



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 : P Laltlanzova Assistant Drugs Inspector (Food and Drugs)
CMO Office,
Lawngtlai District- 796891, Mizoram
2. Serial No. and date of Inspector's memorandum : 7/067/IPA-LTI/III-25, 11-AUG-2025
3. Number of Sample : Not mentioned.
4. Date of receipt : 03-SEP-2025
5. Names of drugs purporting to be contained in the sample : Metronidazole Tablets I.P. 400 mg. (Metrobex-400)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg. & Exp	Marketed By	Mfg. By
LSD/GUW/2025-26/1178	GUW/LS/2025-26/1149	MT-24027	May-2024 Apr-2026	NA	Medivs Biosciences Pvt. Ltd., Khasra No. 1294, Mota, Meerut Road, Ghaziabad, UP- 201003

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 30-Oct-2025 To 07-Jan-2026

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

Protocol Applied : I.P. 2022

Sr No.	Test Name	Result	Limits
1	Description	Orange colored, round, biconvex, film coated tablets, in blister pack.	
2	Identification	Gives positive test for Metronidazole.	
3	Average weight	0.61158 g	
4	Uniformity of weight	Complies.	+5 % of Average weight
5	Dissolution	Does not comply.	NLT 85% of claim

6	Level S1 (6 units)	Does not comply. Release of Metronidazole of each individual unit is found as follows: Unit 1=27.68%; Unit 2=30.69%; Unit 3=25.27%; Unit 4=34.90%; Unit 5=43.93%; Unit 6=48.14% . Release of Metronidazole of all 06 units are found less than 90% of claim i.e. (Q+5%) where Q is 85% of claim.	Each unit is not less than Q+5% i.e. 90% of claim where Q is 85%.
7	Level S2 (6 units)	Does not comply. Release of Metronidazole of each individual unit is found as follows: Unit 1=25.94%; Unit 2=30.76%; Unit 3=42.23%; Unit 4=39.81%; Unit 5=41.02%; Unit 6=42.83% . Average release of Metronidazole of 12 units (S1+S2) is 36.1% of claim. Release of all units found less than 70% of claim (Q-15%).	Average of 12 units (S1+S2) $\geq$ 85% of claim and no unit is less than 70% of claim (Q-15%)
8	Level S3	Does not comply. Release of Metronidazole of all 12 units are found less than (Q-15%) i.e. 70% of claim as well as less than (Q-25%) i.e.60% of claim.	Average of 24 units (S1+S2+S3) $\geq$ 85% of claim, not more than 2 units are less than 70% of claim (Q-15%) and no unit is less than 60% of claim (Q-25%)

Assay

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
1	Metronidazole	401.22 mg/Tablet	400 mg/Tablet	100.305	90 % to 110 %	I.P. 2022

In the opinion of the undersigned the sample referred to above **is not of standard quality** as defined in the Drugs and Cosmetics Act, 1940, and Rules there under for the reasons given below:-

The sample does not comply as per I.P. 2022 with respect to the test for "Dissolution" of Metronidazole.

Date: 29-JAN-2026

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

Report in the red colored paper indicates the sample is not of standard quality.

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