

## SPECIFICATION

**Product name** Vitamin D3 100.000 I.U./g SD CWS/S  
Food Grade (USP/EP)

**Product code** SP03-03

**Production unit** Xinchang NHU Vitamins

**Description** The product consists of Vitamin D3 (Ph. Eur./USP), maltodextrin, modified starch, sucrose, vegetable oil, sodium ascorbate and dl-a-tocopherol as antioxidants, silicon dioxide 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  
Arsenic (As) Max. 10 mg/Kg  
Lead (Pb) Max. 1 mg/Kg  
Max. 0,5 mg/Kg

Traces of BHT max. 0,1 %

### Microbiological specs

Total plate count ≤ 1000 CFU/g  
Mould and Yeast ≤ 100 CFU/g  
Enterobacteriaceae < 10 CFU/g  
Salmonella negative (in 25 g)  
Coagulase pos. Staph. aureus negative (in 10 g)  
E. Coli negative (in 10 g)

### Handling

Stability Material is sensitive to moisture, oxygen, heat and light  
Once opened, use contents quickly

Storage Store in a cool and dry place  
Recommended storage temperature: below 25°C

Usage for food industry

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

## NHU EUROPE GmbH