

Title

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Certificate of Analysis Finished Product

Product Name	MORENAM Injection	A.R. No.	ARB/FP/26/013
Generic Name	Meropenem Injection IP 1.0gm	Sampled qty.	45 vials
Batch No.	ARB2610A	Sampled by	Aakash
Batch Size	10,000 Vials	Sampled on	01/06/2026
Mfg. Date	05/2026	Date of Testing	02/06/2026
Exp. Date	04/2028	Date of Release	16/06/2026

S. No.	Tests	Specifications	Observations
1.	Description	A white dry powder filled in clear glass vial.	A white dry powder filled in clear glass vial.
2.	Identification	In the Assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the working standard solution.	Complies
3.	Uniformity of weight	Average weight $\pm 10\%$	-2.04 % & + 1.87 %
4.	Average weight	Informative $\pm 2\%$.	1354.8 mg
5.	Related Substance (By HPLC)		
	Meropenem Open Ring	NMT 0.8%	Not Detected
	Meropenem Dimer	NMT 2.0%	Not Detected
	Single Maximum Impurity	NMT 0.1%	Not Detected
	Sum of All Other Secondary Peaks	NMT 1.0%	Not Detected
	Sum Of All Secondary Peaks	NMT 2.0%	Not Detected
6.	pH	7.3 to 8.3	8.13
7.	Content of Sodium	80 to 120% of labeled amount of Sodium.	100%
8.	Loss on drying	9.0 to 12.0%w/w	10.65 %w/w
9.	Particulate Matter (A.) Light Obscuration Particle Count Test (1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$ (B.) Visual Particle	NMT 6000/vial NMT 600/ vial The reconstituted solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally that can be observed on visual inspection.	88/vial 1/vial Complies
10.	Sterility	No microbial growth should be observed.	Complies
11.	Bacterial Endotoxins	NMT 0.125 EU/mg of Meropenem.	Less than 0.125 EU/mg of Meropenem.

Analysis by

NAME: SACHIN KUMAR

Checked by

NAME: SUFIYAN ANSARI

Approved by

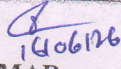
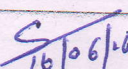
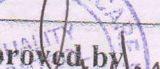
NAME: MRS. SWATI DHAWAN

Title : **Certificate of Analysis Finished Product**

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12.	Assay: (By HPLC) Each glass vial contains:				
Ingredients		Labelled Claim	Found	% of labelled amount	Limits % of labelled amount
Sterile Meropenem IP Eq. to anhydrous Meropenem		1000 mg	978.5552 mg	97.86 %	90.0 to 120.0%
Sodium Carbonate Anhydrous (Sterile)IP Eq. to Sodium		90.2 mg	90.20mg	100%	80.0 to 120.0%

Remarks: In the opinion of the undersigned the sample referred to above is/ is not of the standard quality as The Drug & Cosmetic Act 1940 and the rules made there under. Complies/ ~~not~~ complies as per IP/BP/USP/HS.

Analysis by  NAME: SACHIN KUMAR	Checked by  NAME: SUFIYAN ANSARI	Approved by  NAME: MRS. SWATI DHAWAN
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