

**FERMENTA BIOTECH LIMITED**

Village-Takoli, Post Office-Nagwain, Dist.- Mandi 175121, Himachal Pradesh, India

Fermenta Biotech Limited Tel: 91-1905-287246 Email : info@fermentabiotech.com Website: www.fermentabiotech.com

**CERTIFICATE OF ANALYSIS
(Finished Product)**RF 0045
R# 17487

Product : VITADEE 100 CWD/DS(Vitamin D3 100,000 IU/g) Batch No. : CWD1D21069 6-30-23
 Inspection Lot No. : 080000008174 Date of Release : 11.09.2021
 Date of Mfg. : August, 2021 Expiry date : -
 Retest date : July, 2024 Batch Size : 200.000 KG
 Country of Origin : India

TEST	SPECIFICATION	RESULTS
Description		
Description	White or yellowish - white, small particles.	Complies
Solubility		
Solubility	Disperse quickly in cold water at low temperature as low as 10° C.	Complies
Identification		
TLC	Chromatogram obtained with test solution shall show a bright yellow principal spot, rapidly becomes orange brown then gradually greenish grey, remaining so for 10 min. This spot is similar in position colour & size to spot obtained with Ref.Sol. (a).	Complies
HPLC	The principal peak in the chromatogram obtained with the test solution shall be similar in retention time to the principal peak in the chromatogram obtained with reference solution (a).	Complies
Loss on Drying		
Loss on Drying (105°C,4 HRS)	Maximum 5.0 %	0.43 %
Assay (Cholecalciferol)		
HPLC (on IU basis)	Minimum 100000 IU/g	115135.4 IU/g
HPLC (on percentage basis)	Minimum 100 %	115.1 %
Identity of tocopherol		

Prepared by

Kapil Kumar

10.09.2021 17:06:11 IST +05:30

Assistant Manager - QC

Checked by

Rajeev Kumar

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TEST	SPECIFICATION	RESULTS
Identity of tocopherol	Corresponds	Complies
Particle Size		
By 80 mesh (180 µm)	Minimum 95.0 %	98.75 %
Bulk Density		
Bulk Density	0.5 to 0.7 g/ml	0.56 g/ml
Residual solvents		
Ethanol	Maximum 5000 ppm	67.31 ppm
Acetone	Maximum 5000 ppm	<10.00 ppm
Elemental Impurities		
Arsenic	Maximum 1.5 ppm	<0.05 ppm
Cadmium	Maximum 0.5 ppm	<0.02 ppm
Lead	Maximum 0.5 ppm	<0.05 ppm
Mercury	Maximum 0.1 ppm	<0.01 ppm
Microbiological Test		
Total Aerobic Microbial Count (TAMC)	Maximum 1000 CfU/1g	25 CfU/1g
Total Combined Yeasts & Mold Count (TYMC)	Maximum 100 CfU/1g	<10 CfU/1g
Enterobacteria	Maximum 10 CfU/1g	<10 CfU/1g
Escherichia Coli	Should be absent /10g	Complies
Salmonella Species	Should be absent in 25 g	Complies

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TEST	SPECIFICATION	RESULTS
Staphylococcus Aureus	Should be absent /10g	Complies
Pseudomonas Aeruginosa	Should be absent/10g	Complies

Conclusion: Product complies to all above parameters w.r.t ANS/FG/054.

Vitamin D3 Powder 100,000 Iu Cwd Ds
Batch# CWD1D21069
Pack of 5 Kg Net(SKG KG)
Fermenta Natural Supplements LLC.
Registration No: SO#00017486 (06/13/23)

YOUR ITEM RI0045
Mfg Dat: 08/01/2021 RTST Dat: 07/01/2024
PO# P10677 (06/07/23)

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