

**ANG LIFESCIENCES INDIA LIMITED (UNIT-V)**

Village: Malkumajra, Nalagarh Road, Baddi Distt.: Solan (H.P.) 173205, India

**FINISHED PRODUCT
CERTIFICATE OF ANALYSIS
QUALITY CONTROL DEPARTMENT**

Product Name	Stigvex 2.5 Injection (5 mL Ampoule).		
Generic Name	Neostigmine Injection IP 2.5mg/5ml.	A.R. No.	ANG/FPI/260323
Batch No.	I326001	Batch Size	53921 Ampoules
Mfg. Date	08/2026	Exp. Date	07/2029
Received Date	05/08/2026	Release Date	27/08/2026

S.No.	PARAMETERS	RELEASE SPECIFICATION	RESULT
1.	Description	Clear colourless sterile solution filled in transparent glass ampoule having blue coloured dot on the neck.	Clear colourless sterile solution filled in transparent glass ampoule having blue coloured dot on the neck.
2.	Identification: A. By UV: B. By TLC: C. By Chemically:	When examined in the range 230 nm to 360 nm, the resulting solution shows absorption maxima at about 260 nm and 267 nm. The principal spot in the chromatogram obtained with the test solution corresponds to that in the Chromatogram obtained with reference solution (a). An orange-red colour should be produced.	Complies Complies Complies
3.	Extractable Volume	Between 5.00 mL to 5.15 mL.	5.011 mL
4.	pH	Between 4.5 to 6.5.	6.148
5.	3-Hydroxy trimethylanilinium methyl sulphate	NMT 1.0%.	Complies

	PREPARED BY	CHECKED BY	APPROVED BY
Name	Surendra Chandel	Sandeep Kumar	Vinay Kumar
Designation	Officer	Sr. Executive	Asst. Exec.
Signature			
Date	27/08/2026	27/08/2026	27/08/2026



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6.	Particulate Matter	For Visible Particles	Should be free from particulate matter when examine visually.	Complies
		For Sub-Visible Particles	For particles $\geq 10 \mu\text{m}$: NMT 6000 per ampoule. For particles $\geq 25 \mu\text{m}$: NMT 600 per ampoule.	165 72
7.	Sterility Test (By Membrane Filtration)		No evidence of microbial growth at the end of incubation period.	Complies
8.	Bacterial Endotoxins Test		NMT 0.25 Endotoxin Unit/mL	Less than 0.25 Endotoxin Unit/mL
9.	Assay: Each mL contains: Neostigmine Methylsulfate IP 0.5 mg		Between 0.450 mg to 0.550 mg (90.0% to 110.0% of label claim)	0.5064 mg 101.28%

Remark: The above sample complies / ~~does not comply~~ as per IP/BP/USP and In-house Specification.

	PREPARED BY	CHECKED BY	APPROVED BY
Name	Suvuchi Chandel	Sandeep Kumar	Vijay Kumar
Designation	Officer	Sr. Executive	Plant Head
Signature			
Date	27/08/2026	27/08/2026	27/08/2026