

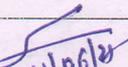
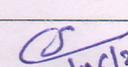
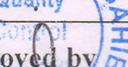
Title : Certificate of Analysis Finished Product

Product Name	AZIDIME-AVB Injection	A.R. No.	BD/FP/25/148
Generic Name	Ceftazidime & Avibactam Powder for Concentrate for Solution for Infusion 2.5gm	Sampled qty.	45 Vials
Batch No.	B25138B	Sampled by	Rakesh
Batch Size	2000 Vials	Sampled on	09/06/2025
Mfg. Date	06/2025	Date of Testing	09/06/2025
Exp. Date	05/2027	Date of Release	24/06/2025

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 (By HPLC)	In the Assay, the principal peak of Ceftazidime & Avibactam Sodium in the chromatogram obtained with the test solution corresponds to the peak of Ceftazidime & Avibactam Sodium in the chromatogram obtained with the working standard solution.	Complies
3.	Uniformity of Weight	Average weight $\pm 10\%$	-0.72% & +1.32%
4.	Average weight	Informative.	3167.6 mg
5.	Particulate Matter (a.) Sub-Visible particle count (1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$ (b.) Visual	NMT-6000/vial NMT-600/vial The solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally.	1069/vial 12/vial Complies
6.	Sterility	No microbial growth should be observed.	Complies
7.	Bacterial Endotoxins	NMT 0.1 EU/mg of Ceftazidime & Avibactam.	Less than 0.1 EU/mg of Ceftazidime & Avibactam.
8.	Assay: Each glass vial contains :		

Ingredients	Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Ceftazidime Pentahydrate (Sterile) IP Eq. to Anhydrous Ceftazidime (A sterile mixture of Ceftazidime & Sodium Carbonate)	2000 mg	2001.85 mg	100.09%	90.0% to 110%
Avibactam Sodium (Sterile) Eq. to Avibactam	500 mg	497.00 mg	99.40%	90.0% to 110%

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: SUFIYAN ANSARI	Checked by  NAME: SANDHYA	Approved by  NAME: SWATI DHANWAN
---	--	--