

| | |
|--|--|
| | "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. : K1090347 | A.R. No. : KAPL/FP/25/K1090347 |
| Batch Size : 500 Ltrs | Quantity sampled : 110 Nos |
| Fill Volume : 2.0 ml | Received Date : 27/08/25 |
| Mfg. Date : 08/2025 | Testing Date : 28/08/25 |
| Exp. Date : 07/2027 | Completion Date : 02/09/25 |

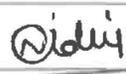
| Sr. No. | Tests | Observation | Specifications | Reference to Test Method |
|---------|--------------------|---|--|-----------------------------|
| 1.0 | Description | A white colour suspension Confirms | A white colour suspension. | BP Monograph |
| 2.0 | Identification: | | | |
| 2.1 | Test A: By UV | maximum absorbance only at 247 nm is 0.383 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 | 4.35 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: 0.0807% Total impurity:0.0269% Confirms | Any secondary impurity: NMT 0.5% Total impurity: NMT 1.5%. | BP Monograph Appendix III D |
| 6.0 | Epimer A | 45.01% Confirms | Between 40.0% and 51.0% | BP Monograph Appendix III D |
| 7.0 | Assay | 0.5100 mg/2ml 102.00% Confirms | Between 92.5% and 105.0% (Label Claim: 0.5mg/2ml) | BP Monograph Appendix III D |

| | |
|---|--|
| "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. : K1090347 | A.R. No. : KAPL/FP/25/K1090347 |
| Batch Size : 500 Ltrs | Quantity sampled : 110 Nos |
| Fill Volume : 2.0 ml | Received Date : 27/08/25 |
| Mfg. Date : 08/2025 | Testing Date : 28/08/25 |
| Exp. Date : 07/2027 | Completion Date : 02/09/25 |

| Sr. No. | Tests | Observation | Specifications | Reference to Test Method |
|---------|------------------------|--------------|--|--------------------------|
| 8.0 | Additional Test | | | |
| 8.1 | Pre- Sterile Bioburden | 00 CFU/100ml | Bacteria Count :10 ² CFU per ml Yeast & Mold Count: 10 ¹ CFU per ml | BP Monograph |
| 8.2 | Microbial Limit Test | 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 | 02/09/25 | 02/09/25 | 02/09/25 |
| Name | Nidhi Raval | Kuldeep Nai | Jigar Patel |
| Designation | Q.C. Analyst | Q.C. Officer/Executive | Asst.Manager Q.C. |