AARGE HEALTHCRAFT

PLOT NO-12A/1 SECTOR-2 PARWANOO (H.P.)

CERTIFICATE OF ANALYSIS

Product Name: Morenam-1.0GM (Meropenem Injection IP 1.0g)

Batch No.	:	UMDA6E01A	AR. No.	:	CHB-0023/2027
Mfg. date	:	05/2026	Sampling Date	:	04/05/2026
Exp. Date	:	04/2028	Sampled Qty.	:	42 Vials
Batch Size	:	20500 Vials	Sampled By	:	Vineet
Specification No.	:	FP/SPC/DCP/001-05	Release date	:	18/05/2026

S. No.	Test	Specifications	Observations
1.	Description	White to off white powder filled in 20 ml clear glass vials, plugged with Grey butyl rubber plugs & sealed with Dark Green color F/O aluminum seal.	White powder filled in 20 ml clear glass vials, plugged with Grey butyl rubber plugs & sealed with Dark Green color F/O aluminum seal.
2.	Identification By HPLC	The retention time of Meropenem peak of the sample solution corresponds to that of the standard solution, as it obtained in the Assay	**Complies**
3.	Average filled weight	1345.0 mg ± 2.0 %	**1346.83 mg**
4.	Uniformity of weight	± 10.0%of avg. fill weight. (Not more than two individual weight deviates from the average weight by more than ± 10.0%and none deviate by more than ± 20.0%)	**+0.56 %** **-0.23 %**
5.	pH (5% w/v Solution)	Between 7.3 and 8.3.	**7.92**
6.	**Related substances** Individual Impurity Total Impurity	 NMT 0.80% NMT 2.00%	 **0.12%** **0.34%**
7.	Content of sodium	Not less than 80.0% and not more than 120.0%	**90.68 mg/vial** **100.76%**

Analyzed By		Checked By
Name:	Shubham	Alamgir
Sing.:		
Date:	18/05/2026	18/05/2026

Approved By:
Full Name: Rajesh Kumar Patel
Sign./Date: 18/05/2026
Registration No. 06740101021573
Name of Institute: H. U.
Place of Institute: Itanagar,
Arunachal Pradesh

8.	Loss on Drying	Between 9.0% and 12.0%	9.88 %
9.	Assay Each vial contains: Meropenem Trihydrate (Sterile) IP eq. to Meropenem 1.0gm	**Limit** Claim **900.0**mg to 1200.0mg 1000.0mg **(90.0% to 120.0% of label claim)**	1005.13 mg (100.51%)
10.	Bacterial Endotoxins Test	NMT 0.125 EU/mg of Meropenem	Less than 0.126 EU/mg
11.	Sterility	Should be sterile	Complies
12.	Constituted Solution	When reconstituted with SWFI the materials should dissolve completely leaving no visible residue as undissolved matter.	Complies
13.	Completeness and clarity of solution	The constituted solution not significantly less clear than an equal volume of the diluents or of water for injections content in a similar vessel and examined similarly.	Complies
14.	Particulate Matter	The solution after reconstitution should free from particles of foreign matters /black particles that can be observed on visual inspection.	Complies
	Sub visual particulate matter	≥10µm-NMT 6000 particle/vial	764
		≥25µm-NMT 600 particle/vial	32

Remarks: - In the opinion of under sign the above material Complies/~~Does not~~ complies with IP/BP/USP/In-House Specifications.

As per test report No.: CHB-0023/2027 from: AARGE HEALTHCRAFT

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Name:	Shubham	Alamgir
Sing.		
Date:	18/05/2026	18/05/2026

Approved By:
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Sign./Date: 18/05/2026
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