

Pacé

Add Pace To Health

Pace Biotech

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

Title

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Certificate of Analysis Finished Product

Product Name	Atranium Injection	A.R. No.	NL/FP/24/507
Generic Name	Atracurium Besylate Injection IP 50mg/5ml	Sampled qty.	45 Ampoules
Batch No.	A24408B	Sampled by	Rakesh
Batch Size	24,610 Ampoules	Sampled on	30/01/2025
Mfg. Date	01/2025	Date of Testing	30/01/2025
Exp. Date	12/2026	Date of Release	15/02/2025

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	3.49
6.	Related Substance		
	Area of any peak corresponding to acidic compound	NMT- 6.0%	Not detected
	Sum of the areas of any peaks corresponding to cis and trans-isomers of the hydroxyl compound	NMT- 6.0%	Not detected
	Sum of the areas of any peaks corresponding to cis and trans-isomers of the monoacrylate	NMT- 3.0%	Not detected
	Area of any other unspecified degradation product	NMT- 0.1%	Not detected
	Sum of areas of all secondary	NMT- 0.15%	Not detected

Analysis by 
NAME: SUFIYAN ANSARI

Checked by 
NAME: SANDHYA

Approved by 
NAME: P. N. TRIPATHI



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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.	94/Ampoules 1/Ampoules Complies		
	(a.) Sub-Visible particle count (1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$ (b.) Visual				
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: Each ml contains:				
Ingredients		Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Atracurium Besylate I.P		10 mg	10.412 mg	104.12%	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 NAME: SUFIYAN ANSARI	Checked by NAME: SANDHYA	Approved by NAME: P. N. TRIPATHI
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