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 500** Injection	**A.R. No.**	ARN/FP/25/020
Generic Name	Methylprednisolone Sodium Succinate for Injection USP 500mg	**Sampled qty.**	45 vials
Batch No.	ARN2527A	**Sampled by**	Anuj Verma
Batch Size	10,000 Vials	**Sampled on**	17/09/2025
Mfg. Date	09/2025	**Date of Testing**	18/09/2025
Exp. Date	08/2027	**Date of Release**	03/10/2025

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 ±10%	-1.97% & +2.14%
4.	Average weight	Informative ±2%.	699.7 mg
5.	Free Methylprednisolone	NMT 6.6% of the labeled amount of methylprednisolone.	0.54%
6.	Particulate Matter (A.) Light Obscuration Particle Count Test 1.Particles ≥10 µm 2.Particles ≥25 µm (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.	 1309.33/vial 152.00/vial Complies
7.	pH	7.0 to 8.0	7.29
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	1.35%w/w

Analysis by	Checked by	Approved by
03/10/2025	03/10/25	03/10/25
NAME: NIKHIL SHARMA	NAME: SUFIYAN ANSARI	NAME: MRS. SWATI DHAWAN

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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	500 mg	488.96 mg	97.79%	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~~.

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NAME: NIKHIL SHARMA	NAME: SUFIYAN ANSARI	NAME: MRS. SWATI DHAWAN

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