



ALVENTA PHARMA LIMITED

VILL. KISHANPURA, TEHSIL BADDI- NALAGARH ROAD, DISTT.- SOLAN (H.P) 174101

Quality Control Department

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Product Name	Pipracan 4.5g	A.R. No.	FG/B/24A0027
Generic Name	Piperacillin and Tazobactam Injection IP	Sample Quantity	65 Vials
Batch No.:	ABD41002	Sample Received on	26/10/2024
Batch Size:	10200 Vials	Analysis Date	26/10/2024
Mfg. Date.	10/2024	Release Date	09/11/2024
Exp. Date	09/2026	Page No.:	Page 1 of 2

Sr. No.	Test Parameter	Acceptance Criteria	Result		
1.	Description	A White powder filled in a transparent 30 ml molded glass vial sealed with rubber stopper orange coloured flip off having aluminium seal.	A White powder filled in a transparent 30 ml molded glass vial sealed with rubber stopper orange coloured flip off having aluminium seal.		
2.	Identification	In the assay, the principal peak in the chromatogram obtained with the test solution should corresponds to the peak in the chromatogram obtained with the reference solution.	Complies		
3.	Average filled weight	± 7.5 % of Target filled weight.	4828.83 mg		
4.	Uniformity of filled weight	± 10 % of its average filled weight	Min: 4754.25 mg ; Max: 4942.59 mg -1.54% ; +2.36%		
5.	pH	Between 5.0 to 7.0	6.11		
6.	Water	Not more than 2.5%w/w	1.01%w/w		
7.	Clarity of Solution	Solid should dissolve completely when, leaving no visible residue as undissolved matter.	Solid dissolve completely when, leaving no visible residue as undissolved matter.		
8.	Particulate matter	The Sample Solution should be clear and free from any visible particles	The Sample Solution is clear and free from any visible particles.		
9.	Bacterial Endotoxins Tests	NMT 0.08 EU/mg	Less than 0.08 EU/mg		
10.	Sterility	Should be sterile	Sterile		
11.	Assay:				
	Each Vial contains:	Claim	Limit	gm	%
	Sterile Piperacillin Sodium IP Eq. to Piperacillin	4 gm	Between 90.00 % to 110.00 % of stated amount of Piperacillin (Between 3.6 gm to 4.4 gm)	3.8871 gm	97.18%

Particulars	Prepared By	Checked By	Approved By
Name	Harveen Kumar	Kuljeet Kaur	RamAwadh Yadav
Designation	Executive	Head QC	Head QA
Signature			
Date	09/11/2024	09/11/2024	11/11/2024



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Sr. No.	Test Parameter	Acceptance Criteria		Result	
	Sterile Tazobactam Sodium IP Eq. to Tazobactam	0.5 gm	Between 90.00 % to 110.00 % of stated amount of Tazobactam (Between 0.45 gm to 0.55gm)	0.5108 gm	102.16%

Remarks: The above test parameters are ~~not~~ complies/ complies as per IP/BP/USP & In-House Specification.

Particulars	Prepared By	Checked By	Approved By
Name	Praveen Kumar	Kuljeet Kaur	Rama Chaudhary
Designation	Executive	Head QC	Head QA
Signature			
Date	09/11/2024	09/11/2024	11/11/2024