



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** : Lalruatdika Varte, Drugs Inspector
Office of the Chief Medical Officer
Kolasib, Mizoram- 796082
2. **Serial No. and date of Inspector's memorandum** : KLB/09/2024/DRUGS , 26-NOV-2024
3. **Number of Sample** : NIL
4. **Date of receipt** : 09-DEC-2024
5. **Names of drugs purporting to be contained in the sample** : Norfloxacin Tablets I.P. 400mg

Lab. Sample No.	Report No.	Batch No.	Date of Mfg.	Date of Exp.	Mfg. By
LSD/GUW/2024-25/1726	GUW/LS/2024-25/1750	NFXT-1002	Jun-2023	May-2026	WINGS BIOTECH LLP, 43 & 44, HPSIDC, Industrial Area, Baddi - 173205 (H.P.)

6. **Condition of seals on** : Seals were intact & identical to the specimen impression of the seal received from Drugs Inspector.
 [the packet or on portion of sample or container]

7. **Result of test or analysis with protocols or test or analysis applied** : Please see below

Date of Testing : From 08-Jan-2025 To 18-Feb-2025

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

Protocol Applied : I.P. 2022

Sr No.	Test Name	Result	Limits
1	Description	Orange colored, oval shape, bi-convex, scored on one surface, film coated tablets, in blister pack.	NA
2	Identification	Gives positive test for Norfloxacin.	NA
3	Average weight	0.5574 g	NA
4	Uniformity of weight	Complies.	±5% of average weight
5	Dissolution	Does not comply.	NLT 70% of claim
6	Level S1 (6 units)	Does not comply. Release of Norfloxacin of each individual unit is found as follows: Unit 1=23.0%; Unit 2=22.2%; Unit 3=21.8%; Unit 4=22.2%; Unit 5=22.5%; Unit 6=24.4% . Release of Norfloxacin of all 06 units are found less than 75% of claim i.e. (Q+5%) where Q is 70% of claim.	Each unit is not less than Q+5% i.e., 75% of claim where Q is 70%.

7	Level S2 (6 units)	Does not comply. Release of Norfloxacin of each individual unit is found as follows: Unit 1=24.93%; Unit 2=22.99%; Unit 3=14.08%; Unit 4=19.26%; Unit 5=20.56%; Unit 6=23.47% . Average release of Norfloxacin of 12 units (S1+S2) is 21.8% of claim which is less than Q i.e. 70% of claim. Release of Norfloxacin of all 12 units are found less than 55% of claim(Q-15%).	Average of 12 units (S1+S2) \geq 70% of claim and no unit is less than 55% of claim (Q-15%)
8	Level S3	Release of Norfloxacin of all 12 units are found less than (Q-15%) i.e. 55% of claim as well as (Q- 25%) i.e. 45% of clam.	Average of 24 units (S1+S2+S3) \geq 70% of claim, not more than 2 units are less than 55% of claim (Q-15%) and no unit is less than 45% of claim (Q-25%)

Assay

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
1	Norfloxacin	432.8 mg/Tablet	400 mg/Tablet	108.2	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 Norfloxacin.

Date: 20-FEB-2025

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

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

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