Olmesartan Medoxomil Tablets

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In accordance with the Rules and Procedures of the 2015–2020 Council of Experts, the Chemical Medicines Monographs 2 Expert Committee has revised the Olmesartan Medoxomil Tablets monograph. The purpose for the revision is to add *Dissolution Test 6* to accommodate drug products with different dissolution conditions and/or tolerances than the existing dissolution tests.

- *Dissolution Test 6* was validated using the Thermo Scientific Hypersil BDS C18 brand of column with L1 packing. The typical retention time for olmesartan medoxomil is between 2.5 and 3.5 min.

The Olmesartan Medoxomil Tablets Revision Bulletin supersedes the currently official Olmesartan Medoxomil Tablets monograph.

See below for additional information about the proposed text.¹

Should you have any questions, please contact Donald Min, Senior Scientific Liaison (301-230-7457 or ddm@usp.org).

¹ Note: Addition of *Dissolution Test 5* to the Olmesartan Medoxomil Tablets monograph is currently being proposed under the Pending Monograph process.
Olmesartan Medoxomil Tablets

DEFINITION
Olmesartan Medoxomil Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of olmesartan medoxomil (C_{29}H_{30}N_{6}O_{6}).

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>
<thead>
<tr>
<th>Time (min)</th>
<th>Solution B (%)</th>
<th>Solution C (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>68.8</td>
<td>31.2</td>
</tr>
<tr>
<td>1.5</td>
<td>37.5</td>
<td>62.5</td>
</tr>
<tr>
<td>1.6</td>
<td>68.8</td>
<td>31.2</td>
</tr>
<tr>
<td>3.0</td>
<td>68.8</td>
<td>31.2</td>
</tr>
</tbody>
</table>

**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_{6}O_{6}) in the portion of Tablets taken:

\[
\text{Result} = \left( \frac{r_U}{r_S} \right) \times \left( \frac{C_S}{C_U} \right) \times 100
\]

\( r_U \) = 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:** (U/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_{6}O_{6}) dissolved:

\[
\text{Result} = \left( \frac{A_U}{A_S} \right) \times C_S \times V \times (1/L) \times 100
\]

\( A_U \) = 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_{6}O_{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 (C₂₉H₃₅N₂O₄) dissolved:

\[ \text{Result} = \left( \frac{A_u - A_t}{A_l} \right) \times \frac{C_l \times V \times (1/L) \times 100}{C} \]

\( A_u \) = absorbance of the Sample solution
\( A_t \) = absorbance of the Standard solution
\( C_l \) = 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 (C₂₉H₃₅N₂O₄) 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 0.05 M hydrochloric acid; 900 mL

Solution A: Acetonitrile and Buffer (20:80)
Solution B: Acetonitrile and Buffer (80:20)
Mobile phase: See Table 2.

<table>
<thead>
<tr>
<th>Time (min)</th>
<th>Solution A (%)</th>
<th>Solution B (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>75</td>
<td>25</td>
</tr>
<tr>
<td>4.0</td>
<td>52</td>
<td>48</td>
</tr>
<tr>
<td>5.0</td>
<td>75</td>
<td>25</td>
</tr>
<tr>
<td>7.0</td>
<td>75</td>
<td>25</td>
</tr>
</tbody>
</table>

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

Temperature
Autosampler: 5°C
Column: 30°C
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_l) of olmesartan medoxomil (C₂₉H₃₅N₂O₄) in the Sample solution:

\[ \text{Result} = \left( \frac{r_0}{r_1} \right) \times C_l \]

\( r_0 \) = peak response of olmesartan medoxomil from the Sample solution
\( r_1 \) = peak response of olmesartan medoxomil from the Standard solution

Calculate the concentration (C_S) of olmesartan as olmesartan medoxomil (C₂₉H₃₅N₂O₄) in the Sample solution:

\[ \text{Result} = \left( \frac{r_0}{r_1} \right) \times C_S \]

\( r_0 \) = peak response of olmesartan from the Sample solution
\( r_1 \) = peak response of olmesartan medoxomil from the Standard solution

Calculate the percentage of the labeled amount of olmesartan medoxomil (C₂₉H₃₅N₂O₄) dissolved:

\[ \text{Result} = \left( \frac{C_l + C_S}{D} \right) \times V \times \left( \frac{1}{L} \right) \times 100 \]

\( C_l \) = concentration of olmesartan medoxomil in the Sample solution (mg/mL)
\( C_S \) = 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

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C223352-M6047-CHM22015, rev. 00 20190830
If the product complies with this test, the labeling

Tolerances: NLT 75% (Q) of the labeled amount of olmesartan medoxomil \((\text{C}_{22}\text{H}_{33}\text{N}_{2}\text{O}_{5})\) 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

Temperature: 4°

Buffer: Dissolve 2.0 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 \((\text{C}_{22}\text{H}_{33}\text{N}_{2}\text{O}_{5})\) dissolved:

\[
\text{Result} = \left(\frac{r_s}{r_u}\right) \times C_s \times V \times (1/L) \times 100
\]

where:

- \(r_u\) = 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)

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

\(V\) = volume of Medium, 900 mL

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

Tolerances: NLT 80% (Q) of the labeled amount of olmesartan medoxomil \((\text{C}_{22}\text{H}_{33}\text{N}_{2}\text{O}_{5})\) 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-µL 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_{38}N_{6}O_{5}) dissolved:

\[
\text{Result} = \left( \frac{r_U}{r_S} \right) \times C_j \times D \times V \times (1/L) \times 100
\]

- \( r_U \): peak response of olmesartan medoxomil from the Sample solution
- \( r_S \): peak response of olmesartan medoxomil from the Standard solution
- \( C_j \): 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_{38}N_{6}O_{5}) is dissolved. ▲ (RR 1-Sep-2019)

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

**IMPURITIES**

**Change to read:**

- **ORGANIC IMPURITIES**
  - Buffer: 0.015 M monobasic potassium phosphate. Adjust with phosphoric acid to a pH of 3.5.
  - Solution A: Acetonitrile and Buffer (79:21)
  - Solution B: Acetonitrile and Buffer (20:80)
  - 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-μm pore size.

**Chromatographic system**

(See Chromatography (621), System Suitability.)

- **Mode**: LC
- **Detector**: UV 250 nm
- **Column**: 4.6-mm x 10-cm; 3.5-μm packing L7
- **Column temperature**: 40°C
- **Flow rate**: 1 mL/min
- **Injection volume**: 10 μL

**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:

\[
\text{Result} = \left( \frac{r_U}{r_S} \right) \times \left( \frac{C_j}{C_o} \right) \times \left( \frac{1}{F} \right) \times 100
\]

- \( r_U \): peak response of each degradation product from the Sample solution
- \( r_S \): peak response of olmesartan medoxomil from the Standard solution
- \( C_j \): concentration of a USP Olmesartan Medoxomil RS in the Standard solution (mg/mL)
- \( C_o \): 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**

<table>
<thead>
<tr>
<th>Name</th>
<th>Relative Retention Time</th>
<th>Relative Response Factor</th>
<th>Acceptance Criteria, NMT (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Olmesartan</td>
<td>0.2</td>
<td>1.0</td>
<td>2.5</td>
</tr>
<tr>
<td>Olmesartan medoxomil related compound A</td>
<td>0.7</td>
<td>1.6</td>
<td>—</td>
</tr>
<tr>
<td>Olmesartan medoxomil</td>
<td>1.0</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Olmesartan dimer</td>
<td>1.2</td>
<td>0.8</td>
<td>0.5</td>
</tr>
<tr>
<td>Olefinic impurity</td>
<td>1.5</td>
<td>1.0</td>
<td>0.6</td>
</tr>
<tr>
<td>Any unspecified degradation product</td>
<td>—</td>
<td>1.0</td>
<td>0.2</td>
</tr>
<tr>
<td>Total degradation products</td>
<td>—</td>
<td>—</td>
<td>4.1</td>
</tr>
</tbody>
</table>

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

- USP Olmesartan Medoxomil RS
- USP Olmesartan Medoxomil Related Compound A RS

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

C_{24}H_{24}N_{6}O_{2}  428.49