

"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. : K1090299	A.R. No. : KAPL/FP/24/K1090299
Batch Size : 500 Ltrs	Quantity sampled : 110 Nos
Fill Volume : 2.0 ml	Received Date : 16/10/24
Mfg. Date : 10/2024	Testing Date : 17/10/24
Exp. Date : 09/2026	Completion Date : 22/10/24

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 245 nm is 0.265 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	4.50 Confirms	Between 4.0 and 5.0.	BP Monograph Appendix V L
4.0	Extractable volume	2.1 ml Confirms	The volume is not less than the nominal volume.	BP Monograph Appendix XII C
5.0	Related Substances	Any Secondary impurity: 0.16% Total impurity:0.19% Confirms	Any secondary impurity: NMT 0.5% Total impurity: NMT 1.5%.	BP Monograph Appendix III D
6.0	Epimer A	45.29% Confirms	Between 40.0% and 51.0%	BP Monograph Appendix III D
7.0	Assay	0.4915mg/2ml 98.30% 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	00 CFU/100ml Absent	Bacterial colonies: Not more than 10 CFU/100 ml Fungal colonies: Should be Absent	BP Monograph

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

	Prepared By	Checked by	Verified by
Signature	<i>P. B. Patel</i>	<i>Jaypal Vaghela</i>	<i>Jigar Patel</i>
Date	22/10/24	22/10/24	22/10/24
Name	Priya Patel	Jaypal Vaghela	Jigar Patel
Designation	Q.C. Analyst	Q.C. Officer/Executive	Asst. Manager Q.C.