



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. Zarzokimi, Assistant Drugs Inspector (Food and Drugs)
C.M.O. Office,
Champhai-796321 Mizoram
2. Serial No. and date of Inspector's memorandum : 057/IPA-CPI/25 , 27-MAR-2025
3. Number of Sample : NIL
4. Date of receipt : 02-APR-2025
5. Names of drugs purporting to be contained in the sample : Labetalol Tablets IP (Labetag 100 mg)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg. & Exp	Marketed By	Mfg. By
LSD/GUW/2025-26/0376	GUW/LS/2025-26/376	LBG1T-032	Mar-2024 Feb-2026	NA	Iosis Remedies Pvt. Ltd., Rajpura Road, Village- Khera Nihla Tehsil- Nalagarh, District - Solan, Himachal Pradesh - 174 101, India.

6. Condition of seals on : Seals were intact & identical to the specimen impression of the seal received from Drugs Inspector
 [the packet or on portion of sample or container]

7. Result of test or analysis with protocols or test or analysis applied : Please see below
 Date of Testing : From 08-May-2025 To 09-Jun-2025

COMPOSITION : Each film coated tablet contains:
 Labetalol Hydrochloride IP 100 mg.

Protocol Applied : I.P. 2022

Sr No.	Test Name	Result	Limits
1	Description	Pink colored, round, bi-convex, film coated tablets, in blister pack.	NA
2	Identification	Gives positive test for Labetalol Hydrochloride.	NA
3	Average weight	0.3157 g	NA
4	Uniformity of weight	Complies.	+5 % of Average weight
5	Dissolution	Complies.	NLT 80 % of claim

Assay

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

1	Labetalol Hydrochloride	101.92 mg/Tablet	100 mg/Tablet	101.92	95 % to 105 %	I.P. 2022
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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: 18-JUN-2025

GOVERNMENT ANALYST

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

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

