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Telmisartan Tablets

DEFINITION

Telmisartan Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of telmisartan ($C_{33}H_{30}N_4O_2$).

IDENTIFICATION

• **A. Spectroscopic Identification Tests ⟨197⟩, *Ultraviolet-Visible Spectroscopy*: 197U:** The spectrum of the solution under test corresponds to that of the *Standard solution*, as obtained in *Dissolution Test 1*.

• **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

ASSAY

Change to read:

• **Procedure**

Diluent: 0.005 N methanolic solution of sodium hydroxide

Buffer: 2.0 g/L of ammonium dihydrogen phosphate. Adjust with 1 M phosphoric acid to a pH of 3.0.

Mobile phase: Methanol and *Buffer* (70:30)

Standard stock solution: 0.8 mg/mL of USP Telmisartan RS and 0.1 mg/mL of USP Telmisartan Related Compound A RS in *Diluent*

Standard solution: 0.11 mg/mL of USP Telmisartan RS and 0.013 mg/mL of USP Telmisartan Related Compound A RS in *Mobile phase* from the *Standard stock solution*. Pass the solution through a membrane filter of 0.45-µm pore size.

Sample solution: Transfer NLT 20 Tablets into a suitable volumetric flask, and add about 80% of the volume of *Diluent*. Swirl to disperse, and sonicate for about 10 min. Allow to cool to room temperature, dilute with *Diluent* to volume, and mix. Pass the resulting solution through a membrane filter of 0.45-µm pore size. Further dilute quantitatively in *Mobile phase* to prepare a solution having a concentration of 0.11 mg/mL.

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 298 nm

Column: 4.0-mm × 4-cm; 5-µm packing L1

Column temperature: 40°

Flow rate: 0.7 mL/min

Injection volume: 5 µL

System suitability

Sample: *Standard solution*

Suitability requirements

[Note—The relative retention times for telmisartan related compound A and telmisartan are 0.53 and 1.00, respectively.]

Resolution: NLT 3 between telmisartan and telmisartan related compound A

Tailing factor: ▲NMT 2.0 for telmisartan▲ (ERR 1-Nov-2023)

▲▲ (ERR 1-Nov-2023)

Relative standard deviation: NMT 2.0% ▲for telmisartan▲ (ERR 1-Nov-2023)

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of telmisartan ($C_{33}H_{30}N_4O_2$) in the portion of Tablets 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 = nominal concentration of telmisartan in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

Change to read:

• **Dissolution** ⟨711⟩

Test 1

Medium: pH 7.5 phosphate buffer (prepared by dissolving 13.61 g of potassium dihydrogen phosphate in about 800 mL of water, adjusting with 2 M sodium hydroxide to a pH of 7.5, and diluting with water to 1000 mL); 900 mL

Apparatus 2: 75 rpm

Time: 30 min

Standard solution: Transfer about 44 mg of USP Telmisartan RS to a 100-mL volumetric flask. Add 1 mL of 0.1 M sodium hydroxide, and dilute with methanol to volume. Dilute this solution quantitatively with *Medium* to obtain a solution having a final concentration of about 0.011 mg/mL.

Sample solution

For Tablets labeled to contain 20 mg: Pass a portion of the solution under test through a suitable filter of 0.45-µm pore size. Further dilute the filtrate with *Medium* (1:2).

For Tablets labeled to contain 40 mg: Pass a portion of the solution under test through a suitable filter of 0.45-µm pore size. Further dilute the filtrate with *Medium* (1:4).

For Tablets labeled to contain 80 mg: Pass a portion of the solution under test through a suitable filter of 0.45-µm pore size. Further dilute the filtrate with *Medium* (1:8).

Instrumental conditions

Mode: UV

Analytical wavelength: 296 nm

Blank: *Medium*

Analysis

Samples: *Standard solution* and *Sample solution*

▲Calculate the percentage of the labeled amount▲ (ERR 1-Nov-2023) of telmisartan ($C_{33}H_{30}N_4O_2$) dissolved:

$$\text{▲Result} = (A_U/A_S) \times C_S \times V \times D \times (1/L) \times 100\text{▲ (ERR 1-Nov-2023)}$$

A_U = absorbance of the *Sample solution*

C_S = concentration of ▲USP Telmisartan RS in▲ (ERR 1-Nov-2023) the *Standard solution* (mg/mL)

V = volume of *Medium*, 900 mL

A_S = absorbance of the *Standard solution*

D = dilution factor of the *Sample solution*

L = label claim (mg/Tablet)

Tolerances: NLT 75% (Q) of the labeled amount of telmisartan ($C_{33}H_{30}N_4O_2$) is dissolved.

Test 2: If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 2*.

Medium: 0.1 N hydrochloric acid; 900 mL

Apparatus 2: 75 rpm

Time: 45 min

Buffer: 2.72 g/L of potassium dihydrogen phosphate. Add 2 mL of triethylamine per liter of solution and adjust with phosphoric acid to a pH of 2.4.

Mobile phase: Acetonitrile and *Buffer* (40:60)

Standard stock solution: 0.44 mg/mL of USP Telmisartan RS prepared as follows. To a suitable amount of USP Telmisartan RS in a suitable volumetric flask add methanol, about 50% of the total volume. Sonicate to dissolve, cool to room temperature, and dilute with *Medium* to volume.

Standard solution: (*L*/900) mg/mL of USP Telmisartan RS in *Medium* from *Standard stock solution*, where *L* is the label claim in mg/Tablet

Sample solution: Pass portions of the solution under test through a suitable filter of 0.45-µm pore size and discard the first 3 mL of the filtrate.

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 298 nm

Column: 4.6-mm × 25-cm; 5-µm packing L1

Flow rate: 1 mL/min

Injection volume: 20 µL

Run time: NLT 1.6 times the retention time of telmisartan

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of telmisartan ($C_{33}H_{30}N_4O_2$) dissolved:

$$\text{Result} = (r_U/r_S) \times C_S \times V \times (1/L) \times 100$$

r_U = peak response ▲of telmisartan▲ (ERR 1-Nov-2023) from the *Sample solution*

r_S = peak response ▲of telmisartan▲ (ERR 1-Nov-2023) from the *Standard solution*

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

V = volume of *Medium*, 900 mL

L = label claim (mg/Tablet)

Tolerances: NLT 80% (*Q*) of the labeled amount of telmisartan ($C_{33}H_{30}N_4O_2$) is dissolved.

Test 3: If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 3*.

Medium, Apparatus 2, and **Instrumental conditions:** Proceed as directed in *Dissolution Test 1*.

Time: 20 min

Standard solution: 0.011 mg/mL of USP Telmisartan RS prepared as follows. Transfer about 44 mg of USP Telmisartan RS to a 100-mL volumetric flask. Add 1 mL of 0.1 M sodium hydroxide, and sonicate to dissolve. Dilute with methanol to volume and mix. Dilute this solution quantitatively with *Medium* to obtain a solution of the required final concentration.

Sample solution: Pass a portion of the solution under test through a suitable filter of 0.45-µm pore size, and discard the first few milliliters. Dilute quantitatively with *Medium* as needed.

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of telmisartan ($C_{33}H_{30}N_4O_2$) dissolved:

$$\text{Result} = (A_U/A_S) \times C_S \times V \times D \times (1/L) \times 100$$

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

C_S = concentration of ▲USP Telmisartan RS in▲ (ERR 1-Nov-2023) the *Standard solution* (mg/mL)

V = volume of *Medium*, 900 mL

D = dilution factor of the *Sample solution*

L = label claim (mg/Tablet)

Tolerances: NLT 80% (*Q*) of the labeled amount of telmisartan ($C_{33}H_{30}N_4O_2$) is dissolved.

• **Uniformity of Dosage Units ⟨905⟩:** Meet the requirements

IMPURITIES

• **Organic Impurities**

Diluent, Buffer, Mobile phase, Sample solution, Chromatographic system, and **System suitability:** Proceed as directed in the *Assay*.

Analysis

Sample: *Sample solution*

Calculate the percentage of each impurity in the portion of Tablets taken:

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

r_U = peak response of each individual impurity from the *Sample solution*

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

Acceptance criteria: NMT 0.2% of any individual impurity

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in well-closed containers, and store at controlled room temperature.

• **Labeling:** When more than one *Dissolution* test is given, the labeling states the test used only if *Test 1* is not used.

• **USP Reference Standards ⟨11⟩**

USP Telmisartan RS

USP Telmisartan Related Compound A RS

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

$C_{19}H_{20}N_4 \cdot H_2O$ 322.41

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

Topic/Question	Contact	Expert Committee
TELMISARTAN TABLETS	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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