Escitalopram Tablets

**DEFINITION**

*Change to read:*

Escitalopram Tablets contain an amount of Escitalopram Oxalate equivalent to NLT 90.0% and NMT 110.0% of the labeled amount of escitalopram (C₂₀H₂₁FN₂O).

• **NOTE—**Throughout the monograph, USP Citalopram Hydrobromide RS is used as a quantitative standard with an appropriate molecular weight correction, as needed.

Escitalopram is an optical isomer of citalopram.

**IDENTIFICATION**

• A. 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**

*Buffer:* 1.5 g of anhydrous sodium acetate and 0.4 mL of glacial acetic acid in 1 L of water. Adjust with 1% sodium hydroxide to a pH of 5.2.

*Methanol, acetonitrile, and Buffer (33:7:60)*

*System suitability solution:* 6.2 μg/mL of USP Citalopram Hydrobromide RS (equivalent to 5 μg/mL of citalopram) and 1 μg/mL of USP Citalopram Related Compound C RS in Mobile phase

*Standard solution:* 0.62 mg/mL of USP Citalopram Hydrobromide RS in Mobile phase (equivalent to 0.5 mg/mL of citalopram)

*Sample solution:* Transfer 10 Tablets to a suitable volumetric flask, add Buffer to 10% of the final volume, and shake vigorously for 10 min. Add methanol to 50% of the final volume, shake for 1 additional min, sonicate for 10 min, and dilute with Mobile phase to volume to obtain a solution having a concentration of about 0.5 mg/mL of escitalopram.

**Chromatographic system**

(See Chromatography (621), System Suitability.)

*Mode:* LC

*Detector:* UV 239 nm

*Column:* 4.6-mm × 10-cm; 3-μm packing L1

*Column temperature:* 45°

*Flow rate:* 1 mL/min

*Injection volume:* 10 μL

**System suitability**

*Samples:* System suitability solution and Standard solution

**Suitability requirements**

*Resolution:* NLT 3.0 between citalopram and citalopram related compound C, System suitability solution

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

**Analysis**

*Samples:* Standard solution and Sample solution

Calculate the concentration of escitalopram (C₂₀H₂₁FN₂O) in the portion of Tablets taken:

\[ \text{Result} = \left( \frac{r_0}{r_1} \right) \times \left( \frac{C_i}{C_0} \right) \times \left( \frac{M_i}{M_o} \right) \times 100 \]

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

\[ r_1 = \text{peak response from the Standard solution} \]

\[ C_i = \text{concentration of the Standard solution (mg/mL)} \]

\[ C_0 = \text{nominal concentration of the Sample solution (mg/mL)} \]

\[ M_i = \text{molecular weight of citalopram, 324.39} \]

\[ M_o = \text{molecular weight of citalopram hydrobromide, 405.30} \]

**Acceptance criteria:** 90.0%–110.0%

**PERFORMANCE TESTS**

**Change to read:**

• **Dissolution** (711)

  **Test 1** *(IRA 01-May-2013)*

  *Medium:* 0.1 N hydrochloric acid; 900 mL

  *Apparatus 2:* 50 rpm

  *Time:* 30 min

  *Standard solution 1:* 3 μg/mL of USP Citalopram Hydrobromide RS in Medium

  *Standard solution 2:* 15 μg/mL of USP Citalopram Hydrobromide RS in Medium

  *Standard solution 3:* 30 μg/mL of USP Citalopram Hydrobromide RS in Medium

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

**Instrumental conditions**

(See Spectrophotometry and Light-Scattering (851)).

*Mode:* UV-Vis

*Analytical wavelength:* 239 nm

*Path length:* 0.5 cm

*Blank:* Medium

**System suitability**

*Samples:* Standard solution 1, Standard solution 2, and Standard solution 3

**Suitability requirements**

*Correlation coefficient:* NLT 0.995, determined using Standard solution 1, Standard solution 2, and Standard solution 3, three replicates of each solution

*Relative standard deviation:* NMT 2.0%, determined using Standard solution 3, six replicates

**Analysis**

*Samples:* Standard solution 1, Standard solution 2, Standard solution 3, and Sample solution

• Calculate the concentration, C₀, in mg/mL of citalopram (free base) for each Standard solution (Q):

\[ \text{Result} = C_0 \times \left( \frac{M_i}{M_o} \right) \]

\[ C_i = \text{concentration of USP Citalopram Hydrobromide RS in the Standard solution (mg/mL)} \]

\[ M_i = \text{molecular weight of citalopram, 324.39} \]

\[ M_o = \text{molecular weight of citalopram hydrobromide, 405.30} \]

Plot the absorbances of Standard solution 1, Standard solution 2, and Standard solution 3 versus the corresponding citalopram (free base) concentrations. Determine the concentration, C₀, in mg/mL of escitalopram in the Sample solution using the calibration curve.

Calculate the percentage of the labeled amount of escitalopram (C₂₀H₂₁FN₂O) dissolved:

\[ \text{Result} = C_0 \times V \times \left( \frac{1}{L} \right) \times 100 \]

\[ C_i = \text{concentration of escitalopram (free base) in the Sample solution (mg/mL)} \]

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

*Tolerances:* NLT 80% (Q) of the labeled amount of escitalopram (C₂₀H₂₁FN₂O) is dissolved.
Test 2: If the product complies with this test, the labeling indicates that it meets USP Dissolution Test 2.

Medium: 0.1 N hydrochloric acid; 900 mL

Apparatus 2: 75 rpm

Buffer: 3.4 g/L of potassium dihydrogen phosphate in water. To each 1 L of the mixture, add 1.0 mL of triethylamine, and adjust with 10% phosphoric (v/v) to a pH of 3.8.

Mobile phase: Acetonitrile, methanol, and Buffer (28:5:67)

Standard solution: \((L/900)\) mg/mL of escitalopram free base from USP Escitalopram Oxalate RS in Medium, where \(L\) is the label claim of escitalopram free base

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

**Analysis**

**Samples:** Standard solution and Sample solution

Calculate the percentage of each impurity in the portion of Tablets taken:

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

- \(r_0\) = peak response of escitalopram from the Sample solution
- \(r_s\) = peak response of citalopram from the Standard solution
- \(C_s\) = concentration of USP Escitalopram Oxalate RS in the Standard solution (mg/mL)
- \(M_s\) = molecular weight of citalopram oxalate, 405.30
- \(M_i\) = molecular weight of citalopram, 324.39
- \(V\) = volume of Medium, 900 mL
- \(L\) = label claim (mg/Tablet)
- \(F\) = relative response factor (see Table 1)
- \(C_i\) = nominal concentration of the Sample solution (mg/mL)

Acceptance criteria: See Table 1.

**ADDITIONAL REQUIREMENTS**

**LABELING:** When more than one Dissolution test is given, the labeling states the Dissolution test used only if the test is not used. (IRA 01-May-2013)

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