

Title

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Certificate of Analysis Finished Product

Product Name	MEDROCAN Injection	A.R. No.	ARN/FP/26/068
Generic Name	Methylprednisolone Sodium Succinate for Injection USP 1000mg	Sampled qty.	45 vials
Batch No.	ARN2673A	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 $\pm 10\%$	-1.48% & +1.24%
4.	Average weight	Informative $\pm 2\%$.	1389.1 mg
5.	Free Methylprednisolone	NMT 6.6% of the labeled amount of methylprednisolone.	0.72%
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.	1,826/vial 1/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	1.24%w/w

Name : Mrs. Swati Dhawan

Designation : QC HOD

Qualification : M.Sc. in Microbiology

Registration : Approved by

NAME: MRS. SWATI DHAWAN

Analysis by

NAME: SHAHRUKH KHAN

Checked by

NAME: SURJEET KAUR

**AMERICAN REMEDIES HEALTHCARE PVT. LTD.**

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

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10.	Sterility	No microbial growth should be observed.	Complies		
11.	Bacterial Endotoxins	NMT 0.17 USP EU/mg of Methylprednisolone.	Less than 0.17 USP EU/mg Methylprednisolone.		
12.	Assay: (By HPLC) Each glass vial Contains:				
Ingredients		Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Sterile Methylprednisolone Sodium Succinate USP Eq. to anhydrous Methylprednisolone		1000 mg	1036.5630 mg	103.66%	90.0 to 110.0%

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.

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