	"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 : (Ipracan-L)

Batch No.	: K1060298	A.R. No.	: KAPL/FP/24/K1060298
Batch Size	: 600 Ltrs.	Quantity sampled	: 70 Nos.
Fill Volume	: 2.5 ml	Received Date	: 09/11/24
Mfg. Date	: 11/2024	Testing Date	: 10/11/24
Exp. Date	: 10/2026	Completion Date	: 15/11/24

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	5.35 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	1.2613 mg/2.5ml 100.90% Confirms	Between 90.0% and 110.0% (Label Claim: 1.25mg/2.5ml)	In-House
	Ipratropium Bromide	491.7520 mcg/2.5ml 98.35% Confirms	Between 90.0% and 110.0% (Label Claim: 500mcg/2.5ml)	
6.0	Additional Test			
6.0	Pre-Sterile Bioburdan	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	15/11/24	15/11/24	15/11/24
Name	Priya Patel	Jaypal Vaghela	Jigar Patel
Designation	Q.C. Analyst	Q.C. Officer/Executive	Asst. Manager Q.C.

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QUALITY CONTROL DEPARTMENT

CERTIFICATE OF ANALYSIS

Generic Name : Levofloxacin Infusion (500mg/100ml) Product Name :			
Batch No.	: AC4374003	A.R. No.	: KAPL/FP/24/AC4374003
Batch Size	: 2450 Ltrs.	Quantity sampled	: 25 Nos.
Fill Volume	: 100 ml	Received Date	: 24/10/24
Mfg. Date	: 10/2024	Testing Date	: 24/10/24
Exp. Date	: 09/2026	Completion Date	: 07/11/24

Sr. No.	Tests	Observation	Specifications	Reference to Test Method
1.0	Description	A Clear and yellow solution Confirms	A yellow to greenish yellow solution essentially free from visible particles.	IP Monograph
2.0	Identification:			
2.1	Identification by HPLC	Confirms	The chromatogram obtained with the test solution corresponds to the chromatogram obtained with standard solution	IP Monograph (2.4.14)
3.0	pH	4.91 Confirms	Between 3.8 to 5.8	IP Monograph (2.4.24)
4.0	Extractable volume	102.0 ml Confirms	The volume is not less than the nominal volume.	IP Monograph
5.0	Particulate matter			
5.1	Particulate matter for ≤100 ml nominal volume			IP Monograph (2.5.9)
	For ≥ 10µm	1.67 particles per container Confirms	Not more than 6000 particles per container	
	For ≥ 25µm	0.00 particles per container Confirms	Not more than 600 particles per container	
6.0	Assay of Sodium Chloride	0.9085 %w/v 100.94% Confirms	Between 95.0% to 105.0% of the Label claim(Label Claim:0.9% w/v)	IP Monograph
7.0	Assay of Levofloxacin (By HPLC)	0.4974 %w/v 99.48% Confirms	Between 90.0% to 120.0% of the Label claim (Label Claim:0.75% w/v)	IP Monograph (2.4.14)