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/25A0004
Generic Name	Meropenem Injection IP	**Sample Quantity**	65 Vials
Batch No.	ABD50201	**Sample Received on**	14/02/2025
Batch Size	15200 Vials	**Analysis Date**	14/02/2025
Mfg. Date	02/2025	**Release Date**	28/02/2025
Exp. Date	01/2027	**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 orange coloured flip off having aluminium seal.	A white crystalline powder filled in a transparent 20 ml molded glass vial sealed with rubber stopper orange 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**	± 7.5 % of Target filled weight.	1396.82 mg
4.	**Uniformity of filled weight**	± 10% of its average filled weight	Min: 1379.70 mg ; Max:1415.13 mg -1.23% : + 1.31%
5.	**pH**	Between 7.3 to 8.3	7.94
6.	**LOD**	Between 9.0% to 12.0%	10.44 %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)	1008.37 mg	100.84%

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	Bravesh Kumar	Ankit Kumar Rai	Kuljeet Kaur
Designation	Executive	Executive	Head QC
Signature			
Date	28/02/2025	28/02/2025	28/02/2025