



Nixi Laboratories Pvt. Ltd.
VPO: MouzaOgli, Sadhora Road, Kala Amb Distt. Sirmour (H.P)

CERTIFICATE OF ANALYSIS FINISHED PRODUCTS

Product Name	BETASTAL-BD	AR. No.	NL/LA/FG/24/297
Generic Name	Betamethasone (As Sodium Phosphate) & Betamethasone (As Dipropionate) Injection		
Mother Batch	A24CW005	Reference	IHS
Child Batch No.	A24CW005	Batch Size	52857 Ampoules
Mfg. Date	06/2024	Exp. Date	05/2027
Specification No. (STS No)	QC/LA/FG/STS/073	Standard Test Procedure No.	QC/LA/FG/STP/073
Sample Quantity	55 Ampoules	Sampling Date	21/07/2024
Released Date	05/08/2024		

Sr. No.	Test	Specification	Observation
1.	Description	White colour suspension free from foreign particles filled in transparent 2 ml glass ampoule	White colour suspension free from foreign particles filled in transparent 2 ml 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	2.02 ml
4.	Extractable Volume	Not Less Than-2.0 ml	2.02 ml
5.	pH (At 25.0°C)	7.0 to 9.0	8.16
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 (Aa Sodium Phosphate) USP 4 mg Betamethasone (As Dipropionate) USP 10 mg	3.6 mg to 4.4 mg (90.0% to 110.0%) 9 mg to 11mg (90.0% to 110.0%)	4.20 mg (105.10%) 10.55 mg (105.5%)

	ANALYSED BY	CHECKED BY	APPROVED BY
Name	Rahul Singh	Ganesh jaiswal	Aditya Singh
Signature			
Date	05/08/24	05/08/24	05/08/24





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Result: The above sample **COMPLIES/DOES NOT COMPLY** as per Specification No. QC/LA/FG/STS/073
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	Ganesh jaiswal	Aditya Singh
Signature			
Date	05/08/24	05/08/24	05/08/24

