Regional Drugs Testing Laboratory
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Regional Drugs Testing Laboratory Govt of India Guwahati-22

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 & D)
CMO West Office
Kulikawn, Aizawl- 796005

2. **Serial No. and date of Inspector's memorandum** : B.11012/5/2024-CMO(W)/DRUGS/2 , Dated Aizawl, the 25-JUL-2024

3. **Number of Sample** : SMP/MZ/TMT/2024-25/008

4. **Date of receipt** : 23-AUG-2024

5. **Names of drugs purporting to be contained in the sample** : Enteric Coated Rabeprazole Sodium &Sustained Release Levosulpiride Capsules (RABALKEM-LS)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg.	Date of Exp.	Mfg. By
LSD/GUW/2024-25/1902	GUW/LS/2024-25/1922	RLC23016MB	Oct-2023	Sep-2025	M/s. Sri Ram Healthcare Pvt. Ltd., 81-C/2, EPIP - I, Jharmajri, Baddi, Distt. Solan (H.P.) - 173 205.

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 16-Mar-2025 To 21-Mar-2025

COMPOSITION : Each hard gelatin capsule contains:
Rabeprazole Sodium IP 20 mg
(As enteric coated pellets)
Levosulpiride 75 mg
(As sustained release pellets)

Protocol Applied : Manufacturer's Specification

Sr No.	Test Name	Result	Limits
1	Description	Bi-colour (black and red), hard capsule containing white and brown pellets in blister strip.	NA
2	Identification	Gives positive test for Rabeprazole Sodium & Levosulpiride.	NA
3	Average filled content	0.5143 g	NA
4	Dissolution	Rabeprazole Sodium: Complies.	Acid Stage: NLT 90% Buffer Stage: NLT 70%

		Levosulpiride: Complies.	1st hour: 15% to 50% 4th hours: 30% to 75% 8th hours: 55% to 90% 12th hours: NLT 70%

Assay

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
1	Rabeprazole Sodium	21.88 mg/Capsule	20 mg/Capsule	109.4	90 % to 110 %	Manufacturer's Specification
2	Levosulpiride	75.71 mg/Capsule	75 mg/Capsule	100.946	90 % to 110 %	Manufacturer's 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 conforms to Manufacturer's Specification with respect to the above tests only.

Date: 21-MAR-2025

GOVERNMENT ANALYST
Amar Jyoti Chamuah
Government Analyst
R.D.T.L., Guwahati-22

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
CDSCO CDSCO
सत्यमेव जयते
MINISTRY OF HEALTH, GOVERNMENT OF INDIA

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