

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

: K. Lalngilneia

Asst. Director (F&D)

CMO Office, Mamit Distric: Mamit

Pin - 796441.

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

: B.17011/12/09-CMO (M)/DRUGS/37

Date 9th Dec, 24

3. Number of Sample

:MD08/37

Date of receipt

:08-JAN-2025

5. Names of drugs purporting to be contained in the sample: Metronidazole Injection I.P. 0.5% w/v (METROZEST);100ml

Lab. Sample No.	Report No.	Batch No.	Date of Mfg.	Date of Exp.	Mfg. By
LSD/GUW/2024- 25/1846	GUW/LS/2024- 25/1868	2822-216	08/2022	07/2025	ZEE LABORATORIES LTD. Behind 47,Industrial Area, Paonta Sahib-173025

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 11-Mar-2025

COMPOSITION

Each 100 ml contains

Metronidazole I.P. 500 mg

Protocol Applied: I

Sr No.	Test Name	Result	Limits	
1	Description	Colourless liquid in sealed translucent plastic container.	NA	
2	Identification	Gives positive test for Metronidazole.	NA	
3	рH	Complies (Found: 5.41).	4.5 to 7.0	
4	Sterility	Complies.	NA	
5	Bacterial endotoxins	Complies.	NA	

<u>Assay</u>

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
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9.1	Metronidazole	486.2 mg/100ml	500 mg/100ml	97.24	90 % to 110 %	I.P. 2022
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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 claim with respect to the above tests only.

Date: 17-MAR-2025

GOVERNMENT ANALYST

Dilip Kr. Sarkar

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

