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Pace Biotech

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

Title	:	Certificate of Analysis Finished Product

Product Name	**ATRANIUM** Injection	**A.R. No.**	NL/FP/26/216
Generic Name	Atracurium Besylate Injection IP 2.5ml	**Sampled qty.**	45 Ampoules
Batch No.	A26196B	**Sampled by**	Shivanand
Batch Size	51,000 Ampoules	**Sampled on**	08/09/2026
Mfg. Date	08/2026	**Date of Testing**	09/09/2026
Exp. Date	07/2028	**Date of Release**	23/09/2026

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	In the assay, the principle peaks of three isomers of Atracurium Besylate in the chromatogram obtained with the test solution corresponds to the peaks in the chromatogram obtained with the reference solution.	Complies
3.	Nominal fill volume	NLT 2.5 ml	2.5 ml
4.	Extractable Volume	NLT Nominal volume or NMT 110% of Nominal volume.	2.5 ml
5.	pH	3.0 to 3.65	3.44
6.	Related Substance		
	Area of any peak corresponding to acidic compound	NMT 6.0%	0.445%
	Sum of the areas of any peaks corresponding to cis and trans-isomers of the hydroxyl compound	NMT 6.0%	0.476%
	Area of any peak corresponding to laudanosine	NMT 3.0%	0.193%
	Sum of the areas of any peaks corresponding to cis and trans-isomers of the monoacrylate	NMT 3.0%	0.088%
	Sum of all the secondary peaks	NMT 15.0%	2.240%
	Area of any other unspecified degradation product	NMT 0.10%	0.086%

Analysis by 23/09/26	Checked by 23/09/26	Approved by 23/09/26
NAME: SHAHRUKH KHAN	NAME: SURJEET KAUR	NAME: MRS. SWATI DHAWAN

Name : Mrs. Swati Dhawan
Designation : QC HOD
Qualification : M.Sc. Clinical Microbiology
Registration No. : [illegible]

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7.	Particulate Matter (A.) Light Obscuration Particle Count Test (1.) Particles ≥10µm (2.) Particles ≥25µm (B.) Visual Particle	NMT 6000/Ampoules NMT 600/ Ampoules The solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally that can be observed on visual inspection.	33/Ampoules 1/Ampoules Complies
8.	Sterility	No microbial growth should be observed.	Complies
9.	Bacterial Endotoxins	NMT 5.56 EU/mg of Atracurium Besylate.	Less than 5.56 EU/mg of Atracurium Besylate.
10.	Assay: (By HPLC) Each ml contains:		

Ingredients	Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Atracurium Besylate IP	10 mg	10.42372 mg	104.24%	90.0% to 115.0%

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 23/09/26 **NAME: SHAHRUKH KHAN**	**Checked by** 23/9/26 **NAME: SURJEET KAUR**	**Approved by** **NAME: MRS. SWATI DHAWAN**

Name : Mrs. Swati Dhawan
Designation : QC HOD
Qualification : M.Sc. Clinical Microbiology
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