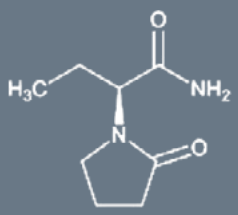
Small Molecules

Levetiracetam

Quality Solutions

Category: Psychiatric



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

Official and Proposed Documentary Standards and Associated Physical Materials

Authorized Distributor

MONOGRAPH 1

LEVETIRACETAM Official as of 01-May-2020	
USP Levetiracetam RS	USP-1359404
USP Levetiracetam Related Compound A RS	USP-1359426
USP Levetiracetam Related Compound B RS	USP-1359437
USP Levetiracetam Racemic Mixture RS	USP-1359415

MONOGRAPH 2

LEVETIRACETAM EXTENDED-RELEASE TABLETS Official as of 01-Jan-2020	
USP Levetiracetam RS	USP-1359404

MONOGRAPH 3

LEVETIRACETAM TABLETS Official as of 16-Jun-2022	
USP Levetiracetam Related Compound B RS	USP-1359437
USP Levetiracetam RS	USP-1359404

MONOGRAPH 4

LEVETIRACETAM INJECTION Official as of 01-May-2018	
USP Levetiracetam RS	USP-1359404

MONOGRAPH 5

LEVETIRACETAM ORAL SOLUTION Official as of 01-Dec-2019	
USP Levetiracetam RS	USP-1359404
USP Levetiracetam Related Compound A RS	USP-1359426
PHARMACEUTICAL ANALYTICAL IMPURITIES (PAI)*	
USP Levetiracetam Impurity 21 PAI	USP-1A00370
USP Levetiracetam Impurity 19 PAI	USP-1A00440
USP N6-(1-Iminoethyl)-D-lysine PAI	USP-1A00530
USP Bis((R)-butyramide) PAI	USP-1A00540
USP Levetiracetam Crotonamide PAI	USP-1A02220
USP Levetiracetam acid PAI | *NEW*	USP-1A05810

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	

<71> STERILITY TESTS Official as of 31-Dec-2012	

<85> BACTERIAL ENDOTOXINS TEST Official as of 01-May-2018	
USP Endotoxin RS	USP-1235503

<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

<788> PARTICULATE MATTER IN INJECTIONS Official as of 01-May-2013	
USP Particle Count RS	USP-1500502

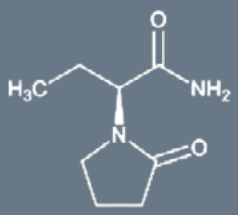
<791> PH Official as of 01-Nov-2020	

Small Molecules

Levetiracetam

Quality Solutions

Category: Psychiatric



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

Official and Proposed Documentary Standards and Associated Physical Materials

Authorized Distributor

<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

INCLUDED EXCIPIENTS

WATER FOR INJECTION
Official as of 01-Nov-2018

USP 1,4-Benzoquinone RS	USP-1056504

SILICON DIOXIDE
Official as of 01-Jun-2023

TITANIUM 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

TALC
Official as of 01-May-2022

 # 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.