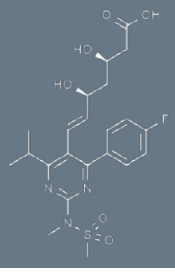
Small Molecules

Rosuvastatin

Quality Solutions

Category: Antihyperlipidemics



Authorized Distributor

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

Official and Proposed Documentary Standards and Associated Physical Materials

MONOGRAPH 1

ROSUVASTATIN CALCIUM | *NEW* Official as of 01-Aug-2024	
USP Rosuvastatin Calcium RS	USP-1606015
USP Rosuvastatin Enantiomer RS	USP-1606059
USP Rosuvastatin Related Compound A RS	USP-1606026
USP Rosuvastatin Related Compound B RS	USP-1606037
USP Rosuvastatin Related Compound C RS	USP-1606048
USP Rosuvastatin System Suitability Mixture RS	USP-1606004

MONOGRAPH 3

ROSUVASTATIN TABLETS | *NEW* Official as of 01-Aug-2024	
USP Rosuvastatin Calcium RS	USP-1606015
USP Rosuvastatin System Suitability Mixture RS	USP-1606004
PHARMACEUTICAL ANALYTICAL IMPURITYIES* (PAI)	
USP Rosuvastatin Ethyl Ester PAI | NEW	USP-1A06130
USP Rosuvastatin Lactone PAI	USP-1A01200
USP Rosuvastatin Isoamyl Ester PAI	USP-1A00170
USP Rosuvastatin Ketone PAI	USP-1A00050

INCLUDED GENERAL CHAPTERS

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

<191> IDENTIFICATION TESTS—GENERAL Official as of 01-May-2021

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

<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

<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

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

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

TITANIUM DIOXIDE Official as of 01-Jun-2023

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

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