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Add the following:

▲Pirfenidone Capsules

DEFINITION

Pirfenidone Capsules contain NLT 95.0% and NMT 105.0% of the labeled amount of pirfenidone ($C_{12}H_{11}NO$).

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 pirfenidone peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

• PROCEDURE

Buffer: Dissolve 1.4 mL of [triethylamine](#) in each liter of [water](#). Adjust with [phosphoric acid](#) to a pH of 3.0.

Mobile phase: [Acetonitrile](#), [methanol](#), and *Buffer* (22:13:65)

Standard solution: 0.1 mg/mL of [USP Pirfenidone RS](#) in *Mobile phase*

Sample stock solution: Nominally 1.1 mg/mL of pirfenidone in *Mobile phase* prepared as follows. Transfer a portion of contents from Capsules (NLT 10), equivalent to 267 mg of pirfenidone, to a 250-mL volumetric flask. Add 150 mL of *Mobile phase*, and shake on a mechanical shaker for 10 min. Sonicate for 10 min and cool to ambient temperature. Dilute with *Mobile phase* to volume.

Sample solution: Nominally 0.11 mg/mL of pirfenidone from the *Sample stock solution* in *Mobile phase*. Pass a portion of the solution through a suitable filter of 0.45- μ m pore size, and discard the initial 2–3 mL of filtrate.

Chromatographic system

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

Mode: LC

Detector: UV 220 nm. For *Identification B*, use a diode array detector in the range of 200–400 nm.

Column: 4.6-mm $\times$ 25-cm; 5- μ m packing [L7](#)

Column temperature: 40°

Flow rate: 1 mL/min

Injection volume: 15 μ L

Run time: NLT 1.5 times the retention time of pirfenidone

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 1.5

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of pirfenidone ($C_{12}H_{11}NO$) in the portion of Capsules taken:

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

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

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

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

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

Acceptance criteria: 95.0%–105.0%

PERFORMANCE TESTS

• [DISSOLUTION \(711\)](#)

Tier 1

Medium: [Water](#); 1000 mL

Apparatus 2: 50 rpm, with a suitable sinker

Time: 30 min

Standard solution: 0.134 mg/mL of [USP Pirfenidone RS](#) in *Medium*

Sample solution: Pass a portion of the solution under test through a suitable filter of 0.45-μm pore size and discard the first 3 mL of filtrate.

Transfer 5.0 mL of the filtrate to a 10-mL volumetric flask and dilute with *Medium* to volume.

Instrumental conditions

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

Mode: UV

Analytical wavelength: 318 nm

Path length: 2.0 mm

Blank: *Medium*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of pirfenidone ($C_{12}H_{11}NO$) dissolved:

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

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

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

V = volume of *Medium*, 1000 mL

D = dilution factor, 2

L = label claim (mg/Capsule)

Tolerances: NLT 85% (Q) of the labeled amount of pirfenidone ($C_{12}H_{11}NO$) is dissolved

Tier 2

Medium: [pH 7.0 phosphate buffer](#) containing 1750 units of [pancreatin](#)/L, 1000 mL, deaerated

Apparatus 2: 50 rpm, with a suitable sinker

Time: 30 min

Standard solution: 0.134 mg/mL of [USP Pirfenidone RS](#) in *Medium*

Sample solution: Pass a portion of the solution under test through a suitable filter of 0.45-μm pore size and discard the first 3 mL of filtrate.

Instrumental conditions

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

Mode: UV

Analytical wavelength: 318 nm

Path length: 1.0 mm

Blank: *Medium*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of pirfenidone ($C_{12}H_{11}NO$) dissolved:

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

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

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