



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/C/24A0017
Generic Name	Meropenem Injection IP 1000 mg	Sample Quantity	65 Vials
Batch No.:	ACD40401	Sample Received on	25/04/2024
Batch Size:	5200 Vials	Analysis Date	25/04/2024
Mfg. Date.	04/2024	Release Date	09/05/2024
Exp. Date	03/2026	Page No.:	Page 1 of 2

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	1384 mg \pm 5.0 %	1371.31 mg
4.	Uniformity of filled weight	\pm 10% of its average filled weight.	Min: 1349.59 mg ;Max: 1390.79 mg -1.58% : + 1.42%
5.	pH	Between 7.3 to 8.3, determine in a 5.0 % w/v solution.	8.01
6.	LOD	Between 9.0% to 12.0% determined on 1.0 g by drying it in vacuum oven at 65° for 6 hours.	11.38 %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.	Reconstitution Solution	When reconstitute with (0.9 %w/v) Sodium chloride solution, it is clear and free from suspended matters.	Clear Solution.
9.	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.

Particulars	Prepared By	Checked By	Approved By
Name	Praveen kumar	DURGESH KUMAR	Goutam Singh
Designation	Executive	AG Head	Head-QA
Signature			
Date	09/05/2024	09/05/2024	09/05/2024



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Sr. No.	Test Parameter	Acceptance Criteria	Result		
10.	Bacterial Endotoxins Tests	NMT 0.125 EU/mg of Meropenem	Less than 0.125 EU /mg		
11.	Sterility	Should be sterile	Sterile		
12.	Assay:				
	Each Vial contains:	Claim	Limit	mg	%
	Meropenem Trihydrate IP Eq. to anhydrous Meropenem	1000 mg	Between 90.0 % to 120.0 % of stated amount of Meropenem. (Between 900.0 mg to 1200.0 mg)	1010.39 mg	101.04%
	Sodium Carbonate IP Eq. to Sodium	90.2 mg	Between 80.0 % to 120.0 % of stated amount of Sodium Carbonate. (Between 72.16 mg to 108.24 mg)	88.968 mg	98.85%

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	DURGESH KUMAR	Gaurtan Singh
Designation	Executive	QC Head	Head-QA
Signature			
Date	09/05/2024	09/05/2024	09/05/2024