



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 : TIMOTHY THANCHUNGNUNGA, Assistant Director (F and D)
 CMO West Office
 Kulikawn, Aizawl- 796005
- Serial No. and date of Inspector's memorandum : B.11012/5/2024-CMO(W)/DRUGS/9 , 23-SEP-2024
- Number of Sample : SMP/MZ/TMT/2024-2025/014
- Date of receipt : 04-OCT-2024
- Names of drugs purporting to be contained in the sample : PANTOPRAZOLE GASTRO- RESISTANT TABLETS IP 40 mg (Pantop® 40)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg.	Date of Exp.	Mfg. By
LSD/GUW/2024-25/1295	GUW/LS/2024-25/1326	SPD240540	Apr-2024	Sep-2026	ARISTO Pharmaceuticals Private Limited., Plot Nos.: 2040-46, N.H.10, Baghey Khola, P.O. Majhitar, East-Sikkim, 737 136

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-Nov-2024 To 28-Nov-2024

COMPOSITION : Each gastro-resistant tablets is purported to contain Pantoprazole Sodium IP equivalent to Pantoprazole 40 mg.

Protocol Applied : I.P. 2022

Sr No.	Test Name	Result	Limits
1	Description	Yellow colored, round, biconvex tablets, in alu-alu strip.	NA
2	Identification	Gives positive test for Pantoprazole sodium.	NA
3	Average weight	0.1989 gm	NA
4	Dissolution	Complies.	NA
5	Dissolution For Pantoprazole (Acid Stage)	Complies.	NMT 10 % of claim
6	Dissolution For Pantoprazole (Buffer Stage)	Complies.	NLT 75 % of claim

Assay

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
1	Pantoprazole Sodium eq. to Pantoprazole	36.67 mg/Tablet	40 mg/Tablet	91.675	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 conforms to claim as per I.P. 2022 in respect of test performed.

Date: 04-DEC-2024

Rinku Kalita
GOVERNMENT ANALYST

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

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

