

# **Form : Test Report**Drug International Ltd. Laboratory

Document No.	FM-DIL-GN-021			
Revision No.	01			
<b>Effective Date</b>	01 Aug 2020			

T (D)	DD CN 2010 0010			
Test Report No.	RP-GN-2010-0019			
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	Shell Flupen 500			
Sample ID	CM20R0019			
Date of Sample Received	14-Apr-2020			
Batch No	0220			
Manufacturing Date	15-Apr-2020			
Expiry Date	30-Apr-2020			
Received Quantity	406.0 null			
Condition of Sample	8			
Condition as received	In Case of "Abnormal" please specify			
✓ Normal	Control Leak Description On the second of			
Abormal	Other			
Test Date	null			

# **Detailed Description of Test Analysis:**

SL.	Test Items	Acceptance Criteria	Test Result	Unit	LOD	Reference Method
1 (*)	Description	i) Cap - White opaque color and printed monogram in Grey ink. ii) Body - White opaque color and printed Flupen- 500 in red brick ink in between over and and underline.	gh	n/a	-	
2 (*)	Weight Variation	Not more than ± 10%	df	%	-	
3 (*)	Average Weight	97 mg ± 10%	as	null	-	
4 (*)	Outer Diameter	Cap: $7.63 \pm 0.06$ mm Body : $7.32 \pm 0.06$ mm	hfg	null	-	
5 (*)	Length	Cap : $11.18 \pm 0.36$ mm Body: $18.72 \pm 0.36$ mm	cxv	null	-	
6 (*)	Size	#0	rt	n/a	-	
7 (*)	Disintegration Time	Not more than 10 minutes.	zxc	null	-	
8 (*)	Loss On Drying (LOD)	12.5% to 17.5%	kjk	%	-	
9 (*)	Total Aerobic Microbial Count (TAMC)	1000 CFU/gm	ok	cfu/g	-	



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10 (*)	Total Combined Yeasts and Molds Count (TYMC)	100 CFU/gm	ds Count (TYMC)	cfu/g	-	
11 (*)	Escherichia coli	Absent in 1 gm	Escherichia c	n/a	-	
12 (**)	Salmonella spp.	Absent in 10 gm	lmonella sp	n/a	-	
13 (*)	Pseudomonas aeruginosa	Absent in 1gm	nas aeruginosa	n/a	-	
14 (*)	Staphylococcus aureus	Absent in 1 gm	taphylococcus a	n/a	-	

#### Remarks (If any)

tm new remarks

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

Not Applicable

# **Additional Information from Customer**

Not Applicable

### **Definition/ Abbreviation**

1. \*means that item(s) is/are not accreditation. 2. \*\*means that item(s) is/are sub-contracted.

Verified by

MD. ABDUL OWARES General Manager (Factory)

14.04.2020

14.04.2020

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.