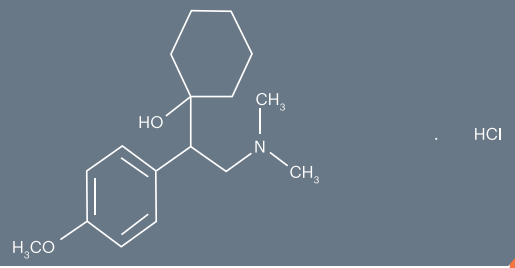
Small Molecules

Venlafaxine

Quality Solutions

Category: SSRI/SNRI



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

MONOGRAPH 1

Venlafaxine Hydrochloride Official as of 01-May-20	
USP Venlafaxine Hydrochloride RS	1711268
USP Venlafaxine Related Compound A RS	1711279

MONOGRAPH 2

Venlafaxine Tablets Official as of 01-Aug-17	
USP Venlafaxine Hydrochloride RS	1711268
USP Venlafaxine Related Compound A RS	1711279

MONOGRAPH 3

Venlafaxine Hydrochloride Extended-Release Capsules Official as of 01-Sep-2022	
USP Venlafaxine Hydrochloride RS	1711268
USP Venlafaxine Related Compound A RS	1711279

MONOGRAPH 4

Desvenlafaxine Official as of 01-Oct-2020	
USP Desvenlafaxine RS	1175751
USP Desvenlafaxine Related Compound A RS	1175784
USP Venlafaxine Hydrochloride RS	1711268

MONOGRAPH 5

Desvenlafaxine Extended-Release Tablets PF 51(3) 01-May-2025 to 31-Jul-2025	
USP Desvenlafaxine RS	1175751
USP Desvenlafaxine Related Compound A RS	1175784
USP Desvenlafaxine Related Compound B RS	1175795
USP Desvenlafaxine Succinate RS	1175773
USP Venlafaxine Hydrochloride RS	1711268

MONOGRAPH 6

Desvenlafaxine Succinate PF 51(4) 01-Jul-2025 to 30-Sep-2025	
USP Desvenlafaxine Related Compound B RS	1175795
USP Desvenlafaxine Succinate RS	1175773

PHARMACEUTICAL ANALYTICAL IMPURITIES (PAI)

Deoxy Venlafaxine (25 mg)	1A07010
Didesmethyl Venlafaxine Hydrochloride (25 mg)	1A07940

INCLUDED EXCIPIENTS

MAGNESIUM STEARATE Official as of 01-Aug-16	
USP Palmitic Acid RS	1492007
USP Stearic Acid RS	1621008

TITANIUM DIOXIDE Official as of 01-Jun-23

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

LACTOSE MONOHYDRATE Official as of 01-Dec-24	
USP Dextrose RS	1181302
USP Fructose RS	1286504
USP Lactose Monohydrate RS	1356701
USP Sucrose RS	1623637

PURIFIED WATER Official as of 01-Nov-2018	
USP 1,4-Benzoquinone RS	1056504

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 01-May-25

<62> Microbiological Examination of Nonsterile Products: Tests for Specified Microorganisms Official as of 31-Dec-12

<621> Chromatography Official as of 01-Dec-2024

<698> Deliverable Volume Official as of 01-Dec-20

<791> pH Official as of 01-Aug-24

<711> Dissolution Official as of 01-May-23	
USP Dissolution Performance Verification Standard-Prednisone RS	1222818

<905> Uniformity of Dosage Units Official as of 01-Aug-2023

<191> Identification Tests—General Official as of 01-May-21

<197> Spectroscopic Identification Tests Official as of 01-Sep-2021

<281> Residue on Ignition Official as of 31-Dec-2012

<921> Water Determination Official as of 01-May-22	
USP Sodium Tartrate Dihydrate RS	1614909

 # 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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