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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- $\mu$ m 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- $\mu$ m 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- $\mu$ m 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.