RAY LIFE
SCIENCES

Factory Address : Survey No.25/1, Hubli-Karwar
.Highway, Kadanakoppa, Kalghatagi,
Dharwad, Karnataka-581204, India

CERTIFICATE OF ANALYSIS

Product Name	DEXACAN		
Generic Name	Dexamethasone Sodium Phosphate Injection IP 4mg/m, 2ml	Product Code	DX
Batch No.	DXV24031	Batch size	250 Liters
Mfg. Date	JUN.2024	Exp. Date	MAY 2027
Date of sampling	12/06/2024	Completed Date	27/06/2024
A.R. No.	RLS/FP/240150	Specification No.	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	7.91
4	Extractable volume	IP	NLT nominal volume in ml	2.0 ml
5	Particulate matter:	IP	Clear and practically free from particles when observed by visual inspection by the unaided eyes.	Complies
	A Visual inspection			
	B Particle size ≥ 10µm	IH	NMT 6000 per container.	424.40 particles per container
	Particle size ≥ 25µm		NMT 600 per container.	3.33 particles per container
6	Free Dexamethasone	IP	NMT 0.5 %.	0.187 %
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)	100.4 % (4.014 mg/ml)

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8	BET	IP	NMT 31.3 EU/ mg of Dexamethasone phosphate.	Less than 15.6 EU/mg
9	Sterility	IP	Should be sterile.	Sterile
Additional tests				
10	Methyl paraben content	IH	NLT 90.0% and NMT 110.0%	102.0 %
	Propyl paraben content	IH	NLT 90.0% and NMT 110.0%	100.0 %

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

	Analysed by	Checked by	Approved by
Signature			
Date	08/11/2024	08/11/2024	08/11/2024