AARGE HEALTHCRAFT

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

CERTIFICATE OF ANALYSIS

Product Name: MORENAM 1GM (Meropenem Injection IP 1.0g)

Batch No.	:	UMDA5K02A	AR. No.	:	CHB-012/2026
Mfg. date	:	10/2025	Sampling Date	:	30/10/2025
Exp. Date	:	09/2027	Sampled Qty.	:	42 Vials
Batch Size	:	10200 Vials	Sampled By	:	NITISH
Specification No		FP/SPC/DCP/001-04	Release date	:	14/11/2025

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 Green color F/O aluminium seal.	White powder filled in 20 ml clear glass vials, plugged with Grey butyl rubber plugs & sealed with Green color F/O aluminium 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	1350.0 mg ± 2.0 %	1350.43 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%)	+1.23 % -1.13 %
5.	pH (5% w/v Solution)	Between 7.3 and 8.3.	7.90
6.	**Related substances** Individual Impurity Total Impurity	NMT 0.80% NMT 2.00%	0.11% 0.39%
7.	Content of sodium	Not less than 80.0% and not more than 120.0%	90.72 mg/vial 100.8 %
8.	Loss on Drying	Between 9.0% and 12.0%	9.94 %
9.	Assay Each vial contains: Meropenem Trihydrate (Sterile) IP eq. to Meropenem 1.0gm	Limit Claim 900.0mg to 1200.0mg 1000.0mg **(90.0% to 120.0% of label claim)**	1004.18 mg (100.42%)
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	937
		≥25µm-NMT 600 particle/vial	32

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

As per test report No.: CHB-012/2026

From:- AARGE HEALTHCRAFT.

Analyzed By: Anand	**Checked By:** Alamgir	**Approved By:**
Date: 14/11/2025	**Date:** 14/11/2025	**Date:** 14/11/2025