Donepezil Hydrochloride Tablets

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Reason for Revision: Compliance

In accordance with the Rules and Procedures of the 2015–2020 Council of Experts, the Chemical Medicines Monographs 4 Expert Committee has revised the Donepezil Hydrochloride Tablets monograph. The purpose for the revision is to add **Dissolution Test 4** to accommodate FDA-approved drug products with different dissolution conditions and/or tolerances than the existing dissolution tests.

- **Dissolution Test 4** was validated using an ACE C8 brand of L7 column. The typical retention time for donepezil is about 3 min.

Existing references to reagents were updated for consistency with the reagent entry names. For additional information about reagent cross references, please see the related [Compendial Notice](#). The revision also necessitates a change in the table numbering in the tests for **Organic Impurities, Procedure 1** and **Organic Impurities, Procedure 2**.

The Donepezil Hydrochloride Tablets Revision Bulletin supersedes the currently official monograph.

Should you have any questions, please contact Heather Joyce, Senior Scientific Liaison (301-998-6792 or [hrj@usp.org](mailto:hrj@usp.org)).
Donepezil Hydrochloride Tablets

**DEFINITION**
Donepezil Hydrochloride Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of donepezil hydrochloride (C_{29}H_{39}NO_{5}·HCl).

**IDENTIFICATION**

**Change to read:**

- **A. ULTRAVIOLET ABSORPTION (197U)**
  Wavelength range: 220–360 nm
  Sample solution: Crush a suitable number of Tablets, and transfer an amount of powder, equivalent to 10 mg of donepezil hydrochloride, to a 100-mL volumetric flask. Add 80 mL of 0.1 N hydrochloric acid VS (88-1-Mar-2019) and sonicate for 5 min. Cool the solution to room temperature, and dilute with 0.1 N hydrochloric acid VS (88-1-Mar-2019) to volume. Transfer a portion of this solution to a centrifuge tube, and centrifuge for 15 min. Transfer 5 mL of the clear supernatant to a 25-mL volumetric flask, and dilute with 0.1 N hydrochloric acid VS (88-1-Mar-2019) to volume.
  
  Analysis: Using a 1-cm cell, record the UV spectrum of the Sample solution.
  
  Acceptance criteria: The solution exhibits absorption maxima at 230, 271, and 315 nm.

- **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**

**Change to read:**

- **PROCEDURE**
  Diluent: Methanol and 0.1 N hydrochloric acid VS (88-1-Mar-2019)
  Mobile phase: Dissolve 2.5 g of sodium 1-decanesulfonate in 650 mL of water, and add 1.0 mL of perchloric acid and 350 mL of acetonitrile. If necessary, adjust with an additional 0.5 mL of perchloric acid to a pH of about 1.8.
  System suitability solution: 0.2 mg/mL of USP Donepezil Hydrochloride RS and 0.008 mg/mL of USP Donepezil Related Compound A RS. [NOTE—Dissolve in 40% of the flask volume of methanol, swirl, and dilute with water to volume.]
  Standard solution: 0.4 mg/mL of USP Donepezil Hydrochloride RS in Diluent. [NOTE—Dissolve in 60% of the flask volume of Diluent, swirl, and dilute with Diluent to volume.]
  Sample solution: Nominally 0.4 mg/mL of donepezil hydrochloride prepared as follows. Dissolve a suitable number of Tablets in 75% of the flask volume of Diluent, and sonicate in an ultrasonic bath for 20 min. Swirl the mixture for 30 s, allow to cool to room temperature, and dilute with Diluent to volume. [NOTE—If necessary, add a magnetic stirring bar to the flask, and mix for 10 min on the magnetic stirrer, to aid in dissolution.] Allow a few min for the solids to settle. Pass through a suitable filter, discarding the first 2–3 mL of the filtrate.
  
  Chromatographic system
  (See Chromatography (621), System Suitability.)
  Mode: LC
  Detector: UV 271 nm
  Column: 4.6-mm × 15-cm; 5-µm packing L1
  Column temperature: 35°
  Flow rate: 1.4 mL/min
  Injection volume: 20 µL

**System suitability**

**Samples: System suitability solution and Standard solution**
[NOTE—The relative retention times for donepezil related compound A and donepezil are about 0.92 and 1.0, respectively.]

**Suitability requirements**

- **Resolution:** NLT 1.5 between donepezil related compound A and donepezil, System suitability solution
- **Tailing factor:** NMT 1.5 for the donepezil peak, System suitability solution

**Relative standard deviation:** NMT 2.0%, Standard solution

**Analysis**

**Samples:** Standard solution and Sample solution

Calculate the percentage of the labeled amount of donepezil hydrochloride (C_{29}H_{39}NO_{5}·HCl) in the portion of Tablets taken:

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

- \(r_U\) = peak response of donepezil hydrochloride from the Sample solution
- \(r_S\) = peak response of donepezil hydrochloride from the Standard solution
- \(C_U\) = concentration of USP Donepezil Hydrochloride RS in the Standard solution (mg/mL)
- \(C_S\) = nominal concentration of donepezil hydrochloride in the Sample solution (mg/mL)

**Acceptance criteria:** 90.0%–110.0%

**PERFORMANCE TESTS**

**Change to read:**

- **DISSOLUTION (711)**
  **Test 1**
  Medium: 0.1 N hydrochloric acid VS (88-1-Mar-2019)
  900 mL
  Apparatus 2: 50 rpm
  Time: 30 min
  Analytical procedure: Determine the amount of donepezil hydrochloride (C_{29}H_{39}NO_{5}·HCl) dissolved, by using one of the following methods.
  
  **Chromatographic method**
  Diluent: Methanol and 0.1 N hydrochloric acid VS (88-1-Mar-2019)
  Mobile phase: Acetonitrile, water, and perchloric acid (35: 65: 0.1)
  Standard stock solution A: 1.1 mg/mL of USP Donepezil Hydrochloride RS in Diluent
  Standard stock solution B: 0.11 mg/mL of USP Donepezil Hydrochloride RS from Standard stock solution A in Medium
  Standard solution: (L/1000) mg/mL of USP Donepezil Hydrochloride RS from Standard stock solution B in Medium, 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, discarding the first few mL of the filtrate.
  
  **Chromatographic system**
  (See Chromatography (621), System Suitability.)
  Mode: LC
  Detector: UV 271 nm
  Column: 4.6-mm × 15-cm; 5-µm packing L1
  Column temperature: 35°
  Flow rate: 1.0 mL/min
  Injection volume: 50 µL

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For Tablets which contain 23 mg of donepezil hydrochloride

Test 2: If the product complies with this test, the labeling indicates that it meets USP Dissolution Test 2.

Medium: pH 6.8 phosphate buffer; 900 mL

Apparatus 2: 50 rpm

Times: 1, 3, and 8h

Buffer: 5.0 g/L of monobasic ammonium phosphate in water adjusted with phosphoric acid to a pH of 2.3

Mobile phase: Acetonitrile and Buffer (25:75)

Standard stock solution: 0.26 mg/mL of USP Donepezil Hydrochloride RS prepared as follows. Transfer a suitable quantity of USP Donepezil Hydrochloride RS to an appropriate volumetric flask. Add 70% of the flask volume of Medium. Sonicate to dissolve and dilute with Medium to volume.

Standard solution: (L/900) mg/mL of USP Donepezil Hydrochloride RS from Standard stock solution in Medium, where L is the label claim in mg/Tablet. Pass the solution through a suitable filter, discarding the first 3 mL of the filtrate.

Sample solution: Pass a portion of the solution under test through a suitable filter, discarding the first 3 mL of the filtrate.

Chromatographic system

(See Chromatography (621), System Suitability.)

Mode: LC
Detector: UV 210 nm
Column: 4.6-mm × 15-cm; 5-µm packing L1
Column temperature: 35°
Flow rate: 1.5 mL/min
Injection volume: 50 µL
Run time: NLT 1.7 times the retention time of donepezil

System suitability

Sample: Standard solution

Spectrometric method

Standard stock solution: 0.11 mg/mL of USP Donepezil Hydrochloride RS in water

Standard solution: (L/900) mg/mL of USP Donepezil Hydrochloride RS from the Standard stock solution in Medium, where L is the label claim in mg/Tablet

Sample: Pass a portion of the solution under test through a suitable filter of 0.45-µm pore size.

Suitability requirements

Table 1

<table>
<thead>
<tr>
<th>Table 1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time Point (h)</td>
</tr>
<tr>
<td>-----------</td>
</tr>
<tr>
<td>1</td>
</tr>
<tr>
<td>2</td>
</tr>
<tr>
<td>3</td>
</tr>
</tbody>
</table>

The percentages of the labeled amount of donepezil hydrochloride (C₂₉H₂₉NO₃·HCl) dissolved at the times specified conform to Dissolution (711), Acceptance Table 2.

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

Medium: pH 6.8 phosphate buffer; 900 mL

Sample solution: Pass a portion of the solution under test through a suitable filter, discarding the first 3 mL of the filtrate.

System suitability

Sample: Standard solution

Suitability requirements

Tailing factor: NMT 1.5
Relative standard deviation: NMT 2.0%

Analysis

Samples: Standard solution and Sample solution

Calculate the concentration (C) of donepezil hydrochloride (C₂₉H₂₉NO₃·HCl) in the sample withdrawn from the vessel at each time point (t):

Result = (r_i/r_s) × C_j

where:
- r_i = peak response from donepezil from the Sample solution at each time point (mg/mL)
- r_s = peak response from donepezil from the Standard solution (mg/mL)
- C_j = concentration of USP Donepezil Hydrochloride RS in the Standard solution (mg/mL)
- C = concentration of donepezil hydrochloride in the portion of the sample withdrawn at the specified time point (mg/mL)
- V = volume of Medium, 900 mL
- L = label claim (mg/Tablet)
- S = concentration of the Standard solution (mg/mL)
- U = concentration of USP Donepezil Hydrochloride RS in the Standard solution (mg/mL)
- L = label claim (mg/Tablet)
- V = volume of Medium, 900 mL
- S = concentration of the Standard solution (mg/mL)

Spectrometric method

Standard stock solution: 0.11 mg/mL of USP Donepezil Hydrochloride RS in water

Standard solution: (L/900) mg/mL of USP Donepezil Hydrochloride RS from the Standard stock solution in Medium, 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.

Instrumental conditions

(See Ultraviolet-Visible Spectroscopy (857,).

Mode: UV
Analytical wavelength: 230 nm
Blank: Medium

Calculate the percentage of the labeled amount of donepezil hydrochloride (C₂₉H₂₉NO₃·HCl) dissolved:

Result = ({(A_i/A_j) × (C_j/L)} × V × 100

where:
- A_i = absorbance of the Sample solution
- A_j = absorbance of the Standard solution
- C_j = concentration of the Standard solution (mg/mL)
- L = label claim (mg/Tablet)
- V = volume of Medium, 900 mL

Suitability requirements

Tolerances: NLT 80% (Q) of the labeled amount of donepezil hydrochloride is dissolved.

For Tablets which contain 23 mg of donepezil hydrochloride

Test 2: If the product complies with this test, the labeling indicates that it meets USP Dissolution Test 2.

Medium: pH 6.8 phosphate buffer; 900 mL

Apparatus 2: 50 rpm

Times: 1, 3, and 8 h

Buffer: 5.0 g/L of monobasic ammonium phosphate in water adjusted with phosphoric acid to a pH of 2.3

Mobile phase: Acetonitrile and Buffer (25:75)

Standard stock solution: 0.26 mg/mL of USP Donepezil Hydrochloride RS prepared as follows. Transfer a suitable quantity of USP Donepezil Hydrochloride RS to an appropriate volumetric flask. Add 70% of the flask volume of Medium. Sonicate to dissolve and dilute with Medium to volume.

Standard solution: (L/900) mg/mL of USP Donepezil Hydrochloride RS from Standard stock solution in Medium, where L is the label claim in mg/Tablet. Pass the solution through a suitable filter, discarding the first 3 mL of the filtrate.

Sample solution: Pass a portion of the solution under test through a suitable filter, discarding the first 3 mL of the filtrate.
Donepezil Hydrochloride RS in the Standard solution (mg/mL) dissolved at times specified conform to Dissolution (711), Acceptance Table 2.

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

Medium: 0.05 M sodium phosphate buffer, pH 6.8 [0.1 N hydrochloric acid VS and 76 g/L of tribasic sodium phosphate (25:75) adjusted with 2 N hydrochloric acid TS or 2 N sodium hydroxide TS to a pH of 6.8]; 900 mL, degassed

Apparatus 2: 50 rpm, with sinkers; see Dissolution (711), Figure 2a.

Times: 1, 3, and 8 h

Buffer: 1.36 g/L of monobasic potassium phosphate prepared as follows. To each 1 L of 1.36 g/L of monobasic potassium phosphate in water, add 3 mL of triethylamine and adjust with phosphoric acid to a pH of 2.8.

Mobile phase: Methanol and Buffer (47:53)

Diluent: Methanol and water (50:50)

Standard stock solution: 0.53 mg/mL of USP Donepezil Hydrochloride RS in Diluent

Standard solution: 0.027 mg/mL of USP Donepezil Hydrochloride RS from Standard stock solution in Medium

Sample solution: Pass a portion of the solution under test through a suitable filter.

Instrumental conditions

(See Ultraviolet-Visible Spectroscopy (857).)

Mode: UV-Vis

Analytical wavelength: 315 nm

Blank: Medium

System suitability

Sample: Standard solution

Suitability requirements

Relative standard deviation: NMT 2.0%

Analysis

Samples: Standard solution and Sample solution

Calculate the concentration (C) of donepezil hydrochloride \((C_{29H32NO3} \cdot \text{HCl})\) in the sample withdrawn from the vessel at each time point \((i)\):

\[
\text{Result}_1 = \left( \frac{A_i}{A_s} \right) \times C_i
\]

\(A_i\) = absorbance of donepezil from the Sample solution

\(A_s\) = absorbance of donepezil from the Standard solution

\(C_i\) = concentration of USP Donepezil Hydrochloride RS in the Standard solution (mg/mL)

Calculate the percentage of the labeled amount of donepezil hydrochloride \((C_{29H32NO3} \cdot \text{HCl})\) dissolved at each time point \((i)\):

\[
\text{Result}_1 = C_i \times V \times \left( \frac{1}{L} \right) \times 100
\]

\[
\text{Result}_2 = \left( (C_i \times \left[ V - (V_i) \right]) + \left( (C_s \times V_s) \right) \right) \times \left( \frac{1}{L} \right) \times 100
\]

\[
\text{Result}_3 = \left( (C_i \times \left[ V - (2 \times V_i) \right]) + \left( (C_s \times C_i \times V_s) \right) \right) \times \left( \frac{1}{L} \right) \times 100
\]

\(C_i\) = concentration of donepezil hydrochloride in the portion of the sample withdrawn at the specified time point (mg/mL)

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

\(L\) = label claim (mg/Tablet)

\(V_s\) = volume of the Sample solution withdrawn at each time point (mL)

Tolerances: See Table 2.

<table>
<thead>
<tr>
<th>Time Point ((i))</th>
<th>Time ((h))</th>
<th>Amount Dissolved ((%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1</td>
<td>10–30</td>
</tr>
<tr>
<td>2</td>
<td>3</td>
<td>33–53</td>
</tr>
<tr>
<td>3</td>
<td>10</td>
<td>NLT 80</td>
</tr>
</tbody>
</table>

The percentages of the labeled amount of donepezil hydrochloride \((C_{29H32NO3} \cdot \text{HCl})\) dissolved at the times specified conform to Dissolution (711), Acceptance Table 2.
4 Donepezil

\[ C_i \] = concentration of donepezil hydrochloride in the portion of the sample withdrawn at time point \( i \) (mg/mL)

\[ V \] = volume of Medium, 900 mL

\[ L \] = label claim (mg/Tablet)

\[ V_j \] = volume of Sample solution withdrawn at each time point and replaced with Medium (mL)

**Tolerances:** See Table 3.

<table>
<thead>
<tr>
<th>Time Point (h)</th>
<th>Time (min)</th>
<th>Amount Dissolved (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1</td>
<td>10–30</td>
</tr>
<tr>
<td>2</td>
<td>3</td>
<td>40–60</td>
</tr>
<tr>
<td>3</td>
<td>8</td>
<td>NLT 80</td>
</tr>
</tbody>
</table>

The percentages of the labeled amount of donepezil hydrochloride (C\(_2\)H\(_3\)NO\(_3\)) dissolved at the times specified conform to Dissolution (711). Acceptance Table 2.

**Change to read:**

**IMPURITIES**

**Organic Impurities, Procedure 1**

[Note—On the basis of the synthetic route, perform either Procedure 1 or Procedure 2. Procedure 2 is recommended if any of the impurities included in either Procedure 1 or Procedure 2 are potential degradation products.]

Diluent, Mobile phase, System suitability solution, Sample solution, and Chromatographic system: Proceed as directed in the Assay.

Standard solution: 0.0008 mg/mL of USP Donepezil Hydrochloride RS in Diluent

System suitability

Samples: System suitability solution and Standard solution

[NNote—The relative retention times for donepezil related compound A and donepezil are about 0.92 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 1.5 between donepezil related compound A and donepezil, System suitability solution

Relative standard deviation: NMT 8.0%, Standard solution

Analysis

Samples: Standard solution and Sample solution

[NNote—Identify the impurities using the relative retention times given in Table 3.]

Calculate the percentage of any individual impurity in the portion of Tablets taken:

\[ \text{Result} = \left( \frac{r_i}{r_0} \right) \times \left( \frac{C_j}{C_0} \right) \times \left( \frac{1}{F} \right) \times 100 \]

\[ r_0 \] = peak response of each individual impurity from the Sample solution

\[ r_i \] = peak response of donepezil hydrochloride from the Standard solution

\[ C_j \] = concentration of USP Donepezil Hydrochloride RS in the Standard solution (mg/mL)

\[ C_0 \] = nominal concentration of donepezil hydrochloride in the Sample solution (mg/mL)

\[ F \] = relative response factor (see Table 3)

Acceptance criteria: See Table 4.

**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>Desbenzyl donepezil(^a)</td>
<td>0.33</td>
<td>1.0</td>
<td>0.5</td>
</tr>
<tr>
<td>Donepezil open ring(^b)</td>
<td>0.70</td>
<td>0.6</td>
<td>0.5</td>
</tr>
<tr>
<td>Donepezil hydrochloride</td>
<td>1.0</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Donepezil N-oxide(^c)</td>
<td>1.2</td>
<td>1.0</td>
<td>0.5</td>
</tr>
<tr>
<td>Any individual unspecified degradation product</td>
<td>—</td>
<td>—</td>
<td>0.2</td>
</tr>
</tbody>
</table>

\(^a\) 5,6-Dimethoxy-2-(piperidin-4-y1)methylindan-1-one.

\(^b\) 2-(3-(1-Benzylpiperidin-4-yl)-2-oxopropyl)-4,5-dimethoxybenzoic acid.

\(^c\) 2-[(1-Benzylpiperidin-4-yl)methyl]-5,6-dimethoxyindan-1-one N-oxide.

**Change to read:**

**Organic Impurities, Procedure 2**

Diluent: Acetonitrile and water (25:75)

Solution A: Add 1 mL of phosphoric acid in 1 L of water. Adjust with triethylamine to a pH of 6.5. Pass through a filter of 0.45-µm or finer pore size.

Solution B: Acetonitrile

Mobile phase: See Table 5.

**Table 5**

<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>10</td>
<td>40</td>
<td>60</td>
</tr>
<tr>
<td>40</td>
<td>40</td>
<td>60</td>
</tr>
<tr>
<td>41</td>
<td>75</td>
<td>25</td>
</tr>
<tr>
<td>50</td>
<td>75</td>
<td>25</td>
</tr>
</tbody>
</table>

Standard solution: 0.01 mg/mL of USP Donepezil Hydrochloride RS in Diluent. Sonication may be used to aid the dissolution.

Sample solution: Nominally 1.0 mg/mL of donepezil hydrochloride in Diluent. Sonication may be used to aid the dissolution.

Chromatographic system

(See Chromatography (621), System Suitability.)

Mode: LC

Detector: UV 286 nm

Column: 4.6-mm × 25-cm; 5-µm packing L1

Column temperature: 50°

Flow rate: 1.5 mL/min

Injection volume: 20 µL

System suitability

Sample: Standard solution

Suitability requirements

Tailing factor: NMT 1.5

Relative standard deviation: NMT 2.0%, for five replicate injections

Analysis

Samples: Standard solution and Sample solution

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Calculate the percentage of each specified impurity or any individual degradation product in the portion of Tablets taken:

\[
\text{Result} = \left( \frac{r_{U}}{r_{S}} \right) \times \left( \frac{C_{S}}{C_{U}} \right) \times \left( \frac{1}{F} \right) \times 100
\]

- \( r_{U} \) = peak response of each individual impurity from the Sample solution
- \( r_{S} \) = peak response of donepezil hydrochloride from the Standard solution
- \( C_{S} \) = concentration of USP Donepezil Hydrochloride RS in the Standard solution (mg/mL)
- \( C_{U} \) = nominal concentration of donepezil hydrochloride in the Sample solution (mg/mL)
- \( F \) = relative response factor for the corresponding impurity peak from Table 6

Acceptance criteria: See Table 6.

### Table 6 (RB 1-Mar-2019)

<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>Desbenzyl donepezil(^b)</td>
<td>0.23</td>
<td>1.5</td>
<td>0.15</td>
</tr>
<tr>
<td>Donepezil pyridine analog(^c)</td>
<td>0.49</td>
<td>1.9</td>
<td>0.15</td>
</tr>
<tr>
<td>Donepezil quaternary salt(^d)</td>
<td>0.68</td>
<td>0.74</td>
<td>0.15</td>
</tr>
<tr>
<td>Donepezil hydrochloride</td>
<td>1.0</td>
<td>1.0</td>
<td>—</td>
</tr>
<tr>
<td>Donepezil indene analog(^f)</td>
<td>1.7</td>
<td>2.2</td>
<td>0.15</td>
</tr>
</tbody>
</table>

\(^a\) Relative retention times are based on 1-mL gradient delay volume.

\(^b\) 5,6-Dimethoxy-2-(piperidin-4-ylmethyl)indan-1-one.

\(^c\) 5,6-Dimethoxy-2-(pyridin-4-ylmethyl)indan-1-one; also known as DPMI.

\(^d\) 1,1-Dibenzyl-4-[(5,6-dimethoxy-1-oxoindan-2-yl)methyl]piperidinium; also known as donepezil benzyl.

\(^e\) 1-Benzyl-4-[(5,6-dimethoxyindan-2-yl)methyl]piperidine; also known as dehydrodeoxy donepezil.

\(^f\) 1-Benzyl-4-[(5,6-dimethoxyindan-2-yl)methyl]piperidine.

### ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in well-closed containers. Store at controlled room temperature.

- **LABELING:** If a test for Organic Impurities other than Procedure 1 is used, the labeling states the test with which the article complies. If a test for Dissolution other than Test 1 is used, the labeling states the test with which the article complies.

- **USP REFERENCE STANDARDS (11)**
  - USP Donepezil Hydrochloride RS
  - USP Donepezil Related Compound A RS
    - \((\text{E})\)-2-\{(1-Benzylpiperidin-4-yl)methylene\}-5,6-dimethoxyindan-1-one.
    - \( \text{C}_{24}\text{H}_{27}\text{NO}_3 \) 377.48