



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/26/083
Generic Name	Betamethasone (As Sodium Phosphate) & Betamethasone (As Dipropionate) Injection		
Mother Batch	A26CW002	Reference	IHS
Child Batch No.	A26CW002A	Batch Size	64285 Amp
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	18/02/2026
Released Date	05/03/2026		

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	2.08 ml
4.	Extractable Volume	Not Less Than-2.0 ml	2.08 ml
5.	pH (At 25.0°C)	7.0 to 9.0	8.08
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: 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%)	4.15 mg (103.75%) 9.96 mg (99.60%)
10.	Diethylene glycol and Ethylene glycol (By GC)	Not more than 0.1%	Not Detected

	ANALYSED BY	CHECKED BY	APPROVED BY
Name	Rajan	Sabir	Aditya Singh
Designation	Officer QC	Sr. Officer QC	Asst. Manager QC
Signature			
Date	05/03/26	05/03/26	05/03/26

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

Approved By
Name: Aditya Singh
Designation: Asst. Manager QC
Qualification: B.Pharm
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	Rajan	Sabir	Aditya Singh
Designation	Officer QC	Sr. Officer QC	Asst. Manager QC
Signature			
Date	05/03/26	05/03/26	05/03/26

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

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Name: Aditya Singh
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