



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-125	A.R. No.	FG/G/26A0275
Generic Name	Methylprednisolone Sodium Succinate for Injection USP	Sample Quantity	65 Vials
Batch No.:	AGD60103	Sample Received on	04/02/2026
Batch Size:	10000 Vials	Analysis Date	04/02/2026
Mfg. Date.	01/2026	Release Date	19/02/2026
Exp. Date	12/2027	Page No.:	Page 1 of 1

Sr. No.	Test Parameter	Acceptance Criteria	Result		
1.	Description	White or off white crystalline powder filled in 10 ml clear glass vials, sealed with grey butyl rubber plug and flip off aluminum seal.	Off white crystalline powder filled in 10 ml clear glass vials, sealed with grey butyl rubber plug and flip off aluminum seal.		
2.	Identification	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	$\pm 7.5\%$ of Target filled weight.	170.31 mg		
4.	Uniformity of filled weight	$\pm 10\%$ of its average filled weight	Min: 167.29 mg ; Max: 172.08 mg -1.77% ; + 1.04%		
5.	pH	7.0 to 8.0	7.21		
6.	LOD	Not more than 2.0%	0.43%		
7.	Free Methylprednisolone	Not more than 6.6%	2.18%		
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)	1.77		
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 0.17EU/mg		
12.	Sterility	Should be sterile	Sterile		
13.	Assay:				
	Each Vial contains:	Claim	Limit	mg	%
	Sterile Methylprednisolone Sodium succinate USP Eq. to Methylprednisolone	125 mg	Between 90.0 % to 110.0 % stated amount of Methylprednisolone (Between 112.5 mg to 137.5 mg)	126.123 mg	100.90 %

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	Braveen Kumar	KamapKant	For. Monitd
Designation	Executive	Executive	Sr. Executive
Signature			
Date	19/02/2026	19/02/2026	19/02/2026