



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**

<b>Product Name</b>	AMERICAN STIGVEX Injection		
<b>Generic Name</b>	Neostigmine Injection IP 2.5 mg/5 ml	<b>A.R. No.</b>	ANG/FPI/250297
<b>Batch No.</b>	1325001	<b>Batch Size</b>	16346 Ampoules
<b>Mfg. Date</b>	09/2025	<b>Exp. Date</b>	08/2027
<b>Received Date</b>	13/11/2025	<b>Release Date</b>	27/11/2025

S.No.	PARAMETER	RELEASE SPECIFICATION	RESULT
1.	Description	Clear, colorless sterile solution filled in Amber coloured glass Ampoule having blue dot on the neck.	Clear, colorless sterile solution filled in Amber coloured glass Ampoule having blue dot on the neck.
2.	Identification: A. By UV  B. TLC  C. By Chemical	When examined in the range 230nm to 360nm the resulting solution shows absorption maxima at about 260nm and 267nm.  The principal spot in the chromatogram obtained with reference solution (b) appears as a single, compact spot.  An orange-red colour should produced.	Complies  Complies  Complies
3.	pH	Between 4.5 to 6.5	6.31
4.	Extractable Volume	5.00 mL to 5.15 mL	5.02 mL
5.	3-Hydroxy trimethylanilinium methyl sulphate	Not more than 1.0%	Not detected
6.	Particulate Matter  Visible Sub visible	Should be free from particulate matter when examine visually. Particle size $\geq 10 \mu\text{m}$ /Ampoule: NMT 6000. Particle size $\geq 25 \mu\text{m}$ /Ampoule: NMT 600.	Complies  180 49
7.	Bacterial Endotoxins	Not more than 0.25 Endotoxin Units per mL.	Less than 0.25 Endotoxin Units per mL.
8.	Sterility (By Membrane Filtration)	No evidence of microbial growth at the end of incubation period.	Complies
9.	Assay: Each mL contains: Neostigmine methylsulphate IP 0.5 mg	Between 0.450 mg to 0.550 mg (90.0 % to 110.0 % of label claim)	0.495 mg (99.1 %)

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

	<b>ANALYZED BY</b>	<b>CHECKED BY</b>	<b>APPROVED BY</b>
<b>Name</b>	Kavita Kumari	Sandeep Kumar	CH-IPR/IN/IAJ
<b>Designation</b>	Executive	Sr. Executive	Dy. Manager
<b>Signature</b>			
<b>Date</b>	27/11/2025	27/11/2025	27/11/2025