

### **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

: Mrs. C. Ramdinmawii, Assistant Director (Food and

Drugs)

C.M.O. Office,

Champhai-796321 Mizoram

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

: 006/IPA-CPI/24, 27-NOV-2024

3. Number of Sample

: NIL

Date of receipt

: 11-DEC-2024

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

Lab. Sample No.	Report No.	Batch No.	Date of Mfg.	Date of Exp.	Mfg. By
LSD/GUW/2024- 25/1562	GUW/LS/2024- 25/1586	T230128	Apr-2023		MAXFORD HEALTHCARE BY: UNITED BIOCEUTICALS PVT. LTD., Plot No. 33C, Industrial
	, S				Park-IV, Begumpur, Haridwar-249 402 (Uttarakhand)

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 16-Jan-2025

COMPOSITION

Each uncoated tablet contains:

Glimepiride IP 2 mg

# Protocol Applied: I.P. 2022

Sr No.	Test Name	Result	Limits	
1 Description		White, round, slightly bi-convex, uncoated tablets, in blister pack.	NA	
2	Identification	Identification Gives positive test for Glimepiride.		
3	3 Average weight 0.1729 g		NA	
4	4 Dissolution Complies.		NLT 75 % of claim	

### **Assay**

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
		· y				

1	Glimepiride	2.02 mg/Tablet	2 mg/Tablet	101	90 % to 110 %	I.P. 2022	
Cosmetics	Act, 1940, and Rule	ed the sample referre s there under for the n as per I.P. 2022 in	reasons given	below:-	d quality as defined in	the Drugs and	
		•				M	

Date: 22-JAN-2025

GOVERNMENT ANALYST

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

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