Simvastatin **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	

SIMVASTATIN Official as of 1-May-2020	
USP Lovastatin RS	<u>USP-1370600</u>
USP Simvastatin RS	<u>USP-1612700</u>
MONOGRAPH 2	

SIMVASTATIN TABLETS Official as of 1-Dec-2019		
USP Lovastatin RS	<u>USP-1370600</u>	
USP Tenivastatin Calcium monohydrate RS	<u>USP-1612719</u>	
USP Simvastatin RS	<u>USP-1612700</u>	
PHARMACEUTICAL ANALYTICAL IMPURITIES (PAI)*		
EPI LOVASTATIN - NEW	<u>USP-1A10320</u>	
AMMONIUM TENIVASTATIN	<u>USP-1A08000</u>	

INCLUDED EXCIPIENTS

MICROCRYSTALLINE CELLULOSE Official as of 1-Dec-2019	
USP Microcrystalline Cellulose RS	<u>USP-1098388</u>
TITANIUM DIOXIDE Official as of 1-Jun-2023	
MAGNESIUM STEARATE	
Official as of 1-Aug-2016	
	<u>USP-1492007</u>
Official as of 1-Aug-2016	<u>USP-1492007</u> <u>USP-1621008</u>
Official as of 1-Aug-2016 USP Palmitic Acid RS	

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Official as of 1-Aug-2024

DIBASIC SODIUM PHOSPHATE Official as of 1-Jun-2023

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**

USP-1222818 Standard Prednisone RS

<731> LOSS ON DRYING

<781> OPTICAL ROTATION Official as of 01-Dec-2024

<905> UNIFORMITY OF DOSAGE UNITS Official as of 01-Aug-23

* 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.

BUNDLE PROMOTION

Receive a 15% discount when purchasing all of the products listed below:

- USP Lovastatin RS (USP-1370600)
- USP Simvastatin RS (USP-1612700) .
- USP Tenivastatin Calcium monohydrate RS (USP-1612719) •
- EPI LOVASTATIN PAI (USP-1A10320) •

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AMMONIUM TENIVASTATIN PAI (USP-1A08000)

Add at least one unit of each product in the bundle in order to receive the discount.

Discount is a limited time offer and may be subject to terms and conditions. Discount applies only to products in the bundle and may not be combined with other discounts. All sales are final. USP Reference Standards and other USP materials may not be returned for exchange or refund.

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