

# Pace

Add Pace To Health

# Pace Biotech




Surajpur, Paonta sahib Dist. Sirmour (H.P)

## Certificate of Analysis Finished Product

Title :			
Product Name	Canrise D3 Injection	A.R. No.	NL/FP/24/219
Generic Name	Vitamin D <sub>3</sub> Injection IP 600000 IU/ml	Sampled qty.	45 Ampoules
Batch No.	A24120I	Sampled by	Aakash
Batch Size	50,010 Ampoules	Sampled on	17/07/2024
Mfg. Date	06/2024	Date of Testing	17/07/2024
Exp. Date	05/2026	Date of Conditionally Release	25/07/2024

S. No.	Tests	Specifications	Observations		
1.	Description	A clear colourless oily solution filled in clear glass ampoule.	A clear colourless oily solution filled in clear glass ampoule.		
2.	Identification	To 1 ml of a 0.2 per cent v/v solution of the injection in ethanol-free chloroform, add 9 ml of antimony trichloride solution, the light absorption of the resulting solution exhibits a maximum at 500 nm.	Complies		
3.	Nominal fill volume	NLT-1ml	1.0 ml		
4.	Extractable Volume	NLT Nominal volume or NMT 110% of Nominal volume.	1.1 ml		
5.	Particulate Matter (a) Sub-Visible particle count (1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$ (b) Visual	NMT-6000/Ampoule NMT-600/ Ampoule The solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally.	10/Ampoule 2/Ampoule Complies		
6.	Sterility	No microbial growth should be observed.	Under process		
7.	Bacterial Endotoxins (IHS)	NMT-23.33 EU/mg of Cholecalciferol.	Less than-23.33 EU/mg of Cholecalciferol.		
8.	Assay: Each ml contains:				
Ingredients		Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Cholecalciferol (600,000 IU) IP		15 mg	16.030 mg	106.87%	90.0% to 110.0%

Remarks: In the opinion of the undersigned the sample referred to above is/is not of the standard quality as The Drug & Cosmetic Act 1940 and the rules made there under. Complies/not complies as per IP/BP/USP/IHS.

Analysis by 	Checked by 	Approved by 
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