AMERICAN REMEDIES
Care & Cure with Research

AMERICAN REMEDIES HEALTHCARE PVT. LTD.

Vill. Surajpur, Nahan Road, Paonta Sahib, Dist. Sirmour (H.P) 173025

Title : Certificate of Analysis Finished Product

Product Name	**MORENAM** Injection	**A.R. No.**	ARB/FP/25/028
Generic Name	Meropenem Injection IP 1.0gm	**Sampled qty.**	45 vials
Batch No.	ARB2536A	**Sampled by**	Anuj Verma
Batch Size	6,330 Vials	**Sampled on**	18/02/2026
Mfg. Date	02/2026	**Date of Testing**	19/02/2026
Exp. Date	01/2028	**Date of Release**	05/03/2026

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 ±10%	-1.54 % & + 0.69 %
4.	Average weight	Informative ±2%.	1359.2 mg
5.	Related Substance (By HPLC)		
	Individual impurity	NMT 0.8%	0.63 %
	Total impurities	NMT 2.0%	0.79 %
6.	pH	7.3 to 8.3	7.95
7.	Content of Sodium	80 to 120% of labeled amount of Sodium.	98.69 %
8.	Loss on drying	9.0 to12.0%w/w	9.89 %w/w
9.	Particulate Matter		
	(A.) Light Obscuration Particle Count Test		
	(1.) Particles ≥10µm	NMT 6000/vial	73/vial
	(2.) Particles ≥25µm	NMT 600/ vial	1/vial
	(B.) Visual Particle	The reconstituted solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally that can be observed on visual inspection.	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	Checked by	Approved by
05/03/26	05/03/26	05/03/26
NAME: NIKHIL SHARMA	NAME: SUFIYAN ANSARI	NAME: MRS. SWATI DHAWAN

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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	990.7779 mg	99.08 %	90.0 to 120.0%
Sodium Carbonate Anhydrous (Sterile)IP Eq. to Sodium		90.2 mg	89.02 mg	98.69 %	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/IHS~~.

Analysis by	Checked by	Approved by
05/03/26	05/03/26	05/03/26
NAME: NIKHIL SHARMA	NAME: SUFIYAN ANSARI	NAME: MRS. SWATI DHAWAN