



# ALERIS PHARMACEUTICALS

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/25A0054
Generic Name	Meropenem Injection IP 1000 mg	Sample Quantity	65 Vials
Batch No.	ABD50504	Sample Received on	29/05/2025
Batch Size	15000 Vials	Analysis Date	29/05/2025
Mfg. Date	05/2025	Release Date	12/06/2025
Exp. Date	04/2027	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 20 ml molded glass vial sealed with rubber stopper blue coloured flip off having aluminium seal.	A white crystalline powder filled in a transparent 20 ml molded glass vial sealed with rubber stopper blue coloured flip off having aluminium 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.	1422.93 mg
4.	Uniformity of filled weight	$\pm 10\%$ of its average filled weight	Min: 1395.73 mg ; Max: 1458.61 mg -1.91% : + 2.51%
5.	pH	Between 7.3 to 8.3	7.84
6.	LOD	Between 9.0% to 12.0%	10.27 %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.	Related Substances		
	Individual Impurity	Not more than 0.8%	Not Detected
	Total Impurities	Not more than 2.0%	Not Detected

Particulars	Prepared By	Checked By	Approved By
Name	Praveen Kumar	Kamal Kant	Subjit Kaur
Designation	Executive	Executive	Head QC
Signature			
Date	12/06/2025	12/06/2025	12/06/2025



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12.	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)	992.328 mg	99.23%

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	Kamal Khat	Kuljeet Kaur
Designation	Executive	Executive	Head QC
Signature			
Date	12/06/2025	12/06/2025	12/06/2025