

 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-2010-0007
Report Date	04-Oct-2020

Customer Information

Company	Drug International Ltd
Address	DIL Laboratory, Drug International Ltd. (Unit-2) 13A, 14A, Tongi I/A, Gazipur, Bangladesh.
Contact No.	+880-02-9811886
Email	Not Applicable

Sample Information

Name of Sample	Flucloxacillin Sodium Micronized
Sample ID	C20R0007
Date of Sample Received	11-Apr-2020
Batch No	BN002
Manufacturing Date	15-Apr-2020
Expiry Date	23-Jul-2020
Received Quantity	6.82 gm
Condition of Sample	2nd flucloxacillin sample

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	comply	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	comply	n/a	-	
5 (*)	pH	5.0 to 7.0	comply	n/a	-	
6 (*)	Specific Optical Rotation	+ 158° to + 168° (Anhydrous substance).	comply	null	-	
7 (*)	Related Substances	Each impurity: Not more than 1.0% Total Impurities: Not more than 5.0%	comply	%	-	
8 (*)	Water	3.0% to 4.5% determined on 0.300 g.	result is ok	%	-	
9 (*)	Assay (As Such Basis)	As Flucloxacillin	result is 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)	result is ok	%	-	

Remarks (If any)

remarks for flucloxacillin 07

Additional Information from Laboratory

note for flucloxacillin 07

Additional Information from Customer

Not Applicable

Definition/ Abbreviation

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


DRUG INTERNATIONAL LIMITED

11.04.2020

Verified by
MD. ABDUL OWARES
General Manager (Factory)


DRUG INTERNATIONAL LIMITED

11.04.2020

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.