



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. : K1060195	A.R. No. : KAPL/FP/23/K1060195
Batch Size : 500 Ltrs.	Quantity sampled : 70 Nos.
Fill Volume : 2.5 ml	Received Date : 25/09/23
Mfg. Date : 09/2023	Testing Date : 25/09/23
Exp. Date : 08/2025	Completion Date : 30/09/23

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	5.15 Confirms	Between 4.0 and 6.0	In-House
4.0	Extractable volume	2.5 ml Confirms	The volume is not less than the nominal volume.	In-House
5.0	Assay:			
	Levosulbutamol Sulphate	1.2574 mg/2.5ml 100.59% Confirms	Between 90.0% and 110.0% (Label Claim: 1.25mg/2.5ml)	In-House
	Ipratropium Bromide	510.8697 mcg/2.5ml 102.17% Confirms	Between 90.0% and 110.0% (Label Claim: 500mcg/2.5ml)	
6.0	Additional Test			
6.0	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.

	Prepared By	Checked by	Verified by
Signature			
Date	30/09/23	30/09/23	30/09/23
Name	Dhruvi Patel	Savan Kadiya	Sachin Saple
Designation	Q.C. Analyst	Q.C. Officer/Executive	Q.A/Q.C Manager

Issue No. 03	Issue Date: 23/03/23	Revision No. 02	Eff. Date: 01/04/23	Page No.: 1 / 1
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