

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 : Mr. R. Vanlalruata,
Assistant Director (F&D)
Office of Chief Medical Officer,
Aizwal, Mizoram- 796017
2. Serial No. and date of Inspector's memorandum : MZ/24/A 'E'/09 , Date: 15-OCT-2024
3. Number of Sample : -
4. Date of receipt : 01-NOV-2024
5. Names of drugs purporting to be contained in the sample : Nitrofurantoin Tablets IP 100 mg

Lab. Sample No.	Report No.	Batch No.	Date of Mfg.	Date of Exp.	Mfg. By
LSD/GUW/2024-25/1724	GUW/LS/2024-25/1749	T-2485	Nov-2023	Oct-2025	Jackson Laboratories Pvt.Ltd, 22-24, Majitha Road, Bye Pass, Amritsar- 143001(India)

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 12-Feb-2025 To 18-Feb-2025

COMPOSITION : Each uncoated tablet contains:
 Nitrofurantoin IP 100 mg

Protocol Applied : I.P. 2022

Sr No.	Test Name	Result	Limits
1	Description	Light yellow colour, round, flat, uncoated tablet having engraved "JACKSON" on one side and a dosage line on the other side in blister strip.	NA
2	Identification	Gives positive test for Nitrofurantoin.	NA
3	Average weight	0.3917 g	NA
4	Uniformity of weight	Passes the test.	NA
5	Dissolution	Does not comply.	

Level	Number Tested	Result	Acceptance Criteria
S1 (60 Min)	6	Drug release of 6 units are found as follows: i. 22.99%, ii. 22.1%, iii. 16.1%, iv. 15.3%, v. 15.6%, vi. 21.0%. Drug release of all units are found less than 25+5%.	Each unit is not less than Q+5% where "Q" is 25% in 60 minutes
S1 (120 min)	6	Drug release of 6 units are found as follows: i. 38.7%, ii. 39.5%, iii. 36.8%, iv. 21.5%, v. 28.2%, vi. 29.0%. Drug release of all units are found less than 85+5%.	Each unit is not less than Q+5% where "Q" is 85% in 120 minutes
S2 (60 Min)	6	Drug release of 6 units are found as follows: i. 21.3%, ii. 21.2%, iii. 23.1%, iv. 22.1%, v. 10.7%, vi. 10.6%. Average of 12 units (S ₁ +S ₂) 18.5%.	Average of 12 units (S ₁ +S ₂) is ≥Q, and no unit is less than Q-15% in 60 minutes
S2 (120 min)	6	Drug release of 6 units are found as follows: i. 29.1%, ii. 29.0%, iii. 28.5%, iv. 31.4%, v. 30.6%, vi. 29.8%. 1. Average drug release of 12 units (S ₁ +S ₂) 31.0% 2. Drug release of all units are found less than 60%, i.e. Q-25%.	Average of 12 units (S ₁ +S ₂) is ≥Q, and no unit is less than Q-15% in 120 minutes
S3 (60 Min)	12	--	Average of 24 units (S ₁ +S ₂ +S ₃) is ≥Q, not more than 2 units are less than Q-15% and no unit is less than Q - 25% in 60 minutes
S3 (120 min)	12	--	Average of 24 units (S ₁ +S ₂ +S ₃) is ≥Q, not more than 2 units are less than Q-15% and no unit is less than Q - 25% in 120 minutes

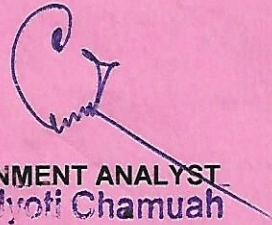
Assay

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
1	Nitrofurantoin	104.4 mg/Tablet	100 mg/Tablet	104.4	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 conform to I.P. with respect to the test for "Dissolution".

Date: 21-FEB-2025


GOVERNMENT ANALYST
Amer Jyoti Chamuah
 Government Analyst
 R.D.T.L., Guwahati-22

Report in red coloured paper indicates the sample is Not of Standard Quality.

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