

## **Regional Drugs Testing Laboratory**

Directorate General of Health Services, Guwahati (India) - 781022

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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

: SARAH LALDINTLUANGI, ASSISTANT DIRECTOR

(FOOD DRUGS) Sr. CMO Office Serchhip-796181

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

: 004/IPA/2024, 25-NOV-2024

3. Number of Sample

: nil

4. Date of receipt

: 26-DEC-2024

5. Names of drugs purporting to be contained in the sample : Glimepiride Tablets IP (GLIMESTAR-2)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg.	Date of Exp.	Mfg. By
LSD/GUW/2024- 25/1563	GUW/LS/2024- 25/1587	B75W004	Apr-2023	Mar-2025	Mankind Pharma Ltd,, Doring Block, Bermiok Elaka, South Sikkim-737 126.

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 10-Jan-2025 To 17-Jan-2025

COMPOSITION

Each uncoated tablet contains: Glimepiride IP 2 mg.

## Protocol Applied: I.P. 2022

Sr No. Test Name		Result	Limits	
1	Description	Light pink colored, round, flat, having a dosage line on one surface, uncoated tablets, in blister pack.	NA	
2	Identification	NA		
3	Average weight	0.2028 g	NA	
4	Dissolution	Complies.	NLT 75 % of claim	

## **Assay**

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
1	Glimepiride	2.09 mg/Tablet	2 mg/Tablet	104.5	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.

Date: 22-JAN-2025

GOVERNMENT ANALYST

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

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