



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/24A0023
Generic Name	Piperacillin and Tazobactam Injection IP	Sample Quantity	65 Vials
Batch No.:	ABD40903	Sample Received on	14/09/2024
Batch Size:	10200 Vials	Analysis Date	14/09/2024
Mfg. Date.	09/2024	Release Date	NA
Exp. Date	08/2026	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 green coloured flip off having aluminium seal.	A White powder filled in a transparent 30 ml molded glass vial sealed with rubber stopper green 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	4874.00 mg \pm 5.0 %	4891.64 mg		
4.	Uniformity of filled weight	\pm 10% of its average filled weight	Min: 4652.73 mg ; Max: 5054.93 mg -4.88% ; +3.34%		
5.	pH	Between 5.0 to 7.0, determine in a 10 % w/v solution.	6.06		
6.	Water	Not more than 2.5%w/w	1.80%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	Under test		
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)	3.975 gm	99.37%

Particulars	Prepared By	Checked By	Approved By
Name	Braveen Kumar	Tamvej	Gaurav Singh
Designation	Executive	Sr. Executive	Head-QA
Signature			
Date	27/09/2024	27/09/2024	27/09/2024



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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)	0.4913 gm	98.26%

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

Particulars	Prepared By	Checked By	Approved By
Name	Pravesh Kumar	Tanvej	Ranveer Singh
Designation	Executive	Sr. Executive	Head-QA
Signature			
Date	27/09/2024	27/09/2024	27/09/2024