

Title : Certificate of Analysis Finished Product

Product Name	PIPRACAN Injection	A.R. No.	ARB/FP/26/017
GenericName	Piperacillin & Tazobactam for Injection IP 4.5gm	Sampled qty.	45 vials
Batch No.	ARB2613A	Sampled by	Rakesh
Batch Size	20,000 Vials	Sampled on	26/06/2026
Mfg. Date	06/2026	Date of Testing	27/06/2026
Exp. Date	05/2028	Date of Release	11/07/2026

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 $\pm 10\%$	-0.74% & +1.64%
4.	Average weight	Informative $\pm 2\%$.	4945.3 mg
5.	pH	5.0 to 7.0	6.15
6.	Related Substance (By HPLC)		
	Any secondary peak	NMT 1.0%	0.234%
	Acetylated penicilloic acid of Piperacillin	NMT 1.0%	0.733%
	Tazobactam related compound A	NMT 1.0%	0.081%
	Piperacillin penilloic acid	NMT 1.0%	0.005%
	Sum of area of all the secondary peaks other than piperacillin penicilloic acid	NMT 5.0%	1.682%
	Piperacillin impurity B	NMT 1.0%	Not Detected
	The area of any peak corresponding to Piperacillin penicilloic acid	NMT 5.0%	0.076%
	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: MRS. SWATI DHAWAN

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7.	Particulate Matter	NMT 6000/vial NMT 600/ vial The solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally that can be seen with naked eyes.	940/vial 5/vial Complies		
	(A.) Light Obscuration Particle Count Test (1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$ (B.) Visual Particle				
8.	Water (By KF)	NMT 2.5%w/w	1.25%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		Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Sterile Piperacillin Sodium IP Eq. to Anhydrous Piperacillin		4000 mg	4218.1185mg	105.45%	90.0% to 110%
Sterile Tazobactam Sodium IP Eq. to Tazobactam (A sterile mixture of Piperacillin Sodium & Tazobactam Sodium)		500 mg	491.6074 mg	98.32%	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/THS.

Analysis by NAME: NIKHIL SHARMA	Checked by NAME: SUFIYAN ANSARI	Approved by NAME: MRS. SWATI DHANAN
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