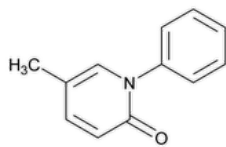


Status: Currently Official on 16-Feb-2025
Official Date: Official as of 01-May-2024
Document Type: USP Monographs
DocId: GUID-28777F80-B668-4200-A5A4-20BBAE557431_2_en-US
DOI: https://doi.org/10.31003/USPNF_M9923_02_01
DOI Ref: hzub6

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Add the following:

▲Pirfenidone



C₁₂H₁₁NO 185.23
2(1*H*)-Pyridinone, 5-methyl-1-phenyl-;
5-Methyl-1-phenyl-2(1*H*)-pyridone CAS RN®: 53179-13-8; UNII: D7NLD2JX7U.

DEFINITION
Pirfenidone contains NLT 98.0% and NMT 102.0% of pirfenidone (C₁₂H₁₁NO), calculated on the dried basis.

- IDENTIFICATION**
- **A.** [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy](#): 197K or 197A
 - **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**

[NOTE—Protect solutions containing pirfenidone from light.]
Solution A: 3.0 g/L of [sodium phosphate monobasic anhydrous](#) in [water](#). Adjust with [0.1 N sodium hydroxide](#) to a pH of 4.8 ± 0.2.
Solution B: [Methanol](#)
Solution C: [Acetonitrile](#)
Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)	Solution C (%)
0	93	5	2
10	72.5	12.5	15
20	40	25	35
35	40	25	35
35.1	93	5	2
50	93	5	2

Standard solution: 1.3 mg/mL of [USP Pirfenidone RS](#) prepared as follows. Transfer a suitable amount of [USP Pirfenidone RS](#) to a suitable volumetric flask, and add 10% of the final volume of [acetonitrile](#) to dissolve. Dilute with *Solution A* to volume.

Sample solution: 1.3 mg/mL of Pirfenidone prepared as follows. Transfer a suitable amount of Pirfenidone to a suitable volumetric flask, and add 10% of the final volume of [acetonitrile](#) to dissolve. Dilute with *Solution A* to volume.

[NOTE—It is recommended not to exceed 1.45 mg/mL of [USP Pirfenidone RS](#) or Pirfenidone for the preparation of the *Standard solution* or the *Sample solution*, respectively.]

Chromatographic system

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

Mode: LC

Detector: UV 220 nm

Column: 4.6-mm × 15-cm; 4-μm packing [L1](#)

Column temperature: 35°

Flow rate: 1.25 mL/min

Injection volume: 5 μL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 0.73%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of pirfenidone ($C_{12}H_{11}NO$) in the portion of Pirfenidone 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 = concentration of Pirfenidone in the *Sample solution* (mg/mL)

Acceptance criteria: 98.0%–102.0% on the dried basis

IMPURITIES

• [RESIDUE ON IGNITION \(281\)](#): NMT 0.2%

• **ORGANIC IMPURITIES**

[NOTE—Protect solutions containing pirfenidone from light.]

Solution A, Solution B, Solution C, Mobile phase, and Chromatographic system: Proceed as directed in the Assay.

Diluent: [Acetonitrile](#) and *Solution A* (10:90)

System suitability stock solution: 0.15 mg/mL each of [USP Pirfenidone Related Compound A RS](#) and [USP Pirfenidone Related Compound B RS](#) in *Diluent* prepared as follows. Transfer a suitable amount of [USP Pirfenidone Related Compound A RS](#) and [USP Pirfenidone Related Compound B RS](#) to a suitable volumetric flask, and add 10% of the final volume of [acetonitrile](#) to dissolve. Dilute with *Solution A* to volume.

System suitability solution: 1.5 μg/mL each of [USP Pirfenidone Related Compound A RS](#) and [USP Pirfenidone Related Compound B RS](#) from the *System suitability stock solution* in *Diluent*

Standard stock solution: 1.3 mg/mL of [USP Pirfenidone RS](#) prepared as follows. Transfer a suitable amount of [USP Pirfenidone RS](#) to a suitable volumetric flask, and add 10% of the final volume of [acetonitrile](#) to dissolve. Dilute with *Solution A* to volume.

Standard solution: 1.6 μg/mL of [USP Pirfenidone RS](#) from the *Standard stock solution* in *Diluent*

Sample solution: 3.0 mg/mL of Pirfenidone in *Diluent* prepared as follows. Transfer a suitable amount of Pirfenidone to a suitable volumetric flask, and add 10% of the final volume of [acetonitrile](#) to dissolve. Dilute with *Solution A* to volume.

System suitability

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

[NOTE—The relative retention times in [Table 2](#) are provided as information that could aid in peak assignment.]

Table 2

Name	Relative Retention Time
Pirfenidone related compound A	0.27



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