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/26/028
Generic Name	Imipenem & Cilastatin Injection IP 1gm	**Sampled qty.**	45 Vials
Batch No.	ARB2625A	**Sampled by**	Rakesh
Batch Size	4,238 Vials	**Sampled on**	12/10/2026
Mfg. Date	10/2026	**Date of Testing**	14/10/2026
Exp. Date	09/2028	**Date of Release**	28/10/2026

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 ±10%	-0.77% & +1.34%
4.	Average weight	Informative ±2%.	1099.8 mg
5.	pH	6.5 to 8.5	7.40
6.	Loss on drying	NMT 3.5%w/w	2.09%w/w
7.	Particulate Matter		
	(A.) Light Obscuration Particle Count Test (1.) Particles ≥10µm (2.) Particles ≥25µm	 NMT 6000/vial NMT 600/ vial	 917/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	508.5179 mg	101.70%	90.0 to 115%
Sterile Cilastatin Sodium IP Eq. to Cilastatin (Sodium Bicarbonate IP added as buffer)	500 mg	504.2093 mg	100.84%	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 28/10/26	Checked by 28/10/26	Approved by 28/10/26
NAME: MOHD. ZAID	NAME: SURJEET KAUR	NAME: MRS. SWATI DHAWAN

Name : Mrs. Swati Dhawan
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