

DERREN HEALTHCARE PVT. LTD.

Plot No. #33, 35/p & 36/p XCELON Industrial Park, Lane besides Chak-de-India
Weighbridge, Sarkhej-Bavla Highway Village: Vasna-Chacharvadi,
Ahmedabad-382 213, Gujarat (India)

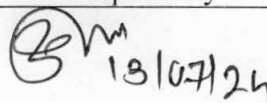
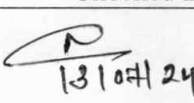

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Name of Product	Citicoline Injection IP 250mg/ml(CITISTROKE 4)		
Batch No.	AU24001	A.R. No.	FP/24/0050
Mfg. Date	06/24	Exp. Date	05/26
Sampled Qty.	41 Nos.	Date of Analysis	27/06/24
Batch Size	100 Ltr.	Date of Release	13/07/24
Container Type	Clear Glass Ampoule	Fill Volume	4.2 ml
Mfg. Lic. No.	G/28/1862		

Sr. No.	Test	Result	Specification
1	Description	Clear, Colourless solution free from visible particles and fibers.	Clear, Colourless or almost colourless solution free from visible particles and fibers.
2	Extractable volume	4.0 ml	NLT 4.0 ml
3	Identification		
3.1	Identification A by HPLC	In the Assay, the principal peak in the chromatogram obtained with the test solution is correspond to the peak in the chromatogram obtained with the reference solution	In the Assay, the principal peak in the chromatogram obtained with the test solution should be correspond to the peak in the chromatogram obtained with the reference solution
4	pH	7.2	6.3 to 8.0
5	Related Substances		
5.1	5'-cytidylic acid	0.08 %	NMT 1.5%
5.2	Any other secondary impurity	0.04 %	NMT 0.5%
5.3	Total impurities other than 5'-cytidylic acid	0.04%	NMT 2.0%
6	Bacterial endotoxin	Less than 0.175 Eu/mg	NMT 0.175 EU/mg of Citicoline
7	Particulate matter		
7.1	By Visual Inspection	The solution is free from particles that is observed by inspection with the unaided eye.	The solution should be free from particles that can be observed by inspection with the unaided eye.
7.2	By Light Obscuration Method	≥10 microns= 814.40/Container ≥ 25 Microns= 40.00/Container	Sub visible particle by LPC ≥10 microns=NMT 6000/Container ≥ 25 Microns=NMT 600/Container
8	Sterility test	Sterile	Should be sterile
9	Assay		
9.1	Each ml Contains: Citicoline Sodium IP eq. to Citicoline 250 mg	101.8%	90.0% to 110.0% of the labeled amount of Citicoline

Conclusion: The above sample complies as per IP specification.

In the opinion of the undersigned the sample referred to above is of standard / ~~not of standard~~ quality as defined in the act and the rules made there under for the reasons given above.

Prepared By  QC EXCECUTIVE	Checked By  QC SR. EXCECUTIVE	Approved By  QA MANAGER
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