

Certificate of Analysis Finished Product

Approved by: 76614
NAME: MRS. SWATI DHAWAN
Punjab Technical University, Jalandhar

Checked by Soblohra
NAME: SURJEET KAUR

Title : **Certificate of Analysis Finished Product**

Product Name	BETASTAL Injection	A.R. No.	NL/FP/26/102
Generic Name	Betamethasone Injection IP 1ml	Sampled qty.	60 Ampoules
Batch No.	A26093A	Sampled by	Aakash
Batch Size	1,00,000 Ampoules	Sampled on	20/06/2026
Mfg. Date	06/2026	Date of Testing	22/06/2026
Exp. Date	05/2028	Date of Release	06/07/2026

7.	Related substances (By HPLC)				
	Betamethasone	NMT 2.6%		0.021%	
	Any secondary peak	NMT 3.0%		0.474%	
	Sum of all secondary peaks	NMT 5.0%		0.729%	
8.	Particulate Matter	NMT 6000/Ampoule NMT 600/Ampoule		13/Ampoule 1/Ampoule	
	(A.) Light Obscuration Particle Count Test (1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$				
	(B.) Visual Particle	The solution is free from particles of foreign matter particles that can be observed on visual inspection.		Complies	
9.	Sterility	Liquid Injection should comply the test for sterility		Complies	
10.	Bacterial Endotoxins	NMT 29.02 EU/mg of Betamethasone.		Less than 29.02 EU/mg of Betamethasone.	
11.	Assay: (By HPLC) Each ml contains:				
Ingredients		Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Betamethasone Sodium Phosphate IP Eq. to Betamethasone		4 mg	4.02409 mg	100.60%	92.5% to 107.5%
Remarks: In the presence of					

Remarks: In the opinion of the undersigned the sample referred to above is/ is ~~not~~ of the standard quality as The Drug & cosmetic Act 1940 and the rules made there under. Complies/ ~~not~~ complies as per IP/BP/USP/HS.

Name : Mrs. Swati Dhawan
Designation : QC HOD

Qualification : M.Sc. Clinical Microbiology
Registration : Approved by 06/07/26
Name : MRS. SWATI DHAWAN

Analysis by 06/07/26
NAME: SHAHRUKH KHAN

Checked by 06/07/26
NAME: SURJEET KAUR