



KAMLAAMRUT PHARMACEUTICAL LLP.
(Survey no. 53, 56, 57, Near Kamla Amrut Industrial Park, Indrad, Ta-Kadi,
Dist.-Mehsana, Gujarat, 382715, India)

QUALITY CONTROL DEPARTMENT

CERTIFICATE OF ANALYSIS

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

Product Name :

Batch No. : K1100022

A.R. No. : KAPL/FP/24/K1100022

Batch Size : 500 Ltrs.

Quantity sampled : 70 Nos.

Fill Volume : 2.5 ml

Received Date : 02/01/24

Mfg. Date : 01/2024

Testing Date : 02/01/24

Exp. Date : 12/2025

Completion Date : 07/01/24

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	maximum absorbance only at 276 nm 0.691 AU 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	4.30 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: 0.01% Any Secondary Impurity: 0.15,0.08,0.07,0.20, 0.24,0.04,0.04% Total impurity: 0.83 % 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	Salbutamol ketone: Not Detected Confirms	Salbutamol ketone: Not more than 0.5%	BP Monograph Appendix III D



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Sr. No.	Tests	Observation	Specifications	Reference to Test Method
7.0	Assay	2.4249 mg/2.5ml 97.00 % 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

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

	Analysed by	Checked by	Verified by
Signature	<i>V. Shah</i>	<i>Savan Kadiya</i>	<i>Sashin Upadhyay</i>
Date	07/01/24	07/01/24	07/01/24
Name	Vidhi Shah	Savan Kadiya	Sashin Upadhyay
Designation	Q.C. Analyst	Q.C. Officer/Executive	Asst. Manager-QA