

## Compendial Approvals for USPNF 2023 ISSUE 2

Date: Thu Nov 03 16:25:27 EDT 2022

Category	Monograph Title	Monograph Section	Scientific Liaison
Revision	EXCIPIENTS (USP and NF), LISTED BY CATEGORY PF 48(2) Pg. ONLINE	Chaotropic Agent, {Wetting and/or Solubilizing Agent} Guanidine Hydrochloride	SanthiKumar Saladi
Revision	<3> TOPICAL AND TRANSDERMAL DRUG PRODUCTS - PRODUCT QUALITY TESTS PF 48(1) Pg. ONLINE	Revision	Margareth Marques
Revision	<5> INHALATION AND NASAL DRUG PRODUCTS GENERAL INFORMATION AND PRODUCT QUALITY TESTS PF 47(4) Pg. ONLINE	Revision	Kahkashan Zaidi
Revision	DESCRIPTION AND SOLUBILITY PF 48(2) Pg. ONLINE	G/Guanidine Hydrochloride, I/Triclabendazole, L/Lamotrigine, T/Norflurane, R/Roflumilast, M/Micafungin Sodium	SanthiKumar Saladi
New	<313> MOLECULAR WEIGHT AND POLYMER CHAIN LENGTH DETERMINATION FOR POLYPROPYLENE GLYCOL FATTY ETHERS PF 47(5) Pg. ONLINE	New	Peng Zhang
New	<1083> SUPPLIER QUALIFICATION PF 47(5) Pg. ONLINE	New	Desmond Hunt
Revision	<1212> PROBE TACK TEST PF 48(1) Pg. ONLINE	Revision	Margareth Marques
Revision	0.002 N SILVER NITRATE IN ISOPROPYL ALCOHOL VS PF 48(2) Pg. ONLINE	0.002 N Silver Nitrate in Isopropyl Alcohol VS	Mingyan Chu
Revision	0.05 M Sodium Arsenite VS PF 48(1) Pg. ONLINE	0.05 M Sodium Arsenite VS	Mingyan Chu
Revision	0.05 N SILVER NITRATE VS PF 48(1) Pg. ONLINE	0.05 N Silver Nitrate VS,	Mingyan Chu
Revision	AMLODIPINE BESYLATE PF 48(2) Pg. ONLINE	Revision	Christine Hiemer
Revision	BIFIDOBACTERIUM BIFIDUM PF 48(2) Pg. ONLINE	Revision	Binu Koshy
Revision	BIFIDOBACTERIUM LONGUM SUBSP LONGUM PF 48(2) Pg. ONLINE	Revision	Binu Koshy
Revision	CALCIUM ASCORBATE PF 47(3) Pg. ONLINE	DEFINITION, IDENTIFICATION/A. Identification Tests—General, Calcium(191), IDENTIFICATION/B., ASSAY/Procedure, ASSAY/Content of Ascorbate, ASSAY/Content of Calcium, ASSAY/Content of Calcium Ascorbate, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Sandeep Putty
New	CEVIMELINE HYDROCHLORIDE PF 47(4) Pg. ONLINE	CHEMICAL IDENTIFICATION, DEFINITION, IDENTIFICATION/A. Spectroscopic Identification Tests (197), Infrared Spectroscopy, IDENTIFICATION/B., IDENTIFICATION/C. Identification Tests—General (191), Chemical Identification Tests, Chloride, ASSAY/Procedure, IMPURITIES/Residue on Ignition (281), IMPURITIES/Organic Impurities, SPECIFIC TESTS/Water Determination (921), Method I, Method Ic, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Shankari Shivaprasad

		DEFINITION, IDENTIFICATION/C., ASSAY/Procedure, ASSAY/Content of Choline, ASSAY/Content of Chloride, ASSAY/Content of Choline Chloride, IMPURITIES/Limit of Total Amines, IMPURITIES/Chromatographic Purity, IMPURITIES/Related Compounds, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	
Revision	CHOLINE CHLORIDE PF 47(1) Pg. ONLINE		Fatkhulla Tadjimukhamedov
Revision	CLONIDINE HYDROCHLORIDE TABLETS PF 47(5) Pg. ONLINE	Revision	Christine Hiemer
Omission	CORTICOTROPIN INJECTION PF 48(2) Pg. ONLINE	Entire document	Rebecca Potts
Omission	CORTICOTROPIN FOR INJECTION PF 48(2) Pg. ONLINE	Entire document	Rebecca Potts
		Thin-Layer Chromatography (202), IDENTIFICATION/B. HPTLC for Articles of Botanical Origin (203), IDENTIFICATION/C. GC Profile of Monoterpenes, IDENTIFICATION/D., COMPOSITION/Content of Monoterpenes, SPECIFIC TESTS/Fats and Fixed Oils (401), Procedures, Acid Value, Method I, SPECIFIC TESTS/Fats and Fixed Oils (401), Procedures, Saponification Value, SPECIFIC TESTS/Fats and Fixed Oils (401), Procedures, Unsaponifiable Matter, SPECIFIC TESTS/Fats and Fixed Oils (401), Procedures, Iodine Value, SPECIFIC TESTS/Fats and Fixed Oils (401), Procedures, Fatty Acid Composition, SPECIFIC TESTS/Refractive Index (831), ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	
New	BLACK CUMIN SEED THYMOQUINONE OIL PF 46(5) Pg. ONLINE		Maria Monagas
Revision	DOBUTAMINE HYDROCHLORIDE PF 48(1) Pg. ONLINE	Revision	Christine Hiemer
		Origin (203), IDENTIFICATION/B. HPLC, COMPOSITION/Content of Butylidenephthalides and Phenylpropanoids, CONTAMINANTS/Articles of Botanical Origin (561), Limits of Elemental Impurities, CONTAMINANTS/Articles of Botanical Origin (561), Pesticide Residue Analysis, CONTAMINANTS/Articles of Botanical Origin (561), Test for Aflatoxins, 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/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, Volatile Oil Determination, 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, SPECIFIC TESTS/Water Determination (921), Method II, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	
New	DONG QUAI ROOT PF 47(3) Pg. ONLINE		Cuiying Ma

		DEFINITION, IDENTIFICATION/A. HPTLC for Articles of Botanical Origin (203), IDENTIFICATION/B. HPLC, COMPOSITION/Content of Butylidenephthalides and Phenylpropanoids, CONTAMINANTS/Articles of Botanical Origin (561), Limits of Elemental Impurities, CONTAMINANTS/Articles of Botanical Origin (561), Pesticide Residue Analysis, CONTAMINANTS/Articles of Botanical Origin (561), Test for Aflatoxins, 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/Botanical Characteristics, SPECIFIC TESTS/Articles of Botanical Origin (561), Methods of Analysis, Volatile Oil Determination, 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, SPECIFIC TESTS/Water Determination (921), Method II, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	
New	DONG QUAI ROOT POWDER PF 47(3) Pg. ONLINE		Cuiying Ma
Revision	DOXYCYCLINE FOR ORAL SUSPENSION PF 47(5) Pg. ONLINE	Revision	Christine Hiemer
Revision	ENSULIZOLE PF 46(5) Pg. ONLINE	IDENTIFICATION/A. Spectroscopic Identification Tests (197), Infrared Spectroscopy, IDENTIFICATION/B. Spectroscopic Identification Tests (197), Ultraviolet-Visible Spectroscopy, ASSAY/Procedure	Christine Hiemer
New	GUANIDINE HYDROCHLORIDE PF 48(2) Pg. ONLINE	New	SanthiKumar Saladi
New	HYDROXYCHLOROQUINE SULFATE COMPOUNDED ORAL SUSPENSION PF 47(6) Pg. ONLINE	New	Brian Serumaga
Omission	SODIUM IODIDE I 123 SOLUTION PF 46(3) Pg. ONLINE	Entire document	Shankari Shivaprasad
Revision	IPRATROPIUM BROMIDE PF 47(6) Pg. ONLINE	Revision	Shankari Shivaprasad
Revision	ISOSORBIDE DINITRATE EXTENDED-RELEASE TABLETS PF 48(2) Pg. ONLINE	Revision	Christine Hiemer
Revision	MESALAMINE EXTENDED-RELEASE CAPSULES PF 47(6) Pg. ONLINE	Revision	Christine Hiemer
Revision	METHYLENE BLUE PF 47(2) Pg. ONLINE	IMPURITIES/Arsenic, IMPURITIES/Copper or Zinc	Christine Hiemer
Revision	MEPROLOL SUCCINATE EXTENDED-RELEASE TABLETS PF 48(1) Pg. ONLINE	Revision	Christine Hiemer



Revision	PRASUGREL HYDROCHLORIDE PF 47(3) Pg. ONLINE	CHEMICAL INFORMATION, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, Procedure 1, IMPURITIES/Organic Impurities, Procedure 2, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Water Determination (921), Method I, Method Ia or Method Ic, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Christine Hiemer
Revision	Rhodamine B PF 48(1) Pg. ONLINE	Rhodamine B	Margareth Marques
Revision	ROFLUMILAST PF 47(5) Pg. ONLINE	Revision Origin (203), IDENTIFICATION/B. HPLC, COMPOSITION/Content of Butylidenephthalides and Phenylpropanoids, CONTAMINANTS/Articles of Botanical Origin (561), Limits of Elemental Impurities, CONTAMINANTS/Articles of Botanical Origin (561), Pesticide Residue Analysis, CONTAMINANTS/Articles of Botanical Origin (561), Test for Aflatoxins, 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/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/Articles of Botanical Origin (561), Methods of Analysis, Total Ash, SPECIFIC TESTS/Articles of Botanical Origin (561), Methods of Analysis, Acid-Insoluble Ash, SPECIFIC TESTS/Water Determination (921), Method II, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Shankari Shivaprasad
New	SICHUAN LOVAGE RHIZOME PF 47(2) Pg. ONLINE		Cuiying Ma

		DEFINITION, IDENTIFICATION/A. HPTLC for Articles of Botanical Origin (203), IDENTIFICATION/B. HPLC, COMPOSITION/Content of Butylidenephthalides and Phenylpropanoids, CONTAMINANTS/Articles of Botanical Origin (561), Limits of Elemental Impurities, CONTAMINANTS/Articles of Botanical Origin (561), Pesticide Residue Analysis, CONTAMINANTS/Articles of Botanical Origin (561), Test for Aflatoxins, 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/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/Articles of Botanical Origin (561), Methods of Analysis, Total Ash, SPECIFIC TESTS/Articles of Botanical Origin (561), Methods of Analysis, Acid-Insoluble Ash, SPECIFIC TESTS/Water Determination (921), Method II, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	
New	SICHUAN LOVAGE RHIZOME POWDER PF 47(2) Pg. ONLINE		Cuiying Ma
New	SILDENAFIL INJECTION PF 47(6) Pg. ONLINE	New	Shankari Shivaprasad
New	0.01 N SILVER NITRATE VS PF 48(2) Pg. ONLINE	0.01 N Silver Nitrate VS DEFINITION, IDENTIFICATION/A. Identification Tests—General (191), Chemical Identification Tests, Silver, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, SPECIFIC TESTS/Clarity and Color of Solution, SPECIFIC TESTS/Copper, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Mingyan Chu
Revision	SILVER NITRATE PF 47(4) Pg. ONLINE		Christine Hiemer
Revision	SODIUM ASCORBATE PF 47(6) Pg. ONLINE	Revision	Sandeep Putty
New	SODIUM CHLORIDE COMPOUNDED INJECTION PF 47(6) Pg. ONLINE	New CHEMICAL INFORMATION, IDENTIFICATION/C., ASSAY/Procedure, IMPURITIES/Limit of Aluminum, Iron, and Selenium, IMPURITIES/Limit of Sodium Nitrate, IMPURITIES/Limit of Calcium and Potassium, IMPURITIES/Limit of Carbonate, IMPURITIES/Total Non-Purgeable Organic Content, IMPURITIES/Limit of Sulfate, IMPURITIES/Limit of Chloride, SPECIFIC TESTS/Bacterial Endotoxins Test (85), SPECIFIC TESTS/pH (791), SPECIFIC TESTS/Insoluble Matter, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Selma Mitiche
Revision	SODIUM NITRITE PF 46(5) Pg. ONLINE	IDENTIFICATION/C., ASSAY/Procedure, IMPURITIES/Limit of Sodium Nitrate, IMPURITIES/Limit of Nitrogen Oxide (NOx) Related Impurities, SPECIFIC TESTS/Bacterial Endotoxins Test (85), ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Christine Hiemer
Revision	SODIUM NITRITE INJECTION PF 46(5) Pg. ONLINE		Christine Hiemer
Revision	SODIUM PICOSULFATE PF 48(1) Pg. ONLINE	Revision	Christine Hiemer

Revision	Starch TS PF 48(1) Pg. ONLINE	Starch TS	Margareth Marques
Revision	Stearic Acid PF 48(1) Pg. ONLINE	Stearic Acid,	Margareth Marques
Revision	TERMINALIA CHEBULA FRUIT PF 48(1) Pg. ONLINE	Revision	Nam-Cheol Kim
Revision	TERMINALIA CHEBULA FRUIT DRY EXTRACT PF 48(1) Pg. ONLINE	Revision	Nam-Cheol Kim
Revision	TERMINALIA CHEBULA FRUIT POWDER PF 48(1) Pg. ONLINE	Revision	Nam-Cheol Kim
Revision	TETRACYCLINE HYDROCHLORIDE OINTMENT PF 48(1) Pg. ONLINE	Revision	Christine Hiemer
Revision	TETRACYCLINE HYDROCHLORIDE TABLETS PF 48(1) Pg. ONLINE	Revision 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	Christine Hiemer
Revision	TRIAZOLAM TABLETS PF 47(4) Pg. ONLINE	Revision	Shankari Shivaprasad
New	TRICLABENDAZOLE PF 47(5) Pg. ONLINE	New	Christine Hiemer
Revision	COMPOUND UNDECYLENIC ACID OINTMENT PF 47(6) Pg. ONLINE	Revision DEFINITION, ASSAY/Procedure, SPECIFIC TESTS/pH (191), ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Beyond-Use Date, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Christine Hiemer
New	VALINE COMPOUNDED ORAL SOLUTION PF 46(3) Pg. ONLINE	Revision	Brian Serumaga
Revision	EMULSIFYING WAX PF 47(6) Pg. ONLINE	Revision  CHEMICAL INFORMATION, DEFINITION, IDENTIFICATION/A. Identification Tests—General (191), Chemical Identification Tests, Zinc, IDENTIFICATION/A., ASSAY/Procedure, IMPURITIES/Limit of Ammonium Salts, IMPURITIES/Alkalies and Alkaline Earths, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	SanthiKumar Saladi
Revision	ZINC CHLORIDE PF 46(6) Pg. ONLINE		Christine Hiemer