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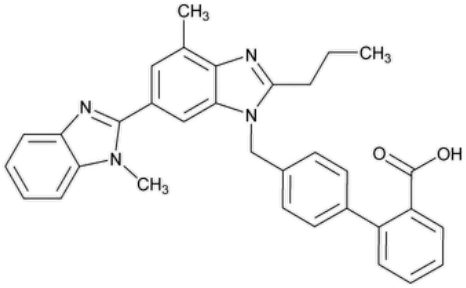
Telmisartan



$C_{33}H_{30}N_4O_2$ 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 ▲102.0%▲ (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 ▲or 197A▲ (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

Change to read:

• **B.** The retention time of the major peak from the *Sample solution* corresponds to that from the *Standard solution*, as obtained in the ▲*Assay*.▲ (USP 1-May-2021)

ASSAY

Change to read:

• **Procedure**

▲[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⟩**

Sample: 1 g

Acceptance criteria: NMT 0.1%

Change to read:

• **Organic Impurities**

▲[Note—Protect all solutions containing telmisartan from light.]

Solution A, Solution B, Mobile phase, Standard stock solution A, Standard stock solution B, System suitability solution, Sample stock solution, and **Chromatographic system:** Proceed as directed in the *Assay*.

Sensitivity solution: 1.25 µg/mL USP Telmisartan RS in methanol, from *Standard solution*▲ (USP 1-May-2021)

Standard solution: ▲25 µg/mL USP Telmisartan RS in methanol, from *Standard stock solution A*▲ (USP 1-May-2021)

Sample solution: ▲2.5 mg/mL of Telmisartan. Use undiluted *Sample stock solution*.▲ (USP 1-May-2021)

System suitability

Samples: *System suitability solution*, ▲*Sensitivity solution*,▲ (USP 1-May-2021) and *Standard solution*

[Note—See *Table 2* for relative retention times.]

Suitability requirements

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

Tailing factor: Between 0.9 and 1.5 for telmisartan related compound B, *System suitability solution*

Relative standard deviation: NMT 5.0% for the telmisartan peak, *Standard solution*

▲**Signal-to-noise ratio:** NLT 10, *Sensitivity solution*▲ (USP 1-May-2021)

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of any individual ▲specified and unspecified▲ (USP 1-May-2021) impurity in the portion of Telmisartan taken:

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

r_U = peak response of each individual impurity 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)▲ (USP 1-May-2021)

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

Acceptance criteria: See *Table 2*. ▲The reporting threshold is 0.05%.▲ (USP 1-May-2021)

Table 2

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Telmisartan related compound A[a]	0.3	0.1
Telmisartan diacid▲[b]▲ (USP 1-May-2021)	0.67	0.1
Telmisartan amide▲[c]▲ (USP 1-May-2021)	0.7	0.1
Telmisartan related compound B▲▲ (USP 1-May-2021)	0.9	0.1
Telmisartan	1.00	—
Telmisartan *tert*-butyl ester▲[d]▲ (USP 1-May-2021)	1.7	0.2

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Telmisartan unknown impurity	1.8	0.2
Any ▲▲ (USP 1-May-2021) individual ▲unspecified▲ (USP 1-May-2021) impurity	—	▲0.10▲ (USP 1-May-2021)
Total impurities	—	1.0

[a] 1,7'-Dimethyl-2'-propyl-1*H*,3'*H*-2,5'-bibenzo[*d*]imidazole.

[b] 1-[(2'-Carboxybiphenyl-4-yl)methyl]-4-methyl-2-propyl-1*H*-benzo[*d*]imidazole-6-carboxylic acid.

[c] 4'-[(1,7'-Dimethyl-2'-propyl-1*H*,3'*H*-2,5'-bibenzo[*d*]imidazol-3'-yl)methyl]biphenyl-2-carboxamide.

[d] *tert*-Butyl 4'-[(1,7'-dimethyl-2'-propyl-1*H*,3'*H*-2,5'-bibenzo[*d*]imidazol-3'-yl)methyl]biphenyl-2-carboxylate.

SPECIFIC TESTS

• **Loss on Drying** ⟨731⟩

Sample: 1.0 g

Analysis: Dry the *Sample* at 105° to constant weight.

Acceptance criteria: NMT 1.5%

ADDITIONAL REQUIREMENTS

Change to read:

• **Packaging and Storage:** Preserve in tight containers, and protect from light. ▲Store at controlled room temperature.▲ (USP 1-May-2021)

• **USP Reference Standards** ⟨11⟩

USP Telmisartan RS

USP Telmisartan Related Compound B RS

4'-[(1,7'-Dimethyl-2'-propyl-1*H*,1'*H*-2,5'-bibenzo[*d*]imidazol-1'-yl)methyl]biphenyl-2-carboxylic acid.

$C_{33}H_{30}N_4O_2$ 514.62

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
TELMISARTAN	Documentary Standards Support	SM22020 Small Molecules 2
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM22020 Small Molecules 2

Chromatographic Database Information: Chromatographic Database

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