

Pace

Add Pace To Health

Pace Biotech

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

Title

:

Certificate of Analysis Finished Product

Product Name	Canrise D3 Injection	A.R. No.	NL/FP/24/291
Generic Name	Vitamin D3 Injection IP 600000/ml	Sampled qty.	60 Ampoules
Batch No.	A24173A	Sampled by	Aakash
Batch Size	78,000 Ampoules	Sampled on	04/09/2024
Mfg. Date	07/2024	Date of Testing	04/09/2024
Exp. Date	06/2026	Date of Release	19/09/2024

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	NMT-6000/Ampoule NMT-600/ Ampoule The solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally.	31/Ampoule 9/Ampoule Complies		
	(a.) Sub-Visible particle count (1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$ (b.) Visual				
6.	Sterility	No microbial growth should be observed.	Complies		
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 (600000 IU) IP		15 mg	15.88 mg	105.87%	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

