

# Pace

Add Pace To Health

# Pace Biotech

Surajpur, Paonta sahib Dist. Sirmour (H.P)

Title :

Certificate of Analysis Finished Product

Product Name	IMSTATIN 500 Injection	A.R. No.	BD/FP/24/502
Generic Name	Imipenem & Cilastatin Injection IP 500mg + 500mg	Sampled qty.	45 Vials
Batch No.	B24505A	Sampled by	Rakesh
Batch Size	13,000 Vials	Sampled on	14/12/2024
Mfg. Date	12/2024	Date of Testing	14/12/2024
Exp. Date	11/2026	Date of Release	30/12/2024

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 peaks 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 $\pm 10\%$	-0.81% & +1.00%
4.	Average weight	Informative.	1111.6 mg
5.	pH	6.5 to 8.5	8.21
6.	Loss on drying	NMT- 3.5% w/w	2.00%w/w
7.	Particulate Matter		
	(a.) Sub-Visible particle count	NMT-6000/vial	4133/vial
	(1.) Particles $\geq 10\mu\text{m}$	NMT-600/ vial	17/vial
	(2.) Particles $\geq 25\mu\text{m}$		
	(b.) Visual	The solution is free from particles of foreign matter particles that can be observed on visual inspection.	Complies
8.	Sterility	No microbial growth should be observed.	Complies
9.	Bacterial Endotoxins	NMT- 0.17 EU/mg of Imipenem & Cilastatin.	Less than- 0.17 EU/mg of Imipenem & Cilastatin.
10.	Assay: Each glass vial Contains		

Ingredients	Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Sterile Imipenem I.P Eq. to Anhydrous Imipenem	500 mg	530.94 mg	106.19%	90.0 to 115%
Sterile Cilastatin Sodium I.P Eq. to Cilastatin (Sodium Bicarbonate IP added as buffer)	500 mg	510.29 mg	102.06%	90.0 to 115%

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/ HHS:

Analysis by  NAME: SUFIYAN ANSARI	Checked by  NAME: SANDHYA	Approved by  NAME: P. N. TRIPATHI
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