

Regional Drugs Testing Laboratory

Directorate General of Health Services, Guwahati (India) - 781022 Fax: 0361-2338555/2330555 Phone No.0361 2338555

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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 22 . 130

1. Name of Inspector from whom received

: Mr. R. Vanlalruata, Assistant Director (F and D)

ASSISTANT DIRECTOR(F&D)

OFFICE OF CHIEF MEDICAL OFFICER, AIZAWL,

MIZORAM, PIN-769017

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

: MZ/24/A E/05, 15-OCT-2024

3. Number of Sample

: NIL

4. Date of receipt

: 01-NOV-2024

5. Names of drugs purporting to be contained in the sample : Montelukast Sodium & Levocetirizine Dihydrochloride

Tablets (Levomont)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg. & Exp	Marketed By	Mfg. By
LSD/GUW/2025- 26/0080	GUW/LS/2025- 26/85	т-3438	Feb-2024 Jan-2026	NAC	Jackson Laboratories Pvt.Ltd, 22-24, Majitha Road, Bye Pass, Amritsar-143 001(India)

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 20-Mar-2025 To 09-Apr-2025

COMPOSITION

Each film coated tablet contains:

Montelukast Sodium IP eq. to Montelukast 10 mg

Levocetirizine Dihydrochloride IP 5 mg

Protocol Applied: I.P. 2022

Test Name	Result	Limits	
Description	White, round, bi-convex, scored on one surface, film coated tablets, in blister packing.	NA NA	
Identification	Gives positive test for Montelukast Sodium & Levocetirizine Dihydrochloride.		
Average weight	0.2013 g	NA	
	Description Identification	Description White, round, bi-convex, scored on one surface, film coated tablets, in blister packing. Identification Gives positive test for Montelukast Sodium & Levocetirizine Dihydrochloride.	

Assay

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
				5		.*
1	Montelukast Sodium eq. to Montelukast	10.14 mg/Tablet	10 mg/Tablet	101.4	90 % to 110 %	I.P. 2022

2	Levocetirizine Dihydrochloride	4.71 mg/Tablet	5 mg/Tabiet	94.2	90 % to 110 %	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: 16-APR-2025

Reall?

GOVERNMENT ANALYST

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

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