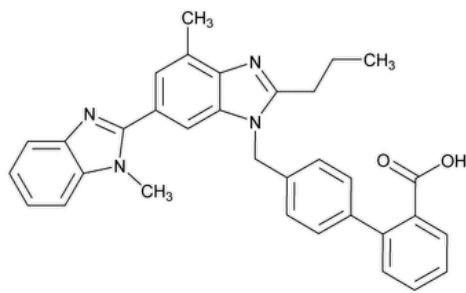


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Telmisartan



$C_{33}H_{30}N_4O_2$ 514.62
[1,1'-Biphenyl]-2-carboxylic acid, 4'-[(1,4'-dimethyl-2'-propyl[2,6'-bi-1*H*-benzimidazol]-1'-yl)methyl-];
4'-[4-Methyl-6-(1-methyl-2-benzimidazolyl)-2-propyl-1-benzimidazolyl]methyl-2-biphenylcarboxylic acid CAS RN[®]: 144701-48-4; UNII:
U5SYW473RQ.

Change to read:

DEFINITION

Telmisartan contains NLT 98.0% and NMT $\blacktriangle$ 102.0% $\blacktriangle$ (USP 1-May-2021) of telmisartan ($C_{33}H_{30}N_4O_2$), calculated on the dried basis.

IDENTIFICATION

Change to read:

- **A. [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy](#):** 197K $\blacktriangle$ or 197A $\blacktriangle$ (USP 1-May-2021)
Analysis: If the spectra obtained shows differences, proceed with the samples prepared as follows. Separately dissolve a quantity of [USP Telmisartan RS](#) and the Telmisartan sample in [alcohol](#). [NOTE—Heating the solution may be necessary for complete dissolution.] Cool the solution in an ice bath, filter the crystals, and dry at 105°.
Acceptance criteria: Meets the requirements
- **B.** The retention time of the major peak from the *Sample solution* corresponds to that from the *Standard solution*, as obtained in the $\blacktriangle$ Assay. $\blacktriangle$ (USP 1-May-2021)

ASSAY

Change to read:

- **PROCEDURE**
 $\blacktriangle$ [NOTE—Protect all solutions containing telmisartan from light.]
Solution A: 2.0 g/L of [monobasic potassium phosphate](#) and 3.8 g/L of [sodium 1-pentanesulfonate](#) in [water](#). Adjust with 1 M phosphoric acid to a pH of 3.0.
Solution B: [Acetonitrile](#) and [methanol](#) (80:20)
Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	70	30

Time (min)	Solution A (%)	Solution B (%)
2	70	30
27	20	80
32	20	80
32.1	70	30
37	70	30

Standard stock solution A: 5 mg/mL of [USP Telmisartan RS](#) prepared as follows. Transfer a suitable amount of [USP Telmisartan RS](#) to a suitable volumetric flask. Add [methanol](#) to about 50% of the flask volume and 1 M sodium hydroxide to 1% of the flask volume. Sonicate to dissolve. Dilute with [methanol](#) to volume.

Standard stock solution B: 25 µg/mL of [USP Telmisartan Related Compound B RS](#) prepared as follows. Transfer a suitable amount of [USP Telmisartan Related Compound B RS](#) to a suitable volumetric flask. Add [methanol](#) to about 50% of the flask volume and 1 M sodium hydroxide to 1% of the flask volume. Sonicate to dissolve. Dilute with [methanol](#) to volume.

System suitability solution: 2.5 mg/mL of the [USP Telmisartan RS](#) and 2.5 µg/mL of [USP Telmisartan Related Compound B RS](#) in [methanol](#), from *Standard stock solution A* and *Standard stock solution B*

Standard solution: 0.25 mg/mL [USP Telmisartan RS](#) in [methanol](#), from *Standard stock solution A*

Sample stock solution: 2.5 mg/mL of Telmisartan prepared as follows. Transfer a suitable amount of Telmisartan to a suitable volumetric flask. Add [methanol](#) to about 50% of the flask volume and 1 M sodium hydroxide to 1% of the flask volume. Sonicate to dissolve. Dilute with [methanol](#) to volume.

Sample solution: 0.25 mg/mL of Telmisartan in [methanol](#), from *Sample stock solution*

Chromatographic system

(See [Chromatography \(621\), System Suitability](#).)

Mode: LC

Detector: UV 230 nm

Column: 4.0-mm × 12.5-cm; 5-µm packing [L1](#)

Column temperature: 40°

Flow rate: 1.0 mL/min

Injection volume: 2 µL

System suitability

Samples: *System suitability solution* and *Standard solution*

Suitability requirements

Resolution: NLT 3.0 between telmisartan and telmisartan related compound B, *System suitability solution*

Tailing factor: NMT 2.0, *Standard solution*

Relative standard deviation: NMT 0.73%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of telmisartan ($C_{33}H_{30}N_4O_2$) in the portion of Telmisartan taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of telmisartan from the *Sample solution*

r_S = peak response of telmisartan from the *Standard solution*

C_S = concentration of [USP Telmisartan RS](#) in the *Standard solution* (mg/mL)

C_U = concentration of Telmisartan in the *Sample solution* (mg/mL)▲ (USP 1-May-2021)

Acceptance criteria: 98.0%–▲102.0%▲ (USP 1-May-2021) on the dried basis

IMPURITIES

• [RESIDUE ON IGNITION \(281\)](#)