

Pace

Add Pace To Health

Pace Biotech

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

Title

:

Certificate of Analysis Finished Product

Product Name	ATRANIUM Injection	A.R. No.	NL/FP/26/104
Generic Name	Atracurium Besylate Injection IP 5ml	Sampled qty.	45 Ampoules
Batch No.	A26095A	Sampled by	Rakesh
Batch Size	40,000 Ampoules	Sampled on	21/06/2026
Mfg. Date	06/2026	Date of Testing	21/06/2026
Exp. Date	05/2028	Date of Release	06/07/2026

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 5 ml	5.0 ml
4.	Extractable Volume	NLT Nominal volume or NMT 110% of Nominal volume.	5.1 ml
5.	pH	3.0 to 3.65	3.43
6.	Related Substance		
	Area of any peak corresponding to acidic compound	NMT 6.0%	0.717%
	Sum of the areas of any peaks corresponding to cis and trans-isomers of the hydroxyl compound	NMT 6.0%	0.731%
	Area of any peak corresponding to laudanosine	NMT 3.0%	1.156%
	Sum of the areas of any peaks corresponding to cis and trans-isomers of the monoacrylate	NMT 3.0%	2.121%
	Sum of all the secondary peaks	NMT 15.0%	6.028%
	Area of any other unspecified degradation product	NMT 0.1%	0.089%

Name : Mrs. Swati Dhawan

Designation : QC HOD

Qualification : M.Sc. Clinical Microbiology

Registration No. : 584402/2025

Approved by : 06/07/26

NAME: MRS. SWATI DHAWAN

Analysis by

NAME: SHAHRUKH KHAN

Checked by

NAME: SURJEET KAUR

Title

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7.	Particulate Matter	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.	13/Ampoules 0/Ampoules Complies		
	(A.) Light Obscuration Particle Count Test (1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$ (B.) Visual Particle				
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	10.27247 mg	102.72%	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/HS.

Name : Mrs. Swati Dhawan

Designation : QC HOD

Qualification : M.Sc. Clinical Microbiology

Registration No. : 580405039593

Approved by: 06/07/26

NAME: MRS. SWATI DHAWAN

Punjab Technical University, Jalandhar

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NAME: SHAHRUKH KHAN

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