	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/26/512
Generic Name	Betamethasone (As Sodium Phosphate) & Betamethasone (As Dipropionate) Injection 2ml		
Mother Batch	A26CW008	**Reference**	IHS
Child Batch No.	A26CW008	**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	12/10/2026		

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:** **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	2.04 ml
4.	**Extractable Volume**	Not Less Than-2.0 ml	2.04 ml
5.	**pH (At 25.0°C)**	7.0 to 9.0	7.79
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%)	4.10 mg (102.50%) 10.46 mg (104.60%)
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	12/10/26	Approved By Name : Aditya Singh Designation : Manager QC Qualification : Bsc Enrollment No. II-009545 Avadh University Ayodhya
Date	12/10/26		

	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/26/512
Generic Name	Betamethasone (As Sodium Phosphate) & Betamethasone (As Dipropionate) Injection 2ml		
Mother Batch	A26CW008	**Reference**	IHS
Child Batch No.	A26CW008	**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	12/10/2026		

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	12/10/26	Approved By Name : Aditya Singh Designation : Manager QC Qualification : Bsc Enrollment No. R-009545 Avadh University Ayodhya
Date	12/10/26		