



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 : Mr.R.Vanlalruata,Assistant Director (F and Drugs)
Assistant Director (F&D)
Office of Chief Medical Officer, Aizwal, Mizoram-
796017
- Serial No. and date of Inspector's memorandum : MZ/24/A'E/06 , 15-OCT-2024
- Number of Sample : NIL
- Date of receipt : 01-NOV-2024
- Names of drugs purporting to be contained in the sample : Albendazole Tablets IP 400 mg (Albendazole 400)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg.	Date of Exp.	Mfg. By
LSD/GUW/2024- 25/1528	GUW/LS/2024- 25/1556	T-3159	Jan-2024	Dec-2025	Jackson Laboratories Pvt.Ltd, 22-24, Majitha Road, Bye Pass, Amritsar-143 001(India)

- 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.

- Result of test or analysis with protocols or test or analysis applied : Please see below
Date of Testing : From 10-Dec-2024 To 07-Jan-2025

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

Protocol Applied : I.P. 2022

Sr No.	Test Name	Result	Limits
1	Description	Off white, elongated, bi-convex, scored on one surface, uncoated tablets, in blister pack.	NA
2	Identification	Gives positive test for Albendazole.	NA
3	Average weight	1.0774 g	NA
4	Uniformity weight of tablet	Complies.	
5	Dissolution	Does not comply.	NLT 80% of claim
6	Level S1 (6 units)	Does not comply. Release of Albendazole of each individual unit is found as follows: Unit 1=55.0%; Unit 2=54.4%; Unit 3=56.9%; Unit 4=56.4%; Unit 5=55.5%; Unit 6=56.4% . Release of Albendazole of all 06 units are found less than 85% of claim i.e. (Q+5%) where Q is 80% of claim.	Each unit is not less than Q+5% i.e., 85% of claim where Q is 80% of claim.

7 Level S2 (6 units)

Does not comply. Release of Albendazole of each individual unit is found as follows: Unit 1=44.3%; Unit 2=47.5%; Unit 3=47.0%; Unit 4=48.2%; Unit 5=49.3%; Unit 6=48.5% . Average release of Albendazole of 12 units (S1+S2) is 51.6% of claim which is less than Q i. e. 80% of claim. Release of all 12 units are found less than 65% of claim (Q-15%).

Average of 12 units (S1+S2) \geq 80% of claim and no unit is less than 65% of claim (Q-15%)

8 Level S3

Out of 12 units all units are found less than 65% of claim (Q-15%) as well as 07 units are found less than 55% of claim (Q-25%)

Average of 24 units(S1+S2+S3) \geq 80% of claim and not more than two units are less than 65% of claim (Q-15%) and no unit is less than 55% of claim (Q-25%)

Assay

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
1	Albendazole	407.14 mg/Tablet	400 mg/Tablet	101.785	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 conform as per I.P. 2022 with respect to the test for "Dissolution" of Albendazole.

Date: 20-JAN-2025

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

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

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