Quetiapine Extended-Release Tablets

Type of Posting: Revision Bulletin
Posting Date: 28–Dec–2018
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Expert Committee: Chemical Medicines Monographs 4
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 Quetiapine Extended-Release Tablets monograph. The purpose for the revision is to add Dissolution Tests 5 and 6 to accommodate FDA-approved drug products with different dissolution conditions and/or tolerances than the existing dissolution tests. The revision also necessitates a change in the table numbering in the Assay and in the test for Organic Impurities.

- Dissolution Test 6 was validated using a Zorbax XDB-C18 brand of L1 column. The typical retention time for quetiapine is about 1.7 min.

The Quetiapine Extended-Release Tablets Revision Bulletin supersedes the currently official monograph.

Should you have any questions, please contact Claire Chisolm, Associate Scientific Liaison (301-230-3215 or cnc@usp.org).
Quetiapine Extended-Release Tablets

**DEFINITION**
Quetiapine Extended-Release Tablets contain quetiapine fumarate \( (C_{21}H_{23}N_2O_5S) \) equivalent to NLT 90.0% and NMT 110.0% of the labeled amount of quetiapine \( (C_{21}H_{23}N_2O_5) \).

**IDENTIFICATION**

- **A. INFRARED ABSORPTION**

  **Standard solution:** Transfer 10 mg of USP Quetiapine Fumarate RS to a suitable vial. Add 10 mL of acetone and cap the vial. Sonicate for about 10 min. Allow the solution to equilibrate to room temperature. Evaporate the acetone completely. Add 2 mL of chloroform. Gently swirl for several minutes. Pass through a suitable filter of 0.45-µm pore size. Use the filtrate.

  **Sample solution:** Grind NLT 10 Tablets. Transfer an amount of powder equivalent to NLT 10 mg of quetiapine fumarate to a suitable vial. Add 10 mL of acetone and cap the vial. Sonicate for about 10 min. Allow the solution to equilibrate to room temperature. Evaporate the acetone completely. Add 2 mL of chloroform. Gently swirl for several minutes. Pass through a suitable filter of 0.45-µm pore size. Use the filtrate.

  **Acceptance criteria:** Meet the requirements

- **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**

  **Buffer:** Dissolve 2.6 g/L of dibasic ammonium phosphate in water.

  **Mobile phase:** Methanol, acetonitrile, and Buffer (54:7:39)

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

  **System suitability stock solution:** 0.05 mg/mL of USP Quetiapine Related Compound H RS in Mobile phase

  **System suitability solution:** 0.005 mg/mL of USP Quetiapine Related Compound H RS and 0.5 mg/mL of USP Quetiapine System Suitability RS in Mobile phase prepared as follows. Transfer 5 mg of USP Quetiapine System Suitability RS to a 10-mL volumetric flask. Add 7 mL of Mobile phase and sonicate to dissolve. Transfer 1 mL of System suitability stock solution to the volumetric flask. Dilute with Mobile phase to volume.

  **Standard solution:** 0.2 mg/mL of USP Quetiapine Fumarate RS in Mobile phase

  **Sample stock solution:** Transfer NLT 5 Tablets to a homogenizer vessel. Add 50 mL of acetonitrile, swirl to wet, and allow to stand for approximately 10 min. Add an additional 160 mL of Diluent and extract for about 10 min. Transfer the contents of the homogenizer to a 500-mL volumetric flask. 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.

  **Sample solution:** Nominally 0.16–0.18 mg/mL of quetiapine from the Sample stock solution in Mobile phase

  **Chromatographic system**

  (See Chromatography (621), System Suitability.)

  **Mode:** LC

  **Detector:** UV 230 nm

  **Column:** 4.6-mm × 25-cm; 5-µm packing L7

  **Flow rate:** 1.3 mL/min

  **Injection volume:** 30 µL

  **Run time:** NLT 2.5 times the retention time of quetiapine

**System suitability**

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

**[Note—See Table 7 for the relative retention times.]**

**Suitability requirements**

**Resolution:** NLT 1.5 between quetiapine related compound G and quetiapine related compound H; NLT 2.0 between the quetiapine desthoxy and quetiapine peaks; System suitability solution

**Tailing factor:** NMT 1.5, Standard solution

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

**Analysis**

**Samples:** Standard solution and Sample solution

Calculate the percentage of the labeled amount of quetiapine \( (C_{21}H_{23}N_2O_5) \) in the portion of Tablets taken:

\[
\text{Result} = \left( \frac{r_1}{r_2} \right) \times (C_a/C_s) \times (M_1/M_2) \times N \times 100
\]

where:

- \( r_1 \) = peak response from the Sample solution
- \( r_2 \) = peak response from the Standard solution
- \( C_a \) = concentration of USP Quetiapine Fumarate RS in the Standard solution (mg/mL)
- \( C_s \) = nominal concentration of quetiapine in the Sample solution (mg/mL)
- \( M_1 \) = molecular weight of quetiapine free base, 383.51
- \( M_2 \) = molecular weight of quetiapine fumarate, 883.09
- \( N \) = number of moles of quetiapine free base per mole of quetiapine fumarate, 2

**Acceptance criteria:** 90.0%–110.0%

**PERFORMANCE TESTS**

**Change to read:**

- **DISSOLUTION**

  **Test 1**

  **Medium 1:** Citrate buffer, pH 4.8. Dissolve 9.6 g of anhydrous citric acid in 600 mL of water. Add 90 mL of 1 N sodium hydroxide. Dilute with water to 1 L; 900 mL

  **Medium 2:** Dissolve 17.9 g of dibasic sodium phosphate dodecahydrate in 400 mL of water. Add 460 mL of 1 N sodium hydroxide and dilute with water to 1 L; 100 mL

  **[Note—It is recommended to check the pH of the mixture of 90 mL of Medium 1 and 10 mL of Medium 2, which should be between 6.4 and 6.8. If the pH of the mixture is less than 6.4, 10 mL/L of 1 N sodium hydroxide may be added to Medium 2. If the pH of the mixture is greater than 6.8, 10 mL/L of 1 N hydrochloric acid may be added to Medium 2.]**

  Start the test with 900 mL of Medium 1. Add 100 mL of Medium 2 to the vessel after 5 h of the test and continue the test.

  **Apparatus 1:** 200 rpm

  **Times:** 1, 6, 12, and 20 h

  **Diluent:** Medium 1 and Medium 2 (90:10)

  **Standard solution:** \( (L/400) \) mg/mL of USP Quetiapine Fumarate RS in Diluent, where \( L \) is the label claim in mg/Tablet

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

  **Instrumental conditions**

  **Mode:** UV

  **Analytical wavelength:** About 290 nm

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Blank: Diluent

Analysis

Samples: Standard solution and Sample solution

Calculate the concentration, \( C_i \), of quetiapine (\( C_{21}H_{23}N_0O_5 \)) in \( \text{Medium} \) (mg/mL) after time point (\( t \)):

\[
C_i = \left( \frac{A_i}{A_0} \right) \times C_i \times (M_{1}/M_2) \times N
\]

\( A_0 \) = absorbance of the Sample solution

\( A_i \) = absorbance of the Standard solution

\( C_i \) = concentration of quetiapine fumarate in the Standard solution (mg/mL)

\( M_{1/2} \) = molecular weight of quetiapine free base, 383.51

\( N \) = number of moles of quetiapine free base per mole of quetiapine fumarate, 2

Calculate the percentage of the labeled amount of quetiapine (\( C_{21}H_{23}N_0O_5 \)) dissolved at each time point (\( t \)):

\[
\text{Result}_1 = C_i \times V \times (1/L) \times 100 \\
\text{Result}_2 = [(C_i \times V) + (C_i \times V)] \times (1/L) \times 100 \\
\text{Result}_3 = [(C_i \times V) + (C_i + C_i) \times V] \times (1/L) \times 100 \\
\text{Result}_4 = [(C_i \times V) + (C_i + C_i) \times V] \times (1/L) \times 100
\]

\( C_i \) = concentration of quetiapine in \( \text{Medium} \) in the portion of sample withdrawn at each time point (mg/mL)

\( V \) = volume of \( \text{Medium} \), 900 mL for 1 h; 1000 mL for 6-, 12-, and 20-h time points

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

\( V_s \) = volume of the Sample solution withdrawn from the vessel and replaced with \( \text{Medium} \) (mL)

Tolerances: See Table 1.

<table>
<thead>
<tr>
<th>Time Point (h)</th>
<th>Amount Dissolved (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>NMT 20</td>
</tr>
<tr>
<td>2</td>
<td>47–69</td>
</tr>
<tr>
<td>3</td>
<td>65–95</td>
</tr>
<tr>
<td>4</td>
<td>NLT 85</td>
</tr>
</tbody>
</table>

The percentages of the labeled amount of quetiapine (\( C_{21}H_{23}N_0O_5 \)) dissolved at the times specified conform to Dissolution (711), Acceptance Table 2.

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

Medium: Water; 900 mL

Apparatus 1: 100 rpm

Times: 2, 4, 8, and 24 h

Standard solution: 0.03 mg/mL of USP Quetiapine Fumarate RS in water

Sample solution: Pass a suitable portion of the solution under test through a suitable filter of 0.45-µm pore size. Discard the first few milliliters of filtrate. Replace the volume withdrawn with an equal volume of \( \text{Medium} \). Dilute with \( \text{Medium} \) to a concentration that is similar to that of the Standard solution.

Instrumental conditions

Mode: UV

Analytical wavelength: 290 nm

Blank: Water

Analysis

Samples: Standard solution and Sample solution

Calculate the concentration, \( C_i \), of quetiapine (\( C_{21}H_{23}N_0O_5 \)) in \( \text{Medium} \) (mg/mL) after each time point (\( t \)):

\[
C_i = \left( \frac{A_i}{A_0} \right) \times C_i \times D \times (M_{1}/M_2) \times N
\]

\( A_0 \) = absorbance of the Sample solution

\( A_i \) = absorbance of the Standard solution

\( C_i \) = concentration of quetiapine fumarate in the Standard solution (mg/mL)

\( D \) = dilution factor for the Sample solution, if needed

\( M_{1/2} \) = molecular weight of quetiapine free base, 383.51

\( N \) = number of moles of quetiapine free base per mole of quetiapine fumarate, 2

Calculate the percentage of the labeled amount of quetiapine (\( C_{21}H_{23}N_0O_5 \)) dissolved at each time point (\( t \)):

\[
\text{Result}_1 = C_i \times V \times (1/L) \times 100 \\
\text{Result}_2 = [(C_i \times V) + (C_i \times V)] \times (1/L) \times 100 \\
\text{Result}_3 = [(C_i \times V) + (C_i + C_i) \times V] \times (1/L) \times 100 \\
\text{Result}_4 = [(C_i \times V) + (C_i + C_i) \times V] \times (1/L) \times 100
\]

\( C_i \) = concentration of quetiapine in \( \text{Medium} \) in the portion of sample withdrawn at each time point (mg/mL)

\( V \) = volume of \( \text{Medium} \), 900 mL

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

\( V_s \) = volume of the Sample solution withdrawn from the vessel and replaced with \( \text{Medium} \) (mL)

Tolerances: See Table 2.

<table>
<thead>
<tr>
<th>Time Point (h)</th>
<th>Amount Dissolved (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>5–25</td>
</tr>
<tr>
<td>2</td>
<td>20–45</td>
</tr>
<tr>
<td>3</td>
<td>45–75</td>
</tr>
<tr>
<td>4</td>
<td>NLT 85</td>
</tr>
</tbody>
</table>

The percentages of the labeled amount of quetiapine (\( C_{21}H_{23}N_0O_5 \)) 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: 0.1 N hydrochloric acid; 900 mL

Apparatus 2: 50 rpm

Times: 1, 4, and 8 h

Standard solution: USP Quetiapine Fumarate RS, equivalent to (\( L/900 \)) mg/mL of quetiapine in Medium, where \( L \) is the label claim in mg/Tablet

Sample solution: Pass a suitable portion of the solution under test through a suitable full flow filter of 10-µm pore size.
Official January 1, 2019

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

**Medium**: Water; 900 mL

**Apparatus**: 2; 100 rpm

**Times**: 1, 4, 8, and 16 h

**Standard solution**: USP Quetiapine Fumarate RS, equivalent to (L/900) mg/mL of quetiapine in Medium, where L is the label claim in mg/Tablet

**Instrumental conditions**

**Mode**: UV

**Analytical wavelength**: 295 nm

**Cell**

For 50-mg Tablets: 10 mm
For 150-, 200-, 300-, and 400-mg Tablets: 1 mm

**Blank**: Medium

**Analysis**

**Samples**: Standard solution and Sample solution

Calculate the percentage of the labeled amount of quetiapine (C_{21}H_{23}N_{4}O_{5}) dissolved at each time point (t):

Result = \left(\frac{A_i}{A_j}\right) \times C_i \times V \times \left(\frac{1}{L}\right) \times \left(\frac{M_i}{M_j}\right) \times N \times 100

- \( A_i \) = absorbance of the Sample solution
- \( A_j \) = absorbance of the Standard solution
- \( C_i \) = concentration of quetiapine fumarate in the Standard solution (mg/mL)
- \( V \) = volume of Medium, 900 mL
- \( L \) = label claim (mg/Tablet)
- \( M_i \) = molecular weight of quetiapine fumarate, 383.51
- \( M_j \) = molecular weight of quetiapine fumarate, 883.09
- \( N \) = number of moles of quetiapine free base per mole of quetiapine fumarate, 2

**Tolerances**: See Table 3.

### Table 3

<table>
<thead>
<tr>
<th>Time Point (h)</th>
<th>Time (h)</th>
<th>Amount Dissolved (for 50-, 150-, and 200-mg Tablets) (%)</th>
<th>Amount Dissolved (for 300- and 400-mg Tablets) (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1</td>
<td>NMT 40</td>
<td>NMT 35</td>
</tr>
<tr>
<td>2</td>
<td>4</td>
<td>55–75</td>
<td>45–65</td>
</tr>
<tr>
<td>3</td>
<td>8</td>
<td>NLT 85</td>
<td>NLT 80</td>
</tr>
</tbody>
</table>

The percentages of the labeled amount of quetiapine (C_{21}H_{23}N_{4}O_{5}) dissolved at the times specified conform to Dissolution (711), Acceptance Table 2.

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

**Medium**: Apparatus 1, Times, Standard solution, Sample solution, Instrumental conditions, and Analysis: Proceed as directed in Dissolution Test 2.

**Tolerances**: See Table 5.

### Table 5

<table>
<thead>
<tr>
<th>Time Point (h)</th>
<th>Time (h)</th>
<th>Amount Dissolved (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>10–30</td>
</tr>
<tr>
<td>2</td>
<td>4</td>
<td>30–50</td>
</tr>
<tr>
<td>3</td>
<td>8</td>
<td>60–80</td>
</tr>
<tr>
<td>4</td>
<td>24</td>
<td>NLT 85</td>
</tr>
</tbody>
</table>

The percentages of the labeled amount of quetiapine (C_{21}H_{23}N_{4}O_{5}) dissolved at the times specified conform to Dissolution (711), Acceptance Table 2.

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

### Table 4

<table>
<thead>
<tr>
<th>Time Point (h)</th>
<th>Time (h)</th>
<th>Amount Dissolved (for 50-mg Tablets) (%)</th>
<th>Amount Dissolved (for 150-mg Tablets) (%)</th>
<th>Amount Dissolved (for 200-mg Tablets) (%)</th>
<th>Amount Dissolved (for 300-mg Tablets) (%)</th>
<th>Amount Dissolved (for 400-mg Tablets) (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1</td>
<td>NMT 20</td>
<td>NMT 20</td>
<td>NMT 20</td>
<td>NMT 15</td>
<td>NMT 15</td>
</tr>
<tr>
<td>3</td>
<td>8</td>
<td>60–85</td>
<td>65–90</td>
<td>60–85</td>
<td>52–76</td>
<td>50–75</td>
</tr>
<tr>
<td>4</td>
<td>16</td>
<td>NLT 85</td>
<td>NLT 85</td>
<td>NLT 85</td>
<td>NLT 85</td>
<td>NLT 85</td>
</tr>
</tbody>
</table>
Medium: pH 6.8 phosphate buffer (6.8 g/L of monobasic potassium phosphate and 0.9 g/L of sodium hydroxide in water. Adjust with 1 N sodium hydroxide VS or phosphoric acid to a pH of 6.8, and sonicate for NLT 10 min); 900 mL

Apparatus 2: 100 rpm, with sinker

Times: 1, 4, 8, and 16 h

Mobile phase: Methanol, trifluoroacetic acid, and water (40: 0.1: 60)

Standard solution: 0.1 mg/mL of USP Quetiapine Fumarate RS prepared as follows. Transfer an appropriate amount of USP Quetiapine Fumarate RS to a suitable volumetric flask, and add 5% of the final flask volume of methanol. Sonicate to dissolve, then dilute with Medium to volume.

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

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

Mode: LC
Detector: UV 280 nm
Column: 4.6-mm x 5.0-cm; 5-µm packing
Flow rate: 1.2 mL/min
Injection volume: 10 µL
Run time: NLT 2.0 times the retention time of quetiapine

System suitability
Sample: Standard solution
Suitability requirements
Tailing factor: NLT 2.0
Relative standard deviation: NMT 3.0%

Analysis
Samples: Standard solution and Sample solution
Calculate the concentration, C, of quetiapine (C₂₁H₂₃N₄O₅S) in Medium (mg/mL) after each time point (h):

\[ C = \left( \frac{r_0}{r_s} \right) \times C_i \times \left( \frac{M_i}{M_o} \right) \times N \]

Where:
- \( r_0 \) = peak response from the Sample solution
- \( r_s \) = peak response from the Standard solution
- \( C_i \) = concentration of USP Quetiapine Fumarate RS in the Standard solution (mg/mL)
- \( M_i \) = molecular weight of quetiapine free base, 383.51
- \( M_o \) = molecular weight of quetiapine fumarate, 883.09
- \( N \) = number of moles of quetiapine free base per mole of quetiapine fumarate, 2

Calculate the percentage of the labeled amount of quetiapine (C₂₁H₂₃N₄O₅S) dissolved at each time point (h):

\[ \text{Result}_1 = C \times V \times (1/L) \times 100 \]
\[ \text{Result}_2 = \left( [C \times (V - V_o) + (C \times V_o)] \times (1/L) \times 100 \right) \]
\[ \text{Result}_3 = (C \times (V - 2 \times V_o)) + (C \times C \times V_o) \times (1/L) \times 100 \]
\[ \text{Result}_4 = (C \times (V - 3 \times V_o)) + (C \times C \times C \times V_o) \times (1/L) \times 100 \]

Where:
- \( C \) = concentration of quetiapine in Medium in the portion of sample withdrawn at each time point (mg/mL)
- \( V \) = volume of Medium, 900 mL

The percentages of the labeled amount of quetiapine (C₂₁H₂₃N₄O₅S) dissolved at the times specified conform to Dissolution (711), Acceptance Table 2, ▲ (88 1-Jan-2019)

- **Uniformity of dosage units (905):** Meet the requirements

Change to read:

**Impurities**

- **Organic impurities**
  Buffer, Mobile phase, Diluent, System suitability solution, Sample solution, and Chromatographic system: Proceed as directed in the Assay.
  Sample: System suitability solution
  [NOTE—See ▲ Table 7▲ (88 1-Jan-2019) for the relative retention times.]

Suitability requirements
Resolution: NLT 1.5 between quetiapine related compound G and quetiapine related compound H; NLT 2.0 between the quetiapine desthoxo and quetiapine peaks

Analysis
Sample: Sample solution
[NOTE—See ▲ Table 7▲ (88 1-Jan-2019) for the relative retention times.]
Calculate the percentage of each degradation product in the portion of Tablets taken:

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

Where:
- \( r_0 \) = peak response of each degradation product from the Sample solution
- \( r_s \) = peak response of quetiapine from the Sample solution
- \( F \) = relative response factor for the corresponding degradation product from ▲ Table 7▲ (88 1-Jan-2019)

Acceptance criteria: See ▲ Table 7▲ (88 1-Jan-2019) Disregard peaks less than 0.05%.

**Table 7▲ (88 1-Jan-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>Fumaric acid</td>
<td>0.1</td>
<td>—</td>
<td>—</td>
</tr>
</tbody>
</table>

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### Table 7 (RB 1-Jan-2019) (continued)

<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>Quetiapine related compound G</td>
<td>0.48</td>
<td>1.4</td>
<td>0.2</td>
</tr>
<tr>
<td>Quetiapine related compound H</td>
<td>0.57</td>
<td>1.0</td>
<td>0.2</td>
</tr>
<tr>
<td>Quetiapine desethoxy(^b)</td>
<td>0.87</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Quetiapine</td>
<td>1.0</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Quetiapine related compound B(^b)</td>
<td>1.9</td>
<td>—</td>
<td>—</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>0.4</td>
</tr>
</tbody>
</table>

\(^a\) Counter ion peak, not to be included in the total degradation products.
\(^b\) Process impurity controlled in the drug substance. Included for identification purposes only. Not reported for the drug product and not included in the total degradation products.

### 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 Quetiapine Fumarate RS
  - USP Quetiapine Related Compound H RS
    - 4-(Dibenzo[b,f][1,4]thiazepin-11-yl)-1-[2-(2-hydroxyethoxy)ethyl]piperazine 1-oxide.
    - \(\text{C}_{21}\text{H}_{25}\text{N}_{3}\text{O}_{3}\text{S} = 399.51\)
  - USP Quetiapine System Suitability RS
    - It contains quetiapine fumarate and at least 0.1% of each of the following impurities:
      - Quetiapine related compound B: 11-(Piperazin-1-yl) dibenzo[b,f][1,4]thiazepine; Quetiapine related compound G: Dibenzo[b,f][1,4]thiazepin-11(10H)-one; and Quetiapine desethoxy: 2-[4-(Dibenzo[b,f][1,4] thiazepin-11-yl)piperazin-1-yl]ethanol.