

# 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/25/100
GenericName	Piperacillin & Tazobactam for Injection IP 4.5gm	Sampled qty.	45 vials
Batch No.	B25099F	Sampled by	Rakesh
Batch Size	2968 Vials	Sampled on	15/05/2025
Mfg. Date	05/2025	Date of Testing	15/05/2025
Exp. Date	04/2027	Date of Release	31/05/2025

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 $\pm 10\%$	-2.99% & +2.13%
4.	Average weight	Informative.	4981.3 mg
5.	pH	5.0 to 7.0	6.60
6.	Related Substance (By HPLC)		
	Any secondary peak	NMT-1.0%	0.51%
	Acetylated penicilloic acid of Piperacillin	NMT-1.0%	Not detected
	Tazobactam related compound A	NMT-1.0%	Not detected
	Piperacillin penicilloic acid	NMT-1.0%	Not detected
	Sum of area of all the secondary peaks other than piperacillin penicilloic acid	NMT-5.0%	0.51%
	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

Analysis by

NAME: NIKHIL SHARMA

Checked by

NAME: SUFIYAN ANSARI

Approved by

NAME: SWATI DHAWAN



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7.	Particulate Matter (a.) Sub-Visible particle count (1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$ (b.) Visual	NMT-6000/vial NMT-600/ vial The solution is free from particles of foreign matter particles that can be observed on visual inspection.	551/vial 12/vial Complies		
8.	Water (By KF)	NMT- 2.5% w/w	1.37% 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: Each glass vial Contains				
<b>Ingredients</b>		<b>Labeled Claim</b>	<b>Found</b>	<b>% of labeled amount</b>	<b>Limits % of labeled amount</b>
Sterile Piperacillin Sodium IP Eq. to Anhydrous Piperacillin		4000 mg	4315.78 mg	107.89%	90.0% to 110%
Sterile Tazobactam Sodium IP Eq. to Tazobactam (A sterile mixture of Piperacillin Sodium & Tazobactam Sodium)		500 mg	504.36 mg	100.87%	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/HS.

<b>Analysis by</b> NAME: NIKHIL SHARMA	<b>Checked by</b> NAME: SUFIYAN ANSARI	<b>Approved by</b> NAME: SWATI DHAWAN
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