Pacé
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/24/554
Generic Name	Ceftazidime for Injection IP 1gm	**Sampled qty.**	45 Vials
Batch No.	B24456B	**Sampled by**	Rakesh
Batch Size	4600 Vials	**Sampled on**	04/01/2025
Mfg. Date	12/2024	**Date of Testing**	04/01/2025
Exp. Date	11/2026	**Date of Release**	20/01/2025

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 ±10%	-1.73% & +1.44%
4.	Average weight	Informative.	1296.1 mg
5.	pH	5.0 to 7.5	6.93
6.	Loss On Drying	NMT- 13.5%	10.18%
7.	Particulate Matter		
	(a.) Sub-Visible particle count (1.) Particles ≥10µm (2.) Particles ≥25µm	NMT-6000/vial NMT-600/vial	224/vial 2/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 vial Contains :		

Analysis by	Checked by	Approved by
NAME: SUFIYAN ANSARI	NAME: SANDHYA	NAME: P. N. TRIPATHI

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

Pace To Health

Pace Biotech

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

Title	:	Certificate of Analysis Finished Product

roduct Name	**AZIDIME** Injection	**A.R. No.**	BD/FP/24/554
Generic Name	Ceftazidime for Injection IP 1gm	**Sampled qty.**	45 Vials
Batch No.	B24456B	**Sampled by**	Rakesh
Batch Size	4600 Vials	**Sampled on**	04/01/2025
Mfg. Date	12/2024	**Date of Testing**	04/01/2025
Exp. Date	11/2026	**Date of Release**	20/01/2025

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	1030.05 mg	103.01%	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
NAME: SUFIYAN ANSARI	NAME: SANDHYA	NAME: D.N. TRIPATHI