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/25/083
Generic Name	Methylprednisolone Sodium Succinate for Injection USP 40mg	**Sampled qty.**	45 vials
Batch No.	ARN2694A	**Sampled by**	Rakesh
Batch Size	50,000 Vials	**Sampled on**	17/09/2026
Mfg. Date	09/2026	**Date of Testing**	18/09/2026
Exp. Date	08/2028	**Date of Release**	02/10/2026

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%	-9.57% & +5.09%
4.	Average weight	Informative ±2%.	56.6mg
5.	Free Methylprednisolone	NMT 6.6% of the labeled amount of methylprednisolone.	0.58%
6.	Particulate Matter		
	(A.) Light Obscuration Particle Count Test 1.Particles ≥10 µm 2.Particles ≥25 µm	NMT 6000/vial NMT 600/vial	1,565/vial 5/vial
	(B.) Visual Particle	The solution is free from particles of foreign matter particles that can be observed on visual inspection.	Complies
7.	pH	7.0 to 8.0	7.62
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	1.21%w/w

Name : Mrs. Swati Dhawan
Designation : QC HOD
Qualification : M.Sc. Clinical Microbiology
Registration No. : 5904/03/2020

Analysis by	Checked by	Approved by
02/10/26	02/10/26	02/10/26
NAME: NIKHIL SHARMA	NAME: SURJEET KAUR	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	40 mg	42.1209 mg	105.30 %	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	Checked by	Approved by
NAME: NIKHIL SHARMA 02/10/26	NAME: SURJEET KAUR 02/10/26	NAME: MRS. SWATI DHAWAN

Name : Mrs. Swati Dhawan
Designation : QC HOD
Qualification : M.Sc. Clinical Microbiology
Registration No. : 5[illegible]
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