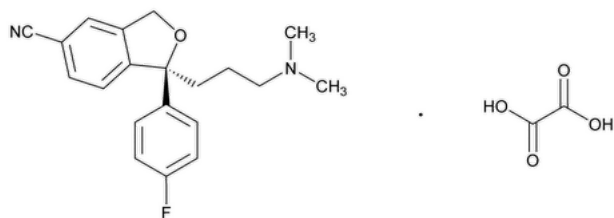


Status: Currently Official on 17-Feb-2025
Official Date: Official as of 01-May-2020
Document Type: USP Monographs
DocId: GUID-8CBF3705-BDD1-41E1-910E-72670691C252_4_en-US
DOI: https://doi.org/10.31003/USPNF_M1412_04_01
DOI Ref: pi1g4

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Escitalopram Oxalate



$C_{20}H_{21}FN_2O \cdot C_2H_2O_4$ 414.43
S-(+)-5-Isobenzofurancarbonitrile, 1-[3-(dimethylamino)propyl]-1-(4-fluorophenyl)-1,3-dihydro-, oxalate;
S-(+)-1-[3-(Dimethylamino)propyl]-1-(p-fluorophenyl)-5-phthalancarbonitrile oxalate CAS RN®: 219861-08-2; UNII: 5U85DBW7LO.

DEFINITION

Escitalopram Oxalate contains NLT 98.0% and NMT 102.0% of escitalopram oxalate ($C_{20}H_{21}FN_2O \cdot C_2H_2O_4$), calculated on the anhydrous basis.

IDENTIFICATION

Change to read:

- **A.** ▲ [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy: 197K](#) ▲ (CN 1-MAY-2020)
- **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

• **PROCEDURE**

Buffer: 3.4 g/L of monobasic potassium phosphate in water. Adjust with phosphoric acid or sodium hydroxide solution to a pH of 3.0 before final dilution.

Solution A: Acetonitrile and *Buffer* (10:90)

Solution B: Acetonitrile and *Buffer* (65:35)

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

Table 1

Time (min)	Solution A (%)	Solution B (%)	Flow Rate (mL/min)
0	95	5	1
35	65	35	1
45	0	100	1
45.1	0	100	2
60	0	100	2
60.1	95	5	1
68	95	5	1

[NOTE—The gradient was established on an HPLC system with a dwell volume of approximately 1.6 mL.]

System suitability solution: 2 µg/mL each of [USP Escitalopram Oxalate RS](#) and [USP Citalopram Related Compound D RS](#) in *Solution A*

Standard solution: 0.5 mg/mL of [USP Escitalopram Oxalate RS](#) in *Solution A*

Sample solution: 0.5 mg/mL of Escitalopram Oxalate in *Solution A*

Chromatographic system

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

Mode: LC**Detector:** UV 237 nm**Column:** 4.6-mm × 25-cm; 5-μm packing L1**Column temperature:** 45°**Flow rate:** See [Table 1](#).**Injection volume:** 20 μL**System suitability****Samples:** *System suitability solution* and *Standard solution***Suitability requirements****Resolution:** NLT 1.5 between escitalopram and citalopram related compound D, *System suitability solution***Tailing factor:** 0.8–3, *Standard solution***Relative standard deviation:** NMT 2.0%, *Standard solution***Analysis****Samples:** *Standard solution* and *Sample solution*Calculate the percentage of escitalopram oxalate ($C_{20}H_{21}FN_2O \cdot C_2H_2O_4$) in the portion of Escitalopram Oxalate taken:

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

 r_U = peak response from the *Sample solution* r_S = peak response from the *Standard solution* C_S = concentration of the *Standard solution* (mg/mL) C_U = concentration of the *Sample solution* (mg/mL)**Acceptance criteria:** 98.0%–102.0% on the anhydrous basis**IMPURITIES**• **RESIDUE ON IGNITION (281):** NMT 0.1%• **ENANTIOMERIC PURITY****Buffer:** Dissolve 6.8 g of monobasic potassium phosphate in 250 mL of water, add 150 mL of 0.2 N sodium hydroxide, adjust with phosphoric acid or sodium hydroxide solution to a pH of 7.0, and dilute with water to 1 L.**Mobile phase:** Acetonitrile and *Buffer* (15:85)**System suitability solution:** 125 μg/mL each of [USP R-Citalopram Oxalate RS](#) and [USP Escitalopram Oxalate RS](#) in *Mobile phase***Sample solution:** 125 μg/mL of Escitalopram Oxalate in *Mobile phase***Chromatographic system**(See [Chromatography \(621\), System Suitability](#).)**Mode:** LC**Detector:** UV 240 nm**Column:** 4.6-mm × 15-cm; 5-μm packing L57**Column temperature:** 30°**Flow rate:** 0.6 mL/min**Injection volume:** 15 μL**System suitability****Sample:** *System suitability solution***Suitability requirements****Resolution:** NLT 1.3 between *R*-citalopram and escitalopram**Tailing factor:** 0.8–2.5 for escitalopram**Analysis****Sample:** *Sample solution*Calculate the percentage of *R*-citalopram oxalate in the portion of Escitalopram Oxalate taken:

$$\text{Result} = (r_U/r_T) \times 100$$

 r_U = peak response of *R*-citalopram from the *Sample solution* r_T = sum of peak responses of *R*-citalopram and escitalopram from the *Sample solution***Acceptance criteria:** NMT 3.0%• **ORGANIC IMPURITIES****Buffer, Solution A, Solution B, Mobile phase, Sample solution, and Chromatographic system:** Proceed as directed in the Assay.**System suitability solution A:** 2 μg/mL each of [USP Escitalopram Oxalate RS](#) and [USP Citalopram Related Compound D RS](#) in *Solution A***System suitability solution B:** 0.5 mg/mL of [USP Escitalopram Oxalate RS](#) in *Solution A*