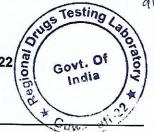


Regional Drugs Testing Laboratory Directorate General of Health Services, Guwahati (India)-781022 Fax: 0361-2338555/2330555 Phone No.0361 2338555

Email: rdtlguwahati@cdsco.nic.in



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 & Drugs) C.M.O. Office, Champhai-796321

Mizoram.

2. Serial No. and date of Inspector's memorandum

:001/IPA-CPI/24

Date: 27/11/2024

3. Number of Sample

:Nil

4. Date of receipt

:11-DEC-2024

5. Names of drugs purporting to be contained in the sample: Diclofenac Sodium & Paracetamol Tablets.

(DICLOGIN FORTF)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg.	Date of Exp.	Mfg. By
LSD/GUW/2024- 25/1760	GUW/LS/2024- 25/1790	M-9404	JUN. 2024	MAY 2026	Herb Edge Health Care Pvt. Ltd. 81, 82, 86, 87, - Indusrtial Area, Nagzir Dewas Road, Ujjain. 456010

6. Condition of seals on

[the packet or on portion of sample or container]

Seals were intact & identical to the 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 20-Feb-2025 To 25-Feb-2025

COMPOSITION

Each uncoated tablet contains:

Diclofenac Sodium IP

50mg

Paracetamol सत्याचेत्र अस्ति 325 mg

Protocol Applied: I.P. 2022

Sr No.	Test Name	Result	Limits	
1	Description	White, oval shape, bi-convex, uncoated tablet having a dosage line on one side pack in blister pack.	NA	
2	Identification	Gives positive test for Diclofenac Sodium & Paracetamol.	NA	
3	Average Weight	0.7018 gm.	NA	
4	Uniformity of Weight	Complies.	NA	
5	Dissolution	Complies.	NA	
6	Dissolution Complies for Diclofenac Sodium (Release of all six units are found above 'Q' 70+5%).		NLT 70 % of Claim	
7	Dissolution Complies for Paracetamol (Release of all six units are found above 'Q' 70+5%).		NLT 70 % of Claim	

<u>Assay</u>

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
1	Diclofenac Sodium	52.2 mg/Tablet	50 mg/Tablet	104.4	90 % to 110 %	I.P. 2022
2	Paracetamol	318.1 mg/Tablet	325 mg/Tablet	97.876	90 % to 110 %	I.P. 2022

In the opinion of the under signed the sample release.

Cosmetics Act, 1940, and Rules thereunder for the reasons given below.

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

GOVERNMENT ANALYST

Palyst

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

END OF REPORT