

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/25/114
Generic Name	Imipenem & Cilastatin Injection IP 500mg	Sampled qty.	45 Vials
Batch No.	B25114K	Sampled by	Rakesh
Batch Size	2000 Vials	Sampled on	24/05/2025
Mfg. Date	05/2025	Date of Testing	24/05/2025
Exp. Date	04/2027	Date of Release	08/06/2025

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 $\pm 10\%$	-2.31% & +1.54%
4.	Average weight	Informative.	1106.1 mg
5.	pH	6.5 to 8.5	7.31
6.	Loss on drying	NMT 3.5% w/w	1.65%w/w
7.	Particulate Matter		
	(a.) Sub-Visible particle count		
	(1.) Particles $\geq 10\mu\text{m}$	NMT-6000/vial	4317/vial
	(2.) Particles $\geq 25\mu\text{m}$	NMT-600/ vial	25/vial
	(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 IP Eq. to Anhydrous Imipenem	500 mg	544.73 mg	108.95%	90.0 to 115%
Sterile Cilastatin Sodium IP Eq. to Cilastatin (Sodium Bicarbonate IP added as buffer)	500 mg	520.95 mg	104.19%	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/PHS.

Analysis by

NAME: SUFIYAN ANSARI

Checked by

NAME: SANDHYA

Approved by

NAME: SWATI DHAWAN