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Pace Biotech

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

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.	N24188F	**Sampled by**	Vineet
Batch Size	3000 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 ±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 ≥10 µm 2.Particles ≥25 µm	NMT-6000/vial NMT-600/vial	530/vial 4/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	7.45
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/BP/USP/IHS~~.

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

PACE BIOTECH PAONTA SAHIB (H.P.) Quality Control Manager