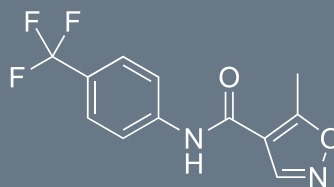


# Leflunomide

## Quality Solutions

Category: Immunosuppressant



Authorized Distributor

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

### Official and Proposed Documentary Standards and Associated Physical Materials

#### MONOGRAPH 1

<b>LEFLUNOMIDE</b> Official as of 01-May-2020	
USP Leflunomide RS	<a href="#">USP-1356960</a>
USP Leflunomide Related Compound A RS	<a href="#">USP-1357045</a>
USP Leflunomide Related Compound B RS	<a href="#">USP-1357056</a>
USP Leflunomide Related Compound C RS	<a href="#">USP-1357067</a>

#### MONOGRAPH 2

<b>DEXAMETHASONE ORAL SOLUTION</b> Official as of 01-Dec-2014	
USP Leflunomide RS	<a href="#">USP-1356960</a>
USP Leflunomide Related Compound A RS	<a href="#">USP-1357045</a>
USP Leflunomide Related Compound B RS	<a href="#">USP-1357056</a>
USP Leflunomide Related Compound C RS	<a href="#">USP-1357067</a>

#### MONOGRAPH 3

<b>LEFLUNOMIDE COMPOUNDED ORAL SUSPENSION</b> Official as of 01-Mar-2019	
USP Leflunomide RS	<a href="#">USP-1356960</a>

<b>PHARMACEUTICAL ANALYTICAL IMPURITIES* (PAI)</b>	
5-Methylisoxazole-4-Carboxylic Acid - <b>NEW</b>	<a href="#">USP-1A08740</a>
Fluvoxketone   <b>NEW</b>	<a href="#">USP-1A08580</a>

#### INCLUDED GENERAL CHAPTERS

<b>&lt;11&gt; USP REFERENCE STANDARDS</b> Official as of 01-Nov-2020
<b>&lt;197&gt; SPECTROSCOPIC IDENTIFICATION TESTS</b> Official as of 01-Sep-2021
<b>&lt;281&gt; RESIDUE ON IGNITION</b> Official as of 31-Dec-2012
<b>&lt;621&gt; CHROMATOGRAPHY</b> Official as of 01-Oct-2023
<b>&lt;711&gt; DISSOLUTION</b> Official as of 01-May-2023
<b>&lt;731&gt; LOSS ON DRYING</b> Official as of 01-Nov-2020

**<741> MELTING RANGE OR TEMPERATURE**  
Official as of 01-Aug-2018

**<791> PH**  
Official as of 01-Nov-2020

**<795> PHARMACEUTICAL COMPOUNDING—NONSTERILE PREPARATIONS**  
Official as of 01-Nov-2023

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

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

#### INCLUDED EXCIPIENTS

<b>MAGNESIUM STEARATE</b> Official as of 01-Aug-2016	
USP Palmitic Acid RS	<a href="#">USP-1492007</a>
USP Stearic Acid RS	<a href="#">USP-1621008</a>

**STERILE PURIFIED WATER**  
Official as of 01-May-2021

**TITANIUM DIOXIDE**  
Official as of 01-Jun-2023

<b>MICROCRYSTALLINE CELLULOSE</b> Official as of 01-Dec-2019	
USP Microcrystalline Cellulose RS	<a href="#">USP-1098388</a>

<b>LACTOSE MONOHYDRATE</b> Official as of 01-May-2020	
USP Dextrose RS	<a href="#">USP-1181302</a>
USP Fructose RS	<a href="#">USP-1286504</a>
USP Lactose Monohydrate RS	<a href="#">USP-1356701</a>
USP Sucrose RS	<a href="#">USP-1623637</a>

**SILICON DIOXIDE**  
Official as of 01-Jun-2023

**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.