



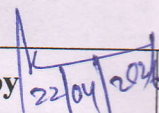
# AMERICAN REMEDIES HEALTHCARE PVT. LTD.

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

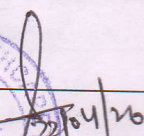
## Title : Certificate of Analysis Finished Product

Product Name	PIPRACAN Injection	A.R. No.	ARB/FP/26/004
Generic Name	Piperacillin & Tazobactam for Injection IP 4.5gm	Sampled qty.	45 vials
Batch No.	ARB2543A	Sampled by	Rakesh
Batch Size	20,000 Vials	Sampled on	07/04/2026
Mfg. Date	03/2026	Date of Testing	08/04/2026
Exp. Date	02/2028	Date of Release	22/04/2026

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 $\pm 10\%$	-1.29% & +1.18%
4.	Average weight	Informative $\pm 2\%$ .	4988.0 mg
5.	pH	5.0 to 7.0	6.27
6.	Related Substance (By HPLC)		
	Any secondary peak	NMT 1.0%	0.286%
	Acetylated penicilloic acid of Piperacillin	NMT 1.0%	0.925%
	Tazobactam related compound A	NMT 1.0%	0.160%
	Piperacillin penilloic acid	NMT 1.0%	0.054%
	Sum of area of all the secondary peaks other than piperacillin penicilloic acid	NMT 5.0%	2.111%
	Piperacillin impurity B	NMT 1.0%	0.001%
	The area of any peak corresponding to Piperacillin penicilloic acid	NMT 5.0%	0.121%
	Piperacillin impurity C	NMT 1.0%	Not Detected
	Piperacillin impurity D	NMT 1.0%	0.172%

Analysis by   
NAME: NIKHIL SHARMA

Checked by   
NAME: SUFIYAN ANSARI

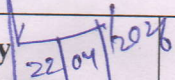
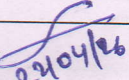
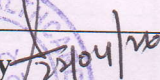
Approved by   
NAME: MRS. SWATI DHAWAN

**Title : Certificate of Analysis Finished Product**

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<b>Batch Size</b>	20,000 Vials	<b>Sampled on</b>	07/04/2026
<b>Mfg. Date</b>	03/2026	<b>Date of Testing</b>	08/04/2026
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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.	280/vial 4/vial Complies		
8.	Water (By KF)	NMT 2.5%w/w	1.39%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:				
<b>Ingredients</b>		<b>Labeled Claim</b>	<b>Found</b>	<b>% of labeled amount</b>	<b>Limits % of labeled amount</b>
Sterile Piperacillin Sodium IP Eq. to Anhydrous Piperacillin		4000 mg	4243.6766 mg	106.09%	90.0% to 110%
Sterile Tazobactam Sodium IP Eq. to Tazobactam (A sterile mixture of Piperacillin Sodium & Tazobactam Sodium)		500 mg	495.7424 mg	99.15%	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.**

<b>Analysis by</b>  NAME: NIKHIL SHARMA	<b>Checked by</b>  NAME: SUFIYAN ANSARI	<b>Approved by</b>  NAME: MRS. SWATI DHAWAN
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