



Nixi Laboratories Pvt. Ltd.,
Village Mouza Ogli, Sadhaura Road, Kala-Amb, District Sirmour -173030,
Himachal Pradesh (INDIA).

CERTIFICATE OF ANALYSIS FINISHED PRODUCTS

Product Name	CITISTROKE 4	AR. No.	NL/LA/FG/26/316
Generic Name	Citicoline Sodium Injection IP		
Mother Batch No.	A26BR007	Reference	IP
Child Batch No.	A26BR007A	Batch Size	10487 Ampoules
Mfg. Date	05/2026	Exp. Date	04/2028
Specification No. (STS No)	QC/LA/FG/STS/002-02	Standard Test Procedure No.	QC/LA/FG/STP/002
Sample Quantity	76 Ampoules	Sampling Date	30/05/2026
Released Date	30/06/2026		

Sr.No.	TEST	SPECIFICATION	OBSERVATION
1.	Description	Clear, colourless liquid free from foreign particles filled in 4 ml clear / amber colour glass ampoule.	Clear, colourless liquid free from foreign particles filled in 4 ml clear colour glass ampoule.
2.	Identification: A. By High Performance Liquid Chromatography (HPLC)	In the assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with reference solution.	Complies
3.	Average filled volume	NLT 2.0 ml	4.05 ml
4.	Extractable Volume	NLT 2.0 ml	4.05 ml
5.	pH (At 25°C)	6.3 to 8.0	7.18
6.	Particulate matter		
	For Visible Particles:	Should be free from visible particles	Complies
	For sub visible particles: Equal to or greater than 10µm. Equal to or greater than 25µm.	NMT 6000 particles/container NMT 600 particles/container	593.0 particles/container 17.0 particles/container
7.	Sterility	Should be complies	Complies
8.	Bacterial Endotoxins	NMT 0.175 EU/mg of Citicoline	Complies
9.	Related Substances		
	i. 5'-cytidylic acid	NMT 1.5%	Not Detected
	ii. Any other secondary impurity	NMT 0.5%	Not Detected
	iii. Total impurity other than 5'-cytidylic acid	NMT 2.0%	Not Detected

	ANALYSED BY	CHECKED BY	APPROVED BY
Name	Sony Rani	Ganesh Jaiswal	Aditya Singh
Designation	Chemist QC	Sr. Executive QC	Asst. Manager QC
Signature			
Date	30/06/26	30/06/26	30/06/26



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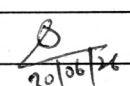
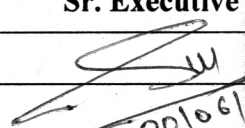
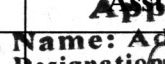
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Sr.No.	TEST	SPECIFICATION	OBSERVATION
10.	Assay		
	Each ml contains:		
	Citicoline Sodium IP	225.00 mg to 275.00 mg	259.64 mg
	Eq. to Citicoline 250 mg	(90.00 % To 110.00 %)	(103.86%)

RESULT: The above sample ~~COMPLIES/DOES NOT COMPLY~~ as per Specification No-QC/LA/FG/STS/002-02.

CONCLUSION: In the opinion of the under signed the sample referred above is of ~~STANDARD QUALITY~~ / ~~IS NOT STANDARD QUALITY~~ as defined in the Drugs & Cosmetics Act, 1940 and the rules made hereunder further.

	ANALYSED BY	CHECKED BY	APPROVED BY
Name	Sony Rani	Ganesh Jaiswal	Aditya Singh
Designation	Chemist QC	Sr. Executive QC	Asst. Manager QC
Signature			
Date	30/06/26	20/06/26	30/06/26