



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/24A0004
Generic Name	Piperacillin and Tazobactam Injection IP	Sample Quantity	65 Vials
Batch No.:	ABD40201	Sample Received on	01/03/2024
Batch Size:	10573 Vials	Analysis Date	01/03/2024
Mfg. Date.	02/2024	Release Date	15/03/2024
Exp. Date	01/2026	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	4721 mg \pm 3.0 % of target filled weight.	4709.90 mg
4.	Uniformity of filled weight	\pm 10% of its average filled weight	Min: 4480.81 mg ; Max: 4860.93 mg -4.86% ; +3.21%
5.	pH	Between 5.0 to 7.0, determine in a 10 % w/v solution.	6.32
6.	Water	Not more than 2.5%w/w	1.31%w/w
7.	Reconstitution Solution	When reconstitution with the sterile water for injection the sample solution should be clear and free from suspended matters.	When reconstitution with the sterile water for injection the sample solution is clear and free from suspended matters.
8.	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.
9.	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.
10.	Bacterial Endotoxins Tests	NMT 0.08 EU/mg	Less than 0.08 EU/mg
11.	Sterility	Should be sterile	Sterile

Particulars	Prepared By	Checked By	Approved By
Name	Baveen Kumar	Tanvej	Gautam Singh
Designation	Executive	Sr. Executive	Head- QA
Signature			
Date	15/03/2024	15/03/2024	15/03/2024



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CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Product Name	Pipracan 4.5g	A.R. No.	FG/B/24A0004
Generic Name	Piperacillin and Tazobactam Injection IP	Sample Quantity	65 Vials
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Sr. No.	Test Parameter	Acceptance Criteria			Result	
12.	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)	4.1351 gm	103.38%	
	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)	0.4862 gm	97.23 %	

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	Harveen Kumar	Tanvej	Gautam Singh
Designation	Executive	Sr. Executive	Head-QA
Signature			
Date	15/03/2024	15/03/2024	15/03/2024