

Title

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Certificate of Analysis Finished Product

Product Name	Medrocan-40 Injection	A.R. No.	NB/FP/24/148
Generic Name	Methylprednisolone Sodium Succinate for Injection USP 40mg	Sampled qty.	45 vials
Batch No.	N24117A	Sampled by	Rakesh
Batch Size	15,000 Vials	Sampled on	25/08/2024
Mfg. Date	07/2024	Date of Testing	25/08/2024
Exp. Date	06/2026	Date of Conditionally Release	05/09/2024

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 $\pm 10\%$	-8.79% & +4.87%
4.	Average weight	Informative.	60.7 mg
5.	Uniformity of Dosage Units	Complies as per USP.	Complies
6.	Free Methylprednisolone	NMT- 6.6%	2.93%
7.	Particulate Matter		
	(A.) Light Obscuration Particle Count Test		
	1. Particles $\geq 10 \mu\text{m}$	NMT-6000/vial	505/vial
	2. Particles $\geq 25 \mu\text{m}$	NMT-600/vial	0/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	7.46
9.	Loss on drying	NMT-2.0% w/w	1.07% w/w
10.	Sterility	No microbial growth should be observed.	Under process
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	40 mg	42.17 mg	105.43%	90.0% - 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	Checked by	Approved by
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