

Compendial Deferrals for USPNF 2023 ISSUE 2

Date: Thu Nov 03 11:29:13 EDT 2022

Category	Monograph Title	Monograph Section	Scientific Liaison
Revision	EXCIPIENTS (USP and NF), LISTED BY CATEGORY PF 48(2) Pg. ONLINE	{Emulsifier} Soybean Phospholipids, {Emulsifying Agent} Soybean Phospholipids, {Suspending and/or Viscosity-Increasing Agent} Soybean Phospholipids, {Wetting and/or Solubilizing Agent} Soybean Phospholipids, {Emulsifying Agent} Sodium Oleate, {pH Modifier} Sodium Oleate	Peng Zhang
Revision	DESCRIPTION AND SOLUBILITY PF 48(1) Pg. ONLINE	C/Clobazam, G/Guanfacine Hydrochloride, S/Soybean Phospholipids, C/Choline Fenofibrate, N/Nebivolol Hydrochloride, K/Ketotifen Fumarate, B/Bemotrizinol, D/Dimethyl Fumarate, S/Sodium Oleate, C/Carglumic Acid, E/Esomeprazole Sodium, C/Cevimeline Hydrochloride, D/Darunavir, A/Armodafinil	Yanyin Yang
New	</2> RESPIRATION BASED RAPID MICROBIAL METHODS FOR THE RELEASE OF STERILE SHORT- LIFE PRODUCTS PF 46(6) Pg. ONLINE	New	Radhakrishna Tirumalai
New	</3> ATP BIOLUMINESCENCE BASED RAPID MICROBIAL METHODS FOR THE RELEASE OF STERILE SHORT -LIFE PRODUCTS PF 46(6) Pg. ONLINE	New	Radhakrishna Tirumalai
Revision	<232> ELEMENTAL IMPURITIES--LIMITS PF 47(1) Pg. ONLINE	Revision	Kakhshan Zaidi
New	<314> MOLECULAR WEIGHT DETERMINATION FOR COPOLYMERS CONTAINING ALKYL METHACRYLATE OR ALKYL ACRYLATE PF 47(5) Pg. ONLINE	New	Peng Zhang
Omission	</8/> SUBVISIBLE PARTICULATE MATTER IN THERAPEUTIC PROTEIN INJECTIONS PF 47(3) Pg. ONLINE	Entire document	Desmond Hunt
New	<901> DETECTION OF ASBESTOS IN PHARMACEUTICAL TALC PF 48(2) Pg. ONLINE	New	Jenny Liu
Revision	<1112> APPLICATION OF WATER ACTIVITY DETERMINATION TO NONSTERILE PHARMACEUTICAL PRODUCTS PF 47(1) Pg. ONLINE	Revision	Radhakrishna Tirumalai
New	<1229.19> SIMULTANEOUS DECONTAMINATION AND STERILIZATION PF 47(5) Pg. ONLINE	New	Radhakrishna Tirumalai
New	<1229.20> DECONTAMINATION AND STERILIZATION PRE, MID AND POST PROCESS-CONSIDERATIONS PF 47(5) Pg. ONLINE	New	Radhakrishna Tirumalai
Revision	<1236> SOLUBILITY MEASUREMENTS PF 48(2) Pg. ONLINE	Revision	Margareth Marques
New	<1504> QUALITY ATTRIBUTES OF STARTING MATERIALS FOR THE CHEMICAL SYNTHESIS OF THERAPEUTIC PEPTIDES PF 48(1) Pg. ONLINE	New	Julie Zhang
New	<1567> PYRROLIZIDINE ALKALOIDS AS CONTAMINANTS PF 48(1) Pg. ONLINE	New	Sandeep Putty
Revision	<1604> PRESENTATION OF AERODYNAMIC PARTICLE SIZE DISTRIBUTION MEASUREMENT DATA PF 48(1) Pg. ONLINE	Revision	Kakhshan Zaidi

New	<1901> THEORY AND PRACTICE OF ASBESTOS DETECTION IN PHARMACEUTICAL TALC PF 48(2) Pg. ONLINE	New	Jenny Liu
New	<2800> MULTI-INGREDIENT DIETARY SUPPLEMENT PRODUCTS - DEVELOPMENT OF QUALITY TESTS PF 47(5) Pg. ONLINE	New	Natalia Davydova
New	ACAMPROSATE DELAYED-RELEASE TABLETS PF 46(6) 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/Limit of Acamprosate Related Compound A, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Shankari Shivaprasad
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	Christine Hiemer
Revision	ALUMINA AND MAGNESIUM TRISILICATE TABLETS PF 47(2) Pg. ONLINE	IDENTIFICATION/A. Identification Tests—General (191), Chemical Identification Tests, Magnesium, IDENTIFICATION/A., IDENTIFICATION/B. Identification Tests—General (191), Chemical Identification Tests, Aluminum, IDENTIFICATION/B., IDENTIFICATION/C. Silicon Dioxide, ASSAY/Procedure 1: Aluminum Hydroxide, ASSAY/Procedure 2: Magnesium Trisilicate, ASSAY/Procedure, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Christine Hiemer
New	ARGATROBAN IN SODIUM CHLORIDE INJECTION PF 46(6) Pg. ONLINE	DEFINITION, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Sterility Tests (71), SPECIFIC TESTS/Bacterial Endotoxins Test (85), SPECIFIC TESTS/pH (791), SPECIFIC TESTS/Osmolality and Osmolarity (785), SPECIFIC TESTS/Particulate Matter in Injections (788), SPECIFIC TESTS/Other Requirements, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Christine Hiemer
New	ARMODAFINIL 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/Limit of S-Enantiomer, SPECIFIC TESTS/Water Determination (921), ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Shankari Shivaprasad

New	ARMODAFINIL TABLETS PF 46(5) 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, IMPURITIES/Limit of S-Enantiomer, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Shankari Shivaprasad
New	ARTEMETHER AND LUMEFANTRINE TABLETS PF 47(5) Pg. ONLINE	New	Christine Hiemer
Revision	ASPIRIN PF 48(2) Pg. ONLINE	Revision	Christine Hiemer
Revision	ASPIRIN SUPPOSITORIES PF 48(2) Pg. ONLINE	Revision	Christine Hiemer
New	BEMOTRIZINOL PF 47(5) Pg. ONLINE	New	Christine Hiemer
Revision	BETAMETHASONE ACETATE PF 46(6) Pg. ONLINE	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)	Shankari Shivaprasad
Revision	BETAMETHASONE VALERATE PF 47(4) Pg. ONLINE	CHEMICAL INFORMATION, IDENTIFICATION/A. Spectroscopic Identification Tests (197), Infrared Spectroscopy, IDENTIFICATION/B. Thin-Layer Chromatographic Identification Test (201), ASSAY/Procedure, IMPURITIES/Limit of Betamethasone Valerate Related Compound H, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Shankari Shivaprasad
New	BITTER ORANGE YOUNG FRUIT PF 47(5) Pg. ONLINE	New	Cuiying Ma
New	BITTER ORANGE YOUNG FRUIT POWDER PF 47(5) Pg. ONLINE	New	Cuiying Ma
New	BIVALIRUDIN PF 48(2) Pg. ONLINE	Revision	Julie Zhang
New	BIVALIRUDIN FOR INJECTION PF 48(2) Pg. ONLINE	Revision	Julie Zhang
Revision	BUMETANIDE PF 47(4) Pg. ONLINE	IDENTIFICATION/A. Spectroscopic Identification Tests (197), Infrared Spectroscopy, IDENTIFICATION/B.Spectroscopic Identification Tests (197), Ultraviolet-Visible Spectroscopy, IDENTIFICATION/C., ASSAY/Procedure, IMPURITIES/Residue on Ignition (281), IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Christine Hiemer
Revision	BUMETANIDE INJECTION PF 47(4) Pg. ONLINE	DEFINITION, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Bacterial Endotoxins Test (85), ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Christine Hiemer
Revision	BUMETANIDE TABLETS PF 47(4) Pg. ONLINE	IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution (711), IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Christine Hiemer

New	BUPRENORPHINE COMPOUNDED SUBLINGUAL SOLUTION PF 47(6) Pg. ONLINE	New DEFINITION, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/pH (791), SPECIFIC TESTS/Particulate Matter in Injections (788), SPECIFIC TESTS/Sterility Tests (71), SPECIFIC TESTS/Bacterial Endotoxins Test (85), SPECIFIC TESTS/Other Requirements, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Selma Mitiche
New	BUPRENORPHINE INJECTION PF 46(6) Pg. ONLINE	DEFINITION, IDENTIFICATION/A., IDENTIFICATION/B., IDENTIFICATION/C., IDENTIFICATION/D., ASSAY/Betamethasone Dipropionate, ASSAY/Calcipotriene, IMPURITIES/Organic Impurities: Betamethasone Dipropionate, IMPURITIES/Organic Impurities: Calcipotriene, PERFORMANCE TESTS/Minimum Fill (755), SPECIFIC TESTS/Microbial Enumeration Tests (61) and Tests for Specified Microorganisms (62), ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Christine Hiemer
New	CALCIPOTRIENE AND BETAMETHASONE DIPROPIONATE OINTMENT PF 46(6) Pg. ONLINE	DEFINITION, IDENTIFICATION/A., IDENTIFICATION/B., IDENTIFICATION Tests—General (191), Chemical Identification Tests, Acetate, ASSAY/Procedure, SPECIFIC TESTS/pH (791), SPECIFIC TESTS/Microbial Enumeration Tests (61) and Tests for Specified Microorganisms (62), ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards (11), FOOTNOTES	Shankari Shivaprasad
New	CALCIUM ACETATE ORAL SOLUTION PF 46(5) Pg. ONLINE	ASSAY/Procedure, PERFORMANCE TESTS/DISSOLUTION (711), IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Shankari Shivaprasad
Revision	CANDESARTAN CILEXETIL AND HYDROCHLOROTHIAZIDE TABLETS PF 47(4) Pg. ONLINE	Revision	Christine Hiemer
Revision	CARBAMAZEPINE PF 48(2) Pg. ONLINE	Revision	Shankari Shivaprasad
New	CARGLUMIC ACID PF 47(6) Pg. ONLINE	New IDENTIFICATION/A. Thin layer Chromatography, IDENTIFICATION/A., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Christine Hiemer
Revision	CARTEOLOL HYDROCHLORIDE OPHTHALMIC SOLUTION PF 46(5) Pg. ONLINE	Revision	Christine Hiemer
Revision	CHLORZOXAZONE PF 48(2) Pg. ONLINE	Revision	Shankari Shivaprasad
Revision	CHLORZOXAZONE TABLETS PF 48(2) Pg. ONLINE	Revision	Shankari Shivaprasad
New	CHOLINE FENOFIBRATE PF 47(6) Pg. ONLINE	NEW 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)	Christine Hiemer
New	CISPLATIN INJECTION PF 46(5) Pg. ONLINE		Christine Hiemer

New	CLOBAZAM PF 48(1) Pg. ONLINE	New	Shankari Shivaprasad
Revision	CLOMIPRAMINE HYDROCHLORIDE PF 47(6) Pg. ONLINE	Revision	Shankari Shivaprasad
New	COCOYL CAPRYLOCAPRATE PF 47(6) Pg. ONLINE	New	SanthiKumar Saladi
New	CRANBERRY FRUIT JUICE DRY EXTRACT CAPSULES PF 47(3) Pg. ONLINE	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)	Maria Monagas
Revision	DALFAMPRIDINE PF 46(6) Pg. ONLINE	DEFINITION, ASSAY/Procedure, IMPURITIES/LIMIT OF Dalfampridine Related Compound B and Dalfampridine Related Compound C, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Water Determination (921), Method I, Method Ia, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Shankari Shivaprasad
New	DAPAGLIFLOZIN PROPANEDIOL PF 47(4) Pg. ONLINE	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)	Christine Hiemer
New	DARUNAVIR PF 47(4) 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/Content of Ethanol, SPECIFIC TESTS/Water Determination (921), Method I, Method Ia, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Christine Hiemer
New	DARUNAVIR ORAL SUSPENSION PF 47(6) Pg. ONLINE	New	Christine Hiemer
New	DARUNAVIR TABLETS PF 47(4) 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, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Christine Hiemer
New	DIMETHYL FUMARATE PF 47(5) Pg. ONLINE	New	Shankari Shivaprasad

New	DIMETHYL FUMARATE DELAYED-RELEASE CAPSULES PF 47(5) Pg. ONLINE	New IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Bacterial Endotoxins Test (85), ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Shankari Shivaprasad
Revision	DOBUTAMINE INJECTION PF 47(1) Pg. ONLINE	IDENTIFICATION/C., ASSAY/DoButamine, IMPURITIES/Organic Impurities, IMPURITIES/Limit of 5-Hydroxymethylfurfural, SPECIFIC TESTS/Bacterial Endotoxins Test (85), ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Christine Hiemer
Revision	DOBUTAMINE IN DEXTROSE INJECTION PF 47(2) Pg. ONLINE		Christine Hiemer
New	DOFETILIDE CAPSULES PF 48(1) Pg. ONLINE	New	Christine Hiemer
Revision	DOPAMINE HYDROCHLORIDE INJECTION PF 47(5) Pg. ONLINE	Revision IDENTIFICATION/C., ASSAY/Dopamine hydrochloride, IMPURITIES/Organic Impurities, IMPURITIES/Limit of 5-Hydroxymethylfurfural and Related Substances, SPECIFIC TESTS/Bacterial Endotoxins Test (85), ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Christine Hiemer
Revision	DOPAMINE HYDROCHLORIDE AND DEXTROSE INJECTION PF 47(4) 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/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Christine Hiemer
Revision	DUTASTERIDE CAPSULES PF 46(5) Pg. ONLINE		Shankari Shivaprasad
Revision	ERYTHROMYCIN PF 48(1) Pg. ONLINE	Revision Spectroscopic Identification Tests (197), Infrared Spectroscopy, IDENTIFICATION/B., IDENTIFICATION/C. Identification Tests—General (191), Chemical Identification Tests, Sodium, ASSAY/Procedure, IMPURITIES/Organic Impurities, IMPURITIES/Enantiomeric Purity, SPECIFIC TESTS/Water determination (921), Method I, SPECIFIC TESTS/Bacterial Endotoxins Test (85), SPECIFIC TESTS/Microbial Enumeration Tests (61) and Test for Specified Microorganisms (62), ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Julie Zhang
New	ESOMEPRAZOLE SODIUM PF 47(3) Pg. ONLINE		Christine Hiemer

		DEFINITION, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Uniformity of Dosage Units (905), IMPURITIES/Organic Impurities, SPECIFIC TESTS/pH (791), SPECIFIC TESTS/Water Determination (921), Method I, SPECIFIC TESTS/Particulate Matter in Injections (788), SPECIFIC TESTS/Bacterial Endotoxins Test (85), SPECIFIC TESTS/Sterility Tests (71), SPECIFIC TESTS/Injections and Implanted Drug Products (1), Product Quality Tests Common to Parenteral Dosage Forms, Specific Tests, Completeness and Clarity of Solutions, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	
New	ESOMEPRAZOLE SODIUM FOR INJECTION PF 47(3) Pg. ONLINE		Christine Hiemer
Revision	ETHACRYNIC ACID TABLETS PF 47(5) Pg. ONLINE	Revision	Christine Hiemer
Revision	ETODOLAC PF 47(5) Pg. ONLINE	Revision	Christine Hiemer
Revision	ETODOLAC TABLETS PF 47(5) Pg. ONLINE	Revision	Christine Hiemer
New	FENOFIBRIC ACID DELAYED-RELEASE CAPSULES PF 47(6) Pg. ONLINE	NEW	Christine Hiemer
Revision	FEVERFEW LEAF PF 47(6) Pg. ONLINE	Revision	Anton Bzhelyansky
Revision	FEVERFEW LEAF POWDER PF 47(6) Pg. ONLINE	Revision	Anton Bzhelyansky
Revision	FLUOROURACIL INJECTION PF 47(3) Pg. ONLINE	IDENTIFICATION/B. Spectroscopic Identification Tests (197), Infrared Spectroscopy, IDENTIFICATION/C., ASSAY/Procedure, IMPURITIES/Organic Impurities, IMPURITIES/Limit of Urea, SPECIFIC TESTS/Bacterial Endotoxins Test (85), SPECIFIC TESTS/Particulate Matter in Injections (788), SPECIFIC TESTS/Sterility test (71), ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Christine Hiemer
Revision	FLUOXETINE CAPSULES PF 46(5) Pg. ONLINE	IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution (711), ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards (11), IMPURITIES/Organic Impurities	Shankari Shivaprasad
Revision	FLUOXETINE DELAYED-RELEASE CAPSULES PF 46(5) Pg. ONLINE	IMPURITIES/Organic Impurities, IDENTIFICATION/A. Spectroscopic Identification Tests (197), Infrared Spectroscopy, IDENTIFICATION/A., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution (711), ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Shankari Shivaprasad
Revision	FLUOXETINE ORAL SOLUTION PF 46(5) Pg. ONLINE	IDENTIFICATION/A. Spectroscopic Identification Tests (197), Infrared Spectroscopy, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards (11), IMPURITIES/Organic Impurities	Shankari Shivaprasad
Revision	FLUOXETINE TABLETS PF 46(5) Pg. ONLINE	IDENTIFICATION/A. Spectroscopic Identification Tests (197), Infrared Spectroscopy, IDENTIFICATION/A., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution (711), ADDITIONAL REQUIREMENTS/USP Reference Standards (11), IMPURITIES/Organic Impurities	Shankari Shivaprasad

Revision	FLUOXETINE HYDROCHLORIDE PF 46(5) Pg. ONLINE	IDENTIFICATION/A. Spectroscopic Identification Tests (197), Infrared Spectroscopy, ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards (11), IMPURITIES/Residue on Ignition (281)	Shankari Shivaprasad
New	GABAPENTIN COMPOUNDED CREAM PF 47(5) Pg. ONLINE	New	Selma Mitiche
Revision	GANCICLOVIR FOR INJECTION PF 47(5) Pg. ONLINE	Revision	Christine Hiemer
Revision	GLUCAGON PF 48(2) Pg. ONLINE	Revision	Julie Zhang
Revision	L-ALPHA-GLYCERYLPHOSPHORYLCHOLINE PF 47(3) Pg. ONLINE	DEFINITION, SPECIFIC TESTS/Optical Rotation (7815), Procedures, Specific Rotation, SPECIFIC TESTS/Water Determination (921), Method I, Method Ia, ASSAY/Procedure	Fatkhulla Tadjimukhamedov
Revision	GUANFACINE HYDROCHLORIDE PF 48(1) Pg. ONLINE	Revision	Christine Hiemer
New	HYDROCORTISONE COMPOUNDED ORAL SUSPENSION PF 47(5) Pg. ONLINE	New	Brian Serumaga
New	IBANDRONATE SODIUM PF 47(6) Pg. ONLINE	New	Christine Hiemer
New	INOSITOL NIACINATE PF 48(2) Pg. ONLINE	New	Sandeep Putty
Revision	DILUTED ISOSORBIDE MONONITRATE PF 47(3) Pg. ONLINE	IDENTIFICATION/A. Spectroscopic Identification Tests (197), Infrared Spectroscopy, ASSAY/Procedure, IMPURITIES/Limit of Nitrate, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Christine Hiemer
Revision	ISOSORBIDE MONONITRATE TABLETS PF 47(4) Pg. ONLINE	IDENTIFICATION/A. Thin-Layer Chromatographic Identification Test (201), ASSAY/Procedure, PERFORMANCE TESTS/Dissolution (711), PERFORMANCE TESTS/Uniformity of Dosage Units (905), IMPURITIES/Limit of Nitrate, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Christine Hiemer
Revision	ISOSORBIDE MONONITRATE EXTENDED-RELEASE TABLETS PF 47(5) Pg. ONLINE	Revision	Christine Hiemer
New	KETOTIFEN FUMARATE PF 47(5) Pg. ONLINE	NEW, Revision	Heather Joyce
Revision	LABETALOL HYDROCHLORIDE PF 48(2) Pg. ONLINE	Revision	Christine Hiemer
Revision	LABETALOL HYDROCHLORIDE INJECTION PF 48(2) Pg. ONLINE	Revision	Christine Hiemer
Revision	LABETALOL HYDROCHLORIDE TABLETS PF 48(2) Pg. ONLINE	Revision	Christine Hiemer
Revision	LECITHIN PF 48(2) Pg. ONLINE	Revision	Peng Zhang
Revision	MESALAMINE DELAYED-RELEASE TABLETS PF 47(6) Pg. ONLINE	Revision	Christine Hiemer
Revision	METHADONE HYDROCHLORIDE PF 48(1) Pg. ONLINE	Revision	Christine Hiemer
Revision	METHADONE HYDROCHLORIDE INJECTION PF 48(1) Pg. ONLINE	Revision	Christine Hiemer
Revision	METHADONE HYDROCHLORIDE TABLETS PF 47(4) Pg. ONLINE	IDENTIFICATION/A. Thin-Layer Chromatographic Identification Test (201), IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution (711), IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage	Christine Hiemer

Revision	NAPROXEN PF 47(4) Pg. ONLINE	DEFINITION, IDENTIFICATION/A. Spectroscopic Identification Tests (197), Infrared Spectroscopy, IDENTIFICATION/B. Spectroscopic Identification Tests (197), Ultraviolet-Visible Spectroscopy, ASSAY/Procedure, IMPURITIES/Organic Impurities, IMPURITIES/Enantiomeric Purity Test, SPECIFIC TESTS/Optical Rotation (781S), Procedures, Specific Rotation, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Christine Hiemer
Revision	NAPROXEN SODIUM PF 47(4) Pg. ONLINE	CHEMICAL INFORMATION, IDENTIFICATION/A. Spectroscopic Identification Tests (197), Infrared Spectroscopy, IDENTIFICATION/B. Spectroscopic Identification Tests (197), Ultraviolet-Visible Spectroscopy, ASSAY/Procedure, IMPURITIES/Organic Impurities, Procedure 1, IMPURITIES/Limit of Free Naproxen, IMPURITIES/Enantiomeric Purity Test, SPECIFIC TESTS/Optical Rotation (781S), Procedures, Specific Rotation, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Christine Hiemer
New	NEBIVOLOL HYDROCHLORIDE PF 47(6) Pg. ONLINE	New	Christine Hiemer
New	NEEM LEAF PF 47(5) Pg. ONLINE	New	Nam-Cheol Kim
New	NEEM LEAF DRY EXTRACT PF 47(5) Pg. ONLINE	New	Nam-Cheol Kim
New	NEEM LEAF POWDER PF 47(5) Pg. ONLINE	New	Nam-Cheol Kim
Revision	NORTRIPTYLINE HYDROCHLORIDE CAPSULES PF 48(1) Pg. ONLINE	Revision	Shankari Shivaprasad
Revision	OXYBUTYNIN CHLORIDE ORAL SOLUTION PF 47(2) Pg. ONLINE	IDENTIFICATION/A. Thin-Layer Chromatographic Identification Test (201), IDENTIFICATION, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Microbiological Examination of Nonsterile Products—Tests for Burkholderia Cepacia Complex (60), SPECIFIC TESTS/Microbial Enumeration Tests (61) and Tests for Specified Microorganisms (62), ADDITIONAL REQUIREMENTS/Packaging and Storage	Christine Hiemer
Revision	OXYCODONE HYDROCHLORIDE TABLETS PF 47(3) Pg. ONLINE	IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution (711), IMPURITIES/Organic Impurities, IMPURITIES, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Christine Hiemer
New	PALONOSETRON INJECTION PF 46(5) Pg. ONLINE	DEFINITION, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Uniformity of Dosage Units (905), IMPURITIES/Organic Impurities, SPECIFIC TESTS/pH (791), SPECIFIC TESTS/Particulate Matter in Injections (788), SPECIFIC TESTS/Sterility (71), SPECIFIC TESTS/Bacterial Endotoxins Test (85), SPECIFIC TESTS/Other Requirements, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Christine Hiemer
Revision	PANTOPRAZOLE SODIUM PF 48(2) Pg. ONLINE	Revision	Christine Hiemer
New	PANTOPRAZOLE SODIUM FOR INJECTION PF 48(2) Pg. ONLINE	New	Christine Hiemer

Revision	PIROXICAM CAPSULES PF 47(1) Pg. ONLINE	IDENTIFICATION/A. Thin-Layer Chromatography, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution (711), IMPURITIES/Organic Impurities, SPECIFIC TESTS/Water Determination (921), Method I, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Christine Hiemer
New	POLYETHYLENE GLYCOL 3350 FOR ORAL SOLUTION PF 47(3) Pg. ONLINE	DEFINITION, IDENTIFICATION/A. Spectroscopic Identification Tests (197), Infrared Spectroscopy, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, IMPURITIES/Limit of Formaldehyde and Acetaldehyde, SPECIFIC TESTS/pH (791), SPECIFIC TESTS/Water Determination (921), Method I, SPECIFIC TESTS/Completeness of Solution (641), ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Christine Hiemer
Revision	PUMMELO PEEL PF 48(2) Pg. ONLINE	Revision	Cuiying Ma
Revision	PUMMELO PEEL FLAVONOIDS DRY EXTRACT PF 48(2) Pg. ONLINE	Revision	Cuiying Ma
Revision	PUMMELO PEEL POWDER PF 48(2) Pg. ONLINE	Revision	Cuiying Ma
Revision	ROSUVASTATIN CALCIUM PF 47(4) Pg. ONLINE	CHEMICAL INFORMATION, DEFINITION, IDENTIFICATION/A. Spectroscopic Identification Tests (197), Infrared Spectroscopy, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, IMPURITIES/Enantiomeric Purity, IMPURITIES/Limit of Chloride, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Christine Hiemer
Revision	ROSUVASTATIN TABLETS PF 47(4) Pg. ONLINE	DEFINITION, IDENTIFICATION/A., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution (711), IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Christine Hiemer
New	SODIUM OLEATE PF 47(6) Pg. ONLINE	NEW	Devendra Vasant Chavan
New	SOYBEAN PHOSPHOLIPIDS PF 48(2) Pg. ONLINE	New	Peng Zhang
Revision	SULBACTAM SODIUM PF 47(4) Pg. ONLINE	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)	Christine Hiemer
Revision	TALC PF 48(2) Pg. ONLINE	Revision	Jenny Liu
Revision	TERBUTALINE SULFATE PF 47(5) Pg. ONLINE	Revision	Shankari Shivaprasad
Revision	TERBUTALINE SULFATE INJECTION PF 47(5) Pg. ONLINE	Revision	Shankari Shivaprasad

New	TIAGABINE HYDROCHLORIDE TABLETS 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)	Shankari Shivaprasad
Revision	TIMOLOL MALEATE OPHTHALMIC SOLUTION PF 47(4) Pg. ONLINE	IDENTIFICATION/A., IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and storage, ADDITIONAL REQUIREMENTS/USP Reference standards (11)	Christine Hiemer
Revision	TOLTERODINE TARTRATE PF 48(1) Pg. ONLINE	Revision	Christine Hiemer
New	TOLTERODINE TARTRATE EXTENDED-RELEASE CAPSULES PF 48(1) Pg. ONLINE	New	Christine Hiemer
New	TOPIRAMATE EXTENDED-RELEASE CAPSULES PF 48(2) Pg. ONLINE	New	Shankari Shivaprasad
New	VALGANCICLOVIR FOR ORAL SOLUTION PF 47(3) Pg. ONLINE	DEFINITION, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Uniformity of Dosage Units (905), IMPURITIES/Organic Impurities, SPECIFIC TESTS/• pH (791), SPECIFIC TESTS/Water Determination (921), Method I, SPECIFIC TESTS/Microbial Enumeration Tests (61) and Tests for Specified Microorganisms (62), ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Christine Hiemer