



## PRODUCT SPECIFICATION SHEET

Vitamin D3 133IU drops/BOT-15 ml

Version no: 1.2  
Material No: S1572014  
Author: MR  
Reviewed by: AF, DK  
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### 1. General Description

Vitamin D3 (cholecalciferol) drops containing 133 IU of vitamin D3 per drop, in a 15 ml bottle with a dropper.

### 2. Indications

Prevention of vitamin D deficiency

### 3. Technical Specifications

Oral solution containing vitamin D3 (cholecalciferol) drops containing 133 IU of vitamin D3 per drop, in a 15 ml bottle with a built-in dropper. Drops/ Bottle pack.

Vitamin D3(cholecalciferol) 133IU drops/BOT-15ml, complying with one of the 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

Do not store above 25°C. Protect from light and moisture. Keep out of the reach and sight of children

### 6. Storage and transportation

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

### 7. 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 at 1 drop equivalent to / not more than 133 IU of cholecalciferol. The measuring device should be enclosed with or attached to each bottle and will require validation reports for the same.)

## 7.1 Primary packaging

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

### 7.1.1 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.

### 7.1.2 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 date clearly identified and visible
- Storage conditions
- Instructions for administration

Refer to UNICEF Technical requirements for pharmaceutical products [5 \(unicef.org\)](https://www.unicef.org/5)

### 7.1.3 Language Text

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

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

## Useful Resources

1. Minimum stability testing reporting requirements (guidance) for stability reports- Nutritional supplements (Tablets & oral solutions)
2. Interagency finished pharmaceutical product questionnaire
3. Technical questionnaire for pharmaceutical manufacturers
4. Technical Requirements for Pharmaceutical and Nutrition Products

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### FOR MORE INFORMATION

CPHHQ-SD- Nutrition Supplies [sd.nutritionsupplies@unicef.org](mailto:sd.nutritionsupplies@unicef.org)

[Technical resources for nutrition products | UNICEF Supply Division](#)

