



KAMLAAMRUT PHARMACEUTICAL LLP.
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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. : K1060275	A.R. No. : KAPL/FP/24/K1060275
Batch Size : 600 Ltrs.	Quantity sampled : 70 Nos.
Fill Volume : 2.5 ml	Received Date : 06/05/24
Mfg. Date : 05/2024	Testing Date : 06/05/24
Exp. Date : 04/2026	Completion Date : 11/05/24

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	5.02 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:			In-House
	Levosalbutamol Sulphate	1.2217 mg/2.5 ml 97.74% Confirms	Between 90.0% and 110.0% (Label Claim: 1.25mg/2.5ml)	
	Ipratropium Bromide	493.7515 mcg/2.5 ml 98.75% 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. D. Shah	S. K. Patel	Jigar Patel
Date	11/05/24	11/05/24	11/05/24
Name	Vidhi Shah	Sidhharth Patel	Jigar Patel
Designation	Q.C. Analyst	Q.C. Officer/Executive	Asst. Manager QC