



KAMLAAMRUT PHARMACEUTICAL LLP.
"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)

QUALITY CONTROL DEPARTMENT

CERTIFICATE OF ANALYSIS

Generic Name : Levosalbutamol (1.25 mg) & Ipratropium Bromide (500 mcg) Respirator Solution (2.5ml)	
Product Name :	
Batch No. : K1060353	A.R. No. : KAPL/FP/25/ K1060353
Batch Size : 600 Ltrs.	Quantity sampled : 70 Nos.
Fill Volume : 2.5 ml	Received Date : 21/11/25
Mfg. Date : 11/2025	Testing Date : 21/11/25
Exp. Date : 10/2027	Completion Date : 26/11/25

Sr. No.	Tests	Observation	Specifications	Reference to Test Method
1.0	Description	A clear and colourless solution Confirms	A clear and colourless solution.	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	5.32 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	1.2456mg/2.5ml 99.65% Confirms ✓	Between 90.0% and 110.0% (Label Claim: 1.25mg/2.5ml)	In-House
	Ipratropium Bromide	498.9408 mcg/2.5ml 99.79% Confirms	Between 90.0% and 110.0% (Label Claim: 500mcg/2.5ml)	In-House
6.0	Additional Test			
6.1	Pre-Sterile Bioburden	00CFU/100 ml 00CFU/100 ml	Bacteria Count :10 ² CFU per ml Yeast & Mold Count: 10 ¹ CFU per ml	In-House
6.2	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.

	Prepared By	Checked by	Verified by
Signature			
Date	28/11/25	26/11/25	26/11/25
Name	Sahil Patel	Baldev Makwana	Shashin Upadhyay
Designation	Q.C. Analyst	Q.C. Officer/Executive	Asst. QA Manager