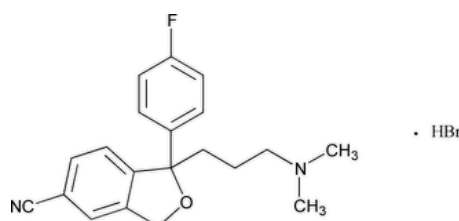


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Citalopram Hydrobromide



$C_{20}H_{21}FN_2O \cdot HBr$ 405.30

5-Isobenzofurancarbonitrile, 1-[3-(dimethylamino)propyl]-1-(4-fluorophenyl)-1,3-dihydro-, monohydrobromide;

1-[3-(Dimethylamino)propyl]-1-(*p*-fluorophenyl)-5-phthalan carbonitrile monohydrobromide CAS RN[®]: 59729-32-7; UNII: I1E9D14F36.

DEFINITION

Citalopram Hydrobromide contains NLT 98.0% and NMT 102.0% of citalopram hydrobromide ($C_{20}H_{21}FN_2O \cdot HBr$), 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.
- **C.** [IDENTIFICATION TESTS—GENERAL 191, Bromide](#)
Sample solution: 10 mg/mL of Citalopram Hydrobromide in water
Acceptance criteria: Meets the requirements of test B

ASSAY

PROCEDURE

Buffer: Dissolve 1 g of sodium acetate in 800 mL of water, and add 6 mL of triethylamine. Adjust with acetic acid to a pH of 4.6, and dilute with water to 1 L.

Mobile phase: Acetonitrile and *Buffer* (20:80). The apparent pH is 5.0 ± 0.1 . Make adjustments, if necessary.

Diluent: Methanol and water (50:50)

System suitability solution: 1 µg/mL each of [USP Citalopram Hydrobromide RS](#) and [USP Citalopram Related Compound D RS](#) in *Diluent*

Standard solution: 0.625 mg/mL of [USP Citalopram Hydrobromide RS](#) in *Diluent*

Sample solution: 0.625 mg/mL of Citalopram Hydrobromide in *Diluent*

Chromatographic system

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

Mode: LC

Detector: UV 239 nm

Column: 4.6-mm × 15-cm; 5-µm packing L7

Column temperature: 50°

Flow rate: 1 mL/min

Injection volume: 20 µL

Run time: NLT 1.3 times the retention time of citalopram

System suitability

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

Suitability requirements

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

Column efficiency: NLT 3000 theoretical plates, *Standard solution*



Tailing factor: NMT 3.0, *Standard solution*

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

Analysis

Samples: *Diluent*, *Standard solution*, and *Sample solution*

Verify that there are no interfering peaks, using the *Diluent*.

Calculate the percentage of citalopram hydrobromide ($C_{20}H_{21}FN_2O \cdot HBr$) in the portion of Citalopram Hydrobromide 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 [USP Citalopram Hydrobromide RS](#) in the *Standard solution* (mg/mL)

C_U = concentration of Citalopram Hydrobromide in the *Sample solution* (mg/mL)

Acceptance criteria: 98.0%–102.0% on the anhydrous basis

IMPURITIES

• [RESIDUE ON IGNITION \(281\)](#)

Analysis: Moisten the sample with 2 mL of nitric acid and 5 drops of sulfuric acid.

Acceptance criteria: NMT 0.1%

• ORGANIC IMPURITIES, PROCEDURE 1

[NOTE—On the basis of the synthetic route used, perform either *Procedure 1* or *Procedure 2*. However, if the chloro and bromo analogs are potential related compounds in the synthetic route used, *Procedure 2* is recommended.]

Buffer, Mobile phase, Diluent, System suitability solution, and Sample solution: Proceed as directed in the Assay.

Standard solution: 0.625 µg/mL of [USP Citalopram Hydrobromide RS](#) in *Diluent*

Sensitivity solution: 0.0625 µg/mL of [USP Citalopram Hydrobromide RS](#) in *Diluent*

Chromatographic system: Proceed as directed in the Assay, except use a *Run time* of 1.7 times the retention time of citalopram.

System suitability

Samples: *System suitability solution* and *Sensitivity solution*

[NOTE—See [Table 1](#) for the relative retention times.]

Suitability requirements

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

Tailing factor: 0.8–1.5 for citalopram, *System suitability solution*

Relative standard deviation: NMT 5% for citalopram, *System suitability solution*

Signal-to-noise ratio: NLT 3, *Sensitivity solution*

Analysis

Samples: *Diluent*, *Standard solution*, and *Sample solution*

Verify that there are no interfering peaks, using the *Diluent*.

Calculate the percentage of each impurity in the portion of Citalopram Hydrobromide taken:

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

r_U = peak response of each impurity 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 = concentration of Citalopram Hydrobromide in the *Sample solution* (mg/mL)

M_{r1} = molecular weight of citalopram, 324.39

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

F = relative response factor (see [Table 1](#))