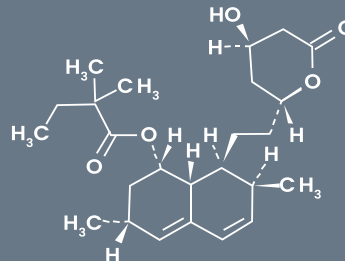


Simvastatin

Quality Solutions

Category: Antihyperlipidemic



Authorized Distributor

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

MONOGRAPH 1

SIMVASTATIN

Official as of 1-May-2020

USP Lovastatin RS	USP-1370600
USP Simvastatin RS	USP-1612700

MONOGRAPH 2

SIMVASTATIN TABLETS

Official as of 1-Dec-2019

USP Lovastatin RS	USP-1370600
USP Tenivastatin Calcium monohydrate RS	USP-1612719
USP Simvastatin RS	USP-1612700

PHARMACEUTICAL ANALYTICAL IMPURITIES (PAI)*

EPI LOVASTATIN - NEW	USP-1A10320
AMMONIUM TENIVASTATIN	USP-1A08000

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
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<731> LOSS ON DRYING

Official as of 01-Nov-2020

<781> OPTICAL ROTATION

Official as of 01-Dec-2024

<905> UNIFORMITY OF DOSAGE UNITS

Official as of 01-Aug-23

INCLUDED EXCIPIENTS

MICROCRYSTALLINE CELLULOSE

Official as of 1-Dec-2019

USP Microcrystalline Cellulose RS	USP-1098388
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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

HYPROMELLOSE

Official as of 1-Aug-2024

DIBASIC SODIUM PHOSPHATE

Official as of 1-Jun-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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