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Olmesartan Medoxomil Tablets

To view the Notice from the Expert Committee that posted in conjunction with this accelerated revision, please click <https://www.uspnf.com/rb-olmesartan-medoxomil-tabs-20250131>.

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*.

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*

V = volume of *Medium*, 900 mL

L = label claim for olmesartan medoxomil (mg/Tablet)

Tolerances: NLT 75% (Q) of the labeled amount of olmesartan medoxomil ($C_{29}H_{30}N_6O_6$) is dissolved.

Test 4: If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 4*.

Medium: 0.1 M [hydrochloric acid](#); 900 mL

Apparatus 2: 50 rpm

Time: 15 min

Buffer: Dissolve 2.04 g of [monobasic potassium phosphate](#) in 1000 mL of [water](#). Adjust with [phosphoric acid](#) to a pH of 3.0.

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

Diluent: [Acetonitrile](#) and [water](#) (60:40)

Standard stock solution: 1.1 mg/mL of [USP Olmesartan Medoxomil RS](#) in *Diluent*

Standard solution

[NOTE—Preserve immediately at 2°–8° after preparation.]

For Tablets labeled to contain 5 mg: 5.5 µg/mL of [USP Olmesartan Medoxomil RS](#) in *Medium* from the *Standard stock solution*

For Tablets labeled to contain 20 mg: 22 µg/mL of [USP Olmesartan Medoxomil RS](#) in *Medium* from the *Standard stock solution*

For Tablets labeled to contain 40 mg: 44 µg/mL of [USP Olmesartan Medoxomil 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 and discard the first 1 mL of the filtrate. [NOTE—Preserve immediately at 2°–8° after preparation.]

Chromatographic system

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

Mode: LC

Detector: UV 250 nm

Column: 4.0-mm × 12.5-cm; 5-µm packing [L1](#)

Temperatures

Autosampler: 8°

Column: 40°

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 0.24 and 1.00, respectively.]

Suitability requirements

Tailing factor: 0.8–1.5 for olmesartan medoxomil

Relative standard deviation: NMT 2.0% for the sum of the peak responses of olmesartan and olmesartan medoxomil

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:

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

r_U = sum of the peak responses of olmesartan and olmesartan medoxomil from the *Sample solution*

r_S = sum of the peak responses of olmesartan and olmesartan medoxomil from the *Standard solution*

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

V = volume of *Medium*, 900 mL

L = label claim of olmesartan medoxomil (mg/Tablet)

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

Test 5: If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 5*.

Medium: pH 6.8 phosphate buffer (Dissolve 68.0 g of [monobasic potassium phosphate](#) in 8000 mL of [water](#) in a suitable container. Adjust with diluted [sodium hydroxide](#) to a pH of 6.8 ± 0.05. Dilute with [water](#) to 10,000 mL); 900 mL. [NOTE—Tight control of the pH is critical.]

Apparatus 2: 50 rpm. Use apex vessels.

Time: 30 min

Buffer: Dissolve 6.8 g of [monobasic potassium phosphate](#) in 1000 mL of [water](#). Add 5 mL of [triethylamine](#) and mix. Adjust with [phosphoric acid](#) to a pH of 2.5.

Mobile phase: [Acetonitrile](#) and *Buffer* (50:50)

Diluent: [Acetonitrile](#) and *Medium* (50:50)

Standard stock solution: 0.222 mg/mL of [USP Olmesartan Medoxomil RS](#) in *Diluent*. Sonication may be needed to dissolve.

Standard solution

[NOTE—Preserve at 2°–8° after preparation.]

For Tablets labeled to contain 5 mg: 0.0027 mg/mL of [USP Olmesartan Medoxomil RS](#) in *Diluent* from the *Standard stock solution*

For Tablets labeled to contain 20 mg: 0.0111 mg/mL of [USP Olmesartan Medoxomil RS](#) in *Diluent* from the *Standard stock solution*

For Tablets labeled to contain 40 mg: 0.0222 mg/mL of [USP Olmesartan Medoxomil RS](#) in *Diluent* 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 2 mL of the filtrate. Transfer 5.0 mL of the solution into a 10-mL volumetric flask. Dilute with [acetonitrile](#) to volume. [NOTE—Preserve at 2°–8° after preparation.]

Chromatographic system

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

Mode: LC

Detector: UV 250 nm

Column: 4.0-mm × 12.5-cm; 5-µm packing [L1](#)

Temperatures

Autosampler: 5°

Column: 40°

Flow rate: 1.0 mL/min

Injection volume: 20 µL

Run time: NLT 2 times the retention time of olmesartan medoxomil

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 olmesartan medoxomil ($C_{29}H_{30}N_6O_6$) dissolved:

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

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)

D = dilution factor of the *Sample solution*

V = volume of *Medium*, 900 mL

L = label claim of olmesartan medoxomil (mg/Tablet)

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

Test 6: If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 6*.

Medium: 0.05 M pH 6.8 phosphate buffer (dissolve 68 g of [monobasic potassium phosphate](#) and 9 g of [sodium hydroxide](#) in 10,000 mL of [water](#); adjust with diluted [sodium hydroxide](#) solution or diluted [phosphoric acid](#) to a pH of 6.8); 900 mL

Apparatus 2: 50 rpm

Time: 30 min

Buffer: Dissolve 6.8 g of [monobasic potassium phosphate](#) in 1000 mL of [water](#). Adjust with diluted [phosphoric acid](#) to a pH of 3.0.

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

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

Standard stock solution A: 0.55 mg/mL of [USP Olmesartan Medoxomil RS](#) in *Diluent*. Sonication may be needed to dissolve.

For Tablets labeled to contain 5 mg

Standard stock solution B: 5.5 µg/mL of [USP Olmesartan Medoxomil RS](#) in *Medium* from *Standard stock solution A*

Standard solution: 2.75 µg/mL of [USP Olmesartan Medoxomil RS](#) in *Mobile phase* from *Standard stock solution B*

For Tablets labeled to contain 20 mg

Standard stock solution C: 22 µg/mL of [USP Olmesartan Medoxomil RS](#) in *Medium* from *Standard stock solution A*

Standard solution: 11 µg/mL of [USP Olmesartan Medoxomil RS](#) in *Mobile phase* from *Standard stock solution C*

For Tablets labeled to contain 40 mg

Standard stock solution D: 44 µg/mL of [USP Olmesartan Medoxomil RS](#) in *Medium* from *Standard stock solution A*

Standard solution: 22 µg/mL of [USP Olmesartan Medoxomil RS](#) in *Mobile phase* from the *Standard stock solution D*

Sample solution: Pass a portion of the solution under test through a suitable filter of 0.45-µm pore size. Transfer 5.0 mL of the filtrate into a 10-mL volumetric flask. Dilute with *Mobile phase* to volume. Pass a portion of the solution through a suitable filter of 0.45-µm pore size.

[NOTE—The *Sample solution* is stable for 25 h at 5°.]

Chromatographic system

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

Mode: LC

Detector: UV 250 nm

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

Temperatures

Autosampler: 5°

Column: 30°

Flow rate: 2.0 mL/min

Injection volume: 100 µL

Run time: NLT 1.5 times the retention time of olmesartan medoxomil

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 olmesartan medoxomil ($C_{29}H_{30}N_6O_6$) dissolved:

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

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)

D = dilution factor for the *Sample solution*

V = volume of *Medium*, 900 mL

L = label claim of olmesartan medoxomil (mg/Tablet)

Tolerances: NLT 70% (Q) of the labeled amount of olmesartan medoxomil ($C_{29}H_{30}N_6O_6$) is dissolved.

Test 7: If the product complies with this test, the labeling indicates that it meets *USP Dissolution Test 7*.

Medium: 0.1 N [hydrochloric acid](#); 900 mL

Apparatus 2: 50 rpm

Time: 20 min

Diluent: [Acetonitrile](#) and [water](#) (60:40)

Standard stock solution: 1.12 mg/mL of [USP Olmesartan Medoxomil RS](#) in *Diluent*

Standard solution

For Tablets labeled to contain 5 mg: 5.6 µg/mL of [USP Olmesartan Medoxomil RS](#) in *Medium* from the *Standard stock solution*

For Tablets labeled to contain 20 mg or 40 mg: 11.2 µg/mL of [USP Olmesartan Medoxomil 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- μ m pore size and discard at least the first 5 mL of the filtrate. Dilute with *Medium* to a concentration that is similar to the *Standard solution* if necessary.

Instrumental conditions

(See [Ultraviolet-Visible Spectroscopy \(857\)](#).)

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:

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

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

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

D = dilution factor of the *Sample solution*

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 8: If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 8*.

Medium: 0.05 M pH 6.8 phosphate buffer (dissolve 6.8 g of [monobasic potassium phosphate](#) and 0.9 g of [sodium hydroxide](#) in 1000 mL of [water](#); adjust with 0.2 M [sodium hydroxide](#) solution or 0.2 M [hydrochloric acid](#) solution to a pH of 6.8); 900 mL

Apparatus 2: 50 rpm

Times

For Tablets labeled to contain 5 mg and 20 mg: 30 min

For Tablets labeled to contain 40 mg: 45 min

Mobile phase: [Acetonitrile](#) and [0.2% phosphoric acid TS](#) (35:65)

Standard stock solution: 0.55 mg/mL of [USP Olmesartan Medoxomil RS](#) prepared as follows. Transfer a suitable amount of [USP Olmesartan Medoxomil RS](#) to a suitable volumetric flask. Dissolve in 60% of the flask volume of [acetonitrile](#). Sonicate to dissolve if necessary. Dilute with *Medium* to volume.

Standard solution

For Tablets labeled to contain 5 mg: 2.8 μ g/mL of [USP Olmesartan Medoxomil RS](#) prepared as follows. Dilute 2 mL of the *Standard stock solution* with *Medium* to 200 mL. Pass through a suitable filter of 0.45- μ m pore size. Further dilute 5 mL of this solution with *Mobile phase* to 10 mL, and mix well.

For Tablets labeled to contain 20 mg: 11 μ g/mL of [USP Olmesartan Medoxomil RS](#) prepared as follows. Dilute 4 mL of the *Standard stock solution* with *Medium* to 100 mL. Pass through a suitable filter of 0.45- μ m pore size. Further dilute 5 mL of this solution with *Mobile phase* to 10 mL, and mix well.

For Tablets labeled to contain 40 mg: 22 μ g/mL of [USP Olmesartan Medoxomil RS](#) prepared as follows. Dilute 4 mL of the *Standard stock solution* with *Medium* to 50 mL. Pass through a suitable filter of 0.45- μ m pore size. Further dilute 5 mL of this solution with *Mobile phase* to 10 mL, and mix well.

Sample solution: Pass a portion of the solution under test through a suitable filter of 0.45- μ m pore size, and discard the first 3 mL of the filtrate. Immediately dilute 5 mL of the filtrate with *Mobile phase* to 10 mL, and mix well.

Chromatographic system

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

Mode: LC

Detector: UV 250 nm

Column: 4.6-mm \times 25-cm; 5- μ m packing [L1](#)

Temperatures

Autosampler: 6°

Column: 40°

Flow rate: 1 mL/min

Injection volume: 50 µL

Run time: NLT 1.5 times the retention time of olmesartan medoxomil

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 olmesartan medoxomil ($C_{29}H_{30}N_6O_6$) dissolved:

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

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)

D = dilution factor for the *Sample solution*

V = volume of *Medium*, 900 mL

L = label claim of olmesartan medoxomil (mg/Tablet)

Tolerances: NLT 75% (Q) of the labeled amount of olmesartan medoxomil ($C_{29}H_{30}N_6O_6$) is dissolved.

▲**Test 9:** If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 9*.

Medium: 0.05 M phosphate buffer, pH 6.8 (dissolve 6.8 g of [monobasic potassium phosphate](#) in 1000 mL of [water](#); adjust with 2.5 M [sodium hydroxide](#) solution to a pH of 6.8); 900 mL

Apparatus 2: 75 rpm

Time: 45 min

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

Standard stock solution A: 2.2 mg/mL of [USP Olmesartan Medoxomil RS](#) in *Diluent*. Sonicate to dissolve

Standard stock solution B: 0.22 mg/mL of [USP Olmesartan Medoxomil RS](#) from *Standard stock solution A* in *Medium*

Standard solution

For Tablets labeled to contain 5 mg: 5.5 µg/mL of [USP Olmesartan Medoxomil RS](#) from *Standard stock solution B* in *Medium*

For Tablets labeled to contain 20 mg or 40 mg: 11 µg/mL of [USP Olmesartan Medoxomil RS](#) from *Standard stock solution B* in *Medium*

Sample solution: Pass a portion of the solution under test through a suitable filter of 0.45-µm pore size, discarding an appropriate volume of filtrate so that a consistent result can be obtained. Dilute with *Medium* to a concentration that is similar to the *Standard solution* if necessary.

Instrumental conditions

(See [Ultraviolet-Visible Spectroscopy \(857\)](#).)

Mode: UV

Analytical wavelength: 256 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:

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

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

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

D = dilution factor of the *Sample solution*

V = volume of *Medium*, 900 mL

L = label claim (mg/Tablet)

Tolerances:

For Tablets labeled to contain 5 mg or 20 mg: NLT 80% (Q) of the labeled amount of olmesartan medoxomil ($C_{29}H_{30}N_6O_6$) is dissolved.

For Tablets labeled to contain 40 mg: NLT 75% (Q) of the labeled amount of olmesartan medoxomil ($C_{29}H_{30}N_6O_6$) is dissolved. ▲ (RB 1-Feb-2025)

- **UNIFORMITY OF DOSAGE UNITS (905):** Meet the requirements

IMPURITIES

• ORGANIC IMPURITIES

Buffer: 0.015 M [monobasic potassium phosphate](#). Adjust with [phosphoric acid](#) to a pH of 3.5.

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

Solution B: [Acetonitrile](#) and *Buffer* (79:21)

Mobile phase: See [Table 3](#).

Table 3

Time (min)	Solution A (%)	Solution B (%)
0	75	25
10	75	25
35	0	100
45	0	100

Diluent: [Acetonitrile](#) and [water](#) (90:10)

System suitability solution: 0.01 mg/mL each of [USP Olmesartan Medoxomil RS](#) and [USP Olmesartan Medoxomil Related Compound A RS](#) in *Diluent*

Standard solution: 0.01 mg/mL of [USP Olmesartan Medoxomil RS](#) in *Diluent*

Sensitivity solution: 0.002 mg/mL of [USP Olmesartan Medoxomil RS](#) in *Diluent* from the *Standard solution*

Sample solution: Nominally 1 mg/mL of olmesartan medoxomil in *Diluent* prepared as follows. Dissolve a suitable number of Tablets in *Diluent*. Sonicate and/or shake occasionally to disintegrate the Tablets completely. Centrifuge and pass the supernatant through a suitable filter of 0.45- μ m pore size.

Chromatographic system

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

Mode: LC

Detector: UV 250 nm

Column: 4.6-mm \times 10-cm; 3.5- μ m packing [L7](#)

Column temperature: 40°

Flow rate: 1 mL/min

Injection volume: 10 μ L

System suitability

Samples: *System suitability solution* and *Sensitivity solution*

Suitability requirements

Resolution: NLT 5 between olmesartan medoxomil and olmesartan medoxomil related compound A, *System suitability solution*

Relative standard deviation: NMT 2.0% for both peaks, *System suitability solution*

Signal-to-noise ratio: NLT 30, *Sensitivity solution*

Analysis

Samples: *Standard solution* and *Sample solution*

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

Result = (r_U/r_S) × (C_S/C_U) × (1/F) × 100

- r_U = peak response of each degradation product 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)
- F = relative response factor (see [Table 4](#))

Acceptance criteria: See [Table 4](#). Disregard peaks below 0.1%.

Table 4

Name	Relative Retention Time	Relative Response Factor	Acceptance Criteria, NMT (%)
Olmesartan ^a	0.2	1.0	2.5
Olmesartan medoxomil related compound A ^b	0.7	1.6	—
Olmesartan medoxomil	1.0	—	—
Olmesartan dimer ^c	1.2	0.8	0.5
Olefinic impurity ^d	1.5	1.0	0.6
Any unspecified degradation product	—	1.0	0.2
Total degradation products	—	—	4.1

- ^a 1-{{2'-(1*H*-Tetrazol-5-yl)biphenyl-4-yl)methyl}-4-(2-hydroxypropan-2-yl)-2-propyl-1*H*-imidazole-5-carboxylic acid.
- ^b This is a process-related impurity that is controlled in the drug substance.
- ^c 1-{{2'-(1*H*-Tetrazol-5-yl)-[1,1'-biphenyl]-4-yl)methyl}-4-(2-{{1'-{{2'-(1*H*-tetrazol-5-yl)-[1,1'-biphenyl]-4-yl)methyl}-4-(2-hydroxypropan-2-yl)-2-propyl-1*H*-imidazole-5-carboxyl}oxy}propan-2-yl)-2-propyl-1*H*-imidazole-5-carboxylic acid.
- ^d (5-Methyl-2-oxo-1,3-dioxol-4-yl)methyl 1-((2'-(1*H*-tetrazol-5-yl)biphenyl-4-yl)methyl)-4-(prop-1-en-2-yl)-2-propyl-1*H*-imidazole-5-carboxylate.

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in well-closed 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 Olmesartan Medoxomil RS](#)

[USP Olmesartan Medoxomil Related Compound A RS](#)

1-{{2'-(1*H*-Tetrazol-5-yl)biphenyl-4-yl)methyl}-4,4-dimethyl-2-propyl-1*H*-furo[3,4-*d*]imidazol-6(4*H*)-one.
C₂₄H₂₄N₆O₂ 428.49

Topic/Question	Contact	Expert Committee
OLMESARTAN MEDOXOMIL TABLETS	Documentary Standards Support	SM22020 Small Molecules 2
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM22020 Small Molecules 2

Chromatographic Database Information: [Chromatographic Database](#)

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