

Regional Drugs Testing Laboratory Directorate General of Health Services, Guwahati (India)-781022 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

: TIMOTHY THANCHUNGNUNGA,

Assistant Director (F & D)

CMO West Office

Kulikawn, Aizawl-796005

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

: B.11012/5/2024-CMO (W)/DRUGS/40

Dated Aizawl, the 21st January, 2025

3. Number of Sample

: SMP/MZ/TMT/2024-2025/035

4. Date of receipt

:03-FEB-2025

5. Names of drugs purporting to be contained in the sample: TRAMADOL INJECTION B.P. (Supridol); 2ml

Lab. Sample No.	Report No.	Batch No.	Date of Mfg.	Date of Exp.	Mfg. By
LSD/GUW/2024- 25/1860	GUW/LS/2024- 25/1881	KP1568097	MAY 2024	APR. 2026	NEON LABORATORIES LIMITED At: Shantisthal, Plot No. 1-5, At & Post
	<	\$ ·		To the second	Shirgaon, Tal.Palghar,Dist.Thane- 401407, M.S.

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 14-Feb-2025 To 07-Mar-2025

COMPOSITION

Each ml contains:

Tramadol Hydrochloride I.P.

50 ma

Protocol Applied: B.P.

Sr No.	Test Name	Result		
1	Description	Colorless, transparent liquid, filled in a transparent glass ampoule, packed in blister pack.		
2	Identification	Gives positive test for Tramadol Hydrochloride.		
3	Sterility	Complies.	NA -	
4	Particulate matter	Complies.	NA	
5	Extractable volume	Complies.	NA ·	
6	рН	Complies (Found: 6.24)	6.0 to 7.0.	

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Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
1	Tramadol Hydrochloride	50.16 mg/ml	50 mg/ml	100.32	95 % to 105 %	B.P.

In the opinion of the under signed the sample referred to above **is of standard quality** as defined in the Drugs and Cosmetics Act, 1940, and Rules thereunder for the reasons given below:-

The sample conforms to B.P. with respect to the above tests only.

Date: 18-MAR-2025

GOVERNMENT ANALYST

Dilip Kr. Sarkar

Government Analyst

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

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

