



FORM 13  
(See rule 46)

CERTIFICATE OF TEST OR ANALYSIS BY GOVERNMENT ANALYST UNDER  
SECTION 25(1) OF THE DRUGS AND COSMETICS ACT, 1940

1. Name of Inspector from whom received : Mrs. C. Ramdinmawii,  
Assistant Director (Food and Drugs)  
C.M.O. Office, Champhai-796321 Mizoram
2. Serial No. and date of Inspector's memorandum : 368/24 , Date: 16-AUG-2024
3. Number of Sample : --
4. Date of receipt : 30-AUG-2024
5. 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/2024-25/1039	GUW/LS/2024-25/1064	CT-7129	Sep-2023	Aug-2026	CHEMETAC PHARMACEUTICALS 42, MAINA PUR, MEERUT ROAD, GHAZIABAD-201003

6. 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

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

Date of Testing : From 09-Oct-2024 To 16-Oct-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, flat, round, uncoated tablet having a dosage line on one side in blister strip.	NA
2	Identification	Gives positive test for Paracetamol.	NA
3	Average weight	0.6038 g	NA
4	Uniformity of weight	Complies.	NA
5	Dissolution	Does not comply.	

Level	Number Tested	Result	Acceptance Criteria
S <sub>1</sub>	6	Drug release of 6 units are found as follows: i. 41.12%, ii. 50.10%, iii. 74.63%, iv. 73.60%, v. 92.25%, vi. 77.40%. Drug release of all 5 units are found less than 80+5%.	Each unit is not less than Q+5%, Where Q is 80%
S <sub>2</sub>	6	Drug release of 6 units are found as follows: i. 47.83%, ii. 50.21%, iii. 51.26%, iv. 49.41%, v. 51.26%, vi. 54.70%. 1. Average drug release of 12 units (S <sub>1</sub> +S <sub>2</sub> ) 59.48%. 2. Drug release of 8 units are found less than 65% of claim i.e. Q-15%.	Average of 12 units (S <sub>1</sub> +S <sub>2</sub> ) is equal or greater than Q and No unit is less than Q-15%
S <sub>3</sub>	12	Drug release of 12 units are found as follows: i. 51.26%, ii. 48.64%, iii. 54.14%, iv. 49.69%, v. 50.74%, vi. 52.04%, vii. 55.44%, viii. 53.61%, ix. 57.27%, x. 52.31%, xi. 54.14%, xii. 52.57%. 1. Average drug release of 24 units (S <sub>1</sub> +S <sub>2</sub> +S <sub>3</sub> ) 56.07%. 2. Drug release of 20 units are found less than 65% of claim i.e. Q-15%. 3. Drug release of 18 units are found less than 55% of claim i.e. Q-25%.	Average of 24 units (S <sub>1</sub> +S <sub>2</sub> +S <sub>3</sub> ) is equal to or greater than Q, Not more than 2 units are less than Q-15% and no unit is less than (Q-25%)

### Assay

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
1	Paracetamol	502.5 mg/Tablet	500 mg/Tablet	100.5	95 % to 105 %	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 to I.P. with respect to the test for "Dissolution".

Date: 22-OCT-2024



GOVERNMENT ANALYST  
Amar Jyoti Chamuah  
Government Analyst  
R.D.T.L., Guwahati-22

Report in red coloured paper indicates the sample is Not of Standard Quality.

.....END OF REPORT.....