



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 : Mrs. Zarzokimi, (Assistant Drugs Inspector (Food and Drugs))
Champhai-796321 Mizoram
- Serial No. and date of Inspector's memorandum : 383/26 , 23-JAN-2026
- Number of Sample : NIL
- Date of receipt : 02-FEB-2026
- Names of drugs purporting to be contained in the sample : Promethazine Injection IP (PROZINE)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg. & Exp	Marketed By	Mfg. By
LSD/GUW/2025-26/1226	GUW/LS/2026-27/13	I-3909	Dec-2024 Nov-2026	NA	Jackson Laboratories Pvt.Ltd, 22-24, Majitha Road, Bye Pass, Amritsar-143 001(India)

- 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]

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

Date of Testing : From 11-Feb-2026 To 11-Mar-2026

COMPOSITION : Each ml. contains:
Promethazine HCl. IP 25 mg.

Protocol Applied : I.P. 2022

Sr No.	Test Name	Result	Limits
1	Description	Clear and colorless liquid filled in sealed amber colored glass ampoules.	NA
2	Identification	Gives positive test for Promethazine HCl.	NA
3	Sterility	Passes the test.	NA
4	BET	Complies.	NA
5	pH	5.8; Complies.	5 to 6 .

Assay

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

1	Promethazine Hydrochloride	26.2 mg/ml	25 mg/ml	104.8	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: 08-APR-2026

GOVERNMENT ANALYST

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

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

