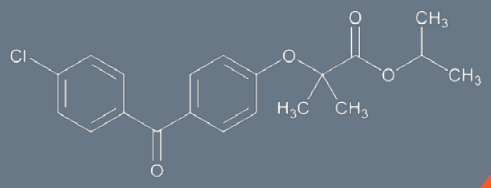
Small Molecules

Fenofibrate

Quality Solutions

Category: Antihyperlipidemics



Authorized Distributor

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

Official and Proposed Documentary Standards and Associated Physical Materials

MONOGRAPH 1

FENOFIBRATE Official as of 01-May-2020	
USP Fenofibrate RS	USP-1269447
USP Fenofibrate Related Compound A RS	USP-1269607
USP Fenofibrate Related Compound B RS	USP-1269618
USP Fenofibrate Related Compound C RS	USP-1269629

MONOGRAPH 2

FENOFIBRATE TABLETS Official as of 01-May-2019vv	
USP Fenofibrate RS	USP-1269447
USP Fenofibrate Related Compound A RS	USP-1269607
USP Fenofibrate Related Compound B RS	USP-1269618

MONOGRAPH 3

FENOFIBRATE CAPSULES Official as of 01-May-2021	
USP Fenofibrate RS	USP-1269447
USP Fenofibrate Related Compound B RS	USP-1269618
PHARMACEUTICAL ANALYTICAL IMPURITIES (PAI)*	
USP Atazanavir Ditertbutyl Analog PAI | NEW	USP-1A06390
USP Methyl Fenofibrate PAI | NEW	USP-1A07360
USP Ethyl Fenofibrate PAI | NEW	USP-1A07370
USP Fenofibrate Ether PAI | NEW	USP-1A07200

INCLUDED GENERAL CHAPTERS

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

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

<221> CHLORIDE AND SULFATE
Official as of 01-May-2019

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

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

<631> COLOR AND ACHROMICITY
Official as of 01-Dec-2023

<711> DISSOLUTION Official as of 01-May-2023	
USP Dissolution Performance Verification Standard Prednisone RS	USP-1222818

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

<741> MELTING RANGE OR TEMPERATURE
Official as of 01-Aug-2018

<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

SODIUM LAURYL SULFATE Official as of 01-May-2021	
USP Sodium Lauryl Sulfate RS	USP-1614363

TALC
Official as of 01-May-2022

MAGNESIUM STEARATE Official as of 01-Aug-2016	
USP Palmitic Acid RS	USP-1492007
USP Stearic Acid RS	USP-1621008

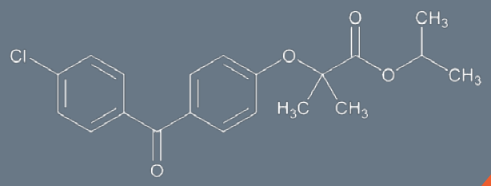
 # Pharmaceutical Analytical Impurities (PAI products) are released using a process developed by USP's subject matter experts. The release process is based on internal policies, standard operating procedures, and requirements as defined by USP's Quality Management System. USP is an ISO 9001:2015 certified facility. PAI products are different from official USP Reference Standards. PAI products are not required for compendial compliance.

Small Molecules

Fenofibrate

Quality Solutions

Category: Antihyperlipidemics



Authorized Distributor

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

Official and Proposed Documentary Standards and Associated Physical Materials

LACTOSE MONOHYDRATE Official as of 01-May-2020	
USP Dextrose RS	USP-1181302
USP Fructose RS	USP-1286504
USP Lactose Monohydrate RS	USP-1356701
USP Sucrose RS	USP-1623637

SILICON DIOXIDE Official as of 01-Jun-2023

GELATIN Official as of 01-Nov-2020	
USP Gelatin RS	USP-1288485

FERRIC OXIDE Official as of 01-Jun-2023

MICROCRYSTALLINE CELLULOSE Official as of 01-Dec-2019	
USP Microcrystalline Cellulose RS	USP-1098388

CROSPOVIDONE Official as of 01-May-2020	
USP Crospovidone RS	USP-1150706