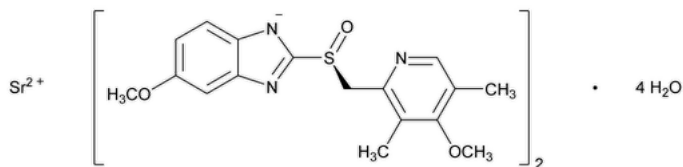


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Esomeprazole Strontium



$C_{34}H_{36}N_6O_6S_2Sr \cdot 4H_2O$ Tetrahydrate: 848.50

$C_{34}H_{36}N_6O_6S_2Sr$ Anhydrous: 776.44

1*H*-Benzimidazole, 5-methoxy-2-[(*S*)-[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl], strontium salt, hydrate (2:1:4);

(-)-5-Methoxy-2-[(*S*)-[(4-methoxy-3,5-dimethylpyridin-2-yl)methyl]sulfinyl]-1*H*-benzimidazole strontium salt tetrahydrate CAS RN®: 934714-36-0.

DEFINITION

Esomeprazole Strontium contains NLT 98.0% and NMT 102.0% of esomeprazole strontium ($C_{34}H_{36}N_6O_6S_2Sr$), calculated on the dried basis.

IDENTIFICATION

Change to read:

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

Sample solution: 1 mg/mL of Esomeprazole Strontium in 20% [acetonitrile](#) (v/v)

Acceptance criteria: The *Sample solution* imparts a red color to the nonluminous flame.

ASSAY

PROCEDURE

Buffer: Dissolve 1.12 g of [dibasic sodium phosphate anhydrous](#) and 0.18 g of [monobasic sodium phosphate anhydrous](#) in 1000 mL of water.

If necessary, adjust with [phosphoric acid](#) to a pH of 7.6.

Solution A: Acetonitrile and *Buffer* (10:30)

Solution B: Acetonitrile and *Buffer* (20:30)

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

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	100	0
15	100	0
25	0	100
50	0	100

Return to the original conditions, and re-equilibrate the system for about 5 min.

System suitability solution: 0.5 mg/mL of [USP Omeprazole RS](#) and 0.5 µg/mL of [USP Omeprazole Related Compound A RS](#) in *Solution A*

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

Sample solution: 0.5 mg/mL of Esomeprazole Strontium in *Solution A*

Chromatographic system

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

Mode: LC

Detector: UV 280 nm

Column: 4.6-mm × 15-cm; 5-μm packing [L7](#)

Column temperature: 30°

Flow rate: 1 mL/min

Injection volume: 5 μL

System suitability

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

Suitability requirements

Resolution: NLT 2.0 between omeprazole related compound A and omeprazole, *System suitability solution*

Tailing factor: NMT 1.5, *Standard solution*

Relative standard deviation: NMT 0.73%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of esomeprazole strontium ($C_{34}H_{36}N_6O_6S_2Sr$) in the portion of Esomeprazole Strontium taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times [M_{r1}/(2 \times M_{r2})] \times 100$$

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

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

C_U = concentration of Esomeprazole Strontium in the *Sample solution* (mg/mL)

M_{r1} = molecular weight of esomeprazole strontium, 776.44

M_{r2} = molecular weight of omeprazole, 345.42

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

OTHER COMPONENTS

• CONTENT OF STRONTIUM

Solution A: 37.2 mg/mL of [edetate sodium](#) in water

Solution B: 24.9 mg/mL of [cupric sulfate](#) in water

Solution C: *Solution A* and *Solution B* (1:1)

Buffer: Transfer 54 g of [ammonium chloride](#) to a 1000-mL volumetric flask, add 350 mL of [ammonium hydroxide](#), and dilute with water to volume.

Sample: 400 mg of Esomeprazole Strontium

Analysis: Transfer the *Sample* to a suitable flask, dissolve in 30 mL of [methanol](#), add 40 mL of *Buffer*, and mix. Add 0.5 mL of [pH 7.0 phosphate buffer](#) and 1 mL of *Solution C*, and mix. Titrate with [0.05 M edetate disodium VS](#) to a potentiometric endpoint (see [Titrimetry \(541\)](#)). Perform a blank determination. Each mL of [0.05 M edetate disodium VS](#) is equivalent to 4.381 mg of strontium.

Acceptance criteria: 10.8%–11.8% on the dried basis

IMPURITIES

• ORGANIC IMPURITIES

Buffer, Solution A, Solution B, Mobile phase, and Chromatographic system: Proceed as directed in the Assay.

System suitability solution: 500 μg/mL of [USP Omeprazole RS](#) and 0.5 μg/mL of [USP Omeprazole Related Compound A RS](#) in *Solution A*

Standard solution: 0.5 μg/mL each of [USP Omeprazole RS](#) and [USP Omeprazole Related Compound A RS](#), and 0.25 μg/mL of [\(S\)-binol](#) in *Solution A*

Sample solution: 500 μg/mL of Esomeprazole Strontium in *Solution A*

System suitability

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

[NOTE—See [Table 2](#) for relative retention times.]

Suitability requirements

Resolution: NLT 2.0 between omeprazole related compound A and omeprazole, *System suitability solution*

Relative standard deviation: NMT 10% for each peak, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentages of omeprazole related compound A and (S)-binol in the portion of Esomeprazole Strontium taken:

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

r_U = peak response of omeprazole related compound A or (S)-binol from the *Sample solution*