

QUALITY CONTROL DEPARTMENT

CERTIFICATE OF ANALYSIS

Generic Name : Salbutamol Nebuliser solution BP (2.5mg/2.5ml)
Product Name :

Batch No. : K1100053	A.R. No. : KAPL/FP/25/ K1100053
Batch Size : 300 Ltrs.	Quantity sampled : 70 Nos.
Fill Volume : 2.5 ml	Received Date : 29/10/25
Mfg. Date : 10/2025	Testing Date : 30/10/25
Exp. Date : 09/2027	Completion Date : 04/11/25

Sr. No.	Tests	Observation	Specifications	Reference to Test Method
1.0	Description	A clear and colourless solution Confirms	A clear and colourless solution.	BP Monograph
2.0	Identification:			
2.1	Test A: By UV	Confirms	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	4.74 Confirms	Between 3.0 and 5.0.	BP Monograph Appendix V L
4.0	Extractable volume	2.6 ml Confirms	The volume is not less than the nominal volume.	BP Monograph Appendix XII C
5.0	Related Substances	Salbutamol impurity D: 0.0625% Any Secondary Impurity: 0.2095% Total impurity: 0.3233% Confirms	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	0.0039%	Salbutamol ketone: Not more than 0.5%	BP Monograph Appendix III D

"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)

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Sr. No.	Tests	Observation	Specifications	Reference to Test Method
7.0	Assay	2.4571% 2.5mg/2.5ml 98.28 % Confirms	Between 95.0% and 105.0% (Label Claim: 2.5mg/2.5ml)	BP Monograph Appendix II B
8.0	Additional Test			
8.1	Pre -Sterile Bioburden	00 CFU/100ml Absent	Bacterial colonies: Not more than 10 CFU/100 ml Fungal colonies: Should be Absent	In-House
8.2	Microbial Limit Test	Absent Absent Absent	<u>Ps.aeruginosa</u> - absent in 1 g or 1 ml <u>S.aureus</u> - absent in 1 g or 1 ml Bile-tolerant Gram-negative bacteria - absent 1 g or 1 ml	In-House

Remarks: The finish product **Confirms** with the defined specifications.

	Analysed by	Checked by	Verified by
Signature			
Date	04/11/25	04/11/25	04/11/25
Name	Jinal Patel	Baldev Makvana	Jigar Patel
Designation	Q.C. Analyst	Q.C. Officer/Executive	Asst. Manager Q.C.