

**KamlaAmrut Pharmaceuticals LLP****QUALITY CONTROL DEPARTMENT****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.	: K1100071	A.R. No.	: KAPL/FP/26/K1100071
Batch Size	: 600 Ltr	Quantity sampled	: 70 Nos
Fill Volume	: 2.5 ml	Received Date	: 08/08/2026
Mfg. Date	: 01/08/2026	Testing Date	: 09/08/2026
Exp. Date	: 30/07/2028	Completion Date	: 25/08/2026

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	Maximum abs. only at 275.90nm 0.691	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	4.27	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 Impurity D: 0.0265% Any Secondary Impurity : 0.1324% Total Impurity : 0.2669%	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	0.0290%	Salbutamol ketone: Not more than 0.5%	BP Monograph Appendix III D
7.0	Assay	2.5512 mg/ml 102.05%	Between 95.0% To 105.0%	BP Monograph Appendix II B
8.1	Pre - Sterile Bioburden	00 CFU/ml 00 CFU/ml	Bacteria Count : 10^2 CFU per ml Yeast & Mold Count: 10^1 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 specification.

Revision No.: 4.00	Issue Date: 31/05/2025	Eff. Date: 01/06/2025	Page 1 of 2
--------------------	------------------------	-----------------------	-------------

This is software generated COA so not required sign

**KamlaAmrut Pharmaceuticals LLP****QUALITY CONTROL DEPARTMENT****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.	: K1100071	A.R. No.	: KAPL/FP/26/K1100071
Batch Size	: 600 Ltr	Quantity sampled	: 70 Nos
Fill Volume	: 2.5 ml	Received Date	: 08/08/2026
Mfg. Date	: 01/08/2026	Testing Date	: 09/08/2026
Exp. Date	: 30/07/2028	Completion Date	: 25/08/2026

Sr. No.	Tests	Observation	Specifications	Reference to Test Method
---------	-------	-------------	----------------	--------------------------

	Analysed by	Checked by	Verified by
Date	25/08/2026	25/08/2026	25/08/2026
Name	Jagriti Singh	Jaypal Vaghela	Vijay Prajapati
Designation	OFFICER	QC Executive	QA Manager
Revision No.: 4.00	Issue Date: 31/05/2025	Eff. Date: 01/06/2025	Page 2 of 2

This is software generated COA so not required sign