



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 : P. Lalitanzova, (Asst Drugs Inspector)  
Lawngtlai District- 796891, Mizoram
2. Serial No. and date of Inspector's memorandum : 002/LTI-FDA/I-26 , 20-JAN-2026
3. Number of Sample : NIL
4. Date of receipt : 10-FEB-2026
5. Names of drugs purporting to be contained in the sample : Nitrofurantoin Sustained Release Tablets (Ntlife-SR-100)

| Lab. Sample No.      | Report No.        | Batch No. | Date of Mfg. & Exp   | Marketed By | Mfg. By                                                                                                                                                                 |
|----------------------|-------------------|-----------|----------------------|-------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| LSD/GUW/2026-27/0086 | GUW/LS/2026-27/60 | AER01AFA  | Jan-2025<br>Dec-2026 | NA          | Pure & Cure Healthcare Pvt. Ltd., (A Subsidiary of Akums Drugs & Pharmaceuticals Ltd.) Plot No. -26A, 27-30, Sector- 8A, I.I.E., SIDCUL, Haridwar- 249 403, Uttarakhand |

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 22-Apr-2026 To 24-Apr-2026

COMPOSITION : Each uncoated sustained release tablets contains:  
Nitrofurantoin IP 100 mg

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

| Sr No. | Test Name            | Result                                                              | Limits                 |
|--------|----------------------|---------------------------------------------------------------------|------------------------|
| 1      | Description          | Yellow colored, round, biconvex, uncoated tablets, in blister pack. | NA                     |
| 2      | Identification       | Gives positive test for Nitrofurantoin.                             | NA                     |
| 3      | Average weight       | 0.28541 g                                                           | NA                     |
| 4      | Uniformity of Weight | Complies.                                                           | +5 % of Average weight |

**Assay**

| Sr.No | Ingredient Name | Found           | Claim         | % of claim | Limits        | Procedure / Method |
|-------|-----------------|-----------------|---------------|------------|---------------|--------------------|
| 1     | Nitrofurantoin  | 96.87 mg/Tablet | 100 mg/Tablet | 96.87      | 90 % to 110 % | 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 conform to claim as per I.P. 2022 in respect of test performed.

*Rinku Kalita*

Date: 06-MAY-2026

GOVERNMENT ANALYST

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

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

