

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/24/171
Generic Name	Piperacillin & Tazobactam for Injection IP	Sampled qty.	45 vials
Batch No.	B24134G	Sampled by	Vineet
Batch Size	2000 Vials	Sampled on	23/06/2024
Mfg. Date	06/2024	Date of Testing	23/06/2024
Exp. Date	05/2026	Date of Release	08/07/2024

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 $\pm 10\%$	-1.13% & +0.75%
4.	Average weight	Informative.	2499.2 mg
5.	pH	5.0 to 7.0	6.37
6.	Related Substance (By HPLC)		
	Any secondary peak	NMT-1.0%	0.02%
	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%	0.02%
	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

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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.	251/vial 12/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	1.99% 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.		
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			2000 mg	2183.45 mg	109.17%	90.0% to 110%
Sterile Tazobactam Sodium IP Eq. to Tazobactam (A sterile mixture of Piperacillin Sodium & Tazobactam Sodium)			250 mg	260.31 mg	104.12%	90.0% to 110%
Remarks: In the opinion of the undersigned the sample referred to above is of quality as the product is intended to be used.						

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.

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