

Regional Drugs Testing Laboratory Directorate General of Health Services, Guwahati (India) - 78102 Fax: 0361-2338555/2330555 Phone No.0361 2338555

Email: rdtlguwahati@cdsco.nic.in

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

: MR.R.VANLALRUATA

Dillip Mr. Sarkar Government Analyst ASSISTANT DIRECTOR (F & D)
OFFICE OF CHIEF MEDICAL OFFICER,

AIZAWL, MIZORAM, PIN-796017.

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

: MZ/24/A 'E'/04

Date 15/10/24

Testino

Guwaha

3. Number of Sample

: Nil

4. Date of receipt

: 01-NOV-2024

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

Lab. Sample No.	Report No.	Batch No.	Date of Mfg.	Date of Exp.	Mfg. By
LSD/GUW/2024- 25/1286	GUW/LS/2024- 25/1314	T-2589	Dec-2023	Nov-2025	Jackson Laboratories Pvt.Ltd. 22-24, Majitha Road, Bye Pass,
		Y 63		₹ .	Amritsar-143 001(India)

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 26-Nov-2024 To 27-Nov-2024

COMPOSITION

Each uncoated tablet contains: Fluconazole IP 150 mg.

Protocol Applied: J.P. 2022

Sr No.	Test Name	Result	Limits
1	Description	White, circular, flat, scored on one side, uncoated tablet and engraved 'JACKSON' on the other side, packed in amber colour blister pack.	NA
2	Identification	Gives positive test for Fluconazole.	NA
3	Average weight	0.4129 gm.	NA
4	Uniformity of weight	Complies.	NA
5	Dissolution	Complies (Release of all six units found above 'Q' 80+5%).	NLT 80 % c

Assay

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
		V V				1

1	es come co						
15	1 1	Fluconazole	156.295 mg/Tablet	150 mg/Tablet	104.196	90 % to 110 %	I.P. 2022
103	10 3400	33	ALC: Y				1867
1	Sibni	100	1 1,4 % 1	remark have a 196 or			

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: 29-NOV-2024

GOVERNMENT ANALYST

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

CDSCO CONTROL STANDARD CONTROL OR STANDARD CON