

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 and Drugs) Sr. CMO Office, Serchhip-796181

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

: 017/IPA/2024 , Date: 13-DEC-2024

3. Number of Sample

4. Date of receipt

: 02-JAN-2025

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

Govt a Incid

(Glimrica G1 Tablets)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg.	Date of Exp.	
LSD/GUW/2024- 25/1758	GUW/LS/2024- 25/1781	PT-40619	Feb-2024	Jan-2026	Pharmaroots Healthcare, Khasra No. 411, Village Tipra, P.O. Barotiwala, Tehsil Baddi, 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: 24-Feb-2025, 25-Feb-2025

COMPOSITION

Each uncoated tablet contains:

Glimepiride IP 1 mg

Metformin Hydrochloride IP 500 mg

Protocol Applied: Manufacturer's Specification

Sr No.	Test Name	Result	Limits
1	Description	White, elongated, bi-convex, uncoated tablet in blister strip.	NA
2	Identification	Gives positive test for Glimepiride and Metformin Hydrochloride.	NA
3	Average weight	0.9929 g	NA -
4	Uniformity of weight	Passes the test. (Method I.P.)	ŃA
5	Disintegration Passes the test. (Time taken for disintegration 04 minutes 08 second		NMT 15 minutes

ay Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
1	Glimepiride	1.004 mg/Tablet	1 mg/Tablet	100.4	90 % to 110 %	Manufacturer's Specification
2	Metformin Hydrochloride	513.18 mg/Tablet	500 mg/Tablet	102.636	90 % to 110 %	Manufacturer's Specification

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 conforms to Manufacturer's Specification with respect to the above tests only.

Date: 26-FEB-2025

Amar Jyoti Chamuah Government Analyst R.D.T.L., Guwahati-22

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