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Lansoprazole Delayed-Release Capsules

DEFINITION

Lansoprazole Delayed-Release Capsules contain NLT 90.0% and NMT 110.0% of the labeled amount of lansoprazole ($C_{16}H_{14}F_3N_3O_2S$).

IDENTIFICATION

• A. [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Ultraviolet-Visible Spectroscopy: 197U](#)

[NOTE—The UV spectra of the major peaks of the *Sample solution* and the *Standard solution* as obtained in the Assay may also be used to meet the *Acceptance criteria*.]

Standard solution: 10 µg/mL of [USP Lansoprazole RS](#) in [methanol](#)

Sample solution: Nominally equivalent to 10 µg/mL of lansoprazole prepared as follows. Powder a portion of Capsule contents equivalent to 5 mg of lansoprazole. Add 5 mL of [methanol](#), shake well, and centrifuge. To 0.1 mL of the supernatant, add 10 mL of [methanol](#).

Acceptance criteria: The UV absorption spectra exhibit a maximum between 281 and 286 nm.

• B. 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

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

Diluent: Acetonitrile, [water](#), and [triethylamine](#) (40:60:1). Adjust with [phosphoric acid](#) to a pH of 10.0.

System suitability solution: 0.1 mg/mL each of [USP Lansoprazole RS](#) and [USP Lansoprazole Related Compound A RS](#) in *Diluent*

Standard stock solution: 3.0 mg/mL of [USP Lansoprazole RS](#) in a mixture of acetonitrile and 0.1 M [sodium hydroxide](#) (2:3)

Standard solution: 0.09 mg/mL of [USP Lansoprazole RS](#) in *Diluent*, from *Standard stock solution*

Sample stock solution: Transfer the contents of NLT 10 Capsules, equivalent to 300 mg of lansoprazole, to a 100-mL volumetric flask. Add 60.0 mL of 0.1 M [sodium hydroxide](#) and sonicate until completely disintegrated. Add 20.0 mL of acetonitrile and sonicate for about 20 min, dilute with acetonitrile to volume, allow to settle, and use a clear supernatant.

Sample solution: Nominally 0.09 mg/mL of lansoprazole prepared as follows. Transfer 3.0 mL of the *Sample stock solution* to a 100-mL volumetric flask and dilute with *Diluent* to volume. Pass the solution through a PVDF filter having a 0.5-µm pore size or another suitable filter, discarding the first few milliliters of the filtrate.

Chromatographic system

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

Mode: LC

Detector: UV 285 nm

Column: 4.6-mm × 25-cm; 5-µm packing L1. For *Identification A*, use a diode array detector in the range of 200–400 nm.

Flow rate: 1 mL/min

Injection volume: 10 µL

System suitability

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

Suitability requirements

Resolution: NLT 5 between lansoprazole and lansoprazole related compound A, *System suitability solution*

Tailing factor: NMT 1.5, *Standard solution*

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

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of lansoprazole ($C_{16}H_{14}F_3N_3O_2S$) in the portion of Capsules taken:

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

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

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

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

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

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• [DISSOLUTION \(711\), Procedure, Apparatus 1 and Apparatus 2, Delayed-Release Dosage Forms, Method A Procedure](#)

Test 1

Acid stage

Acid stage medium: [0.1 N hydrochloric acid](#); 500 mL

Apparatus 2: 75 rpm

Time: 60 min

Acid stage standard solution: $(L \times 0.08/500)$ mg/mL of [USP Lansoprazole RS](#) in *Acid stage medium*, where L is the label claim, in mg/Capsule

[NOTE—An amount of [methanol](#) NMT 0.5% of the total volume of the *Acid stage standard solution* may be used to dissolve [USP Lansoprazole RS](#) prior to dilution with *Acid stage medium*.]

Instrumental conditions

Mode: UV

Analytical wavelength: Maximum absorbance at about 306 nm

Blank: *Acid stage medium*

Analysis: Withdraw a 25-mL aliquot, leaving the remaining 475 mL in the vessel for use in the *Buffer stage*, and proceed immediately as directed for *Buffer stage sample solution*. Use a filtered portion of the aliquot as an *Acid stage sample solution*.

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

Calculate the percentage of the labeled amount of lansoprazole ($C_{16}H_{14}F_3N_3O_2S$) dissolved during the *Acid stage*:

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

A_U = absorbance of the *Acid stage sample solution*

A_S = absorbance of the *Acid stage standard solution*

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

L = label claim of lansoprazole (mg/Capsule)

V = volume of *Acid stage medium*, 500 mL

Tolerances: NMT 10% of the labeled amount of lansoprazole ($C_{16}H_{14}F_3N_3O_2S$) is dissolved.

Buffer stage

Buffer stage medium: pH 6.8 buffer; 900 mL. Proceed as directed in *Buffer stage sample solution*.

Apparatus 2: 75 rpm

Time: 60 min

Buffer concentrate: Dissolve 65.4 g of [monobasic sodium phosphate](#), 28.2 g of [sodium hydroxide](#), and 12 g of [sodium dodecyl sulfate](#) in 4 L of [water](#).

Blank solution: *Acid stage medium* and *Buffer concentrate* (19:17). Adjust, if necessary, with either [phosphoric acid](#) or [sodium hydroxide](#) solution to a pH of 6.8.

Buffer stage standard solution: $(L \times 0.7/900)$ mg/mL of [USP Lansoprazole RS](#) in the *Blank solution*, where L is the label claim in mg/Capsule

[NOTE—An amount of [methanol](#) NMT 2% of the total volume of the *Buffer stage standard solution* may be used to dissolve [USP Lansoprazole RS](#) prior to dilution with *Blank solution*.]

Buffer stage sample solution: Add 425 mL of *Buffer concentrate* to the remaining 475 mL of solution in each vessel from the *Acid stage*.

Adjust, if necessary, with either [phosphoric acid](#) or [sodium hydroxide](#) solution to a pH of 6.8, and pass through a suitable filter.

Instrumental conditions

Mode: UV-Vis

Analytical wavelength: About 286 and 650 nm

Blank: *Blank solution*

Analysis

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

Determine the percentage of the labeled amount of lansoprazole ($C_{16}H_{14}F_3N_3O_2S$) dissolved using the difference between the absorbances at the wavelengths of about 286 nm and 650 nm.

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

A_U = difference between absorbances of the *Buffer stage sample solution*