

**AMERICAN REMEDIES HEALTHCARE PVT. LTD.**

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

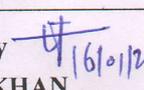
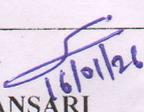
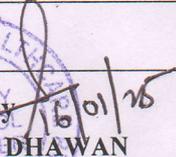
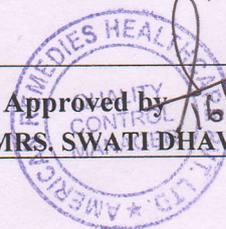
**Title**

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**Certificate of Analysis Finished Product**

<b>Product Name</b>	ATRANIUM Injection	<b>A.R. No.</b>	ARN/FP/25/080
<b>Generic Name</b>	Atracurium Besylate Injection IP 5ml	<b>Sampled qty.</b>	45 Ampoules
<b>Batch No.</b>	ARN2581A	<b>Sampled by</b>	Anuj Verma
<b>Batch Size</b>	98,700 Ampoules	<b>Sampled on</b>	29/12/2025
<b>Mfg. Date</b>	12/2025	<b>Date of Testing</b>	29/12/2025
<b>Exp. Date</b>	11/2027	<b>Date of Release</b>	16/01/2026

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	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	3.37
6.	Related substances (By HPLC)		
	Acidic compound	NMT 6.0	Not Detected
	Sum of cis & trans isomers hydroxyl compound	NMT 6.0	Not Detected
	laudanosine	NMT 3.0	Not Detected
	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 0.1	Not Detected
	Sum of all secondary peaks	NMT 15.0	Not Detected
7.	Particulate Matter		
	(A.) Light Obscuration		
	Particle Count Test		
	(1.) Particles $\geq 10\mu\text{m}$	NMT 6000/Ampoule	15/Ampoule
	(2.) Particles $\geq 25\mu\text{m}$	NMT 600/ Ampoule	1/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: FIROJ KHANChecked by   
NAME: SUFIYAN ANSARIApproved by   
NAME: MRS. SWATI DHAWAN



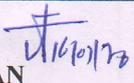
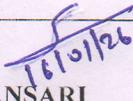
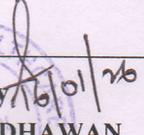
# AMERICAN REMEDIES HEALTHCARE PVT. LTD.

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

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Mfg. Date	12/2025	Date of Testing	29/12/2025
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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	10.35057 mg	103.51%	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: FIROJ KHAN		Checked by NAME: SUFIYAN ANSARI		Approved by NAME: MRS. SWATI DHAWAN	
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