

Title : Certificate of Analysis Finished Product			
Product Name	ATRANIUM Injection	A.R. No.	NL/FP/26/101
Generic Name	Atracurium Besylate Injection IP 5ml	Sampled qty.	45 Ampoules
Batch No.	A26070B	Sampled by	Rakesh
Batch Size	10,000 Ampoules	Sampled on	19/06/2026
Mfg. Date	06/2026	Date of Testing	19/06/2026
Exp. Date	05/2028	Date of Release	03/07/2026

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	3.51
6.	Related Substance		
	Area of any peak corresponding to acidic compound	NMT 6.0%	0.711%
	Sum of the areas of any peaks corresponding to cis and trans-isomers of the hydroxyl compound	NMT 6.0%	0.722%
	Area of any peak corresponding to laudanosine	NMT 3.0%	1.154%
	Sum of the areas of any peaks corresponding to cis and trans-isomers of the monoacrylate	NMT 3.0%	2.114%
	Sum of all the secondary peaks	NMT 15.0%	6.002%
	Area of any other unspecified degradation product	NMT 0.1%	0.085%

Name : Mrs. Swati Dhawan
Designation : QC HOD

Qualification : M.Sc. in Microbiology
Registration No. : 580/2019/2023
Approved by :
NAME: MRS. SWATI DHAWAN
Punjab Technical University, Jalandhar

Analysis by :
NAME: SHAHRUKH KHAN

Checked by :
NAME: RAMANJEET SINGH

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

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.	11/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	10.25497 mg	102.55%	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.

Analysis by

NAME: SHAHRUKH KHAN

Checked by

NAME: RAMANJEET SINGH

Name : Mrs. Swati Dhawan

Designation : QC Head

Qualification : Approved by

NAME: MRS. SWATI DHAWAN

Punjab Technical University, Jalandhar