

FORM 13
(See rule 46)

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

- Name of Inspector from whom received : K. Lalngilneia,
Asst. Director (F&D),
CMO Office, Mamit District: Mamit,
Pin- 796441.
- Serial No. and date of Inspector's memorandum : B.17011/12/09-CMO(M)/DRUGS/31 , Date: 09-DEC-2024
- Number of Sample : MD08/31
- Date of receipt : 20-DEC-2024
- Names of drugs purporting to be contained in the sample : Telmisartan Tablets IP 40mg (Savtel 40 Tablets)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg.	Date of Exp.	Mfg. By
LSD/GUW/2024-25/1745	GUW/LS/2024-25/1771	PT-40584	Feb-2024	Jan-2026	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
[the packet or on portion of sample or container] 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 17-Feb-2025 To 21-Feb-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, film coated, bi-convex tablet having scored on one side in blister strip.	NA
2	Identification	Gives positive test for Telmisartan.	NA
3	Average weight	0.3508 g	NA
4	Uniformity of weight	Passes the test.	NA
5	Dissolution	Does not comply.	NA

Level	Number Tested	Result	Acceptance Criteria
S1	6	Drug release of 6 units are found as follows: i. 61.3%, ii. 60.2%, iii. 66.1%, iv. 59.7%, v. 59.7%, vi. 59.5%. Drug release of all units are found less than 75+5%.	Each unit is not less than Q+5% where "Q" is 75%
S2	6	Drug release of 6 units are found as follows: i. 72.1%, ii. 72.3%, iii. 77.3%, iv. 77.1%, v. 78.0%, vi. 73.4%. 1. Average drug release of 12 units (S ₁ +S ₂) 68.1%.	Average of 12 units (S ₁ +S ₂) is ≥Q, and no unit is less than Q-15%
S3	12	Drug release of 12 units are found as follows: i. 60.0%, ii. 59.3%, iii. 61.5%, iv. 61.1%, v. 56.7%, vi. 56.7%, vii. 68.5%, viii. 68.3%, ix. 63.7%, x. 66.3%, xi. 67.2%, xii. 68.3%. 1. Average drug release of 24 units (S ₁ +S ₂ +S ₃) 65.6%. 2. Drug release of 06 units are found less than 60% of claim i.e. Q-15%.	Average of 24 units (S ₁ +S ₂ +S ₃) is ≥Q, not more than 2 units are less than Q-15% and no unit is less than Q-25%


Assay

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
1	Telmisartan	38.9 mg/Tablet	40 mg/Tablet	97.25	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 conform to I.P. with respect to the test for "Dissolution".

Date: 25-FEB-2025


GOVERNMENT ANALYST
 Amar Jyoti Chamuah
 Government Analyst
 R.D.T.Ly, Guwahati-22

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

-----END OF REPORT-----