



AMERICAN REMEDIES HEALTHCARE PVT. LTD.

Vill. Surajpur, Nahan Road, Paonta Sahib, Dist. Sirmour (H.P) 173025

Title

Certificate of Analysis Finished Product

Product Name	Atranium Injection	A.R. No.	ARN/FP/25/013
Generic Name	Atracurium Besylate Injection IP 2.5ml	Sampled qty.	45 Ampoules
Batch No.	ARN2501A	Sampled by	Anuj Verma
Batch Size	25,000 Ampoules	Sampled on	30/08/2025
Mfg. Date	07/2025	Date of Testing	30/08/2025
Exp. Date	06/2027	Date of Release	14/09/2025

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 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	3.52
6.	Related substances (By HPLC)		
	Acidic compound	NMT 6.0	1.13%
	Sum of cis & trans isomers hydroxyl compound laudanosine	NMT 6.0	0.45%
	Sum of any peaks corresponding to cis-isomers and trans-isomers of the monoacrylate	NMT 3.0	Not detected
	Area of any other unspecified degradation product	NMT 3.0	Not detected
	Sum of all secondary peaks	NMT 0.1	Not detected
		NMT 15.0	1.58%
7.	Particulate Matter		
	(A.) Light Obscuration Particle Count Test		
	(1.) Particles $\geq 10\mu\text{m}$	NMT 6000/Ampoule	14/Ampoule
	(2.) Particles $\geq 25\mu\text{m}$	NMT 600/ Ampoule	0/Ampoule
	(B.) Visual Particle	The solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally that can be observed on visual inspection.	Complies

Analysis by

NAME: RAMANJEET SINGH

Checked by

NAME: SUFIYAN ANSARI

Approved by

NAME: MRS. SWATI DHAWAN



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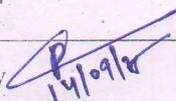
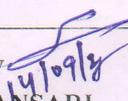
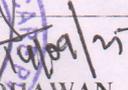
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8.	Sterility	No microbial growth should be observed.	Complies		
9.	Bacterial Endotoxins	NMT 5.56 EU/mg of Atracurium Besylate.	Less than 5.56 EU/mg of Atracurium Besylate.		
10.	Assay: (By HPLC) Each ml contains:				
Ingredients		Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Atracurium Besylate IP		10 mg	9.950 mg	99.50%	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: RAMANJEET SINGH	Checked by  NAME: SUFIYAN ANSARI	Approved by  NAME: MRS. SWATI DHAWAN
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