

Pace

Add Pace To Health

Pace Biotech

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

Title

:

Certificate of Analysis Finished Product

Product Name	AZIDIME Injection	A.R. No.	BD/FP/24/264
Generic Name	Ceftazidime for Injection IP 1g	Sampled qty.	45 Vials
Batch No.	B24176B	Sampled by	Aakash
Batch Size	5000 Vials	Sampled on	22/08/2024
Mfg. Date	06/2024	Date of Testing	22/08/2024
Exp. Date	05/2026	Date of Release	06/09/2024

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 $\pm 10\%$	-0.59% & +0.83%
4.	Average weight	Informative.	1300.8 mg
5.	pH	5.0 to 7.5	6.09
6.	Loss On Drying	NMT- 13.5%	10.45%
7.	Particulate Matter		
	(a.) Sub-Visible particle count		
	(1.) Particles $\geq 10\mu\text{m}$	NMT-6000/vial	88/vial
	(2.) Particles $\geq 25\mu\text{m}$	NMT-600/vial	4/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 %	0.12%
9.	Sodium Carbonate (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.	4.82%
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

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