

Pace

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Pace Biotech

Surajpur, Paonta sahib Dist. Sirmour (H.P)

Title		: Certificate of Analysis Finished Product	
Product Name	PIRATICAN Injection	A.R. No.	NL/FP/25/328
Generic Name	Piracetam Injection 15ml	Sampled qty.	45 Ampoules
Batch No.	A25342C	Sampled by	Aakash
Batch Size	6,120 Ampoules	Sampled on	04/02/2026
Mfg. Date	01/2026	Date of Testing	05/02/2026
Exp. Date	12/2027	Date of Conditionally Release	18/02/2026

S. No.	Tests	Specifications	Observations
1.	Description	A clear colourless solution filled in clear glass ampoule.	A clear colourless solution filled in clear glass ampoule.
2.	Identification (By HPLC)	In the assay, the principle peak in the chromatogram obtained with the test solution corresponds to that in the chromatogram obtained with reference solution.	Complies
3.	Nominal fill volume	NLT 15ml	15.0 ml
4.	Extractable Volume	NLT Nominal volume or NMT 110% of Nominal volume.	15.1 ml
5.	pH	4.0 to 8.0	7.30
6.	Particulate Matter (A.) Light Obscuration Particle Count Test (1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$ (B.) Visual Particle	NMT 6000/Ampoule NMT 600/Ampoule The solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally that can be seen on visual inspection.	6/Ampoule 1/Ampoule Complies
7.	Sterility	Liquid Injection should comply with the test for sterility.	Under Process
8.	Bacterial Endotoxins (IHS)	NMT 0.073 EU/mg of Piracetam.	Less than 0.073 EU/mg of Piracetam.
9.	Assay: (By HPLC) Each ml contains:		

Ingredients	Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Piracetam IP	200 mg	201.02944 mg	100.51%	90.0% to 110.0%

Remarks: In the opinion of the undersigned the sample referred to above is/ is not of the standard quality as The Drug & Cosmetic Act 1940 and the rules made there under. Complies/ not complies as per IP/ BP/ USP/ IHS.

Analysis by  NAME: FIROJ KHAN	Checked by  NAME: SUFIYAN ANSARI	Approved by  NAME: MRS. SWATI DHAWAN
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