

Compendial Approvals for USPNF 2021 ISSUE 3

Date: Mon Apr 05 16:52:44 EDT 2021

Category	Monograph Title	Monograph Section	Scientific Liaison
Revision	EXCIPIENTS (USP and NF), LISTED BY CATEGORY PF 46(3) Pg. ONLINE	{Emulsifying Agent} Sodium Lauroyl Sarcosinate, Surfactant, {Wetting and/or Solubilizing Agent} Sodium Lauroyl Sarcosinate, {Diluent} Propylene Glycol Mono and Dicaprylate, {Emulsifying Agent} Propylene Glycol Mono and Dicaprylate, {Vehicle} Propylene Glycol Mono and Dicaprylate	Galina Holloway
Revision	<17> PRESCRIPTION CONTAINER LABELING PF 46(2) Pg. ONLINE	Revision	Diana Kwan
Revision	DESCRIPTION AND SOLUBILITY PF 46(3) Pg. ONLINE	S/Sodium Lauroyl Sarcosinate, R/Riociguat, A/Alosetron Hydrochloride, P/Propylene Glycol Mono and Dicaprylate, E/Etoposide Phosphate:, A/Amino Methacrylate Copolymer, I/Ibandronate Sodium	Galina Holloway
Revision	ALCOHOLOMETRIC TABLE PF 46(4) Pg. ONLINE	INTRODUCTION	Antonio Hernandez-Cardoso
Omission	<130> PROTEIN A QUALITY ATTRIBUTES PF 46(2) Pg. ONLINE	Entire document	Krishna Menon
Omission	<1010> ANALYTICAL DATA -- INTERPRETATION AND TREATMENT PF 46(4) Pg. ONLINE		
Revision	ONLINE	Revision	Steven Walfish
Revision	<1231> WATER FOR PHARMACEUTICAL PURPOSES PF 46(3) Pg. ONLINE	Revision	Antonio Hernandez-Cardoso
New	<1469> NITROSAMINE IMPURITIES	New	Edmond Biba
New	<1149> GUIDELINES FOR ASSESSING AND CONTROLLING THE PHYSICAL STABILITY OF CHEMICAL AND BIOLOGICAL PHARMACEUTICAL RAW MATERIALS, INTERMEDIATES, AND DOSAGE FORMS PF 46(3) Pg. ONLINE		
New	ACRYLAMIDE PF 46(4) Pg. ONLINE	New	Antonio Hernandez-Cardoso
Revision	ALCOHOL PF 46(4) Pg. ONLINE	Acrylamide,	Margareth Marques
Revision	DEHYDRATED ALCOHOL PF 46(4) Pg. ONLINE	SPECIFIC TESTS/♣ Specific Gravity (841)	Tong Liu
Revision	Ammonium Reineckate PF 46(3) Pg. ONLINE	SPECIFIC TESTS/♣ Specific Gravity (841)	Tong Liu
New	AMPHOLYTES PF 46(4) Pg. ONLINE	Ammonium Reineckate	Margareth Marques
		Ampholytes,	Margareth Marques
		DEFINITION, IDENTIFICATION/A., COMPOSITION/Content of δ- and γ-Tocotrienols, SPECIFIC TESTS/Fats and Fixed Oils (401), Procedures, Peroxide Value, SPECIFIC TESTS/Water Determination (921), Method I, Method Ia, SPECIFIC TESTS/Limit of α-Tocopherol, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	
Revision	ANNATTO SEED OIL TOCOTRIENOLS PF 46(4) Pg. ONLINE		Maria Monagas
		DEFINITION, IDENTIFICATION/A. HPTLC For Articles of Botanical Origin (203), IDENTIFICATION/B. HPLC, COMPOSITION/Content of Ginsenosides, 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/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 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/Loss on Drying (731), ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	
New	RED ASIAN GINSENG ROOT AND RHIZOME PF 46(4) Pg. ONLINE		Cuiying Ma

		DEFINITION, IDENTIFICATION/A. HPTLC For Articles of Botanical Origin (203), IDENTIFICATION/B. HPLC, COMPOSITION/Content of Ginsenosides, 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/Botanical Characteristics, SPECIFIC TESTS/Articles of Botanical Origin (561), Methods of Analysis, Alcohol-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/Loss on Drying (731), ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	
New	RED ASIAN GINSENG ROOT AND RHIZOME POWDER PF 46(4) Pg. ONLINE		Cuiying Ma
Revision	AZELASTINE HYDROCHLORIDE PF 46(2) Pg. ONLINE	ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Acidity or Alkalinity, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Mary Koleck
Revision	BENDROFLUMETHIAZIDE PF 46(4) Pg. ONLINE	CHEMICAL INFORMATION, IMPURITIES/Selenium (291), ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Yanyin Yang
New	BENZOIN PF 46(3) Pg. ONLINE	Benzoin	Margareth Marques
New	BISACRYLAMIDE PF 46(4) Pg. ONLINE	Bisacrylamide	Margareth Marques
Revision	BITTER ORANGE FRUIT FLAVONOIDS DRY EXTRACT PF 46(4) Pg. ONLINE	IDENTIFICATION/A. HPTLC for Articles of Botanical Origin (203), SPECIFIC TESTS/Limit for Synephrine, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Maria Monagas
New	CALCIPOTRIENE CREAM PF 45(6) Pg. ONLINE	DEFINITION, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Minimum Fill (755), IMPURITIES/Organic Impurities, SPECIFIC TESTS/Microbial Enumeration Tests (61) and Tests for Specified Microorganisms (62), SPECIFIC TESTS/pH (791), ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Jane Li
New	CARBOBENZOXY-L-VALYL-L-GLYCYL-L-ARGININE-4-NITRANILIDE ACETATE PF 46(3) Pg. ONLINE	Carbobenzoxy-l-valyl-l-glycyl-l-arginine-4-nitranylde acetate,	Margareth Marques
New	CHOLINE C 11 INJECTION PF 46(4) Pg. ONLINE	DEFINITION, IDENTIFICATION/A. Radionuclidic Identity, IDENTIFICATION/B. Radiochemical Identity, ASSAY/Radioactive Concentration (Strength), PURITY/Radionuclidic Purity, PURITY/Radiochemical Purity, IMPURITIES/Radionuclidic Impurities, IMPURITIES/Radiochemical Impurities, IMPURITIES/Limit of 2-Dimethylaminoethanol, IMPURITIES/Limit of Ethanol, SPECIFIC TESTS/Specific Activity, SPECIFIC TESTS/pH, SPECIFIC TESTS/Bacterial Endotoxins Test (85), SPECIFIC TESTS/Sterility Tests (71), SPECIFIC TESTS/Appearance, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Gerald Hsu
New	0.1 N CERIC AMMONIUM SULFATE VS PF 46(4) Pg. ONLINE	0.1 N Ceric Ammonium Sulfate VS	Margareth Marques
New	0.01 N CERIC AMMONIUM SULFATE VS PF 46(4) Pg. ONLINE	0.01 N Ceric Ammonium Sulfate VS	Margareth Marques
Omission	CHLORAL HYDRATE CAPSULES PF 46(3) Pg. ONLINE	Entire document	Heather Joyce
Omission	CHLORAL HYDRATE ORAL SOLUTION PF 46(3) Pg. ONLINE	Entire document	Heather Joyce
Revision	CHLOROPROCAINE HYDROCHLORIDE INJECTION PF 46(4) Pg. ONLINE	IDENTIFICATION/A., IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, ADDITIONAL REQUIREMENTS/Packaging and Storage	Mary Koleck
Omission	CHLORPROMAZINE SUPPOSITORIES PF 46(3) Pg. ONLINE	Entire document	Heather Joyce
Revision	CHYMOTRYPSIN PF 46(3) Pg. ONLINE	IDENTIFICATION/A., IDENTIFICATION/B., IMPURITIES/Limit of Trypsin, SPECIFIC TESTS/Microbial Enumeration Tests (61) and Tests for Specified Microorganisms (62), ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Krishna Menon
Revision	CHYMOTRYPSIN FOR OPHTHALMIC SOLUTION PF 46(3) Pg. ONLINE	IMPURITIES/Limit of Trypsin, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Krishna Menon

Revision	CISPLATIN FOR INJECTION PF 46(4) Pg. ONLINE	IDENTIFICATION, IDENTIFICATION/A. By UV Spectrum Match, ASSAY/Procedure, IMPURITIES/Limit of Aminotrichloro-platinum, SPECIFIC TESTS/Bacterial Endotoxins Test (85), SPECIFIC TESTS/Sterility Tests (71), ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Jane Li
Revision	CLONIDINE TRANSDERMAL SYSTEM PF 46(3) Pg. ONLINE	IDENTIFICATION/A. Spectroscopic Identification Tests (197), Infrared Spectroscopy, ASSAY/Procedure, PERFORMANCE TESTS/Drug Release (724), IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Yanvin Yang
Omission	COLISTIN SULFATE FOR ORAL SUSPENSION PF 46(2) Pg. ONLINE	Entire document	Julie Zhang
Revision	CYCLOSPORINE PF 46(4) Pg. ONLINE	IDENTIFICATION/A. Spectroscopic Identification Tests (197), Infrared Spectroscopy, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Loss on Drying (731), ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Slavica Shane
Revision	DAPSONE PF 46(4) Pg. ONLINE	ASSAY/Procedure, IMPURITIES/Selenium (291)	Shankari Shivaprasad
Omission	DEMECARIUM BROMIDE OPHTHALMIC SOLUTION PF 46(4) Pg. ONLINE	Entire document	Heather Joyce
New	DEXAMETHASONE COMPOUNDED ORAL SUSPENSION PF 46(2) Pg. ONLINE	DEFINITION, ASSAY/Procedure, SPECIFIC TESTS/pH (791), ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Beyond-Use Date, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Brian Serumaga
Revision	DEXPANTHENOL PREPARATION PF 46(3) Pg. ONLINE	IDENTIFICATION/A. Spectroscopic Identification Tests (197), Infrared Spectroscopy, COMPOSITION/Content of Pantolactone	Natalia Davydova
Revision	DEXTROSE INJECTION PF 46(3) Pg. ONLINE	ASSAY/Procedure	Mary Koleck
Omission	DIDANOSINE TABLETS FOR ORAL SUSPENSION PF 46(4) Pg. ONLINE	Entire document	Shankari Shivaprasad
Revision	DIPHENOXYLATE HYDROCHLORIDE PF 46(4) Pg. ONLINE	IDENTIFICATION/C., ASSAY/Procedure, IMPURITIES/Organic Impurities	Behnaz Almasi
Revision	DORZOLAMIDE HYDROCHLORIDE OPHTHALMIC SOLUTION PF 46(4) Pg. ONLINE	IDENTIFICATION/A. Thin-Layer Chromatographic Identification Test (201), ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Other Requirements, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Devarshi Narendra Thaker
Revision	DORZOLAMIDE HYDROCHLORIDE AND TIMOLOL MALEATE OPHTHALMIC SOLUTION PF 46(4) Pg. ONLINE	IDENTIFICATION/A. Thin-Layer Chromatographic Identification Test (201), IDENTIFICATION/D., ASSAY/Procedure for Dorzolamide, ASSAY/Procedure for Timolol, IMPURITIES/Organic Impurities, Dorzolamide Hydrochloride, IMPURITIES/Organic Impurities, Timolol Maleate, IMPURITIES/Limit of Dorzolamide Maleic Acid Adducts, SPECIFIC TESTS/Other Requirements, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Devarshi Narendra Thaker
New	ENDOPROTEINASE GLU-C PF 46(4) Pg. ONLINE	Endoproteinase Glu-C	Margareth Marques
Omission	EPITETRACYCLINE HYDROCHLORIDE PF 46(4) Pg. ONLINE	Entire document	Praveen Pabba
Revision	ERGOCALCIFEROL ORAL SOLUTION PF 46(4) Pg. ONLINE	ASSAY/Procedure, ADDITIONAL REQUIREMENTS/Labeling	Natalia Davydova
Omission	ERGONOVINE MALEATE TABLETS PF 46(4) Pg. ONLINE	Entire document	Gerald Hsu
Omission	ERYTHROMYCIN ESTOLATE PF 46(4) Pg. ONLINE	Entire document	Julie Zhang
Omission	ERYTHROMYCIN ESTOLATE CAPSULES PF 46(2) Pg. ONLINE	Entire document	Julie Zhang
Omission	ERYTHROMYCIN ESTOLATE ORAL SUSPENSION PF 46(3) Pg. ONLINE	Entire document	Julie Zhang
Omission	ERYTHROMYCIN ESTOLATE FOR ORAL SUSPENSION PF 46(4) Pg. ONLINE	Entire document	Julie Zhang
Omission	ERYTHROMYCIN ESTOLATE TABLETS PF 46(2) Pg. ONLINE	Entire document	Julie Zhang
Omission	ERYTHROMYCIN ESTOLATE AND SULFISOXAZOLE ACETYL ORAL SUSPENSION PF 46(2) Pg. ONLINE	Entire document	Julie Zhang
Omission	ESTRONE INJECTABLE SUSPENSION PF 46(4) Pg. ONLINE	Entire document	Gerald Hsu

Revision	ETHACRYNIC ACID PF 45(4) Pg. ONLINE	IDENTIFICATION/A. Spectroscopic Identification Tests (197), Infrared Spectroscopy, IDENTIFICATION/B. Ultraviolet Absorption (197U), IDENTIFICATION/B., IDENTIFICATION/C. Procedure, ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Equivalent Weight, SPECIFIC TESTS/Toluene Extractives, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Tzion Bililign
New	ETOPOSIDE PHOSPHATE PF 45(2) Pg. ONLINE	CHEMICAL INFORMATION, DEFINITION, IDENTIFICATION/A. Spectroscopic Identification Tests (197), Infrared Spectroscopy:, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Optical Rotation (781S), Procedures, Specific Rotation, SPECIFIC TESTS/Water Determination (921), Method I:, SPECIFIC TESTS/Bacterial Endotoxins Test (85):, ADDITIONAL REQUIREMENTS/Packaging and Storage:, ADDITIONAL REQUIREMENTS/Labeling:, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Jane Li
New	ETOPOSIDE PHOSPHATE FOR INJECTION PF 45(2) Pg. ONLINE	DEFINITION, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Uniformity of Dosage Units (905):, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Bacterial Endotoxins Test (85):, SPECIFIC TESTS/Sterility Tests (71):, SPECIFIC TESTS/Particulate Matter in Injections (788):, SPECIFIC TESTS/pH (791), SPECIFIC TESTS/Other Requirements:, ADDITIONAL REQUIREMENTS/Packaging and Storage:, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Jane Li
Revision	FERROUS FUMARATE TABLETS PF 46(4) Pg. ONLINE	PERFORMANCE TESTS/Dissolution (711)	Natalia Davydova
New	FLUDROCORTISONE ACETATE COMPOUNDED ORAL SUSPENSION PF 46(2) Pg. ONLINE	DEFINITION, ASSAY/Procedure, SPECIFIC TESTS/pH (791), ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Beyond-Use Date, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Brian Serumaga
New	FLUDROCORTISONE ACETATE COMPOUNDED ORAL SUSPENSION, VETERINARY PF 46(2) Pg. ONLINE	DEFINITION, ASSAY/Procedure, SPECIFIC TESTS/pH (791), ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Beyond-Use Date, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Brian Serumaga
Revision	FLUOROMETHOLONE ACETATE PF 46(2) Pg. ONLINE	DEFINITION, IDENTIFICATION/A. Spectroscopic Identification Tests (197), Infrared Spectroscopy, IDENTIFICATION/B. Spectroscopic Identification Tests (197), Ultraviolet-Visible Spectroscopy, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities	Gerald Hsu
New	GABAPENTIN COMPOUNDED ORAL SUSPENSION PF 46(2) Pg. ONLINE	DEFINITION, ASSAY/Procedure, SPECIFIC TESTS/pH (791), ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Beyond-Use Date, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Brian Serumaga
Revision	Gadolinium (Gd III) Acetate Tetrahydrate PF 46(3) Pg. ONLINE	Gadolinium (Gd III) Acetate Tetrahydrate,	Margareth Marques
Omission	GADOVERSETAMIDE PF 46(4) Pg. ONLINE	Entire document	Gerald Hsu
Omission	GADOVERSETAMIDE INJECTION PF 46(4) Pg. ONLINE	Entire document	Gerald Hsu
Revision	GLUCONOLACTONE PF 46(4) Pg. ONLINE	IMPURITIES/Lead (251)	Behnaz Almasi
New	GLYCINE PF 46(4) Pg. ONLINE	Glycine,	Margareth Marques
New	GRANULOCYTE COLONY STIMULATING FACTOR PF 46(4) Pg. ONLINE	Granulocyte Colony Stimulating Factor	Margareth Marques
Omission	HYDROXYAMPHETAMINE HYDROBROMIDE OPHTHALMIC SOLUTION PF 46(3) Pg. ONLINE	Entire document	Devarshi Narendra Thaker
New	INTERLEUKIN 3 PF 46(4) Pg. ONLINE	Interleukin 3	Margareth Marques
Omission	IDOQUINOL TABLETS PF 46(3) Pg. ONLINE	Entire document	Shankari Shivaprasad
Revision	IOHEXOL PF 46(4) Pg. ONLINE	IMPURITIES/Limit of Free Iodide, IMPURITIES/Limit of 2-Methoxyethanol, IMPURITIES/Limit of 3-Chloropropane-1,2-diol	Gerald Hsu
Omission	IRON SORBITEX INJECTION PF 46(3) Pg. ONLINE	Entire document	Tzion Bililign

Omission	KANAMYCIN SULFATE CAPSULES PF 46(3) Pg. ONLINE	Entire document	Slavica Shane
New	KETAMINE COMPOUNDED ORAL SOLUTION PF 46(3) Pg. ONLINE	DEFINITION, ASSAY/Procedure, SPECIFIC TESTS/pH (791), ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Beyond-Use Date, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Brian Serumaga
New	L123 PF 46(3) Pg. ONLINE	L123	Margareth Marques
New	LATANOPROST COMPOUNDED TOPICAL SOLUTION PF 46(3) Pg. ONLINE	DEFINITION, ASSAY/Procedure, SPECIFIC TESTS/pH (791), ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Beyond-Use Date, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Brian Serumaga
Revision	Lead Tetraacetate PF 46(3) Pg. ONLINE	Lead Tetraacetate,	Margareth Marques
Revision	LEVOCARNITINE PF 46(3) Pg. ONLINE	SPECIFIC TESTS/Water Determination (921), Method I, Method Ia	Fatkhulla Tadjimukhamedov
Omission	LIME PF 46(4) Pg. ONLINE	Entire document	Shankari Shivaprasad
Revision	LORAZEPAM PF 46(3) Pg. ONLINE	ASSAY/Procedure, IMPURITIES/Organic Impurities	Ren-Hwa Yeh
New	M-NFS-60 CELLS PF 46(4) Pg. ONLINE	M-NFS-60 Cells	Margareth Marques
Revision	MAFENIDE ACETATE PF 46(4) Pg. ONLINE	ASSAY/Procedure, IMPURITIES/Selenium (291), IMPURITIES/Organic Impurities	Shankari Shivaprasad
New	MALATHION IMPURITY B PF 46(4) Pg. ONLINE	Malathion Impurity B	Margareth Marques
Omission	METHACYCLINE HYDROCHLORIDE ORAL SUSPENSION PF 46(4) Pg. ONLINE	Entire document	Praveen Pabba
New	1-METHYL-2-PYRROLIDINONE PF 46(3) Pg. ONLINE	1-Methyl-2-pyrrolidinone,	Margareth Marques
Revision	METHYL SALICYLATE PF 46(3) Pg. ONLINE	SPECIFIC TESTS/Optical Rotation (781A), Procedures, Angular Rotation	Galina Holloway
Revision	MUPIROCIN CALCIUM PF 45(3) Pg. ONLINE	IDENTIFICATION/A. Spectroscopic Identification Tests (197), Infrared Spectroscopy:, IDENTIFICATION/C. Identification Tests—General (191), Chemical Identification Tests, Calcium, ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage:, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Slavica Shane
Revision	MUPIROCIN OINTMENT PF 45(4) Pg. ONLINE	IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Microbial Enumeration Tests (61) and Tests for Specified Microorganisms (62), ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Slavica Shane
Revision	NALTREXONE HYDROCHLORIDE COMPOUNDED CREAM PF 46(2) Pg. ONLINE	DEFINITION, ASSAY/Procedure, SPECIFIC TESTS/pH (791), SPECIFIC TESTS/Viscosity—Rotational Methods (912), ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Beyond-Use Date, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Brian Serumaga
Omission	NEOMYCIN AND POLYMYXIN B SULFATES AND HYDROCORTISONE ACETATE OPHTHALMIC SUSPENSION PF 46(4) Pg. ONLINE	Entire document	Julie Zhang
Revision	NORETHINDRONE ACETATE AND ETHINYL ESTRADIOL TABLETS PF 46(4) Pg. ONLINE	IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution (711), ADDITIONAL REQUIREMENTS/Labeling	Ren-Hwa Yeh
Revision	OXACILLIN INJECTION PF 46(2) Pg. ONLINE	IDENTIFICATION/B., ASSAY/Procedure, SPECIFIC TESTS/Sterility Tests (71), SPECIFIC TESTS/Pyrogen Test (151)	Christine Hiemer
Omission	OXTRIPHYLLINE EXTENDED-RELEASE TABLETS PF 46(4) Pg. ONLINE	Entire document	Ren-Hwa Yeh
Revision	OXYCODONE HYDROCHLORIDE EXTENDED-RELEASE TABLETS PF 46(4) Pg. ONLINE	IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution (711), IMPURITIES/Limit of Oxycodone Related Compound B (Oxycodone N-Oxide), IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Labeling	Hillary Cai
Revision	PENICILLAMINE CAPSULES PF 46(3) Pg. ONLINE	IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution (711), ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Christine Hiemer

New	WHITE PEONY ROOT DRY EXTRACT PF 46(1) Pg. ONLINE	DEFINITION, IDENTIFICATION/A. HPTLC for Articles of Botanical Origin (203), IDENTIFICATION/B. HPLC, COMPOSITION/Content of Benzoyl Monoterpenoid Glycosides, CONTAMINANTS/Botanical Extracts (565), Preparations, General Pharmacopeial Requirements, Pesticide Residues, 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/Articles of Botanical Origin (561), Methods of Analysis, Total Ash, SPECIFIC TESTS/Loss on Drying (731), SPECIFIC TESTS/Botanical Extracts (565), Preparations, General Pharmacopeial Requirements, Residual Solvents, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Cuiying Ma
New	WHITE PEONY ROOT PF 46(1) Pg. ONLINE	DEFINITION, IDENTIFICATION/A. HPTLC for Articles of Botanical Origin (203), IDENTIFICATION/B. HPLC, COMPOSITION/Content of Benzoyl Monoterpenoid Glycosides, 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/Loss on Drying (731), ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Cuiying Ma
New	WHITE PEONY ROOT POWDER PF 46(1) Pg. ONLINE	DEFINITION, IDENTIFICATION/A. HPTLC for Articles of Botanical Origin (203), IDENTIFICATION/B. HPLC, COMPOSITION/Content of Benzoyl Monoterpenoid glycosides, 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/Loss on Drying (731), ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Cuiying Ma
Omission	PHENOBARBITAL SODIUM FOR INJECTION PF 45(3) Pg. ONLINE	Entire document	Claire Chisolm
New	pH 7.4 PHOSPHATE BUFFERED SALINE TS PF 46(4) Pg. ONLINE	pH 7.4 Phosphate Buffered Saline TS	Margareth Marques
Revision	POLOXAMER PF 46(3) Pg. ONLINE	DEFINITION	Galina Holloway
New	POLYACRYLAMIDE PF 46(4) Pg. ONLINE	Polyacrylamide,	Margareth Marques

Revision	PROPOFOL INJECTABLE EMULSION PF 46(4) Pg. ONLINE	IDENTIFICATION/A. Spectroscopic Identification Tests (197), Ultraviolet-Visible Spectroscopy: 197U, ASSAY/Procedure, IMPURITIES/Limit of Free Fatty Acids, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Ren-Hwa Yeh
New	PROPYLENE GLYCOL MONO AND DICAPRYLATE PF 46(3) Pg. ONLINE	CHEMICAL INFORMATION, DEFINITION, IDENTIFICATION/A. Spectroscopic Identification Tests (197), Infrared Spectroscopy, IDENTIFICATION/B. Thin-Layer Chromatographic Identification Test (201), IDENTIFICATION/C., ASSAY/Procedure, IMPURITIES/Limit of Propylene Glycol, SPECIFIC TESTS/Fats and Fixed Oils (401), Procedures, Acid Value, SPECIFIC TESTS/Fats and Fixed Oils (401), Procedures, Fatty Acid Composition, SPECIFIC TESTS/Fats and Fixed Oils (401), Procedures, Iodine Value, SPECIFIC TESTS/Fats and Fixed Oils (401), Procedures, Saponification Value, SPECIFIC TESTS/Fats and Fixed Oils (401), Procedures, Peroxide Value, SPECIFIC TESTS/Water Determination (921), Method I, Method Ia, SPECIFIC TESTS/Articles of Botanical Origin (561), Methods of Analysis, Total Ash, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Peng Zhang
Revision	PROPYLENE GLYCOL MONOCAPRYLATE PF 46(3) Pg. ONLINE	DEFINITION, IDENTIFICATION/B. Thin-Layer Chromatographic Identification Test (201), ASSAY/Procedure, IMPURITIES/Limit of Propylene Glycol, SPECIFIC TESTS/Fats and Fixed Oils (401), Procedures, Saponification Value, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Peng Zhang
Revision	PYRROLOQUINOLINE QUINONE DISODIUM PF 46(4) Pg. ONLINE	DEFINITION, Assay, IDENTIFICATION/A., IDENTIFICATION/B.	Fatkhulla Tadiimukhamedov
Omission	QUINIDINE SULFATE CAPSULES PF 46(4) Pg. ONLINE	Entire document	Donald Min
Omission	RESERPINE AND CHLOROTHIAZIDE TABLETS PF 46(4) Pg. ONLINE	Entire document	Donald Min
Revision	RINGER'S INJECTION PF 46(3) Pg. ONLINE	DEFINITION, ASSAY/Calcium, ASSAY/Potassium, ASSAY/Sodium, ASSAY/Chloride, SPECIFIC TESTS/Sterility Tests (71)	Gerald Hsu
New	RIOCIGUAT PF 46(3) 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, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Ren-Hwa Yeh
New	RPMI 1640 MEDIUM PF 46(4) Pg. ONLINE	RPMI 1640 Medium	Margareth Marques
Revision	SCOPOLAMINE HYDROBROMIDE PF 46(4) Pg. ONLINE	CHEMICAL INFORMATION, IDENTIFICATION/A.Spectroscopic Identification Tests (197), Infrared Spectroscopy	Devarshi Narendra Thaker
New	0.001 N SILVER NITRATE VS PF 46(3) Pg. ONLINE	0.001 N Silver Nitrate VS	Margareth Marques
New	DEUTERATED SODIUM 3-TRIMETHYLSILYLPROPIONATE PF 46(4) Pg. ONLINE	Deuterated Sodium 3-Trimethylsilylpropionate	Margareth Marques
New	SODIUM LAUROYL SARCOSINATE PF 46(3) Pg. ONLINE	CHEMICAL INFORMATION, DEFINITION, IDENTIFICATION/A. Spectroscopic Identification Tests (197), Infrared Spectroscopy, IDENTIFICATION/B. Chromatographic Identity, IDENTIFICATION/C. Presence of Sodium, ASSAY/Procedure, IMPURITIES/Limit of Sodium Decanoyl Sarcosinate and Sodium Myristoyl Sarcosinate, IMPURITIES/Limit of Sodium Sarcosinate, IMPURITIES/Limit of Sodium Laurate, IMPURITIES/Limit of Sodium Chloride, IMPURITIES/Limit of Sodium Sulfate, SPECIFIC TESTS/pH <791>, SPECIFIC TESTS/Water Determination (921), Method I, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards (11), FOOTNOTES	Galina Holloway
Revision	SODIUM MONOFLUOROPHOSPHATE PF 46(3) Pg. ONLINE	IDENTIFICATION/A., IDENTIFICATION/B., IDENTIFICATION/B. Identification Tests—General (191), Chemical Identification Tests, Sodium, ASSAY/Procedure, IMPURITIES/Limit of Fluoride Ion, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Michael Chang

DEFINITION, IDENTIFICATION/A. HPTLC for Articles of Botanical Origin (203): Flavone C-Glycosides, IDENTIFICATION/B. HPTLC for Articles of Botanical Origin (203): Triterpenoid Glycosides, IDENTIFICATION/C. HPLC, COMPOSITION/Content of Triterpenoid Glycosides, COMPOSITION/Content of Flavone C-Glycosides, 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/Loss on Drying (731), ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)

New SOUR JUJUBE SEED PF 45(6) Pg. ONLINE [Cuiying Ma](#)

DEFINITION, IDENTIFICATION/A. HPTLC for Articles of Botanical Origin (203): Flavone C-Glycosides, IDENTIFICATION/B. HPTLC for Articles of Botanical Origin (203): Triterpenoid Glycosides, IDENTIFICATION/C. HPLC, COMPOSITION/Content of Triterpenoid Glycosides, COMPOSITION/Content of Flavone C-Glycosides, CONTAMINANTS/Botanical Extracts (565), Preparations, General Pharmacopeial Requirements, Pesticide Residues, 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/Articles of Botanical Origin (561), Methods of Analysis, Total Ash, SPECIFIC TESTS/Loss on Drying (731), SPECIFIC TESTS/Botanical Extracts (565), Preparations, General Pharmacopeial Requirements, Residual Solvents, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)

New SOUR JUJUBE SEED DRY EXTRACT PF 45(6) Pg. ONLINE [Cuiying Ma](#)

DEFINITION, IDENTIFICATION/A. HPTLC for Articles of Botanical Origin (203): Flavone C-Glycosides, IDENTIFICATION/B. HPTLC for Articles of Botanical Origin (203): Triterpenoid Glycosides, IDENTIFICATION/C. HPLC, COMPOSITION/Content of Triterpenoid Glycosides, COMPOSITION/Content of Flavone C-Glycosides, 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/Loss on Drying (731), ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)

New SOUR JUJUBE SEED POWDER PF 45(6) Pg. ONLINE [Cuiying Ma](#)

Revision	Starch TS PF 46(3) Pg. ONLINE	Starch TS,	Margareth Marques
Omission	INVERT SUGAR INJECTION PF 46(4) Pg. ONLINE	Entire document	Gerald Hsu
Revision	SULFACETAMIDE SODIUM PF 46(4) Pg. ONLINE	IMPURITIES/Selenium (291)	Praveen Pabba
Revision	SULFADIAZINE PF 46(4) Pg. ONLINE	IMPURITIES/Selenium (291)	Praveen Pabba
Revision	SULFADIAZINE SODIUM PF 46(4) Pg. ONLINE	IDENTIFICATION/A. Spectroscopic Identification Tests (197), Infrared Spectroscopy, IDENTIFICATION/C. Melting Range or Temperature (741), IMPURITIES/Selenium (291)	Praveen Pabba
Revision	THIOGUANINE PF 46(4) Pg. ONLINE	IMPURITIES/Selenium (291), IMPURITIES/Organic Impurities	Devarshi Narendra Thaker
Omission	TIMOLOL MALEATE AND HYDROCHLOROTHIAZIDE TABLETS PF 46(3) Pg. ONLINE	Entire document	Donald Min
Omission	TOLBUTAMIDE FOR INJECTION PF 46(3) Pg. ONLINE	Entire document	Andrea Carney
Revision	TRICLOSAN PF 46(3) Pg. ONLINE	IDENTIFICATION/A. Spectroscopic Identification Tests (197), Infrared Spectroscopy, ASSAY/Procedure, IMPURITIES/Limit of 1,3,7-Trichlorodibenzo-p-dioxin, 2,8-Dichlorodibenzo-p-dioxin, 2,8-Dichlorodibenzofuran, and 2,4,8-Trichlorodibenzofuran, IMPURITIES/Limit of 2,3,7,8-Tetrachlorodibenzo-p-dioxin and 2,3,7,8-Tetrachlorodibenzofuran, IMPURITIES/Limit of Monochlorophenols and 2,4-Dichlorophenol, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Sujatha Ramakrishna
Omission	TRIMEPRAZINE TARTRATE TABLETS PF 46(3) Pg. ONLINE	Entire document	Devarshi Narendra Thaker
Revision	URSODIOL COMPOUNDED ORAL SUSPENSION PF 46(2) Pg. ONLINE	DEFINITION, ASSAY/Procedure 1: Oral Suspension in Ora-Sweet SF and Ora-Plus, ASSAY/Procedure 2: Oral Suspension in SuspendIt, SPECIFIC TESTS/pH (791), ADDITIONAL REQUIREMENTS/Beyond-Use Date	Brian Serumaga
New	ZINC OXIDE PF 46(3) Pg. ONLINE	Zinc Oxide,	Margareth Marques
New	ZINCON PF 46(3) Pg. ONLINE	Zincon,	Margareth Marques
New	ZOLEDRONIC ACID PF 45(4) Pg. ONLINE	CHEMICAL INFORMATION, DEFINITION, IDENTIFICATION/A. Spectroscopic Identification Tests (197), Infrared Spectroscopy, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, IMPURITIES/Limit of Phosphate and Phosphite (if present), SPECIFIC TESTS/Bacterial Endotoxins Test (85), SPECIFIC TESTS/Microbial Enumeration Tests (61) and Tests for Specified Microorganisms (62), SPECIFIC TESTS/Water Determination (921), Method I, Method Ia, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Andrea Carney