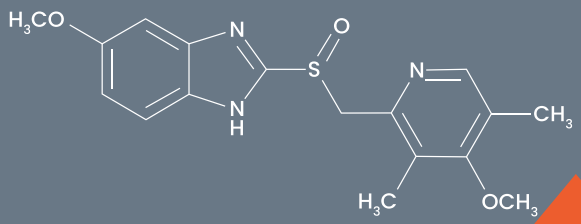
Small Molecules

Omeprazole

Quality Solutions

Category: Gastrointestinal



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

Authorized Distributor

MONOGRAPH 1

OMEPRAZOLE MAGNESIUM Official as of 1-May-2021	
USP Omeprazole RS	USP-1478505
USP Omeprazole Magnesium RS	USP-1478549
USP Omeprazole Related Compound A RS	USP-1478516

MONOGRAPH 2

OMEPRAZOLE Official as of 1-May-2020	
USP Omeprazole Related Compound A RS	USP-1478516
USP Omeprazole RS	USP-1478505
USP Omeprazole Related Compound E RS	USP-1478527
USP Omeprazole Related Compound I RS	USP-1478561

MONOGRAPH 3

OMEPRAZOLE DELAYED-RELEASE CAPSULES Official as of 31-Dec-2012	
USP Omeprazole RS	USP-1478505
USP Omeprazole Related Compound F and G Mixture RS	USP-1478491

MONOGRAPH 4

OMEPRAZOLE DELAYED-RELEASE TABLETS PF 50(6) as of 14-Feb-2025	
USP Desmethoxyomeprazole RS - *NEW*	USP-1173164
USP Omeprazole RS	USP-1478505
USP Omeprazole Related Compound B RS	USP-1478480
USP Omeprazole Related Compound C RS	USP-1478468
PHARMACEUTICAL ANALYTICAL IMPURITIES (PAI)*	
4-CHLORO OMEPRAZOLE	USP-1A07810
DESMETHOXY OMEPRAZOLE	USP-1A00060

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

<641> COMPLETENESS OF SOLUTION OFFICIAL AS OF 01-NOV-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	

<781> OPTICAL ROTATION Official as of 01-Dec-2024	

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

 # 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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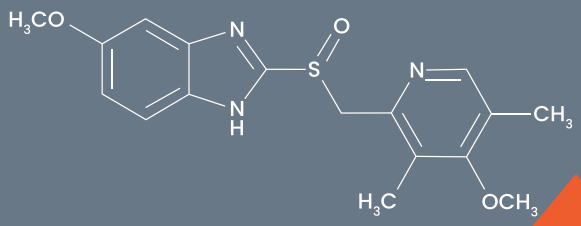

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INCLUDED EXCIPIENTS

TALC
Official as of 01-May-22

TITANIUM DIOXIDE
Official as of 1-Jun-2023

GELATIN
Official as of 1-Nov-2020

USP Gelatin RS	USP-1288485

FERRIC OXIDE
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