

Regional Drugs Testing Laboratory Directorate General of Health Services, Guwahati (India) - 781022 Fax: 0361-2338555/2330555 Phone No.0361 2338555

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FORM 13

(See rule 46)

CERTIFICATE OF TEST OR ANALYSIS BY GOVERNMENT ANALYST UNDER SECTION 25(1) OF THE DRUGS AND COSMETICS ACT, 1940

1. Name of Inspector from whom received

Dillin N.S. Sarkar

: Lalruatdika Varte

Drugs Inspector

Office of the Senior Chief Medical Officer

Kolasib, Mizoram-796082

2. Serial No. and date of Inspector's memorandum

: KLB/02/2024/DRUGS

Dated Kolasib, the 20th September, 2024

3. Number of Sample

: NIL

4. Date of receipt

: 16-OCT-2024

5. Names of drugs purporting to be contained in the sample : Fluconazole Tablets IP 150 mg (FLUZON 150)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg.	Date of Exp.	Mfg. By
LSD/GUW/2024-	GUW/LS/2024-	IIXOXXXXXXX	II IN 2002	MANGOOG	CADILA PHARMACEUTICALS LIMITED
25/1189	89 25/1208 JKCK23002 JUN.2023 MAY2026	MAY2026	Industrial Growth Center		
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6. Condition of seals on

[the packet or on portion of sample or container]

Seals were intact & identical to the specimen impression of the seal received

from Drugs Inspector

7. Result of test or analysis with protocols or test or analysis applied : Please see below

Date of Testing: From 29-Oct-2024 To 06-Nov-2024

COMPOSITION

Each uncoated tablet contains:

Fluconazole IP 150 mg

Protocol Applied: I.P. 2023

Sr No.	Test Name	Result	Limits
1	Description	Pink colour, round, bi-convex, uncoated tablets, packed in aluminium blister pack.	NA
2	Identification	Gives positive test for Fluconazole.	NA
3	Average weight	0.2305 gm.	NA
4	Uniformity of weight	Complies.	NA
5	Dissolution	Complies (Release of all six units found above 'Q' 80+5%).	NLT 80 % of Claim

<u>Assay</u>

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
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1	Fluconazole	151.96 mg/Tablet	150 mg/Tablet	101.306	90 % to 110 %	I.P. 2022
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In the opinion of the undersigned the sample referred to above **is of standard quality** as defined in the Drugs and Cosmetics Act, 1940, and Rules thereunder for the reasons given below:-

The sample conforms to I.P. with respect to the above tests only.

Date: 13-NOV-2024

GOVERNMENT ANALYST

Dilip Kr. Sarkar Government Analyst R.D.T.L., Guwahati-22

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