



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. C. Ramdinmawii, Assistant Director (Food and Drugs)
C.M.O. Office,
Champhai-796321 Mizoram
2. Serial No. and date of Inspector's memorandum : 021/IPA-CPI/24 , 07-FEB-2025
3. Number of Sample : NIL
4. Date of receipt : 06-MAR-2025
5. Names of drugs purporting to be contained in the sample : Diclofenac Sodium Injection I.P. (Volifen injection 3 ml.)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg. & Exp	Marketed By	Mfg. By
LSD/GUW/2025-26/0310	GUW/LS/2025-26/326	IDFB458	Feb-2024 Jan-2026	NA	Regain Laboratories, 134/5, HTM Road, Raipur Lane, Hisar-125001

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 24-Mar-2025 To 05-Jun-2025

COMPOSITION : Each ml. contains: Diclofenac Sodium I.P. 25 mg.
Benzyl Alcohol IP 4% v/v (As preservative)

Protocol Applied : I.P. 2022

Sr No.	Test Name	Result	Limits
1	Description	Clear and colorless liquid filled in colorless transparent sealed glass vials, in blister pack.	NA
2	Identification	Positive for Diclofenac Sodium.	NA
3	Sterility	Passes the test.	NA
4	pH	8.61	8.1 to 9 .

Assay

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
1	Diclofenac Sodium	25.8 mg/ml	25 mg/ml	103.2	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 conform to claim as per I.P. 2022 in respect of test performed.

Date: 06-JUN-2025

GOVERNMENT ANALYST

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

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

