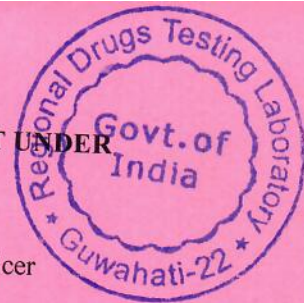


FORM 13

(See rule 46)

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

1. Name of Inspector from whom received : Lalruatdika varte
Drugs Inspector
Office of the Chief Medical Officer
Kolasib, Mizoram- 796082
2. Serial No. and date of Inspector's Memorandum : KLB/23/2022/DRUGS
Dated Kolasib, the 20th September, 2022
3. Number of Sample : Nil
4. Date of Receipt : 06/10/2022
5. Name of Drugs purporting to be contained in the sample :
Name of the Drug Batch No. Mfg. Date Exp. Date Mfd. By
PARACETAMOL PLA22004 04/2022 03/2024 M/s Danish Health Care (P) Ltd.
TABLETS IP 500 mg 76/27-28, Industrial Estate, Maxi Road,
Ujjain - 456 010 INDIA
6. Condition of seals on the packet or on portion of sample or container : Seals were intact and identical to the specimen impression of the seal received from the Drugs Inspector
7. Result of test or analysis with protocols of test or analysis applied :
Method: I.P. 2018

- Description : White, circular, flat, one side scored uncoated tablets in paper plastic strip.
- Identification : Gives positive test for Paracetamol.
- Average weight : 0.5562 g
- Uniformity of weight : Complies I.P.
- Dissolution : Does not Comply I.P.

Level	No. units Tested	Result	Acceptance Criteria
S ₁	06	Release of each individual unit obtained are as follows:- Unit 1=14.4%; Unit 2=15.0%; Unit 3=14.3%; Unit 4=14.1%; Unit 5=14.5%; Unit 6=16.6% Drug releases of all (6) units are found less than: 85% of claim (80+5%)	Each unit is not less than D+5% (80+ 5) of Claim. Where 'D' is 80%, (Specified in individual monograph)
S ₂	06	Release of each individual unit obtained are as follows:- Unit1=23.0%; Unit 2=22.8%; Unit 3=23.2%; Unit 4=23.8%; Unit 5=22.3%; Unit 6=22.5% Average drug release of 12 units (S₁+S₂) is: 18.9% of Claim (<80%) All 12 units are found less than 65% of claim (<D-15)	Average of 12 units (S ₁ +S ₂) is ≥ 80% (≥D) and not unit is < 65% of claim (D-15%).
S ₃	12	Release of each individual unit obtained are as follows:- Unit 1 = 14.4%; Unit 2 = 13.2%; Unit 3 = 12.6%; Unit 4 = 13.7%; Unit 5 = 14.2%; Unit 6 = 14.0%; Unit 7 = 13.5%; Unit 8 = 14.1%; Unit 9 = 14.6%; Unit 10 = 16.1%; Unit 11 = 16.8%; Unit 12 = 18.6% (i) Average drug release of 24 units (S₁+S₂+S₃) is: 16.8% of claim (<80%) (ii) All 24 units are found less than 65% of claim (<D-15) & (iii) All 24 units are found less than 55% of claim (<D-25)	Average of 24 units (S ₁ +S ₂ +S ₃) ≥ 80% (≥D), Not more than 2 units are <D-15% (i.e. 65%) and no unit is <D-25% (i.e. 55%)

Related substances : Complies I.P.

Assay :

Content of	Found mg/Tablet	Claim mg/Tablet	% of Claim	Limit (%) of Claim
Paracetamol	483.91	500.0	96.8	95.0-105.0

Date of Testing: 04/11/2022, 11/11/2022, 22/11/2022 to 25/11/2022

No. RDTL/Report/S/2022-2023/A.N.23140/ 7300 - 7302

Date: 28/11/2022

In the opinion of the undersigned the sample referred to above is **Not of Standard Quality** as defined in the Drugs & Cosmetics Act, 1940, and Rules thereunder for the reasons given below.

Remarks: The sample does not conform to I.P. with respect to the test for "Dissolution".

Dated: 28/11/2022

(Dilip Kr. Sarkar)

Government Analyst
RDTL, Guwahati

Dilip Kr. Sarkar
Government Analyst
R.D.T.L., Guwahati-22

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