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Amlodipine and Olmesartan Medoxomil Tablets

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DEFINITION

Amlodipine and Olmesartan Medoxomil Tablets contain an amount of Amlodipine Besylate equivalent to NLT 90.0% and NMT 110.0% of the labeled amount of amlodipine ($C_{20}H_{25}ClN_2O_5$) and NLT 90.0% and NMT 110.0% of the labeled amount of olmesartan medoxomil ($C_{29}H_{30}N_6O_6$).

IDENTIFICATION

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

ASSAY

• **PROCEDURE**

Solution A: 6.9 g/L of [sodium phosphate, monobasic](#). Adjust with [phosphoric acid](#) to a pH of 2.5.

Solution B: [Acetonitrile](#)

Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	68	32
12	68	32
15	30	70
21	30	70
23	68	32
25	68	32

Diluent: [Acetonitrile](#) and [water](#) (50:50)

Standard stock solution: 0.28 mg/mL of [USP Amlodipine Besylate RS](#) and 0.8 mg/mL of [USP Olmesartan Medoxomil RS](#) in *Diluent*

Standard solution: 0.056 mg/mL of [USP Amlodipine Besylate RS](#) and 0.16 mg/mL of [USP Olmesartan Medoxomil RS](#) in *Diluent* from *Standard stock solution*

Sample stock solution: Nominal concentrations given in [Table 2](#) are prepared as follows.

For Tablet strength 5/20, transfer NLT 5 Tablets equivalent to 25 mg of amlodipine and 100 mg of olmesartan medoxomil into a suitable volumetric flask. Add [water](#) to 20% of the total volume and sonicate for 5 min. Add [acetonitrile](#) to 20% of the total volume and sonicate for 5 min. Add *Diluent* to 30% of the total volume and sonicate for 15 min. Dilute with *Diluent* to volume. Centrifuge a portion of the solution for 10 min and pass through a filter of 0.45-µm pore size.

For Tablet strength 5/40, 10/20, or 10/40, transfer NLT 5 Tablets equivalent to 25 mg of amlodipine and 200 mg of olmesartan medoxomil, 50 mg of amlodipine and 100 mg of olmesartan medoxomil, or 50 mg of amlodipine and 200 mg of olmesartan medoxomil into a suitable volumetric flask. Add [water](#) to 10% of the total volume and sonicate for 5 min. Add [acetonitrile](#) to 10% of the total volume and sonicate for 5 min. Add *Diluent* to 30% of the total volume and sonicate for 15 min. Dilute with *Diluent* to volume. Centrifuge a portion of the solution for 10 min and pass through a filter of 0.45-µm pore size.

Table 2

Tablet Strength Amlodipine/ Olmesartan Medoxomil (mg/mg)	Nominal Concentration of Amlodipine (mg/mL)	Nominal Concentration of Olmesartan Medoxomil (mg/mL)
5/20, 10/40	0.5	2
5/40	0.25	2
10/20	0.5	1

Sample solution: Nominal concentrations in *Diluent* from *Sample stock solution* are given in [Table 3](#).

Table 3

Tablet Strength Amlodipine/ Olmesartan Medoxomil (mg/mg)	Nominal Concentration of Amlodipine (mg/mL)	Nominal Concentration of Amlodipine/ Olmesartan Medoxomil (mg/mL)
5/20, 10/40	0.04	0.16
5/40	0.02	0.16
10/20	0.04	0.08

Chromatographic system

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

Mode: LC

Detector: UV 254 nm. For *Identification A*, use a diode array detector in the range of 200–400 nm.

Column: 4.6-mm × 25-cm; 5-μm packing [L11](#)

Temperatures

Autosampler: 5°

Column: 60°

Flow rate: 2 mL/min

Injection volume: 10 μL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0 for amlodipine and olmesartan medoxomil peaks

Relative standard deviation: NMT 2.0% for amlodipine and olmesartan medoxomil peaks

Analysis

Samples: *Standard solution* and *Sample solution*

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 in the *Sample solution* (mg/mL)

M_{r1} = molecular weight of amlodipine, 408.88

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

Calculate the percentage of the labeled amount of olmesartan medoxomil ($C_{29}H_{30}N_6O_6$) in the portion of Tablets taken:

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

r_U = peak response of olmesartan medoxomil from the *Sample solution*

r_S = peak response of olmesartan medoxomil from the *Standard solution*

C_S = concentration of [USP Olmesartan Medoxomil RS](#) in the *Standard solution* (mg/mL)

C_U = nominal concentration of olmesartan medoxomil in the *Sample solution* (mg/mL)

Acceptance criteria

Amlodipine: 90.0%–110.0%

Olmesartan medoxomil: 90.0%–110.0%

PERFORMANCE TESTS

Change to read:

- [DISSOLUTION \(711\)](#).

Test 1

Medium: 6.8 g/L of [potassium phosphate, monobasic](#). Adjust with [0.2 N sodium hydroxide solution](#) to a pH of 6.8; 900 mL.

Apparatus 2: 50 rpm

Times

Amlodipine: 30 min

Olmesartan medoxomil: 45 min

Buffer: 4.08 g/L of [potassium phosphate, monobasic](#). Adjust with [phosphoric acid](#) to a pH of 2.5.

Mobile phase: [Acetonitrile](#) and *Buffer* (40:60)

Standard stock solution A: 0.16 mg/mL of [USP Amlodipine Besylate RS](#) in *Mobile phase*

Standard stock solution B: 0.44 mg/mL of [USP Olmesartan Medoxomil RS](#) in *Mobile phase*

Standard solution: 0.016 mg/mL of [USP Amlodipine Besylate RS](#) and 0.044 mg/mL of [USP Olmesartan Medoxomil RS](#) in *Medium* from *Standard stock solution A* and *Standard stock solution B*

Sample solution: Pass a portion of the solution under test through a suitable filter of 0.45-µm pore size and discard the first 2–3 mL of the filtrate.

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 4.6-mm × 15-cm; 5-µm packing [L1](#)

Autosampler temperature: 5°

Flow rate: 1.2 mL/min

Injection volume: 10 µL

Run time: NLT 1.4 times the retention time of olmesartan medoxomil

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0 for amlodipine and olmesartan medoxomil peaks

Relative standard deviation: NMT 2.0% for amlodipine and olmesartan medoxomil peaks

Analysis

Samples: *Standard solution* and *Sample solution*

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

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

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*, 900 mL

M_{r1} = molecular weight of amlodipine, 408.88

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

L = label claim of amlodipine (mg/Tablet)

Calculate the concentration (C_1 or C_2) of olmesartan medoxomil ($C_{29}H_{30}N_6O_6$) in the sample withdrawn from the vessel at the 30- or 45-min time point: