

**QUALITY CONTROL DEPARTMENT**  
**"A/C of American Remedies Healthcare Pvt. Ltd."**  
**(Survey no. 53, 56, 57, Near Kamla Amrut Industrial Park, Indrad, Ta-Kadi, Dist.-Mehsana,Gujarat, 382715, India)**  
**CERTIFICATE OF ANALYSIS**

Generic Name	: SALBUTAMOL NEBULISER SOLUTION BP (2.5 MG)		
Product Name	: (2.5 MG) SALBUTAMOL NEBULISER SOLUTION BP - 2.5ML (ASTHANOX) - AMERICAN REMEDIES		
Batch No.	: K1100057	A.R. No.	: KAPL/FP/25/K1100057
Batch Size	: 600 Ltr	Quantity sampled	: 70 Nos
Fill Volume	: 2.5 ml	Received Date	: 21/12/2025
Mfg. Date	: 01/12/2025	Testing Date	: 21/12/2025
Exp. Date	: 30/11/2027	Completion Date	: 26/12/2025

Sr. No.	Tests	Observation	Specifications	Reference to Test Method
1.0	Description	A clear and colorless solution	A clear and colourless solution.	BP Monograph
2.1	Test A : By UV	Maximum Absorbance At 276nm :0.677	0.008%w/v solution gives maximum absorbance only at 276 nm.	BP Monograph Appendix II B
2.2	Test B : By HPLC	Confirms	The principal peak in the chromatogram obtained with solution (2) corresponds to the salbutamol peak in the chromatogram obtained with solution (3).	BP Monograph Appendix III D
2.3	Test C: By reaction (a) of sulfates	Confirms	A white precipitate is formed.	BP Monograph Appendix VI
3.0	pH	4.51	Between 3.0 To 5.0	BP Monograph Appendix V L
4.0	Extractable Volume	2.6ml	The volume is not less than the nominal volume.	BP Monograph Appendix XII C
5.0	Related Substances	Salbutamol Imp D : ND Any secondary Imp : ND Total Imp : ND	Salbutamol impurity D: Not more than 0.5% Any Secondary Impurity: Not more than 0.5% Total impurity: Not more than 1.0%.	BP Monograph Appendix III D
6.0	Salbutamol Ketone	0.0260%	Salbutamol ketone: Not more than 0.5%	BP Monograph Appendix III D
7.0	Assay	100.90%	Between 95.0% To 105.0%	BP Monograph Appendix II B
8.1	Pre - Sterile Bioburden	00 CFU/ml 00 CFU/ml	Bacteria Count :10 <sup>2</sup> CFU per ml Yeast & Mold Count: 10 <sup>1</sup> CFU per ml	BP Monograph
8.2	Microbial Limit Test	Absent Absent Absent	Ps.aeruginosa - absent in 1 g or 1 ml S.aureus - absent in 1 g or 1 ml Bile-tolerant Gram-negative bacteria - absent 1 g or 1 ml	BP Monograph

**Remarks :** The finish product confirms with the defined specifications

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	Analysed by	Checked by	Verified by
Date	26/12/2025	26/12/2025	26/12/2025
Name	Jinal Patel	Baldev Makwana	Kirit Patel
Designation	OFFICER	QC Executive	QA Manager

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