



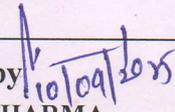
AMERICAN REMEDIES HEALTHCARE PVT. LTD.

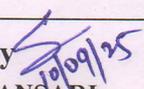
Vill. Surajpur, Nahan Road, Paonta Sahib, Dist. Sirmour (H.P) 173025

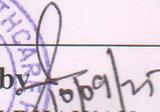
Title : Certificate of Analysis Finished Product

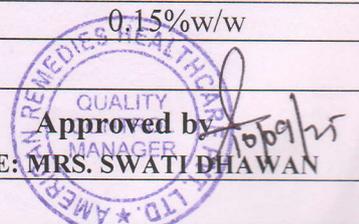
Product Name	Medrocan-40 Injection	A.R. No.	ARN/FP/25/009
Generic Name	Methylprednisolone Sodium Succinate for Injection USP 40mg	Sampled qty.	45 vials
Batch No.	ARN2523A	Sampled by	Rakesh
Batch Size	30,000 Vials	Sampled on	26/08/2025
Mfg. Date	08/2025	Date of Testing	27/08/2025
Exp. Date	07/2027	Date of Release	10/09/2025

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 $\pm 10\%$	-3.23% & +4.63%
4.	Average weight	Informative $\pm 2\%$.	58.6 mg
5.	Free Methylprednisolone	NMT 6.6% of the labeled amount of methylprednisolone.	1.10%
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.	1695.47/vial 117.87/vial Complies
7.	pH	7.0 to 8.0	7.44
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	0.15%w/w

Analysis by 
NAME: NIKHIL SHARMA

Checked by 
NAME: SUFIYAN ANSARI

Approved by 
NAME: MRS. SWATI DHAWAN





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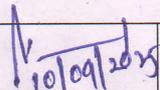
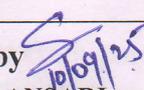
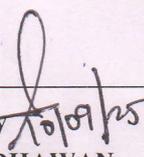
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10.	Sterility	No microbial growth should be observed.	Complies	
11.	Bacterial Endotoxins	NMT 0.17 USP EU/mg of Methylprednisolone.	Less than 0.17 USP EU/mg Methylprednisolone.	
12.	Assay: (By HPLC) Each glass vial contains:			
Ingredients	Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Sterile Methylprednisolone Sodium Succinate USP Eq. to anhydrous Methylprednisolone	40 mg	41.20 mg	103.00%	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/IHS.

Analysis by  NAME: NIKHIL SHARMA	Checked by  NAME: SUFIYAN ANSARI	Approved by  NAME: MRS. SWATI DHAWAN
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