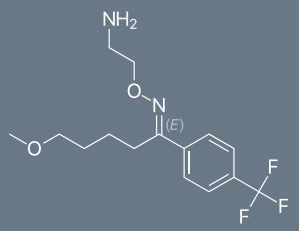
Small Molecules

Fluvoxamine

Quality Solutions

Category: Psychiatric



Authorized Distributor

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

Official and Proposed Documentary Standards and Associated Physical Materials

MONOGRAPH 1

FLUVOXAMINE MALEATE Official as of 01-May-2020	
USP Fluvoxamine Maleate RS	USP-1285909

MONOGRAPH 2

FLUVOXAMINE MALEATE TABLETS Official as of 01-May-2023	
USP Fluvoxamine Maleate RS	USP-1285909

MONOGRAPH 3

FLUVOXAMINE MALEATE EXTENDED-RELEASE CAPSULES Published in PF 50(4) 30-Sep-2024	
USP Fluvoxamine Maleate RS	USP-1285909

PHARMACEUTICAL ANALYTICAL IMPURITYIES* (PAI)	
USP Aminoethyl Fluvoxamine Dihydrochloride PAI | *NEW*	USP-1A08490
USP Fluvoxamine Z-Isomer Maleate PAI | *NEW*	USP-1A08500
USP Desmethoxy Fluvoxamine Maleate PAI | *NEW*	USP-1A08400
USP Fluvoxketone PAI	USP-1A08670
USP Fluvoxamine Maleamide PAI	USP-1A07380

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

<731> LOSS ON DRYING
Official as of 01-Nov-2020

<857> ULTRAVIOLET-VISIBLE SPECTROSCOPY
Official as of 01-Dec-2022

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

INCLUDED EXCIPIENTS

TITANIUM DIOXIDE
Official as of 01-Jun-2023

MANNITOL Official as of 01-May-2020	
USP Mannitol RS	USP-1375105

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

CORN STARCH
Official as of 01-Jun-2023

SODIUM STEARYL FUMARATE Official as of 01-Jun-2023	
USP Monostearyl Maleate RS	USP-1446804
USP Sodium Stearyl Fumarate RS	USP-1614705
USP Stearyl Alcohol RS	USP-1622000

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

 # 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.