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# 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**  
**Change to read:**

- 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:** ▲Prepare the following solutions of [USP Telmisartan RS](#) and [USP Amlodipine Besylate RS](#) in *Diluent* at the concentrations shown in [Table 1](#). Transfer a suitable volume of *Standard stock solution 1* and *Standard stock solution 2* into a suitable volumetric flask. Dilute with *Diluent* to volume.

Table 1

Tablet Strength Telmisartan/Amlodipine (mg/mg)	Concentration of Telmisartan (mg/mL)	Concentration of Amlodipine Besylate (mg/mL)
40/5	0.08	0.14
40/10	0.08	0.28
80/5	0.16	0.14
80/10	0.08	0.14▲ (USP 1-Dec-2020)

**Sample solution:** ▲Transfer Tablets (NLT 10) 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 flask volume and sonicate until the Tablets are completely dispersed. Dilute with *Diluent* to volume. Centrifuge and use the supernatant. Dilute with *Diluent*, if necessary, to obtain the solutions of nominal concentrations of telmisartan and amlodipine stated in [Table 1](#). Pass a portion of the solution under test through a suitable filter of 0.45-µm pore size.▲ (USP 1-Dec-2020)

**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:** ▲NLT 1.5 times the retention time of telmisartan▲ (USP 1-Dec-2020)

#### 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, Mobile phase, and Diluent:** Prepare as directed in the Assay.

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

##### 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*▲

(USP 1-Dec-2020)

**Sample solution:** Pass a portion of the solution under test through a suitable filter of 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:** ▲NLT 1.5 times the retention time of telmisartan▲ (USP 1-Dec-2020)

### 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 0.5 and 1.0, respectively.]▲ (USP 1-Dec-2020)

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 1, 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

▲**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*▲ (USP 1-Dec-2020)

**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 each of telmisartan ( $C_{33}H_{30}N_4O_2$ ) and 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- $\mu$ m pore size.

#### Chromatographic system

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

**Mode:** LC

**Detector:** UV 230 nm

**Column:** 4.6-mm  $\times$  15-cm; 5- $\mu$ m packing [L7](#)

#### Temperatures

**Autosampler:** 10°

**Column:** 35°

**Flow rate:** 1.5 mL/min

**Injection volume:** 10  $\mu$ L

**Run time:** NLT 2 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*

[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- $\mu$ m pore size.

### Chromatographic system

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

**Mode:** LC

**Detector:** UV 238 nm

**Column:** 4.6-mm  $\times$  15-cm; 5- $\mu$ m packing [L7](#)

### Temperatures

**Autosampler:** 10°

**Column:** 35°

**Flow rate:** 1.5 mL/min

**Injection volume:** 40  $\mu$ L

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

### 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 ( $C_{20}H_{25}ClN_2O_5$ ) is 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 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*

[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 *Test 3, 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 3, Test for telmisartan* except for the *Run time*.

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

**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 ( $C_{20}H_{25}ClN_2O_5$ ) is dissolved.

- [UNIFORMITY OF DOSAGE UNITS \(905\)](#): Meet the requirements

**IMPURITIES**

**Change to read:**

- **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 2](#).

**Table 2**

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 under test 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 A▲ (IRA 1-Dec-2020) 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 A▲ (IRA 1-Dec-2020) 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 3](#))

$M_{r1}$  = 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 3](#). ▲The reporting threshold is 0.1%.▲ (USP 1-Dec-2020)

**Table 3**

Name	Relative Retention Time	Relative Response Factor	Acceptance Criteria, NMT (%)
Besylate <sup>a</sup>	0.08	—	—
▲Amlodipine related compound A▲ (IRA 1-Dec-2020) <sup>b</sup>	0.59	0.39	1.0
Amlodipine mannitol adduct	0.67	1.00	0.50
Amlodipine	0.74	—	—
Telmisartan related compound A <sup>c,d</sup>	0.78	—	—
Telmisartan related compound B <sup>d,e</sup>	0.86	—	—
Telmisartan	1.0	—	—
Any individual unspecified degradation product	—	—	0.2
Total degradation products	—	—	2.0

<sup>a</sup> Peak due to besylate (benzenesulfonic acid).

<sup>▲b</sup> 3-Ethyl 5-methyl [2-(2-aminoethoxymethyl)-4-(2-chlorophenyl)-6-methyl-3,5-pyridinedicarboxylate] fumarate.▲ (IRA 1-Dec-2020)

<sup>c</sup> 1,7'-Dimethyl-2'-propyl-1*H*,3'*H*-2,5'-bibenzo[*d*]imidazole.

<sup>d</sup> Process impurities controlled in the drug substance.

<sup>e</sup> 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](#)

**Auxiliary Information** - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
TELMISARTAN AND AMLODIPINE TABLETS	<a href="#">Documentary Standards Support</a>	SM22020 Small Molecules 2

Topic/Question	Contact	Expert Committee
REFERENCE STANDARD SUPPORT	RS Technical Services <a href="mailto:RSTECH@usp.org">RSTECH@usp.org</a>	SM22020 Small Molecules 2

Chromatographic Database Information: [Chromatographic Database](#)

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