

Regional Drugs Testing Laboratory

Directorate General of Health Services, Guwahati (India) - 781022

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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

: R. Vanlalsiama, Asst Director (F D)

Asst Director (F&D), CMO Office, Lunglei.

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

:8,27-JAN-2025

3. Number of Sample

: MS-26

4. Date of receipt

: 07-FEB-2025

5. Names of drugs purporting to be contained in the sample : Metronidazole Tablet IP 400 mg (Metrol-400)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg. & Exp	Marketed By	Mfg. By
LSD/GUW/2025- 26/0047	GUW/LS/2025- 26/51	ME-324	Apr-2024 Mar-2026	NA, NA	High Tech Pharma,, Plot No. 49, Khandelwal compound, Nemwar road, Palda, Dist. Indore MP-452020

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

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Date of Testing: From 11-Mar-2025 To 02-Apr-2025

COMPOSITION

Each coated tablet contains:

Metronidazole IP 400 mg

Protocol Applied : I.P. 2022

Sr No.	Test Name	Result	Limits		
1 Description		Pink colored, round, bi-convex, coated tablets, in blister pack.	NA		
2	Identification	dentification Gives positive test for Metronidazole.			
3	Average weight	0.6189 g	NA		
4	Uniformity of weight	Complies.	NA		
5	Dissolution	Complies.	NLT 85 % of claim		

<u>Assay</u>

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

1	Metronidazole	401.7 mg/Tablet	400 mg/Tablet	100.425	95 % to 105 %	I.P. 2022
						X

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 there under for the reasons given below:-

The sample conform to claim as per I.P. 2022 in respect of test performed.

double

Date: 07-APR-2025

GOVERNMENT ANALYST

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

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

