

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 : MR. R. VANLALRUATA  
 ASSISTANT DIRECTOR (F & D)  
 OFFICE OF CHIEF MEDICAL OFFICER,  
 AIZAWL, MIZORAM. PIN:-796017
- Serial No. and date of Inspector's memorandum :MZ/2025/CMO 'E'/IPA/7 Date 20/1/25
- Number of Sample :Nil
- Date of receipt :29-JAN-2025
- Names of drugs purporting to be contained in the sample: Nitrofurantoin Tablets IP 100mg

Lab. Sample No.	Report No.	Batch No.	Date of Mfg.	Date of Exp.	Mfg. By
LSD/GUW/2024-25/1722	GUW/LS/2024-25/1745	T-2485	NOV. 2023	OCT. 2025	Jackson Laboratories Pvt. Ltd. 22-24, Majitha Road, Bye Pass, Amritsar-143 001(India)

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 13-Feb-2025 To 17-Feb-2025

COMPOSITION :

Each uncoated tablet contains:  
 Nitrofurantoin IP 100 mg

**Protocol Applied: I.P. 2022**

Sr No.	Test Name	Result	Limits
1	Description	Yellow colour, circular, flat, scored on one side, uncoated tablet having engraved 'JACKSON' on the unscored surface in blister pack.	NA
2	Identification	Gives positive test for Nitrofurantoin.	NA
3	Average weight	0.390655 gm.	NA
4	Uniformity of weight	Complies.	NA
5	Dissolution	Does not comply.	NA
Level	No. units tested	Result	Acceptance Criteria
S <sub>1</sub>	6 (in 60 minutes)	Release of each individual unit obtained are as follows: Unit 1=56.11%; Unit 2=57.10%;Unit 3=43.25%; Unit 4=43.62%; Unit 5=59.20%; Unit 6=52.65% Drug release of all (6) units are found more than 30% of claim (25+5%).	Each unit is NLT 'Q' 25+ 5% of Claim. Where 'Q' is 25%, (Specified in individual monograph)

S <sub>1</sub>	6 (in 120 minutes)	Release of each individual unit obtained are as follows: <b>Unit 1=63.03%; Unit 2=63.78%; Unit 3=62.77%; Unit 4=61.65%; Unit 5=62.70%; Unit 6=57.18%</b> Drug release of all (6) units are found less than 90% of claim (85+5%).	Each unit is NLT 'Q' 85+ 5% of Claim. Where 'Q' is 85% (Specified in individual monograph)
S <sub>2</sub>	6 (in 60 minutes)	Release of each individual unit obtained are as follows: Unit 1=21.33%; Unit 2=21.21%; Unit 3=23.06%; Unit 4=22.07%; Unit 5=10.73%; Unit 6=10.66% i).Average drug release of 12 units (S <sub>1</sub> +S <sub>2</sub> ) is:35.08% of claim >(25%) ii) Drug release of all 12 units are found more than 10% of claim > (Q- 15%)	Average of 12 units (S <sub>1</sub> +S <sub>2</sub> ) is ≥ 25% (≥Q) and no unit is < 10% of claim Q-15%).
S <sub>2</sub>	6 (in 120 minutes)	Release of each individual unit obtained are as follows: <b>Unit 1=29.34 ; Unit 2=29.21%; Unit 3=28.74%; Unit 4=31.68%; Unit 5=30.70%; Unit 6=29.96%</b> i).Average drug release of 12 units (S <sub>1</sub> +S <sub>2</sub> ) is: <b>45.90%</b> of claim (<85%). ii).Drug release of all 12 units are found less than <b>70%</b> of claim (<Q- 15%) as well as 7 units are found less than <b>60%</b> of claim (<Q- 25%)	Average of 12 units (S <sub>1</sub> +S <sub>2</sub> ) is ≥ 85% (≥Q) and no unit is < 70% of claim Q-15%).
S <sub>3</sub>	- (in 60 minutes)	-	Average of 24 units (S <sub>1</sub> +S <sub>2</sub> +S <sub>3</sub> ) ≥ 25% (≥Q), Not more than 2 units are <Q-15% and no unit is <Q-25%
S <sub>3</sub>	- (in 120 minutes)	-	Average of 24 units (S <sub>1</sub> +S <sub>2</sub> +S <sub>3</sub> ) ≥ 85% (≥Q), Not more than 2 units are <Q-15% and no unit is <Q-25%

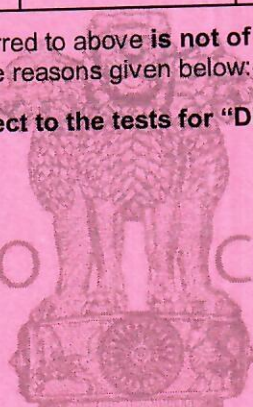
### Assay

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
1	Nitrofurantoin	102.93 mg/Tablet	100 mg/Tablet	102.93	90 % to 110 %	I.P. 2022

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

**The sample does not conform to I.P. with respect to the tests for "Dissolution".**

Date: 21-FEB-2025

  
 सत्यमेव जयते  
 CDSCO GOVERNMENT ANALYST  
**Dilip Kr. Sarkar**  
 Government Analyst  
 R.D.T.L., Guwahati-22  
 MINISTRY OF HEALTH, GOVERNMENT OF INDIA

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

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