



Nixi Laboratories Pvt. Ltd.,
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/26/082 |
| Generic Name | Betamethasone (As Sodium Phosphate) & Betamethasone (As Dipropionate) Injection | | |
| Mother Batch | A26CW001 | Reference | IHS |
| Child Batch No. | A26CW001 | Batch Size | 142857 Ampoules |
| Mfg. Date | 02/2026 | Exp. Date | 01/2029 |
| 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 | 17/02/2026 |
| Released Date | 03/03/2026 | | |

| 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: 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 | 2.09 ml |
| 4. | Extractable Volume | Not Less Than-2.0 ml | 2.09 ml |
| 5. | pH (At 25.0°C) | 7.0 to 9.0 | 8.13 |
| 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 ampoule 2ml contains: Betamethasone (as sodium phosphate) USP 4 mg Betamethasone (as dipropionate) USP 10 mg | 3.60 mg to 4.40 mg (90.0% to 110.0%) 9.00 mg to 11.00mg (90.0% to 110.0%) | 4.17 mg (104.25%) 10.19 mg (101.90%) |
| 10. | Diethylene glycol and Ethylene glycol (By GC) | Not more than 0.1% | Not Detected |

| | ANALYSED BY | CHECKED BY | APPROVED BY |
|-------------|-------------|------------------|------------------|
| Name | Rajan | Meenakshi Panday | Aditya Singh |
| Designation | Officer QC | Sr. Executive QC | Asst. Manager QC |
| Signature | | | |
| Date | 03/03/26 | 03/03/26 | 03/03/26 |

Format No.:F/QC/013/03-04

Approved By Page 1 of 2
Name: Aditya Singh
Designation: Asst. Manager QC
Qualification: B.Pharm
Enrollment No: 11-009915
Avadh University Ayodhya.



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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 | Rajan | Meenakshi Panday | Aditya Singh |
| Designation | Officer QC | Sr. Executive QC | Asst. Manager QC |
| Signature | | | |
| Date | 03/03/26 | 03/03/26 | 03/03/26 |

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