

**Compendial Approvals for USPNF 2023 ISSUE 3**

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Category	Monograph Title	Monograph Section	Scientific Liaison
Revision	EXCIPIENTS (USP and NF), LISTED BY CATEGORY PF 48(3) Pg. ONLINE	{Coating Agent} Candelilla wax, {Colloid Stabilizing Agent} Candelilla Wax, {Emollient} Candelilla Wax, {Emulsifying Agent} Candelilla Wax, {Film-Forming Agent} Candelilla Wax, {Ointment Base} Candelilla Wax, {Stiffening Agent} Candelilla Wax, {Vehicle} Candelilla Wax	<a href="#">Peng Zhang</a>
Revision	DESCRIPTION AND SOLUBILITY PF 48(1) Pg. ONLINE	C/Clobazam, G/Guanfacine Hydrochloride, C/Candelilla Wax, D/Dimethyl Fumarate, C/Cevimeline Hydrochloride	<a href="#">Yanyin Yang</a>
New	<314> MOLECULAR WEIGHT DETERMINATION FOR COPOLYMERS CONTAINING ALKYL METHACRYLATE OR ALKYL ACRYLATE PF 47(5) Pg. ONLINE	New	<a href="#">Peng Zhang</a>
Revision	<581> VITAMIN D ASSAY PF 48(4) Pg. ONLINE	Revision	<a href="#">Natalia Davydova</a>
Revision	<670> AUXILIARY PACKAGING COMPONENTS PF 48(4) Pg. ONLINE	Revision	<a href="#">Desmond Hunt</a>
Revision	<831> REFRACTIVE INDEX PF 48(3) Pg. ONLINE	Revision	<a href="#">Mingyan Chu</a>
New	<901> DETECTION OF ASBESTOS IN PHARMACEUTICAL TALC PF 48(2) Pg. ONLINE	New	<a href="#">Jenny Liu</a>
Revision	<1079> RISKS AND MITIGATION STRATEGIES FOR THE STORAGE AND TRANSPORTATION OF FINISHED DRUG PRODUCTS PF 48(3) Pg. ONLINE	Revision	<a href="#">Desmond Hunt</a>
New	<1079.3> MONITORING DEVICES - TIME, TEMPERATURE, AND HUMIDITY PF 48(4) Pg. ONLINE	New	<a href="#">Desmond Hunt</a>
Revision	<1094> CAPSULES - DISSOLUTION TESTING AND RELATED QUALITY ATTRIBUTES PF 48(4) Pg. ONLINE	Revision	<a href="#">Margareth Marques</a>
Omission	<1118> MONITORING DEVICES--TIME, TEMPERATURE, AND HUMIDITY PF 48(4) Pg. ONLINE	Entire document	<a href="#">Desmond Hunt</a>
New	<1504> QUALITY ATTRIBUTES OF STARTING MATERIALS FOR THE CHEMICAL SYNTHESIS OF THERAPEUTIC PEPTIDES PF 48(1) Pg. ONLINE	New	<a href="#">Julie Zhang</a>
New	<1567> PYRROLIZIDINE ALKALOIDS AS CONTAMINANTS PF 48(1) Pg. ONLINE	New	<a href="#">Sandeep Putty</a>
Revision	<1604> PRESENTATION OF AERODYNAMIC PARTICLE SIZE DISTRIBUTION (APSD) MEASUREMENT DATA FOR ORALLY INHALED PRODUCTS PF 48(1) Pg. ONLINE	Revision	<a href="#">Kahkashan Zaidi</a>
Revision	<1724> SEMISOLID DRUG PRODUCTS - PERFORMANCE TESTS PF 48(3) Pg. ONLINE	Revision	<a href="#">Margareth Marques</a>
New	<1901> THEORY AND PRACTICE OF ASBESTOS DETECTION IN PHARMACEUTICAL TALC PF 48(2) Pg. ONLINE	New	<a href="#">Jenny Liu</a>
Revision	<1912> MEASUREMENT OF YIELD STRESS OF SEMISOLIDS PF 48(3) Pg. ONLINE	Revision	<a href="#">Antonio Hernandez-Cardoso</a>
New	ACETAZOLAMIDE EXTENDED-RELEASE CAPSULES PF 46(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), FOOTNOTES IMPURITIES/Organic Impurities, CHEMICAL INFORMATION, IDENTIFICATION/A. Spectroscopic Identification Tests (197), Infrared Spectroscopy, IDENTIFICATION/B.Thin-Layer Chromatographic Identification Test (201), ASSAY/Procedure, IMPURITIES/Ordinary Impurities (466), ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	<a href="#">Christine Hiemer</a>
Revision	BETAMETHASONE ACETATE PF 46(6) Pg. ONLINE	Revision	<a href="#">Shankari Shivaprasad</a>
New	BIVALIRUDIN PF 48(2) Pg. ONLINE	Revision	<a href="#">Julie Zhang</a>
New	BIVALIRUDIN FOR INJECTION PF 48(2) Pg. ONLINE	Revision	<a href="#">Julie Zhang</a>
Revision	Bromelain PF 48(4) Pg. ONLINE	Bromelain	<a href="#">Margareth Marques</a>
New	BROMELAIN PF 47(6) Pg. ONLINE	New, New	<a href="#">Maria Monagas</a>
Revision	CALCIUM PANTOTHENATE PF 48(3) Pg. ONLINE	Revision	<a href="#">Natalia Davydova</a>
Revision	CANDELILLA WAX PF 48(3) Pg. ONLINE	Revision	<a href="#">Peng Zhang</a>
Revision	CARBAMAZEPINE PF 48(2) Pg. ONLINE	Revision	<a href="#">Shankari Shivaprasad</a>
Revision	CEFOPERAZONE SODIUM PF 48(3) Pg. ONLINE	Revision	<a href="#">Christine Hiemer</a>
Revision	CETOSTEARYL ALCOHOL PF 48(4) Pg. ONLINE	Revision	<a href="#">SanthiKumar Saladi</a>
New	CISPLATIN INJECTION PF 46(5) Pg. ONLINE	DEFINITION, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, 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)	<a href="#">Christine Hiemer</a>
New	CLOBAZAM PF 48(1) Pg. ONLINE	New	<a href="#">Shankari Shivaprasad</a>
New	CRANBERRY FRUIT JUICE DRY EXTRACT PF 48(3) Pg. ONLINE	New	<a href="#">Maria Monagas</a>

		DEFINITION, IDENTIFICATION/B. HPLC Profile of Botanical Origin (203), IDENTIFICATION/B. HPLC Profile of Flavonoids, STRENGTH/Content of Total Proanthocyanidins, PERFORMANCE TESTS/Disintegration and Dissolution (2040), Disintegration, PERFORMANCE TESTS/Weight Variation (2091), 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, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	
New	CRANBERRY FRUIT JUICE DRY EXTRACT CAPSULES PF 47(3) Pg. ONLINE		<a href="#">Maria Monagas</a>
Revision	CROMOLYN SODIUM PF 48(3) Pg. ONLINE	Revision	<a href="#">Shankari Shivaprasad</a>
Revision	CYANOCOBALAMIN PF 48(4) Pg. ONLINE	Revision	<a href="#">Natalia Davydova</a>
Revision	DALTEPARIN SODIUM PF 48(3) Pg. ONLINE	Revision	<a href="#">Hangsik Moon</a>
		CHEMICAL INFORMATION, DEFINITION, IDENTIFICATION/A. Spectroscopic Identification Tests (197), Infrared Spectroscopy, IDENTIFICATION/B., ASSAY/Procedure, OTHER COMPONENTS/Content of Propanediol, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Water Determination (921), Method I, Method Ic, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	
New	DAPAGLIFLOZIN PROPANEDIOL PF 47(4) Pg. ONLINE		<a href="#">Christine Hiemer</a>
New	DIMETHYL FUMARATE PF 47(5) Pg. ONLINE	New	<a href="#">Shankari Shivaprasad</a>
New	DIMETHYL FUMARATE DELAYED-RELEASE CAPSULES PF 47(5) Pg. ONLINE	New	<a href="#">Shankari Shivaprasad</a>
Revision	SODIUM FLUORIDE F 18 INJECTION PF 48(4) Pg. ONLINE	Revision	<a href="#">Shankari Shivaprasad</a>
Revision	FLURBIPROFEN PF 48(3) Pg. ONLINE	Revision	<a href="#">Christine Hiemer</a>
Revision	FLURBIPROFEN TABLETS PF 48(3) Pg. ONLINE	Revision	<a href="#">Christine Hiemer</a>
New	GABAPENTIN COMPOUNDED CREAM PF 47(5) Pg. ONLINE	New	<a href="#">Selma Mitiche</a>
New	GAMMA-DECALACTONE PF 48(3) Pg. ONLINE	Gamma-Decalactone	<a href="#">Margareth Marques</a>
Revision	GLUCAGON PF 48(2) Pg. ONLINE	Revision	<a href="#">Julie Zhang</a>
		DEFINITION, SPECIFIC TESTS/Optical Rotation (/81S), Procedures, Specific Rotation, SPECIFIC TESTS/Water Determination (921), Method I, Method Ia, ASSAY/Procedure	
Revision	L-ALPHA-GLYCERYLPHOSPHORYLCHOLINE PF 47(3) Pg. ONLINE		<a href="#">Fatkhulla Tadjimukhamedov</a>
New	GLYCOLIDE PF 48(3) Pg. ONLINE	Glycolide	<a href="#">Margareth Marques</a>
Revision	GRAMICIDIN PF 48(3) Pg. ONLINE	Revision	<a href="#">Julie Zhang</a>
Revision	Guanine Hydrochloride PF 48(4) Pg. ONLINE	Guanine Hydrochloride,	<a href="#">Margareth Marques</a>
New	INOSITOL NIACINATE PF 48(2) Pg. ONLINE	New	<a href="#">Sandeep Putty</a>
Revision	ISOPROPYL ALCOHOL PF 48(3) Pg. ONLINE	Revision, Revision	<a href="#">Galina Holloway</a>
New	DL-LACTIDE PF 48(3) Pg. ONLINE	DL-Lactide	<a href="#">Margareth Marques</a>
Revision	LACTOBACILLUS REUTERI PF 48(3) Pg. ONLINE	Revision	<a href="#">Binu Koshy</a>
Revision	LACTOBACILLUS RHAMNOSUS PF 48(3) Pg. ONLINE	Revision	<a href="#">Maria Monagas</a>
Revision	Methylbenzothiazolone Hydrazone Hydrochloride PF 48(4) Pg. ONLINE	Methylbenzothiazolone Hydrazone Hydrochloride,	<a href="#">Margareth Marques</a>
Revision	METHYLPREDNISOLONE PF 48(4) Pg. ONLINE	Revision	<a href="#">Shankari Shivaprasad</a>
Revision	MORPHINE SULFATE PF 48(3) Pg. ONLINE	Revision	<a href="#">Christine Hiemer</a>
Revision	NADOLOL PF 48(4) Pg. ONLINE	Revision	<a href="#">Christine Hiemer</a>
		IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution (711), IMPURITIES/Organic Impurities, IMPURITIES, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	
Revision	OXYCODONE HYDROCHLORIDE TABLETS PF 47(3) Pg. ONLINE		<a href="#">Christine Hiemer</a>
Revision	PANTOPRAZOLE SODIUM PF 48(2) Pg. ONLINE	Revision	<a href="#">Christine Hiemer</a>
Revision	PUMMELO PEEL PF 48(2) Pg. ONLINE	Revision	<a href="#">Cuiying Ma</a>
Revision	PUMMELO PEEL FLAVONOIDS DRY EXTRACT PF 48(2) Pg. ONLINE	Revision	<a href="#">Cuiying Ma</a>
Revision	PUMMELO PEEL POWDER PF 48(2) Pg. ONLINE	Revision	<a href="#">Cuiying Ma</a>
Revision	SPIRONOLACTONE AND HYDROCHLOROTHIAZIDE TABLETS PF 48(4) Pg. ONLINE	Revision	<a href="#">Christine Hiemer</a>
Revision	SUCRALOSE PF 48(3) Pg. ONLINE	Revision	<a href="#">Galina Holloway</a>
		CHEMICAL INFORMATION, IDENTIFICATION/A. Spectroscopic Identification Tests (197), Infrared Spectroscopy, IDENTIFICATION/B., IDENTIFICATION/C. Identification Tests—General (191), Chemical Identification Tests, Sodium, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Bacterial Endotoxins Test (85), SPECIFIC TESTS/Sterility Tests (71), ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	
Revision	SULBACTAM SODIUM PF 47(4) Pg. ONLINE		<a href="#">Christine Hiemer</a>
Revision	TALC PF 48(2) Pg. ONLINE	Revision	<a href="#">Jenny Liu</a>
Revision	TERBUTALINE SULFATE PF 47(5) Pg. ONLINE	Revision	<a href="#">Shankari Shivaprasad</a>
Revision	TERBUTALINE SULFATE INJECTION PF 47(5) Pg. ONLINE	Revision	<a href="#">Shankari Shivaprasad</a>
New	Alpha tocopherol PF 48(4) Pg. ONLINE	Alpha Tocopherol	<a href="#">Margareth Marques</a>
Revision	Water, Deaerated PF 48(4) Pg. ONLINE	Water, Deaerated	<a href="#">Margareth Marques</a>