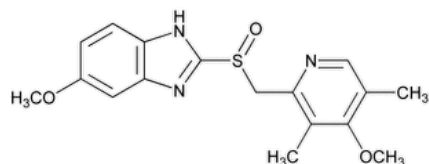


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Omeprazole



$C_{17}H_{19}N_3O_3S$ 345.42

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

5-Methoxy-2-[[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]benzimidazole CAS RN[®]: 73590-58-6; UNII: KG60484QX9.

DEFINITION

Omeprazole contains NLT 98.0% and NMT 102.0% of omeprazole ($C_{17}H_{19}N_3O_3S$), calculated on the dried basis.

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.

Change to read:

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

ASSAY

PROCEDURE

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

Mobile phase: Acetonitrile and *Buffer* (1:3)

Diluent: Acetonitrile and 0.01 M sodium borate (1:3)

Standard solution: 0.2 mg/mL of [USP Omeprazole RS](#) in *Diluent*

System suitability solution: 0.1 mg/mL of [USP Omeprazole RS](#) in *Diluent* from the *Standard solution*

Sample solution: 0.2 mg/mL of Omeprazole in *Diluent*

Chromatographic system

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

Mode: LC

Detector: UV 280 nm

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

Flow rate: 0.8 mL/min

Injection volume: 20 μL

System suitability

Sample: *System suitability solution*

Suitability requirements

Tailing factor: NMT 1.5

Relative standard deviation: NMT 1.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of omeprazole ($C_{17}H_{19}N_3O_3S$) in the portion of Omeprazole 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 Omeprazole RS](#) in the *Standard solution* (mg/mL)

C_u = concentration of Omeprazole in the *Sample solution* (mg/mL)

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

IMPURITIES

• **RESIDUE ON IGNITION (281):** NMT 0.1%

• ORGANIC IMPURITIES

Solution A: Dissolve 0.725 g of monobasic sodium phosphate and 4.472 g of anhydrous dibasic sodium phosphate in 1000 mL of water. Dilute 250 mL of this solution with water to 1000 mL. Adjust with phosphoric acid to a pH of 7.0.

Solution B: Acetonitrile

Mobile phase: See [Table 1](#). Return to the original conditions, and re-equilibrate the system for about 10 min.

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	75	25
12	75	25
22	50	50
45	50	50
45.1	75	25

Diluent: *Solution A* and *Solution B* (3:1)

System suitability solution: 0.6 mg/mL of [USP Omeprazole RS](#), 0.6 µg/mL each of [USP Omeprazole Related Compound A RS](#), [USP Omeprazole Related Compound E RS](#), [USP Omeprazole Related Compound I RS](#), and 5-methoxy-1*H*-benzimidazol-2-thiol in *Diluent*. [NOTE—This solution is stable for 14 h when stored at 4°.]

Standard solution: 6.0 µg/mL of [USP Omeprazole RS](#) in *Diluent*. [NOTE—This solution is stable for 14 h when stored at 4°.]

Sample solution: 0.6 mg/mL of Omeprazole in *Diluent*. [NOTE—Inject within 1 h of preparation.]

Sensitivity solution: 0.3 µg/mL of [USP Omeprazole RS](#) from the *Standard solution*

Chromatographic system

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

Mode: LC

Detector: UV 264 nm

Column: 4.6-mm × 25-cm; 5-µm packing L7

Flow rate: 0.8 mL/min

Injection volume: 40 µL

Autosampler temperature: 4°

System suitability

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

Suitability requirements

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

Relative standard deviation: NMT 5%, *Standard solution*

Signal-to-noise ratio: NLT 10, *Sensitivity solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of any individual impurity in the portion of Omeprazole taken:

$$\text{Result} = (r_u/r_s) \times (C_s/C_u) \times (1/F) \times 100$$