

**CERTIFICATE OF ANALYSIS**

<b>Product Name</b>	DEXACAN				
<b>Generic Name</b>	Dexamethasone Sodium Phosphate Injection IP, 4 mg/ml, 2 ml	<b>Product Code</b>	DX		
<b>Batch No.</b>	DXV24030	<b>Batch Size</b>	250 Liters		
<b>Mfg. Date</b>	JUN.2024	<b>Exp. Date</b>	MAY 2027		
<b>Date of Sampling</b>	11/06/2024	<b>Completed Date</b>	26/06/2024		
<b>A. R. No.</b>	RLS/FP/240149	<b>Specification No.</b>	FPS006		
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, 2ml 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	112.00
Particle size $\geq 25 \mu\text{m}$		NMT 600 per container		0.67	
6	Free Dexamethasone	IP	NMT 0.5 %	0.211%	
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)	99.8% (3.990 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	




Corporate Office: No.07, KHB, Industrial Estate, Yelahanka New Town, Bengaluru-560064, India  
CIN : U24111KA19991PT012343

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Additional tests				
10	Methyl paraben content	IH	NLT 90.0% and NMT 110.0%	103.0%
	Propyl paraben content	IH	NLT 90.0% and NMT 110.0%	101.4%

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

	Analysed by	Checked by	Approved by
<b>Signature</b>			
<b>Date</b>	17/03/2025	17/03/2025	17/03/2025

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