

Regional Drugs Testing Laboratory Directorate General of Health Services, Guwahati (India)-781022 Fax: 0361-2338555/2330555 Phone No.0361 2338555 Email: rdtlguwahati@cdsco.nic.in

Testing Govt. Of India Guwahat

Date 9th Dec. 24

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

: K. Lalngilneia

Asst. Director (F & D)

CMO Office, Mamit District: Mamit

Pin-796441

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

:B.17011/12/09-CMO(M)/DRUGS/40

:MD08/40

3. Number of Sample

4. Date of receipt

:20-DEC-2024

5. Names of drugs purporting to be contained in the sample: Frusemide Injection IP; (2ml)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg.	Date of Exp.	Mfg. By
LSD/GUW/2024- 25/1582	GUW/LS/2024- 25/1599	I-3277	Feb. 2024	Jan. 2026	JACKSON LABORATORIES PVT. LTD. Majitha Road Bye Pass. Amritsar - 143001

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 03-Jan-2025 To 23-Jan-2025

COMPOSITION

Each ml. contains:

Frusemide I.P.

10 mg.

Sr No.	Test Name	Result	Limits	
1	Description	Colorless solution in sealed amber colour glass ampoule with blue dot mark on the neck.		
2	Identification	Gives positive test for Frusemide.		
3	Sterility	Complies.	NA	
4	Bacterial endotoxins	Complies.	NA	
5	Particulate matter	Complies.	NA	
6	Extractable volume Complies.		NA	
7	pН	Complies (Found: 9.13).	8.0 to 9.3	

<u>Assay</u>

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
1	Frusemide	10.35 mg/ml	10 mg/ml	103.5	95% to 105 %	I.P. 2022

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 I.P. with respect to the above tests only.

Date: 29-JAN-2025

GOVERNMENT ANALYST

Dilip Kr. Sarkar

Government Analyst

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

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

