



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 : Mrs. C. Ramdinmawii, Assistant Director (Food and Drugs)
C.M.O. Office,
Champhai-796321 Mizoram
- Serial No. and date of Inspector's memorandum : 349/23, 15-APR-2024
- Number of Sample : NIL
- Date of receipt : 30-APR-2024
- Names of drugs purporting to be contained in the sample : Albendazole Tablets IP 400 mg (Zento™ 400)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg.	Date of Exp.	Mfg. By
LSD/GUW/2024-25/0522	GUW/LS/2024-25/544	VGT230119	May-2023	Apr-2026	VAPI CARE PHARMA PVT. LTD., PLOT NO.225/3, NEAR MORARJI CIRCLE, GIDC VAPI DIST.VALSAD-396195 GUJARAT

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 26-Jun-2024 To 02-Jul-2024

COMPOSITION : Each uncoated chewable tablet contains:
Albendazole IP 400 mg

Protocol Applied : I.P. 2022

Sr No.	Test Name	Result	Limits
1	Description	Light orange colored, elongated, biconvex, scored on one surface, uncoated tablets, in alu-alu strip.	NA
2	Identification	Gives positive test for Albendazole.	NA
3	Average weight	0.6491 gm	NA
4	Uniformity of weight	Complies.	NA
5	Dissolution	Does not comply.	Not less than 80% of claim.

5	Level S1 (6 units)	Does not comply. Release of Albendazole of each individual unit is found as follows: Unit 1=1.37 %, Unit 2=2.27%, Unit 3=1.67 %, Unit 4= 2.27 %, Unit 5=1.21 %, Unit 6=1.97 %. Drug release of all 06 units are found less than 85% of claim i.e.(80% +5%). Where Q is 80%.	Each unit is not less than Q+5% i.e., 85% of claim. Where Q is 80%.
7	Level S2 (6 units)	Does not comply. Release of Albendazole of each individual unit is found as follows: Unit 1=1.67 %, Unit 2=3.49 %, Unit 3=2.73 %, Unit 4= 3.03%, Unit 5=2.73 %, Unit 6=2.88 %. Average release of Albendazole of 12 units (S1+S2) is 2.27% of claim i.e. less than 80% of claim. All unites are less than 65% of claim i.e.Q-15% of claim.	Average of 12 units (S1+S2) is greater than or equal to 80% of claim and no unit is less than 65% of claim i.e. (less than Q-15%)
8	Level S3	Out of 12 units in S1 stage and S2 stage release of Albendazole of all units are found less than 65% of claim i.e. (Q-15%) as well as all units are found less than 55%of claim i.e.(Q-25%)	Average of 24 units (S1+S2+S3) is $\geq 80\%$ of claim, not more than 2 units are less than 65% of claim (less than Q-15%) and no unit is less than 55% of claim (less than Q-25%)

Assay

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
1	Albendazole	399.29 mg/Tablet	400 mg/Tablet	99.822	92.5 % to 107.5 %	I.P. 2022

In the opinion of the undersigned the sample referred to above is **not of standard quality** as defined in the Drugs and Cosmetics Act, 1940, and Rules there under for the reasons given below:-

The sample does not comply I.P. with respect to the test for "Dissolution" of Albendazole.

Date: 02-JUL-2024

R Kalita
GOVERNMENT ANALYST

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

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

Report in red color paper indicates the sample is not of standard quality.