## Telmisartan and Amlodipine Tablets

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In accordance with the Rules and Procedures of the 2015–2020 Council of Experts, the Chemical Medicines Monographs 2 Expert Committee has revised the Telmisartan and Amlodipine Tablets monograph. The purpose for the revision is to add *Dissolution Test 3* to accommodate FDA-approved drug products with different dissolution tolerances than the existing dissolution tests.

- *Dissolution Test 3* uses separate HPLC methods for telmisartan and amlodipine that were validated using a GL Sciences Inertsil ODS-3V brand of L1 column. The typical retention times for amlodipine and telmisartan are about 2.8 min and 3.5 min, respectively.

The Telmisartan and Amlodipine Tablets Revision Bulletin supersedes the currently official monograph.

Should you have any questions, please contact Donald Min, Senior Scientific Liaison (301-230-7457 or ddm@usp.org).

# Telmisartan and Amlodipine Tablets

## DEFINITION

Telmisartan and Amlodipine Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount each of telmisartan ($C_{33}H_{30}N_4O_2$) and amlodipine ($C_{20}H_{25}ClN_2O_5$).

## IDENTIFICATION

- **A.** The retention times of the two major peaks of the *Sample solution* correspond to those of the *Standard solution*, as obtained in the *Assay*.
- **B.** The UV spectra of the two major peaks of the *Sample solution* correspond to those of the *Standard solution*, as obtained in the *Assay*.

## ASSAY

- **PROCEDURE**

**Buffer:** 0.022 M monobasic sodium phosphate dihydrate and 2 mL of triethylamine in 1 L of water. Adjust with phosphoric acid to a pH of 6.0.

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

**Diluent:** Add 5 mL of triethylamine to 500 mL of water. Add 500 mL of acetonitrile and mix.

**Standard stock solution 1:** 0.4 mg/mL of USP Telmisartan RS in *Diluent*

**Standard stock solution 2:** 0.4 mg/mL of USP Amlodipine Besylate RS in *Diluent*

**Standard solution:** 0.08 mg/mL of USP Telmisartan RS and 0.03 mg/mL of USP Amlodipine Besylate RS in *Diluent* from *Standard stock solution 1* and *Standard stock solution 2*

**Sample stock solution:** Nominally 0.4 mg/mL of telmisartan and 0.1 mg/mL of amlodipine from Tablets prepared as follows. Transfer NLT 10 Tablets to a suitable volumetric flask. Add acetonitrile to about 20% of the volume of the flask, and sonicate for 5 min with intermittent shaking. Add *Diluent* to about 80% of the volume of the flask and sonicate until the Tablets are completely dispersed. Dilute with *Diluent* to the volume. Centrifuge and use the supernatant.

**Sample solution:** Nominally 0.08 mg/mL of telmisartan and 0.02 mg/mL of amlodipine from *Sample stock solution* in *Diluent*. Pass a portion of the solution through a suitable filter of 0.45-µm pore size.

**Chromatographic system**

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

**Mode:** LC

**Detector:** UV 257 nm. For *Identification B*, use a diode array detector in the range of 200–350 nm.

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

**Temperatures**

**Autosampler:** 10°

**Column:** 30°

**Flow rate:** 1 mL/min

**Injection volume:** 20 µL

**Run time:** 20 min

**System suitability**

**Sample:** *Standard solution*

[NOTE—The relative retention times for amlodipine and telmisartan are 0.5 and 1.0, respectively.]

**Suitability requirements**

**Tailing factor:** NMT 2.0 for telmisartan; NMT 2.5 for amlodipine

**Relative standard deviation:** NMT 2.0% for telmisartan and amlodipine

**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)

Calculate the percentage of the labeled amount of amlodipine ($C_{20}H_{25}ClN_2O_5$) in the portion of Tablets taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (M_{r1}/M_{r2}) \times 100$$

$r_U$ = peak response of amlodipine from the *Sample solution*

$r_S$ = peak response of amlodipine from the *Standard solution*

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

$C_U$ = nominal concentration of amlodipine besylate in the *Sample solution* (mg/mL)

$M_{r1}$ = molecular weight of amlodipine, 408.88

$M_{r2}$ = molecular weight of amlodipine besylate, 567.05

**Acceptance criteria:** 90.0%–110.0% each of telmisartan and amlodipine

## PERFORMANCE TESTS

***Change to read:***

- **DISSOLUTION** ⟨711⟩

**Test 1**

**Test for telmisartan**

**Medium:** pH 7.5 phosphate buffer (0.05 M monobasic potassium phosphate and 0.038 M sodium hydroxide in 1 L of water; adjusted with diluted sodium hydroxide solution to a pH of 7.5); 900 mL

**Apparatus 2:** 75 rpm

**Time:** 20 min

**Buffer:** 0.022 M monobasic sodium phosphate dihydrate and 2 mL of triethylamine in 1 L of water. Adjust with phosphoric acid to a pH of 6.0.

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

**Diluent:** Add 5 mL of triethylamine to 500 mL of water. Add 500 mL of acetonitrile and mix.

**Standard stock solution:** 0.9 mg/mL of USP Telmisartan RS in *Diluent*. [NOTE—Sonication may be required to aid dissolution.]

**Standard solution:** 0.045 mg/mL of USP Telmisartan RS from *Standard stock solution* in *Medium*

**Sample solution:** Pass a portion of the solution under test through a suitable filter with suitable pore size.

**Chromatographic system**

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

**Mode:** LC

**Detector:** UV 257 nm

**Column:** 4.6-mm × 15-cm; 5-µm packing L1

**Temperatures**

**Autosampler:** 10°

**Column:** 30°

**Flow rate:** 1 mL/min

**Injection volume:** 20 µL

**Run time:** 12 min

**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:

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

$r_U$ = 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)
$D$ = dilution factor for the *Sample solution*, if needed
$V$ = volume of *Medium*, 900 mL
$L$ = label claim of telmisartan (mg/Tablet)

**Test for amlodipine**
**Medium:** 0.01 N hydrochloric acid; 500 mL
**Apparatus 2:** 75 rpm
**Time:** 20 min
**Mobile phase** and **Chromatographic system:** Proceed as directed in *Test for telmisartan*.
**Standard stock solution:** 0.7 mg/mL of USP Amlodipine Besylate RS in *Medium*. [NOTE—Sonication may be required to aid dissolution.]
**Standard solution:** 0.03 mg/mL of USP Amlodipine Besylate RS from *Standard stock solution* in *Medium*
**Sample solution:** Pass a portion of the solution under test through a suitable filter of suitable pore size.
**System suitability**
**Sample:** *Standard solution*
**Suitability requirements**
**Tailing factor:** NMT 2.5
**Relative standard deviation:** NMT 2.0%
**Analysis**
**Samples:** *Standard solution* and *Sample solution*
Calculate the percentage of the labeled amount of amlodipine ($C_{20}H_{25}ClN_2O_5$) dissolved:

$$\text{Result} = (r_U/r_S) \times (C_S \times D) \times V \times (1/L) \times (M_{r1}/M_{r2}) \times 100$$

$r_U$ = peak response of amlodipine from the *Sample solution*
$r_S$ = peak response of amlodipine from the *Standard solution*
$C_S$ = concentration of USP Amlodipine Besylate RS in the *Standard solution* (mg/mL)
$D$ = dilution factor for the *Sample solution*, if needed
$V$ = volume of *Medium*, 500 mL
$L$ = label claim of amlodipine (mg/Tablet)
$M_{r1}$ = molecular weight of amlodipine, 408.88
$M_{r2}$ = molecular weight of amlodipine besylate, 567.05

**Tolerances:** NLT 80% ($Q$) of the labeled amount of telmisartan ($C_{33}H_{30}N_4O_2$) is dissolved. NLT 80% ($Q$) of the labeled amount of amlodipine ($C_{20}H_{25}ClN_2O_5$) is dissolved.

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

**Test for telmisartan**
**Medium:** pH 7.5 phosphate buffer (6.805 g/L of monobasic potassium phosphate and 1.6 g/L of sodium hydroxide in water; adjusted with 5 N sodium hydroxide solution or phosphoric acid to a pH of 7.5); 900 mL
**Apparatus 2:** 75 rpm
**Time:** 30 min
**Buffer:** 1.54 g/L of ammonium acetate in water. Adjust with acetic acid to a pH of 5.0.
**Mobile phase:** Acetonitrile and *Buffer* (50:50)
**Diluent:** 0.01 N hydrochloric acid
**Standard stock solution:** 0.56 mg/mL of USP Telmisartan RS, prepared as follows. Transfer a quantity of USP Telmisartan RS to a suitable volumetric flask. Add 40% of the total volume of both methanol and *Diluent*. Sonicate to dissolve. Dilute with *Diluent* to volume and mix well.
**Standard solution**
**For Tablets labeled to contain 80 mg of telmisartan:** 0.09 mg/mL of USP Telmisartan RS in *Medium* from the *Standard stock solution*
**For Tablets labeled to contain 40 mg of telmisartan:** 0.045 mg/mL of USP Telmisartan RS in *Medium* from the *Standard stock solution*
**Sample solution:** Pass a portion of the solution under test through a suitable filter of 0.45-µm pore size.
**Chromatographic system**
(See *Chromatography* ⟨621⟩*, System Suitability*.)
**Mode:** LC
**Detector:** UV 230 nm
**Column:** 4.6-mm × 15-cm; 5-µm packing L7
**Temperatures**
**Autosampler:** 10°
**Column:** 35°
**Flow rate:** 1.5 mL/min
**Injection volume:** 10 µL
**Run time:** NLT 2 times the retention time of the telmisartan peak
**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*
[NOTE—The relative retention times for amlodipine and telmisartan are 0.69 and 1.00, respectively.]
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 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)
$V$ = volume of *Medium*, 900 mL
$L$ = label claim of telmisartan (mg/Tablet)

**Test for amlodipine**
**Medium:** 0.01 N hydrochloric acid; 500 mL
**Apparatus 2:** 75 rpm
**Time:** 30 min
**Buffer:** 1.54 g/L of ammonium acetate in water. Adjust with acetic acid to a pH of 5.0.
**Mobile phase:** Acetonitrile and *Buffer* (40:60)

**Standard stock solution:** 0.35 mg/mL of USP Amlodipine Besylate RS prepared as follows. Transfer a quantity of USP Amlodipine Besylate RS to a suitable volumetric flask. Add 5% of the total volume of methanol. Sonicate to dissolve. Dilute with water to volume and mix well.

**Standard solution**

**For Tablets labeled to contain 10 mg of amlodipine:** 0.028 mg/mL of USP Amlodipine Besylate RS in *Medium* from the *Standard stock solution*

**For Tablets labeled to contain 5 mg of amlodipine:** 0.014 mg/mL of USP Amlodipine Besylate RS in *Medium* from the *Standard stock solution*

**Sample solution:** Pass a portion of the solution under test through a suitable filter of 0.45-µm pore size.

**Chromatographic system**

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

**Mode:** LC

**Detector:** UV 238 nm

**Column:** 4.6-mm × 15-cm; 5-µm packing L7

**Temperatures**

**Autosampler:** 10°

**Column:** 35°

**Flow rate:** 1.5 mL/min

**Injection volume:** 40 µL

**Run time:** NLT 2.5 times the retention time of the amlodipine peak

**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*

[NOTE—The relative retention times for amlodipine and telmisartan are 1.0 and 1.9, respectively.]

Calculate the percentage of the labeled amount of amlodipine ($C_{20}H_{25}ClN_2O_5$) dissolved:

$$\text{Result} = (r_U/r_S) \times C_S \times V \times (1/L) \times (M_{r1}/M_{r2}) \times 100$$

$r_U$ = peak response of amlodipine from the *Sample solution*

$r_S$ = peak response of amlodipine from the *Standard solution*

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

$V$ = volume of *Medium*, 500 mL

$L$ = label claim of amlodipine (mg/Tablet)

$M_{r1}$ = molecular weight of amlodipine, 408.88

$M_{r2}$ = molecular weight of amlodipine besylate, 567.05

**Tolerances:** NLT 80% (*Q*) of the labeled amount each of telmisartan ($C_{33}H_{30}N_4O_2$) and amlodipine ($C_{20}H_{25}ClN_2O_5$) are dissolved.

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

**Test for telmisartan**

**Medium:** pH 7.5 phosphate buffer (dissolve 6.8 g of monobasic potassium phosphate in 1000 mL of water; adjusted with sodium hydroxide to a pH of 7.5); 900 mL

**Apparatus 2:** 75 rpm

**Time:** 30 min

**Buffer:** Dissolve 2.72 g of monobasic potassium phosphate in 1000 mL of water. Adjust with phosphoric acid to a pH of 2.4.

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

**Standard stock solution:** 0.89 mg/mL of USP Telmisartan RS in methanol. Sonication may be needed to aid dissolution.

**Standard solution**

**For Tablets labeled to contain 80 mg of telmisartan:** 0.089 mg/mL of USP Telmisartan RS in *Medium* from the *Standard stock solution*

**For Tablets labeled to contain 40 mg of telmisartan:** 0.045 mg/mL of USP Telmisartan RS in *Medium* from the *Standard stock solution*

**Sample solution:** Pass a portion of the solution under test through a suitable filter of 0.45-µm pore size.

**Chromatographic system**

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

**Mode:** LC

**Detector:** UV 237 nm

**Column:** 4.6-mm × 15-cm; 5-µm packing L1

**Flow rate:** 1 mL/min

**Injection volume:** 10 µL

**Run time:** NLT 2 times the retention time of the telmisartan peak

**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*

[NOTE—The relative retention times for amlodipine and telmisartan are 0.78 and 1.00, respectively.]

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 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)

$V$ = volume of *Medium*, 900 mL

$L$ = label claim of telmisartan (mg/Tablet)

**Test for amlodipine**

**Medium:** 0.01 N hydrochloric acid; 500 mL

**Apparatus 2:** 75 rpm

**Time:** 15 min

**Buffer** and **Mobile phase:** Prepare as directed in the *Test for telmisartan*.

**Standard stock solution:** 0.28 mg/mL of USP Amlodipine Besylate RS prepared as follows. Transfer a quantity of USP Amlodipine Besylate RS to a suitable volumetric flask. Add about 3% of the total volume of methanol. Sonicate to dissolve. Dilute with *Medium* to volume and mix well.

**Standard solution**

**For Tablets labeled to contain 10 mg of amlodipine:** 0.028 mg/mL of USP Amlodipine Besylate RS in *Medium* from the *Standard stock solution*

**For Tablets labeled to contain 5 mg of amlodipine:** 0.014 mg/mL of USP Amlodipine Besylate RS in *Medium* from the *Standard stock solution*

**Sample solution:** Pass a portion of the solution under test through a suitable filter of 0.45-µm pore size.

**Chromatographic system:** Proceed as directed in the *Test for telmisartan* except for the *Run time*.

**Run time:** NLT 2 times the retention time of the amlodipine peak

**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*

[NOTE—The relative retention times for amlodipine and telmisartan are 1.00 and 1.28, respectively.]

Calculate the percentage of the labeled amount of amlodipine ($C_{20}H_{25}ClN_2O_5$) dissolved:

$$\text{Result} = (r_U/r_S) \times C_S \times V \times (1/L) \times (M_{r1}/M_{r2}) \times 100$$

$r_U$ = peak response of amlodipine from the *Sample solution*

$r_S$ = peak response of amlodipine from the *Standard solution*

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

$V$ = volume of *Medium*, 500 mL

$L$ = label claim of amlodipine (mg/Tablet)

$M_{r1}$ = molecular weight of amlodipine, 408.88

$M_{r2}$ = molecular weight of amlodipine besylate, 567.05

**Tolerances:** NLT 80% ($Q$) of the labeled amount each of telmisartan ($C_{33}H_{30}N_4O_2$) and amlodipine ($C_{20}H_{25}ClN_2O_5$) are dissolved.▲ (RB 1-Feb-2019)

- **UNIFORMITY OF DOSAGE UNITS** ⟨905⟩**:** Meet the requirements

## IMPURITIES

- **ORGANIC IMPURITIES**

**Buffer 1:** 0.023 M ammonium acetate in water. Adjust with phosphoric acid to a pH of 5.5.

**Solution A:** Acetonitrile and *Buffer 1* (20:80)

**Solution B:** Acetonitrile and *Buffer 1* (65:35)

**Mobile phase:** See *Table 1*.

**Table 1**

| Time (min) | Solution A (%) | Solution B (%) |
|---|---|---|
| 0 | 95 | 5 |
| 5 | 95 | 5 |
| 15 | 70 | 30 |
| 35 | 45 | 55 |
| 50 | 5 | 95 |
| 65 | 0 | 100 |
| 70 | 0 | 100 |
| 75 | 95 | 5 |
| 80 | 95 | 5 |

**Buffer 2:** 0.023 M ammonium acetate in water. Adjust with phosphoric acid to a pH of 2.0.

**Diluent:** Acetonitrile and *Buffer 2* (40:60)

**Standard stock solution 1:** 0.5 mg/mL of USP Telmisartan RS in *Diluent*

**Standard stock solution 2:** 0.17 mg/mL of USP Amlodipine Besylate RS in *Diluent*

**Standard solution:** 25 µg/mL of USP Telmisartan RS from *Standard stock solution 1* and 4.25 µg/mL of USP Amlodipine Besylate RS from *Standard stock solution 2* in *Diluent*

**Sensitivity solution:** 0.25 µg/mL of USP Telmisartan RS from *Standard stock solution 1* and 0.11 µg/mL of USP Amlodipine Besylate RS from *Standard stock solution 2* in *Diluent*

**Sample solution:** Nominally 0.25 mg/mL of amlodipine prepared as follows. Transfer a suitable quantity, nominally equivalent to 25 mg of amlodipine from finely powdered Tablets (NLT 10), to a suitable volumetric flask. Add *Diluent* to 70% of the volume of the flask. Sonicate in cold water for 15 min with intermittent shaking. Dilute with *Diluent* to volume. Pass a portion of the solution through a suitable filter of 0.45-µm pore size.

**Chromatographic system**

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

**Mode:** LC

**Detector:** UV 257 nm

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

**Temperatures**

**Autosampler:** 10°

**Column:** 30°

**Flow rate:** 1 mL/min

**Injection volume:** 20 µL

**System suitability**

**Samples:** *Standard solution* and *Sensitivity solution*

[NOTE—The relative retention times for amlodipine and telmisartan are 0.74 and 1.0, respectively.]

**Suitability requirements**

**Tailing factor:** NMT 2.5, *Standard solution*

**Relative standard deviation:** NMT 5.0%, *Standard solution*

**Signal-to-noise ratio:** NLT 10, *Sensitivity solution*

**Analysis**

**Samples:** *Standard solution* and *Sample solution*

Calculate the percentage of amlodipine related compound D or amlodipine mannitol adduct in the portion of Tablets taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (1/F) \times (M_{r1}/M_{r2}) \times 100$$

$r_U$ = peak response of amlodipine related compound D or amlodipine mannitol adduct from the *Sample solution*

$r_S$ = peak response of amlodipine from the *Standard solution*

$C_S$ = concentration of USP Amlodipine Besylate RS in the *Standard solution* (µg/mL)

$C_U$ = nominal concentration of amlodipine in the *Sample solution* (µg/mL)

$F$ = relative response factor (see *Table 2*)

$M_{r1}$ = molecular weight of amlodipine, 408.88

$M_{r2}$ = molecular weight of amlodipine besylate, 567.05

Calculate the percentage of each individual unspecified degradation product in the portion of Tablets taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (M_{r1}/M_{r2}) \times 100$$

$r_U$ = peak response of each individual unspecified degradation product from the *Sample solution*

$r_S$ = peak response of amlodipine from the *Standard solution*

$C_S$ = concentration of USP Amlodipine Besylate RS in the *Standard solution* (µg/mL)

$C_U$ = nominal concentration of amlodipine in the *Sample solution* (µg/mL)

$M_{r1}$ = molecular weight of amlodipine, 408.88

$M_{r2}$ = molecular weight of amlodipine besylate, 567.05

**Acceptance criteria:** See *Table 2*. Disregard any peak less than 0.1%.

**Table 2**

| Name | Relative Retention Time | Relative Response Factor | Acceptance Criteria, NMT (%) |
|---|---|---|---|
| Besylate[a] | 0.08 | — | — |
| Amlodipine related compound D[b] | 0.59 | 0.39 | 1.0 |
| Amlodipine mannitol adduct | 0.67 | 1.00 | 0.50 |
| Amlodipine | 0.74 | — | — |
| Telmisartan related compound A[c, d] | 0.78 | — | — |
| Telmisartan related compound B[d, e] | 0.86 | — | — |
| Telmisartan | 1.0 | — | — |
| Any individual unspecified degradation product | — | — | 0.2 |
| Total degradation products | — | — | 2.0 |

[a] Peak due to besylate (benzenesulfonic acid).
[b] 3-Ethyl 5-methyl 4-(2-chlorophenyl)-2-{[2-(1,3-dioxoisoindolin-2-yl)ethoxy] methyl}-6-methyl-1,4-dihydropyridine-3,5-dicarboxylate.
[c] 1,7′-Dimethyl-2′-propyl-1*H*,3′*H*-2,5′-bibenzo[*d*]imidazole.
[d] Process impurities controlled in the drug substance.
[e] 4′-[(1,7′-Dimethyl-2′-propyl-1*H*,1′*H*-2,5′-bibenzo[*d*]imidazol-1′-yl)methyl] biphenyl-2-carboxylic acid.

## ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight containers. Store at controlled room temperature.
- **LABELING:** When more than one *Dissolution* test is given, the labeling states the *Dissolution* test used only if *Test 1* is not used.
- **USP REFERENCE STANDARDS** ⟨11⟩
  USP Amlodipine Besylate RS
  USP Telmisartan RS