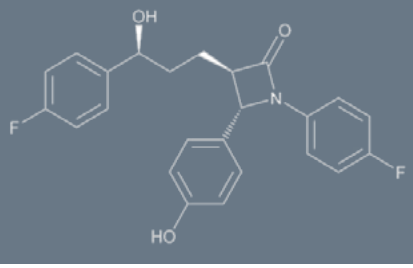
Small Molecules

Ezetimibe

Quality Solutions

Category: Antihyperlipidemic



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

Authorized Distributor

Official and Proposed Documentary Standards and Associated Physical Materials

MONOGRAPH 1

EZETIMIBE Official as of 01-Aug-2024	
USP Ezetimibe System Suitability Mixture RS	USP-1269039
USP Ezetimibe RS	USP-1269028

MONOGRAPH 2

EZETIMIBE TABLETS Official as of 01-Feb-2018	
USP Ezetimibe RS	USP-1269028
PHARMACEUTICAL ANALYTICAL IMPURITYIES* (PAI)	
USP Ezetimibe 2-Fluorobenzene Isomer PAI | *NEW*	USP-1A07340
USP Ezetimibe Desfluoroaniline Analog PAI	USP-1A07330
USP Ezetimibe Tetrahydropyran Analog PAI	USP-1A06770
USP Ezetimibe Ketone PAI	USP-1A07350
USP R,R,S-Ezetimibe PAI	USP-1A00140

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

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

<781> OPTICAL ROTATION Official as of 01-Dec-2022
<857> ULTRAVIOLET-VISIBLE SPECTROSCOPY Official as of 01-Dec-2022
<905> UNIFORMITY OF DOSAGE UNITS Official as of 01-Aug-2023

<921> WATER DETERMINATION Official as of 01-May-2022	
USP Sodium Tartrate Dihydrate RS	USP-1614909

INCLUDED EXCIPIENTS

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

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

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

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

HYPROMELLOSE | *NEW* Official as of 01-Aug-2024

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