DERREN HEALTHCARE PVT. LTD.

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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 250mg/ml (CITISTROKE 2)		
Batch No.	AU24002	**A.R. No.**	FP/24/0093
Mfg. Date	09/24	**Exp. Date**	08/26
Sampled Qty.	71 Nos.	**Date of Analysis**	22/09/24
Batch Size	50 Ltr.	**Date of Release**	09/10/24
Container Type	Clear Glass Ampoule	**Fill Volume**	2.0 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	2.2 ml	NLT 2.0 ml
3	pH	7.17	6.3 to 8.0
4	Bacterial endotoxin	Less than 0.175 Eu/mg	NMT 0.175 EU/mg of Citicoline
5	Particulate matter		
5.1	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.
5.2	By Light Obscuration Method	≥10 microns= 55.60/Container ≥ 25 Microns= 1.87/Container	Sub visible particle by LPC ≥10 microns=NMT 6000/Container ≥ 25 Microns=NMT 600/Container
6	Sterility test	Sterile	Should be sterile
7	Assay		
7.1	Each ml Contains: Citicoline Sodium eq. to Citicoline 250 mg	99.1% of the labeled amount of Citicoline	90.0% to 110.0% of the labeled amount of Citicoline

Conclusion: The above sample complies as per IHS 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	Checked By	Approved By
09/10/24 QC OFFICER	09/10/24 QC SR. EXCECUTIVE	09/10/24 QA MANAGER

DERREN HEALTHCARE PVT. LTD. QUALITY ASSURANCE