

Title

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Certificate of Analysis Finished Product

Product Name	MEDROCAN Injection	A.R. No.	ARN/FP/26/066
Generic Name	Methylprednisolone Sodium Succinate for Injection USP 1000mg	Sampled qty.	45 vials
Batch No.	ARN2674A	Sampled by	Rakesh
Batch Size	5,030 Vials	Sampled on	28/08/2026
Mfg. Date	08/2026	Date of Testing	29/08/2026
Exp. Date	07/2028	Date of Release	13/09/2026

S. No.	Tests	Specifications	Observations
1.	Description	A white to pale yellow dry powder filled in clear glass vial.	A white dry powder filled in clear glass vial.
2.	Identification	The IR absorption spectrum of a mineral oil dispersion of the residue so obtained the exhibits maxima only at the same wavelength as those of a similar preparation of USP Methylprednisolone Hemisuccinate RS.	Complies
3.	Uniformity of Dosage units	Average weight $\pm 10\%$	-2.86% & +7.85%
4.	Average weight	Informative $\pm 2\%$.	1417.8 mg
5.	Free Methylprednisolone	NMT 6.6% of the labeled amount of methylprednisolone.	0.70%
6.	Particulate Matter (A.) Light Obscuration Particle Count Test 1. Particles $\geq 10 \mu\text{m}$ 2. Particles $\geq 25 \mu\text{m}$ (B.) Visual Particle	NMT 6000/vial NMT 600/vial The solution is free from particles of foreign matter particles that can be observed on visual inspection.	1,850/vial 2/vial Complies
7.	pH	7.0 to 8.0.	7.38
8.	Constituted solution: Completeness and clarity of solution:	The solid dissolves completely, leaving no undissolved matter. The constituted solution is not significantly less clear than an equal volume of the diluents or of purified water contained in a similar vessel and examined similarly. The constituted solution is free from particulate matter that can be observed on visual inspection.	Complies
9.	Loss on drying	NMT 2.0%w/w	1.31%w/w

Name : Mrs. Swati Dhawan

Designation : QC HOD

Qualification : M.Sc. Clinical Microbiology

Registered Approved by 13/09/26

NAME: MRS. SWATI DHAWAN

Analysis by

NAME: SHAHRUKH KHAN

Checked by

NAME: SURJEET KAUR



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