



FORM 13
(See rule 46)

CERTIFICATE OF TEST OR ANALYSIS BY GOVERNMENT ANALYST UNDER
SECTION 25(1) OF THE DRUGS AND COSMETICS ACT, 1940

- Name of Inspector from whom received : SARAH LALDINTLUANGI, Assistant Director (Food and Drugs)
Sr. CMO Office
Serchhip-796181
- Serial No. and date of Inspector's memorandum : 013/IPA/2024 , 27-NOV-2024
- Number of Sample : NIL
- Date of receipt : 26-DEC-2024
- Names of drugs purporting to be contained in the sample : Phenytoin Tablets I.P. (100 mg)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg.	Date of Exp.	Mfg. By
LSD/GUW/2024-25/1925	GUW/LS/2024-25/1949	2269	Nov-2022	Oct-2026	RELIANCE Formulation Pvt. Ltd., 7/2-A, G.I.D.C. Estate, Phase-I, Vatva, Ahmedabad - 382 445.

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 21-Mar-2025 To 25-Mar-2025

COMPOSITION : Each film coated tablet is purported to contains: Phenytoin Sodium IP 100 mg

Protocol Applied : I.P. 2022

Sr No.	Test Name	Result	Limits
1	Description	White, round, bi-convex, film coated tablets, in amber colored glass bottles.	NA
2	Identification	Gives positive test for Phenytoin Sodium.	NA
3	Average weight	0.1334 g	NA
4	Uniformity of weight	Complies.	NA
5	Disintegration	Complies. (Time taken for disintegration 05 minutes 12 seconds)	NMT 30 minutes

Assay

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

1	Phenytoin Sodium	107.58 mg/Tablet	100 mg/Tablet	107.58	90 % to 110 %	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: 26-MAR-2025

Rinku Kalita
GOVERNMENT ANALYST

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

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

