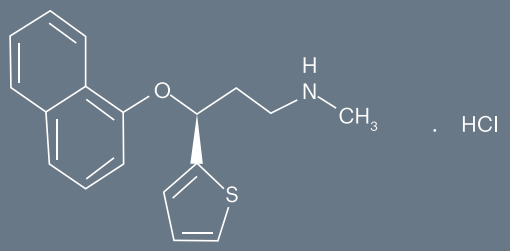
Small Molecules

Duloxetine

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

Duloxetine Hydrochloride Official as of 01-May-20	
USP Duloxetine Hydrochloride RS	1229817
USP Duloxetine Related Compound A RS	1229828

MONOGRAPH 2

Duloxetine Delayed-Release Capsules Official as of 01-May-20	
USP Duloxetine Hydrochloride RS	1229817
USP Duloxetine Related Compound F RS	1229872
USP Duloxetine Related Compound H RS	1229883

PHARMACEUTICAL ANALYTICAL IMPURITIES (PAI)

4-Hydroxy Duloxetine Acetate (25 mg)	1A02160
Duloxetine 4-Naphthyl Isomer Hydrobromide (25 mg)	1A00940
Duloxetine Alcohol (25 mg)	1A00960
Duloxetine beta-Naphthol-1-yl Isomer (50 mg)	1A00950
Duloxetine Phenylcarbamate (50 mg)	1A02170
Duloxetine Phthalamide (25 mg)	1A02190
Duloxetine Regioisomer (25 mg)	1A02200
N-Methyl Duloxetine 3-Isomer Oxalate (25 mg)	1A02210
N-Methyl Duloxetine Oxalate (25 mg)	1A00970
N-Nitroso Duloxetine Solution (1 mL (1 mg/mL))	1A04000
rac-Duloxetine-d7 Maleate (25 mg)	1A02180

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-24

<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-23

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

<197> Spectroscopic Identification Tests Official as of 01-Sep-21

<281> Residue on Ignition Official as of 31-Dec-12

<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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