



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 : 364/24 , 15-MAY-2024
- Number of Sample : NIL
- Date of receipt : 22-MAY-2024
- Names of drugs purporting to be contained in the sample : Paracetamol Tablets IP 500 mg (Pararex-500)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg.	Date of Exp.	Mfg. By
LSD/GUW/2024-25/0581	GUW/LS/2024-25/611	CT-5063	Dec-2022	Nov-2025	CHEMETAC PHARMACEUTICALS 42, MAINA PUR, MEERUT ROAD, GHAZIABAD-201003

- 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]

- Result of test or analysis with protocols or test or analysis applied : Please see below

Date of Testing : From 19-Jun-2024 To 11-Jul-2024

COMPOSITION : Each uncoated tablet contains:
Paracetamol I.P. 500 mg

Protocol Applied : I.P. 2022

Sr No.	Test Name	Result	Limits
1	Description	White, round, flat, scored on one surface, uncoated tablets, in blister pack.	NA
2	Identification	Gives positive test for Paracetamol.	NA
3	Average weight	0.6018 g	NA
4	Uniformity of weight	Complies.	NA
5	Dissolution	Does not comply.	NLT 80% of claim
6	Dissolution (Stage- 1)	Does not comply. Release of Paracetamol of each individual unit is found as follows: Unit1=58.8%; Unit2=56.7%; Unit3=49.2%; Unit 4=56.3%; Unit 5=52.3%; Unit 6=53.0% Release of Paracetamol of all 06 units are found less than 85% of claim i.e. (Q+5%), where Q is 80%.	Each unit is not less than Q+5% i.e., 85% of claim. Where Q is 80%.

7	Dissolution (Stage- 2)	Does not Comply. Release of Paracetamol of each individual unit is found as follows: Unit 1=45.0%; Unit 2=45.1%; Unit 3=45.0%; Unit 4=53.9%; Unit 5=43.5%; Unit 6=51.6%, Average release of Paracetamol of 12units (S1+S2) is found 50.9% of claim i.e. less than 80% of claim. All 12 units are found less than 65% of claim i.e. (Q-15%)	Average of 12 units(S1+S2) is greater than or equal to 80% and no unit is less than 65% of claim i.e. Q-15%
8	Dissolution (Stage- 3)	Out of 12 units in S1 stage and S2 stage release of Paracetamol of all 12 units are found less than 65% of claim i.e. (Q-15%) as well as 09 units are found less than 55% of claim i.e. (Q-25%).	Average of 24 units(S1+S2+S3) is greater than or equal to 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	Paracetamol	508.77 mg/Tablet	500 mg/Tablet	101.754	95.0%-105.0 %	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 as per I.P. 2022 with respect to the Test for "Dissolution" of Paracetamol.

Date: 16-JUL-2024

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.