




Title : Certificate of Analysis Finished Product

Product Name	Medrocan 500 Injection	A.R. No.	NB/FP/24/229
Generic Name	Methylprednisolone Sodium Succinate for Injection USP 500mg	Sampled qty.	45 vials
Batch No.	N24188A	Sampled by	Vineet
Batch Size	1000 Vials	Sampled on	10/11/2024
Mfg. Date	10/2024	Date of Testing	10/11/2024
Exp. Date	09/2026	Date of Release	25/11/2024

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 $\pm 10\%$	-5.28% & +2.94%
4.	Average weight	Informative.	704.3 mg
5.	Uniformity of Dosage Units	Complies as per USP.	Complies
6.	Free methylprednisolone (By HPLC)	NMT 6.6%	2.63%
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.	530/vial 4/vial Complies
8.	pH	7.0 to 8.0	7.45
9.	Loss on drying	NMT-2.0% w/w	0.98% 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	500 mg	492.39 mg	98.48%	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/USP/IHS.~~ ~~IP/USP/IHS.~~

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