

|                                                                                  |                                                                                                                                                               |  |
|----------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
|  | <b>KAMLAAMRUT PHARMACEUTICAL LLP.</b><br>(Survey no. 53, 56, 57, Near Kamla Amrut Industrial Park, Indrad, Ta-Kadi,<br>Dist.-Mehsana, Gujarat, 382715, India) |  |
|                                                                                  | <b>QUALITY CONTROL DEPARTMENT</b>                                                                                                                             |  |
|                                                                                  | <b>Certificate of Analysis</b>                                                                                                                                |  |

|                                                               |                                |
|---------------------------------------------------------------|--------------------------------|
| Generic Name : Budesonide Nebuliser Suspension BP (0.5mg/2ml) |                                |
| Product Name :                                                |                                |
| Batch No. : K1090260                                          | A.R. No. : KAPL/FP/24/K1090260 |
| Batch Size : 500 Ltrs                                         | Quantity sampled : 110 Nos     |
| Fill Volume : 2.0 ml                                          | Received Date : 21/02/24       |
| Mfg. Date : 02/2024                                           | Testing Date : 22/02/24        |
| Exp. Date : 01/2026                                           | Completion Date : 27/02/24     |

| 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 At 244 nm 0.475 AU Confirms                                                                                                                                            | 0.002%w/v solution gives maximum absorbance only at 247 nm.                                                                                                                      | BP Monograph Appendix II B  |
| 2.2     | Test B: By HPLC    | 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). 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                 | 4.77 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: 0.24% Total impurity: 0.15% Confirms                                                                                                                              | Any secondary impurity: NMT 0.5% Total impurity: NMT 1.5%.                                                                                                                       | BP Monograph Appendix III D |
| 6.0     | Epimer A           | 43.317% Confirms                                                                                                                                                                          | Between 40.0% and 51.0%                                                                                                                                                          | BP Monograph Appendix III D |
| 7.0     | Assay              | 0.5148mg/2.0 ml 102.95% Confirms                                                                                                                                                          | Between 92.5% and 105.0% (Label Claim: 0.5mg/2ml)                                                                                                                                | BP Monograph Appendix III D |

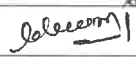
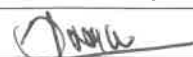
|              |                      |                 |                     |                 |
|--------------|----------------------|-----------------|---------------------|-----------------|
| Issue No. 03 | Issue Date: 05/06/22 | Revision No. 02 | Eff. Date: 06/06/22 | Page No.: 1 / 2 |
|--------------|----------------------|-----------------|---------------------|-----------------|

|                                                                                  |                                                                                                                                                            |
|----------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  | <b>KAMLAAMRUT PHARMACEUTICAL LLP.</b><br>(Survey no. 53, 56, 57, Near Kamla Amrut Industrial Park, Indrad, Ta-Kadi, Dist.-Mehsana, Gujarat, 382715, India) |
|                                                                                  | <b>QUALITY CONTROL DEPARTMENT</b><br><br><b>Certificate of Analysis</b>                                                                                    |

|                                                               |                                |
|---------------------------------------------------------------|--------------------------------|
| Generic Name : Budesonide Nebuliser Suspension BP (0.5mg/2ml) |                                |
| Product Name :                                                |                                |
| Batch No. : K1090260                                          | A.R. No. : KAPL/FP/24/K1090260 |
| Batch Size : 500 Ltrs                                         | Quantity sampled : 110 Nos     |
| Fill Volume : 2.0 ml                                          | Received Date : 21/02/24       |
| Mfg. Date : 02/2024                                           | Testing Date : 22/02/24        |
| Exp. Date : 01/2026                                           | Completion Date : 27/02/24     |

| Sr. No. | Tests                  | Observation                | Specifications                                                                       | Reference to Test Method |
|---------|------------------------|----------------------------|--------------------------------------------------------------------------------------|--------------------------|
| 8.0     | Additional Test        |                            |                                                                                      |                          |
| 8.1     | Pre- Sterile Bioburden | 00 CFU/100ml<br><br>Absent | Bacterial colonies: Not more than 10 CFU/100 ml<br>Fungal colonies: Should be Absent | BP Monograph             |

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

|             | Prepared By                                                                         | Checked by                                                                          | Verified by                                                                           |
|-------------|-------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------|
| Signature   |  |  |  |
| Date        | 27/02/24                                                                            | 27/02/24                                                                            | 27/02/24                                                                              |
| Name        | Bhoomi Chavada                                                                      | Siddharth Patel                                                                     | Sachin Saple                                                                          |
| Designation | Q.C. Analyst                                                                        | Q.C. Officer/Executive                                                              | Q.A/Q.C Manager                                                                       |