

Compendial Approvals for USPNF 2023 ISSUE 1

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Category	Monograph Title	Monograph Section	Scientific Liaison
New	DESCRIPTION AND SOLUBILITY PF 46(3) Pg. ONLINE	E/Emtricitabine	Robyn Fales
Revision	<126>SOMATROPIN BIOIDENTITY TESTS PF 47(4) Pg. ONLINE	Revision	Rebecca Potts
Revision	<345> ASSAY FOR CITRIC ACID/CITRATE AND PHOSPHATE PF 47(6) Pg. ONLINE	Revision	Edmond Biba
Revision	<432> DETERMINATION OF ZETA POTENTIAL BY ELECTROPHORETIC LIGHT SCATTERING PF 47(5) Pg. ONLINE	Revision	Edmond Biba
New	<1042> CELL BANKING PRACTICES FOR RECOMBINANT BIOLOGICS PF 47(1) Pg. ONLINE	New	Rebecca Potts
Revision	ACETYLTRIETHYL CITRATE PF 46(6) Pg. ONLINE	DEFINITION, IDENTIFICATION/B. Chromatographic Identity, ASSAY/Procedure, ASSAY, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Specific Gravity (841), SPECIFIC TESTS/Refractive Index (831), SPECIFIC TESTS/Acidity, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Galina Holloway
Revision	ALBUTEROL TABLETS PF 47(4) Pg. ONLINE	IDENTIFICATION/A., IDENTIFICATION/B. Identification Tests—General (191), Sulfate, ASSAY/Procedure, PERFORMANCE TESTS/Dissolution (711), IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Shankari Shivaprasad
Revision	ALGINIC ACID PF 47(4) Pg. ONLINE	IMPURITIES/Arsenic (211), Procedures, Method II, IMPURITIES/Lead (251), IMPURITIES/Limit of Lead and Arsenic	Devendra Vasant Chavan
Revision	ALOE PF 47(5) Pg. ONLINE	Revision	Nam-Cheol Kim
Revision	AMPHETAMINE SULFATE TABLETS PF 47(5) Pg. ONLINE	Revision	Shankari Shivaprasad
New	ARTEMETHER PF 47(5) Pg. ONLINE	New	Christine Hiemer
Revision	ATOMOXETINE HYDROCHLORIDE PF 47(4) Pg. ONLINE	CHEMICAL INFORMATION, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Shankari Shivaprasad
Revision	BAEL TREE FRUIT PF 47(3) Pg. ONLINE	DEFINITION, IDENTIFICATION/A. HPTLC for Articles of Botanical Origin (203), IDENTIFICATION/B. HPLC, COMPOSITION/Content of Marmelosin, CONTAMINANTS/Articles of Botanical Origin (561), Limits of Elemental Impurities, CONTAMINANTS/Articles of Botanical Origin (561), Pesticide Residue Analysis, CONTAMINANTS/Microbial Enumeration Tests (2021), CONTAMINANTS/Absence of Specified Microorganisms (2022), Test Procedures, Test for Absence of Salmonella Species and Test for Absence of Escherichia coli, SPECIFIC TESTS/Limit of Egeline, Method 1, SPECIFIC TESTS/Limit of Egeline, Method 2, SPECIFIC TESTS/Botanical Characteristics, SPECIFIC TESTS/Articles of Botanical Origin (561), Methods of Analysis, Foreign Organic Matter, SPECIFIC TESTS/Articles of Botanical Origin (561), Methods of Analysis, Alcohol-Soluble Extractives, Method 1, SPECIFIC TESTS/Articles of Botanical Origin (561), Methods of Analysis, Water-Soluble Extractives, Method 2, SPECIFIC TESTS/Loss on Drying (731), SPECIFIC TESTS/Articles of Botanical Origin (561), Methods of Analysis, Total Ash, SPECIFIC TESTS/Articles of Botanical Origin (561), Methods of Analysis, Acid-Insoluble Ash, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Nam-Cheol Kim
Revision	BAEL TREE FRUIT DRY EXTRACT PF 47(3) Pg. ONLINE	DEFINITION, IDENTIFICATION/A. HPTLC for Articles of Botanical Origin (203), IDENTIFICATION/B. HPLC, COMPOSITION/Content of Marmelosin, CONTAMINANTS/Articles of Botanical Origin (561), Limits of Elemental Impurities, CONTAMINANTS/Articles of Botanical Origin (561), Pesticide Residue Analysis, CONTAMINANTS/Microbial Enumeration Tests (2021), CONTAMINANTS/Absence of Specified Microorganisms (2022), Test Procedures, Test for Absence of Salmonella Species and Test for Absence of Escherichia coli, SPECIFIC TESTS/Limit of Egeline, Method 1, SPECIFIC TESTS/Limit of Egeline, Method 2, SPECIFIC TESTS/Loss on Drying (731), ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Nam-Cheol Kim

		DEFINITION, IDENTIFICATION/A. HPLC for Articles of Botanical Origin (203), IDENTIFICATION/B. HPLC, COMPOSITION/Content of Marmelosin, CONTAMINANTS/Articles of Botanical Origin (561), Limits of Elemental Impurities, CONTAMINANTS/Articles of Botanical Origin (561), Pesticide Residue Analysis, CONTAMINANTS/Microbial Enumeration Tests (2021), CONTAMINANTS/Absence of Specified Microorganisms (2022), Test Procedures, Test for Absence of Salmonella Species and Test for Absence of Escherichia coli, SPECIFIC TESTS/Limit of Egeline, Method 1, SPECIFIC TESTS/Limit of Egeline, Method 2, SPECIFIC TESTS/Botanical Characteristics, SPECIFIC TESTS/Articles of Botanical Origin (561), Methods of Analysis, Alcohol-Soluble Extractives, Method 1, SPECIFIC TESTS/Articles of Botanical Origin (561), Methods of Analysis, Water-Soluble Extractives, Method 2, SPECIFIC TESTS/Loss on Drying (731), SPECIFIC TESTS/Articles of Botanical Origin (561), Methods of Analysis, Total Ash, SPECIFIC TESTS/Articles of Botanical Origin (561), Methods of Analysis, Acid-Insoluble Ash, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Nam-Cheol Kim
Revision	BAEL TREE FRUIT POWDER PF 47(3) Pg. ONLINE		
Revision	BIFIDOBACTERIUM ANIMALIS SUBSP. LACTIS PF 47(5) Pg. ONLINE	Revision	Binu Koshy
		CHEMICAL INFORMATION, DEFINITION, IDENTIFICATION/A. Spectroscopic Identification Tests (197), Infrared Spectroscopy, IDENTIFICATION/B. Chromatographic Identity, ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Loss on Drying (731), ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Peng Zhang
Revision	CALCIUM PROPIONATE PF 46(6) Pg. ONLINE		
		DEFINITION, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Limit of Cyclobutane Dicarboxylic Acid, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Bacterial Endotoxins Test (85), SPECIFIC TESTS/Particulate Matter in Injections (788), SPECIFIC TESTS/pH (791), SPECIFIC TESTS/Sterility Tests (71), SPECIFIC TESTS/Other requirements, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Christine Hiemer
New	CARBOPLATIN INJECTION PF 46(5) Pg. ONLINE	IDENTIFICATION/A. Spectroscopic Identification Tests (197), Infrared Spectroscopy, IDENTIFICATION/B. Spectroscopic Identification Tests (197), Ultraviolet-Visible Spectroscopy, IDENTIFICATION/B., IDENTIFICATION/C. Identification Tests—General (191) Chemical Identification Tests, Chloride, ASSAY/Procedure, IMPURITIES/Arsenic (211), Procedures, Method II, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Christine Hiemer
Revision	CARTEOLOL HYDROCHLORIDE PF 46(5) Pg. ONLINE		
		DEFINITION, IDENTIFICATION/B. Chromatographic Identity, ASSAY/Content of Palmitic Acid, ASSAY/Procedure, IMPURITIES/Limit of Fatty Alcohols, Fatty Acids, and Fatty esters, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	SanthiKumar Saladi
Revision	CETYL PALMITATE PF 46(6) Pg. ONLINE	Revision	Christine Hiemer
Revision	CHLOROTHALIDONE PF 47(5) Pg. ONLINE	Revision, Revision	Christine Hiemer
Revision	CHLOROTHALIDONE TABLETS PF 47(5) Pg. ONLINE	Revision	Natalia Davydova
Revision	CURCUMINOIDS CAPSULES PF 47(5) Pg. ONLINE	Revision	Natalia Davydova
Revision	CURCUMINOIDS TABLETS PF 47(5) Pg. ONLINE	Revision	Christine Hiemer
Revision	CYCLOPHOSPHAMIDE CAPSULES PF 47(5) Pg. ONLINE	Revision	Christine Hiemer
Omission	DEMECLOCYCLINE PF 47(6) Pg. ONLINE	Entire document	Christine Hiemer
		CHEMICAL INFORMATION, DEFINITION, IDENTIFICATION/A. Spectroscopic Identification Tests (197), Infrared Spectroscopy, IDENTIFICATION/B. Melting Range or Temperature (741), ASSAY/Dextrose Equivalent, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	SanthiKumar Saladi
Revision	DEXTRATES PF 47(1) Pg. ONLINE		
		IDENTIFICATION/B. Sodium, IDENTIFICATION/C. Identification Tests—General (191), Chemical Identification Tests, Sodium(191)and Chloride, ASSAY/Dextrose, ASSAY/Sodium Chloride, SPECIFIC TESTS/pH (791), ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling	Mary Kolec
Revision	DEXTROSE AND SODIUM CHLORIDE INJECTION PF 47(2) Pg. ONLINE	DEFINITION, IDENTIFICATION/A., IDENTIFICATION/B., IDENTIFICATION/C., IDENTIFICATION/D., ASSAY/Procedure 1: Dutasteride, ASSAY/Procedure 2: Tamsulosin Hydrochloride, OTHER COMPONENTS/Content of Butylated Hydroxytoluene (if present in the product), PERFORMANCE TESTS/Dissolution (711), PERFORMANCE TESTS/Uniformity of Dosage Units (905), IMPURITIES/Organic Impurities, Procedure 1: Dutasteride, IMPURITIES/Organic Impurities, Procedure 2: Tamsulosin Hydrochloride, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Christine Hiemer
New	DUTASTERIDE AND TAMSULOSIN HYDROCHLORIDE CAPSULES PF 46(5) Pg. ONLINE	CHEMICAL INFORMATION, DEFINITION, IDENTIFICATION/A. Spectroscopic Identification Tests (197), Infrared Spectroscopy, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Residue on Ignition (281), IMPURITIES/Organic Impurities, IMPURITIES/Enantiomeric and Diastereomeric Purity, SPECIFIC TESTS/Loss on Drying (731), ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Christine Hiemer
New	EMTRICITABINE PF 46(3) Pg. ONLINE		

		DEFINITION, IDENTIFICATION/A. Spectroscopic Identification Tests (197), Infrared Spectroscopy, IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution (711), PERFORMANCE TESTS/Uniformity of Dosage Units (905), IMPURITIES/Organic Impurities: Early-Eluting Impurities, IMPURITIES/Organic Impurities: Late-Eluting Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Christine Hiemer
New	FOSAMPRENAVIR CALCIUM TABLETS PF 46(4) Pg. ONLINE	G52	Margareth Marques
New	G52 PF 47(5) Pg. ONLINE	G53	Margareth Marques
New	G53 PF 47(6) Pg. ONLINE		Christine Hiemer
Omission	LINDANE LOTION PF 47(6) Pg. ONLINE	Entire document DEFINITION, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution 1(711), PERFORMANCE TESTS/Dissolution 2 (711), PERFORMANCE TESTS/Uniformity of Dosage Units (905), IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Christine Hiemer
New	LINEZOLID TABLETS PF 46(3) Pg. ONLINE	DEFINITION, IMPURITIES/Limit of Benzo[a]pyrene, SPECIFIC TESTS/Fats and Fixed Oils, (401), Procedures, Fatty Acid Composition	Sandeep Putty
Revision	CONJUGATED LINOLEIC ACIDS-FREE FATTY ACIDS PF 47(3) Pg. ONLINE	ADDITIONAL REQUIREMENTS/Packaging and Storage	SanthiKumar Saladi
Revision	MALTODEXTRIN PF 46(6) Pg. ONLINE	Revision	Christine Hiemer
Revision	MANGANESE SULFATE INJECTION PF 47(5) Pg. ONLINE	CHEMICAL INFORMATION, IDENTIFICATION/B. Spectroscopic Identification Tests (197), Ultraviolet-Visible Spectroscopy, IDENTIFICATION/C. Spectroscopic Identification Tests (197), Ultraviolet-Visible Spectroscopy, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Limit of Copper, IMPURITIES/Organic Impurities	Christine Hiemer
Revision	MECLOFENAMATE SODIUM PF 46(4) Pg. ONLINE	Revision	Mingyan Chu
Revision	Methanol PF 47(5) Pg. ONLINE	Bromocresol Purple Sodium Salt TS	Mingyan Chu
New	BROMOCRESOL PURPLE SODIUM SALT TS PF 47(6) Pg. ONLINE	DEFINITION, ASSAY/Procedure, IMPURITIES/Limit of Beta Alanine, SPECIFIC TESTS/Particulate Matter in Injections (788), SPECIFIC TESTS/Bacterial Endotoxins Test (85), ADDITIONAL REQUIREMENTS/USP Reference standards (11)	Christine Hiemer
Revision	PAMIDRONATE DISODIUM FOR INJECTION PF 47(4) Pg. ONLINE	25% Phosphoric Acid TS	Margareth Marques
New	25 PERCENT PHOSPHORIC ACID TS PF 47(5) Pg. ONLINE	IDENTIFICATION/F. Chromatographic Identity, ASSAY/Procedure, IMPURITIES/Limit of Nickel, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Devendra Vasant Chavan
Revision	HYDROGENATED POLYDEXTRROSE PF 46(6) Pg. ONLINE	Revision	Peng Zhang
Revision	POLYPROPYLENE GLYCOL 11 STEARYL ETHER PF 47(5) Pg. ONLINE	Revision	Devendra Vasant Chavan
Revision	POLYVINYL ALCOHOL PF 47(5) Pg. ONLINE	IMPURITIES/Arsenic (211), Procedures, Method II, IMPURITIES/Lead (251), IMPURITIES/Limit of Lead and Arsenic	Devendra Vasant Chavan
Revision	POTASSIUM ALGINATE PF 47(4) Pg. ONLINE	IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution (711), IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Christine Hiemer
Revision	QUINAPRIL AND HYDROCHLOROTHIAZIDE TABLETS PF 46(3) Pg. ONLINE	New	Christine Hiemer
New	RISEDRONATE SODIUM DELAYED-RELEASE TABLETS PF 47(5) Pg. ONLINE	DEFINITION, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution (711), PERFORMANCE TESTS/Uniformity of Dosage Units (905), IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Christine Hiemer
New	RIVAROXABAN TABLETS PF 46(3) Pg. ONLINE	S13	Christine Hiemer
New	S13 PF 47(6) Pg. ONLINE	ASSAY/Alginates, ASSAY/Procedure, IMPURITIES/Arsenic (211), Procedures, Method II, IMPURITIES/Lead (251), IMPURITIES/Limit of Lead and Arsenic	Margareth Marques
Revision	SODIUM ALGINATE PF 47(4) Pg. ONLINE	0.1 N Sodium Hydroxide VS	Devendra Vasant Chavan
Revision	0.1 N SODIUM HYDROXIDE VS PF 47(6) Pg. ONLINE	0.025 N Sodium Hydroxide VS	Mingyan Chu
Revision	0.025 N SODIUM HYDROXIDE VS PF 47(6) Pg. ONLINE	0.01 N Sodium Hydroxide VS	Mingyan Chu
Revision	0.01 N SODIUM HYDROXIDE VS PF 47(6) Pg. ONLINE	0.1 N Alcoholic Sodium Hydroxide VS	Mingyan Chu
Revision	0.1 N Alcoholic Sodium Hydroxide VS PF 47(6) Pg. ONLINE	1 N Sodium Hydroxide VS	Mingyan Chu
Revision	1 N Sodium Hydroxide VS PF 47(6) Pg. ONLINE	0.5 N Sodium Methoxide in Methanol VS	Mingyan Chu
Revision	0.5 N Sodium Methoxide in Methanol VS PF 47(5) Pg. ONLINE	0.1 N Sodium Methoxide in Toluene VS	Mingyan Chu
Revision	0.1 N Sodium Methoxide in Toluene VS PF 47(5) Pg. ONLINE	Revision	Galina Holloway
Revision	SUGAR SPHERES PF 47(6) Pg. ONLINE	Tetrahydrofuran,	Margareth Marques
Revision	Tetrahydrofuran PF 47(5) Pg. ONLINE	New	Christine Hiemer
New	TINIDAZOLE TABLETS PF 47(6) Pg. ONLINE	Revision	Shankari Shivaprasad
Revision	TRAZODONE HYDROCHLORIDE TABLETS PF 47(5) Pg. ONLINE	DEFINITION, IDENTIFICATION/B. Chromatographic Identity, ASSAY/Procedure, ASSAY, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Specific Gravity (841), SPECIFIC TESTS/Refractive Index (831), ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Galina Holloway
Revision	TRIETHYL CITRATE PF 46(6) Pg. ONLINE		

Revision	VALACYCLOVIR HYDROCHLORIDE PF 47(3) Pg. ONLINE	<p>IDENTIFICATION/C. Identification Tests—General (191), Chemical Identification Tests, Chloride, ASSAY/Procedure, IMPURITIES/Limit of Palladium (if present), IMPURITIES/Organic Impurities, Procedure 1 (for related compounds E, F, and G), IMPURITIES/Organic Impurities, Procedure 2, IMPURITIES/Organic Impurities, Procedure 3, SPECIFIC TEST/Water Determination, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)</p>	Christine Hiemer
Revision	VALGANCICLOVIR HYDROCHLORIDE PF 47(4) Pg. ONLINE	<p>IDENTIFICATION/B. Spectroscopic Identification Tests (197), Ultraviolet-Visible Spectroscopy, IDENTIFICATION/C. Identification Tests—General (191), Chloride, ASSAY/Procedure, IMPURITIES/Residue on Ignition (281), IMPURITIES/Limit of Isopropyl Alcohol, IMPURITIES/Organic Impurities, IMPURITIES/Limit of Ganciclovir Mono-N-methyl Valinate, IMPURITIES/Enantiomeric Purity of Valganciclovir, SPECIFIC TESTS/Diastereomer Ratio, SPECIFIC TESTS/Water Determination (921), Method 1, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)</p>	Christine Hiemer
Revision	VALSARTAN TABLETS PF 47(5) Pg. ONLINE	Revision	Christine Hiemer