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-GN-2010-0004
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	Capsule Demoxil 500
Sample ID	CM20F0004
Date of Sample Received	06-Apr-2020
Batch No	0120
Manufacturing Date	06-Apr-2020
Expiry Date	06-Apr-2022
Received Quantity	78.0 null
Condition of Sample	warehouse

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 (*)	Description	A white opaque color cap and body capsule, printed monogram in black ink on cap and	n3	n/a	-	
2 (*)	Identification	The retention time of main peak of sample in chromatogram is identical to that of Amoxicillin standard.	n5	n/a	-	
3 (*)	Moisture Content	Not more than 14.5 % w/w	n6	%	-	
4 (*)	Average Filling Weight	Claim: 605.0 mg/Capsule (±5.0%)	n4	null	-	
5 (*)	Uniformity of Weight	Not more than 2 of the 20 capsules deviate from the average weight by more than (±) 7.5 % and none deviates by more than (±) 15%	n1	%	-	
6 (*)	Size of Capsule	Size # 0	n8	n/a	-	
7 (*)	Disintegration Time	Not more than 30 minutes.	n2	null	-	
8 (*)	Dissolution Rate	Not less than 80 % (Q) is dissolved in 60 minutes.	n7	%	-	
9 (*)	Leak Test	Must be leak proof.	a1	n/a	-	

SL.	Test Items	Acceptance Criteria	Test Result	Unit	LOD	Reference Method
10 (*)	Uniformity of Dosage Unit	i) Acceptance value: AV is less than or equal to L1=15 (Specified in 10 units) ii) Acceptance value: AV is less than or equal to L1=15 and no unit is out of range (1-L2*0.01) M to (1+L2*0.01) M (specified in 30 units)	a4	n/a	-	
11 (*)	Content of Active Ingredient Found in Assay Per Capsule	Amoxicillin BP 462.5 mg to 550.0 mg	a2	null	-	
12 (*)	Potency (% Claim)	92.5 to 110.0 % of the stated amount.	a3	%	-	
13 (*)	Blister / Blistering / Carton / Cartooning / Inserts	10 capsules in each blister & 3 blisters with one insert in each inner carton.	a5	n/a	-	
14 (*)	Total Combined Yeasts and Molds Count (TYMC)	100 CFU/gm	c1	cfu/g	-	
15 (*)	Escherichia coli	Absent in 1 gm	c2	n/a	-	
16 (*)	Total Aerobic Microbial Count (TAMC)	1000 CFU/gm	c3	cfu/g	-	

Remarks (If any)

Tm Remarks

Additional Information from Laboratory

TM Note

Additional Information from Customer

Not Applicable

Definition/ Abbreviation

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

06.04.2020

Verified by
MD. ABDUL OWARES
General Manager (Factory)

06.04.2020

Approved by
MD. ABDUL OWARES
General Manager (Factory)

 # End of the Test Report #