

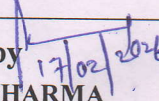
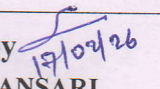
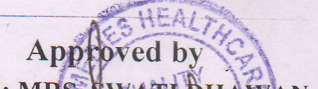
Title : Certificate of Analysis Finished Product

Product Name	AMPIGYL-SB 1.5 Injection	A.R. No.	ARB/FP/25/026
Generic Name	Ampicillin & Sulbactam for Injection 1.5gm	Sampled qty.	45 Vials
Batch No.	ARB2532A	Sampled by	Aakash
Batch Size	9,841 Vials	Sampled on	01/02/2026
Mfg. Date	01/2026	Date of Testing	02/02/2026
Exp. Date	12/2027	Date of Release	17/02/2026

S. No.	Tests	Specifications	Observations
1.	Description	A white or almost white powder filled in clear glass vial.	Almost white powder filled in clear glass vial.
2.	Identification	In the Assay, the principal peaks of Ampicillin & sulbactam in the chromatogram obtained with the test solution corresponds to the peak of Ampicillin & sulbactam in the chromatogram obtained with the working standard solution.	Complies
3.	Uniformity of Weight	Average weight $\pm 10\%$	-0.89% & +1.34%
4.	Average weight	Informative $\pm 2\%$.	1643.5 mg
5.	Particulate Matter (A.) Light Obscuration Particle Count Test (1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$ (B.) Visual Particle	NMT 6000/vial NMT 600/vial Constitute the injection as directed on the label; The solution is essentially free from particles of foreign matter that can be seen on visual inspection.	116/vial 1/vial Complies
6.	Sterility	Powder for Injection comply with the test for sterility.	Complies
7.	Bacterial Endotoxins	NMT 0.17 EU/mg of Ampicillin & Sulbactam.	Less than 0.17 EU/mg of Ampicillin & Sulbactam.
8.	Assay: (By HPLC) Each vial contains:		

Ingredients	Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Ampicillin Sodium (Sterile) IP Eq. to anhydrous Ampicillin	1000 mg	1082.22 mg	108.22%	90.0 to 110.0%
Sulbactam Sodium (Sterile) IP Eq. to anhydrous Sulbactam	500 mg	469.09 mg	93.82%	90.0 to 110.0%

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  NAME: NIKHIL SHARMA	Checked by  NAME: SUFIYAN ANSARI	Approved by  NAME: MRS. SWATI DHAWAN
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