

**AMERICAN REMEDIES HEALTHCARE PVT. LTD.**

Vill. Surajpur, Nahan Road, Paonta Sahib, Dist. Sirmour (H.P) 173025

Title : Certificate of Analysis Finished Product

Product Name	CANRISE Injection	A.R. No.	ARN/FP/25/049
Generic Name	Cholecalciferol Injection IP 1ml	Sampled qty.	60 Ampoules
Batch No.	ARN2559A	Sampled by	Anuj Verma
Batch Size	78,000 Ampoules	Sampled on	05/11/2025
Mfg. Date	11/2025	Date of Testing	05/11/2025
Exp. Date	10/2027	Date of Release	20/11/2025

S. No.	Tests	Specifications	Observations
1.	Description	A clear colourless to pale yellow liquid filled in clear glass ampoule.	A clear colourless to pale yellow liquid 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.) Light Obscuration Particle Count Test (1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$ (B.) Visual Particle	NMT 6000/Ampoule NMT 600/ Ampoule The solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally that can be observed on visual inspection.	14/Ampoule 3/Ampoule Complies
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: (By HPLC) Each ml contains:		

Ingredients	Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Cholecalciferol (600,000 IU) IP	15 mg	14.672 mg	97.81%	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/AHS.

Analysis by NAME: RAMANJEET SINGH	Checked by NAME: SUFIYAN ANSARI	Approved by NAME: MRS. SWATI DHAWAN
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