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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/23/768
Generic Name	Ceftazidime For Injection IP 1gm	**Sampled qty.**	45 Vials
Batch No.	B23713C	**Sampled by**	Arvind
Batch Size	4716 Vials	**Sampled on**	01/03/2024
Mfg. Date	02/2024	**Date of Testing**	01/03/2024
Exp. Date	01/2026	**Date of Release**	16/03/2024

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) By Cemical	**A.** 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. **B.** Gives the reaction of sodium salts and reaction A of carbonates.	Complies Complies
3.	Uniformity of Weight	Average weight ±10%	-1.87% & +1.48%
4.	Average weight	Informative.	1325.9 mg
5.	pH	5.0 to 7.5	6.32
6.	Loss On Drying	NMT- 13.5%	10.23%
7.	Particulate Matter		
	(a.) Sub-Visible particle count (1.) Particles ≥10µm (2.) Particles ≥25µm	NMT-6000/vial NMT-600/vial	206/vial 42/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%	Complies
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.	Complies
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 glass vial Contains :		

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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	1038.05 mg	103.81%	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~~.

PACE BIOTECH PAONTA SAHIB (H.P.) Quality Control Manager

Analysis by	Checked by	Approved by