



AMERICAN REMEDIES HEALTHCARE PVT. LTD.

Vill. Surajpur, Nahan Road, Paonta Sahib, Dist. Sirmour (H.P) 173025

Title : Certificate of Analysis Finished Product

Product Name	PIPRACAN Injection	A.R. No.	ARB/FP/25/030
GenericName	Piperacillin & Tazobactam for Injection IP 4.5gm	Sampled qty.	45 vials
Batch No.	ARB2538A	Sampled by	Anuj Verma
Batch Size	15,000 Vials	Sampled on	11/03/2026
Mfg. Date	02/2026	Date of Testing	12/03/2026
Exp. Date	01/2028	Date of Release	27 /03/2026

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 $\pm 10\%$	-1.25% & +1.47%
4.	Average weight	Informative $\pm 2\%$.	4908.6 mg
5.	pH	5.0 to 7.0	6.70
6.	Related Substance (By HPLC)		
	Any secondary peak	NMT 1.0%	0.176%
	Acetylated penicilloic acid of Piperacillin	NMT 1.0%	0.362%
	Tazobactam related compound A	NMT 1.0%	0.108%
	Piperacillin penilloic acid	NMT 1.0%	0.004%
	Sum of area of all the secondary peaks other than piperacillin penicilloic acid	NMT 5.0%	1.328%
	Piperacillin impurity B	NMT 1.0%	0.021%
	The area of any peak corresponding to Piperacillin penicilloic acid	NMT 5.0%	0.005%
	Piperacillin impurity C	NMT 1.0%	0.005%
	Piperacillin impurity D	NMT 1.0%	0.143%

Analysis by

NAME: NIKHIL SHARMA

Checked by

NAME: SUEIVAN ANSARI

Approved by

NAME: MRS. ANITA KUMAR



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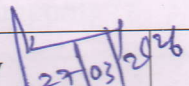
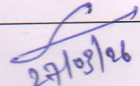
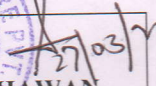
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7.	Particulate Matter (A.) Light Obscuration Particle Count Test (1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$ (B.) Visual Particle	NMT 6000/vial NMT 600/ vial The solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally that can be seen with naked eyes.	444/vial 3/vial Complies
8.	Water (By KF)	NMT 2.5%w/w	1.31%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	4255.1071 mg	106.38%	90.0% to 110%
Sterile Tazobactam Sodium IP Eq. to Tazobactam (A sterile mixture of Piperacillin Sodium & Tazobactam Sodium)	500 mg	484.4059 mg	96.88%	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.

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