



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 : Lalruatdika varte
Drugs Inspector
Office of the Senior Chief Medical Officer
Kolasib, Mizoram- 796082
2. Serial No. and date of Inspector's memorandum : KLB/09/2025/IPA/DRUGS
Dated Kolasib, the 3rd February, 2025
3. Number of Sample : Nil
4. Date of receipt : 13-FEB-2025
5. Names of drugs purporting to be contained in the sample: Rabeprazole Sodium 20mg (Enteric Coated) and
Domperidone 30mg (Sustained Release) Capsules

Lab. Sample No.	Report No.	Batch No.	Date of Mfg. & Exp	Marketed By	Mfg. By
LSD/GUW/2025-26/0270	GUW/LS/2025-26/281	RBDC-1045	FEB.2024 JAN.2026	NA	Wings Biotech LLP 43 & 44, HPSIDC ,Industrial Area, Baddi- 173 205 (H.P.)

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 26-Mar-2025To 23-May-2025

COMPOSITION : Each hard gelatin capsule contains:
Rabeprazole Sodium I.P. 20mg
(As Enteric Coated Pellets)
Domperidone I.P. 30mg
(As Sustained Release Pellets)

Protocol Applied : Manufacturer's Specification

Sr No.	Test Name	Result	Limits
1	Description	Orange and brown colour pellets filled in hard gelatin capsule having pink colour cap and transparent body in aluminium strip pack.	NA
2	Identification	Gives positive test for Rabeprazole Sodium & Domperidone.	NA
3	Filled content	0.2740 gm.	NA
4	Uniformity of weight	Complies.	± 10%
5	Dissolution	Passes the test for Rabeprazole Sodium	NA
6	Dissolution (Acid stage)	Passes the test for Rabeprazole Sodium (Release of all six units are found below 15%)	NMT 15 % of claim

7	Dissolution (Buffer stage)	Passes the test for Rabeprazole Sodium (Release of all six units are found above 70%).			NLT 70 % of claim
8	Dissolution	Passes the test for Domperidone			NA
Level	No. of unit taken	Time	Result (Drug release range between)	Acceptance Criteria	
L ₁	6	1 st hour	24.4% to 26.6%	NLT 15 % to NMT 40 %	
		4 th hour	56.2% to 60.9%	NLT 30 % to NMT 70 %	
		12 th hour	101.7% to 108.5%	NLT 70 % of claim	

Assay

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
1	Rabeprazole Sodium	19.08 mg/Capsule	20 mg/Capsule	95.4	90 % to 110 %	Manufacturer's Specification
2	Domperidone	29.73 mg/Capsule	30 mg/Capsule	99.1	90 % to 110 %	

In the opinion of the under signed the sample referred to above **is of standard quality** as defined in the Drugs and Cosmetics Act, 1940, and Rules thereunder for the reasons given below:-

The sample conforms to Manufacturer's specification with respect to the above tests only.

Date: 27-MAY-2025

GOVERNMENT ANALYST

Dilip Kr. Sarkar

Government Analyst

R.D.T.L., Guwahati-22



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

