



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 : Levosalbutamol (1.25 mg) & Ipratropium Bromide (500 mcg) Respirator
Solution (2.5ml)

Product Name :

Batch No. : K1060287

A.R. No. : KAPL/FP/24/K1060287

Batch Size : 600 Ltrs.

Quantity sampled : 70 Nos.

Fill Volume : 2.5 ml

Received Date : 10/09/24

Mfg. Date : 09/2024

Testing Date : 11/09/24

Exp. Date : 08/2026

Completion Date : 16/09/24

Sr. No.	Tests	Observation	Specifications	Reference to Test Method
1.0	Description	A clear and colourless solution Confirms	A clear and colourless solution.	In-House
2.0	Identification:			
2.1	Test A: By HPLC	Confirms	The principal peaks in the chromatogram obtained with the test solution correspond to the peaks in the chromatogram obtained with the standard solution.	In-House
3.0	pH	4.94 Confirms	Between 4.0 and 6.0	In-House
4.0	Extractable volume	2.6 ml Confirms	The volume is not less than the nominal volume.	In-House
5.0	Assay:			
	Levosulbutamol Sulphate	1.2485mg/2.5ml 99.88% Confirms	Between 90.0% and 110.0% (Label Claim: 1.25mg/2.5ml)	In-House
	Ipratropium Bromide	499.0041mcg/2.5ml 99.80% Confirms	Between 90.0% and 110.0% (Label Claim: 500mcg/2.5ml)	
6.0	Additional Test			
6.0	Pre-Sterile Bioburden	00 CFU/100 ml 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.

	Prepared By	Checked by	Verified by
Signature	V. Shah	Ravisinh Dabhi	Jigar Patel
Date	16/09/24	16/09/24	16/09/24
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