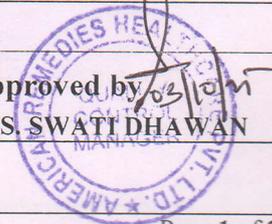


Title		: Certificate of Analysis Finished Product	
Product Name	Medrocan 500 Injection	A.R. No.	ARN/FP/25/020
Generic Name	Methylprednisolone Sodium Succinate for Injection USP 500mg	Sampled qty.	45 vials
Batch No.	ARN2527A	Sampled by	Anuj Verma
Batch Size	10,000 Vials	Sampled on	17/09/2025
Mfg. Date	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 $\pm 10\%$	-1.97% & +2.14%
4.	Average weight	Informative $\pm 2\%$.	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 $\geq 10 \mu\text{m}$ 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.	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 NAME: NIKHIL SHARMA	Checked by NAME: SUFIYAN ANSARI	Approved by 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/HS.

Analysis by Nikhil Sharma 03/10/2025
 NAME: NIKHIL SHARMA

Checked by Sufiyan Ansari 03/10/25
 NAME: SUFIYAN ANSARI

Approved by Mrs. Swati Dhawan 03/10/25
 NAME: MRS. SWATI DHAWAN

