



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 : Sarah Laldintluangi, Assistant Director (Food and Drugs)
Sr. CMO Office
Serchhip-796181
- Serial No. and date of Inspector's memorandum : 015/2024 , 10-OCT-2024
- Number of Sample : NIL
- Date of receipt : 30-OCT-2024
- Names of drugs purporting to be contained in the sample : Montelukast Sodium and Levocetirizine Hydrochloride
Tablets i.P.(10 mg/5 mg)

| Lab. Sample No. | Report No. | Batch No. | Date of Mfg. | Date of Exp. | Mfg. By |
|----------------------|---------------------|-----------|--------------|--------------|--|
| LSD/GUW/2024-25/1570 | GUW/LS/2024-25/1602 | MLHT-1024 | Sep-2023 | Aug-2026 | WINGS BIOTECH LLP, 43 & 44, HPSIDC, Industrial Area, Baddi - 173205 (H.P.) |

6. 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]

7. Result of test or analysis with protocols or test or analysis applied : Please see below

Date of Testing : From 18-Dec-2024 To 22-Jan-2025

COMPOSITION : Each film coated tablet contains: Montelukast Sodium I.P. eq. to Montelukast 10 mg.
Levocetirizine Hydrochloride I.P. 5 mg.

Protocol Applied : I.P. 2022

| Sr No. | Test Name | Result | Limits |
|--------|--|--|-------------------|
| 1 | Description | Peach color, round, bi-convex, film coated tablets, in alu-alu strip. | NA |
| 2 | Identification | Gives positive test for Montelukast Sodium and Levocetirizine Hydrochloride. | NA |
| 3 | Average weight | 0.1786 g | NA |
| 4 | Dissolution | Complies. | NA |
| 5 | Dissolution (for Montelukast)) | Complies. | NLT 70 % of claim |
| 6 | Dissolution (for Levocetirizine Hydrochloride) | Complies. | NLT 70 % of claim |

Assay

| Sr.No | Ingredient Name | Found | Claim | % of claim | Limits | Procedure / Method |
|-------|---------------------------------------|----------------|--------------|------------|---------------|--------------------|
| 1 | Montelukast Sodium eq. to montelukast | 10.6 mg/Tablet | 10 mg/Tablet | 106 | 90 % to 110 % | I.P. 2022 |
| 2 | Levocetirizine Hydrochloride | 4.9 mg/Tablet | 5 mg/Tablet | 98 | 90 % to 110 % | I.P. 2022 |

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: 27-JAN-2025

R Kalita
GOVERNMENT ANALYST

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

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

