



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 500 mg	A.R. No.	FG/B/25A0005
Generic Name	Meropenem Injection IP 500 mg	Sample Quantity	65 Vials
Batch No.:	ABD50202	Sample Received on	14/02/2025
Batch Size:	5200 Vials	Analysis Date	14/02/2025
Mfg. Date.	02/2025	Release Date	28/02/2025
Exp. Date	01/2027	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 10 ml molded glass vial sealed with rubber stopper dark green coloured flip off having aluminum seal.	A White crystalline powder filled in a transparent 10 ml molded glass vial sealed with rubber stopper dark green 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	± 7.5 % of Target filled weight.	686.75 mg
4.	Uniformity of filled weight	± 10 % of its average filled weight.	Min: 665.98 mg ; Max: 696.05 mg -3.02% : + 1.35%
5.	pH	Between 7.3 to 8.3, determine in a 5.0 % w/v solution.	7.80
6.	LOD	Between 9.0% to 12.0%	10.54 %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

Particulars	Prepared By	Checked By	Approved By
Name	Praveen Kumar	Ashutosh Kumar Ken	Kuljeet Kaur
Designation	Executive	Executive	Head QC
Signature			
Date	28/02/2025	28/02/2025	28/02/2025



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 500 mg	A.R. No.	FG/B/25A0005
Generic Name	Meropenem Injection IP 500 mg	Sample Quantity	65 Vials
Batch No.:	ABD50202	Sample Received on	14/02/2025
Batch Size:	5200 Vials	Analysis Date	14/02/2025
Mfg. Date.	02/2025	Release Date	28/02/2025
Exp. Date	01/2027	Page No.:	Page 2 of 2

11.	Assay:				
	Each Vial contains:	Claim	Limit	mg	%
	Sterile Meropenem Trihydrate IP Eq. to anhydrous Meropenem	500 mg	Between 90.0 % to 120.0 % of stated amount of Meropenem. (Between 450.0 mg to 600.0 mg)	503.48 mg	100.70%

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	Anshul Kumar Keri	Kuljeet Kaur
Designation	Executive	Executive	Head QC
Signature			
Date	28/02/2025	28/02/2025	28/02/2025