

TECHNICAL DATA SHEET

Vitamin D3 (Cholecalciferol)

40MIU/g BP

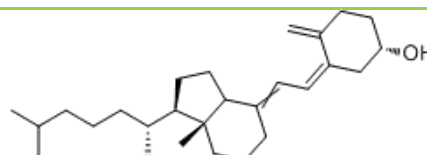
Chemical Properties

CAS No: 67-97-0;

EINECS No.: 200-673-2

Chemical Formula: $C_{27}H_{44}O$

Molecular Weight: 384.64



Description

Vitamin D3 40MIU is made by a series of reactions of cholesterol. It is insoluble in water, freely soluble in ethanol (96 per cent), soluble in trimethylpentane and in fatty oils. It is sensitive to air, heat and light. Solutions in solvents without an antioxidant are unstable and are to be used immediately.

Solubility

Practically insoluble in water, freely soluble in ethanol (96 per cent), soluble in trimethylpentane and in fatty oils

Specification

Item	Specification	Test Method
Appearance	White or almost white crystals.	Visual
Identification		
A: Infrared Absorption	Meets the requirements	BP
B: Comparison cholecalciferol CRS.	Meets the requirements	BP
Specific rotation	+105.0°~ +112.0°	BP
Melting Point	82.0°C~87.0°C	In-house
Assay (as $C_{27}H_{44}O$)	97.0-102.0% 38,800,000-40,800,000IU/G	BP
Related substances		BP
Impurity A	Max 0.1%	
Unspecified impurities	Max 0.1%	
Total related impurities	Max 0.5%	
Disregard limit	Max 0.05%	
Total Plate Count	Max 1000cfu/g	BP
Mold & Yeast	Max 100cfu/g	BP
<i>E. Coli</i>	Negative	BP
<i>Salmonella</i>	Negative	BP

Ingredients

Pure Vitamin D3 crystalline

Labeling

In the United States and the European Union: Vitamin D3 (Cholecalciferol)

Applications

Used as API in the pharmaceutical industry for preparation, and also used as vitamin additive in food and drink industry. For the prevention and treatment of rickets, osteomalacia, osteoporosis, and hypoparathyroidism.

Safety

This product is safe for the intended use. Avoid ingestion, inhalation of dust or direct contact by applying suitable protective measures and personal hygiene. See Material Safety Data Sheet for full safety information.

Handling recommendations

Keep locked up Keep away from heat. Keep away from sources of ignition. Empty containers pose a fire risk, evaporate the residue under a fume hood. Ground all equipment containing material. Do not ingest. Do not breathe dust. Avoid contact with eyes. In case of insufficient ventilation, wear suitable respiratory equipment. If ingested, seek medical advice immediately and show the container or the label.

Packaging, Storage & Shelf Life

Package	500g/tin; or according to customers' requirements.
Storage	Store in a well-closed container away from moisture and direct sunlight.
Shelf life	3 years if sealed and stored properly.