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

Regional Drugs Testing Laboratory Govt. Of India Guwahati-22

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** : 028/IPA-CPI/24 Date: 16/12/2024
3. **Number of Sample** : Nil
4. **Date of receipt** : 31-DEC-2024
5. **Names of drugs purporting to be contained in the sample:** Telmisartan and Hydrochlorothiazide Tablets IP (Tellme- 80H)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg. & Exp	Marketed By	Mfg. By
LSD/GUW/2025-26/0018	GUW/LS/2025-26/17	TA-24042	JAN. 2024 DEC. 2025	NA	Horizon Bioceuticals Pvt. Ltd. Plot No. 3 & 3-A, Industrial Area, Trilokpur Road, Kala Amb, Distt. Sirmour (HP) -173030.

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 22-Jan-2025 To 01-Apr-2025

COMPOSITION : Each uncoated tablet contains:
Telmisartan IP 80 mg
Hydrochlorothiazide IP 12.5 mg

Protocol Applied: I.P. 2022

Sr No.	Test Name	Result	Limits
1	Description	Bi-layer (orange & white), elongated, bi-convex, uncoated tablet in alu-alu blister pack.	NA
2	Identification	Gives positive test for Telmisartan and Hydrochlorothiazide.	NA
3	Average weight	0.5953 gm.	NA
4	Uniformity of weight	Complies.	NA
5	Dissolution	Complies.	NA
6	Dissolution for Telmisartan	Complies (Release of all six units were found above 'Q' 80+5%).	NLT 80 % of claim

7	Dissolution for Hydrochlorothiazide	Complies (Release of all six units were found above 'Q' 80+5%).	NLT 80 % of claim

Assay

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
1	Telmisartan	82.33 mg/Tablet	80 mg/Tablet	102.912	95 % to 105 %	I.P. 2022
2	Hydrochlorothiazide	11.77 mg/Tablet	12.5 mg/Tablet	94.16	90 % to 107.5 %	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.

Date: 03-APR-2025

GOVERNMENT ANALYST

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

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
CDSCO CDSCO
सत्यमेव जयते
MINISTRY OF HEALTH, GOVERNMENT OF INDIA

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