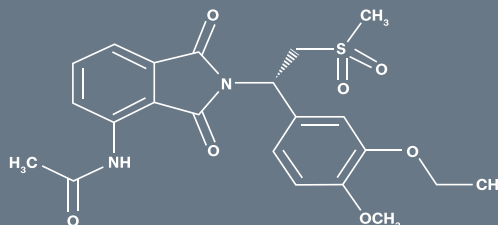


Apremilast

Quality Solutions

Category: Anti-Inflammatory/Psoriasis



Authorized Distributor

USP can support your development and manufacturing activities on Anti-inflammatory/Psoriasis-based medicines with these existing and upcoming standards

INCLUDED EXCIPIENTS

MAGNESIUM STEARATE

Official as of 01-Aug-2016

USP Palmitic Acid RS	USP-1492007
USP Stearic Acid RS	USP-1621008

TITANIUM DIOXIDE

Official as of 01-Jun-2023

LACTOSE MONOHYDRATE

Official as of 1-Dec-2024

USP Dextrose RS	USP-1181302
USP Fructose RS	USP-1286504
USP Lactose Monohydrate RS	USP-1356701
USP Sucrose RS	USP-1623637

MICROCRYSTALLINE CELLULOSE

Official as of 1-Dec-2019

USP Microcrystalline Cellulose RS	USP-1098388
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TALC

Official as of 01-May-22

USP Apremilast R-Enantiomer RS	USP-1041851
USP Apremilast RS	USP-1041850
USP Apremilast Related Compound E RS	USP-1041855
USP N-Acetyl-L-leucine RS	USP-1010081

USP Apremilast RS	USP-1041850
USP Apremilast Related Compound E RS	USP-1041855

PHARMACEUTICAL ANALYTICAL IMPURITIES (PAI)*

Apremilast Open Ring 3-acetamide (25 mg)	USP-1A04460
O-Desmethyl Apremilast (25 mg)	USP-1A04470
Desacetyl Apremilast (25 mg)	USP-1A13780
Apremilast Desphthalyl Amine (25 mg)	USP-1A04480
3-Acetamidophthalic acid (25 mg)	USP-1A04490

Disclaimer: USP Quality Solution Sheets are provided as a convenience and for informational purposes only. Labmix24 makes reasonable efforts to provide correct information but assumes no liability for the completeness, timeliness or accuracy of the information contained in each QSS. It is the responsibility of the user to verify the information. The US Pharmacopeia remains the official source of this information.

* 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.