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Pantoprazole Sodium Delayed-Release Tablets

DEFINITION

Pantoprazole Sodium Delayed-Release Tablets contain an amount of Pantoprazole Sodium equivalent to NLT 90.0% and NMT 110.0% of the labeled amount of pantoprazole ($C_{16}H_{15}F_2N_3O_4S$).

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.
- **B.** The UV spectrum of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

• PROCEDURE

Dilute ammonium hydroxide: [Ammonium hydroxide](#) and [water](#) (50:50)

Buffer: 3.85 g/L of [ammonium acetate](#) and 1.1 g/L of [tetrabutylammonium hydrogen sulfate](#) in [water](#). Adjust with *Dilute ammonium hydroxide* to a pH of 7.9.

Mobile phase: [Acetonitrile](#) and *Buffer* (35:65)

Diluent: [Acetonitrile](#) and 0.02 N [sodium hydroxide](#) (50:50)

System suitability solution: 0.2 mg/mL of [USP Pantoprazole Sodium RS](#) and 0.0004 mg/mL each of [USP Pantoprazole Related Compound A RS](#) and [USP Pantoprazole Related Compound B RS](#) in 0.02 N [sodium hydroxide](#). Sonicate to dissolve, if necessary.

Standard solution: 0.2 mg/mL of [USP Pantoprazole Sodium RS](#) prepared as follows. Transfer a suitable amount of [USP Pantoprazole Sodium RS](#) to a suitable volumetric flask, add 0.02 N [sodium hydroxide](#) to about 60% of the final volume and sonicate for about 5 min to dissolve. To this solution add about 2% of the final volume of [acetonitrile](#), and dilute with 0.02 N [sodium hydroxide](#) to volume.

Sample solution: Nominally 0.2 mg/mL of pantoprazole from Tablets prepared as follows. Transfer 5 Tablets to a suitable volumetric flask. [NOTE—Use 50- or 100-mL volumetric flasks for Tablets containing 20 or 40 mg of pantoprazole per Tablet, respectively.] Add *Diluent* to about 60% of the final volume, shake mechanically for about 60 min, and dilute with *Diluent* to volume. Pass through a suitable filter, and dilute the filtrate with 0.02 N [sodium hydroxide](#) to obtain a solution having a known concentration of about 0.2 mg/mL, based on the label claim.

Chromatographic system

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

Mode: LC

Detector: UV 290 nm. For *Identification B*, use a diode array detector in the range of 200–400 nm.

Column: 4.6-mm × 25-cm; 5-μm packing [L1](#)

Flow rate: 1 mL/min

Injection volume: 20 μL

Run time: NLT 3 times the retention time of pantoprazole

System suitability

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

Suitability requirements

Resolution: NLT 3 between pantoprazole and pantoprazole related compound A, *System suitability solution*

Tailing factor: NMT 2.0 for pantoprazole, *System suitability solution*

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

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of pantoprazole ($C_{16}H_{15}F_2N_3O_4S$) 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 of pantoprazole from the *Sample solution*

r_S = peak response of pantoprazole from the *Standard solution*

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

C_U = nominal concentration of pantoprazole in the *Sample solution* (mg/mL)

M_{r1} = molecular weight of pantoprazole, 383.37

M_{r2} = molecular weight of pantoprazole sodium, 405.35

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

Change to read:

• [DISSOLUTION \(711\)](#)

Test 1: Proceed as directed for [Dissolution \(711\)](#), [Procedure, Apparatus 1 and Apparatus 2, Delayed-Release Dosage Forms, Method B Procedure](#).

Acid stage

Acid stage medium: 0.1 N [hydrochloric acid](#); 1000 mL

Apparatus 2: 75 rpm

Time: 120 min

Mobile phase: [Acetonitrile](#), [triethylamine](#), and [water](#) (40:1:60). Adjust with [phosphoric acid](#) to a pH of 7.0 ± 0.05 .

Diluent: pH 6.8 phosphate buffer and 0.5 N [sodium hydroxide](#) (50:50)

Standard stock solution: 0.4 mg/mL of [USP Pantoprazole Sodium RS](#) prepared as follows. Transfer about 20 mg of [USP Pantoprazole Sodium RS](#) to a 50-mL volumetric flask. Add about 30 mL of 0.02 N [sodium hydroxide](#), and sonicate until dissolved. Add 2 mL of [acetonitrile](#), and dilute with 0.02 N [sodium hydroxide](#) to volume.

Standard solution: 0.02 mg/mL of [USP Pantoprazole Sodium RS](#) from the *Standard stock solution* in *Diluent*

Sample solution: After 120 min pass a portion of the solution under test through a suitable filter of 0.45- μ m pore size, and immediately dilute a portion of the filtrate by a factor of 2 with 0.5 N [sodium hydroxide](#). Transfer the Tablets to the vessels containing the *Buffer stage medium*.

Chromatographic system

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

Mode: LC

Detector: UV 290 nm

Column: 4.6-mm $\times$ 7.5-cm; 3- μ m packing [L1](#)

Column temperature: 30°

Flow rate: 1 mL/min

Injection volume: 10 μ L

Run time: NLT 3 times the retention time of pantoprazole

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.5

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of pantoprazole ($C_{16}H_{15}F_2N_3O_4S$) dissolved in the *Acid stage*:

$$\text{Result} = (r_U/r_S) \times C_S \times V \times D \times (M_{r1}/M_{r2}) \times (1/L) \times 100$$

r_U = peak response of pantoprazole from the *Sample solution*

r_S = peak response of pantoprazole from the *Standard solution*

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

V = volume of *Acid stage medium*, 1000 mL



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D = dilution factor for the *Sample solution*, 2

M_{r1} = molecular weight of pantoprazole, 383.37

M_{r2} = molecular weight of pantoprazole sodium, 405.35

L = label claim (mg/Tablet)

Tolerances: NMT 10% of the labeled amount of pantoprazole ($C_{16}H_{15}F_2N_3O_4S$) is dissolved.

Buffer stage

Buffer stage medium: [pH 6.8 phosphate buffer](#); 1000 mL

Apparatus 2: 75 rpm

Time: 30 min

Standard solution: Prepared as directed in the *Acid stage*.

Sample solution: After 30 min, pass a portion of the sample solution under test through a suitable filter of 0.45- μ m pore size and immediately dilute a portion of the filtrate by a factor of 2 with 0.5 N [sodium hydroxide](#).

Chromatographic system: Proceed as directed in the *Acid stage*.

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of pantoprazole ($C_{16}H_{15}F_2N_3O_4S$) dissolved:

$$\text{Result} = (r_U/r_S) \times C_S \times V \times D \times (M_{r1}/M_{r2}) \times (1/L) \times 100$$

r_U = peak response of pantoprazole from the *Sample solution*

r_S = peak response of pantoprazole from the *Standard solution*

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

V = volume of *Buffer stage medium*, 1000 mL

D = dilution factor for the *Sample solution*, 2

M_{r1} = molecular weight of pantoprazole, 383.37

M_{r2} = molecular weight of pantoprazole sodium, 405.35

L = label claim (mg/Tablet)

Tolerances: NLT 75% (Q) of the labeled amount of pantoprazole ($C_{16}H_{15}F_2N_3O_4S$) is dissolved.

Test 2: If the product complies with this test, the labeling indicates that the product meets USP *Dissolution Test 2*. Proceed as directed for [Dissolution \(711\)](#), [Procedure, Apparatus 1 and Apparatus 2, Delayed-Release Dosage Forms, Method B Procedure](#).

Acid stage

Acid stage medium: 0.1 N [hydrochloric acid](#); 1000 mL

Apparatus 2: 100 rpm

Time: 2 h

Standard stock solution: 0.46 mg/mL of [USP Pantoprazole Sodium RS](#) prepared as follows. Transfer a quantity of [USP Pantoprazole Sodium RS](#) to a suitable volumetric flask. Dissolve first in 0.1 N [sodium hydroxide](#), using 10% of the final volume, then dilute with [pH 6.8 phosphate buffer](#) to volume. Mix well until a clear solution is obtained.

Acid stage standard solution: $\Delta(L/10000)\Delta$ (ERR 1-Dec-2023) mg/mL of [USP Pantoprazole Sodium RS](#) from the *Standard stock solution* in *Acid stage medium*, where L is the label claim in mg/Tablet

Sample solution: Pass a portion of the solution under test through a suitable filter of 10- μ m pore size.

Instrumental conditions

(See [Ultraviolet-Visible Spectroscopy \(857\)](#).)

Mode: UV

Analytical wavelength: UV 305 nm

Path length: 4 cm

Blank: *Acid stage medium*

Analysis

Samples: *Acid stage standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of pantoprazole ($C_{16}H_{15}F_2N_3O_4S$) dissolved in the *Acid stage*:

$$\text{Result} = (A_U/A_S) \times C_S \times V \times (M_{r1}/M_{r2}) \times (1/L) \times 100$$

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Acid stage standard solution*

C_S = concentration of [USP Pantoprazole Sodium RS](#) in the *Acid stage standard solution* (mg/mL)

V = volume of *Acid stage medium*, 1000 mL

M_{r1} = molecular weight of pantoprazole, 383.37

M_{r2} = molecular weight of pantoprazole sodium, 405.35

L = label claim (mg/Tablet)

Tolerances: NMT 10% of the labeled amount of pantoprazole ($C_{16}H_{15}F_2N_3O_4S$) is dissolved.

Buffer stage

Buffer stage medium: [pH 6.8 phosphate buffer](#); 1000 mL

Apparatus 2: 100 rpm

Time: 45 min

Standard stock solution: Prepare as directed in the *Acid stage*.

Buffer stage standard solution: $(L/1000) \Delta$ mg/mL Δ (ERR 1-Dec-2023) of [USP Pantoprazole Sodium RS](#) Δ from the *Standard stock solution* in *Buffer stage medium*, Δ (ERR 1-Dec-2023) where L is the label claim in mg/Tablet

Sample solution: After 2 h in *Acid stage medium*, continue with *Buffer stage medium* as follows. Completely drain the vessel of *Acid stage medium* carefully and add *Buffer stage medium*. After 45 min, pass a portion of the solution under test through a suitable filter of 10- μ m pore size.

Instrumental conditions

(See [Ultraviolet-Visible Spectroscopy \(857\)](#).)

Mode: UV

Analytical wavelength: UV 288 nm

Path length: 0.5 cm

Blank: *Buffer stage medium*

Analysis

Samples: *Buffer stage standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of pantoprazole ($C_{16}H_{15}F_2N_3O_4S$) dissolved:

$$\text{Result} = (A_U/A_S) \times C_S \times V \times (M_{r1}/M_{r2}) \times (1/L) \times 100$$

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Buffer stage standard solution*

C_S = concentration of [USP Pantoprazole Sodium RS](#) in the *Buffer stage standard solution* (mg/mL)

V = volume of the *Buffer stage medium*, 1000 mL

M_{r1} = molecular weight of pantoprazole, 383.37

M_{r2} = molecular weight of pantoprazole sodium, 405.35

L = label claim (mg/Tablet)

Tolerances: NLT 75% (Q) of the labeled amount of pantoprazole ($C_{16}H_{15}F_2N_3O_4S$) is dissolved.

Test 3: If the product complies with this test, the labeling indicates that the product meets *USP Dissolution Test 3*. Proceed as directed for [Dissolution \(711\)](#), [Procedure, Apparatus 1 and Apparatus 2, Delayed-Release Dosage Forms, Method B Procedure](#).

Acid stage