

	"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 : Budesonide Nebuliser Suspension BP (0.5mg/2ml)	
Product Name :	
Batch No. : K1090361	A.R. No. : KAPL/FP/25/K1090361
Batch Size : 500 Ltrs	Quantity sampled : 110 Nos
Fill Volume : 2.0 ml	Received Date : 12/10/25
Mfg. Date : 10/2025	Testing Date : 12/10/25
Exp. Date : 09/2027	Completion Date : 19/10/25

Sr. No.	Tests	Observation	Specifications	Reference to Test Method
1.0	Description	A white colour suspension Confirms	A white colour suspension.	BP Monograph
2.0	Identification:			
2.1	Test A: By UV	maximum absorbance only at 243 nm is 0.396 Confirms	0.002%w/v solution gives maximum absorbance only at 247 nm.	BP Monograph Appendix II B
2.2	Test B: By HPLC	Confirms	The retention time of the principal peak in the chromatogram obtained with solution (1) is similar to that of the principal peak in the chromatogram obtained with solution (2).	BP Monograph Appendix III D
3.0	pH	4.44 Confirms	Between 4.0 and 5.0.	BP Monograph Appendix V L
4.0	Extractable volume	2.2 ml Confirms	The volume is not less than the nominal volume.	BP Monograph Appendix XII C
5.0	Related Substances	Any Secondary impurity: 0.1178% Total impurity:0.0393% Confirms	Any secondary impurity: NMT 0.5% Total impurity: NMT 1.5%.	BP Monograph Appendix III D
6.0	Epimer A	44.231% Confirms	Between 40.0% and 51.0%	BP Monograph Appendix III D
7.0	Assay	0.5131 mg/2ml 102.62% Confirms	Between 92.5% and 105.0% (Label Claim: 0.5mg/2ml)	BP Monograph Appendix III D

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Sr. No.	Tests	Observation	Specifications	Reference to Test Method
8.0	Additional Test			
8.1	Pre- Sterile Bioburden	100 CFU/ml Confirms 1000 CFU/ml Confirms	Bacteria Count : 10^2 CFU per ml Yeast & Mold Count: 10^1 CFU per ml	BP Monograph
8.2	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	BP Monograph

Remarks: The finish product **Confirms** with the defined specifications.

	Prepared By	Checked by	Verified by
Signature			
Date	19/10/25	19/10/25	19/10/25
Name	Jinal Patel	Baldev Makwana	Jigar Patel
Designation	Q.C. Analyst	Q.C. Officer/Executive	Asst. Manager Q.C

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