

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

: K.Lalngilneia, Asst. Director (F and D) Asst. Director (F&D), CMO Office,

Mamit Distric: Mamit, Mizoram- 796441.

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

: B.17011/12/09-CMO(M)/DRUGS/36 , 09-DEC-2024

3. Number of Sample

: MD08/36

Date of receipt

: 20-DEC-2024

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

Lab. Sample No.	Report No.	Batch No.	Date of Mfg.	Date of Exp.	Mfg. By
LSD/GUW/2024- 25/1618	GUW/LS/2024- 25/1646	ME-224	Apr-2024	Mar-2026	High Tech Pharma, Plot No. 49, Khandelwal compound, Nemwar road, Palda, Dist.

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 23-Jan-2025 To 28-Jan-2025

COMPOSITION

Each coated tablet contains: Metronidazole I.P. 400 mg

Protocol Applied: I.P. 2022

Sr No.	Test Name	Result	Limits	
1	Description	Pink colored, round shaped, bi-convex tablets, in blister pack.	NA	
2	Identification	Gives positive test for Metronidazole.	NA	
3	Average weight	0.6110g	NA	
4	Uniformity of weight	Complies.	NA	
5	Dissolution	Complies.	NLT 85 % of claim	

<u>Assay</u>

	Sr.No	Ingredient Name	Found	01:	T		
	Or.NO	ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
1			2 A				

-	1	Metronidazole	395.21 mg/Tablet	400 mg/Tablet	98.802	95 % to 105 %	I.P. 2022
In	the opinio	on of the undersi	<u> </u>			250	

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.

Date: 03-FEB-2025

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GOVERNMENT ANALYST

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

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

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