

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

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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

R. Vanlalsiama,

Asst Director (F & D), Sr.CMO Office, Lunglei.

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

:8

Date 27.01. 25

3. Number of Sample

:MS-6

4. Date of receipt

:07-FEB-2025

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

(DICLOGIN FORTE)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg.	Date of Exp.	Mfg. By
LSD/GUW/2024- 25/1751	GUW/LS/2024- 25/1772	M=9402	JUN. 2024	MAY 2026	Herb Edge Health Care Pvt. Ltd. 81, 82, 86, 87,- Indusrtial Area, Nagziri, 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 21-Feb-2025

COMPOSITION

Each uncoated tablet contains

Diclofenac Sodium

IP. 50mg

Paracetamol

325 mg

Protocol Applied:

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	0.695515 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

Sr.No	Ingredient Name	Found	Claim	0/ 05 -1-1		
			Gidini	% of claim	Limits	Procedure Method
1	Diclofenac Sodium	52.52 mg/Tablet	50 mg/Tablet	105.04	90 % to 110 %	I.P. 2022
2	Paracetamol	312 20 ma (T. I.)				
		312.28 mg/Tablet	325 mg/Tablet	96.086	90 % to 110 %	I.P. 2022

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.

Note: The monograph of "Diclofenac Sodium & Paracetamol Tablets" is in I.P. hence the label of the sample should be corrected accordingly.

Date: 24-FEB-2025

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

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