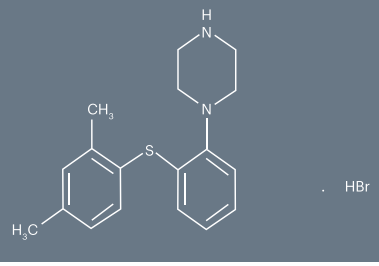
Small Molecules

Vortioxetine

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

Vortioxetine Hydrobromide PF 50(4) 01-Jul-2024 to 30-Sep-2024	
USP Vortioxetine Hydrobromide RS	1718100
USP Vortioxetine Related Compound G RS	1718111
USP Vortioxetine Related Compound H RS	1718122
USP Vortioxetine Related Compound I RS	1718133

PHARMACEUTICAL ANALYTICAL IMPURITIES (PAI)

Despiperazine Vortioxetine Hydrobromide (25 mg)	1A12550
Formyl Vortioxetine (25 mg)	1A12530
Vortioxetine Open Chain Hydrochloride Analog (25 mg)	1A12540
Vortioxetine Sulfoxide Hydrochloride (25 mg)	1A12520

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-19	
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-20

<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-Dec-2024

<731> Loss on Drying
Official as of 01-Nov-20

<1> Injections and Implanted Drug Products (Parenterals)—Product Quality Tests
Official as of 01-Aug-25

<71> Sterility Tests
Official as of 31-Dec-12

<85> Bacterial Endotoxins Test Official as of 01-May-18	
USP Endotoxin RS	1235503

<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-23

<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

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

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

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