

Status: Currently Official on 16-Feb-2025
Official Date: Official as of 01-Dec-2020
Document Type: USP Monographs
DocId: GUID-28BAF205-CE48-4560-8D78-F368969563E6_7_en-US
DOI: https://doi.org/10.31003/USPNF_M5502_07_01
DOI Ref: tk61g

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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.**Documents**

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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:

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

