



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. Zarzokimi, Assistant Drugs Inspector (Food and Drugs)
C.M.O. Office,
Champhai-796321 Mizoram
2. Serial No. and date of Inspector's memorandum : 101/IPA-CPI/II-25, 28-MAY-2025
3. Number of Sample : Not mentioned.
4. Date of receipt : 16-JUN-2025
5. Names of drugs purporting to be contained in the sample : Telmisartan Tablets IP 40 mg. (Savtel 40 Tablets)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg. & Exp	Marketed By	Mfg. By
LSD/GUW/2025-GUW/LS/2025-26/0682	26/681	PT-40585	Feb-2024 Jan-2026	NA	Pharmaroots Healthcare, Khasra No. 411, Village Tipra, P.O. Barotiwala, Tehsil Baddi, Distt. Solan, H.P.

6. Condition of seals on : Seals were intact & identical to the specimen impression of the seal received from Drugs Inspector
(the packet or on portion of sample or container)

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

Date of Testing : From 22-Jul-2025 To 10-Sep-2025

COMPOSITION : Each film coated tablet contains: Telmisartan IP 40 mg.

Protocol Applied : I.P. 2022

Sr No.	Test Name	Result	Limits
1	Description	White, round, bi-convex, scored on one surface, film coated tablets, in alu-alu strip.	NA
2	Identification	Gives positive test for Telmisartan.	NA
3	Average weight	0.3487 g	NA
4	Uniformity of weight	Complies.	±5 % of Average weight
5	Dissolution	Does not comply.	NLT 75% of claim
6	Level S1 (6 units)	Does not comply. Release of Telmisartan of each individual unit is found as follows: Unit 1=68.9%; Unit 2=67.7%; Unit 3=71.0%; Unit 4=70.3%; Unit 5=72.9%; Unit 6=71.9%. Release of Telmisartan of all 06 units are found less than 80% of claim i.e. (Q+5%) where Q is 75% of claim.	Each unit is not less than Q+5% i.e. 80% of claim where Q is 75%.

7	Level S2 (6 units)	Does not comply. Release of Telmisartan of each individual unit is found as follows: Unit 1=65.5%; Unit 2=67.1%; Unit 3=60.7%; Unit 4=66.6%; Unit 5=65.5%; Unit 6=64.6% . Average release of Telmisartan of 12 units (S1+S2) is 67.7% of claim which is less than Q i.e. 75% of claim.	Average of 12 units (S1+S2) $\geq$ 75% of claim and no unit is less than 60% of claim (Q-15%)
8	Level S3 (12 units)	Does not comply. Release of Telmisartan of each individual unit is found as follows: Unit 1=66.9%; Unit 2=65.9%; Unit 3=68.2%; Unit 4=67.9%; Unit 5=66.1%; Unit 6=65.2%; Unit 7=68.3%; Unit 8=64.4%; Unit 9=63.5%; Unit 10=63.8%; Unit 11=64.3%; Unit 12=64.9% . Average release of Telmisartan of 24 units (S1+S2+S3) is 66.76% of claim which is less than Q i.e. 75% of claim.	Average of 24 units (S1+S2+S3) $\geq$ 75% of claim, not more than 2 units are less than 60% of claim (Q-15%) and no unit is less than 50% of claim (Q-25%)

Assay

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
1	Telmisartan	39.5 mg/Tablet	40 mg/Tablet	98.75	90 % to 110 %	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 comply as per I.P. 2022 with respect to the test for "Dissolution" of Telmisartan.

Date: 11-SEP-2025

GOVERNMENT ANALYST

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

Report in the red colored paper indicates the sample is not of standard quality.

END OF REPORT