

# Pace

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# Pace Biotech

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

**Title :** Certificate of Analysis Finished Product

<b>Product Name</b>	PIPRACAN Injection	<b>A.R. No.</b>	BD/FP/25/408
<b>GenericName</b>	Piperacillin & Tazobactam for Injection IP 2.25gm	<b>Sampled qty.</b>	45 vials
<b>Batch No.</b>	B25405E	<b>Sampled by</b>	Anuj Verma
<b>Batch Size</b>	1,982Vials	<b>Sampled on</b>	16/10/2025
<b>Mfg. Date</b>	10/2025	<b>Date of Testing</b>	16/10/2025
<b>Exp. Date</b>	09/2027	<b>Date of Release</b>	01/11/2025

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	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 $\pm 10\%$	-1.32% & +2.13%
4.	Average weight	Informative $\pm 2\%$ .	2465.0 mg
5.	pH	5.0 to 7.0	6.23
6.	Related Substance (By HPLC)		
	Any secondary peak	NMT 1.0%	Not detected
	Acetylated penicilloic acid of Piperacillin	NMT 1.0%	Not detected
	Tazobactam related compound A	NMT 1.0%	Not detected
	Piperacillin penilloic acid	NMT 1.0%	Not detected
	Sum of area of all the secondary peaks other than piperacillin penicilloic acid	NMT 5.0%	Not detected
	Piperacillin impurity B	NMT 1.0%	Not detected
	The area of any peak corresponding to Piperacillin penicilloic acid	NMT 5.0%	Not detected
	Piperacillin impurity C	NMT 1.0%	Not detected
	Piperacillin impurity D	NMT 1.0%	Not detected

Name : Mrs. Swati Dhawan  
Designation : QC HOD  
Qualification : M.Sc. Clinical Microbiology  
Registration No. : 580406039593  
Approved by  
NAME: MRS. SWATI DHAWAN  
Punjab Technical University, Jalandhar

Analysis by *Nikhil Sharma*  
NAME: NIKHIL SHARMA

Checked by *Sufiyan Ansari*  
NAME: SUFIYAN ANSARI

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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.	419/vial 12/vial Complies		
8.	Water (By KF)	NMT 2.5%w/w	1.29%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	2085.29 mg	104.26%	90.0% to 110%
Sterile Tazobactam Sodium IP Eq. to Tazobactam (A sterile mixture of Piperacillin Sodium & Tazobactam Sodium)		250 mg	240.17 mg	96.07%	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.

Name : Mrs. Swati Dhawan

Designation : QC HOD

Qualification : M.Sc. Clinical Microbiology

Registration No. 58016089593

Name: MRS. SWATI DHAWAN

Analysis by

NAME: NIKHIL SHARMA

Checked by

NAME: SUFIYAN ANSARI