



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 & Drugs)
C.M.O. Office, Champhai-796321
Mizoram.
- Serial No. and date of Inspector's memorandum : 041/IPA-CPI/24 Date: 17/01/2025
- Number of Sample : Nil
- Date of receipt : 03-FEB-2025
- Names of drugs purporting to be contained in the sample: Azithromycin Tablets IP 500 mg (AZYMO Star 500)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg. & Exp	Marketed By	Mfg. By
LSD/GUW/2025-26/0288	GUW/LS/2025-26/296	TML-231271	JUL. 2023 JUN. 2025	NA	Prochem Pharmaceuticals (P) Ltd. 140-141, Makkanpur, Bhagwanpur, Roorkee, Dist. Haridwar (U.K.) 247661

- Condition of seals on : Seals were intact & identical to the
[the packet or on portion of sample or container] Specimen impression of the sea
I received from Drugs Inspector

- Result of test or analysis with protocols or test or analysis applied : Please see below
Date of Testing : From 25-Mar-2025 To 27-May-2025

COMPOSITION : Each film coated tablet contains:
Azithromycin IP
equivalent to Anhydrous Azithromycin 500 mg

Protocol Applied: I.P. 2022

Sr No.	Test Name	Result	Limits
1	Description	Light yellow colour, elongated, bi-convex, scored on one side, film coated tablet packed in blister pack.	NA
2	Identification	Gives positive test for Azithromycin.	NA
3	Average Weight	0.64486 gm.	NA
4	Uniformity of Weight	Complies.	± 5%
5	Dissolution	Complies (Release of all six units found above 'Q' 75+5%).	NLT 75 % of Claim

Assay

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method

1	Azithromycin equivalent to Anhydrous Azithromycin	523.28 mg/Tablet	500 mg/Tablet	104.656	90 % to 110 %	I.P. 2022
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In the opinion of the under signed the sample referred to above **is of standard quality** as defined in the Drugs and Cosmetics Act, 1940, and Rules thereunder for the reasons given below:-

The sample conforms to I.P. with respect to the above tests only.

Date: 28-MAY-2025



GOVERNMENT ANALYST

Dilip Kr. Sarkar

Government Analyst

R.D.T.L., Guwahati-22

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

