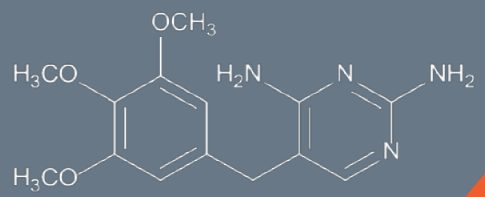
Small Molecules

Trimethoprim

Quality Solutions

Category: Antibiotic



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

Authorized Distributor

Official and Proposed Documentary Standards and Associated Physical Materials

MONOGRAPH 1

TRIMETHOPRIM Official as of 01-May-2020	
USP Trimethoprim RS	USP-1692505

MONOGRAPH 2

TRIMETHOPRIM SULFATE Official as of 01-May-2020	
USP Trimethoprim RS	USP-1692505

MONOGRAPH 3

TRIMETHOPRIM TABLETS Official as of 31-Dec-2012	
USP Trimethoprim RS	USP-1692505

MONOGRAPH 4

SULFAMETHOXAZOLE AND TRIMETHOPRIM TABLETS Official as of 31-Dec-2012	
USP Sulfamethoxazole RS	USP-1631001
USP Trimethoprim RS	USP-1692505

MONOGRAPH 5

SULFAMETHOXAZOLE AND TRIMETHOPRIM INJECTION Official as of 31-Dec-2012	
USP Sulfanilamide RS	USP-1632004
USP Sulfamethoxazole RS	USP-1631001
USP Sulfanilic Acid RS	USP-1633506
USP Trimethoprim RS	USP-1692505

MONOGRAPH 6

SULFAMETHOXAZOLE AND TRIMETHOPRIM ORAL SUSPENSION Official as of 31-Dec-2012	
USP Alcohol Determination–Acetonitrile RS	USP-1012699
USP Alcohol Determination–Alcohol RS	USP-1012688
USP Diaveridine RS	USP-1184118
USP Sulfamethoxazole N4-Glucoside RS	USP-1631500
USP Sulfamethoxazole RS	USP-1631001
USP Sulfamethoxazole Related Compound C RS	USP-1631533
USP Trimethoprim RS	USP-1692505
USP Trimethoprim Related Compound A RS	USP-1692516
USP Trimethoprim Related Compound B RS	USP-1692527

MONOGRAPH 7

POLYMYXIN B SULFATE AND TRIMETHOPRIM OPHTHALMIC SOLUTION Official as of 31-Dec-2012	
USP Polymyxin B Sulfate RS	USP-1547007
USP Trimethoprim RS	USP-1692505
PHARMACEUTICAL ANALYTICAL IMPURITIES (PAI)*	
USP Trimethoprim 4-ol PAI | *NEW*	USP-1A05950
USP Trimethoprim Acrylonitrile Analog PAI | *NEW*	USP-1A05500
USP Ethoxytrimethoprim Analog PAI | *NEW*	USP-1A05480

INCLUDED GENERAL CHAPTERS

<1> INJECTIONS AND IMPLANTED DRUG PRODUCTS (PARENTERALS)—PRODUCT QUALITY TESTS | *NEW* **OFFICIAL AS OF 01-MAY-2024**
<11> USP REFERENCE STANDARDS Official as of 01-Nov-2020
<71> STERILITY TESTS Official as of 31-Dec-2012
<81> ANTIBIOTICS—MICROBIAL ASSAYS Official as of 01-Jan-2024
<151> PYROGEN TEST Official as of 01-May-2017
<191> IDENTIFICATION TESTS—GENERAL Official as of 01-May-2021
<197> SPECTROSCOPIC IDENTIFICATIONTESTS Official as of 01-Sep-2021

<201> THIN-LAYER CHROMATOGRAPHIC IDENTIFICATION TEST Official as of 01-May-2018	
USP Bacitracin Zinc RS	USP-1048007
USP Neomycin Sulfate RS	USP-1458009
USP Polymyxin B Sulfate RS	USP-1547007

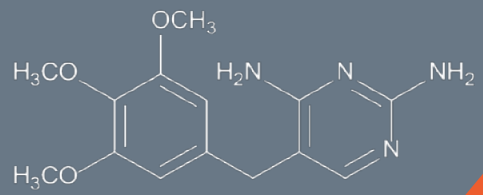
 # Pharmaceutical Analytical Impurities (PAI products) are released using a process developed by USP's subject matter experts. The release process is based on internal policies, standard operating procedures, and requirements as defined by USP's Quality Management System. USP is an ISO 9001:2015 certified facility. PAI products are different from official USP Reference Standards. PAI products are not required for compendial compliance.

Small Molecules

Trimethoprim

Quality Solutions

Category: Antibiotic



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Authorized Distributor

Official and Proposed Documentary Standards and Associated Physical Materials

<281> RESIDUE ON IGNITION Official as of 31-Dec-2012	
<611> ALCOHOL DETERMINATION Official as of 31-Dec-2012	
USP Alcohol Determination±Alcohol RS	USP-1012688
USP Alcohol Determination—Acetonitrile RS	USP-1012699
<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
<731> LOSS ON DRYING Official as of 01-Nov-2020	
<741> MELTING RANGE OR TEMPERATURE Official as of 01-Aug-2018	
<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	
<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

MAGNESIUM STEARATE Official as of 01-Aug-2016	
USP Palmitic Acid RS	USP-1492007
USP Stearic Acid RS	USP-1621008
POLYSORBATE 80 Official as of 01-May-2020	
USP Polysorbate 80 RS	USP-1547969
SILICON DIOXIDE Official as of 01-Jun-2023	
MICROCRYSTALLINE CELLULOSE Official as of 01-Dec-2019	
USP Microcrystalline Cellulose RS	USP-1098388
CARBOXYMETHYLCELLULOSE SODIUM Official as of 01-Jan-2018	
METHYLPARABEN Official as of 01-May-2020	
USP Methylparaben RS	USP-1432005
SODIUM BENZOATE Official as of 01-May-2020	
USP Benzoic Acid RS	USP-1055002
USP Salicylic Acid RS	USP-1609002
USP Sodium Benzoate RS	USP-1613564
STERILE WATER FOR INJECTION Official as of 01-May-2021	
ALCOHOL Official as of 01-Dec-2021	
USP Alcohol RS	USP-1012768
SODIUM HYDROXIDE Official as of 01-Jan-2018	