

**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)

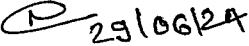
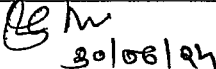

**CERTIFICATE OF ANALYSIS  
(FINISHED PRODUCT)**

Name of Product	Piracetam Injection 200 mg/ml IP (PIRATICAN)		
Batch No.	CH24001	A.R. No.	FP/24/0045
Mfg. Date	06/24	Exp. Date	05/26
Sampled Qty.	36 Nos.	Date of Analysis	12/06/24
Batch Size	435 Ltr.	Fill Volume	15.0 ml
Container Type	Clear Glass Ampoule	Date of Release	29/06/24
Mfg. Lic. No.	G/28/1862		

Sr. No.	Test	Result	Specification
1	Description	Clear, colourless liquid free from visible particles and fibers.	Clear, colourless or almost colourless liquid free from visible particles and fibers.
2	Extractable volume	15.5 ml	NLT 15.0 ml
3	Identification		
3.1	Identification A by HPLC	In the Assay, principle peak in the chromatogram obtained with the test solution is correspond to that in the chromatogram obtained with reference solution	In the Assay, principle peak in the chromatogram obtained with the test solution should be correspond to that in the chromatogram obtained with reference solution
4	pH	6.0	5.0 to 7.0
5	Bacterial endotoxin	Less than 0.012 EU/gm	NMT 0.012 EU/gm of Piracetam
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 = 124.00/Container $\geq 25$ Microns = 12.00/Container	Sub visible particle by LPC $\geq 10$ microns=NMT 6000/Container $\geq 25$ Microns=NMT 600/Container
7	Sterility test	Sterile	Should be sterile
8	Assay		
8.1	Each ml contains Piracetam 200 mg/ml	105.1 %of the stated amount of Piracetam	90.0% to 110.0% of the stated amount of Piracetam

**Conclusion:** The above sample complies as per IP specification.

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

Prepared By	Checked By	Approved By
 29/06/24 QC Executive	 30/06/24 QC Sr. Executive	 30/06/24 QA MANAGER

