



AMERICAN REMEDIES HEALTHCARE PVT. LTD.

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

Title

:

Certificate of Analysis Finished Product

Product Name	CITISTROKE 2 Injection	A.R. No.	ARN/FP/25/097
Generic Name	Citicoline Injection IP 2ml	Sampled qty.	45 Ampoules
Batch No.	ARN25102A	Sampled by	Rakesh
Batch Size	25,000 Ampoules	Sampled on	24/02/2026
Mfg. Date	01/2026	Date of Testing	25/02/2026
Exp. Date	12/2027	Date of Release	11/03/2026

S. No.	Tests	Specifications	Observations		
1.	Description	A clear colourless solution filled in clear glass ampoule.	A clear colourless solution filled in clear glass ampoule.		
2.	Identification	In the Assay, the principal peak in the chromatogram obtained with the test solution corresponds to the principal peak in the chromatogram obtained with the working standard solution.	Complies		
3.	Nominal fill volume	NLT 2 ml	2.0 ml		
4.	Extractable Volume	NLT Nominal volume or NMT 110% of Nominal volume.	2.1 ml		
5.	Related Substances				
	5-cytidylic acid	NMT- 1.5%	Not Detected		
	Any other secondary peak	NMT- 0.5%	Not Detected		
	Sum of all secondary peak other than 5'cytidylic acid	NMT- 2.0%	Not Detected		
6.	pH	6.3 to 8.0	7.08		
7.	Particulate Matter	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.	15/Ampoule 0/Ampoule Complies		
	(A.) Light Obscuration Particle Count Test (1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$ (B.) Visual Particle				
8.	Sterility	No microbial growth should be observed.	Complies		
9.	Bacterial Endotoxins	NMT 0.175 EU/mg of Citicoline.	Less than 0.175 EU/mg of Citicoline.		
10.	Assay: Each ml contains:				
Ingredients		Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Citicoline Sodium I.P Eq. to Citicoline		250mg	261.29949mg	104.52%	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/FP/USP/HS.

Checked by

Approved by

25/02/26