

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

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C.M.O. Office,

Champhai-796321 Mizoram

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

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

Number of Sample

: NIL

Date of receipt

: 11-DEC-2024

5. Names of drugs purporting to be contained in the sample: Metformin Hydrochloride & Glimepiride Tablets

(Glimrica G1 Tablets)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg.	Date of Exp.	Mfg. By
LSD/GUW/2024- 25/1688	GUW/LS/2024- 25/1717	PT-40618	Feb-2024	Jan-2026	Pharmaroots Healthcare, Khasra No. 411, Village Tipra, P.O. Barotiwala, Tehsil Baddi,
			(03/4)		Distt. Solan, H.P.

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 20-Jan-2025 To 06-Feb-2025

COMPOSITION

Each uncoated tablet contains:

Glimepiride IP 1 mg

Metformin Hydrochloride IP 500 mg

Protocol Applied: I.P. 2022

Sr No. Test Name		Result	Limits	
1	Description	White, elongated, biconvex, having scored on one surface, uncoated tablets, in blister pack.	NA	
2	Identification	Gives positive test for Metformin Hydrochloride and Glimepiride.	NA	
3	Average weight	0.9828 gm	NA	
4	Uniformity of weight	Complies.	NA	
5	Dissolution (for Glimepiride)	Complies.	NLT 70 % of claim	

<u>Assay</u>

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
•	= 1					
	L L.					

1	Metformin Hydrochloride	473.81 mg/Tablet	500 mg/Tablet	94.762	90 % to 110 %	I.P. 2022
2	Glimepiride	1.02 mg/Tablet	1 mg/Tablet	102	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: 13-FEB-2025

GOVERNMENT ANALYST

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

END OF REPORT