



VELLINTON HEALTHCARE

(Earlier Known as Texus Meditech)

Village Rampur Jattan; Trilokpur Road, Kala Amb, Dist. Sirmour-173030. HP

QUALITY CONTROL DEPARTMENT CERTIFICATE OF ANALYSIS

Product Name : MORENAM Meropenem Injection IP	
Batch No. : PN24J-08A	Mfg. Date : 11/2024
Batch Size : 10080 Vials	Exp. Date : 10/2026
Sample Qty : 50 Vials	Analytical Report No.: NFP20240081
Date of Receiving : 22/10/2024	Date of Completion : 05/11/2024
Mfg. License No. : N-MB/18/201	

Sr.No.	Tests	Specifications	Observations		
1.	Description	White to off white crystalline powder filled in transparent glass vial.	A white crystalline powder filled in transparent glass vial		
2.	Identification	In the assay, the principal peak in the chromatogram obtained with the test solution correspond to the peak in the chromatogram obtained with the reference solution.	Complies		
3.	Uniformity of weight	$\pm 10.0\%$ of the average fill weight	Complies		
4.	Average fill Weight	1351.58 mg $\pm 2.0\%$	1354.10 mg		
5.	pH (5.0% w/v solution)	Between (7.3 to 8.3)	8.02		
6.	Related Substance				
	Individual Impurity	NMT 0.8 %	Not Detected		
	Total Impurities	NMT 2.0 %	Not Detected		
7.	Clarity of solution	The solid dissolves completely leaving no visible residue as undissolved matter.	Complies		
8.	Particulate Matter	The solution is essentially free from particles of foreign matter that can be seen on visual inspection.	Complies		
9.	Sterility	Should be Sterile	Sterile		
10.	Content of Sodium	Between (80.0 to 120.0) percent of labeled amount of Sodium.	92.09 %		
11.	Loss on drying	Between 9.0 to 12.0 %	10.14 %		
12.	Bacterial Endotoxins	NMT 0.125 EU/mg	Less than 0.125 EU/mg		
13.	Assay : Each vial contains:-				
Ingredients		Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Meropenem (Sterile) IP Eq. to Meropenem Anhydrous.		1000 mg	999.54 mg	99.95 %	90.0% to 120.0%

Remarks: In the opinion of the undersigned the sample submitted ~~complies/does not comply~~ with the prescribed ~~standard/not standard~~ of quality, as according to I.P. and IHS with respect to the above test only.

Name	Prepared By Punam Kumari	Checked By Anuj Kumar	
Designation	Executive	Sr. Executive	
Sign/ Date			

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