

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

Name of Inspector from whom received

B.LALZAMLIANA,

Drugs Inspector (F & D),

CMO West Office,

Kulikawn, Aizawl- 796005

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

: B.11012/5/2024-CMO (W)/DRUGS/18

Dated Aizawl, the 12th December, 2024

3. Number of Sample

: SMP/MZ/TMT/2024-2025/023

4. Date of receipt

: 06-JAN-2025

5. Names of drugs purporting to be contained in the sample: Fluconazole Capsules IP (DR FZOL 150)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg.	Date of Exp.	Mfg. By
LSD/GUW/2024- 25/1915	GUW/LS/2024- 25/1942	NC-1570	05/2024	/04/2026	Neptune Life Sciences Pvt. Ltd. 100-B, EPIP, Phase-II, Thana, Baddi- 173205 (H.P.)

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 18-Feb-2025 To 24-Mar-2025

COMPOSITION

Each hard gelatin capsule contains:

Fluconazole I.P. 150 mg

Sr No.	Test Name	Result White powder in red colour hard gelatin capsule, packed in strip pack in paper carton. Gives positive test for Fluconazole.		
1	Description			
2	Identification			
3	Average filled content	0.3525 gm.	NA	
4	Uniformity of weight	Complies.	NA	
5	Dissolution	Complies (Release of all six units were found above 'Q' 80 +5%).	NLT 80 % of claim	

<u>Assay</u>

Sr.No Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
a -					

1 1	Fluconazole	161.42 mg/Capsule	150 mg/Capsule	107.613	90 % to 110 %	1 D 0000
					00 70 10 110 70	I.P. 2022
In the eni						

--- END OF REPORT -----

In the opinion of the under signed 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: 25-MAR-2025

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

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