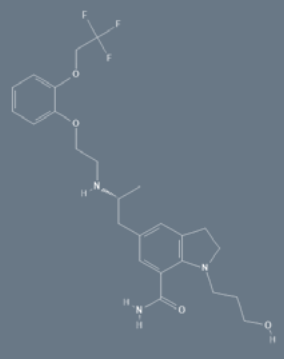
Small Molecules

Silodosin

Quality Solutions

Category: Renal



Authorized Distributor

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

Official and Proposed Documentary Standards and Associated Physical Materials

MONOGRAPH 1

SILODOSIN
Published in PF 49(3) 01-May-2023

USP Silodosin RS	USP-1612776
USP Silodosin S-Enantiomer RS | *NEW*	USP-1612822

MONOGRAPH 2

SILODOSIN CAPSULES
Published in PF 49(3) 01-May-2023

USP Silodosin RS	USP-1612776

INCLUDED GENERAL CHAPTERS

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

<61> MICROBIOLOGICAL EXAMINATION OF NONSTERILE PRODUCTS: MICROBIAL ENUMERATION TESTS
Official as of 31-Dec-2012

<62> MICROBIOLOGICAL EXAMINATION OF NONSTERILE PRODUCTS: TESTS FOR SPECIFIED MICROORGANISMS
Official as of 31-Dec-2012

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

<281> RESIDUE ON IGNITION
Official as of 31-Dec-2012

<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

<905> UNIFORMITY OF DOSAGE UNITS
Official as of 01-Aug-2023

INCLUDED EXCIPIENTS

MANNITOL
Official as of 01-May-2020

USP Mannitol RS	USP-1375105

TITANIUM DIOXIDE
Official as of 01-Jun-2023

GELATIN
Official as of 01-Nov-2020

USP Gelatin RS	USP-1288485

PROPYLENE GLYCOL
Official as of 01-May-2020

USP Ethylene Glycol RS	USP-1265515
USP Diethylene Glycol RS	USP-1193265
USP Propylene Glycol RS	USP-1576708

SODIUM LAURYL SULFATE
Official as of 01-May-2021

USP Sodium Lauryl Sulfate RS	USP-1614363

SHELLAC
Official as of 01-May-2020

USP Aleuritic Acid RS	USP-1012799
USP Refined Bleached Shellac RS	USP-1600303
USP Regular Bleached Shellac RS	USP-1600314

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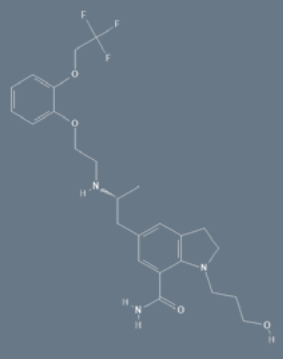

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POTASSIUM HYDROXIDE
Official as of 01-Jan-2018

MAGNESIUM STEARATE
Official as of 01-Aug-2016

USP Palmitic Acid RS	USP-1492007
USP Stearic Acid RS	USP-1621008

** Documents in PF Online are not official and not suitable to demonstrate compliance. They may never become official.*

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