



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 : 011/IPA/2024 , 27-NOV-2024
3. Number of Sample : NIL
4. Date of receipt : 26-DEC-2024
5. Names of drugs purporting to be contained in the sample : Esomeprazole (E.C.) & Domperidone Sustained Release Capsule (Esozo-DSR Capsule)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg. & Exp	Marketed By	Mfg. By
LSD/GUW/2025-26/0161	GUW/LS/2025-26/172	SBC-162	Aug-2023 Jul-2025	NA	Sarthak Biotech Pvt. Ltd., 198-A, Sector-3, HSIIDC, Karnal-132001 (Hr.)

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 07-Apr-2025 To 29-Apr-2025

COMPOSITION : Each hard gelatin capsule contains:
Esomeprazole Magnesium Trihydrate IP Eq. to Esomeprazole 40 mg (As Enteric Coated pellets)
Domperidone IP 30 mg
(As Sustained release pellets)

Protocol Applied : Manufacturer's Specification

Sr No.	Test Name	Result	Limits
1	Description	White and orange colored pellets filled in transparent colorless and pink colored hard gelatin capsules, in blister pack.	NA
2	Identification	Gives positive test for Esomeprazole Magnesium & Domperidone.	NA
3	Average filled content	0.2662 g	NA
4	Uniformity of weight	Complies.	+ - 10 % of Average weight
5	Dissolution of Esomeprazole (acid stage)	Complies.	NMT 15 % of claim
6	Dissolution of Esomeprazole (buffer stage)	Complies.	NLT 70 % of claim

7	Dissolution For Domperidone (1st Hour)	Complies.	15% to 40 % of claim
8	Dissolution For Domperidone (4th Hour)	Complies.	30% to 60 % of claim
9	Dissolution For Domperidone (8th Hour)	Complies.	55% to 85 % of claim
10	Dissolution For Domperidone (12th Hour)	Complies.	NLT 70 % of claim

Assay

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
1	Esomeprazole Magnesium Trihydrate eq. to Esomeprazole	39.11 mg/Capsule	40 mg/Capsule	97.775	90 % to 110 %	Manufacturer's Specification
2	Domperidone	29.87 mg/Capsule	30 mg/Capsule	99.566	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 conform to claim as per Manufacturer's Specification in respect of test performed.

Date: 05-MAY-2025

GOVERNMENT ANALYST

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

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