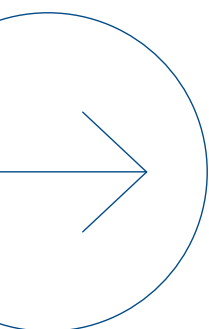
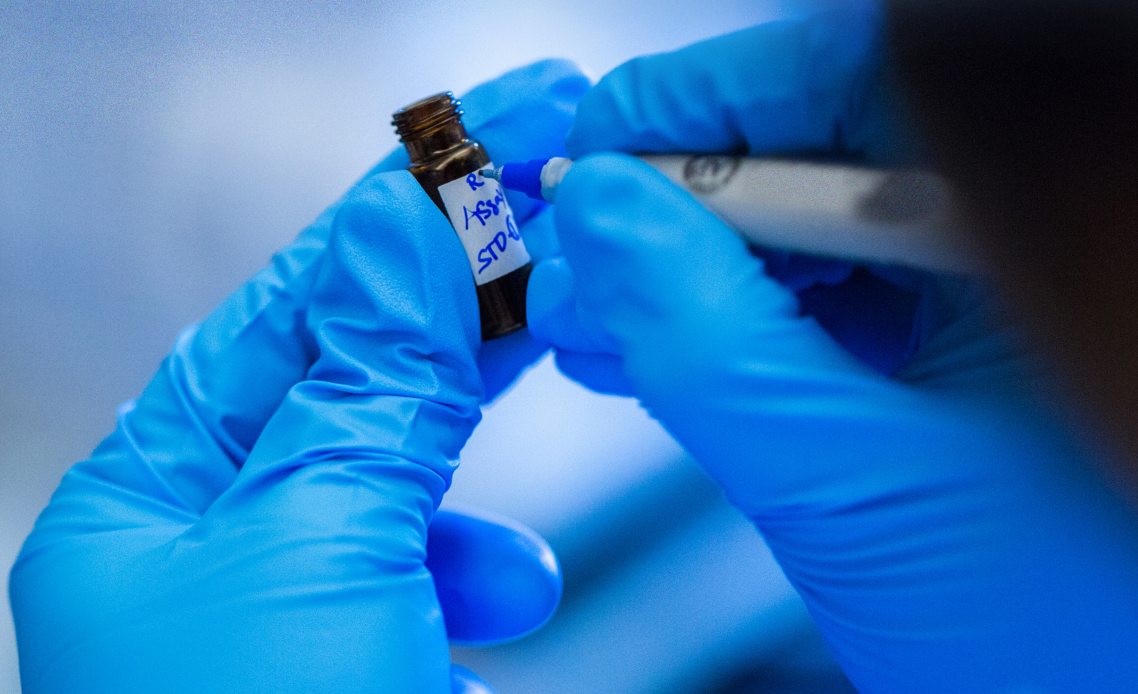


June 2023

Antibiotics-related USP-NF Documentary Standards and USP Reference Standards



Below are the antibiotic-related monographs and chapters published and official in the United States Pharmacopeia-National Formulary (USP-NF) that support the quality of antibiotic medicines. We also offer Reference Standards, highly characterized physical specimens that are suitable for use in compendial testing. These reference standards, in combination with their associated documentary standard(s), help ensure the identity, strength, quality, and purity of antibiotic medicines.

Support development of new antibiotic standards

USP-NF Documentary Standard	Related USP Reference Standards
<i>USP General Chapters</i>	
Qualification of Raw Materials	
<426> Histamine Test Methods	Histamine Dihydrochloride
<1083> Supplier Qualification	
<1149> Guidelines for Assessing and Controlling the Physical Stability of Chemical and Biological Pharmaceutical Raw Materials, Intermediates, and Dosage Forms	
Media Preparation and Sterilization	
<1229> Sterilization of Compendial Articles	
Drug Substance Testing	
<81> Antibiotics—Microbial Assays	
<197> Spectrophotometric Identification Tests	
<425> Iodometric Assay— Antibiotics	
<1223.1> Validation of Alternative Methods to Antibiotic Microbial Assays	
<621> Chromatography	
<85> Bacterial Endotoxins Test	Endotoxin
<695> Crystallinity	
<791> pH	
<921> Water Determination	Sodium Tartrate Dihydrate

To order or for more information:

Visit <https://www.usp.org/biologics/reference-standards> to order, visit <https://www.usp.org/biologics/reference-standards/igg> to learn more

Support development of new antibiotic standards

USP-NF Documentary Standard	Related USP Reference Standards
Formulation & Drug Product Testing	
<1> Injections and Implanted Drug Products	
<71> Sterility Tests	
<788> Particulate Matter in Injections	Particle Count Set
<905> Uniformity of Dosage Units	
<711> Dissolution	Dissolution Performance Verification Standard - Prednisone
<1080> Bulk Pharmaceutical Excipients—Certificate of Analysis	
Packaging & Distribution	
<7> Labeling	
<659> Packaging and Storage Requirements	
<1079> Risks and Mitigation Strategies for the Storage and Transportation of Finished Drug Products	

Featured Antibiotic Families

Antibiotic family	API	Impurity	System Suitability / Other Compendial Uses
Amoxicillin	Amoxicillin	Amoxicillin Related Compound: A/C/D/F/G/H/I/J/D and E	Clavulanate Lithium
		Clavam-2-carboxylate Potassium	
Amphotericin B	Amphotericin B		
Azithromycin	Azithromycin	Azithromycin Related Compound: F/H	
		Desosaminylazithromycin	
		N-Demethylazithromycin	
		3'-N-Demethyl-3'-N-[(4-methyl-phenyl)sulfonyl]azithromycin	
		Azaerythromycin A	
		Azithromycin N-Oxide	

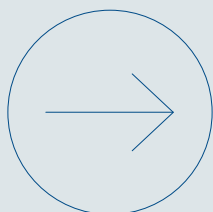
Featured Antibiotic Families

Antibiotic family	API	Impurity	System Suitability / Other Compendial Uses
Bacitracin Zinc	Bacitracin Zinc		
Bleomycin Sulfate	Bleomycin Sulfate		
Capreomycin Sulfate	Capreomycin Sulfate		
Chlortetracycline Hydrochloride	Chlortetracycline Hydrochloride		
Ciprofloxacin	Ciprofloxacin	Ciprofloxacin Related Compound A	
Ciprofloxacin Hydrochloride	Ciprofloxacin Hydrochloride	Ciprofloxacin Ethylenediamine Analog	
		Ciprofloxacin Formamide	
		Fluoroquinolonic Acid	
Clarithromycin	Clarithromycin	Clarithromycin Related Compound A	Clarithromycin Identity
Clindamycin Hydrochloride	Clindamycin Hydrochloride	Clindamycin 2,3-Dipalmitate	Clindamycin Phosphate System Suitability
Clindamycin Phosphate	Clindamycin Phosphate	Clindamycin 3-Phosphate	
Clindamycin Palmitate Hydrochloride	Clindamycin Palmitate Hydrochloride		
	Lincomycin Hydrochloride		
Colistimethate Sodium	Colistimethate Sodium		
Colistin sulfate	Colistin sulfate		
Dihydrostreptomycin Sulfate	Dihydrostreptomycin Sulfate		
Erythromycin	Erythromycin		Erythromycin System Suitability Mixture
Erythromycin Ethylsuccinate	Erythromycin Ethylsuccinate		
Erythromycin Lactobionate for injection	Erythromycin Lactobionate		
Gentamicin Sulfate	Gentamicin Sulfate		
Gramicidin	Gramicidin		
Levofloxacin	Levofloxacin	Levofloxacin Related Compound: A / C / B	
	Ofloxacin	R-Ofloxacin	
Moxifloxacin Hydrochloride	Moxifloxacin Hydrochloride	Moxifloxacin Related Compound: A / F / G / B / C / D / E	

Featured Antibiotic Families

Antibiotic family	API	Impurity	System Suitability / Other Compendial Uses
Neomycin Sulfate	Neomycin Sulfate Neomycin B		Neomycin Sulfate System Suitability
Novobiocin Sodium	Novobiocin		
Nystatin	Nystatin		
Paromomycin Sulfate	Paromomycin Sulfate		
Penicillin G Potassium	Penicillin G Potassium		
Polymyxin B Sulfate	Polymyxin B Sulfate		
Sisomicin Sulfate	Sisomicin Sulfate		
Thiostrepton	Thiostrepton		
Tobramycin	Tobramycin	Kanamycin Sulfate	
Tylosin	Tylosin		
Tylosin Tartrate	Tylosin Tartrate		
Vancomycin Hydrochloride	Vancomycin Hydrochloride		

For additional antibiotics, including associated documentary standards, antibiotic active pharmaceutical ingredients (APIs), antibiotic impurities, antibiotic system suitability, pharmaceutical analytical impurities (PAIs), and products for other compendial and non-compendial uses, please [click here](#).



About USP

USP is an independent scientific organization that collaborates with the world's top experts in health and science to develop quality resources and standards for medicines, dietary supplements, and food ingredients. Through our resources, standards, advocacy and education, USP helps increase the availability of quality medicines, supplements and foods for billions of people worldwide.