



ALVENTA PHARMA LIMITED

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

Quality Control Department

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Product Name	Morenam 1g	A.R. No.	FG/B/24A0034
Generic Name	Meropenem Injection IP 1000 mg	Sample Quantity	65 Vials
Batch No.:	ABD41202	Sample Received on	18/12/2024
Batch Size:	15200 Vials	Analysis Date	18/12/2024
Mfg. Date.	12/2024	Release Date	01/01/2025
Exp. Date	11/2026	Page No.:	Page 1 of 1

Sr. No.	Test Parameter	Acceptance Criteria	Result		
1.	Description	A White to off white crystalline powder filled in a transparent 20 ml molded glass vial sealed with rubber stopper dark blue coloured flip off having aluminum seal.	A White crystalline powder filled in a transparent 20 ml molded glass vial sealed with rubber stopper dark blue coloured flip off having aluminum seal.		
2.	Identification	In the assay, the principal peak in the chromatogram obtained with the test solution should corresponds to the peak in the chromatogram obtained with the reference solution.	Complies		
3.	Average filled weight	$\pm 7.5\%$ of Target filled weight.	1383.30 mg		
4.	Uniformity of filled weight	$\pm 10\%$ of its average filled weight	Min: 1362.93 mg ;Max: 1407.28 mg -1.47% : + 1.73%		
5.	pH	Between 7.3 to 8.3	7.76		
6.	LOD	Between 9.0% to 12.0%	10.96 %w/w		
7.	Particulate matter	The Sample Solution should be clear and free from any visible particles when examine visually against black background.	The Sample Solution is clear and free from any visible particles.		
8.	Clarity of Solution	Solid should dissolve completely when, leaving no visible residue as undissolved matter.	Solid dissolve completely when, leaving no visible residue as undissolved matter.		
9.	Bacterial Endotoxins Tests	NMT 0.125 EU/mg of Meropenem	Less than 0.125 EU /mg		
10.	Sterility	Should be sterile	Sterile		
11.	Assay:				
	Each Vial contains:	Claim	Limit	mg	%
	Sterile Meropenem Trihydrate IP Eq. to Meropenem (A blend of Meropenem & Sodium Carbonate)	1000 mg	Between 90.0 % to 120.0 % of stated amount of Meropenem. (Between 900.0 mg to 1200.0 mg)	984.72 mg	98.47%

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	01/01/2025	01/01/2025	01/01/2025