

**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)

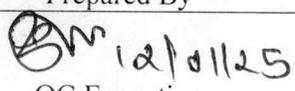
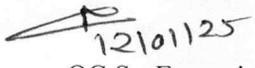
**CERTIFICATE OF ANALYSIS
(FINISHED PRODUCT)**

Name of Product	Piracetam Injection 200 mg/ml IP (PIRATICAN)		
Batch No.	CH24002	A.R. No.	FP/24/0154
Mfg. Date	12/24	Exp. Date	11/26
Sampled Qty.	36 Nos.	Date of Analysis	25/12/24
Batch Size	125 Ltr.	Date of Release	12/01/25
Container Type	Clear Glass Ampoule	Fill Volume	15.0 ml
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	15.0 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	5.94	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	≥10 microns = 25.00/Container ≥25 Microns = 1.00/Container	Sub visible particle by LPC ≥10 microns=NMT 6000/Container ≥ 25 Microns=NMT 600/Container
7	Sterility test	Sterile	Should be sterile
8	Assay		
8.1	Each ml contains Piracetam 200 mg/ml	100.81 %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 **standard** / ~~not of standard~~ quality as defined in the act and the rules made there under for the reasons given above.

Prepared By  QC Executive	Checked By  QC Sr. Executive	Approved By  QA MANAGER
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