



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/26/010
Generic Name	Betamethasone (As Sodium Phosphate) & Betamethasone (As Dipropionate) Injection		
Mother Batch	A25CW019	Reference	IHS
Child Batch No.	A25CW019	Batch Size	142857 Ampoules
Mfg. Date	12/2025	Exp. Date	11/2028
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	05/01/2026
Released Date	19/01/2026		

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	2.08 ml
4.	Extractable Volume	Not Less Than-2.0 ml	2.08 ml
5.	pH (At 25.0°C)	7.0 to 9.0	7.99
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%)	4.20 mg (105.00%) 10.16 mg (101.60%)
10.	Diethylene glycol and Ethylene glycol (By GC)	Not more than 0.1%	Complies

	ANALYSED BY	CHECKED BY	APPROVED BY
Name	Sabir	Meenakshi Panday	Aditya Singh
Designation	Sr. Officer QC	Sr. Executive QC	Asst. Manager QC
Signature			
Date	19/01/26	19/01/26	19/01/26

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

Approved By
Name: Aditya Singh Page 1 of 2
Designation: Asst. Manager QC
Qualification: Bsc
Enrollment No. II-009545
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	Sabir	Meenakshi Panday	Aditya Singh
Designation	Sr. Officer QC	Sr. Executive QC	Asst. Manager QC
Signature			
Date	19/01/26	19/01/26	19/01/26

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