

	<b>"A/C of American Remedies Healthcare Pvt. Ltd."</b> <b>(Survey no. 53, 56, 57, Near Kamla Amrut Industrial Park, Indrad, Ta-Kadi, Dist.-</b> <b>Mehsana, Gujarat, 382715, India)</b>
	<b>QUALITY CONTROL DEPARTMENT</b>  <b>CERTIFICATE OF ANALYSIS</b>

Generic Name : Levosalbutamol (1.25 mg) & Ipratropium Bromide (500 mcg) Respirator Solution (2.5ml)	
Product Name :	
Batch No. : K1060270	A.R. No. : KAPL/FP/24/K1060270
Batch Size : 600 Ltrs.	Quantity sampled : 70 Nos.
Fill Volume : 2.5 ml	Received Date : 15/04/24
Mfg. Date : 04/2024	Testing Date : 15/04/24
Exp. Date : 03/2026	Completion Date : 20/04/24

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	5.24 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:			
	Levosalbutamol Sulphate	1.2500 mg/2.5ml 100.00% Confirms	Between 90.0% and 110.0% (Label Claim: 1.25mg/2.5ml)	In-House
	Ipratropium Bromide	518.3436 mcg/2.5ml 103.67% 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			
Date	20/04/24	20/04/24	20/04/24
Name	Darshil Ghanchi	Siddharth Patel	Jigar Patel
Designation	Q.C. Analyst	Q.C. Officer/Executive	Asst. Manager QC

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