

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/24/079A
Generic Name	Vitamin D ₃ Injection I.P 600000 IU/ml	Sampled qty.	45 Ampoules
Batch No.	A23647J	Sampled by	Vineet
Batch Size	30,000 Ampoules	Sampled on	01/04/2024
Mfg. Date	03/2024	Date of Testing	01/04/2024
Exp. Date	02/2026	Date of Release	14/04/2024

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 NMT110% 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.	38/Ampoule 21/Ampoule Complies		
6.	Sterility	No microbial growth should be observed.	Complies		
7.	Bacterial Endotoxin (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	15.573 mg	103.82%	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 

