

Pace

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Pace Biotech

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

Certificate of Analysis Finished Product

Title :

Product Name	Paracan 150 Injection	A.R. No.	NL/FP/25/171
Generic Name	Paracetamol Injection 150mg/ml	Sampled qty.	45 Ampoules
Batch No.	A25175C	Sampled by	Rakesh
Batch Size	50,000 Ampoules	Sampled on	21/08/2025
Mfg. Date	08/2025	Date of Testing	21/08/2025
Exp. Date	07/2027	Date of Release	06/09/2025

S. No.	Tests	Specifications	Observations		
1.	Description	A clear colourless, oily solution filled in amber glass ampoule.	A clear colourless, oily solution filled in amber glass ampoule.		
2.	Identification (By HPLC)	The retention time and sizes of the principal peaks in the chromatogram obtained with the test solution are similar to those of the principal peaks in the chromatogram obtained with reference solution.	Complies		
3.	Nominal fill volume	NLT 2 ml	2.0 ml		
4.	Extractable Volume	NLT Nominal volume or NMT 110% of Nominal volume.	2.1 ml		
5.	pH	6.0 to 7.0	6.46		
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 observed on visual inspection.	9/Ampoule 0/Ampoule Complies		
7.	Sterility	No microbial growth should be observed.	Complies		
8.	Bacterial Endotoxins	NMT 2.0 EU/ml of Paracetamol.	Less than 2.0 EU/ml of Paracetamol.		
9.	Assay: (By HPLC) Each ml contains:				
Ingredients		Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Paracetamol IP		150 mg	154.10 mg	102.73%	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 P 06/09/25
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Checked by S 06/09/25
NAME: SUFIYAN ANSARI

Approved by S 06/09/25
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