



FORM 13  
(See rule 46)  
CERTIFICATE OF TEST OR ANALYSIS BY GOVERNMENT ANALYST UNDER  
SECTION 25(1) OF THE DRUGS AND COSMETICS ACT, 1940

- Name of Inspector from whom received : Mrs. C. Ramdinmawii, Assistant Director (Food and Drugs)  
C.M.O. Office,  
Champhai-796321 Mizoram
- Serial No. and date of Inspector's memorandum : 375/24 , 04-OCT-2024
- Number of Sample : NIL
- Date of receipt : 23-OCT-2024
- Names of drugs purporting to be contained in the sample : Levocetirizine Hydrochloride & Montelukast Sodium Tablets IP (Montura-L)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg.	Date of Exp.	Mfg. By
LSD/GUW/2024-25/1610	GUW/LS/2024-25/1636	ZT23547C	Nov-2023	Oct-2025	M/s Zenon Lifesciences Pvt. Ltd., Survey-no. 343/P, Bavla Sanand Highway, Modasar Ahmedabad, Gujarat, INDIA 382220.

- 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]

- Result of test or analysis with protocols or test or analysis applied : Please see below  
Date of Testing : From 18-Dec-2024 To 21-Jan-2025

COMPOSITION : Each film coated tablet contains:  
Levocetirizine Hydrochloride IP 5 mg  
Montelukast Sodium IP Eq. to Montelukast 10 mg

**Protocol Applied : I.P. 2022**

Sr No.	Test Name	Result	Limits
1	Description	White, round, bi-convex, having scored on one surface, film coated tablets, in alu-alu strip.	NA
2	Identification	Gives positive test for Levocetirizine Hydrochloride and Montelukast Sodium.	NA
3	Average weight	0.1253 gm	NA
4	Dissolution (for Levocetirizine Hydrochloride)	Complies.	NLT 70 % of claim
5	Dissolution (for Montelukast)	Does not comply.	NLT 70% of claim



6	Level S1 (6 units)	Does not comply. Release of Montelukast of each individual unit is found as follows: Unit 1=21.0%; Unit 2=23.8%; Unit 3=20.4%; Unit 4=20.5%; Unit 5=20.9%; Unit 6=23.9% . Release of Montelukast of all 06 units are found less than 75% of claim i.e. (Q+5%) where Q is 70% of claim.	Each unit is not less than Q+5% i.e., 75% of claim where Q is 70%.
7	Level S2 (6 units)	Does not comply. Release of Montelukast of each individual unit is found as follows: Unit 1=13.4%; Unit 2=56.3%; Unit 3=15.4%; Unit 4=64.5%; Unit 05=64%; Unit 6=47.7% . Average release of Montelukast of 12 units (S1+S2) is 32.7% of claim which is less than Q i.e. 70% of claim. Release of Montelukast of 09 units are found less than 55% of claim(Q-15%).	Average of 12 units (S1+S2) $\geq$ 70% of claim and no unit is less than 55% of claim (Q-15%)
8	Level S3	Release of Montelukast of 09 units are found less than 55% of claim(Q-15%) as well as 08 units are found less than 45%of claim (Q-25%).	Average of 24 units (S1+S2+S3) $\geq$ 70% of claim, not more than 2 units are less than 55% of claim (Q-15%) and no unit is less than 45% of claim (Q-25%)

### Assay

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
1	Montelukast Sodium eq. to Montelukast	10.95 mg/Tablet	10 mg/Tablet	109.5	90 % to 110 %	I.P. 2022
2	Levocetirizine Hydrochloride	5.02 mg/Tablet	5 mg/Tablet	100.4	90 % to 110 %	I.P. 2022

In the opinion of the undersigned the sample referred to above is **not of standard quality** as defined in the Drugs and Cosmetics Act, 1940, and Rules there under for the reasons given below:-

The sample does not comply as per I.P. 2022 with respect to the test for "Dissolution" of Montelukast.

Date: 31-JAN-2025

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

Report in red color paper indicates the sample is not of standard quality.

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