

#### Regional Drugs Testing Laboratory

## Directorate General of Health Services, Guwahati (India) - 781022 Drugs Fax: 0361-2338555/2330555 Phone No.0361 2338555

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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

: 001/2024, 03-OCT-2024

3. Number of Sample

: NIL

4. Date of receipt

: 28-OCT-2024

5. Names of drugs purporting to be contained in the sample : Metformin Hydrochloride Prolonged Release Tablets IP

500 mg

Lab. Sample No.	Report No.	Batch No.	Date of Mfg.	Date of Exp.	Mfg. By
LSD/GUW/2024- 25/1599	GUW/LS/2024- 25/1627	240134	Feb-2024	Jul-2026	BAL PHARMA LIMITED, Plot No. 1,2,3 And 69, Sector-4, IIE, SIDCUL Pantnagar,
					Rudrapur, Distt Udham Singh Nagar, Uttarakhand, INDIA

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 27-Jan-2025 To 28-Jan-2025

COMPOSITION

Each uncoated Prolonged Release tablet contains:

Metformin Hydrochloride IP 500 mg.

# Protocol Applied: I.P. 2022

Sr No.	Test Name	Result	Limits	
1	Description	White, round shaped, bi-convex, uncoated tablets, in blister pack.	NA	
2	Identification Gives positive test for Metformin Hydrochloride.		NA	
3	Average weight	0.7695 gm	NA	
4	Uniformity of weight	Complies.	NA	

#### <u>Assay</u>

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
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1	Metformin Hydrochloride	505.72 mg/Tablet	500 mg/Tablet	101.144	90 % to 110 %	I.P. 2022
	0 - Sr					, , į

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. Note: Test for "Dissolution" could not be perform due to want of Dissolution profile for Metformin Hydrochloride Prolonged Release Tablets.

Date: 29-JAN-2025

GOVERNMENT ANALYST

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

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