

Title

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Certificate of Analysis Finished Product

Product Name	STIGVEX Injection	A.R. No.	ARN/FP/26/026
Generic Name	Neostigmine Methylsulphate Injection IP 1ml	Sampled qty.	45 Ampoule
Batch No.	ARN2619A	Sampled by	Rakesh
Batch Size	50,000 Ampoules	Sampled on	03/06/2026
Mfg. Date	05/2026	Date of Testing	04/06/2026
Exp. Date	04/2028	Date of Release	18/06/2026

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 (By UV) (By TLC)	A. When examined in the range 230 nm to 360 nm (2.4.7), the resulting solution shows absorption maxima at about 260 nm and 267 nm. B. The principal spot, in the chromatogram obtained with the test solution corresponds to that in the Chromatogram obtained with reference solution (a). The principal spot in the chromatogram obtained with reference solution (b) appears as a single, compact spot.	Complies Complies
3.	Nominal fill volume	NLT 1.0 ml	1.0 ml
4.	Extractable Volume	NLT Nominal volume or NMT 110% of Nominal volume.	1.1 ml
5.	pH	4.5 to 6.5	5.64
6.	3-Hydroxy trimethylanilinium methyl sulphate the area of any secondary peak with a retention time corresponding to that of the peak due to (3-hydroxy) trimethylanilinium methylsulphate in the chromatogram obtained with reference solution (b) is not greater than the area of the principal peak in the chromatogram obtained with reference solution (a)	NMT 1.0%	0.046%

Analysis by

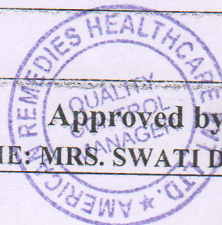
NAME: SHAHRUKH KHAN

Checked by

NAME: SUFIYAN ANSARI

Approved 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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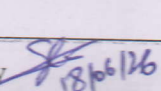
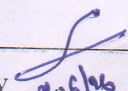
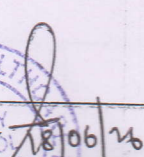
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7.	Particulate Matter		
8.	(A.) Light Obscuration Particle Count Test (1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$ (B.) Visual Particle	NMT 6000/Ampoule NMT 600/Ampoule The solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally that can be observed on visual inspection.	13/Ampoule 1/Ampoule Complies
9.	Bacterial Endotoxins Test	NMT 140 EU/mg of Neostigmine methyl sulphate.	Less than 25.0EU/mg of Neostigmine methyl sulphate..
10.	Sterility	No microbial growth should be observed.	Complies
11.	Assay: Each ml contains:		

Ingredients	Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Neostigmine Methylsulphate IP	0.5 mg	0.51718 mg	103.44%	90.0% to 110.0%

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/THS.

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