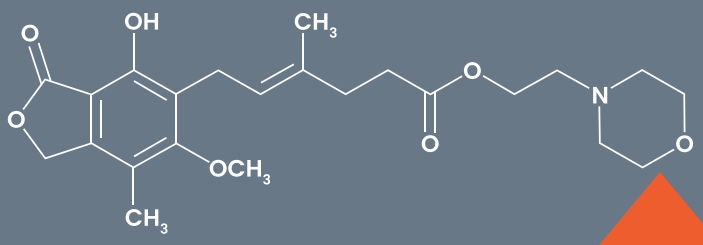
Small Molecules

Mycophenolate
Quality Solutions

Category: Immunosuppressant



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

Authorized Distributor

MONOGRAPH 1

MYCOPHENOLATE MOFETIL Official as of 1-May-2020	
USP Mycophenolate Mofetil RS	USP-1448956
USP Mycophenolate Mofetil Related Compound A RS	USP-1448967
USP Mycophenolate Mofetil Related Compound B RS	USP-1448978

MONOGRAPH 2

MYCOPHENOLATE SODIUM Official as of 1-May-2022	
USP Mycophenolate Mofetil Related Compound B RS	USP-1448978
USP Mycophenolate Sodium RS	USP-1448989

MONOGRAPH 3

MYCOPHENOLATE MOFETIL TABLETS Official as of 1-Aug-2023	
USP Mycophenolate Mofetil RS	USP-1448956

MONOGRAPH 4

MYCOPHENOLATE MOFETIL FOR INJECTION Official as of 1-May-2019	
USP Mycophenolate Mofetil Related Compound B RS	USP-1448978
USP Mycophenolate Mofetil Related Compound A RS	USP-1448967
USP Mycophenolate Mofetil RS	USP-1448956

MONOGRAPH 5

MYCOPHENOLATE MOFETIL FOR ORAL SUSPENSION Official as of 1-May-2020	
USP Mycophenolate Mofetil RS	USP-1448956
USP Mycophenolate Mofetil Related Compound A RS	USP-1448967
USP Mycophenolate Mofetil Related Compound B RS	USP-1448978

MONOGRAPH 6

MYCOPHENOLATE MOFETIL CAPSULES Official as of 1-Aug-2023	
USP Mycophenolate Mofetil RS	USP-1448956
PHARMACEUTICAL ANALYTICAL IMPURITIES (PAI)*	
MYCOPHENOLATE O-METHYL ANALOG - NEW	USP-1A08550
MYCOPHENOLATE MOFETIL N-OXIDE	USP-1A06840
ETHYL MYCOPHENOLATE	USP-1A07710
METHYL MYCOPHENOLATE	USP-1A08590

INCLUDED GENERAL CHAPTERS

<1> INJECTIONS AND IMPLANTED DRUG PRODUCTS (PARENTERALS)—PRODUCT QUALITY TESTS
Official as of 01-May-2024

<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 SPECIFIEC 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 - *NEW*
Official as of 01-Dec-2024

<698> DELIVERABLE VOLUME
Official as of 01-Dec-2020

 # 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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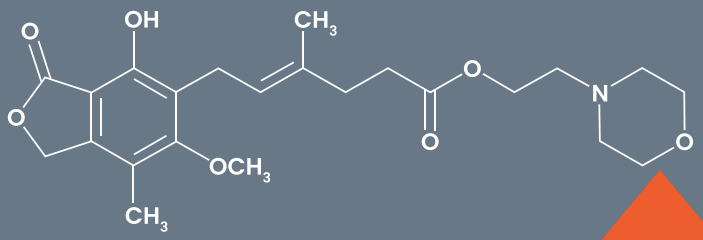
Mycophenolate
Quality Solutions

Category: Immunosuppressant



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Authorized Distributor

<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

<788> PARTICULATE MATTER IN INJECTIONS
Official as of 01-May-2013

USP Particle Count RS	USP-1500502

<791> PH
Official as of 01-Aug-2024

<852> ATOMIC ABSORPTION SPECTROSCOPY
Official as of 01-Aug-2022

<857> ULTRAVIOLET-VISIBLE SPECTROSCOPY
Official as of 01-Deca-2022

<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

<941> CHARACTERIZATION OF CRYSTALLINE AND PARTIALLY CRYSTALLINE SOLIDS BY X-RAY POWDER DIFFRACTION (XRPD)
Official as of 01-May-2022

INCLUDED EXCIPIENTS

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	USP-1621008

CROSCARMELLOSE SODIUM
Official as of 1-May-2022

USP Croscarmellose Sodium RS	USP-1150659

FERRIC OXIDE
Official as of 1-Jun-2023

MICROCRYSTALLINE CELLULOSE
Official as of 1-Dec-2019

USP Microcrystalline Cellulose RS	USP-1098388