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Add the following:

▲Pirfenidone Tablets

DEFINITION
Pirfenidone Tablets 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. Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*:** 197A or 197K
  Sample: Portion of finely powdered Tablets (NLT 5)
  Acceptance criteria: Meet the requirements

ASSAY

- **Procedure**
  Solution A: 0.1% (v/v) phosphoric acid solution in water prepared as follows. Add 1.0 mL of phosphoric acid to 1 L of water.
  Solution B: Acetonitrile
  Mobile phase: See *Table 1*.

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	95	5
6	45	55
6.1	5	95
9	5	95
9.1	95	5
12	95	5

Diluent: Isopropyl alcohol and water (30:70)
Standard solution: 1.0 mg/mL of USP Pirfenidone RS in *Diluent*
Sample stock solution: Nominally 13 mg/mL of pirfenidone in *Diluent* prepared as follows. Transfer a suitable quantity of Tablets (NLT 5 for 267 mg Tablets or NLT 4 for 801 mg Tablets) to a suitable volumetric flask. Add *Diluent* to 90% of the final volume and stir for at least 30 min to completely disperse. Dilute with *Diluent* to volume. Allow to stand for at least 15 min.
Sample solution: Nominally 1.1 mg/mL of pirfenidone from the *Sample stock solution* in *Diluent*. Pass a portion of the solution through a suitable filter of 0.20-µm pore size and discard the first 3 mL of filtrate.
Chromatographic system
(See *Chromatography ⟨621⟩, System Suitability*.)
Mode: LC
Detector: UV 220 nm
Column: 4.6-mm × 10-cm; 2.7-µm packing L7
Column temperature: 60°

Flow rate: 2.5 mL/min

Injection volume: 1 µL

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 Tablets 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⟩**

Medium: Water; 1000 mL

Apparatus 2: 50 rpm

Time: 30 min

Standard solution: (*L*/1000) mg/mL of USP Pirfenidone RS in *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 1.0-µm pore size.

Instrumental conditions

(See *Ultraviolet-Visible Spectroscopy ⟨857⟩*.)

Mode: UV

Analytical wavelength: 312 nm

Path length: 0.05 cm

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)

V = volume of *Medium*, 1000 mL

L = label claim (mg/Tablet)

Tolerances: NLT 80% (*Q*) of the labeled amount of pirfenidone ($C_{12}H_{11}NO$) is dissolved

• **Uniformity of Dosage Units ⟨905⟩:** Meet the requirements

IMPURITIES

• **Organic Impurities**

Solution A, Solution B, Mobile phase, Diluent, Sample stock solution, Sample solution, and **Chromatographic system:** Proceed as directed in the *Assay*.

Standard solution: 1.5 µg/mL of USP Pirfenidone RS in *Diluent*

Sensitivity solution: 0.5 µg/mL of USP Pirfenidone RS from the *Standard solution* in *Diluent*

System suitability

Samples: *Standard solution* and *Sensitivity solution*

Suitability requirements

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 degradation product in the portion of Tablets taken:

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

r_U = peak response of any degradation product 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: The reporting threshold is 0.05%.

Any unspecified degradation product: NMT 0.10%

Total degradation products: NMT 0.30%

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight containers. Store at controlled room temperature.
- **USP Reference Standards** ⟨11⟩

USP Pirfenidone RS▲ (USP 1-May-2024)

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
PIRFENIDONE TABLETS	Documentary Standards Support	SM52020 Small Molecules 5
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

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