

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/24/594
Generic Name	Piperacillin & Tazobactam for Injection IP 4.5gm	Sampled qty.	45 vials
Batch No.	B24565L	Sampled by	Rakesh
Batch Size	10,368 Vials	Sampled on	17/01/2025
Mfg. Date	01/2025	Date of Testing	17/01/2025
Exp. Date	12/2026	Date of Release	01/02/2025

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 $\pm 10\%$	-3.45% & +2.13%
4.	Average weight	Informative.	4899.9 mg
5.	pH	5.0 to 7.0	6.22
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

Analysis by

NAME: SUFIYAN ANSARI

Checked by

NAME: SANDHYA

Approved by

NAME: P. N. TRIPATHI



Title

:

Certificate of Analysis Finished Product

Product Name	Pipracan Injection	A.R. No.	BD/FP/24/594
Generic Name	Piperacillin & Tazobactam for Injection IP 4.5gm	Sampled qty.	45 vials
Batch No.	B24565L	Sampled by	Rakesh
Batch Size	10,368 Vials	Sampled on	17/01/2025
Mfg. Date	01/2025	Date of Testing	17/01/2025
Exp. Date	12/2026	Date of Release	01/02/2025

7.	Particulate Matter	NMT-6000/vial NMT-600/ vial The solution is free from particles of foreign matter particles that can be observed on visual inspection.	3607/vial 83/vial Complies		
	(a.) Sub-Visible particle count (1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$ (b.) Visual				
8.	Water (By KF)	NMT- 2.5% w/w	1.98% 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				
Ingredients		Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Sterile Piperacillin Sodium IP Eq. to Anhydrous Piperacillin		4000 mg	4089.38 mg	102.23%	90.0% to 110%
Sterile Tazobactam Sodium IP Eq. to Tazobactam (A sterile mixture of Piperacillin Sodium & Tazobactam Sodium)		500 mg	481.82 mg	96.36%	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	Checked by	Approved by
NAME: SUFIYAN ANSARI	NAME: SANDHYA	NAME: P. N. TRIPATHI