



# VELLINTON HEALTHCARE

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

## QUALITY CONTROL DEPARTMENT CERTIFICATE OF ANALYSIS

<b>Product Name</b> : BEROPENAM 1GM Meropenem Injection IP	
<b>Batch No.</b> : PN25J-06F	<b>Mfg. Date</b> : 10/2025
<b>Batch Size</b> : 515 Vials	<b>Exp. Date</b> : 09/2027
<b>Sample Qty</b> : 50 Vials	<b>Analytical Report No.:</b> NFP20250094
<b>Date of Receiving</b> : 08/10/2025	<b>Date of Completion</b> : 24/10/2025
<b>Mfg. License No.</b> : N-MB/18/201	

Sr.No.	Tests	Specifications	Observations		
1.	Description	White to off white crystalline powder filled in transparent glass vial.	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	± 10.0% of the average fill weight	Complies		
4.	Average fill Weight	1337.25 mg ± 2.0%	1346.10 mg		
5.	pH (5.0% w/v solution)	Between (7.3 to 8.3 )	7.99		
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.	97.0 %		
11.	Loss on drying	Between 9.0 to 12.0 %	9.87 %		
12.	Bacterial Endotoxins	NMT 0.125 EU/mg	Less than 0.125 EU/mg		
13.	Assay : Each vial contains:-				
<b>Ingredients</b>		<b>Labeled Claim</b>	<b>Found</b>	<b>% of labeled amount</b>	<b>Limits % of labeled amount</b>
Meropenem (Sterile) IP Eq. to Meropenem Anhydrous.		1000 mg	1044.28 mg	104.45 %	90.0% to 120.0%

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

	Prepared By	Checked By	Approved By
<b>Name</b>	Manisha	Anuj Kumar	Vikas Gupta
<b>Designation</b>	Sr. Officer (QC)	Asst. Manager (QC)	Manager (QC)
<b>Sign/ Date</b>	<i>Manisha</i>	<i>Anuj Kumar</i>	<i>Vikas Gupta</i>

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