

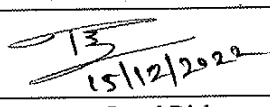
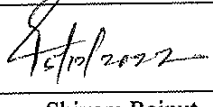
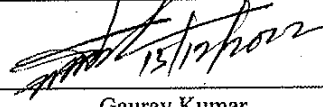
# GMH ORGANICS

PLOT No.5, VILLAGE KUNJHAL, JHARMAJRI, BADDI, DISTT. SOLAN (H.P.)

## Certificate of Analysis

<b>GMH ORGANICS</b>			
<b>Product Name</b>	<b>Tazowis 4.5gm</b>		
<b>Generic Name</b>	<b>Piperacillin &amp; Tazobactam Injection IP</b>		
<b>Batch No.</b>	<b>1412061A</b>	<b>Mfg. date</b>	<b>12/2022</b>
<b>Batch size</b>	<b>20601 Vials</b>	<b>Exp. date</b>	<b>11/2024</b>
<b>A.R. No.</b>	<b>FP22B/0123-01</b>	<b>Specification No.</b>	<b>FP/SPC/01/030</b>
<b>Date of Sampling</b>	<b>01/12/2022</b>	<b>Date of Release</b>	<b>15/12/2022</b>

Sr. No.	Test	Specification	Results
1.	<b>DESCRIPTION</b>	A white to off white crystalline powder.	<b>A white crystalline powder.</b>
2.	<b>IDENTIFICATION By HPLC</b>	In the Assay, the retention time of two principal peaks in the chromatogram obtained with the test solution corresponds to those in the chromatogram obtained with reference solution.	<b>Complies</b>
3.	<b>pH</b>	Between 5.00 to 7.00	<b>5.95</b>
4.	<b>RELATED COMPOUNDS (%)</b> Tazobactam related Compound A Piperacillin penilloic acid Piperacillin impurity B Piperacillin impurity C Piperacillin impurity D Piperacillinpenicilloic acid Acetylated penicillioic acid of piperacillin Any other secondary impurity Total impurities (other than Piperacillin penicilloic acid )	NMT 1.0 % NMT 1.0 % NMT 1.0 % NMT 1.0 % NMT.1.0 % NMT 5.0%  NMT 1.0% NMT 1.0%  NMT 5.0%	<b>Not detected</b> <b>0.05%</b> <b>Not detected</b> <b>Not detected</b> <b>Not detected</b> <b>Not detected</b>  <b>Not detected</b> <b>0.31%</b>  <b>0.56%</b>
5.	<b>WATER CONTENT (%W/W)</b>	NMT 2.50 % w/w	<b>1.19%</b>
6.	<b>BACTERIAL ENDOTOXIN TEST</b>	It contains not more than 0.08 IP endotoxins unit in a portion equivalent to 1 mg of mixture of piperacillin and tazobactam.	<b>Complies</b>
7.	<b>STERILITY</b>	To comply the requirement of Sterility	<b>Complies</b>
8.	<b>CONSTITUTED SOLUTION</b> I)Completeness & clarity of solution	a) The solid dissolves completely, leaving no visible residue as undissolved matter. b) The constituted solution is not significantly less clear than an equal volume of the diluent or purified water contained in similar vessel and examined similarly.	<b>Complies</b>  <b>Complies</b>

Particulars	Prepared By	Checked By	Approved By
Sign. /Date	 15/12/2022	 15/12/2022	 15/12/2022
Name	Payal Bisht	Shivam Rajput	Gaurav Kumar
Designation	Officer -QC	Sr.Officer-QC	Head-QC



# GMH ORGANICS

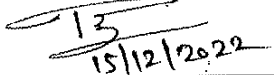
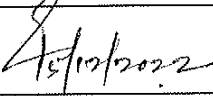
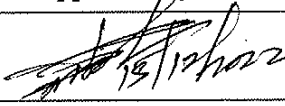
PLOT No.5, VILLAGE KUNJHAL, JHARMAJRI, BADDI, DISTT. SOLAN (H.P.)

## Certificate of Analysis

<b>Product Name</b>	Tazowis 4.5gm		
<b>Generic Name</b>	Piperacillin & Tazobactam Injection IP		
<b>Batch No.</b>	1412061A	<b>Mfg. date</b>	12/2022
<b>Batch size</b>	20601Vials	<b>Exp. date</b>	11/2024
<b>A.R. No.</b>	FP22B/0123-01	<b>Specification No.</b>	FP/SPC/01/030
<b>Date of Sampling</b>	01/12/2022	<b>Date of Release</b>	15/12/2022

Sr. No.	Test	Specification	Results
9.	<b>PARTICULATE MATTER</b> I) By Visible  II) By LBPC ( Per Container ) a) $\geq 10 \mu\text{m}$ b) $\geq 25 \mu\text{m}$	The solution after reconstitution should free from particles of foreign matter /black particles that can be observed on visual inspection.  NMT 6000/Container NMT 600/Container	<b>Complies</b>  <b>1265</b> <b>197</b>
10.	<b>AVERAGE FILLED WEIGHT(mg)</b>	4854mg $\pm 2\%$	4784mg
11.	<b>UNIFORMITY OF WEIGHT</b>	Not more than two of the individual weight deviates from the average weight by more than $\pm 10.0\%$ and none deviates by more than $\pm 20.0\%$	<b>Complies</b>
12.	<b>ASSAY (mg/ vial)</b> Each vial contains: Sterile Piperacillin Sodium IP equivalent to Piperacillin 4000 mg.  Sterile Tazobactam Sodium IP equivalent to Tazobactam 500 mg.	(NLT 90.0% and NMT 110.0%)  NLT 3600.0mg and NMT 4400.0mg  NLT 450.0mg and NMT 550.0mg	<b>4061.7mg/vial</b> <b>101.5%</b>  <b>492.1mg/vial</b> <b>98.4%</b>

**Remark: The test sample complies as per above Specification**

Particulars	Prepared By	Checked By	Approved By
Sign. /Date	 15/12/2022	 15/12/2022	 15/12/2022
Name	Payal Bisht	Shivam Rajput	Gaurav Kumar
Designation	Officer -QC	Sr.Officer-QC	Head-QC