



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 : Lianhmingthangi (Assistant Drugs Inspector (F and D)
CMO Office, Siaha District, Mizoram- 796901
2. Serial No. and date of Inspector's memorandum : SD/26/023N-DRUGS , 16-APR-2026
3. Number of Sample : Not mentioned.
4. Date of receipt : 04-MAY-2026
5. Names of drugs purporting to be contained in the sample : Levocetirizine Hydrochloride and Montelukast Tablets
(Polergy-ML)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg. & Exp	Marketed By	Mfg. By
LSD/GUW/2026-GUW/LS/2026-27/0137	27/263	41046	Nov-2025 Oct-2027	NA	Ronak Life Care Pvt. Ltd, R.S. No. 41 (Part), At & Post Rajpur, Dist Patan-384265

6. Condition of seals on : Seals were intact & identical to the
[the packet or on portion of sample or container] 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 29-Jun-2026 To 04-Aug-2026

COMPOSITION : Each uncoated tablet contains:
Levocetirizine Hydrochloride IP 5 mg
Montelukast Sodium IP Equivalent to Montelukast 10 mg

Protocol Applied : I.P. 2022

Sr No.	Test Name	Result	Limits
1	Description	Off-white, round, flat, scored on one surface, uncoated tablets, in blister pack.	NA
2	Identification	Gives positive test for Levocetirizine Hydrochloride and Montelukast Sodium.	NA
3	Average weight	0.2083 g	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=42.48%; Unit 2=42.49%; Unit 3=40.14%; Unit 4=40.50%; Unit 5=41.72%; Unit 6=39.51% . 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=37.12%; Unit 2=40.93%; Unit 3=38.34%; Unit 4=41.24%; Unit 5=38.95%; Unit 6=37.24% . Average release of Montelukast of 12 units (S1+S2) is 40.05% of claim. Release of Montelukast of all 12 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 (12 units)	Does not comply. Release of Montelukast of each individual unit is found as follows: Unit 1=31.62%; Unit 2=31.78%; Unit 3=38.46%; Unit 4=37.64%; Unit 5=38.22%; Unit 6=36.04%, Unit 7=32.00%, Unit 8=31.12%, Unit 9=38.28%, Unit 10=36.33%, Unit 11=38.44%, Unit 12=36.61%. Average release of Montelukast of 24 units (S1+S2+S3) is 36.21% of claim. Release of Montelukast of all 24 units are found less than 55% of claim(Q-15%) as well as 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%)

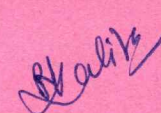
Assay

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
1	Levocetirizine Hydrochloride	4.787 mg/Tablet	5 mg/Tablet	95.74	90 % to 110 %	I.P. 2022
2	Montelukast Sodium Eq. to Montelukast	10.46 mg/Tablet	10 mg/Tablet	104.6	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: 17-AUG-2026


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

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

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