COSMAS
RESEARCH LAB LIMITED

COSMAS RESEARCH LAB LTD., LUDHIANA
CERTIFICATE OF ANALYSIS
FINISHED PRODUCT

Product Name	**PIPTABURG 4.5 g**		
Generic Name	**Piperacillin and Tazobactam for Injection**	**Mfg. date**	**11/2017**
Batch No.	**IB170012B**	**Expiry date**	**10/2019**
A. R. No.	**FP180050**	**Pack Size**	**30 ml**
Start Date of Analysis	**21/11/2017**	**Batch Size**	**3440 vials**
Date of Release	**04/01/2018**	**Page No.**	**1 of 2**

PART A

S. No.	Test	Specification	Result
1.	Description	A white to off crystalline powder filled in clear glass vial.	Off- white crystalline powder filled in clear glass vial.
2.	Identification	The retention times of the major peaks of the sample solution corresponds to those of the standard solution, as obtained in the assay.	In the assay, the retention times of the major peaks of the sample solution corresponds to those of the standard solution.
3.	Average fill weight of the content	4.854 g ± 2.0 %	4.84335 g
4.	Uniformity of dosage units	Acceptance value should not more than 15.	2.18 for Piperacillin 1.73 for Tazobactam
5.	Particulate matter	The average number of the particle present in the units tested does not exceeds 6000 per container equal to or greater than 10 µm and does not exceed 600 per container equal to or greater than 25 µm.	Complies
6.	Clarity of solution	a) The solid dissolve completely, leaving no visible residue as undissolved matter. b) The constituted injection is not significantly less clear than an equal volume of the diluent or of water for injections contained in a similar container.	Complies Complies
7.	Water	NMT 2.5 %	1.14%
8.	pH	5.0 to 7.0	5.544

	Prepared by	Checked by	Approved by
Name	Sukhjit Singh	Vivek Sood	Jasveer Singh
Designation	Officer-QC	Executive-QC	Manager-QC
Signature			
Date	04/01/2018	04/01/2018	04/01/2018

Format No.: F/QC/01/024/02/01

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9.	Related Substances Any other impurity Total impurity	 NMT 1.0% NMT 3.0%	 0.177% 0.305%
10.	Assay Each vial contains: Piperacillin Sodium USP (Sterile) eq. to Anhydrous Piperacillin - 4000 mg Tazobactam Sodium eq. To Tazobactam -500 mg	 NLT 3600 mg and NMT 4400 mg (NLT 90% and NMT 110% of Piperacillin) NLT 450 mg and NMT 550mg (NLT 90% and NMT 110% of Tazobactam)	 4077.19 mg (101.93%) 504.04 mg (100.81%)

PART-B

1.	Bacterial Endotoxin	Not more than 0.08 USP Endotoxin Unit in a portion equivalent to 1 mg of a mixture.	Less than 0.08 USP Endotoxin Unit in a portion equivalent to 1 mg of a mixture.
2.	Sterility	Shall Comply for sterility test	Complies

Remarks: The above sample of finished product **complies/~~does not comply~~** as per specification no. QC/FPS/1010/00.

	Prepared by	**Checked by**	**Approved by**
Name	Sukhjit Singh	Vivek Sood	Jasveer Singh
Designation	Officer-QC	Executive-QC	Manager-QC
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