIFICATION SHEET

Vitamin D3 400IU/1-5 drops/10-20ml

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Material No: S0000838
Author: DK
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1. General Description

Vitamin D3 (cholecalciferol) drops containing 400 IU of vitamin D3 per 1-5 drops, in a 10-20 ml bottle with a dropper.

2. Indications

Prevention of vitamin D deficiency

3. Technical Specifications

Oral solution containing vitamin D3 (cholecalciferol) 400 IU per 1-3 drops, in a 10-20 ml bottle with a built-in dropper. Bottle pack.

Vitamin D3 (cholecalciferol) 400IU/1-5 drops, complying **preferably** with one of the following pharmacopeias:

-British Pharmacopoeia (BP)
-United States Pharmacopoeias (USP)
-European Pharmacopoeias (Ph.Eur.)
-International Pharmacopoeia (Ph.Int.)

4. Shelf life

Minimum 24 months.

5. Storage and transportation

The manufacturer must specify storage and transport temperature, as well as related conditions on the product label and all subsequent packaging.

6. Packaging and Labelling

A Patient Information Leaflet should be attached or enclosed in a box with each bottle. Each dose is to be administered by means of a device suitable for measuring the prescribed volume

(usually graduated by the measurement per 1 drop). The measuring device should be enclosed with or attached to each bottle and will require validation reports for the same.

6.1 Primary packaging

Primary packaging should be sterile and protect the product from light, and microbiological contamination.

6.1.1 Primary label

Labels must have adequate information to permit identification, safe transport, storage and use of the product throughout its shelf life. The writing on primary and secondary packs must be in indelible ink.

6.1.2 The label shall contain the following information

- Name and address of the manufacturer and packer, or distributor, or importer, or exporter, or vendor and country of origin
-Net weight
-Batch number clearly identified and visible
-Date of manufacture and date markings
-Best before by date clearly identified and visible
-Storage conditions
-Instructions for administration

Refer to UNICEF Technical requirements for pharmaceutical products 5 (unicef.org),
Refer to Interagency finished pharmaceutical product questionnaire (***the selected annexes are applicable***).

6.1.3 Language Text

All the packaging material, including label and patient information leaflet, must be in English& French; preferably English, French and & Arabic.

6.2 Material safety data sheet information (MSDS): required.

Useful Resources

1. Minimum stability testing reporting requirements (guidance) for stability reports- Nutritional supplements (Tablets & oral solutions). Found as Stability Study Format for Nutritional Supplements in the Technical Resources for Nutrition Products page.
2. Interagency finished pharmaceutical product questionnaire Only the ticked or ***selected annexes listed in the questionnaire are required.***

3. Technical questionnaire for pharmaceutical manufacturers
4. Technical Requirements for Pharmaceutical and Nutrition Products

FOR MORE INFORMATION

CPHHQ-SD- Nutrition Supplies |sd.nutritionsupplies@unicef.org

Technical resources for nutrition products | UNICEF Supply Division