

Title : Certificate of Analysis Finished Product

Product Name	AZIDIME Injection	A.R. No.	BD/FP/25/179
Generic Name	Ceftazidime for Injection IP 1gm	Sampled qty.	45 Vials
Batch No.	B25172A	Sampled by	Rakesh
Batch Size	6000 Vials	Sampled on	23/06/2025
Mfg. Date	06/2025	Date of Testing	23/06/2025
Exp. Date	05/2027	Date of Release	08/07/2025

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, assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the working standard solution.	Complies
3.	Uniformity of Weight	Average weight $\pm 10\%$	-0.72% & +1.03%
4.	Average weight	Informative.	1304.3 mg
5.	pH	5.0 to 7.5	6.20
6.	Loss On Drying	NMT 13.5%	6.3%
7.	Particulate Matter	NMT 6000/vial NMT 600/vial	42/vial 0/vial
	(a.) Sub-Visible particle count (1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$		
	(b.) Visual	The solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally.	Complies
8.	Pyridine	NMT 0.4%	Not detected
9.	Sodium Content (By AAS)	Weight accurately a quantity containing about 50mg of anhydrous Ceftazidime and dissolve in sufficient water to produce 100.00 ml. Dilute the resulting solution appropriately with water.	9.07%
10.	Sterility	No microbial growth should be observed.	Complies
11.	Bacterial Endotoxins	NMT 0.10 EU/mg of Ceftazidime.	Less than 0.10 EU/mg of Ceftazidime.
12.	Assay Each vial contains :		

Analysis by <u>08/07/2025</u> NAME: NIKHIL SHARMA	Checked by <u>08/07/25</u> NAME: SUFIYAN ANSARI	Approved by <u>08/07/25</u> NAME: SWATI DHAWAN
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Ingredients	Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Ceftazidime (Sterile) IP Eq. to anhydrous Ceftazidime (A sterile mixture of Ceftazidime & sodium carbonate)	1000 mg	975.64 mg	97.56%	90.0 to 105.0%

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 <i>[Signature]</i> NAME: NIKHIL SHARMA	Checked by <i>[Signature]</i> NAME: SUFIYAN ANSARI	Approved by <i>[Signature]</i> NAME: SWATI DHAWAN
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