

SPECIFICATION

Product name Vitamin D3 100.000 I.U./g SD CWS/S
Product code SP03-03
Production unit Xinchang NHU Vitamins

Description The product consists of Vitamin D3 (Ph. Eur./USP), modified starch (E1450), maltodextrin (FCC), sucrose (FCC), vegetable oil (FCC), sodium ascorbate (E301) and dl-a-tocopherol (E307) as antioxidants, silicon dioxide (E551) as anti-caking agent

Synonym Cholecalciferol, Colecalciferol
Formula $C_{27}H_{44}O$
Molecular weight 384,7 g/mol
CAS No 67-97-0

Properties

Shelf life 24 months after production date, in unopened original packaging

Aspect white or off-white free flowing powder

Assay Min. 100.000 I.U./g
EP: 90 – 115 % of active substance
USP: 90 – 110 % in basis

Identification

EP: A. Record the UV spectrum of the principal peak in the chromatogram obtained with the test solution (a) in the assay, with a diode array detector in the range of 210 – 400 nm.

B. Examine the chromatograms obtained in the assay

USP : A. Infrared spectroscopy

B. Ultraviolet-visible spectroscopy

C. The retention time of the major peak of the sample solution corresponds to that of the standard solution, as obtained in the assay.



Loss on drying	Max. 6,0 %
Solubility	Dispersible in cool water, forming a milky emulsion
Sieve analysis	100 % through sieve no. 40 (US) ≥ 90 % through sieve no. 60 (US) ≥ 45 % through sieve no. 100 (US)
Heavy metals	max. 10 mg/kg
Arsenic (As)	max. 1 mg/kg
Lead (Pb)	max. 0,5 mg/kg
Cadmium (Cd)	max. 0,5 mg/kg
Mercury (Hg)	max. 0,1 mg/kg
Traces of BHT	max. 0,1 %
Microbiological specs	
Total plate count	≤ 1000 CFU/g
Mould and Yeast	≤ 100 CFU/g
Coliforms	< 10 CFU/g
E. Coli	negative (in 10 g)
Salmonella	negative (in 25 g)
Handling	
Usage	for food applications
Stability	Sensitive to moisture, oxygen, heat and light.
Storage	Store in a cool and dry place. Recommended storage temperature: below 25°C. Once opened, use contents quickly.
Transport instructions	please see our latest MSDS

Classified as **hazardous substance** as per EU regulation.

Active ingredient Vitamin D3 complies with current EP, USP and FCC.

NHU Life Science GmbH