



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 : R. Vanlalsiama, Asst Director (F D)
Asst Director (F&D),
CMO Office, Lunglei.
2. Serial No. and date of Inspector's memorandum : 8, 27-JAN-2025
3. Number of Sample : MS-23
4. Date of receipt : 07-FEB-2025
5. Names of drugs purporting to be contained in the sample : Metformin Hydrochloride & Glimepiride Tablets
(Glimrjca G1)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg. & Exp	Marketed By	Mfg. By
LSD/GUW/2025-26/0313	GUW/LS/2025-26/323	PT40620	Feb-2024 Jan-2026	NA	Pharmaroots Healthcare,, Khasra No. 411, Village Tipra, P.O. Barotiwala, Tehsil Baddi, Distt. Solan, H.P. -174103

6. Condition of seals on : Seals were intact & identical to the
[the packet or on portion of sample or container] 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 26-May-2025 To 05-Jun-2025

COMPOSITION : Each uncoated tablet contains:
Glimepiride I.P. 1 mg
Metformin Hydrochloride I.P. 500 mg

Protocol Applied : Manufacturer Specification

Sr No.	Test Name	Result	Limits
1	Description	White, elongated, bi-convex, scored on one surface, uncoated tablets, in blister packing.	NA
2	Identification	Gives positive test for Metformin Hydrochloride & Glimepiride.	NA
3	Average weight	0.9730 g	NA
4	Uniformity of weight	Complies.	+5 % of Average weight
5	Disintegration	Complies.	NMT 15 minutes

Assay

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

1	Glimepiride	1.087 mg/Tablet	1 mg/Tablet	108.7	90 % to 110 %	Manufacturer Specification
2	Metformin Hydrochloride	452.3 mg/Tablet	500 mg/Tablet	90.46	90 % to 110 %	Manufacturer 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 conform to claim as per Manufacturer Specification in respect of test performed.

Date: 06-JUN-2025

GOVERNMENT ANALYST

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

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

