

CERTIFICATE OF ANALYSIS

Generic Name	Dexamethasone Sodium Phosphate Injection IP, 4 mg/ml		
Brand Name	Dexacan	Product Code	DX
Batch No.	DXV25024	Batch Size	250 Liters
Mfg. Date	SEP.2025	Exp. Date	AUG.2028
Date of Sampling	10/10/2025	Completed Date	11/10/2025
A. R. No.	RLS/FP/250275	Specification No.	FPS006-03





Sr. No.	Tests	Method	Specification	Results	
1	Description	IP/ IH	A clear, almost colourless solution filled in USP type I / type II / type III glass container.	A clear, almost colourless solution filled in USP type-I, 2 ml clear glass vial with blue colour flip off seal.	
2	Identification A by HPLC	IP	In the Assay, the Principal peak in the chromatogram obtained with the Test solution corresponds to the peak due to Dexamethasone sodium phosphate in the chromatogram obtained with the Reference solution (a).	Complies	
3	pH	IP	NLT 7.0 and NMT 8.5	7.85	
4	Extractable volume	IP	NLT nominal volume in ml	2.0 ml	
5	Particulate matter:				
	A	Visual inspection	IP	Clear and practically free from particles when observed by visual inspection by the unaided eyes.	Complies
	B	Particle size $\geq 10 \mu\text{m}$	IH	NMT 6000 per container	99.87
Particle size $\geq 25 \mu\text{m}$		NMT 600 per container		1.73	
6	Free Dexamethasone	IP	NMT 0.5 %	0.196%	
7	Assay (Each 1 ml of solution contains 4 mg Dexamethasone phosphate)	IP	NLT 95.0 % and NMT 105.0% (NLT 3.8 mg and NMT 4.2 mg)	102.0 % (4.078 mg/ml)	
8	BET	IP	NMT 31.3 EU/ mg of Dexamethasone phosphate	Less than 15.6 EU/mg	
9	Sterility	IP	Should be sterile.	Sterile	

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Additional tests				
10	Methyl paraben content	IH	NLT 90.0% and NMT 110.0%	100.5 %
	Propyl paraben content	IH	NLT 90.0% and NMT 110.0%	100.4 %

Remarks: The product complies as per IP and In-house specification

	Prepared by	Reviewed by	Approved by	Authorized by
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Designation	officer	Executive	manager	manager
Signature				
Date	11/10/2025	11/10/2025	11/10/2025	11/10/2025