

**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/26/002
Generic Name	Imipenem & Cilastatin Injection IP 1gm	Sampled qty.	45 Vials
Batch No.	ARB2544A	Sampled by	Rakesh
Batch Size	5,000 Vials	Sampled on	02/04/2026
Mfg. Date	03/2026	Date of Testing	03/04/2026
Exp. Date	02/2028	Date of Release	18/04/2026

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 $\pm 10\%$	-0.61% & +1.46%
4.	Average weight	Informative $\pm 2\%$.	1108.3 mg
5.	pH	6.5 to 8.5	7.62
6.	Loss on drying	NMT 3.5%w/w	2.11%w/w
7.	Particulate Matter		
	(A.) Light Obscuration		
	Particle Count Test	NMT 6000/vial	110/vial
	(1.) Particles $\geq 10\mu\text{m}$	NMT 600/ vial	1/vial
	(2.) Particles $\geq 25\mu\text{m}$		
	(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	565.62 mg	113.12%	90.0 to 115%
Sterile Cilastatin Sodium IP Eq. to Cilastatin (Sodium Bicarbonate IP added as buffer)	500 mg	470.91 mg	94.18%	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/EHS.

Analysis by

NAME: NIKHIL SHARMA

Checked by

NAME: SUFIYAN ANSARI

Approved by

NAME: MRS. SWATI DHAWAN