



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 : B.LALZAMLIANA, Drugs Inspector (F and D)  
CMO West Office  
Kulikawn, Aizawl- 796005
2. Serial No. and date of Inspector's memorandum : B.11012/5/2024-CMO (W)/DRUGS/55 , 25-FEB-2025
3. Number of Sample : SMP/MZ/TMT/2024-2025/050
4. Date of receipt : 06-MAR-2025
5. Names of drugs purporting to be contained in the sample : Rabeprazole Sodium & Levosulpiride )Sustained Release) Capsules (Dulcacid-LSR)

| Lab. Sample No.      | Report No.         | Batch No. | Date of Mfg. & Exp   | Marketed By | Mfg. By                                                                                                                                                                        |
|----------------------|--------------------|-----------|----------------------|-------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| LSD/GUW/2025-26/0482 | GUW/LS/2025-26/489 | LSR24003  | Nov-2024<br>Oct-2026 | NA          | M/s. Windlas Biotech Limited,<br>Plant-2, Khasra No. 141 to<br>143 & 145, Mohabewala Indl.<br>Area, Dehradun- 248110 (U.<br>K.) R.O.:40/1, Mohabewala<br>Indl. Area, Dehradun. |

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 19-Jun-2025 To 16-Jul-2025

COMPOSITION : Each hard gelatin capsule contains:  
Rabeprazole Sodium IP 20 mg  
(as reddish brown coloured enteric coated pellets)  
Levosulpiride 75 mg  
(as two uncoated sustained release tablet each containing Levosulpiride 37.5 mg)

**Protocol Applied : Manufacturer Specification**

| Sr No. | Test Name                                        | Result                                                                                                                     | Limits            |
|--------|--------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------|-------------------|
| 1      | Description                                      | Two white tablets and brown colored round pellets filled in yellow and red colored hard gelatin capsules, in blister pack. | NA                |
| 2      | Identification                                   | Gives positive test for Rabeprazole Sodium & Levosulpiride.                                                                | NA                |
| 3      | Average filled content                           | 0.3061 g                                                                                                                   | NA                |
| 4      | Dissolution of Rabeprazole Sodium (acid stage)   | Complies.                                                                                                                  | NMT 10 % of claim |
| 5      | Dissolution of Rabeprazole Sodium (buffer stage) | Complies.                                                                                                                  | NLT 70 % of claim |

## Assay

| Sr.No | Ingredient Name    | Found            | Claim         | % of claim | Limits        | Procedure / Method         |
|-------|--------------------|------------------|---------------|------------|---------------|----------------------------|
| 1     | Rabeprazole Sodium | 18.65 mg/Capsule | 20 mg/Capsule | 93.25      | 90 % to 110 % | Manufacturer Specification |
| 2     | Levosulpiride      | 67.94 mg/Capsule | 75 mg/Capsule | 90.586     | 90 % to 110 % | Manufacturer Specification |

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: 17-JUL-2025

GOVERNMENT ANALYST

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

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

