## **Compendial Approvals for USPNF 2023 ISSUE 2**

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

Category		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	Trydroctiloride	Salitilikulliai Salaul
Revision	QUALITY TESTS PF 48(1) Pg. ONLINE	Revision	Margareth Marques
	<5> INHALATION AND NASAL DRUG PRODUCTS GENERAL INFORMATION AND PRODUCT QUALITY TESTS PF 47(4) Pg.		
Revision	ONLINE	Revision	Kahkashan Zaidi
		G/Guanidine Hydrochloride, I/Triclabendazole, L/Lamotrigine,	
Revision	DESCRIPTION AND SOLUBILITY PF 48(2) Pg. ONLINE  <313> MULECULAR WEIGHT AND PULYMER CHAIN LENGTH  DETERMINATION FOR POLYPROPYLENE GLYCOL FATTY ETHERS PF	T/Norflurane, R/Roflumilast, M/Micafungin Sodium	SanthiKumar Saladi
New	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 0.002 N SILVER NITRATE IN ISOPROPYL ALCOHOL VS PF 48(2) Pg.	Revision	Margareth Marques
Revision	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		Binu Koshy
Revision	CALCIUM ASCORBATE PF 47(3) Pg. ONLINE	Calcium(191), 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)  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	Sandeep Putty
New	CEVIMELINE HYDROCHLORIDE PF 47(4) Pg. ONLINE	REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Chankari Chivanrasad
ivew	CLVINLLINL III DROCHLORIDE PF 47(4) Pg. UNLINE	NEQUINEFIENT 3/USP RETEIRING Stalluarus (11)	Shankari Shivaprasad

DEFINITION, IDENTIFICATION/C., ASSAT/FIOCEGUIE, 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

Entire document Entire document Fatkhulla Tadjimukhamedov

Christine Hiemer Rebecca Potts

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)

Maria Monagas Christine Hiemer

New BLACK CUMIN SEED THYMOQUINONE OIL PF 46(5) Pg. ONLINE DOBUTAMINE HYDROCHLORIDE PF 48(1) Pg. ONLINE Revision

CHOLINE CHLORIDE PF 47(1) Pg. ONLINE

Omission CORTICOTROPIN FOR INJECTION PF 48(2) Pg. ONLINE

CORTICOTROPIN INJECTION PF 48(2) Pg. ONLINE

CLONIDINE HYDROCHLORIDE TABLETS PF 47(5) Pq. 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, 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)

DONG QUAI ROOT PF 47(3) Pg. ONLINE

Cuiying Ma

New

Revision

Revision

Omission

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 REOUIREMENTS/USP Reference Standards (11)

New	DONG QUAI ROOT POWDER PF 47(3) Pg. ONLINE	REQUIREMENTS/USP Reference Standards (11)	Cuiying Ma
Revision	DOXYCYCLINE FOR ORAL SUSPENSION PF 47(5) Pg. ONLINE	Revision IDENTIFICATION/A. Spectroscopic Identification Tests (197), Infrared Spectroscopy, IDENTIFICATION/B. Spectroscopic Identification Tests (197), Ultraviolet-Visible Spectroscopy,	Christine Hiemer
Revision	ENSULIZOLE PF 46(5) Pg. ONLINE	ASSAY/Procedure	Christine Hiemer
New	GUANIDINE HYDROCHLORIDE PF 48(2) Pg. ONLINE HYDROXYCHLOROQUINE SULFATE COMPOUNDED OKAL	New	SanthiKumar Saladi
New	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 ISOSORBIDE DINITRATE EXTENDED-RELEASE TABLETS PF 48(2)	Revision	Shankari Shivaprasad
Revision	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 METOPROLOL SUCCINATE EXTENDED-RELEASE TABLETS PF 48(1)	IMPURITIES/Arsenic, IMPURITIES/Copper or Zinc	Christine Hiemer
Revision	Pg. ONLINE	Revision	Christine Hiemer

New	MICAFUNGIN FOR INJECTION PF 46(5) Pg. ONLINE	ASSAY/Procedure, IMPURITIES/Organic Impurities, PERFORMANCE TESTS/Uniformity of Dosage Units (905), SPECIFIC TESTS/pH (791), SPECIFIC TESTS/Particulate Matter in Injections (788), Method 1 Light Obscuration Particle Count Test, SPECIFIC TESTS/Bacterial Endotoxins Test (85), SPECIFIC TESTS/Sterility Tests (71), SPECIFIC TESTS/Constituted Solution, SPECIFIC TESTS/Other Requirements, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Christine Hiemer
		Spectroscopic Identification Tests (197), Infrared Spectroscopy, IDENTIFICATION/B., IDENTIFICATION/C. Identification Tests—General (191), Chemical Identification Tests, Sodium, ASSAY/Procedure, IMPURITIES/Residue on Ignition (281), IMPURITIES/Organic Impurities, SPECIFIC TESTS/Optical Rotation (781S), Procedures, Specific Rotation, SPECIFIC TESTS/Microbial Enumeration Tests (61) and Tests for Specified Microorganisms (62), SPECIFIC TESTS/Bacterial Endotoxins Test (85), SPECIFIC TESTS/Water Determination (921), Method I, Method Ia, SPECIFIC TESTS/PH (791), ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards	
New	MICAFUNGIN SODIUM PF 46(5) Pg. ONLINE MORPHINE SULFATE COMPOUNDED ORAL SOLUTION PF 47(6) Pg.	(11)	Christine Hiemer
New	ONLINE	New	Selma Mitiche
Revision	MYCOPHENOLATE MOFETIL CAPSULES PF 48(1) Pg. ONLINE	Revision	Christine Hiemer
Revision	MYCOPHENOLATE MOFETIL TABLETS PF 48(1) Pg. ONLINE	Revision	Christine Hiemer
New	L-CYSTEINE HYDROCHLORIDE, ANHYDROUS PF 48(1) Pg. ONLINE	I-Cysteine Hydrochloride, Anhydrous	Mingyan Chu
New	TRIS-EDTA BUFFER,pH 8.0 TS PF 48(1) Pg. ONLINE	Tris-EDTA Buffer, pH 8.0 TS	Mingyan Chu
New	WATER, DNASE/RNASE FREE PF 48(1) Pg. ONLINE	Water, DNase::RNase free	Mingyan Chu
New	PROTEOSE PEPTONE PF 48(1) Pg. ONLINE	Proteose peptone	Mingyan Chu
Revision	NEOMYCIN SULFATE PF 48(1) Pg. ONLINE	Revision	Julie Zhang
Revision	NORFLURANE PF 47(6) Pg. ONLINE	Revision	Kahkashan Zaidi
Revision	OXYMORPHONE HYDROCHLORIDE PF 48(2) Pg. ONLINE PANTOPRAZOLE SODIUM DELAYED-RELEASE TABLETS PF 48(2) Pg.	Revision	Christine Hiemer
Revision	ONLINE POLYETHYLENE GLYCOL 30 DIPOLYHYDROXYSTEARATE 5 PF 4/(6)	Revision	Christine Hiemer
New	Pg. ONLINE POLYETHYLENE GLYCOL 12 CETOSTEARYL ETHER PF 4/(6) Pg.	New	Devendra Vasant Chavan
New	ONLINE	New	Devendra Vasant Chavan

Revision PRASUGREL HYDROCHLORIDE PF 47(3) Pg. ONLINE

Revision Rhodamine B PF 48(1) Pg. ONLINE Revision ROFLUMILAST PF 47(5) 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)

Rhodamine B

Reference Standards (11)

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

Christine Hiemer Margareth Marques Shankari Shivaprasad

Cuiying Ma

New SICHUAN LOVAGE RHIZOME PF 47(2) Pg. ONLINE

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  $\langle 921 \rangle$ , Method II, ADDITIONAL REQUIREMENTS/Packaging and

New	SICHUAN LOVAGE RHIZOME POWDER PF 47(2) Pg. ONLINE	Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	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/A. (191), Chemical Identification Tests, Silver, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, SPECIFIC TESTS/Clarity and Color of Solution, SPECIFIC TESTS/Copper, ADDITIONAL	Mingyan Chu
Revision	SILVER NITRATE PF 47(4) Pg. ONLINE	REQUIREMENTS/USP Reference Standards (11)	Christine Hiemer
Revision	SODIUM ASCORBATE PF 47(6) Pg. ONLINE SODIUM CHLORIDE COMPOUNDED INJECTION PF 47(6) Pg.	Revision	Sandeep Putty
New	ONLINE	New 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 REOUIREMENTS/USP	Selma Mitiche
Revision	SODIUM NITRITE PF 46(5) Pg. ONLINE	Reference Standards (11)  IDENTIFICATION/C., ASSAT/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	Christine Hiemer
Revision	SODIUM NITRITE INJECTION PF 46(5) Pg. ONLINE	REQUIREMENTS/USP Reference Standards (11)	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	Christine Hiemer
Revision	TRIAZOLAM TABLETS PF 47(4) Pg. ONLINE	Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage	Shankari Shivaprasad
New	TRICLABENDAZOLE PF 47(5) Pg. ONLINE	New	Christine Hiemer
Revision	COMPOUND UNDECYLENIC ACID OINTMENT PF 47(6) Pg. ONLINE	Revision DEFINITION, ASSAT/PROCECURE, SPECIFIC TESTS/PH (791), ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Beyond-Use Date, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP	Christine Hiemer
New	VALINE COMPOUNDED ORAL SOLUTION PF 46(3) Pg. ONLINE	Reference Standards (11)	Brian Serumaga
Revision	EMULSIFYING WAX PF 47(6) Pg. ONLINE	Revision	SanthiKumar Saladi
Revision	ZINC CHLORIDE PF 46(6) Pg. ONLINE	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)	Christine Hiemer