



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	Spen Formulations Pvt. Ltd. Plot No-123, Industrial Area, Mehatpur, Distt. UNA- 174315 (H.P.)

6. Condition of seals on : Seals were intact & identical to the
[the packet or on portion of sample or container] 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 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.	NA
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

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-----

