

Pace

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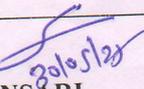
Pace Biotech

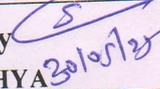
Surajpur, Paonta sahib Dist. Sirmour (H.P)

Title : Certificate of Analysis Finished Product

Product Name	AZIDIME Injection	A.R. No.	BD/FP/25/093
Generic Name	Ceftazidime for Injection IP 1g	Sampled qty.	45 Vials
Batch No.	B25084F	Sampled by	Vineet
Batch Size	1000 Vials	Sampled on	10/05/2025
Mfg. Date	05/2025	Date of Testing	10/05/2025
Exp. Date	04/2027	Date of Release	30/05/2025

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 $\pm 10\%$	-0.90% & +1.01%
4.	Average weight	Informative.	1312.3 mg
5.	pH	5.0 to 7.5	6.41
6.	Loss On Drying	NMT 13.5%	12.01%
7.	Particulate Matter		
	(a.) Sub-Visible particle count		
	(1.) Particles $\geq 10\mu\text{m}$	NMT 6000/vial	534/vial
	(2.) Particles $\geq 25\mu\text{m}$	NMT 600/vial	52/vial
	(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.	9.32%
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 
NAME: SUFIYAN ANSARI

Checked by 
NAME: SANDHYA

Approved by 
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	991.33 mg	99.13%	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

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Checked by

NAME: SANDHYA

Approved by

NAME: SWATI DHAWAN

