

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

Govt. Of India

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

: Lalruatadika Varte

Drugs Inspector

Office of the Senior Chief Medical Officer

Kolasib, Mizoram- 796082

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

:KLB/01/2024/DRUGS

Dated Kolasib, the 20th September, 2024

3. Number of Sample

:Nil

4. Date of receipt

:16-OCT-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- 25/1477	GUW/LS/2024- 25/1501	ME-923	8/23	7/25	High Tech Pharma Plot No. 49,Khandelwal compound,
				Y	Nemwar road, Palda, Dist. Indore MP

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 26-Nov-2024To 07-Jan-2025

COMPOSITION

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

Protocol Applied : 1 P 2022

Sr No. Test Name		Result	Limits	
1	Description	Pink colour, round, bi-convex, film coated tablet, plain on both sides, packed in blister pack.	NA	
2	Identification	Gives positive test for Metronidazole.	NA	
3	Average weight	0.6176 gm.	NA	
4	Uniformity of weight	Complies	NA	
5	Dissolution	Complies (Release of all six units are found above 'Q' 85+5%).	NLT 85 % of Claim	

Assay

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
	-	\$ W				

1	Metronidazole	406.82 mg/Tablet	400 mg/Tablet	101.705	95 % to 105 %	I.P. 2022
			A Blanks			

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: 08-JAN-2025

GOVERNMENT ANALYST

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

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

