

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/23/580
Generic Name	Imipenem & Cilastatin Injection IP 500mg	Sampled qty.	45 Vials
Batch No.	B23469N	Sampled by	Aakash
Batch Size	1000 Vials	Sampled on	05/12/2023
Mfg. Date	10/2023	Date of Testing	05/12/2023
Exp. Date	09/2025	Date of Release	20/12/2023

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 $\pm 10\%$	-2.66% & +1.17%
4.	Average weight	Informative.	1101.5 mg
5.	pH	6.5 to 8.5	7.30
6.	Loss on drying	NMT- 3.5% w/w	2.59%w/w
7.	Particulate Matter		
	(a.) Sub-Visible particle count		
	(1.) Particles $\geq 10\mu\text{m}$	NMT-6000/vial	570/vial
	(2.) Particles $\geq 25\mu\text{m}$	NMT-600/ vial	20/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 I.P Eq. to Anhydrous Imipenem	500 mg	506.24 mg	101.25%	90.0 to 115%
Sterile Cilastatin Sodium I.P Eq. to Cilastatin (Sodium Bicarbonate IP added as buffer)	500 mg	538.67 mg	107.73%	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/IHS.

Analysis by

Checked by

Approved by

