

**DERREN HEALTHCARE PVT. LTD.**

Plot No. #33, 35/p & 36/p XCELON Industrial Park, Lane besides Chak-de-India  
Weighbridge, Sarkhej-Bavla Highway Village: Vasna-Chachrawadi,  
Ahmedabad-382 213, Gujarat (India)

**CERTIFICATE OF ANALYSIS  
(FINISHED PRODUCT)**

<b>Name of Product</b>	Atracurium Besylate Injection 10 mg/ml(ATRANIUM)		
<b>Batch No.</b>	BS24014	<b>A.R. No.</b>	FP/24/0130
<b>Mfg. Date</b>	11/24	<b>Exp. Date</b>	10/26
<b>Sampled Qty.</b>	71 Nos.	<b>Date of Analysis</b>	13/11/24
<b>Batch Size</b>	100. Ltr.	<b>Date of Release</b>	02/12/24
<b>Container Type</b>	Clear Glass Ampoule	<b>Fill volume</b>	2.5 ml
<b>Mfg. Lic. No.</b>	G/28/1862		

Sr. No.	Test	Result	Specification
1	Description	Clear & colorless liquid free from visible particles and fibers.	Clear & colorless liquid free from visible particles and fibers.
2	Extractable volume	2.7 ml	NLT 2.5
3	<b>Identification</b>		
3.1	Identification A By HPLC	The principal peaks of three isomers of atracurium besylate in the chromatogram obtained with the test solution is corresponds to the peaks in the chromatogram obtained with the reference solution..	The principal peaks of three isomers of atracurium besylate in the chromatogram obtained with the test solution should be corresponds to the peaks in the chromatogram obtained with the reference solution..
4	pH	3.49	3.0 to 3.65
5	<b>Related Substance</b>		
5.1	<b>Test - 1</b>		
	Acidic Compound	0.07%	NMT 6.0%
	Sum of Hydroxy compound trans-isomers and cis isomer	0.14%	NMT 6.0%
	laudanosine	0.05%	NMT 3.0%
	Sum of Monoacrylate trans-isomers and cis isomer	0.29%	NMT 3.0%
	Total impurity	0.55%	NMT 15.0%
5.2	<b>Test - 2</b>		
	Atracurium Impurity-A	0.03 %	NMT 1.50%
	Atracurium Impurity-K	0.03% ( Imp I + Imp H + Imp K )	NMT 1.00%
	Atracurium Impurity-I		NMT 1.00%
	Atracurium Impurity-H		NMT 1.00%
	Atracurium Impurity-F		Not detected
6	Bacterial endotoxin	Less than 5.56 EU/mg of	NMT 5.56 EU/mg of Atracurium



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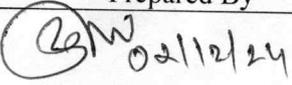
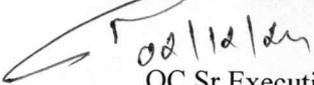
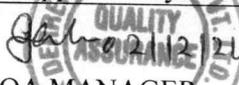
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		Atracurium	
7	<b>Particulate matter</b>		
7.1	By Visual Inspection	The solution is free from particles that is observed by inspection with the unaided eye.	The solution should be free from particles that can be observed by inspection with the unaided eye.
7.2	By Light Obscuration Method	$\geq 10$ microns= 183.73/Container $\geq 25$ Microns=8.27/Container	Sub visible particle by LPC $\geq 10$ microns=NMT 6000/Container $\geq 25$ Microns=NMT 600/Container
8	Sterility test	Sterile	Should be sterile
9	<b>Assay</b>		
9.1	Each ml contains Atracurium besylate (eq. Atracurium IP 10 mg)	102.3 %	90.0% To 115.0 % of the labeled amount of Atracurium
	Trans- trans isomer	6.0%	Not less than 5.0% and Not more than 6.5%.
	cis-trans isomer	37.8%	Not less than 34.5% and Not more than 38.5%.
	cis-cis isomer	58.4%	Not less than 55.0% and Not more than 60.0%.

**Conclusion:** The above sample complies as per IP specification.  
In the opinion of the undersigned the sample referred to above is **of standard** / **not of standard** quality as defined in the act and the rules made there under for the reasons given above.

Prepared By  02/12/24 QC Executive	Checked By  02/12/24 QC Sr.Executive	Approved By  02/12/24 QA MANAGER
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