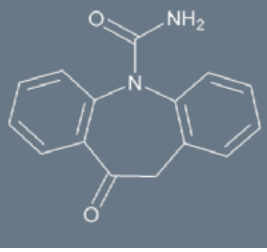
Small Molecules

Oxcarbazepine

Quality Solutions

Category: Psychiatrics



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

Authorized Distributor

Official and Proposed Documentary Standards and Associated Physical Materials

MONOGRAPH 1

OXCARBAZEPINE Official as of 01-May-2020	
USP Oxcarbazepine RS	USP-1483152
USP Carbamazepine RS	USP-1093001
USP Oxcarbazepine Related Compound A RS	USP-1483163
USP Oxcarbazepine Related Compound B RS	USP-1483174
USP Oxcarbazepine Related Compound D RS	USP-1483196
USP Oxcarbazepine Related Compound E RS	USP-1483200

MONOGRAPH 2

OXCARBAZEPINE ORAL SUSPENSION Official as of 05-Jun-2024	
USP Oxcarbazepine RS	USP-1483152
USP Carbamazepine RS	USP-1093001
USP Oxcarbazepine Related Compound A RS	USP-1483163
USP Oxcarbazepine Related Compound C RS	USP-1483185

MONOGRAPH 3

OXCARBAZEPINE TABLETS Official as of 01-May-2021	
USP Oxcarbazepine RS	USP-1483152
USP Carbamazepine RS	USP-1093001
USP Oxcarbazepine Related Compound C RS	USP-1483185
PHARMACEUTICAL ANALYTICAL IMPURITYIES* (PAI)	
USP Carbamazepine Dione PAI | *NEW*	USP-1A07820
USP N-Carbamoyl Oxcarbazepine PAI	USP-1A08190
USP Methoxy Carbamazepine PAI	USP-1A07840
USP Dibenzazepinodione PAI	USP-1A03260

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	
<621> CHROMATOGRAPHY Official as of 01-Oct-2023	
<698> DELIVERABLE VOLUME Official as of 01-Dec-2020	
<711> DISSOLUTION Official as of 01-May-2023	
USP Dissolution Performance Verification Standard Prednisone RS	USP-1222818
<791> PH Official as of 01-Aug-2024	
<905> UNIFORMITY OF DOSAGE UNITS Official as of 01-Aug-2023	
<921> WATER DETERMINATION Official as of 01-May-2022	
USP Sodium Tartrate Dihydrate RS	USP-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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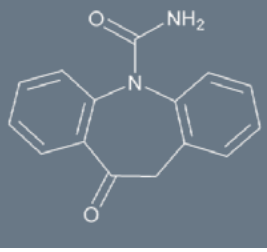

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Official and Proposed Documentary Standards and Associated Physical Materials

INCLUDED EXCIPIENTS

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

SILICON DIOXIDE Official as of 01-Jun-2023

MAGNESIUM STEARATE Official as of 01-Aug-2016	
USP Palmitic Acid RS	USP-1492007
USP Stearic Acid RS	USP-1621008

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

TITANIUM DIOXIDE Official as of 01-Jun-2023