

Pace

Add Pace To Health

Pace Biotech

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

Title : Certificate of Analysis Finished Product

Product Name	PIPRACAN Injection	A.R. No.	BD/FP/26/101
GenericName	Piperacillin & Tazobactam for Injection IP 2.25gm	Sampled qty.	45 vials
Batch No.	B26090G	Sampled by	Rakesh
Batch Size	2,000 Vials	Sampled on	30/05/2026
Mfg. Date	05/2026	Date of Testing	31/05/2026
Exp. Date	04/2028	Date of Release	14/06/2026

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 $\pm 10\%$	-0.66% & +0.63%
4.	Average weight	Informative $\pm 2\%$.	2498.7 mg
5.	pH	5.0 to 7.0	6.70
6.	Related Substance (By HPLC)		
	Any secondary peak	NMT 1.0%	0.119%
	Acetylated penicilloic acid of Piperacillin	NMT 1.0%	0.009%
	Tazobactam related compound A	NMT 1.0%	0.043%
	Piperacillin penilloic acid	NMT 1.0%	0.006%
	Sum of area of all the secondary peaks other than piperacillin penicilloic acid	NMT 5.0%	1.131%
	Piperacillin impurity B	NMT 1.0%	Not Detected
	The area of any peak corresponding to Piperacillin penicilloic acid	NMT 5.0%	0.056%
	Piperacillin impurity C	NMT 1.0%	0.806%
	Piperacillin impurity D	NMT 1.0%	0.056%

Name : Mrs. Swati Dhawan

Designation : QC HOD

Qualification : M.Sc. Clinical Microbiology

Registration No. 580106018533

NAME: MRS. SWATI DHAWAN

Punjab Technical University, Jalandhar

Analysis by

NAME: NIKHIL SHARMA

Checked by

NAME: SUFIYAN ANSARI



Add Pace To Health

Pace Biotech

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

Title

:

Certificate of Analysis Finished Product

Product Name	PIPRACAN Injection	A.R. No.	BD/FP/26/101
GenericName	Piperacillin & Tazobactam for Injection IP 2.25gm	Sampled qty.	45 vials
Batch No.	B26090G	Sampled by	Rakesh
Batch Size	2,000 Vials	Sampled on	30/05/2026
Mfg. Date	05/2026	Date of Testing	31/05/2026
Exp. Date	04/2028	Date of Release	14/06/2026

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.	357/vial 3/vial Complies
8.	Water (By KF)	NMT 2.5%w/w	1.46%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	2100.6956 mg	105.03%	90.0% to 110%
Sterile Tazobactam Sodium IP Eq. to Tazobactam (A sterile mixture of Piperacillin Sodium & Tazobactam Sodium)	250 mg	246.1880 mg	98.48%	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.

Analysis by NAME: NIKHIL SHARMA	Checked by NAME: SUFIYAN ANSARI	Name : Mrs. Swati Dhawan Designation : QC HOD Approved by Qualification : M. Sc. Clinical Microbiology NAME: MRS. SWATI DHAWAN Registration No. : 26940059533
------------------------------------	------------------------------------	--

Punjab Technical University, Jalandhar