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Pace Biotech

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

Title	:	Certificate of Analysis Finished Product

Product Name	**PIPRACAN** Injection	**A.R. No.**	BD/FP/26/369
GenericName	Piperacillin & Tazobactam for Injection IP 2.25gm	**Sampled qty.**	45 vials
Batch No.	B26357A	**Sampled by**	Rakesh
Batch Size	2,200 Vials	**Sampled on**	26/09/2026
Mfg. Date	09/2026	**Date of Testing**	27/09/2026
Exp. Date	08/2028	**Date of Release**	12/10/2026

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	In the Assay, the principal peaks in the chromatogram obtained with the test solution correspond to the peak in the chromatogram obtained with the working standard solution.	Complies
3.	Uniformity of weight	Average weight ±10%	-0.77%& +0.67%
4.	Average weight	Informative ±2%.	2475.7 mg
5.	pH	5.0 to 7.0	5.87
6.	Related Substance (By HPLC)		
	Any secondary peak	NMT 1.0%	0.186%
	Acetylated penicilloic acid of Piperacillin	NMT 1.0%	0.516%
	Tazobactam related compound A	NMT 1.0%	0.121%
	Piperacillin penilloic acid	NMT 1.0%	0.043%
	Sum of area of all the secondary peaks other than piperacillin penicilloic acid	NMT 5.0%	0.028%
	Piperacillin impurity B	NMT 1.0%	0.009%
	The area of any peak corresponding to Piperacillin penicilloic acid	NMT 5.0%	1.901%
	Piperacillin impurity C	NMT 1.0%	0.214%
	Piperacillin impurity D	NMT 1.0%	0.155%

Analysis by 12/10/26	Checked by 12/10/26	Approved by 12/10/26
NAME: NIKHIL SHARMA	NAME: SURJEET KAUR	NAME: MRS. SWATI DHAWAN

Name : Mrs. Swati Dhawan
Designation : QC HOD
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Format No: PB/QC/045/F05-00

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7.	Particulate Matter (A.) Light Obscuration Particle Count Test (1.) Particles ≥10µm (2.) Particles ≥25µm (B.) Visual Particle	NMT 6000/vial NMT 600/ vial The reconstituted solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally that can be seen with naked eye.	885/vial 9/vial Complies
8.	Water (By KF)	NMT 2.5%w/w	1.74%w/w
9.	Sterility	No microbial growth should be observed.	Complies
10.	Bacterial Endotoxins	NMT 0.08 EU/mg in portion eq. to 1mg of mixture of Piperacillin & Tazobactam (0.89mg-0.11 mg).	Less than 0.08 EU/mg in portion eq. to 1mg of mixture of Piperacillin & Tazobactam (0.89mg-0.11 mg).
11.	Assay: (By HPLC) Each glass vial contains:		

Ingredients	Labelled Claim	Found	% of labelled amount	Limits % of labelled amount
Sterile Piperacillin Sodium IP Eq. to Anhydrous Piperacillin	2000 mg	2129.2831 mg	106.46%	90.0% to 110%
Sterile Tazobactam Sodium IP Eq. to Tazobactam (A sterile mixture of Piperacillin Sodium & Tazobactam Sodium)	250 mg	240.2845 mg	96.11%	90.0% to 110%

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~~.

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