

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

1. Name of Inspector from whom received

: Mrs. C. Ramdinmawii, Assistant Director (Food and

Drugs)

C.M.O. Office,

Champhai-796321 Mizoram

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

: 370/24, 30-AUG-2024

3. Number of Sample

: NIL

4. Date of receipt

: 06-SEP-2024

5. Names of drugs purporting to be contained in the sample : Ofloxacin & Ornidazole Tablets I.P. (Mon flox- OZ)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg.	Date of Exp.	Mfg. By
LSD/GUW/2024- 25/1394	GUW/LS/2024- 25/1415	PNT4-0400D	Jun-2024	May-2026	M/s. Pacific India,, Village Dhana (Bagh Bania) Tehsil Nalagarh, District Solan H.P.

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 11-Dec-2024 To 13-Dec-2024

COMPOSITION

Each film coated tablet contains:

Ofloxacin I.P. 200mg Ornidazole I.P. 500mg

Protocol Applied: I.P. 2022

Sr No.	Test Name	Result	Limits	
1	Description	Orange colored, elongated shaped, biconvex, scored on one surface, film coated tablets, in blister pack.	NA	
2	Identification	Gives positive test for Ofloxacin and Ornidazole.	NA	
3	Average weight	0.8507 gm	NA	
4	Uniformity of weight	Complies.	NA	
5	Dissolution	Complies.	NA	
6	Dissolution (for Ofloxacin)	Complies.	NLT 75 % of claim	
7	Dissolution (for Ornidazole)	Complies.	NLT 75 % of claim	

Assay

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
1	Ofloxacin	206.72 mg/Tablet	200 mg/Tablet	103.36	90 % of claim to 110 % of claim	I.P. 2022
2	Ornidazole	494.49 mg/Tablet	500 mg/Tablet	98.898	90 % of claim to 110 % of claim	I.P. 2022

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 conforms to claim as per I.P. 2022 in respect of test performed.

Date: 18-DEC-2024

GOVERNMENT ANALYST

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

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