Paliperidone

Quality Solutions Category: Hepatic



Authorized Distributor

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

Official and Proposed Documentary Standards and Associated Physical Materials

MONOGRAPH 1

PALIPERIDONE Official as of 01-May-2020	
USP Paliperidone RS	<u>USP-1491809</u>
USP Paliperidone Resolution Mixture RS	<u>USP-1491795</u>

MONOGRAPH 2

PALIPERIDONE EXTENDED-RELEASE TABLETS

Published in PF 48(6) 01-Nov-2022

USP Paliperidone RS	<u>USP-1491809</u>
USP Paliperidone Related Compound E RS	<u>USP-1491853</u>

PHARMACEUTICAL ANALYTICAL IMPURITIES (PAI)*

Hydroxybenzoyl Paliperidone	<u>USP-1A04930</u>
nydroxyberizoyi Paliperidone	<u>03P-1A04930</u>

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

01-Apr-2024. For publications related to Paliperidone in PF online after this date, please visit the integrated USP-NF/PF online.

<711> DISSOLUTION

Official as of O1-Nov-2022

<905> UNIFORMITY OF DOSAGE UNITS

Official as of 01-Aug-2023

<921> WATER DETERMINATION

Official as of O1-May-2022

INCLUDED EXCIPIENTS

POLYETHYLENE GLYCOL

Official as of 01-Feb-2020

TITANIUM DIOXIDE

Official as of 01-Jun-2023

FERRIC OXIDE

Official as of 01-Jun-2023

HYPROMELLOSE

Official as of O1-May-2019

SODIUM HYDROXIDE

Official as of 01-Jan-2018

* 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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