

**QUALITY CONTROL DEPARTMENT**  
**"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)**  
**CERTIFICATE OF ANALYSIS**

Generic Name	: BUDESONIDE NEBULISER SUSPENSION BP (0.5 MG)		
Product Name	: (0.5 MG) BUDESONIDE NEBULISER SUSPENSION BP - 2.0 ML (BUDECAN 0.5MG) - AMERICAN		
Batch No.	: K1090377	A.R. No.	: KAPL/FP/25/K1090377
Batch Size	: 500 Ltr	Quantity sampled	: 110 Nos
Fill Volume	: 2.0 ML	Received Date	: 24/12/2025
Mfg. Date	: 01/12/2025	Testing Date	: 24/12/2025
Exp. Date	: 30/11/2027	Completion Date	: 31/12/2025

Sr. No.	Tests	Observation	Specifications	Reference to Test Method
1.0	Description	A White Color suspension	A white color suspension.	BP Monograph
2.1	Test A : By UV	243.60 nm : 0.516	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	4.39	Between 4.0 To 5.0	BP Monograph Appendix V L
4.0	Extractable Volume	2.2 ml	The volume is not less than the nominal volume.	BP Monograph Appendix XII C
5.0	Related Substances	Any Secondary Imp. : 0.0929 % Total Imp: 0.0471 %	Any secondary impurity: Not more than 0.5% Total impurity: Not more than 1.5%	BP Monograph Appendix III D
6.0	A	45.7095	Between 40.0% and 51.0%	BP Monograph Appendix III D
7.0	Assay	0.4998 mg/2ml 99.95 %	Between 92.5% and 105.0% (Label Claim : 0.5 mg/2ml)	BP Monograph Appendix III D
8.1	Pre - Sterile Bioburden	00 CFU/ml 00 CFU/ml	Bacteria Count : $10^2$ CFU per ml Yeast & Mold Count: $10^1$ CFU per ml	BP Monograph
8.2	Microbial count	Absent	Ps. aeruginosa- Absent in 1g or 1ml S. aureus - Absent in 1g or 1ml Bile- tolerant Gram- negative bacterial- Absent 1g or 1ml	BP Monograph

**Remarks :** The finish product confirms with the defined specifications

Revision No.: 4.00	Issue Date: 19/05/2025	Eff. Date: 20/05/2025	Page 1 of 2
--------------------	------------------------	-----------------------	-------------

This is software generated COA so not required sign

**QUALITY CONTROL DEPARTMENT**  
**"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)**  
**CERTIFICATE OF ANALYSIS**

Generic Name	: BUDESONIDE NEBULISER SUSPENSION BP (0.5 MG)		
Product Name	: (0.5 MG) BUDESONIDE NEBULISER SUSPENSION BP - 2.0 ML (BUDECAN 0.5MG) - AMERICAN		
Batch No.	: K1090377	A.R. No.	: KAPL/FP/25/K1090377
Batch Size	: 500 Ltr	Quantity sampled	: 110 Nos
Fill Volume	: 2.0 ML	Received Date	: 24/12/2025
Mfg. Date	: 01/12/2025	Testing Date	: 24/12/2025
Exp. Date	: 30/11/2027	Completion Date	: 31/12/2025

Sr. No.	Tests	Observation	Specifications	Reference to Test Method
---------	-------	-------------	----------------	--------------------------

	Analysed by	Checked by	Verified by
Date	31/12/2025	31/12/2025	31/12/2025
Name	Jinal Patel	Baldev Makwana	Kirit Patel
Designation	OFFICER	QC Executive	QA Manager

Revision No.: 4.00	Issue Date: 19/05/2025	Eff. Date: 20/05/2025	Page 2 of 2
--------------------	------------------------	-----------------------	-------------

This is software generated COA so not required sign