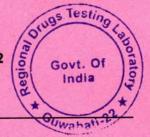


## **Regional Drugs Testing Laboratory** Directorate General of Health Services, Guwahati (India)-781022 Fax: 0361-2338555/2330555 Phone No.0361 2338555

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

: Mrs. C. Ramdinmawii

Assistant Director (Food & Drugs) C.M.O. Office, Champhai-796321

Mizoram

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

: 037/IPA-CPI/24

Date: 17/01/2025

3. Number of Sample

: Nil

4. Date of receipt

: 03-FEB-2025

5. Names of drugs purporting to be contained in the sample: Fluconazole Tablets I.P. 150 mg

(Megmazole-150 Tablets)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg. & Exp	Marketed By	Mfg. By
LSD/GUW/2025- 26/0040	GUW/LS/2025- 26/48	TSF-C0116	01/2024 12/2025	NA CR	Spen Formulations Pvt. Ltd. Plot No-123, Industrial Area, Mehatpur, Distt. UNA- 174315
	9	5			(H.P.)

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

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

Date of Testing: From 18-Feb-2025 To 03-Apr-2025

COMPOSITION

Each uncoated tablet contains:

Fluconazole I.P. 150 mg

Protocol Applied: I.P. 2022

Sr No.	Test Name	Result	Limits
1 Description		Pink colour, elongated, bi-convex, uncoated tablet, plain on both side, packed in blister pack in paper box.	
2	Identification Gives positive test for Fluconazole.		NA
3	Average weight	0.6072 gm.	NA
4	Uniformity of weight	Complies.	NA

## Assay

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
1	Fluconazole	325.39 mg/Tablet	150 mg/Tablet	216.926	90 % to 110 %	I.P. 2022
A STAN						

In the opinion of the under signed the sample referred to above is not of standard quality as defined in the Drugs and Cosmetics Act, 1940, and Rules thereunder for the reasons given below:-

The sample does not conform to I.P. with respect to Assay/Content of "Fluconazole".

Date: 08-APR-2025

GOVERNMENT ANALYST

Dilip Kr. Sarkar

Government Analyst
R.D.T.L., Guwahati-22

Report in red coloured paper indicates the sample is Not of Standard Quality.

----- END OF REPORT -----

