

**BIODEAL PHARMACEUTICALS LIMITED**

NALAGARH – ROPAR ROAD, VILLAGE SAINIMAJRA, NALAGARH, DIST.SOLAN (HP) INDIA.

**CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)**

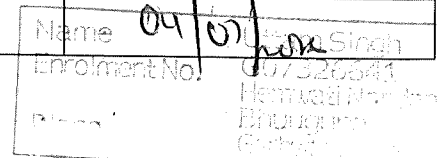
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|                    |   |                                                           |                  |   |                   |
|--------------------|---|-----------------------------------------------------------|------------------|---|-------------------|
| Product Name       | : | ASTHACAN 200                                              |                  |   | Page No. 1 of 2   |
| Generic name       | : | Formoterol Fumarate & Budesonide Powder For Inhalation IP |                  |   |                   |
| Product Code       | : | 1849-BL                                                   | A.R.No.          | : | FP/26/3885        |
| Batch No.          | : | 2606145B                                                  | Batch Size       | : | 1.02 Lac.         |
| Manufacturing Date | : | 06/2026                                                   | Expiry Date      | : | 05/2029           |
| Sample Quantity    | : | 120 Capsules                                              | Pack Size        | : | 1 x 30's Capsules |
| Date of Sampling   | : | 27/06/2026                                                | Date of Analysis | : | 27/06/2026        |
| Ref.Spec. No.      | : | FP/1849                                                   | Date of Release  | : | 04/07/2026        |
| Mfg. LIC. No.      | : | MNB/06/440                                                |                  |   |                   |

| S.No. | TESTS                         | SPECIFICATIONS                                                                                                                                                                                                            | RESULTS                                                                                    |
|-------|-------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------|
| 01.   | Description                   | White powder filled in size "3" capsule with clear transparent body and blue coloured cap.                                                                                                                                | White powder filled in size "3" capsule with clear transparent body and blue coloured cap. |
| 02.   | Average Weight                | 75.0 mg $\pm$ 10.0 % (67.5 mg to 82.5 mg)                                                                                                                                                                                 | 73.7 mg                                                                                    |
| 03.   | Net Content                   | 25.0 mg $\pm$ 10.0 % (22.5 mg to 27.5 mg)                                                                                                                                                                                 | 24.0 mg                                                                                    |
| 04.   | Uniformity of Weight          | $\pm$ 10 % of net content.                                                                                                                                                                                                | Min: -5.8%<br>Max: +5.0%                                                                   |
| 05.   | Identification                | In the assay, the principal peaks due to Formoterol and Budesonide in the chromatogram obtained with test solution should correspond to the principal peaks in the chromatogram obtained with the reference solution (c). | Complies                                                                                   |
| 06.   | Uniformity of content         |                                                                                                                                                                                                                           |                                                                                            |
|       | For Formoterol Fumarate       | Not more than one individual values is outside the limits 85.0% to 115.0% of the average value and none are outside the limits of 75.0% to 125.0%.                                                                        | Min. : 99.5 %<br>Max : 100.7 %                                                             |
|       | For Budesonide                | Not more than one individual values is outside the limits 85.0% to 115.0% of the average value and none are outside the limits of 75.0% to 125.0%.                                                                        | Min.: 97.6 %<br>Max.: 100.7 %                                                              |
| 07.   | Assay (By HPLC)               |                                                                                                                                                                                                                           |                                                                                            |
|       | Formoterol Fumarate IP...6mcg | 90.0 % to 125.0 % of the label claim.                                                                                                                                                                                     | 106.2 %                                                                                    |
|       | Budesonide IP.....200mcg      | 90.0 % to 125.0 % of the label claim.                                                                                                                                                                                     | 102.2 %                                                                                    |

| Responsibility | PREPARED BY    | CHECKED BY | APPROVED BY |
|----------------|----------------|------------|-------------|
| Name           | Shivani Kapoor | Sharvanta  | Vijay Singh |
| Signature      |                |            |             |
| Date           | 04/07/2026     | 04/07/2026 | 04/07/2026  |

Form no.: QC013-F05-07



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|     |                                      |                         |            |
|-----|--------------------------------------|-------------------------|------------|
| 08. | Microbial contamination              |                         |            |
|     | Total viable aerobic bacterial count | Not more than 100 cfu/g | 10 cfu/g   |
|     | Total fungal count                   | Not more than 10 cfu/g  | <10cfu/g   |
|     | <i>Enterobacteriaceae</i>            | Should be absent / g    | Absent/ g  |
|     | <i>Staphylococcus aureus</i>         | Should be absent / g    | Absent/ g  |
|     | <i>Pseudomonas aeruginosa</i>        | Should be absent / g    | Absent / g |

Remarks: The product ~~meets~~/does not meet the specification **ASTHACAN 200** and hence ~~is~~/is not of standard quality.

| Responsibility | PREPARED BY    | CHECKED BY | APPROVED BY    |
|----------------|----------------|------------|----------------|
| Name           | Shivani Kapoor | Shalikaant | Vijendra Singh |
| Signature      |                |            |                |
| Date           | 04/07/2026     | 04/07/2026 | 04/07/2026     |

Form no.: QC013-F05-07

Name: Vikram Singh  
Enrolment No.: G07/2020/41  
Place: Meerut Nandan  
Bharatpur  
Garhwal University