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/23A0013
Generic Name	Piperacillin and Tazobactam Injection IP	**Sample Quantity**	65 Vials
Batch No.:	ABD31104	**Sample Received on**	22/11/2023
Batch Size:	10100 Vials	**Analysis Date**	22/11/2023
Mfg. Date.	11/2023	**Release Date**	NA
Exp. Date	10/2025	**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 (By HPLC)**	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.	4787.76 mg
4.	**Uniformity of filled weight**	± 10% of its average filled weight	Min: 4693.41 mg ; Max: 4832.85 mg -1.97% ; +0.94%
5.	**pH**	Between 5.0 to 7.0, determine in a 10 % w/v solution.	5.80
6.	**Water**	Not more than 2.5%w/w	1.18%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	Under Observation

Particulars	Prepared By	Checked By	Approved By
Name	Praveen Kumar	Tanvej	Gautam Singh
Designation	Executive	Sr. Executive	Head-QA
Signature		Tanvej	
Date	05/12/2023	05/12/2023	05/12/2023

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Sr. No.	Test Parameter	Acceptance Criteria		Result	
12.	**Assay (By HPLC):**				
	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)	3.9712 gm	99.28%
	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)	0.5054 gm	101.08%

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	Praveen Kumar	Tanvej	Gautam Singh
Designation	Executive	Sr. Executive	Head- QA
Signature		Tanvej	
Date	05/12/2023	05/12/2023	05/12/2023