



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 : SARAH LALDINTLUANGI, Assistant Director (Food and Drugs)
Sr. CMO Office
Serchhip-796181
2. Serial No. and date of Inspector's memorandum : 029/IPA/2025 , 17-JAN-2025
3. Number of Sample : NIL
4. Date of receipt : 28-FEB-2025
5. Names of drugs purporting to be contained in the sample : MONTELUKAST & LEVOCETIRIZINE
HYDROCHLORIDE SYRUP (POLERGY-ML SYRUP)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg. & Exp	Marketed By	Mfg. By
LSD/GUW/2025-26/0810	GUW/LS/2025-26/811	76020	May-2024 Apr-2026	NA	Ronak Life Care Pvt. Ltd, R.S. No. 41 (Part), At & Post Rajpur, Dist Patan-384265

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 17-Oct-2025 To 17-Oct-2025

COMPOSITION : EACH 5 ML. CONTAINS:
MONTELUKAST SODIUM IP EQ. TO MONTELUKAST 4 MG.
LEVOCETIRIZINE HYDROCHLORIDE IP 2.5 MG.

Protocol Applied : Manufacturer Specification

Sr No.	Test Name	Result	Limits
1	Description	Orange colored liquid filled in amber colored plastic bottles.	NA
2	Identification	Gives positive test for Montelukast Sodium and Levocetirizine Hydrochloride.	NA
3	Weight Per Ml	1.0449 g/ml	NA

Assay

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
1	Montelukast Sodium eq. to montelukast	3.68 mg/ 5 ml	4 mg/ 5 ml	92	90 % to 110 %	Manufacturer Specification

2	Levocetirizine Hydrochloride	2.46 mg/ 5 ml	2.5 mg/ 5 ml	98.4	90 % to 110 %	Manufacturer Specification
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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 Manufacturer Specification in respect of test performed.

Date: 22-OCT-2025

GOVERNMENT ANALYST

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

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

