



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 : B.LALZAMLIANA, Drugs Inspector (F and D)
CMO West Office
Kulikawn, Aizawl- 796005
2. Serial No. and date of Inspector's memorandum : B.11012/5/2024-CMO (W)/DRUGS/61 , 22-APR-2025
3. Number of Sample : 006/IPA-AZL W/II-25
4. Date of receipt : 05-MAY-2025
5. Names of drugs purporting to be contained in the sample : Frusemide Injection IP (Rasix Injection)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg. & Exp	Marketed By*	Mfg. By
LSD/GUW/2025-26/0525	GUW/LS/2025-26/535	IFMK317	Nov-2023 Oct-2025	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 20-May-2025 To 23-Jul-2025

COMPOSITION : Each 2 ml is purported to contains:
Frusemide IP 20 mg

Protocol Applied : I.P. 2022

Sr No.	Test Name	Result	Limits
1	Description	Clear and colorless liquid filled in amber colored sealed glass ampoules.	NA
2	Identification	Gives positive test for Frusemide.	NA
3	Sterility	Passes the test.	NA
4	BET	Complies.	NA
5	Extractable volume	Complies.	NA
6	Particulate matter	Passes the test.	NA
7	pH	9.25	8 to 9.3 .

Assay

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
1	Frusemide	20 mg/2ml	20 mg/2ml	100	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: 31-JUL-2025

GOVERNMENT ANALYST

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

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

