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Escitalopram Oral Solution

DEFINITION

Escitalopram Oral Solution contains an amount of escitalopram oxalate equivalent to NLT 90.0% and NMT 110.0% of the labeled amount of escitalopram ($C_{20}H_{21}FN_2O$).

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.

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. ▲ (USP 1-May-2021)

ASSAY

Change to read:

• PROCEDURE

Buffer: 6.1 g/L of [monobasic potassium phosphate](#). To each liter of this solution add 1.5 mL of [triethylamine](#). Adjust with [phosphoric acid](#) to a pH of 2.5.

Mobile phase: [Acetonitrile](#) and *Buffer* (32:68)

Diluent: [Acetonitrile](#) and *Buffer* (25:75)

Standard solution: ▲32 µg/mL of [USP Escitalopram Oxalate RS](#) (equivalent to 25 µg/mL of escitalopram) ▲ (USP 1-May-2021) in *Diluent*

Sample solution: Nominally 25 µg/mL of escitalopram from a suitable volume of Oral Solution, prepared as follows. ▲Transfer a suitable portion of Oral Solution to an appropriate volumetric flask. Add 50% of the flask volume of ▲ (USP 1-May-2021) *Diluent*, and sonicate for 10 min with intermittent shaking. Allow the solution to cool, and dilute with *Diluent* to volume.

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. ▲ (USP 1-May-2021)

Column: 4.6-mm × 25-cm; 5-µm packing [L1](#)

Flow rate: 2 mL/min

Injection volume: 20 µL

Run time: ▲NLT ▲ (USP 1-May-2021) 2.1 times the retention time of escitalopram

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT ▲1.0% ▲ (USP 1-May-2021)

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of escitalopram ($C_{20}H_{21}FN_2O$) 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 escitalopram from the *Sample solution*

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

C_S = concentration of [USP Escitalopram Oxalate RS](#) in the *Standard solution* (µg/mL)

C_U = nominal concentration of escitalopram in the *Sample solution* (µg/mL)

M_{r1} = molecular weight of escitalopram, ▲▲ (USP 1-May-2021) 324.39

M_{r2} = molecular weight of escitalopram oxalate, 414.43

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

- **DELIVERABLE VOLUME (698):** Meets the requirements

IMPURITIES

Change to read:

- **LIMIT OF CITALOPRAM RELATED COMPOUND B**

▲ **Dilute**▲ (USP 1-May-2021) **phosphoric acid:** ▲ Transfer 5 mL of [phosphoric acid](#) to a 50-mL volumetric flask containing about 25 mL of [water](#). Cool and dilute with [water](#) to volume.▲ (USP 1-May-2021)

Solution A: 6.8 g/L of [monobasic potassium phosphate](#). ▲ Adjust▲ (USP 1-May-2021) with ▲ **Dilute**▲ (USP 1-May-2021) *phosphoric acid* to a pH of 3.0.

Solution B: [Acetonitrile](#)

Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	90	10
13	60	40
15	60	40
16	90	10
20	90	10

Diluent: [Acetonitrile](#) and *Solution A* (30:70)

Standard solution: 0.6 µg/mL of [USP Escitalopram Oxalate RS](#)▲ (equivalent to 0.5 µg/mL of escitalopram)▲ (USP 1-May-2021) in *Diluent*

System suitability solution: 0.6 µg/mL of [USP Citalopram Related Compound B RS](#) in *Standard solution*

Sample solution: Nominally ▲250 µg/mL▲ (USP 1-May-2021) of escitalopram from a suitable volume of Oral Solution in *Diluent*

Chromatographic system

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

Mode: LC

Detector: UV 237 nm

Column: 2.1-mm × 7.5-cm; 3-µm packing [L1](#)

Column temperature: 45°

Flow rate: 0.5 mL/min

Injection volume: 20 µL

System suitability

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

[NOTE—The relative retention times for citalopram related compound B and escitalopram are about 0.81 and 1.0, respectively. Use the *System suitability solution* to identify ▲citalopram related compound B.▲ (USP 1-May-2021)]

Suitability requirements

Resolution: NLT 2.0 between citalopram related compound B and escitalopram, *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 citalopram related compound B 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 related compound B from the *Sample solution*

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