

**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)

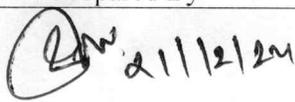
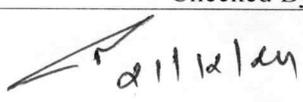
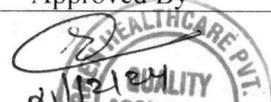
**CERTIFICATE OF ANALYSIS  
(FINISHED PRODUCT)**

<b>Name of Product</b>	Citicoline Injection 250mg/ml(CITISTORK 2)		
<b>Batch No.</b>	AU24006	<b>A.R. No.</b>	FP/24/0143
<b>Mfg. Date</b>	12/24	<b>Exp. Date</b>	11/26
<b>Sampled Qty.</b>	41 Nos.	<b>Date of Analysis</b>	06/12/24
<b>Batch Size</b>	50 Ltr.	<b>Date of Release</b>	21/12/24
<b>Container Type</b>	Clear Glass Ampoule	<b>Fill Volume</b>	2.0 ml
<b>Mfg. Lic. No.</b>	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	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	7.24	6.3 to 8.0
5	Bacterial endotoxin	Less than 0.175 Eu/mg	NMT 0.175 EU/mg of Citicoline
6	Particulate matter		
6.1	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.
6.2	By Light Obscuration Method	$\geq 10$ microns= 156.53/Container $\geq 25$ Microns= 4.67/Container	Sub visible particle by LPC $\geq 10$ microns=NMT 6000/Container $\geq 25$ Microns=NMT 600/Container
8	Sterility test	Sterile	Should be sterile
9	Assay		
9.1	Each ml Contains: Citicoline Sodium eq. to Citicoline 250 mg	98.7%	90.0% to 110.0% of the labeled amount of Citicoline

Conclusion: The above sample complies as per In-House 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
 QC EXECUTIVE	 QC SR. EXECUTIVE	 QA MANAGER

