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Citalopram Oral Solution

DEFINITION

Citalopram Oral Solution contains an amount of citalopram hydrobromide equivalent to NLT 90.0% and NMT 110.0% of the labeled amount of citalopram free base ($C_{20}H_{21}FN_2O$). It may contain a suitable preservative.

IDENTIFICATION

• **A.** The retention time of the citalopram peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

Add the following:

• **B.** The UV spectrum of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.▲_{2S} (USP41)

ASSAY

Change to read:

• PROCEDURE

Solution A: [Methanol](#) and [acetonitrile](#)▲(10:90)▲_{2S} (USP41)

Buffer: 6.1 g/L of [monobasic potassium phosphate](#) in [water](#). Add 1.5 mL of [triethylamine](#) per liter of the solution. Adjust with [phosphoric acid](#) to a pH of 2.5.

Mobile phase: *Solution A* and *Buffer*▲(28:72)▲_{2S} (USP41)

Diluent: [Acetonitrile](#) and *Buffer*▲(25:75)▲_{2S} (USP41)

Standard solution: 0.25 mg/mL of [USP Citalopram Hydrobromide RS](#),▲ equivalent to 0.2 mg/mL of citalopram free base in *Diluent*▲_{2S} (USP41)

Sample solution:▲Nominally equivalent to 0.2 mg/mL of citalopram free base, prepared as follows. Transfer a suitable volume of Oral Solution to a suitable volumetric flask.▲_{2S} (USP41) Add 50% of the flask volume of *Diluent*, and sonicate at room temperature for 3 min with intermittent shaking. Allow the solution to cool, and dilute with *Diluent* to volume. [NOTE—The *Sample solution* may be passed through either a PVDF or nylon membrane filter of suitable pore size.]

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: LC

Detector: UV 240 nm.▲For *Identification B*, use a diode array detector in the range of 210–400 nm.▲_{2S} (USP41)

Column: 4.6-mm × 15-cm; 5-μm packing [L1](#)

Column temperature: 40°

Flow rate: 1.5 mL/min

Injection volume: 10 μL

Run time:▲NLT▲_{2S} (USP41) 2 times the retention time of citalopram

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.5

Relative standard deviation:▲NMT 0.73%▲_{2S} (USP41)

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of citalopram ($C_{20}H_{21}FN_2O$) in the portion of Oral Solution taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (M_{r1}/M_{r2}) \times 100$$

r_U = peak response of citalopram from the *Sample solution*

r_S = peak response of citalopram from the *Standard solution*

C_S = concentration of [USP Citalopram Hydrobromide RS](#) in the *Standard solution* (mg/mL)

C_U = nominal concentration of citalopram in the *Sample solution* (mg/mL)

M_{r1} = molecular weight of citalopram free base, 324.39

M_{r2} = molecular weight of citalopram hydrobromide, 405.30

Acceptance criteria: 90.0%–110.0% of citalopram free base ($C_{20}H_{21}FN_2O$)

IMPURITIES

Change to read:

• ORGANIC IMPURITIES

Solution A: [Acetonitrile](#), [methanol](#), and [tetrahydrofuran](#) $\blacktriangle$ (85:5:10) $\blacktriangle_{2S}$ (USP41)

Buffer: Dissolve 3.0 g of $\blacktriangle$ [octanesulfonic acid sodium salt](#) $\blacktriangle_{2S}$ (USP41) in 1 L of [water](#). Add 2 mL of [triethylamine](#) and 5 mL of $\blacktriangle$ [tetrabutylammonium hydroxide, 40 percent in water](#) $\blacktriangle_{2S}$ (USP41). Mix, and adjust with [phosphoric acid](#) to a pH of 3.0.

Mobile phase: *Solution A* and *Buffer* $\blacktriangle$ (25:75) $\blacktriangle_{2S}$ (USP41)

Diluent: [Acetonitrile](#) and [water](#) $\blacktriangle$ (25:75) $\blacktriangle_{2S}$ (USP41)

System suitability solution: 6 µg/mL of [USP Citalopram Related Compound D RS](#) and 1.3 mg/mL of [USP Citalopram Hydrobromide RS](#) in *Diluent*

Standard solution: $\blacktriangle$ 0.0063 mg/mL $\blacktriangle_{2S}$ (USP41) of [USP Citalopram Hydrobromide RS](#) in *Diluent*

Sample solution: $\blacktriangle$ Nominally equivalent to 1 mg/mL of citalopram free base, prepared as follows. Transfer a suitable volume of Oral Solution to a suitable volumetric flask. $\blacktriangle_{2S}$ (USP41) Add 60% of the flask volume of *Diluent*, and sonicate at room temperature for 3 min with intermittent shaking. Allow the solution to cool, and dilute with *Diluent* to volume. [NOTE—The *Sample solution* may be passed through either a PVDF or nylon membrane filter of suitable pore size.]

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: LC

Detector: UV 225 nm

Column: 4.6-mm × 15-cm; 5-µm packing [L1](#)

Flow rate: 1.5 mL/min

Injection volume: 20 µL

Run time: $\blacktriangle$ NLT $\blacktriangle_{2S}$ (USP41) 2.6 times the retention time of citalopram for the *System suitability solution* and the *Standard solution*; $\blacktriangle$ NLT $\blacktriangle_{2S}$ (USP41) 5.7 times the retention time of citalopram for the *Sample solution*

System suitability

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

Suitability requirements

Resolution: NLT 1.8 between citalopram and citalopram related compound D, *System suitability solution*

Tailing factor: NMT 2.0, *Standard solution*

Relative standard deviation: NMT 5.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of $\blacktriangle$ each degradation product $\blacktriangle_{2S}$ (USP41) in the portion of Oral Solution taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (1/F) \times (M_{r1}/M_{r2}) \times 100$$

r_U = peak response of each $\blacktriangle$ degradation product $\blacktriangle_{2S}$ (USP41) from the *Sample solution*