Sorafenib Quality Solutions

Category: Oncology

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

Official and Proposed Documentary Standards and Associated Physical Materials



SORAFENIB TOSYLATE Official as of 01-May-2021	
USP Sorafenib Tosylate RS	<u>USP-1615876</u>
USP Sorafenib Related Compound H RS	<u>USP-1615887</u>
MONOGRAPH 2	
SORAFENIB TABLETS Official as of 01-Jun-2023	
USP Sorafenib Tosylate RS	<u>USP-1615876</u>
USP Sorafenib Related Compound H RS	<u>USP-1615887</u>
PHARMACEUTICAL ANALYTICAL IMPURIT	IES (PAI)

FIIARMAGEO IIGAE ANAEL IIGAE IMFORT	
USP Sorafenib Isopropyl Carbamate NEW	<u>USP-1A06360</u>
USP Sorafenib Formamide NEW	<u>USP-1A05840</u>
USP Sorafenib Diarylurea Analog <mark>NEW</mark>	<u>USP-1A05990</u>
USP Deschlorosorafenib NEW	<u>USP-1A05820</u>

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

<621> CHROMATOGRAPHY	
Official as of 01-Oct-2023	

<711> DISSOLUTION Official as of 01-May-2023	
USP Dissolution Performance Verification Standard-Prednisone RS	<u>USP-1222818</u>

<905> UNIFORMITY OF DOSAGE UNITS Official as of 01-Aug-2023 INCLUDED EXCIPIENTS

TITANIUM DIOXIDE Official as of 01-Jun-2023	
HYPROMELLOSE Official as of 01-May-2023	
POVIDONE Official as of 01-Jun-2023	
USP Povidone RS	<u>USP-1551503</u>
LACTOSE MONOHYDRATE Official as of 01-May-2020	
USP Fructose RS	<u>USP-1286504</u>
USP Dextrose RS	<u>USP-1181302</u>
USP Sucrose RS	<u>USP-1623637</u>
USP Lactose Monohydrate RS	<u>USP-1356701</u>
ANHYDROUS LACTOSE Official as of 01-May-2020	
USP Anhydrous Lactose RS	<u>USP-1356676</u>
USP Dextrose RS	<u>USP-1181302</u>
USP Sucrose RS	<u>USP-1623637</u>
USP Fructose RS	<u>USP-1286504</u>
CROSPOVIDONE Official as of 01-May-2020	
USP Crospovidone RS	<u>USP-1150706</u>
SODIUM LAURYL SULFATE Official as of 01-May-2021	
USP Sodium Lauryl Sulfate RS	<u>USP-1614363</u>
BUTYLATED HYDROXYTOLUENE Official as of 01-May-2021	
USP Butylated Hydroxytoluene RS	<u>USP-1082708</u>

[#] 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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POLYVINYL ALCOHOL Official as of 01-Aug-2023	
USP Methyl Acetate RS	<u>USP-1424051</u>
USP Methyl Alcohol RS	<u>USP-1424109</u>
USP Polyvinyl Alcohol RS	<u>USP-1548065</u>
CROSCARMELLOSE SODIUM Official as of 01-May-2022	
USP Croscarmellose Sodium RS	<u>USP-1150659</u>
MANNITOL Official as of 01-May-2020	
USP Mannitol RS	<u>USP-1375105</u>
SHELLAC Official as of 01-May-2020	
	<u>USP-1012799</u>
Official as of 01-May-2020	<u>USP-1012799</u> <u>USP-1600303</u>
Official as of 01-May-2020 USP Aleuritic Acid RS	
Official as of 01-May-2020 USP Aleuritic Acid RS USP Refined Bleached Shellac RS	<u>USP-1600303</u>
Official as of 01-May-2020 USP Aleuritic Acid RS USP Refined Bleached Shellac RS USP Regular Bleached Shellac RS MICROCRYSTALLINE CELLULOSE	<u>USP-1600303</u>
Official as of 01-May-2020 USP Aleuritic Acid RS USP Refined Bleached Shellac RS USP Regular Bleached Shellac RS MICROCRYSTALLINE CELLULOSE Official as of 01-Dec-2019	<u>USP-1600303</u> <u>USP-1600314</u>

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