Ziprasidone Capsules

<table>
<thead>
<tr>
<th>Type of Posting</th>
<th>Revision Bulletin</th>
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<tr>
<td>Posting Date</td>
<td>27–Apr–2018</td>
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<tr>
<td>Official Date</td>
<td>01–May–2018</td>
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<tr>
<td>Expert Committee</td>
<td>Chemical Medicines Monographs 4</td>
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<td>Reason for Revision</td>
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</tbody>
</table>

In accordance with the Rules and Procedures of the 2015–2020 Council of Experts, the Chemical Medicines Monographs 4 Expert Committee has revised the Ziprasidone Capsules monograph. The purpose for the revision is to add *Dissolution Test 3* to accommodate drug products that were approved with different dissolution conditions and acceptance criteria.

- *Dissolution Test 3* was validated using the Xterra RP18 brand of L1 column. The typical retention time for ziprasidone is about 8.9 min.

The revision also necessitates a change in the table numbering in the test for *Organic Impurities*.

The Ziprasidone Capsules Revision Bulletin supersedes the currently official monograph. The Revision Bulletin will be incorporated in the *USP 42–NF 37*.

Should you have any questions, please contact Sridevi Ramachandran, PhD., Associate Scientific Liaison ([sdr@usp.org](mailto:sdr@usp.org)).
Ziprasidone Capsules

**ASSAY**

*• Procedure*

**Buffer:** 0.3% (v/v) of triethylamine in water

**Mobile phase:** Acetonitrile and Buffer (35:65). Adjust with glacial acetic acid to a pH of 6.0.

**Diluent:** Acetonitrile, water, and glacial acetic acid (70:30:5)

**Standard stock solution:** 1.0 mg/mL of USP Ziprasidone Hydrochloride RS in Diluent

**Standard solution:** 0.2 mg/mL of USP Ziprasidone Hydrochloride RS from the Standard stock solution in Mobile phase

**Sample stock solution:** Nominally 1 mg/mL of ziprasidone prepared as follows. Empty the contents of NLT 20 Capsules into a container. Blend the contents. Transfer an amount of the contents, equivalent to NLT 50 mg of ziprasidone, to a suitable volumetric flask. Dissolve the contents in 60% of the flask volume of Diluent. Sonicate for NLT 5 min. Dilute with Diluent to volume. Pass a portion of the solution through a suitable filter of 0.45-µm pore size and use the filtrate to prepare the Sample solution.

**Sample solution:** Nominally 0.2 mg/mL of ziprasidone prepared from the filtered Sample stock solution and Mobile phase

**Chromatographic system**

See Chromatography (621), System Suitability.)

**Mode:** LC

**Detector:** UV 254 nm. For Identification B, a diode array detector may be used in the wavelength range of 200–300 nm.

**Column:** 4.6-mm × 15-cm; 5-µm packing L1

**Flow rate:** 2.0 mL/min

**Injection volume:** 20 µL

**Run time:** 1.5 times the retention time of ziprasidone

**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 ziprasidone (C₂₁H₂₇ClN₂O₅S) in the portion of Capsules taken:

\[
\text{Result} = \left( \frac{r_0}{r_S} \right) \times \left( \frac{C_S}{C_0} \right) \times (M_1/M_2) \times 100
\]

\[
r_0 = \text{peak response of ziprasidone from the Sample solution}
\]

\[
r_S = \text{peak response of ziprasidone from the Standard solution}
\]

where:

- \(C_S\) = concentration of USP Ziprasidone Hydrochloride RS in the Standard solution (mg/mL)
- \(C_0\) = nominal concentration of ziprasidone in the Sample solution (mg/mL)
- \(M_1\) = molecular weight of ziprasidone free base, 412.94
- \(M_2\) = molecular weight of ziprasidone hydrochloride; 467.41 for the monohydrate, 449.40 for the anhydrous form

Acceptance criteria: 90.0%–110.0%

**PERFORMANCE TESTS**

**Change to read:**

**• Dissolution (711)**

- **Test 1 a** (88 1-Nov-2017)

<table>
<thead>
<tr>
<th>Tier</th>
<th>Medium</th>
<th>Buffer</th>
<th>Mobile phase</th>
<th>Diluent</th>
<th>Standard solution</th>
<th>Standard stock solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Phosphate buffer, pH 7.5:</td>
<td>Dissolve 7.8 g of monobasic sodium phosphate dihydrate and 20 g of sodium dodecyl sulfate in 1 L water. Sonicate to dissolve and adjust with phosphoric acid or sodium hydroxide to a pH of 7.5.</td>
<td>Acetonitrile and Buffer (45:55)</td>
<td>Acetonitrile, water, and glacial acetic acid (70:30:5)</td>
<td>0.24 mg/mL of USP Ziprasidone Hydrochloride RS</td>
<td>1.0 mg/mL of USP Ziprasidone Hydrochloride RS from the Standard stock solution in Mobile phase</td>
</tr>
<tr>
<td></td>
<td>Medium: Phosphate buffer, pH 7.5:</td>
<td>900 mL</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Apparatus 2:</td>
<td>75 rpm. Use a suitable sinker, if necessary.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Time:</td>
<td>45 min</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Buffer: 0.3% (v/v) of triethylamine in water. Adjust with glacial acetic acid to a pH of 6.0.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Mobile phase: Acetonitrile and Buffer (45:55)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Diluent: Acetonitrile, water, and glacial acetic acid (70:30:5)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Standard stock solution: 0.24 mg/mL of USP Ziprasidone Hydrochloride RS</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Standard solution: 0.024 mg/mL of USP Ziprasidone Hydrochloride RS from the Standard stock solution</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Sample solution: Pass a portion of the solution through a suitable filter of 0.45-µm pore size. Dilute with Medium to a concentration similar to that of the Standard solution.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Chromatographic system**

See Chromatography (621), System Suitability.)

**Mode:** LC

**Detector:** UV 254 nm

**Column:** 4.6-mm × 15-cm; 5-µm packing L1

**Flow rate:** 1.5 mL/min

**Injection volume:** 10 µL

**Run time:** 1.5 times the retention time of ziprasidone

**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 percentage of the labeled amount of ziprasidone (C₂₁H₂₇ClN₂O₅S) dissolved:

\[
\text{Result} = \left( \frac{r_0}{r_S} \right) \times \left( \frac{C_S}{L} \right) \times V \times (M_1/M_2) \times 100
\]

where:

- \(L\) = volume of the solution in the sample holder
2 Ziprasidone

\[ r_u = \text{peak response of ziprasidone from the Sample solution} \]
\[ r_s = \text{peak response of ziprasidone from the Standard solution} \]
\[ C_s = \text{concentration of USP Ziprasidone Hydrochloride RS in the Standard solution (mg/mL)} \]
\[ L = \text{label claim (mg/Capsule)} \]
\[ V = \text{volume of Medium, 900 mL} \]
\[ M_{t1} = \text{molecular weight of ziprasidone free base, 412.94} \]
\[ M_{t2} = \text{molecular weight of ziprasidone hydrochloride; 467.41 for the monohydrate, 449.40 for the anhydrous form} \]

**Tolerances:** NLT 75% (Q) of the labeled amount of ziprasidone (C\(_{21}H_{26}ClN_{2}O_{5}\)) is dissolved. If the above tolerance cannot be met, proceed to Tier 2.

**Tier 2**

**Solution A:** Dissolve 7.8 g of monobasic sodium phosphate dihydrate in 1 L of water. Sonicate to dissolve and adjust with phosphoric acid or sodium hydroxide to a pH of 7.5. Dissolve 10 g of pancreatin in the resulting solution.

**Solution B:** Dissolve 7.8 g of monobasic sodium phosphate dihydrate in 1 L of water. Adjust with phosphoric acid or sodium hydroxide to a pH of 7.5. Dissolve 90 g of sodium dodecyl sulfate in the resulting solution. Sonicate to dissolve.

**Medium:** Transfer 700 mL of Solution A to the dissolution vessel and equilibrate at 37° for 15 min. Add 200 mL of Solution B; 900 mL.

**Apparatus 2:** 75 rpm. Use a suitable sinker, if necessary.

**Time:** 45 min

Analyze the Sample solution using the liquid chromatographic procedure described in Tier 1.

**Tolerances:** NLT 75% (Q) of the labeled amount of ziprasidone (C\(_{21}H_{26}ClN_{2}O_{5}\)) is dissolved.

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

**Tier 1**

**Medium A:** pH 7.5 phosphate buffer (dissolve 6.9 g of monobasic sodium phosphate monohydrate and 1.6 g of sodium hydroxide in 900 mL of water, adjust with 1 N sodium hydroxide to a pH of 7.5 and dilute with water to 1000 mL) with 1% pancreatin; 700 mL

**Medium B:** pH 7.5 phosphate buffer with 9% of sodium lauryl sulfate; 200 mL

**Apparatus 2:** 75 rpm. Use a suitable sinker, if necessary.

**Time:** 15 min for Medium A; 45 min for Medium A with the addition of Medium B

**Solution A:** Dissolve 2.7 g of monobasic sodium phosphate monohydrate in 1 L of water. Adjust with 1 N sodium hydroxide to a pH of 6.0.

**Mobile phase:** Acetonitrile and Solution A (50:50)

**Diluent:** Acetonitrile and water (50:50)

**Standard stock solution:** 0.48 mg/mL of USP Ziprasidone Hydrochloride RS in Diluent

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

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

**Procedure:** Perform the test using the conditions in Tier 1. In the presence of cross-linking repeat the test with new Capsules using the conditions in Tier 2 as follows. After 15 min with 700 mL of Medium A, stop the dissolution bath and timer and add 200 mL of Medium B pre-equilibrated at 37 ± 0.5°. Restart the bath and timer, and continue the dissolution for an additional 45 min.

**Chromatographic system**

(See Chromatography (621), System Suitability.)

**Mode:** LC

**Detector:** UV 254 nm

**Column:** 3.9-mm × 15-cm; 5-µm packing L1

**Column temperature:** 40°

**Flow rate:** 1.5 mL/min

**Injection volume:** 20 µL

**Run time:** 1.8 times the retention time of ziprasidone

**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 ziprasidone (C\(_{21}H_{26}ClN_{2}O_{5}\)) dissolved:

\[
\text{Result} = \left( \frac{r_u}{r_s} \times \frac{C_s}{L} \right) \times V \times \left( \frac{M_{t1}}{M_{t2}} \right) \times 100
\]

\[ r_u = \text{peak response of ziprasidone from the Sample solution} \]
\[ r_s = \text{peak response of ziprasidone from the Standard solution} \]
\[ C_s = \text{concentration of USP Ziprasidone Hydrochloride RS in the Standard solution (mg/mL)} \]
\[ L = \text{label claim (mg/Capsule)} \]
\[ V = \text{volume of Medium, 900 mL} \]
\[ M_{t1} = \text{molecular weight of ziprasidone free base, 412.94} \]
\[ M_{t2} = \text{molecular weight of ziprasidone hydrochloride; 467.41 for the monohydrate, 449.40 for the anhydrous form} \]

**Tolerances:** NLT 75% (Q) of the labeled amount of ziprasidone (C\(_{21}H_{26}ClN_{2}O_{5}\)) is dissolved.

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

**Tier 1**

**Medium:** 2% sodium lauryl sulfate in pH 7.5 phosphate buffer (dissolve 6.9 g of monobasic sodium phosphate monohydrate and 1.6 g of sodium hydroxide in 900 mL of water, adjust with 1 N sodium hydroxide to a pH of 7.5 and dilute with water to 1000 mL) with 1% pancreatin, 700 mL

**Apparatus 2:** 75 rpm. Use a suitable sinker, if necessary.

**Time:** 60 min
Tier 2

Medium A: pH 7.5 phosphate buffer (6.9 g/L of monobasic sodium phosphate pH adjusted with 5 N sodium hydroxide) with 1% pancreatin; 700 mL

Medium B: pH 7.5 phosphate buffer (6.9 g/L of monobasic sodium phosphate pH adjusted with 5 N sodium hydroxide) with 9% sodium lauryl sulfate; 200 mL

Apparatus 2: 75 rpm. Use a suitable sinker.

Time: 15 min for Medium A; 45 min for Medium B with the addition of Medium B

Buffer: 6.8 g/L of monobasic potassium phosphate; To each liter of this solution, add 1 mol of triethylamine and adjust with phosphoric acid to a pH of 3.0.

Mobile phase: Acetonitrile and Buffer (30:70)

Diluent

Diluent 1: Acetonitrile and methanol (35:65)

Tier 1: Medium

Tier 2: Medium A and Medium B (70:30)

Standard stock solution 1: 0.5 mg/mL of USP Ziprasidone Hydrochloride R⃣ in Diluent 1

Standard stock solution 2: Prepare solutions of USP Ziprasidone Hydrochloride R⃣ in Diluent 2 at concentrations given in Table 1 as follows. Transfer a suitable volume of Standard stock solution into a suitable volumetric flask and dilute with Diluent 2 to volume.

<table>
<thead>
<tr>
<th>Strength of Ziprasidone Capsules (mg)</th>
<th>Concentration of Ziprasidone (mg/mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>20</td>
<td>0.025</td>
</tr>
<tr>
<td>40</td>
<td>0.050</td>
</tr>
<tr>
<td>60</td>
<td>0.080</td>
</tr>
<tr>
<td>80</td>
<td>0.100</td>
</tr>
</tbody>
</table>

Standard solution: Transfer 5 mL of Standard stock solution 2 to a 25-mL volumetric flask and dilute with Mobile phase to volume.

Sample solution: Centrifuge a portion of the solution under test. Dilute the supernatant with Mobile phase to volume to obtain nominal concentration of ziprasidone similar to that of the Standard solution. Pass through a suitable filter of 0.45-μm pore size. [Note—A centrifuge speed of 4000 rpm for 10 min may be suitable.]

Procedure: Perform the test using the conditions in Tier 1. In the presence of cross-linking repeat the test with new Capsules using the conditions in Tier 2 as follows. After 15 min with 700 mL of Medium A, stop the dissolution bath and timer and add 200 mL of Medium B pre-equilibrated at 37 ± 0.5°. Restart the bath and timer, and continue the dissolution for an additional 45 min.

Chromatographic system

(See Chromatography (621), System Suitability.)

Mode: LC

Detector: UV 230 nm

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

Flow rate: 1.3 mL/min

Injection volume: 10 μL

Run time: 1.3 times the retention time of ziprasidone

System suitability

Sample: Standard solution

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 1.5%

Analysis

Samples: Standard solution and Sample solution

Calculate the percentage of the labeled amount of ziprasidone (C₂₁H₂₃ClN₄OS) dissolved:

Result = (rₐ/rₘ) × Cₗ × V × D × ((1/L) × (Mₗ/Mₘ)) × 100

rₐ = peak response of ziprasidone from the Sample solution

rₘ = peak response of ziprasidone from the Standard solution

Cₗ = concentration of USP Ziprasidone Hydrochloride R⃣ in the Standard solution (mg/mL)

V = volume of Medium (Tier 1 or Tier 2), 900 mL

D = dilution factor for the Sample solution, 5

L = label claim (mg/Capsule)

Mₗ = molecular weight of ziprasidone, 412.94

Mₘ = molecular weight of ziprasidone hydrochloride; 467.41 for the monohydrate form, 449.40 for the anhydrous form

Tolerances: NLT 70% (Q) of the labeled amount of ziprasidone (C₂₁H₂₃ClN₄OS) is dissolved

• Uniformity of Dosage Units (905): Meet the requirements

Impurities

Change to read:

• Organic Impurities

Buffer: 0.05 M monobasic potassium phosphate

Solution A: Methanol and Buffer (33:67). Adjust with phosphoric acid to a pH of 3.0.

Solution B: Acetonitrile, methanol, and Buffer (55:5:40). Adjust with potassium hydroxide to a pH of 6.0.

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>100</td>
<td>0</td>
</tr>
<tr>
<td>15</td>
<td>100</td>
<td>0</td>
</tr>
<tr>
<td>20</td>
<td>85</td>
<td>15</td>
</tr>
<tr>
<td>30</td>
<td>85</td>
<td>15</td>
</tr>
<tr>
<td>40</td>
<td>55</td>
<td>45</td>
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<td>55</td>
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<td>60</td>
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<td>65</td>
<td>25</td>
<td>75</td>
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<td>70</td>
<td>20</td>
<td>80</td>
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<tr>
<td>71</td>
<td>100</td>
<td>0</td>
</tr>
<tr>
<td>75</td>
<td>100</td>
<td>0</td>
</tr>
</tbody>
</table>

Diluent: Acetonitrile, methanol, and water (40:10:50). Adjust with phosphoric acid to a pH of 2.5.

System suitability solution: 0.5 mg/mL of USP Ziprasidone Hydrochloride R⃣ and 0.05 mg/mL each of USP Ziprasidone Related Compound B R⃣ and USP Ziprasidone Related Compound F R⃣ in Diluent.
4 Ziprasidone

**Standard solution:** 0.002 mg/mL each of USP Ziprasidone Hydrochloride RS and USP Ziprasidone Related Compound B RS in Diluent. Sonication may be used to aid in dissolution.

**Sample solution:** Nominally 1.0 mg/mL of ziprasidone in Diluent from a portion of contents of Capsules (NLT 20) prepared as follows. Transfer a suitable amount of Capsule contents to a suitable volumetric flask. Add 60% of the flask volume of Diluent. Sonicate for 10 min. Dilute with Diluent to volume. Pass through a suitable filter of 0.45-µm pore size.

**Chromatographic system**
(See Chromatography (621), System Suitability.)

**Mode:** LC

**Detector:** UV 229 nm

**Column:** 4.6-mm × 15-cm; 5-µm packing L7

**Column temperature:** 30°

**Flow rate:** 1.5 mL/min

**Injection volume:** 10 µL

**System suitability**

**Samples:** System suitability solution and Standard solution

**Suitability requirements**

- **Resolution:** NLT 2.0 between ziprasidone related compound B and related compound F; NLT 2.0 between ziprasidone related compound F and ziprasidone, System suitability solution
- **Tailing factor:** NMT 1.5 for ziprasidone, Standard solution
- **Relative standard deviation:** NMT 5.0% for both ziprasidone and ziprasidone related compound B, Standard solution

**Analysis**

**Samples:** Standard solution and Sample solution

Calculate the percentage of ziprasidone related compound B in the portion of Capsules taken:

\[ \text{Result} = (r_0/r_f) \times (C_f/C_0) \times 100 \]

- \( r_0 \) = peak response of ziprasidone related compound B from the Sample solution
- \( r_f \) = peak response of ziprasidone related compound B from the Standard solution
- \( C_f \) = concentration of USP Ziprasidone Related Compound B RS in the Standard solution (mg/mL)
- \( C_0 \) = nominal concentration of ziprasidone in the Sample solution (mg/mL)

Calculate the percentage of any other unspecified degradation product in the portion of Capsules taken:

\[ \text{Result} = (r_0/r_f) \times (C_f/C_0) \times (M_1/M_0) \times 100 \]

- \( r_0 \) = peak response of each unspecified degradation product from the Sample solution
- \( r_f \) = peak response of ziprasidone from the Standard solution
- \( C_f \) = concentration of USP Ziprasidone Hydrochloride RS in the Standard solution (mg/mL)
- \( C_0 \) = nominal concentration of ziprasidone in the Sample solution (mg/mL)

\( M_1 \) = molecular weight of ziprasidone free base, 412.94

\( M_0 \) = molecular weight of ziprasidone hydrochloride; 467.41 for the monohydrate, 449.40 for the anhydrous form

**Acceptance criteria:** See Table 3.

Disregard any peak with an area below 0.05% in the Sample solution.

**Table 3**

<table>
<thead>
<tr>
<th>Name</th>
<th>Relative Retention Time</th>
<th>Acceptance Criteria, NMT (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ziprasidone related compound A&lt;sup&gt;a&lt;/sup&gt;</td>
<td>0.22</td>
<td>—</td>
</tr>
<tr>
<td>Chloroindolinone&lt;sup&gt;c&lt;/sup&gt;</td>
<td>0.59</td>
<td>—</td>
</tr>
<tr>
<td>Ziprasidone related compound B</td>
<td>0.70</td>
<td>0.20</td>
</tr>
<tr>
<td>Ziprasidone related compound F&lt;sup&gt;e&lt;/sup&gt;</td>
<td>0.84</td>
<td>—</td>
</tr>
<tr>
<td>Ziprasidone</td>
<td>1.0</td>
<td>—</td>
</tr>
<tr>
<td>Ziprasidone related compound C&lt;sup&gt;d&lt;/sup&gt;</td>
<td>1.84</td>
<td>—</td>
</tr>
<tr>
<td>Ziprasidone related compound D&lt;sup&gt;e&lt;/sup&gt;</td>
<td>2.18</td>
<td>—</td>
</tr>
<tr>
<td>Any individual unspecified degradation product</td>
<td>—</td>
<td>0.20</td>
</tr>
<tr>
<td>Total degradation products</td>
<td>—</td>
<td>0.50</td>
</tr>
</tbody>
</table>

<sup>a</sup> Process impurity included in the table for identification only; controlled in the drug substance. Process impurities are controlled in the drug substance and are not to be reported or included in the total impurities for the drug product.

<sup>b</sup> 3-(Piperazin-1-yl)benzof[d]isothiazole.

<sup>c</sup> 6-Chloroindolin-2-one.

<sup>d</sup> 5,5-Bis[2-[4-(Benzo[d]isothiazol-3-yl)piperazin-1-yl]ethyl]-6,6′-dichloro-3,3′-biindoline-2,2′-dione.

<sup>e</sup> 3-(Benzo[d]isothiazol-3-yl)-5-[2-[4-(Benzo[d]isothiazol-3-yl)piperazin-1-yl]ethyl]-6-chloroindolin-2-one.

**ADDITIONAL REQUIREMENTS**

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

**Add the following:**

- **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 Ziprasidone Hydrochloride RS
  - USP Ziprasidone Related Compound B RS
  - USP Ziprasidone Related Compound F RS

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