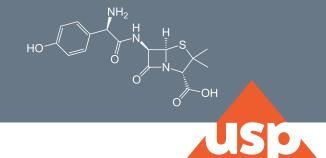
# **Amoxicillin**Quality Solutions

Category: Antibiotic



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

# Official and Proposed Documentary Standards and Associated Physical Materials

# **Authorized Distributor**

MONOGRAPH	
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AMOXICILLIN Official as of 01-May-2020	
USP Amoxicillin Related Compound A RS	<u>USP-1031514</u>
USP Amoxicillin RS	<u>USP-1031503</u>
USP Amoxicillin Related Compound D RS	<u>USP-1031547</u>

#### MONOGRAPH 2

AMOXICILLIN FOR INJECTABLE SUSPENSION Official as of 01-Nov-2023	
USP Amoxicillin RS	<u>USP-1031503</u>

#### MONOGRAPH 3

AMOXICILLIN FOR ORAL SUSPENSION Official as of 01-Aug-2013	
USP Amoxicillin RS	<u>USP-1031503</u>

#### MONOGRAPH 4

SUSPENSION Official as of 31-Dec-2012	
USP Amoxicillin RS	<u>USP-1031503</u>
LISP Clavulanate Lithium RS	USP-113///26

AMOXICILLIN AND CLAVULANATE POTASSIUM FOR ORAL

### MONOGRAPH 5

AMOXICILLIN AND CLAVULANIC ACID EXTENDED-RELEASE TABLETS Official as of 01-Aug-2016	
USP Amoxicillin RS	<u>USP-1031503</u>
USP Clavulanate Lithium RS	<u>USP-1134426</u>
USP Amoxicillin Related Compound D RS	<u>USP-1031547</u>

#### MONOGRAPH 6

AMOXICILLIN BOLUSES Official as of 01-Dec-2023	
USP Amoxicillin RS	<u>USP-1031503</u>

#### MONOGRAPH 7

AMOXICILLIN ORAL SUSPENSION Official as of 01-Feb-2024	
USP Amoxicillin RS	<u>USP-1031503</u>

#### MONOGRAPH 8

AMOXICILLIN AND CLAVULANATE POTASSIUM TABLETS Official as of 31-Dec-2012	
USP Clavulanate Lithium RS	<u>USP-1134426</u>
USP Amoxicillin RS	<u>USP-1031503</u>

#### MONOGRAPH 9

AMOXICILLIN CAPSULES Official as of 01-Nov-2021	
USP Amoxicillin RS	<u>USP-1031503</u>

#### **MONOGRAPH 10**

AMOXICILLIN TABLETS FOR ORAL SUSPENSION Official as of 31-Dec-2012	
USP Amoxicillin RS <u>USP-1031503</u>	

#### **MONOGRAPH 11**

AMOXICILLIN TABLETS Official as of 01-Nov-2021	
USP Amoxicillin RS	<u>USP-1031503</u>

# MONOGRAPH 12

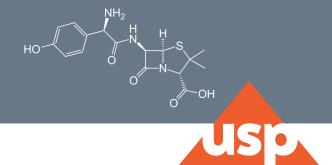
AMOXICILLIN INTRAMAMMARY INFUSION Official as of 01-Dec-2023		
USP Amoxicillin RS	<u>USP-1031503</u>	

**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.



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# Official and Proposed Documentary Standards and Associated Physical Materials

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PHARMACEUTICAL ANALYTICAL IMPURITYIES* (PAI)		
Amoxicilloic Amoxilloic Acid Dimers 1, 2, 3, and 4	<u>USP-1A00330</u>	
Amoxicilloic Acid Dimers 1 and 2	<u>USP-1A00490</u>	
Bis(2-Methylaminoethyl) Ether	<u>USP-1A01350</u>	
Tert-Octylamine	<u>USP-1A01310</u>	
Bis(Dimethylaminoethyl) Ether Dihydrochloride	<u>USP-1A01300</u>	
Dimethylethylamine Hydrochloride	<u>USP-1A01320</u>	
Bis(2-Methylaminoethyl) Ether Hydrochloride	<u>USP-1A01330</u>	
2,3-Dimethyl-2,3 Butanediamine Dihydrochloride	<u>USP-1A01340</u>	
Temed Dihydrochloride	<u>USP-1A01290</u>	
Tetramethyl Ethylene Diamine	<u>USP-1A00400</u>	
Pyrazinediethanol Propionic Acid	<u>USP-1A00380</u>	
Pyrazinediethanol	<u>USP-1A00450</u>	
Pyrrolic Acid Derivative	<u>USP-1A00460</u>	
Ethylpyrazinediethanol	<u>USP-1A00360</u>	

### INCLUDED GENERAL CHAPTERS

# <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 SPECIFIED 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 <u>USP-1235503</u>

# <197> SPECTROSCOPIC IDENTIFICATION TESTS

Official as of 01-Sept-2021

<201> THIN-LAYER CHROMATOGRAPHIC IDENTIFICATION TEST Official as of 01-May-2020		
USP Bacitracin Zinc RS	<u>USP-1048007</u>	
USP Neomycin Sulfate RS	<u>USP-1458009</u>	
USP Polymyxin B Sulfate RS	<u>USP-1547007</u>	

#### <223> DIMETHYLANILINE

Official as of 31-Dec-2012

# <425> IODOMETRIC ASSAY—ANTIBIOTICS

Official as of 31-Dec-2012

#### <621> CHROMATOGRAPHY

Official as of 01-Oct-2023

#### <659> PACKAGING AND STORAGE REQUIREMENTS

Official as of 01-Apr-2021

# <695> CRYSTALLINITY

Official as of 31-Dec-2012

#### <698> DELIVERABLE VOLUME

Official as of 01-Dec-2020

# <701> DISINTEGRATION

Official as of O1-May-2020

# <711> DISSOLUTION

Official as of 01-May-2023

USP Dissolution Performance Verification Standard-Prednisone RS

USP-1222818

### <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

\* 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.

# **Amoxicillin**Quality Solutions

Category: Antibiotic



**Authorized Distributor** 

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Official and Proposed Documentary Standards and Associated Physical Materials

INCLUDED	<b>EXCIPIENTS</b>
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MAGNESIUM STEARATE Official as of 01-Aug-2016	
USP Palmitic Acid RS	<u>USP-1492007</u>
USP Stearic Acid RS	<u>USP-1621008</u>
SILICON DIOXIDE Official as of 01-Jun-2023	
MICROCRYSTALLINE CELLULOSE	

USP Microcrystalline Cellulose RS

USP-1098388

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

TALC
Official as of 01-May-2022

# **HYPROMELLOSE**Official as of 01-May-2023