

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

: TIMOTHY THANCHUNGNUNGA, Assistant Director (F

and D)

CMO West Office

Kulikawn, Aizawl- 796005

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

: B.11012/5/2024-CMO (W)/DRUGS/7, 26-AUG-2024

3. Number of Sample

: SMP/MZ/TMT/2024-25/012

4. Date of receipt

: 06-SEP-2024

5. Names of drugs purporting to be contained in the sample : Metformin Tablets IP 500 mg

Lab. Sample No.	Report No.	Batch No.	Date of Mfg.	Date of Exp.	Mfg. By
LSD/GUW/2024- 25/1345	GUW/LS/2024- 25/1385	LJJZ332	Aug-2023	Jul-2025	M/s. Lok-Beta Pharmaceuticals (I) Pvt. Ltd,
				S.	At : Plot No. 65,66 & 67, Phase II, Atgaon Industrial
					Complex, Atgaon, Taluka -
				Y.	Shahpur, Dist. Thane-412801, Maharashtra State, 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 Drugo Imprestor

from Drugs Inspector

7. Result of test or analysis with protocols or test or analysis applied : Please see below

Date of Testing: From 02-Dec-2024 To 09-Dec-2024

COMPOSITION

Each uncoated tablet is purported to contains:

Metformin Hydrochloride IP

500 mg

Protocol Applied: I.P. 2022

Sr No.	Test Name	Result	Limits	
1	Description White, round shaped, flat, one dosage line on on surface, uncoated tablets, in blister pack.		NA	
2	Identification	Gives positive test for Metformin Hydrochloride.	NA	
3	Average weight	0.6090 gm	NA	
4	Uniformity of weight	iformity of weight Complies.		
5	Dissolution	Complies.	NLT 70 % of	

Assay

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
1 -	Metformin Hydrochloride	504.79 mg/Tablet	500 mg/Tablet	100.958	95 % to 105 %	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 conforms to claim as per I.P. 2022 in respect of test performed.

Date: 13-DEC-2024

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

CDSCO MCDSCO

Required Standard Contraction of the Contraction of the