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| | **Nixi Laboratories Pvt. Ltd.,**<br>**Village Mouza Ogli, Sadhaura Road, Kala-Amb, District Sirmour -173030, Himachal Pradesh (INDIA).** |

## CERTIFICATE OF ANALYSIS FINISHED PRODUCTS

| | | | |
|---|---|---|---|
| **Product Name** | BETASTAL-BD | **AR. No.** | NL/LA/FG/26/507 |
| **Generic Name** | Betamethasone (As Sodium Phosphate) & Betamethasone (As Dipropionate) Injection 2ml | | |
| **Mother Batch** | A26CW007 | **Reference** | IHS |
| **Child Batch No.** | A26CW007 | **Batch Size** | 107142 Ampoules |
| **Mfg. Date** | 07/2026 | **Exp. Date** | 06/2029 |
| **Specification No. (STS No)** | QC/LA/FG/STS/073-01 | **Standard Test Procedure No.** | QC/LA/FG/STP/073 |
| **Sample Quantity** | 76 Ampoules | **Sampling Date** | 26/09/2026 |
| **Released Date** | 10/10/2026 | | |

| Sr. No. | Test | Specification | Observation |
|---|---|---|---|
| 1. | **Description** | White colour suspension free from foreign particles filled in 2 ml Clear glass ampoule | White colour suspension free from foreign particles filled in 2 ml Clear glass ampoule |
| 2. | **Identification:**<br>**A. By High Performance Liquid Chromatography (HPLC)** | In the assay, the to principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution. | Complies |
| 3. | **Average filled Volume** | Not Less Than-2.0 ml | 2.10ml |
| 4. | **Extractable Volume** | Not Less Than-2.0 ml | 2.10 ml |
| 5. | **pH (At 25.0°C)** | 7.0 to 9.0 | 7.85 |
| 6. | **Particulate matter** | | |
| | **Visible particles:** | Should be free from visible particles | Complies |
| 7. | **Sterility** | Should comply the test of sterility | Complies |
| 8. | **Bacterial Endotoxins** | Not More Than 29.75 EU/ml | Complies |
| 9. | **Assay:** | | |
| | **Each 2ml contains:**<br>Betamethasone (as sodium phosphate) USP 4 mg<br>Betamethasone (as dipropionate ) USP 10 mg | 3.60 mg to 4.40 mg<br>(90.0% to 110.0%)<br>9.00 mg to 11.00mg<br>(90.0% to 110.0%) | 4.12 mg<br>(103.00%)<br>10.53mg<br>(105.30%) |
| 10. | **Diethylene glycol and Ethylene glycol (By GC)** | Not more than 0.1% | Not Detected |

| | ANALYSED BY | CHECKED BY | APPROVED BY |
|---|---|---|---|
| **Name** | **Rahul Singh** | **Sunil Kumar** | **Aditya Singh** |
| **Designation** | **Sr.Officer QC** | **Sr.Executive QC** | **Manager QC** |
| **Signature** | Rahul | 10/10/26 | Approved By<br>Name : Aditya Singh<br>Designation : Manager QC<br>Qualification : Bsc<br>Enrollment No. II-009545<br>Avadh University Ayodhya |
| **Date** | 10/10/26 | | |

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| Sr. No. | Test | Specification | Observation |
|---|---|---|---|

**Result:** The above sample **COMPLIES/DOES NOT COMPLY** as per Specification No. QC/LA/FG/STS/073-01

**Conclusion:** In the opinion of the under signed the sample referred above is of **STANDARD QUALITY / IS NOT STANDARD QUALITY** as defined in the Drugs & Cosmetics Act, 1940 and the rules made here under further

| | ANALYSED BY | CHECKED BY | APPROVED BY |
|---|---|---|---|
| **Name** | **Rahul Singh** | **Sunil Kumar** | **Aditya Singh** |
| **Designation** | **Sr.Officer QC** | **Sr.Executive QC** | **Manager QC** |
| **Signature** | Rahul | 10/10/26 | Approved By<br>Name : Aditya Singh<br>Designation : Manager QC<br>Qualification : Bsc,<br>Enrollment No. U009545<br>Avadh University Ayodhya |
| **Date** | 10/10/26 | | |