



KamlaAmrut Pharmaceuticals LLP

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 (ASTHAMOL) - AMERICAN		
Batch No.	: K1100039	A.R. No.	: KAPL/FP/25/K1100039
Batch Size	: 600 Ltr	Quantity sampled	: 70 Nos
Fill Volume	: 2.5 ml	Received Date	: 13/01/2025
Mfg. Date	: 01/01/2025	Testing Date	: 13/01/2025
Exp. Date	: 31/12/2026	Completion Date	: 24/01/2025

Sr. No.	Tests	Observation	Specifications	Reference to Test Method
1.0	Description	A clear and colourless solution.	A clear and colourless solution.	BP Monograph
2.1	Test A : By UV	275 gives max. abs. only :- 0.340	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	4.36	Between 3.0 To 5.0	BP Monograph Appendix V L
4.0	Extractable Volume	2.6 ml	The volume is not less than the nominal volume.	BP Monograph Appendix XII C
5.0	Related Substances	Salbutamol Imp D :- 0.0187 Any secondary Imp :- 0.0762 Total imp :- 0.3361	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	Not Detected	Salbutamol ketone: Not more than 0.5%	BP Monograph Appendix III D
7.0	Assay	2.5017 %w/v 100.07 %	Between 95.0% To 105.0%	BP Monograph Appendix II B
8.1	Additional Test	00 CFU/100 ml	Bacterial colonies: Not more than 10 CFU/100 ml Fungal colonies: Should be Absent	In House

Remarks : The finish product confirms with the defined specifications.

	Analysed by	Checked by	Verified by
Date	24/01/2025	24/01/2025	24/01/2025
Name	Priya Patel	Jigar Patel	Kirit Patel
Designation	QC Officer	ASST. MANAGER	QA Manager
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