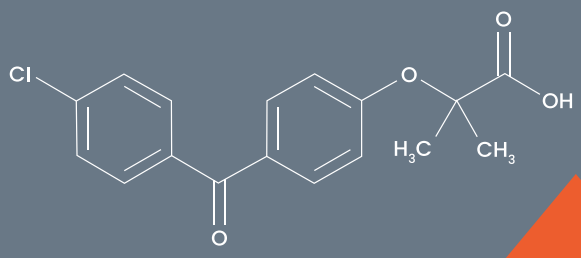
Small Molecules

Fenofibric Acid

Quality Solutions

Category: Antihyperlipidemic



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

Authorized Distributor

MONOGRAPH 1

FENOFIBRIC ACID DELAYED-RELEASE CAPSULES - *NEW* Official as of 01-Dec-2024	
USP Choline Fenofibrate RS	USP-1133558
USP Fenofibric Acid RS	USP-1269436

MONOGRAPH 2

FENOFIBRATE Official as of 1-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 3

FENOFIBRATE CAPSULES Official as of 1-May-2021	
USP Fenofibrate Related Compound B RS	USP-1269618
USP Fenofibrate RS	USP-1269447

MONOGRAPH 4

FENOFIBRATE TABLETS Official as of 1-May-2019	
USP Fenofibrate RS	USP-1269447
USP Fenofibrate Related Compound B RS	USP-1269618
USP Fenofibrate Related Compound A RS	USP-1269607
PHARMACEUTICAL ANALYTICAL IMPURITIES (PAI)*	
DESMETHYL FENOFIBRATE	USP-1A07140
METHYL FENOFIBRATE	USP-1A07360
ETHYL FENOFIBRATE	USP-1A07370
FENOFIBRATE ETHER	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 - *NEW* Official as of 01-Dec-2024	

<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	

 # 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.

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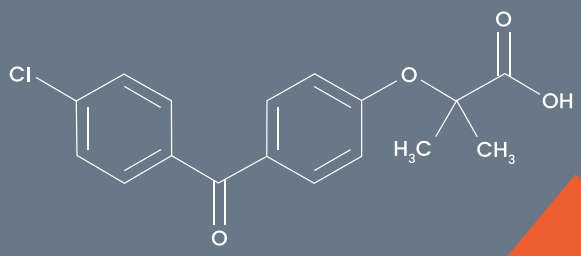

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INCLUDED EXCIPIENTS

SILICON DIOXIDE
Official as of 01-Jun-2023

LACTOSE MONOHYDRATE Official as of 1-Dec-2024	
USP Dextrose RS	USP-1181302
USP Fructose RS	USP-1286504
USP Lactose Monohydrate RS	USP-1356701
USP Sucrose RS	USP-1623637

TALC
Official as of 01-May-22

TITANIUM DIOXIDE
Official as of 1-Jun-2023

MAGNESIUM STEARATE Official as of 1-Aug-2016	
USP Palmitic Acid RS	USP-1492007
USP Stearic Acid RS	USP-1621008