

Title

Certificate of Analysis Finished Product

Product Name	BETASTAL Injection	A.R. No.	ARN/FP/25/058
Generic Name	Betamethasone Injection IP 1ml	Sampled qty.	60 Ampoules
Batch No.	ARN2560A	Sampled by	Anuj verma
Batch Size	2,00,000 Ampoules	Sampled on	27/11/2025
Mfg. Date	11/2025	Date of Testing	27/11/2025
Exp. Date	10/2027	Date of Release	22/12/2025

S. No.	Tests	Specifications	Observations
1.	Description	A clear colourless solution filled in amber glass ampoule.	A clear colourless solution filled in amber glass ampoule.
2.	Identification (By TLC)	<p>A. To a volume of injection containing 4 mg of betamethasone, add 1 ml of water and sufficient ethanol to produce 40 ml. To 2 ml of the solution in a stopper tube, add 10 ml of phenyl hydrazine solution, mix, warm in a water-bath at 60° for 20 minutes and cool immediately; absorbance of the resulting solution at the maximum at 450 nm, not more than 0.1.</p> <p>B. The chromatogram obtained with the test solution, reference solution (a) and reference solution (b) shows, single principal spot with identical Rf values. The chromatogram obtained with reference solution (c) shows two principal spots with almost identical Rf values.</p> <p>C. Evaporate a volume containing the equivalent of 2 mg betamethasone to dryness on a water-bath, dissolve the residue in 2 ml of sulphuric acid and allow to stand for 2 minutes, No red colour is produced.</p>	<p>Complies</p> <p>Complies</p> <p>Complies</p>
3.	Nominal fill volume	NLT 1ml	1.0 ml
4.	Extractable Volume	NLT Nominal volume or NMT 110% of Nominal volume.	1.1 ml
5.	pH	8.0 to 9.0	8.29
6.	Appearance of solution	A 0.2%w/v solution of betamethasone is not more intensely coloured than reference solution BYS4.	Complies

Analysis by

NAME: RAMANJEET SINGH

Checked by

NAME: SUFIYAN ANSARI

Approved by

NAME: MRS. SWATI DHAWAN

**AMERICAN REMEDIES HEALTHCARE PVT. LTD.**

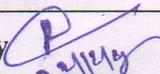
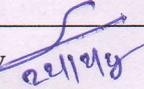
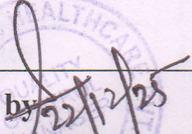
Vill. Surajpur, Nahan Road, Paonta Sahib, Dist. Sirmour (H.P) 173025

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7.	Related substances (By HPLC)				
	Betamethasone	NMT 2.6%		0.171%	
	Any secondary peak	NMT 3.0%		1.334%	
	Sum of all secondary peaks	NMT 5.0%		1.505%	
8.	Particulate Matter				
	(A.) Light Obscuration Particle Count Test (1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$	NMT 6000/Ampoule NMT 600/Ampoule		4/Ampoule 0/Ampoule	
	(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	4.118 mg	102.95 %	92.5% to 107.5%

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.

Analysis by  NAME: RAMANJEET SINGH	Checked by  NAME: SUFIYAN ANSARI	Approved by  NAME: MRS. SWATI BHAWAN
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