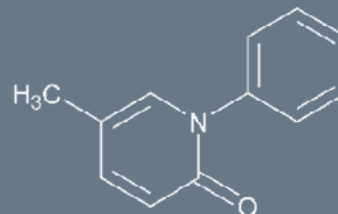


# Pirfenidone

## Quality Solutions

Category: Pulmonary



Authorized Distributor

USP can support your development and manufacturing activities on Pirfenidone-based medicines with these existing and upcoming standards.

### Official and Proposed Documentary Standards and Associated Physical Materials

#### MONOGRAPH 1

**PIRFENIDONE** | NEW  
Official as of 01-May-2024

USP Pirfenidone RS	<a href="#">USP-1544315</a>
USP Pirfenidone Related Compound A RS	<a href="#">USP-1544348</a>
USP Pirfenidone Related Compound B RS	<a href="#">USP-1544359</a>

#### MONOGRAPH 2

**PIRFENIDONE TABLETS** | NEW  
Official as of 01-May-2024

USP Pirfenidone RS	<a href="#">USP-1544315</a>
--------------------	-----------------------------

#### MONOGRAPH 3

**PIRFENIDONE CAPSULES** | NEW  
Official as of 01-May-2024

USP Pirfenidone RS	<a href="#">USP-1544315</a>
USP Pirfenidone Related Compound A RS	<a href="#">USP-1544348</a>
USP Pirfenidone Related Compound B RS	<a href="#">USP-1544359</a>

#### INCLUDED GENERAL CHAPTERS

**<11> USP REFERENCE STANDARDS**  
Official as of 01-Nov-2020

**<197> SPECTROSCOPIC IDENTIFICATION TESTS**  
Official as of 01-Sep-2021

**<281> RESIDUE ON IGNITION**  
Official as of 31-Dec-2012

**<621> CHROMATOGRAPHY**  
Official as of 01-Oct-2023

**<731> LOSS ON DRYING**  
Official as of 01-Nov-2020

**<857> ULTRAVIOLET-VISIBLE SPECTROSCOPY**  
Official as of 01-Dec-2022

**<905> UNIFORMITY OF DOSAGE UNITS**  
Official as of 01-Aug-2023

#### INCLUDED EXCIPIENTS

**TITANIUM DIOXIDE**  
Official as of 01-Jun-2023

**CROSCARMELLOSE SODIUM**  
Official as of 01-May-2022

USP Croscarmellose Sodium RS	<a href="#">USP-1150659</a>
------------------------------	-----------------------------

**MAGNESIUM STEARATE**  
Official as of 01-Aug-2016

USP Palmitic Acid RS	<a href="#">USP-1492007</a>
USP Stearic Acid RS	<a href="#">USP-1621008</a>

**FERRIC OXIDE**  
Official as of 01-Jun-2023

**FERROSOFERRIC OXIDE**  
Official as of 01-Jan-2018

**TALC**  
Official as of 01-May-2022

**SILICON DIOXIDE**  
Official as of 01-Jun-2023

**POLYVINYL ALCOHOL**  
Official as of 01-Aug-2023

USP Methyl Acetate RS	<a href="#">USP-1424051</a>
USP Methyl Alcohol RS	<a href="#">USP-1424109</a>
USP Polyvinyl Alcohol RS	<a href="#">USP-1548065</a>

**MICROCRYSTALLINE CELLULOSE**  
Official as of 01-Dec-2019

USP Microcrystalline Cellulose RS	<a href="#">USP-1098388</a>
-----------------------------------	-----------------------------

**POLYETHYLENE GLYCOL**  
Official as of 01-Feb-2020

**Disclaimer:** USP Quality Solution Sheets are provided as a convenience and for informational purposes only. Labmix24 makes reasonable efforts to provide correct information but assumes no liability for the completeness, timeliness or accuracy of the information contained in each QSS. It is the responsibility of the user to verify the information. The US Pharmacopeia remains the official source of this information.