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Omeprazole Delayed-Release Capsules

DEFINITION
Omeprazole Delayed-Release Capsules contain NLT 90.0% and NMT 110.0% of the labeled amount of omeprazole ($C_{17}H_{19}N_3O_3S$).

IDENTIFICATION
• **A.** The retention time of the major peak in the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY
• **PROCEDURE**
Solution A: Dissolve 6.0 g of glycine in 1500 mL of water, adjust with 50% sodium hydroxide solution to a pH of 9.0, and dilute with water to 2000 mL.
Solution B: Acetonitrile and methanol (85:15)
Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	88	12
20	40	60
21	88	12
25	88	12

Diluent: Dissolve 7.6 g of sodium borate decahydrate in about 800 mL of water. Add 1.0 g of edetate disodium, and adjust with 50% sodium hydroxide solution to a pH of 11.0 ± 0.1 . Transfer the solution to a 2000-mL volumetric flask, add 400 mL of dehydrated alcohol, and dilute with water to volume.

Standard solution: 0.2 mg/mL of [USP Omeprazole RS](#) in *Diluent*, using sonication as necessary

Sample solution: Weigh and mix the contents of NLT 20 Capsules. Transfer an accurately weighed portion of the Capsule content, equivalent to 20 mg of omeprazole, to a 100-mL volumetric flask, add about 50 mL of *Diluent*, and sonicate for 15 min. Cool, dilute with *Diluent* to volume, mix, and pass through a membrane filter of 0.45- μ m or finer pore size. [NOTE—Bubbles may form just before bringing the solution to volume. Add a few drops of dehydrated alcohol to dissipate the bubbles if they persist for more than a few minutes.]

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

Mode: LC
Detector: UV 305 nm
Column: 4.6-mm $\times$ 15-cm; 5- μ m base-deactivated packing L7
Flow rate: 1.2 mL/min
Injection size: 10 μ L

System suitability
Sample: *Standard solution*
Suitability requirements
Column efficiency: NLT 20,000 theoretical plates
Tailing factor: 0.8–2

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of omeprazole ($C_{17}H_{19}N_3O_3S$) in the portion of Capsules 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 = nominal concentration of omeprazole in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• [DISSOLUTION \(711\)](#)

Test 1

Acid resistance stage

Medium: 0.1 N hydrochloric acid; 500 mL

Apparatus 2: 100 rpm

Time: 2 h

Buffer C, Mobile phase, Chromatographic system, and System suitability: Proceed as directed for *Buffer stage*.

Standard solution: Transfer 50 mg of [USP Omeprazole RS](#) to a 250-mL volumetric flask, dissolve in 50 mL of alcohol, and dilute with 0.01 M sodium borate solution to volume. Transfer 10.0 mL of this solution into a 100-mL volumetric flask, add 20 mL of alcohol, dilute with 0.01 M sodium borate solution to volume, and mix.

Sample solution: After 2 h, filter the *Medium* containing the pellets through a sieve with an aperture of NMT 0.2 mm. Collect the pellets on the sieve, and rinse them with water. Using approximately 60 mL of 0.01 M sodium borate solution, carefully transfer the pellets quantitatively to a 100-mL volumetric flask. Sonicate for about 20 min until the pellets are broken up. Add 20 mL of alcohol to the flask, dilute with 0.01 M sodium borate solution to volume, and mix. Dilute an appropriate amount of this solution with 0.01 M sodium borate solution to obtain a solution containing 0.02 mg/mL. At level L_1 , test 6 units. Test 6 additional units at level L_2 , and at level L_3 , test an additional 12 units. Continue testing through the three levels unless the results conform at either L_1 or L_2 .

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the quantity of the labeled amount of omeprazole ($C_{17}H_{19}N_3O_3S$) dissolved in *Medium*, in mg:

$$\text{Result} = T - C_S \times D \times (r_U/r_S)$$

T = labeled quantity of omeprazole in the capsule (mg)

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

D = dilution factor used in preparing the *Sample solution*

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

Tolerances

Level L_1 : No individual value exceeds 15% of the omeprazole dissolved.

Level L_2 : The average of 12 units is NMT 20% of omeprazole dissolved, and no individual unit is greater than 35% of omeprazole dissolved.

Level L_3 : The average of 24 units is NMT 20% of omeprazole dissolved, NMT 2 units are greater than 35% of omeprazole dissolved, and no individual unit is greater than 45% of omeprazole dissolved.

Buffer stage

Medium: pH 6.8 phosphate buffer, 900 mL