

Title

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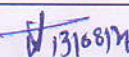
Certificate of Analysis Finished Product

Product Name	CITISTROKE Injection	A.R. No.	NL/FP/26/155
Generic Name	Citicoline Injection IP 2ml	Sampled qty.	45 Ampoules
Batch No.	A26123A	Sampled by	Rakesh
Batch Size	25,000 Ampoules	Sampled on	30/07/2026
Mfg. Date	07/2026	Date of Testing	01/08/2026
Exp. Date	06/2028	Date of Release	13/08/2026

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%	0.160%
	Any other secondary peak	NMT- 0.5%	0.127%
	Sum of all secondary peak other than 5'-cytidylic acid	NMT- 2.0%	0.270%
6.	pH	6.3 to 8.0	7.01
7.	Particulate Matter		
	(A.) Light Obscuration Particle Count Test		
	(1.) Particles $\geq 10\mu\text{m}$	NMT-6000/Ampoule	55/Ampoule
	(2.) Particles $\geq 25\mu\text{m}$	NMT-600/Ampoule	0/Ampoule
	(B.) Visual Particle	The solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally that can be observed on visual inspection.	Complies
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 IP Eq. to Citicoline	250 mg	258.93098 mg	103.57%	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 GMP/USP/ITS

Analysis by 	Checked by 	Approved by 
NAME: FIROJ KHAN	NAME: SURJEET KAUR	NAME: MRS. SWATI DHAWAN