

Olmesartan Medoxomil Tablets

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DEFINITION
Olmesartan Medoxomil Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of olmesartan medoxomil (C₂₉H₃₀N₆O₆).

IDENTIFICATION

- **A.** The UV absorption spectra of the major peak of the *Sample solution* exhibit maxima and minima at the same wavelengths as those of the corresponding peak of the *Standard solution*, as obtained in the Assay.
- **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

- **PROCEDURE**
Solution A: 3.1 g/L of [formic acid](#)
Solution B: [Acetonitrile](#) and *Solution A* (10:90)
Solution C: [Acetonitrile](#) and *Solution A* (90:10)
Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution B (%)	Solution C (%)
0	68.8	31.2
1.5	37.5	62.5
1.6	68.8	31.2
3.0	68.8	31.2

Diluent: [Acetonitrile](#) and [water](#) (60:40)
Standard solution: 40 µg/mL of [USP Olmesartan Medoxomil RS](#) in *Diluent*
Sample stock solution: Prepare solutions of nominal concentrations of olmesartan medoxomil in *Diluent* as follows. To NLT 10 Tablets for 5- and 20-mg Tablet strengths and NLT 5 Tablets for 40-mg Tablet strength in a 200-mL volumetric flask, add *Diluent* to volume. Sonicate with occasional shaking to disintegrate the Tablets completely, centrifuge the suspension, and use the supernatant.
Sample solution: Nominally 40 µg/mL of olmesartan medoxomil in *Diluent* from *Sample stock solution*
Chromatographic system
(See [Chromatography \(621\)](#), [System Suitability](#).)
Mode: LC
Detector: UV 249 nm. For *Identification A*, use a diode array detector in the range of 200–400 nm.
Column: 2.1-mm × 5-cm; 1.7-µm packing [L1](#)
Column temperature: 35°
Flow rate: 0.6 mL/min
Injection volume: 1 µL
System suitability
Sample: *Standard solution*

Suitability requirements**Tailing factor:** NMT 2.0**Relative standard deviation:** NMT 1.0%**Analysis****Samples:** *Standard solution* and *Sample solution*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* (µg/mL) C_U = nominal concentration of olmesartan medoxomil in the *Sample solution* (µg/mL)**Acceptance criteria:** 90.0%–110.0%**PERFORMANCE TESTS****Change to read:**

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

Test 1**Medium:** pH 6.8 phosphate buffer (see [Reagents, Indicators, and Solutions—Buffer Solutions](#))**For Tablets labeled to contain 5 mg:** 500 mL**For Tablets labeled to contain 20 and 40 mg:** 1000 mL**Apparatus 2:** 50 rpm**Time:** 30 min**Diluent:** [Acetonitrile](#) and [water](#) (60:40)**Standard stock solution:** 2 mg/mL of [USP Olmesartan Medoxomil RS](#) in *Diluent***Standard solution:** (L/V) mg/mL of [USP Olmesartan Medoxomil RS](#) in *Medium*, where L is the label claim in mg/Tablet and V is the volume of the *Medium* in mL from the *Standard stock solution***Sample solution:** Pass a portion of the solution under test through a glass fiber filter of 1.2-µm pore size.**Instrumental conditions**(See [Ultraviolet-Visible Spectroscopy \(857\)](#).)**Mode:** UV**Analytical wavelength:** 258 nm**Cells****For Tablets labeled to contain 5 and 20 mg:** 1 cm**For Tablets labeled to contain 40 mg:** 0.5 cm**Blank:** *Medium***Analysis****Samples:** *Standard solution* and *Sample solution*Calculate the percentage of the labeled amount of olmesartan medoxomil ($C_{29}H_{30}N_6O_6$) dissolved:

$$\text{Result} = (A_U/A_S) \times C_S \times V \times (1/L) \times 100$$

 A_U = absorbance of the *Sample solution* A_S = absorbance of the *Standard solution* C_S = concentration of the *Standard solution* (mg/mL) V = volume of *Medium* (see *Medium*) L = label claim (mg/Tablet)**Tolerances:** NLT 75% (Q) of the labeled amount of olmesartan medoxomil ($C_{29}H_{30}N_6O_6$) is dissolved.**Test 2:** If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 2*.**Documents**

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Medium: pH 7.2 phosphate buffer (see [Reagents, Indicators, and Solutions—Buffer Solutions](#)); 900 mL

Apparatus 2: 75 rpm

Time: 30 min

Standard stock solution: 0.2 mg/mL of [USP Olmesartan Medoxomil RS](#) prepared as follows. Transfer an appropriate amount of [USP Olmesartan Medoxomil RS](#) into a suitable volumetric flask. Dissolve in 30% of the flask volume of [acetonitrile](#). Dilute with *Medium* to volume and mix.

Standard solution: (L/1000) mg/mL of [USP Olmesartan Medoxomil RS](#) in *Medium*, from the *Standard stock solution*, where L is the label claim in mg/Tablet

Sample solution: Pass a portion of the solution under test through a suitable filter of 0.45-μm pore size and discard the first few milliliters of the filtrate.

Instrumental conditions

Mode: UV

Analytical wavelength: 257 nm

Cell: 1 cm

Blank: *Medium*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of olmesartan medoxomil ($C_{29}H_{30}N_6O_6$) dissolved:

$$\text{Result} = (A_U/A_S) \times C_S \times V \times (1/L) \times 100$$

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

C_S = concentration of the *Standard solution* (mg/mL)

V = volume of *Medium*, 900 mL

L = label claim (mg/Tablet)

Tolerances: NLT 80% (Q) of the labeled amount of olmesartan medoxomil ($C_{29}H_{30}N_6O_6$) is dissolved.

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

Medium: 0.05 M [hydrochloric acid](#); 900 mL

Apparatus 2: 50 rpm

Time: 45 min

Buffer: 1.36 g/L of [monobasic potassium phosphate](#) in [water](#). Adjust with [phosphoric acid](#) to a pH of 2.5.

Solution A: [Acetonitrile](#) and *Buffer* (20:80)

Solution B: [Acetonitrile](#) and *Buffer* (80:20)

Mobile phase: See [Table 2](#).

Table 2

Time (min)	Solution A (%)	Solution B (%)
0	75	25
4.0	52	48
5.0	75	25
7.0	75	25

Diluent A: [Acetonitrile](#), [water](#), and [phosphoric acid](#) (50:50:2)

Diluent B: *Medium* and *Diluent A* (50:50)

Standard stock solution: 0.22 mg/mL of [USP Olmesartan Medoxomil RS](#) in *Diluent A*, prepared as follows. Transfer an appropriate amount of [USP Olmesartan Medoxomil RS](#) to a suitable volumetric flask. Add *Diluent A* to 60% of the total volume and sonicate to dissolve. Dilute with *Diluent A* to volume and mix well.

Standard solution

For Tablets labeled to contain 5 mg: 2.75 µg/mL of [USP Olmesartan Medoxomil RS](#) in *Diluent B* from the *Standard stock solution*

For Tablets labeled to contain 20 mg: 11 µg/mL of [USP Olmesartan Medoxomil RS](#) in *Diluent B* from the *Standard stock solution*

For Tablets labeled to contain 40 mg: 22 µg/mL of [USP Olmesartan Medoxomil RS](#) in *Diluent B* 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 and discard the first few milliliters of the filtrate. Transfer 5 mL of the filtered test solution to a 10-mL volumetric flask and dilute with *Diluent A* to volume.

Chromatographic system

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

Mode: LC

Detector: UV 250 nm

Column: 4.6-mm × 15-cm; 5-µm packing [L7](#)

Temperatures

Autosampler: 5°

Column: 30°

Flow rate: 1.5 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

[NOTE—The relative retention times for olmesartan and olmesartan medoxomil are 0.45 and 1.00, respectively.]

Suitability requirements

Tailing factor: NMT 2.0 for olmesartan medoxomil

Relative standard deviation: NMT 2.0% for olmesartan medoxomil

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the concentration (C_1) of olmesartan medoxomil ($C_{29}H_{30}N_6O_6$) in the *Sample solution*:

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

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)

Calculate the concentration (C_2) of olmesartan as olmesartan medoxomil ($C_{29}H_{30}N_6O_6$) in the *Sample solution*:

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

r_U = peak response of olmesartan 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)

F = relative response factor, 0.88

M_{r2} = molecular weight of olmesartan medoxomil, 558.59

M_{r1} = molecular weight of olmesartan, 446.50

Calculate the percentage of the labeled amount of olmesartan medoxomil ($C_{29}H_{30}N_6O_6$) dissolved:

$$\text{Result} = [(C_1 + C_2) \times D] \times V \times (1/L) \times 100$$

C_1 = concentration of olmesartan medoxomil in the *Sample solution* (mg/mL)

C_2 = concentration of olmesartan as olmesartan medoxomil in the *Sample solution* (mg/mL)

D = dilution factor for the *Sample solution*