

## **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

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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

: Mrs. C. Ramdinmawii

Assistant Director (Food & Drugs) C.M.O. Office, Champhai-796321

Mizoram.

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

:007/IPA-CPI/24

Date: 27/11/2024

3. Number of Sample

:Nil

4. Date of receipt

:11-DEC-2024

5. Names of drugs purporting to be contained in the sample: Flunarizine Tablets IP (10 mg)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg.	Date of Exp	Mfg. By
LSD/GUW/2024- 25/1626	GUW/LS/2024 25/1649	OCDT03	04/2022	03/2025	Akums Drugs & Pharmaceuticals Ltd. Plot No.19,20,21,Sector-6A,I.I. E., SIDCUL, Ranipur, Haridwar-249 403

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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 28-Jan-2025 To 31-Jan-2025

COMPOSITION

Each uncoated tablet contains: Flunarizine Dihydrochloride IP eq. to Flunarizine 10 mg

## Protocol Applied: I.P. 2022

Sr No.	Test Name	Result	Limits
1 Description		White, round, bi-convex, uncoated tablet, plain on both sides, packed in amber colour blister pack.	NA
2	Identification	Gives positive test for Flunarizine.	NA
3	Average weight	0.12372 gm.	NA
4	Dissolution	Complies (Release of all six units are found above 'Q' 75+5%).	NLT 75 % of claim

## Assay

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

1,	Flunarizine Dihydrochloride eq. to Flunarizine	10.656 mg/Tablet	10 mg/Tablet	106.56	90 % to 110 %	I.P. 2022
		Left and State State	ACTOR DE LA COMPANION DE LA CO			

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: 04-FEB-2025

GOVERNMENT ANALYST

Dilip Kr. Sarkar

Government Analyst

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

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