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 size: 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:

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

r_U = peak response of *R*-citalopram from the *Sample solution*
r_S = peak response of escitalopram from the *Sample solution*
Acceptance criteria: NMT 3.0%

ADDITIONAL REQUIREMENTS
- **PACKAGING AND STORAGE:** Preserve in well-closed containers.
- **USP REFERENCE STANDARDS** ⟨**11**⟩
USP *R*-Citalopram Oxalate RS
[(*R*)-1-[3-(dimethylamino)propyl]-1-(*p*-fluorophenyl)-5-phthalancarbonitrile oxalate]
$C_{20}H_{21}FN_2O \cdot C_2H_2O_4$ 414.43
USP Citalopram Related Compound D RS
[1-(4-fluorophenyl)-1-(3-methylaminopropyl)-1,3-dihydroisobenzofuran-5-carbonitrile hydrochloride]
$C_{19}H_{19}FN_2O \cdot HCl$ 346.83
USP Escitalopram Oxalate RS

Escitalopram Tablets

DEFINITION
Escitalopram Tablets contain an amount of escitalopram oxalate equivalent to NLT 90.0% and NMT 110.0% of the labeled amount of $C_{20}H_{21}FN_2O$.

IDENTIFICATION
- 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 M sodium hydroxide to a pH of 5.2.
Mobile phase: 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 size: 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 percentage of the labeled amount of $C_{20}H_{21}FN_2O$ in the portion of Tablets taken:

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

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 = nominal concentration of the *Sample solution* (mg/mL)
M_{r1} = molecular weight of citalopram, 324.39
M_{r2} = molecular weight of citalopram hydrobromide, 405.30
Acceptance criteria: 90.0–110.0%

PERFORMANCE TESTS
- **DISSOLUTION** ⟨**711**⟩
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 through a suitable filter of 0.45-µm pore size.
Spectrometric 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*
Generate a calibration curve using the data from *Standard solution 1*, *Standard solution 2*, and *Standard solution 3*. Determine the concentration, C_U, in mg/mL, of citalopram hydrobromide in the *Sample solution* using the calibration curve.
Calculate the percentage of citalopram dissolved:

$$\text{Result} = (C_U/L) \times (M_{r1}/M_{r2}) \times V \times 100$$

C_U = concentration of citalopram hydrobromide in the *Sample solution* (mg/mL)
L = label claim (mg/Tablet)
M_{r1} = molecular weight of citalopram, 324.39

M_{r2} = molecular weight of citalopram hydrobromide, 405.30
V = volume of *Medium*, 900 mL

Tolerances: NLT 80% (Q) of the labeled amount of escitalopram is dissolved.

• **UNIFORMITY OF DOSAGE UNITS ⟨905⟩:** Meets the requirements

IMPURITIES

• **Organic Impurities**

Buffer, Mobile phase, System suitability solution, Standard solution, Sample solution, and **Chromatographic system:** Proceed as directed in the *Assay*.

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 percentage of each impurity in the portion of Tablets 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 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*
C_U = nominal concentration of the *Sample solution*
F = relative response factor (see *Impurity Table 1*)
M_{r1} = molecular weight of citalopram, 324.39
M_{r2} = molecular weight of citalopram hydrobromide, 405.30

Acceptance criteria

Individual impurities: See *Impurity Table 1*.

Total impurities: NMT 2.0%

Impurity Table 1

Name	Relative Retention Time	Relative Response Factor	Acceptance Criteria, NMT (%)
Citalopram related compound A[a]	0.33	0.84	0.3
Citalopram related compound B[b]	0.56	0.78	0.5
Citalopram related compound C[c] (3-oxocitalopram)	0.80	0.51	0.5
Escitalopram	1.0	—	—
Citalopram related compound E[d] (citalopram *N*-oxide)	1.4	0.94	0.2
Any other individual, unspecified impurity	—	1.0	0.1

[a] 1-(3-Dimethylaminopropyl)-1-(4-fluorophenyl)-1,3-dihydroisobenzofuran-5-carboxamide.
[b] 1-(3-Dimethylaminopropyl)-1-(4-fluorophenyl)-3-hydroxy-1,3-dihydroisobenzofuran-5-carbonitrile; 3-hydroxycitalopram.
[c] 3-(3-Dimethylaminopropyl)-3-(4-fluorophenyl)-6-cyano-1(3*H*)-isobenzofuranone.
[d] 1-(3-Dimethylaminopropyl)-1-(4-fluorophenyl)-1,3-dihydroisobenzofuran-5-carbonitrile-*N*-oxide.

ADDITIONAL REQUIREMENTS

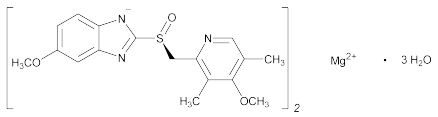
• **PACKAGING AND STORAGE:** Preserve in well-closed containers. Store at controlled room temperature.

• **USP REFERENCE STANDARDS ⟨11⟩**

USP Citalopram Hydrobromide RS

USP Citalopram Related Compound C RS
3-(3-Dimethylaminopropyl)-3-(4-fluorophenyl)-6-cyano-1(3*H*)-isobenzofuranone.
$C_{20}H_{19}FN_2O_2$ 338.22

Esomeprazole Magnesium



$C_{34}H_{36}MgN_6O_6S_2 \cdot 3H_2O$ Trihydrate: 767.17

$C_{34}H_{36}MgN_6O_6S_2$ Anhydrous: 713.12

1*H*-Benzimidazole,5-methoxy-2-[(*S*)-[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl], magnesium salt (2:1), trihydrate; 5-Methoxy-2-[(*S*)-[(4-methoxy-3,5-dimethyl-2-pyridyl) methyl]sulfinyl]benzimidazole, magnesium salt (2:1), trihydrate [217087-09-7].

DEFINITION

Esomeprazole Magnesium contains NLT 98.0% and NMT 102.0% of $C_{34}H_{36}MgN_6O_6S_2$, calculated on the anhydrous basis.

IDENTIFICATION

• **A. INFRARED ABSORPTION ⟨197K⟩**

• **B.** The *Sample solution*, prepared and tested as directed in the test for *Content of Magnesium*, exhibits a significant absorption at 285.2 nm.

ASSAY

• **PROCEDURE**

Solution A: Dissolve 0.725 g of monobasic sodium phosphate and 4.472 g of anhydrous dibasic sodium phosphate in 300 mL of water, and dilute with water to 1000 mL. Dilute 250 mL of this solution with water to 1000 mL. If necessary, adjust with phosphoric acid to a pH of 7.6.

Solution B: Mix 11 mL of 0.25 M tribasic sodium phosphate with 22 mL of 0.5 M dibasic sodium phosphate, and dilute with water to 100 mL.

Mobile phase: Acetonitrile and *Solution A* (7:13)

Standard solution: Transfer 10 mg of USP Omeprazole RS to a 200-mL volumetric flask, and dissolve in about 10 mL of methanol. Add 10 mL of *Solution B*, and dilute with water to volume. [NOTE—This solution contains 0.05 mg/mL of omeprazole.]

Sample solution: Transfer 10 mg of Esomeprazole Magnesium to a 200-mL volumetric flask, and dissolve in about 10 mL of methanol. Add 10 mL of *Solution B*, and dilute with water to volume. [NOTE—This solution contains 0.05 mg/mL of esomeprazole magnesium.]

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 280 nm

Column: 4.0-mm × 12.5-cm or a 4.6-mm × 15-cm; 5-µm packing L7. [NOTE—Alternatively, a 3.9-mm × 15-cm column that contains 4-µm packing L1 may be used.]