

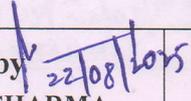
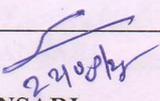
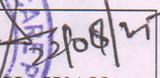
**AMERICAN REMEDIES HEALTHCARE PVT. LTD.**

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

**Title : Certificate of Analysis Finished Product**

<b>Product Name</b>	Pipracan Injection	<b>A.R. No.</b>	ARB/FP/25/003
<b>GenericName</b>	Piperacillin & Tazobactam for Injection IP 4.5g	<b>Sampled qty.</b>	45 vials
<b>Batch No.</b>	ARB2503A	<b>Sampled by</b>	Anuj Verma
<b>Batch Size</b>	10,000 Vials	<b>Sampled on</b>	07/08/2025
<b>Mfg. Date</b>	07/2025	<b>Date of Testing</b>	08/08/2025
<b>Exp. Date</b>	06/2027	<b>Date of Release</b>	22/08/2025

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 $\pm 10\%$	-0.66% & +2.13%
4.	Average weight	Informative $\pm 2\%$ .	4964.4 mg
5.	pH	5.0 to 7.0	6.40
6.	Related Substance (By HPLC)		
	Any secondary peak	NMT 1.0%	Not detected
	Acetylated penicilloic acid of Piperacillin	NMT 1.0%	Not detected
	Tazobactam related compound A	NMT 1.0%	Not detected
	Piperacillin penilloic acid	NMT 1.0%	Not detected
	Sum of area of all the secondary peaks other than piperacillin penicilloic acid	NMT 5.0%	Not detected
	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

Analysis by   
NAME: NIKHIL SHARMAChecked by   
NAME: SUFIYAN ANSARIApproved by   
NAME: MRS. SWATI DHAWAN



# AMERICAN REMEDIES HEALTHCARE PVT. LTD.

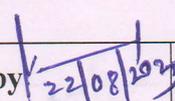
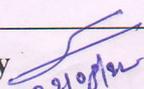
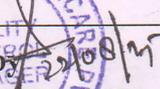
Vill. Surajpur, Nahan Road, Paonta Sahib, Dist. Sirmour (H.P) 173025

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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 eye.	829/vial 5/vial Complies	
8.	Water (By KF)	NMT 2.5%w/w	1.14%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	4192.92 mg	104.82%	90.0% to 110%
Sterile Tazobactam Sodium IP Eq. to Tazobactam (A sterile mixture of Piperacillin Sodium & Tazobactam Sodium)	500 mg	483.28 mg	96.66%	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/HHS.

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