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/26/025
GenericName	Piperacillin & Tazobactam for Injection IP 4.5gm	**Sampled qty.**	45 vials
Batch No.	ARB2622A	**Sampled by**	Shivanand
Batch Size	29,830 Vials	**Sampled on**	21/09/2026
Mfg. Date	09/2026	**Date of Testing**	22/09/2026
Exp. Date	08/2028	**Date of Release**	06/10/2026

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 ±10%	-1.24% & +0.91%
4.	Average weight	Informative ±2%.	4914.5 mg
5.	pH	5.0 to 7.0	6.03
6.	Related Substance (By HPLC)		
	Any secondary peak	NMT 1.0%	0.192%
	Acetylated penicilloic acid of Piperacillin	NMT 1.0%	0.562%
	Tazobactam related compound A	NMT 1.0%	0.123%
	Piperacillin penilloic acid	NMT 1.0%	0.041%
	Sum of area of all the secondary peaks other than piperacillin penicilloic acid	NMT 5.0%	1.949%
	Piperacillin impurity B	NMT 1.0%	0.011%
	The area of any peak corresponding to Piperacillin penicilloic acid	NMT 5.0%	0.042%
	Piperacillin impurity C	NMT 1.0%	0.204%
	Piperacillin impurity D	NMT 1.0%	0.158%

Name : Mrs. Swati Dhawan
Designation : QC HOD
Qualification : M.Sc. Clinical Microbiology
Registration No. : 3804[illegible]

Analysis by	Checked by	Approved by
NAME: MOHD.ZAID	NAME: SURJEET KAUR	NAME: MRS. SWATI DHAWAN

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7.	Particulate Matter (A.) Light Obscuration Particle Count Test (1.) Particles ≥10µm (2.) Particles ≥25µm (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.	 1,248/vial 11/vial Complies
8.	Water (By KF)	NMT 2.5%w/w	1.51%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	4111.5862mg	102.79%	90.0% to 110%
Sterile Tazobactam Sodium IP Eq. to Tazobactam (A sterile mixture of Piperacillin Sodium & Tazobactam Sodium)	500 mg	476.2440 mg	95.25%	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~~.

Name : Mrs. Swati Dhawan
Designation : QC HOD
Qualification : M.Sc. Clinical Microbiology
Registration No. : 580406030503
Punjab Technical University, Jalandhar

Analysis by	Checked by	Approved by
06/10/26	06/10/26	06/10/26
NAME: MOHD. ZAID	NAME: SURJEET KAUR	NAME: MRS. SWATI DHAWAN