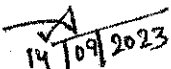
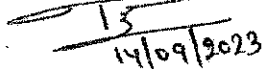
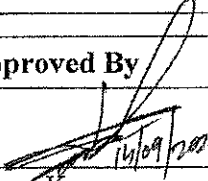


Certificate of Analysis

Zyphar's Pharmaceuticals Pvt. Ltd.
At GMH Organics Under Loan Licence

Product Name	AZETRIM 1		
Generic Name	AZTREONAM FOR INJECTION USP 1gm	Page No.	1 of 2
Batch No.	7013007A	Product Code	701
Batch Size	11232 Vials	Mfg. Date	08/2023
A.R. No.	FP23P/0064-01	Exp. Date	07/2025
Date of Sampling	31/08/2023	Date of Release	14/09/2023
Sampled By	Dheeraj	Specification No.	FP/SPC/02/026

Sr. No.	Test	Specification	Result
01.	DESCRIPTION	A white, odorless, crystalline powder filled in clear glass vials, sealed with grey butyl rubber plug and flip off aluminum seal.	A white crystalline powder filled in 20ml Tubular glass vial, sealed with grey butyl rubber plug and Turkish blue color flip-off aluminum seal.
02.	IDENTIFICATION A) By HPLC	The retention time of the major peak of the sample solution correspond to those of the standard solution, as obtained in the Assay.	Complies
03.	pH	Between 4.50 to 7.50	6.19
04.	WATER (in %w/w)	Not more than 2.00 %	0.59 %
05.	BACTERIAL ENDOTOXIN TEST	Not more than 0.17 USP Endotoxin Unit per mg of Aztreonam.	Less than 0.17 EU
06.	STERILITY	Complies with the test for sterility as per USP.	Complies
07.	AVERAGE FILLED WEIGHT (mg)	1821 mg \pm 2%	1812 mg
08.	UNIFORMITY OF DOSAGE UNITS	Maximum allowed acceptance value L1=15.0	Complies
09.	RECONSTITUTION TIME	Not more than 120 Seconds.	109 Seconds
10.	CONSTITUTED SOLUTION	a) The solid dissolves completely, leaving no visible residue as	Complies

Prepared By	Checked By	Approved By
Sign./Date:  14/09/2023	Sign./Date:  14/09/2023	Sign./Date:  14/09/2023
Name: Abhishek Rana	Name: Payal Bisht	Name: Gaurav Kumar
Designation: Officer-QC	Designation: Sr. Officer-QC	Designation: Head-QC

Format No.: GM/QC/011/F07-00

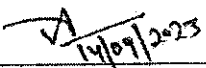
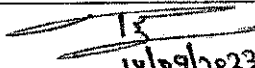
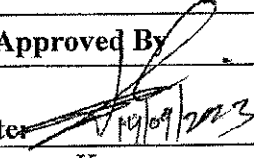
Certificate of Analysis

Zyphar's Pharmaceuticals Pvt. Ltd.
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Product Name	AZETRIM 1		
Generic Name	AZTREONAM FOR INJECTION USP 1gm	Page No.	2 of 2
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Date of Sampling	31/08/2023	Date of Release	14/09/2023
Sampled By	Dheeraj	Specification No.	FP/SPC/02/026

Sr. No.	Test	Specification	Result
	Completeness & Clarity Of Solution	undissolved matter. un-dissolved 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.	Complies
11.	PARTICULATE MATTER i)By Visible ii)By LBPC A)Particles $\geq 10\mu\text{m}$ B)Particles $\geq 25\mu\text{m}$	The solution after reconstitution should free from particles of foreign matters, black particles that can be observed on visual inspection. Not more than 6000/Container Not more than 600/ Container	Complies 883 10
12.	CONTENT OF ARGININE (By HPLC %w/w) L-Arginine 780 mg	NLT 702.00mg and NMT 936.00mg (NLT 90.0% and NMT 120.0% of the label amount Arginine)	783.3mg/vial 100.4%
13.	ASSAY (By HPLC %w/w) Each vial contains : Sterile Aztreonam USP Eq. to Aztreonam 1000 mg	NLT 900.00mg and NMT 1050.00 mg (NLT 90.0 % and NMT 105.0 % of the labeled claim)	998.3mg/vial 99.8%

Remark. The test sample complies /does not Complies with above specification.

Prepared By	Checked By	Approved By
Sign./Date:  14/09/2023	Sign./Date:  14/09/2023	Sign./Date:  14/09/2023
Name: Abhishek Rana	Name: Payal Bisht	Name: Gaurav Kumar
Designation: Officer-QC	Designation: Sr. Officer-QC	Designation: Head-QC