

**AMERICAN REMEDIES HEALTHCARE PVT. LTD.**

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

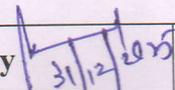
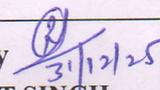
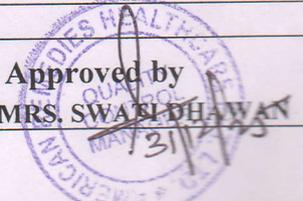
Title

:

Certificate of Analysis Finished Product

Product Name	MEDROCAN Injection	A.R. No.	ARN/FP/25/061
Generic Name	Methylprednisolone Sodium Succinate for Injection USP 1000mg	Sampled qty.	45 vials
Batch No.	ARN2573A	Sampled by	Rakesh
Batch Size	10,000 Vials	Sampled on	02/12/2025
Mfg. Date	11/2025	Date of Testing	03/12/2025
Exp. Date	10/2027	Date of Release	31/12/2025

S. No.	Tests	Specifications	Observations
1.	Description	A white to pale yellow dry powder filled in clear glass vial.	A white to pale yellow 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 $\pm 10\%$	-1.41% & +0.98%
4.	Average weight	Informative $\pm 2\%$.	1407.7 mg
5.	Free Methylprednisolone	NMT 6.6% of the labeled amount of methylprednisolone.	Not Detected
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.	171/vial 1/vial Complies
7.	pH	7.0 to 8.0	7.49
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	7.49%w/w

Analysis by 
NAME: NIKHIL SHARMAChecked by 
NAME: RAMANJEET SINGHApproved by 
NAME: MRS. SWATI DHAWAN

Title : Certificate of Analysis Finished Product

Product Name	MEDROCAN Injection	A.R. No.	ARN/FP/25/061
Generic Name	Methylprednisolone Sodium Succinate for Injection USP 1000mg	Sampled qty.	45 vials
Batch No.	ARN2573A	Sampled by	Rakesh
Batch Size	10,000 Vials	Sampled on	02/12/2025
Mfg. Date	11/2025	Date of Testing	03/12/2025
Exp. Date	10/2027	Date of Release	31/12/2025

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	957.46 mg	95.75%	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/PHS.

Analysis by <u>31/12/2025</u> NAME: NIKHIL SHARMA	Checked by <u>31/12/25</u> NAME: RAMANJEET SINGH	Approved by <u>31/12/25</u> NAME: MRS. SWATI DHAWAN
--	---	--

