



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- 500mg Injection	A.R. No.	ARB/FP/25/018
Generic Name	Imipenem & Cilastatin Injection IP	Sampled qty.	45 Vials
Batch No.	ARB2518A	Sampled by	Anuj Verma
Batch Size	8000 Vials	Sampled on	29/11/2025
Mfg. Date	11/2025	Date of Testing	29/11/2025
Exp. Date	10/2027	Date of Release	16/12/2025

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 $\pm 10\%$	-0.84% & +1.24%
4.	Average weight	Informative $\pm 2\%$.	1096.2 mg
5.	pH	6.5 to 8.5	7.37
6.	Loss on drying	NMT 3.5%w/w	2.38%w/w
7.	Particulate Matter		
	(A.) Light Obscuration		
	Particle Count Test		
	(1.) Particles $\geq 10\mu\text{m}$	NMT 6000/vial	592/vial
	(2.) Particles $\geq 25\mu\text{m}$	NMT 600/ vial	8/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	475.65 mg	95.13%	90.0 to 115%
Sterile Cilastatin Sodium IP Eq. to Cilastatin (Sodium Bicarbonate IP added as buffer)	500 mg	483.23 mg	96.65%	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/THS.

Analysis by NAME: RAMANJEET SINGH	Checked by NAME: SUFIYAN ANSARI	Approved by NAME: MRS. SWATI DHAWAN
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