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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/24/581
Generic Name	Imipenem & Cilastatin Injection IP 500mg + 500mg	**Sampled qty.**	45 Vials
Batch No.	B24547A	**Sampled by**	Rakesh
Batch Size	3000 Vials	**Sampled on**	14/01/2025
Mfg. Date	01/2025	**Date of Testing**	14/01/2025
Exp. Date	12/2026	**Date of Release**	29/01/2024

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 ±10%	-0.69% & +0.56%
4.	Average weight	Informative.	1105.0 mg
5.	pH	6.5 to 8.5	7.39
6.	Loss on drying	NMT- 3.5% w/w	2.24%w/w
7.	Particulate Matter		
	(a.) Sub-Visible particle count (1.) Particles ≥10µm (2.) Particles ≥25µm	 NMT-6000/vial NMT-600/ vial	 2750/vial 8/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	533.97 mg	106.79%	90.0 to 115%
Sterile Cilastatin Sodium I.P Eq. to Cilastatin (Sodium Bicarbonate IP added as buffer)	500 mg	508.38 mg	101.68%	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
NAME: SUFIYAN ANSARI	NAME: SANDHYA	NAME: P. N. TRIPATHI

PACE BIOTECH (P) LTD. PAONTA SAHIB Quality Control Manager