AtazanavirQuality Solutions

Category: Antiviral



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

Authorized Distributor

MONOGRAPH 1

	ATAZANAVIR SULFATE Official as of 1-Aug-2022	
	USP Atazanavir Sulfate RS	<u>USP-1044334</u>
	USP Atazanavir System Suitability Mixture RS	<u>USP-1044345</u>
	USP Atazanavir Related Compound A RS	<u>USP-1044356</u>

PHARMACEUTICAL ANALYTICAL IMPURITIES (PAI)* ATAZANAVIR SULFATE VALINE ANALOG -USP-1A06180 NEW 4-(PYRIDIN-2-YL) BENZALDEHYDE USP-1A06010 ATAZANAVIR DIPEPTIDE ANALOG USP-1A06480 DEALKYL ATAZANAVIR USP-1A06020 ATAZANAVIR BENZYLIDENEHYDRAZINE USP-1A06160 **CARBAMATE** ATAZANAVIR S,R,S,SDIASTEREOMER USP-1A06150 ATA7ANAVIR FORMYL ANALOG USP-1A06170 ATAZANAVIR AMINE ANALOG USP-1A06510 ATAZANAVIR R,S,S,SDIASTEREOMER USP-1A06490 ATAZANAVIR S,S,S,R DIASTEREOMER USP-1A06500 ATAZANAVIR ETHYL ANALOG USP-1A06190

* 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.

ATAZANAVIR DITERTBUTYL ANALOG

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INCLUDED GENERAL CHAPTERS

<11> USP REFERENCE STANDARDS

Official as of 01-Nov-2020

<191> IDENTIFICATION TESTS—GENERAL

Official as of 01-May-2021

<197> SPECTROSCOPIC IDENTIFICATION TESTS

Official as of 01-Sep-2021

<281> RESIDUE ON IGNITION

Official as of 31-Dec-2012

<621> CHROMATOGRAPHY - NEW

Official as of O1-Dec-2024

<781> OPTICAL ROTATION

Official as of O1-Dec-2024

<921> WATER DETERMINATION

Official as of O1-May-2022

USP Sodium Tartrate Dihydrate RS <u>USP-1614909</u>

INCLUDED EXCIPIENTS

LACTOSE MONOHYDRATE Official as of 1-Dec-2024		
USP Dextrose RS	<u>USP-1181302</u>	
USP Fructose RS	<u>USP-1286504</u>	
USP Lactose Monohydrate RS	<u>USP-1356701</u>	
USP Sucrose RS	<u>USP-1623637</u>	

TITANIUM DIOXIDE

Official as of 1-Jun-2023

MAGNESIUM STEARATE Official as of 1-Aug-2016

USP Palmitic Acid RS

USP-1492007

USP Stearic Acid RS <u>USP-1621008</u>

GELATIN

USP-1A06390

Official as of 1-Nov-2020

USP Gelatin RS USP-1288485

CROSPOVIDONE

Official as of 1-May-2020

USP Crospovidone RS <u>USP-1150706</u>

