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Surajpur, Paonta sahib Dist. Sirmour (H.P)

Title	:	**Certificate of Analysis Finished Product**		

Product Name	Medrocan 1G Injection	A.R. No.	NB/FP/24/186
Generic Name	Methylprednisolone Sodium Succinate for Injection USP 1G	Sampled qty.	45 vials
Batch No.	N24159A	Sampled by	Boby Kumar
Batch Size	1000 Vials	Sampled on	25/09/2024
Mfg. Date	09/2024	Date of Testing	25/09/2024
Exp. Date	08/2026	Date of Release	09/10/2024

S. No.	Tests	Specifications	Observations
1.	Description	A white dry powder filled in clear glass vial.	A white dry powder filled in clear glass vial.
2.	Identification	The absorption spectrum of the test preparation should exhibits maxima at same wavelength with that obtained with similar preparation of methylprednisolone sodium Succinate working standard.	Complies
3.	Uniformity of weight	Average weight ±10%	-1.35% & +1.63%
4.	Average weight	Informative.	1398.2 mg
5.	Uniformity of Dosage Units	Complies as per USP.	Complies
6.	Free Methylprednisolone	NMT 6.6% of labeled amount of Methylprednisolone.	2.15%
7.	Particulate Matter		
	(A.) Light Obscuration Particle Count Test		
	1.Particles ≥10 µm	NMT-6000/vial	249/vial
	2.Particles ≥25 µm	NMT-600/vial	3/vial
	(B.) Visual	The solution is free from particles of foreign matter particles that can be observed on visual inspection.	Complies
8.	pH	7.0 to 8.0	7.41
9.	Loss on drying	NMT-2.0% w/w	1.10% w/w
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.

12. Assay:
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	979.35 mg	97.94%	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

Format No : PB/OC/045/F05-00

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