



# AMERICAN REMEDIES HEALTHCARE PVT. LTD.

Vill. Surajpur, Nahan Road, Paonta Sahib, Dist. Sirmour (H.P) 173025

Title

## Certificate of Analysis Finished Product

Product Name	IMSTATIN Injection	A.R. No.	ARB/FP/25/015
Generic Name	Imipenem & Cilastatin Injection IP 500mg	Sampled qty.	45 Vials
Batch No.	ARB2515A	Sampled by	Anuj Verma
Batch Size	5000 Vials	Sampled on	27/10/2025
Mfg. Date	10/2025	Date of Testing	28/10/2025
Exp. Date	09/2027	Date of Release	11/11/2025

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 reference solution.	Complies
3.	Uniformity of Weight	Average weight $\pm 10\%$	-0.92% & +0.76%
4.	Average weight	Informative $\pm 2\%$ .	1106.4 mg
5.	pH	6.5 to 8.5	7.39
6.	Loss on drying	NMT 3.5%w/w	2.21%w/w
7.	Particulate Matter		
	(A.) Light Obscuration Particle Count Test (1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$	NMT 6000/vial NMT 600/ vial	142/vial 0/vial
	(B.) Visual Particle	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: (By HPLC) Each glass vial contains:		

Ingredients	Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Sterile Imipenem IP Eq. to Anhydrous Imipenem	500 mg	498.36 mg	99.67%	90.0 to 115%
Sterile Cilastatin Sodium IP Eq. to Cilastatin (Sodium Bicarbonate IP added as buffer)	500 mg	486.43 mg	97.29%	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/HS.

Analysis by  
NAME: NIKHIL SHARMA

Checked by  
NAME: SUFIYAN ANSARI

Approved by  
NAME: MRS. SWATI DHAWAN