

pace

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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/25/618
GenericName	Piperacillin & Tazobactam for Injection IP 2.25gm	Sampled qty.	45 vials
Batch No.	B25652F	Sampled by	Aakash
Batch Size	2,000 Vials	Sampled on	10/02/2026
Mfg. Date	02/2026	Date of Testing	11/02/2026
Exp. Date	01/2028	Date of Release	25/02/2026

7.	Particulate Matter (A.) Light Obscuration Particle Count Test (1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$ (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.	391/vial 4/vial Complies
8.	Water (By KF)	NMT 2.5%w/w	1.64%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	1986.9104 mg	99.35%	90.0% to 110%
Sterile Tazobactam Sodium IP Eq. to Tazobactam (A sterile mixture of Piperacillin Sodium & Tazobactam Sodium)	250 mg	237.6024 mg	95.04%	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/PHS.

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Analysis by 25/02/2026
NAME: NIKHIL SHARMA

Checked by 25/02/2026
NAME: SUFIYAN ANSARI