

Title : Certificate of Analysis Finished Product

Product Name	Medrocan 1G Injection	A.R. No.	NB/FP/24/327
Generic Name	Methylprednisolone Sodium Succinate for Injection USP 1000mg	Sampled qty.	45 vials
Batch No.	N24287D	Sampled by	Rakesh
Batch Size	1008 Vials	Sampled on	22/01/2025
Mfg. Date	01/2025	Date of Testing	22/01/2025
Exp. Date	12/2026	Date of Release	08/02/2025

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 $\pm 10\%$	-1.78% & +1.42%
4.	Average weight	Informative.	1403.6 mg
5.	Uniformity of Dosage Units	Complies as per USP.	Complies
6.	Free Methylprednisolone	NMT 6.6% of labeled amount of Methylprednisolone.	0.64%
7.	Particulate Matter (A.) Light Obscuration Particle Count Test 1. Particles $\geq 10 \mu\text{m}$ 2. Particles $\geq 25 \mu\text{m}$ (B.) Visual	NMT-6000/vial NMT-600/vial The solution is free from particles of foreign matter particles that can be observed on visual inspection.	565/vial 1/vial Complies
8.	pH	7.0 to 8.0	7.45
9.	Loss on drying	NMT- 2.0%w/w	1.11%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	982.79 mg	98.28%	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/AHS.

Analysis by NAME: SUFIYAN ANSARI	Checked by NAME: SANDHYA	Approved by NAME: P. N. TRIPATHI
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