

 DRUG INTERNATIONAL LIMITED	Form : Test Report Drug International Ltd. Laboratory	Document No.	FM-DIL-GN-021
		Revision No.	01
		Effective Date	01 Aug 2020

Test Report No.	RP-CM-2010-0022
Report Date	04-Oct-2020

Customer Information

Company	ATI Limited
Address	DIL Laboratory, Drug International Ltd. (Unit-2) 13A, 14A, Tongi I/A, Gazipur, Bangladesh.
Contact No.	+88 02 58955573
Email	ati@atilimited.net

Sample Information

Name of Sample	Flucloxacillin Sodium Micronized
Sample ID	C20R0022
Date of Sample Received	14-Apr-2020
Batch No	0120
Manufacturing Date	06-Apr-2020
Expiry Date	23-Apr-2020
Received Quantity	7.0 gm
Condition of Sample	5

Condition as received	In Case of "Abnormal" please specify
<input checked="" type="checkbox"/> Normal <input type="checkbox"/> Abnormal	<input type="radio"/> Leak <input type="radio"/> Broken <input type="radio"/> Size <input type="radio"/> Weight <input type="radio"/> Other

Test Date	null
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Detailed Description of Test Analysis :

SL.	Test Items	Acceptance Criteria	Test Result	Unit	LOD	Reference Method
1 (*)	Appearance	White or almost white, hygroscopic, crystalline powder	ok	n/a	-	
2 (*)	Solubility	Freely soluble in water and methanol, soluble in ethanol (96 per cent).	ok	n/a	-	
3 (*)	Identification	A) The IR absorption spectrum of the sample should be concordant with the infrared absorption spectrum of the Flucloxacillin Sodium standard. B) It gives Reaction (a) of Sodium	ok	n/a	-	
4 (*)	Appearance of Solution	Solution S is clear. The absorbance of solution S is measured at 430 nm is not greater than 0.04	ok	n/a	-	
5 (*)	pH	5.0 to 7.0	ok	n/a	-	
6 (*)	Specific Optical Rotation	+ 158° to + 168° (Anhydrous substance).	ok	null	-	
7 (*)	Related Substances	Each impurity: Not more than 1.0% Total Impurities: Not more than 5.0%	ok	%	-	
8 (*)	Water	3.0% to 4.5% determined on 0.300 g.	ok	%	-	
9 (*)	Assay (As Such Basis)	As Flucloxacillin	ok	%	-	

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SL.	Test Items	Acceptance Criteria	Test Result	Unit	LOD	Reference Method
10 (*)	Assay (On Anhydrous Basis)	95.0% to 102.0% (as Flucloxacillin Sodium)	ok	%	-	

Remarks (If any)

Not Applicable

Additional Information from Laboratory

Not Applicable

Additional Information from Customer

Not Applicable

Definition/ Abbreviation

1. *means that item(s) is/are not accreditation.



15.04.2020

Verified by
MD. ABDUL OWARES
General Manager (Factory)



15.04.2020

Approved by
MD. ABDUL OWARES
General Manager (Factory)

End of the Test Report

The above results are effect only to the sample tested as indicate in this report and shall not be produced except in full, without approval of the laboratory.