

# 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-2010-0008		
Report Date	04-Oct-2020		
<b>Customer Information</b>			
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	C20R0008		
Date of Sample Received	11-Apr-2020		
Batch No	BN001		
Manufacturing Date	09-Apr-2020		
Expiry Date	19-Sep-2020		
Received Quantity	6.8 gm		
Condition of Sample	1st flucloxaicillin sample		
Condition as received	In Case of "Abnormal" please specify		
✓ Normal	Leak Broken Size Weight		
Abormal	Other		
Test Date	null		

### **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	nice	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 (*)	рН	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%	best result	%	-	
8 (*)	Water	3.0% to 4.5% determined on 0.300 g.	best result	%	-	
9 (*)	Assay (As Such Basis)	As Flucloxacillin	best result	%	-	



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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)	best result	%	-	

#### Remarks (If any)

Remarks for flucxocilin 08

#### **Additional Information from Laboratory**

note for flucxocilin 08

#### **Additional Information from Customer**

Not Applicable

#### **Definition/ Abbreviation**

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

11.04.2020

Dort Sout

Verified by MD. ABDUL OWARES General Manager (Factory) 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.