ALVENTA PHARMA LIMITED

VILL. KISHANPURA, TEHSIL BADDI- NALAGARH ROAD, DISTT.- SOLAN (H.P) 174101

Quality Control Department

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Product Name	Medrocan-40	**A.R. No.**	FG/G/25A0024
Generic Name	Methylprednisolone Sodium Succinate for Injection USP	**Sample Quantity**	65 Vials
Batch No.:	AGD50109	**Sample Received on**	14/02/2025
Batch Size:	20,000 Vials	**Analysis Date**	14/02/2025
Mfg. Date.	01/2025	**Release Date**	28/02/2025
Exp. Date	12/2026	**Page No.:**	Page 1 of 1

Sr. No.	Test Parameter	Acceptance Criteria	Result
1.	**Description**	White or off white crystalline powder filled in 7.5 ml clear glass vials, sealed with grey butyl rubber plug and flip off aluminum seal.	Off white crystalline powder filled in 7.5 ml clear glass vials, sealed with grey butyl rubber plug and flip off aluminum seal.
2.	**Identification (By IR)**	The IR absorption spectrum of a mineral oil dispersion of the residue so obtained exhibits maxima only at the same wavelengths as those of a similar preparation of USP Methylprednisolone Hemisuccinate RS.	Complies
3.	**Average filled weight**	± 7.5% of Target filled weight.	60.32 mg
4.	**Uniformity of filled weight**	± 10% of its average filled weight	Min: 58.12 mg ; Max: 61.61 mg -3.64 % : +2.14 %
5.	**pH**	7.0 to 8.0	7.78
6.	**LOD**	Not more than 2.0% w/w	1.218 % w/w
7.	**Free Methylprednisolone**	Not more than 6.6%	1.87%
8.	**Uniformity of dosage units**	The acceptance value (AV) calculated using 10 dosage units must be less than or equal to 15 (L1 =15, L2 =25)	4.31
9.	**Particulate matter**	The Sample Solution should be clear and free from any visible particles	The Sample Solution is clear and free from any visible particles.
10.	**Constituted Solution**	Solid should dissolve completely when, leaving no visible residue as undissolved matter.	Solid dissolve completely when, leaving no visible residue as undissolved matter.
11.	**Bacterial Endotoxins Tests**	NMT 0.17 EU/mg of Methylprednisolone.	Less than 0.17 EU/mg
12.	**Sterility**	Should be sterile	Sterile
13.	**Assay:**		

Each Vial contains:	**Claim**	**Limit**	**mg**	**%**
Sterile Methylprednisolone Sodium succinate USP Eq. to Methylprednisolone	**40 mg**	Between 90.0 % to 110.0 % of stated amount of Methylprednisolone (Between 36.0 mg to 44.0 mg)	39.763 mg	99.41 %

Remarks: The above test parameters are complies/ ~~not complies~~ as per ~~IP/BP~~/USP & ~~In~~-House Specification.

Particulars	**Prepared By**	**Checked By**	**Approved By**
Name	Praveen Kumar	Kuljeet Kaur	Kavita Nandwani
Designation	Executive	Head QC	QA Manager
Signature			
Date	28/02/2025	28/02/2025	28/02/2025

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