



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 : Mr. R. Vanlalruata Assistant Director (F and D)  
OFFICE OF CHIEF MEDICAL OFFICER,  
AIZAWL, MIZORAM, PIN:-796017.
2. Serial No. and date of Inspector's memorandum : 04/IPA-AZL E/II-2025 , 16-APR-2025
3. Number of Sample : NIL
4. Date of receipt : 22-APR-2025
5. 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. & Exp   | Marketed By | Mfg. By                                                                                                           |
|----------------------------------|--------------------|-----------|----------------------|-------------|-------------------------------------------------------------------------------------------------------------------|
| LSD/GUW/2025-GUW/LS/2025-26/0452 | GUW/LS/2025-26/455 | PT-40586  | Feb-2024<br>Jan-2026 | NA          | Pharmaroots Healthcare,<br>Khasra No. 411, Village Tipra,<br>P.O. Barotiwala, Tehsil Baddi,<br>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 13-May-2025 To 24-Jun-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 blister pack.                                                                                                                                                                                                       | NA                                                                  |
| 2      | Identification                 | Gives positive test for Telmisartan.                                                                                                                                                                                                                                                        | NA                                                                  |
| 3      | Average weight                 | 0.3535 gm                                                                                                                                                                                                                                                                                   | NA                                                                  |
| 4      | Uniformity of weight           | Complies.                                                                                                                                                                                                                                                                                   | ±5% of average weight                                               |
| 5      | Dissolution                    | Does not comply.                                                                                                                                                                                                                                                                            | NLT 75% of claim                                                    |
| 6      | Dissolution (Stage- 1) 6 units | Does not comply. Release of Telmisartan of each individual unit is found as follows: Unit 1=73.18%; Unit 2=73.01%; Unit 3=72.84%; Unit 4=70.22%; Unit 5=68.65%; Unit 6=64.30% .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 | Dissolution (Stage- 2) 6 units  | Does not comply. Release of Telmisartan of each individual unit is found as follows: Unit 1=70.06%; Unit 2=67.05%; Unit 3=67.58%; Unit 4=65.46%; Unit 5=65.28%; Unit 6=65.81%. Average release of Telmisartan of 12 units (S1+S2) is found 68.62% of claim which is less 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 | Dissolution (Stage- 3) 12 units | Does not comply. Release of Telmisartan of each individual unit is found as follows: Unit 1=77.86%; Unit 2=76.61%; Unit 3=69.27%; Unit 4=68.20%; Unit 5=70.52%; Unit 6=71.42%; Unit 7=70.17%; Unit 8=68.20%; Unit 9=68.02%; Unit 10=65.69%; Unit 11=77.86%; Unit 12=75.89%. Average release of Telmisartan of 24 units (S1+S2+S3) is found 70.13% of claim which is less than Q i.e. 75% of claim. | Average of 24 units (S1+S2+S3) equal to or greater than 80% and not more than 2 units are less than 60%(Q-15%) and no unit less than(Q-25%) |

### Assay

| Sr.No | Ingredient Name | Found           | Claim        | % of claim | Limits        | Procedure / Method |
|-------|-----------------|-----------------|--------------|------------|---------------|--------------------|
| 1     | Telmisartan     | 41.58 mg/Tablet | 40 mg/Tablet | 103.95     | 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: 08-JUL-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 -----