Compendial Deferrals for USPNF 2023 ISSUE 1

Date: Thu Jul 07 12:09:48 EDT 2022

Category	Monograph Title	Monograph Section	Scientific Liaison
Revision	EXCIPIENTS (USP and NF), LISTED BY CATEGORY PF 47(6) Pg. ONLINE	{Emollient} Polyethylene Glycol 30 Dipolyhydroxystearate 5, {Emulsifying Agent} Polyethylene Glycol 30 Dipolyhydroxystearate 5, {Stiffening Agent} Polyethylene Glycol 30 Dipolyhydroxystearate 5, {Wetting and::or Solubilizing Agent} Polyethylene Glycol 30 Dipolyhydroxystearate 5, {Emollient} Polyethylene Glycol 12 Cetostearyl Ether, {Emulsifying Agent} Polyethylene Glycol 12 Cetostearyl Ether, {Stiffening Agent} Polyethylene Glycol 12 Cetostearyl Ether, {Wetting and::or Solubilizing Agent} Polyethylene Glycol 12 Cetostearyl Ether, {Emollient} Cocoyl Caprylocaprate, {Wetting and::or Solubilizing Agent} Cocoyl Caprylocaprate, {Emulsifying Agent} Sodium Oleate, {ph Modifier} Sodium Oleate, {Emulsifying Agent} Soybean Phosphatidylcholine, {Wetting and::or Solubilizing Agent} Soybean Phosphatidylcholine, {Wetting and::or Solubilizing Agent} Soybean Phosphatidylcholine, {Wetting and::or Solubilizing Agent} Soybean Phosphatidylcholine	Devendra Vasant Chavan
Davision	<5> INHALATION AND NASAL DRUG PRODUCTS GENERAL INFORMATION AND PRODUCT QUALITY TESTS PF 47(4) Pg.	Pavisian	Material State
Revision	ONLINE	Revision C/Choline Fenofibrate, N/Nebivolol Hydrochloride, T/Triclabendazole, P/Polyethylene Glycol 30 Dipolyhydroxystearate 5, K/Ketotifen Fumarate, P/Polyethylene Glycol 12 Cetostearyl Ether, B/Bemotrizinol, C/Cocoyl Caprylocaprate, D/Dimethyl Fumarate, S/Sodium Oleate, L/Lamotrigine, C/Carglumic Acid, T/Norflurane, E/Esomeprazole Sodium, C/Cevimeline Hydrochloride, D/Darunavir, S/Soybean Phosphatidylcholine, R/Roflumilast,	<u>Kahkashan Zaidi</u>
Revision	DESCRIPTION AND SOLUBILITY PF 47(6) Pg. ONLINE 2 RESPIRATION BASED RAPID MICROBIAL METHODS FOR THE RELEASE OF STERILE SHORT- LIFE PRODUCTS PF 46(6) Pg.	A/Armodafinil, U/Ulipristal Acetate, M/Micafungin Sodium	Sujatha Ramakrishna
New	ONLINE A I P BIOLUMINISCENCE BASED RAPID MICROBIAL METHODS FOR THE RELEASE OF STERILE SHORT -LIFE PRODUCTS PF 46(6) Pq. ONLINE	New New	Radhakrishna Tirumalai Radhakrishna Tirumalai
Revision	<232> ELEMENTAL IMPURITIESLIMITS PF 47(1) Pg. ONLINE	Revision	Kahkashan Zaidi
New	<313> MULECULAR WEIGHT AND PULYMER CHAIN LENGTH DETERMINATION FOR POLYPROPYLENE GLYCOL FATTY ETHERS PF 47(5) Pg. ONLINE <314> MOLECULAR WEIGHT DETERMINATION FOR COPOLYMERS	New	Peng Zhang
New	CONTAINING ALKYL METHACRYLATE OR ALKYL ACRYLATE PF 47(5) Pg. ONLINE	New	Peng Zhang
New	<621> CHROMATOGRAPHY PF 43(5) Pg. ONLINE 8/ 8/ SUBVISIBLE PARTICULATE MATTER IN THERAPEUTIC	DEFINITIONS, SYSTEM SUITABILITY, ADJUSTMENT OF CHROMATOGRAPHIC CONDITIONS, QUANTIFICATION	Horacio Pappa
Omission	PROTEIN INJECTIONS PF 47(3) Pg. ONLINE	Entire document	Desmond Hunt
Revision New	<1072> DISINFECTANTS AND ANTISEPTICS PF 46(5) Pg. ONLINE <1083> SUPPLIER QUALIFICATION PF 47(5) Pg. ONLINE	Revision New	Radhakrishna Tirumalai
New	CHOSPS BATCH RELEASE TESTING FOR ENSURING COMPLIANCE WITH UNIFORMITY OF DOSAGE UNITS PF 47(4) Pg. ONLINE CHOSPS LIGHT ON NUMBER OF LAKGE DEVIATIONS WHEN ASSESSING CONTENT UNIFORMITY IN LARGE SAMPLES PF 47(4)	New	<u>Desmond Hunt</u> <u>Steven Walfish</u>
Revision	Pg. ONLINE <1112> APPLICATION OF WATER ACTIVITY DETERMINATION TO	Revision	Steven Walfish
Revision	NONSTERILE PHARMACEUTICAL PRODUCTS PF 47(1) Pg. ONLINE <1229.19> SIMULTANEOUS DECONTAMINATION AND	Revision	Radhakrishna Tirumalai
New	STERILIZATION PF 47(5) Pg. ONLINE <1229.20> DECONTAMINATION AND STERILIZATION PRE, MID	New	Radhakrishna Tirumalai
New	AND POST PROCESS-CONSIDERATIONS PF 47(5) Pg. ONLINE <1604> PRESENTATION OF AERODYNAMIC PARTICLE SIZE	New	Radhakrishna Tirumalai
Revision	DISTRIBUTION MEASUREMENT DATA PF 46(5) Pg. ONLINE <1912> MEASUREMENT OF HARDNESS OF SEMISOLIDS PF 47(2)	Revision	Kahkashan Zaidi
Revision	Pg. ONLINE <2800> MULTI-INGREDIENT DIETARY SUPPLEMENT PRODUCTS -	Revision	Antonio Hernandez-Cardoso
New	DEVELOPMENT OF QUALITY TESTS PF 47(5) Pg. ONLINE ABACAVIR, LAMIVUDINE AND ZIDOVUDINE TABLETS PF 47(3) Pg.	New IDENTIFICATION/A., IDENTIFICATION/B., PERFORMANCE	Natalia Davydova
Revision	ONLINE	TESTS/Dissolution (711), IMPURITIES/Organic Impurities LETATION, DETERMINATION, SPECIOSCOPIC DETIRINATION, 1011 IDEATION, SPECIOSCOPIC DETIRINATION, 1011 IDEATION, SPECIOSCOPIC DETIRINATION (1977), INFORMANCE TESTS/DISSO	<u>Christine Hiemer</u>
New	ACAMPROSATE DELAYED-RELEASE TABLETS PF 46(6) Pg. ONLINE ACETAZOLAMIDE EXTENDED-RELEASE CAPSULES PF 46(5) Pg.	Reference Standards (11) 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	<u>Shankari Shivaprasad</u>
New	ONLINE	REQUIREMENTS/USP Reference Standards (11), FOOTNOTES	Christine Hiemer

New	BUPRENORPHINE COMPOUNDED SUBLINGUAL SOLUTION PF 47(6) Pg. ONLINE	New	<u>Selma Mitiche</u>
Revision	BUMETANIDE TABLETS PF 47(4) Pg. ONLINE	Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Christine Hiemer
Revision	BUMETANIDE INJECTION PF 47(4) Pg. ONLINE	ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Bacterial Endotoxins Test (85), ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards (11) IDENIIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution (711), IMPURITIES/Organic	<u>Christine Hiemer</u>
Revision	BUMETANIDE PF 47(4) Pg. ONLINE	Identification Tests (197), Ultraviolet-Visible Spectroscopy, IDENTIFICATION/C., ASSAY/Procedure, IMPURITIES/Residue on Ignition (281), IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	<u>Christine Hiemer</u>
New	BROCCOLI SEED DRY EXTRACT PF 46(3) Pg. ONLINE	DEFINITION, IDENTIFICATION/A. HPTLC for Articles of Botanical Origin (203), IDENTIFICATION/B. HPLC, COMPOSITION/Content of Glucoraphanin, COMPOSITION, CONTAMINANTS/Botanicals Extracts (565), General Pharmacopeial Requirements, Preparations, Pesticide Residues, 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/Loss on Drying (731), SPECIFIC TESTS/Articles of Botanical Origin (561), Methods of Analysis, Total Ash, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards (11) IDENTIFILALIUN/A. Spectroscopic Identification Lests (197), Infrared Spectroscopy, IDENTIFICATION/B.Spectroscopic	<u>Maria Monagas</u>
New	BITTER ORANGE FOUND FRUIT POWDER PF 47(5) Pg. ONLINE	New	Cuiying Ma
Revision New	BETAMETHASONE VALERATE PF 47(4) Pg. ONLINE BITTER ORANGE YOUNG FRUIT PF 47(5) 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) New	Shankari Shivaprasad Cuiying Ma
Revision	BETAMETHASONE DIPROPIONATE PF 46(3) Pg. ONLINE	IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Shankari Shivaprasad
Revision	BETAMETHASONE ACETATE PF 46(6) Pg. ONLINE	IMPURITIES/OFGAINC 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) IDENTIFICATION/A. Spectroscopic Identification Tests (197), Infrared Spectroscopy, IDENTIFICATION/B. Thin-Layer Chromatographic Identification Test (201), ASSAY/Procedure,	Shankari Shivaprasad
New New	ARTEMETHER AND LUMEFANTRINE TABLETS PF 47(5) Pg. ONLINE BEMOTRIZINOL PF 47(5) Pg. ONLINE	New New	Christine Hiemer Christine Hiemer
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	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	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/DH (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/PACKAGING (11)	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, 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)	<u>Christine Hiemer</u>

IDENTIFICATION/A. IDENUNCATION TESTS—General (191), Chemical

		DEFINITION, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/pH (791), SPECIFIC TESTS/Particulate Matter in Injections (788), SPECIFIC TESTS/Sterlity Tests (71), SPECIFIC TESTS/Bacterial Endotoxins Test (85), SPECIFIC TESTS/Other Requirements, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards	
New	BUPRENORPHINE INJECTION PF 46(6) Pg. ONLINE CALCIPOTRIENE AND BETAMETHASONE DIPROPIONATE OINTMENT	(11) DETITITION, 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	Christine Hiemer
New	PF 46(6) Pg. ONLINE	(11)	Shankari Shivaprasad
		DETINITION, 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	
New	CALCIUM ACETATE ORAL SOLUTION PF 46(5) Pg. ONLINE	(11), FOOTNOTES DETINITION, IDENTIFICATION/A. Identification rests—General, Calcium(191), IDENTIFICATION/B., ASSAY/Procedure, ASSAY/Content of Ascorbate, ASSAY/Content of Calcium, ASSAY/Content of Calcium Ascorbate, ADDITIONAL	Shankari Shivaprasad
Revision	CALCIUM ASCORBATE PF 47(3) Pg. ONLINE	ASSAT/Content of Cardinin Ascorbate, ADDITIONAL REQUIREMENTS/USP Reference Standards (11) ASSAT/Procedure, PERFORMANCE LES IS/Dissolution (/11),	Sandeep Putty
Revision	CANDESARTAN CILEXETIL AND HYDROCHLOROTHIAZIDE TABLETS PF 47(4) Pg. ONLINE	IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards (11) DEFINITION, IDENTIFICATION/B., DEFINITION, IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution (711), PERFORMANCE TESTS/Uniformity of Dosage Units (905), IMPURITIES/Organic Impurities, ADDITIONAL	Christine Hiemer
Name	CARRIDORA TARLETC RE 46/43 R- ONLINE	REQUIREMENTS/Packaging and Storage, ADDITIONAL	Charlest Chinasan d
New New	CARBIDOPA TABLETS PF 46(4) Pg. ONLINE CARGLUMIC ACID PF 47(6) Pg. ONLINE	REQUIREMENTS/USP Reference Standards (11) New	Shankari Shivaprasad Christine Hiemer
	a well with the control of the contr	IDENTIFICATION/A. Thin layer Chromatography,	<u>CHIIStille Fliether</u>
Revision	CARTEOLOL HYDROCHLORIDE OPHTHALMIC SOLUTION PF 46(5) Pg. ONLINE	IDENTIFICATION/A., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards (11) CHICHICAL INFORMATION, DETINITION, DETINITION/A. Spectroscopic Identification Tests (197), Infrared Spectroscopy, IDENTIFICATION/C. Identification Tests—General (191), Chemical Identification Tests, Chloride, ASSAY/Procedure, IMPURITIES/Residue on Ignition (281),	<u>Christine Hiemer</u>
New	CEVIMELINE HYDROCHLORIDE PF 47(4) Pg. ONLINE	IMPURITIES/Organic Impurities, SPECIFIC TESTS/Water Determination (921), Method I, Method Ic, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards (11) DETINITION, IDENTIFICATION/C., ASSAY/Procedure, ASSAY/Content of Choline, ASSAY/Content of Choline, ASSAY/Content of Choline, ASSAY/Content of Choline Chloride, IMPURITIES/Limit of Total Amines, IMPURITIES/Chromatographic Purity, IMPURITIES/Related Compounds, ADDITIONAL REQUIREMENTS/USP Reference	<u>Shankari Shivaprasad</u>
Revision	CHOLINE CHLORIDE PF 47(1) Pg. ONLINE	Standards (11)	<u>Fatkhulla Tadjimukhamedov</u>
New	CHOLINE FENOFIBRATE PF 47(6) Pg. ONLINE	NEW	<u>Christine Hiemer</u>
		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	
New	CISPLATIN INJECTION PF 46(5) Pg. ONLINE	REQUIREMENTS/USP Reference Standards (11) LOUIS AND AN ALTONIAL TIME-LAYER CHROMAGORAPHIC IDENTIFICATION/AL, IDENTIFICATION/AL, ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Microbial Enumeration Tests (61) and Tests for Specified Microorganisms	<u>Christine Hiemer</u>
Revision	CLOBETASOL PROPIONATE CREAM PF 47(2) Pg. ONLINE	(62), SPECIFIC TESTS/pH (791), ADDITIONAL REQUIREMENTS/USP Reference Standards (11) DEFINITION, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, IMPURITIES/Analysis, PERFORMANCE TESTS/Minimum Fill (755), SPECIFIC TESTS/pH (791), SPECIFIC TESTS/Microbial Enumeration Tests (61) and Tests for Specified Microorganisms (62), ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL	Shankari Shivaprasad
New	CLOBETASOL PROPIONATE LOTION PF 47(2) Pg. ONLINE	REQUIREMENTS/USP Reference Standards (11)	Shankari Shivaprasad
Revision	CLOMIPRAMINE HYDROCHLORIDE PF 47(6) Pg. ONLINE	Revision	Shankari Shivaprasad
Revision	CLONIDINE HYDROCHLORIDE TABLETS PF 47(5) Pg. ONLINE	Revision	Christine Hiemer
New	COCOYL CAPRYLOCAPRATE PF 47(6) Pg. ONLINE	New	<u>SanthiKumar Saladi</u>

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/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/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	<u>Maria Monagas</u>
		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	
New	BLACK CUMIN SEED THYMOQUINONE OIL PF 46(5) Pg. ONLINE	Reference Standards (11) DEFINITION, ASSAY/Procedure, IMPURITES/LIMIT OF DAIRAMPHOINE Related Compound B and Dalfampridine Related Compound C, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Water Determination (921), Method I, Method Ia, ADDITIONAL	Maria Monagas
Revision	DALFAMPRIDINE PF 46(6) Pg. ONLINE	REQUIREMENTS/USP Reference Standards (11) CHEMICAL INFORMATION, IDENTIFICATION/B. Spectroscopic	Shankari Shivaprasad
Revision	DANAZOL PF 46(4) Pg. ONLINE	Identification Tests (197), Ultraviolet-Visible Spectroscopy: 197U, ASSAY/Procedure, IMPURITIES/Organic Impurities, IMPURITIES, SPECIFIC TESTS/Optical Rotation (7815), Specific Rotation, ADDITIONAL REQUIREMENTS/USP Reference Standards (11) IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution (711), IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage,	Shankari Shivaprasad
Revision	DANAZOL CAPSULES PF 46(4) Pg. ONLINE	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/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards (11) CHEMICAL INFORMATION, DEFINITION, DEFIN	<u>Christine Hiemer</u>
New	DARUNAVIR PF 47(4) Pg. ONLINE	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)	<u>Christine Hiemer</u>
New	DARUNAVIR ORAL SUSPENSION PF 47(6) Pg. ONLINE	New 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	Christine Hiemer
New	DARUNAVIR TABLETS PF 47(4) Pg. ONLINE	REQUIREMENTS/USP Reference Standards (11) DEFINITION, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, OTHER COMPONENTS/Content of Isopropyl Alcohol (2-Propanol), PERFORMANCE TESTS/Minimum Fill (755), IMPURITIES/Organic Impurities, SPECIFIC TESTS/Microbial Brumeration Tests (61) and Tests for Specified Microorganisms (62), ADDITIONAL REQUIREMENTS/Packaging and storage,	<u>Christine Hiemer</u>
New New	DESOXIMETASONE TOPICAL SPRAY PF 46(4) Pg. ONLINE DIMETHYL FUMARATE PF 47(5) Pg. ONLINE	ADDITIONAL REQUIREMENTS/USP Reference Standards (11) New	Shankari Shivaprasad Shankari Shivaprasad
New	DIMETHYL FUMARATE DELAYED-RELEASE CAPSULES PF 47(5) Pg. ONLINE	New	Shankari Shivaprasad
		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	Stratikati Silivapi dSdU
Revision	DOBUTAMINE INJECTION PF 47(1) Pg. ONLINE	(11) IDENTIFICATION/C., ASSAY/Dobutamine, IMPURITIES/Organic Impurities, IMPURITIES/Limit of 5-Hydroxymethylfurfural, SPECIFIC	<u>Christine Hiemer</u>
Revision	DOBUTAMINE IN DEXTROSE INJECTION PF 47(2) Pg. ONLINE	TESTS/Bacterial Endotoxins Test (85), ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	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
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Characteristics, SPECIFIC TESTS/Articles of Botanical Origin (561),
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TESTS/Articles of Botanical Origin (561), Methods of Analysis,
Volatile Oil Determination, SPECIFIC TESTS/Articles of Botanical
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II, ADDITIONAL REQUIREMENTS/Packaging and Storage,
ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL
REQUIREMENTS/USP Reference Standards (11)
DEFINITION IDENTIFICATION/A LIPTIC for Articles of Betarried

New DONG OUAI 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 DONG QUAI ROOT POWDER PF 47(3) Pg. ONLINE REQUIREMENTS/USP Reference Standards (11) New Cuiving Ma Revision DOPAMINE HYDROCHLORIDE INJECTION PF 47(5) Pg. ONLINE Revision **Christine Hiemer** IDENTIFICATION/C., ASSAT/Dopamine mydrochioride, IMPURITIES/Organic Impurities, IMPURITIES/Limit of 5-Hydroxymethylfurfural and Related Substances, SPECIFIC TESTS/Bacterial Endotoxins Test (85), ADDITIONAL DOPAMINE HYDROCHLORIDE AND DEXTROSE INJECTION PF 47(4) REQUIREMENTS/Packaging and Storage, ADDITIONAL Pg. ONLINE Revision REQUIREMENTS/USP Reference Standards (11) **Christine Hiemer** DOXYCYCLINE FOR ORAL SUSPENSION PF 47(5) Pg. ONLINE Revision Revision **Christine Hiemer** 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 DUTASTERIDE CAPSULES PF 46(5) Pg. ONLINE Revision Reference Standards (11) Shankari Shivaprasad IDENTIFICATION/A. Spectroscopic Identification Tests (197), Infrared Spectroscopy, IDENTIFICATION/B. Spectroscopic Identification Tests (197), Ultraviolet-Visible Spectroscopy, Revision ENSULIZOLE PF 46(5) Pg. ONLINE ASSAY/Procedure **Christine Hiemer** 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 ESOMEPRAZOLE SODIUM PF 47(3) Pg. ONLINE **Christine Hiemer** New Reference Standards (11) 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 $\langle 1 \rangle$, Product Quality Tests Common to Parenteral Dosage Nev Rev Rev Rev Nev

ew	ESOMEPRAZOLE SODIUM FOR INJECTION PF 47(3) Pq. ONLINE	Forms, Specific Tests, Completeness and Clarity of Solutions, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REOUIREMENTS/USP Reference Standards (11)	Christine Hiemer
evision	ETHACRYNIC ACID TABLETS PF 47(5) Pg. ONLINE	Revision	Christine Hiemer
evision	ETODOLAC PF 47(5) Pg. ONLINE	Revision	Christine Hiemer
evision	ETODOLAC TABLETS PF 47(5) Pg. ONLINE		Christine Hiemer
ew	FENOFIBRIC ACID DELAYED-RELEASE CAPSULES PF 4/(6) Pg. ONLINE	NEW	Christine Hiemer
evision	FEVERFEW LEAF PF 47(6) Pg. ONLINE	Revision	Anton Bzhelvansky

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Re	vision	FEVERFEW LEAF POWDER PF 47(6) Pg. ONLINE	Revision IDENTIFICATION/B. SPECTOSCOPIC IDENTIFICATION/C., ASSAY/Procedure, 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	Anton Bzhelyansky
Re	vision	FLUOROURACIL INJECTION PF 47(3) Pg. ONLINE	TESTS/Sterility test (71), ADDITIONAL REQUIREMENTS/USP Reference Standards (11) IDENIFICATIONS., ASSAY/Procedure, PERFURMANCE TESTS/Dissolution (711), ADDITIONAL REQUIREMENTS/Packaging	<u>Christine Hiemer</u>
Re	vision	FLUOXETINE CAPSULES PF 46(5) Pg. ONLINE	and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards (11), IMPURITIES/Organic Impurities IMPURITIES/USPAINCE IMPURITIES/USPAINCE IMPURITIES/USPAINCE IMPURITIES/USPAINCE (197), Infrared Spectroscopy, IDENTIFICATION/A., ASSAY/Procedure, PERFORMANCE	Shankari Shivaprasad
Re	vision	FLUOXETINE DELAYED-RELEASE CAPSULES PF 46(5) Pg. ONLINE	TESTS/Dissolution (711), ADDITIONAL REQUIREMENTS/USP Reference Standards (11) IDENTIFICATION/A. SPECTOSCOPIC IDENTIFICATION/A., IDENTIFICATION/B., ASSAN/Research and ADDITIONAL REQUIREMENTS/(Perkeding and	<u>Shankari Shivaprasad</u>
Re	vision	FLUOXETINE ORAL SOLUTION PF 46(5) Pg. ONLINE	ASSAY/Procedure, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards (11), IMPURITIES/Organic Impurities IUEN LIFLALIUMA. Spectroscopic Identification lests (197), Infrared Spectroscopy, IDENTIFICATION/A., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution (711), ADDITIONAL	Shankari Shivaprasad
Re	vision	FLUOXETINE TABLETS PF 46(5) Pg. ONLINE	REQUIREMENTS/USP Reference Standards (11), IMPURITIES/Organic Impurities IDENTIFICATION/A. Spectroscopic Identification Tests (197), Infrared Spectroscopy, ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards	Shankari Shivaprasad
Re	vision	FLUOXETINE HYDROCHLORIDE PF 46(5) Pg. ONLINE	(11), IMPURITIES/Residue on Ignition (281) DETINITION, JUENTIFICATION/A. SPECTOSCOPIC IDENTIFICATION/A. (197), Infrared Spectroscopy, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Bacterial Endotoxins Test (85), SPECIFIC TESTS/Sterility Tests (71), SPECIFIC TESTS/Particulate Matter in Injections (788), SPECIFIC TESTS/Other Requirements, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL	<u>Shankari Shivaprasad</u>
Ne	w	FULVESTRANT INJECTION PF 46(4) Pg. ONLINE	REQUIREMENTS/USP Reference Standards (11)	Shankari Shivaprasad
Ne	w	GABAPENTIN COMPOUNDED CREAM PF 47(5) Pg. ONLINE	New	Selma Mitiche
Re	vision	GANCICLOVIR FOR INJECTION PF 47(5) Pg. ONLINE	Revision	Christine Hiemer
Ne		GEMCITABINE INJECTION PF 46(4) Pg. ONLINE	DEFINITION, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Bacterial Endotoxins Test (85), SPECIFIC TESTS/Particulate Matter in Injections (788), SPECIFIC TESTS/DH (791), SPECIFIC TESTS/Sterility tests (71), SPECIFIC TESTS/Other Requirements, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards (11) DEFINITION, SPECIFIC TESTS/Uster Determination (921), SPECIFIC TESTS/Water Determination (921),	Christine Hiemer
Re	vision	L-ALPHA-GLYCERYLPHOSPHORYLCHOLINE PF 47(3) Pg. ONLINE	Method I, Method Ia, ASSAY/Procedure IDENTIFICATION/Chromatography (621), General Procedures, Thin-Layer Chromatography, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, OTHER COMPONENTS/Content of Benzyl Alcohol (if present), IMPURITIES/Organic Impurities, SPECIFIC TESTS/Bacterial Endotoxins Test (85), SPECIFIC TESTS/Sterility Tests (71), SPECIFIC TESTS/Particulate Matter in Injections (788), ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL	<u>Fatkhulla Tadjimukhamedov</u>
Re Ne	vision	GLYCOPYRROLATE INJECTION PF 46(4) Pg. ONLINE HYDROCORTISONE COMPOUNDED ORAL SUSPENSION PF 47(5) Pg. ONLINE	REQUIREMENTS/USP Reference Standards (11) New	Christine Hiemer Brian Serumaga
		HYDROXYCHLOROQUINE SULFATE COMPOUNDED ORAL		
Ne		SUSPENSION PF 47(6) Pg. ONLINE	New	Brian Serumaga
Ne	w	IBANDRONATE SODIUM PF 47(6) Pg. ONLINE	New	<u>Christine Hiemer</u>
Ne Ne		IBANDRONATE SODIUM INJECTION PF 46(4) Pg. ONLINE IBANDRONATE SODIUM TABLETS PF 46(4) Pg. ONLINE	DEFINITION, IDENTIFICATION/A. Spectroscopic Identification Tests (197), Ultraviolet-Visible Spectroscopy, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Ph (791), SPECIFIC TESTS/Particulate Matter in Injections (788), SPECIFIC TESTS/Bacterial Endotoxins Test (85), SPECIFIC TESTS/Osmolality and Osmolarity (785), Osmolality, SPECIFIC TESTS/Osmolality and Osmolarity (785), Osmolality, SPECIFIC TESTS/Sterility Tests (71), ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards (11), FOOTNOTES DETINITION, IDENTIFICATION/A. SPECTFOSCOPIC 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/Packaging and Storage, ADDITIONAL REQUIREMENTS/PSCAGGING AND ADDIT	Christine Hiemer Christine Hiemer
On	nission	SODIUM IODIDE I 123 SOLUTION PF 46(3) Pg. ONLINE	Entire document	Shankari Shivaprasad
	vision	IPRATROPIUM BROMIDE PF 47(6) Pg. ONLINE	Revision	Shankari Shivaprasad
				

Revision Revision Revision	DILUTED ISOSORBIDE MONONITRATE PF 47(3) Pg. ONLINE ISOSORBIDE MONONITRATE TABLETS PF 47(4) Pg. ONLINE ISOSORBIDE MONONITRATE EXTENDED-RELEASE TABLETS PF 47(5) 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) IDENTIFICATION/A. TIMIL-Layer CHORNANCE 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) Revision	Christine Hiemer Christine Hiemer Christine Hiemer
New	KETOTIFEN FUMARATE PF 47(5) Pg. ONLINE	NEW, Revision	Heather Joyce
Revision	ANHYDROUS LACTOSE PF 46(5) Pg. ONLINE	IDENTIFICATION/B. Thin-Layer Chromatographic Identification Test (201), OTHER COMPONENTS/• Content of Alpha and Beta Anomers, SPECIFIC TESTS/Microbial Enumeration Tests (61), Tests for Specified Microorganisms (62), and •Microbiological Examination of Nonsterile Products—Tests for Burkholderia Cepacia Complex (60)•, SPECIFIC TESTS/• Bacterial Endotoxins Test (85), ADDITIONAL REQUIREMENTS/•Labeling	Jenny Liu
Revision	LACTOSE MONOHYDRATE PF 46(5) Pg. ONLINE	DEFINITION, IDENTIFICATION B. Inin-Layer Chromatographic Identification Test (201), SPECIFIC TESTS/Microbial Enumeration Tests (61), Tests for Specified Microorganisms (62), 4 and 4Microbiological Examination of Nonsterile Products—Tests for Burkholderia Cepacia Complex (60)4, SPECIFIC TESTS/4 Bacterial Endotoxins Test (85), SPECIFIC TESTS/Loss on Drying (731), ADDITIONAL REQUIREMENTS/4 Labeling	
Kevision	EACTOSE MONOTIDINATE FT 40(3) Fg. ONLINE	IDENTIFICATION/Spectroscopic Identification Tests (197), Infrared Spectroscopy, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Sterility Tests (71), SPECIFIC TESTS/Bacterial Endotoxins Test (85), ADDITIONAL REQUIREMENTS/Packaging and Storage,	<u>Jenny Liu</u>
Revision	LIDOCAINE HYDROCHLORIDE INJECTION PF 46(3) Pg. ONLINE	ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Shankari Shivaprasad
Revision	MESALAMINE EXTENDED-RELEASE CAPSULES PF 47(6) Pg. ONLINE	Revision	Christine Hiemer
Revision	MESALAMINE DELAYED-RELEASE TABLETS PF 47(6) Pg. ONLINE	Revision IDENTIFICATION/A. Thin-Layer Chromatographic Identification Test (201), IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution (711), IMPURITIES/Organic Impurities,	Christine Hiemer
Revision Revision	METHADONE HYDROCHLORIDE TABLETS PF 47(4) Pg. ONLINE METHYLENE BLUE PF 47(2) Pg. ONLINE	ADDITIONAL REQUIREMENTS/Packaging and Storage IMPURITIES/Arsenic, IMPURITIES/Copper or Zinc IDENTIFICATION/A. Spectroscopic IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution (711) Procedure, Apparatus 1 and Apparatus 2, Immediate-release dosage forms, Procedure for a pooled sample for immediate release dosage forms,	Christine Hiemer Christine Hiemer
Revision	METHYLPHENIDATE HYDROCHLORIDE TABLETS PF 46(4) Pg. ONLINE	IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards (11) DETINITION, DETINITION OF THE PROPERTY OF T	Shankari Shivaprasad
New	MICAFUNGIN FOR INJECTION PF 46(5) Pg. ONLINE	REQUIREMENTS/USP Reference Standards (11) 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 (7815), 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	<u>Christine Hiemer</u>
New	MICAFUNGIN SODIUM PF 46(5) Pg. ONLINE MORPHINE SULFATE COMPOUNDED ORAL SOLUTION PF 47(6) Pg.	(11)	Christine Hiemer
New	ONLINE	New 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	<u>Selma Mitiche</u>
Revision	NAPROXEN PF 47(4) Pg. ONLINE	Rotation (781S), Procedures, Specific Rotation, ADDITIONAL REQUIREMENTS/USP Reference Standards (11) 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,	Christine Hiemer
Revision	NAPROXEN SODIUM PF 47(4) Pg. ONLINE	ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Christine Hiemer

IDENTIFICATION/A. Spectroscopic Identification Tests (197),

New	NEBIVOLOL HYDROCHLORIDE PF 47(6) Pg. ONLINE	New	Christina Hiomor
New	NEEM LEAF PF 47(5) Pg. ONLINE	New	Christine Hiemer 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	NORFLURANE PF 47(6) Pg. ONLINE	Revision	Kahkashan Zaidi
Revision	NORTRIPTYLINE HYDROCHLORIDE ORAL SOLUTION PF 46(4) Pg. ONLINE	DEFINITION, IDENTIFICATION/A., IDENTIFICATION/C., ASSAY/Procedure, OTHER COMPONENTS/Alcohol Determination (611), Procedures, Method II (if present), IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards (11) DEFINITION, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution (711), PERFORMANCE TESTS/Uniformity of Dosage Units (905),	Shankari Shivaprasad
New	OLMESARTAN MEDOXOMIL AND HYDROCHLOROTHIAZIDE TABLETS PF 46(3) Pg. ONLINE	IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards (11) IDENTIFICATION/A. Thin-Layer Chromatographic Identification Test	<u>Christine Hiemer</u>
Revision	OXYBUTYNIN CHLORIDE ORAL SOLUTION PF 47(2) Pg. ONLINE OXYBUTYNIN CHLORIDE TABLETS PF 47(1) Pg. ONLINE	(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 IDENTIFICATION/Thin-Layer Chromatographic Identification Test (201), IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution (711), IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/VJSP Reference Standards (11)	Christine Hiemer Christine Hiemer
			Christine memer
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) DEFINITION, IDENTIFICATION/D., ASSAY/Procedure, PERFORMANCE TESTS/Uniformity of Dosage Units (905), IMPURITIES/Organic Impurities, SPECIFIC TESTS/PH	Christine Hiemer
New	PALONOSETRON INJECTION PF 46(5) Pg. ONLINE	(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) IDENTIFICATION/A. ITIIII—LAYER CHIOTINATORYPROPERFORMANCE TESTS/Dissolution (711), IMPURITIES/Organic Impurities, SPECIFIC TESTS/Water Determination (921), Method I,	Christine Hiemer
		ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL	
Revision	PIROXICAM CAPSULES PF 47(1) Pg. ONLINE	REQUIREMENTS/USP Reference Standards (11)	Christine Hiemer
New	POLYETHYLENE GLYCOL 30 DIPOLYHYDROXYSTEARATE 5 PF 47(6) Pg. ONLINE	New	Devendra Vasant Chavan
	POLYETHYLENE GLYCOL 12 CETOSTEARYL ETHER PF 4/(6) Pg.		Devendra vasant onavan
New	ONLINE	New	<u>Devendra Vasant Chavan</u>
New	POLYETHYLENE GLYCOL 3350 FOR ORAL SOLUTION PF 47(3) Pg. ONLINE	(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)	<u>Christine Hiemer</u>
		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	
Revision	PRASUGREL HYDROCHLORIDE PF 47(3) Pg. ONLINE	IC, ADDITIONAL REQUIREMENTS/USP Reference Standards (11) CHEMICAL INFURMATION, DEFINITION, ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL	Christine Hiemer
Revision	PROCARBAZINE HYDROCHLORIDE PF 46(4) Pg. ONLINE	REQUIREMENTS/USP Reference Standards (11)	Christine Hiemer
Revision Revision	ROFLUMILAST PF 47(5) Pg. ONLINE ROSUVASTATIN CALCIUM PF 47(4) Pg. ONLINE	Revision 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)	Shankari Shivaprasad 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
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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)

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

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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 CONTAMINANTS/Microbial Enumeration Tests (2021),
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)

DEFINITION, IDENTIFICATION/A. HPTLC for Articles of Botanical Origin (203), IDENTIFICATION/B. HPLC, COMPOSITION/Content of

SICHUAN LOVAGE RHIZOME POWDER PF 47(2) Pa. ONLINE New New SILDENAFIL INJECTION PF 47(6) Pg. ONLINE

SILVER NITRATE PF 47(4) Pg. ONLINE

SODIUM OLEATE PF 47(6) Pg. ONLINE

SODIUM NITRITE PF 46(5) Pg. ONLINE

Revision SODIUM NITRITE INJECTION PF 46(5) Pa. ONLINE

SODIUM ASCORBATE PF 47(6) Pg. ONLINE

Revision

Revision

Revision

New

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)

Revision

Shankari Shivaprasad

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Christine Hiemer Devendra Vasant Chavan Sandeep Putty

Selma Mitiche

SODIUM CHLORIDE COMPOUNDED INJECTION PF 47(6) Pg. ONLINE New New

CHEPITCAL INFORMATION, IDENTIFICATION/C., ASSAT/FFICEGUIE, 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

IDENTIFICATION/C., ASSAY/Procedure, IMPUKITIES/LIMIT or 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)

Identification of Phospholipids by Thin-Layer Chromatography, IDENTIFICATION/B. Identity by Fatty Acid Composition, ASSAY/Procedure, IMPURITIES/Organic Impurities, IMPURITIES/Free fatty acids and Triglycerides by Thin-layer Chromatography, SPECIFIC TESTS/Peroxide Value, SPECIFIC TESTS/Total Phosphorus Content, 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, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP

Reference Standards (11), FOOTNOTES
CHEMICAL INFORMATION, IDENTIFICATION/A. Spectroscopic Identification Tests (197), Infrared Spectroscopy, IDENTIFICATION/B. JDENTIFICATION/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

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New SOYBEAN PHOSPHATIDYLCHOLINE PF 46(6) Pg. ONLINE

Revision SULBACTAM SODIUM PF 47(4) Pg. ONLINE

Peng Zhang

Christine Hiemer

		CHEMICAL INFORMATION, DEFINITION, IDENTIFICATION/A. Spectroscopic Identification Tests (197), Infrared Spectroscopy, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Residue on Ignition (281), IMPURITIES/Organic Impurities, SPECIFIC TESTS/Loss on Drying (731), ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL	
New	SUNITINIB MALATE PF 46(4) Pg. ONLINE	REQUIREMENTS/USP Reference Standards (11)	Christine Hiemer
Revision	TERBUTALINE SULFATE PF 47(5) Pg. ONLINE	Revision	Shankari Shiyaprasad
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Revision	TERBUTALINE SULFATE INJECTION PF 47(5) Pg. ONLINE	Revision DETINITION, 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	Shankari Shivaprasad
New	TIAGABINE HYDROCHLORIDE TABLETS PF 46(5) Pg. ONLINE	REQUIREMENTS/USP Reference Standards (11) IDENTIFICATION/A., IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL	Shankari Shivaprasad
Revision	TIMOLOL MALEATE OPHTHALMIC SOLUTION PF 47(4) Pg. ONLINE	REQUIREMENTS/Packaging and storage, ADDITIONAL REQUIREMENTS/USP Reference standards (11) CHEMILAL INFURMATION, IDENTIFICATION/A. SPECTROSCOPIC Identification Tests (197), Infrared Spectroscopy,	Christine Hiemer
Revision	TOLMETIN SODIUM PF 46(5) Pg. ONLINE	IDENTIFICATION/B. Spectroscopic Identification Tests (197), Ultraviolet-Visible Spectroscopy: 197U, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities 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
New	TRIMIPRAMINE CAPSULES PF 46(3) Pg. ONLINE	DETINITION, IDENTIFICATIONYA., IDENTIFICATIONYB., 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) DETINITION, IDENTIFICATIONYA., IDENTIFICATIONYB., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution (711), PERFORMANCE TESTS/Uniformity of Dosage Units (905), IMPURITIES/Organic Impurities, ADDITIONAL	Shankari Shivaprasad
		REQUIREMENTS/Packaging and Storage, ADDITIONAL	
New	ULIPRISTAL ACETATE TABLETS PF 46(5) Pg. ONLINE	REQUIREMENTS/USP Reference Standards (11)	Shankari Shivaprasad
Revision	COMPOUND UNDECYLENIC ACID OINTMENT PF 47(6) Pg. ONLINE	Revision 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	Christine Hiemer
New	VALGANCICLOVIR FOR ORAL SOLUTION PF 47(3) Pg. ONLINE	REQUIREMENTS/USP Reference Standards (11) DEFINITION, ASSAY/Procedure, 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) DEFINITION, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Uniformity of Dosage	Brian Serumaga
New	VECURONIUM BROMIDE FOR INJECTION PF 46(3) Pg. ONLINE	Units (905), IMPURITIES/Organic Impurities, SPECIFIC TESTS/pH (791), SPECIFIC TESTS/Water Determination (921), Method I, Method Ic, SPECIFIC TESTS/Bacterial Endotoxins Test (85), SPECIFIC TESTS/Sterility Tests (71), SPECIFIC TESTS/Constituted Solution, SPECIFIC TESTS/Particulate Matter in Injections (788), SPECIFIC TESTS/Other Requirements, ADDITIONAL REQUIREMENTS/Packing and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Shankari Shivaprasad
		Revision	
Revision	EMULSIFYING WAX PF 47(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,	<u>SanthiKumar Saladi</u>
Revision	ZINC CHLORIDE PF 46(6) Pg. ONLINE	ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	<u>Christine Hiemer</u>