## Compendial Deferrals for USP43-NF38 1S

Date: Tue Nov 26 14:00:01 EST 2019

Category	Monograph Title	Monograph Section 2. OFFICIAL STATUS AND LEGAL RECOGNITION, 5. MONOGRAPH COMPONENTS, 2.	Scientific Liaison
Revision	GENERAL NOTICES TO USP-NF PF 45(1) Pg. ONLINE	OFFICIAL STATUS AND LEGAL RECOGNITION, 3. MONOGRAFIT COMPONENTS, 2.	Jessica Simpson
Revision Revision	DESCRIPTION AND SOLUBILITY PF 43(4) Pg. ONLINE <121> INSULIN ASSAYS PF 43(4) Pg. ONLINE	Climbazole, Iscotrizinol, Epinastine Hydrochloride, Nebivolol Hydrochloride, Ranolazine, E/Etoposide Phosphate:, R/Rivaroxaban:, S/Sevelamer Carbonate:, Regorafenib, R/Rosuvastatin Calcium:, Tetrabenazine, Choline Fenofibrate, Nisoldipine ??UNKNOWN??/Rabbit Blood Sugar Method-Quantitative, ??UNKNOWN??/In Vivo Bioidentity Test, ??UNKNOWN??/In Vitro Cell-Based Bioidentity Test for Insulin Glargine and Insulin Lispro	Sujatha Ramakrishna  Diane McCarthy
Revision	<191> IDENTIFICATION TESTS GENERAL PF 45(2) Pg. ONLINE	CHEMICAL IDENTIFICATION TESTS/Chloride	<u>Lucy Botros</u>
Revision	<467> RESIDUAL SOLVENTS PF 45(3) Pg. ONLINE	4. LIMITS OF RESIDUAL SOLVENTS/4.2 Class 2: Solvents to Be Limited, 4. LIMITS OF RESIDUAL SOLVENTS/4.3 Class 3: Solvents with Low Toxic Potential, 8. ANALYTICAL PROCEDURES FOR CLASS 1 AND CLASS 2 RESIDUAL SOLVENTS/8.2 Screening of Water-Soluble Articles, 8. ANALYTICAL PROCEDURES FOR CLASS 1 AND CLASS 2 RESIDUAL SOLVENTS/8.3 Screening of Water-Insoluble Articles, APPENDICES/Appendix 1: Residual Solvents Included in this General Chapter, APPENDICES/USP Reference Standards 11	Edmond Biba
Revision	<476> CONTROL OF ORGANIC IMPURITIES IN DRUG SUBSTANCES AND DRUG PRODUCTS PF 45(1) Pg. ONLINE	INTRODUCTION, IDENTIFICATION OF IMPURITIES, ANALYTICAL PROCEDURES FOR IMPURITIES, REPORTING IMPURITIES, SETTING ACCEPTANCE CRITERIA FOR IMPURITIES, QUALIFICATION OF IMPURITIES, ORGANIC IMPURITIES IN DRUG SUBSTANCES, ORGANIC IMPURITIES IN DRUG PRODUCTS	Antonio Hernandez-Cardoso
Revision	<601> INHALATION AND NASAL DRUG PRODUCTS- AEROSOLS, SPRAYS, AND POWDERSPERFORMANCE QUALITY TESTS PF 44(5) Pg. ONLINE	INTRODUCTION, A. DELIVERED-DOSE UNIFORMITY, B. DROPLET/PARTICLE SIZE DISTRIBUTION-NASAL AEROSOLS, SPRAYS, AND POWDERS, C. AERODYNAMIC SIZE DISTRIBUTION-INHALATION AEROSOLS, SPRAYS, AND POWDERS, INTRODUCTION, A. DELIVERED DOSE UNIFORMITY, B. DROPLET/PARTICLE SIZE DISTRIBUTION-NASAL AEROSOLS AND NASAL SPRAYS, C. AERODYNAMIC PARTICLE SIZE DISTRIBUTION-INHALATION AEROSOLS, SPRAYS, AND POWDERS	<u>Kahkashan Zaidi</u>
New	<621> CHROMATOGRAPHY PF 43(5) Pg. ONLINE	DEFINITIONS, SYSTEM SUITABILITY, ADJUSTMENT OF CHROMATOGRAPHIC CONDITIONS, QUANTIFICATION INIRODUCTION, MOISTURE VAPOR TRANSMISSION FOR PLASTIC PACKAGING SYSTEMS, CLASSIFICATION SYSTEM FOR PLASTIC PACKAGING SYSTEMS, SPECTRAL	Horacio Pappa
Revision Revision	<671> CONTAINERSPERFORMANCE TESTING PF 44(3) Pg. ONLINE  <771> OPTHALMIC PRODUCTS - QUALITY TESTS PF 44(5) Pg. ONLINE	TRANSMISSION, GLOSSARY DRUG PRODUCT QUALITY	Desmond Hunt
		INTRODUCTION, OSMOTIC PRESSUREBACKGROUND, OSMOLALITYOPERATION AND CALIBRATION OF OSMOMETER, OSMOLARITY, MEASUREMENT OF OSMOLALITY,	Margareth Marques
Revision	<785> OSMOLALITY AND OSMOLARITY PF 44(5) Pg. ONLINE	REFERENCES	Margareth Marques
Revision	<941> CHARACTERIZATION OF CRYSTALLINE AND PARTIALLY CRYSTALLINE SOLIDS BY X-RAY POWDER DIFFRACTION (XRPD) PF 45(1) Pg. ONLINE	PRINCIPLES, INSTRUMENT/X-Ray Radiation, QUALITATIVE PHASE ANALYSIS (IDENTIFICATION OF PHASES), QUANTITATIVE PHASE ANALYSIS	<u>Kevin Moore</u>
New Revision	<1042> CELL BANKING PF 44(6) Pg. ONLINE <1086> IMPURITIES IN DRUG SUBSTANCES AND DRUG PRODUCTS PF 45(1) Pg. ONLINE	Title, Introduction, 1. INTRODUCTION, 2. GENERAL PROCESSES AND CONSIDERATIONS OF CELL BANKING, 3. PRODUCTION CELL LINE/STRAIN DEVELOPMENT AND RCB GENERATION, 4. CLONALITY, 5. CELL BANK CHARACTERIZATION, 6. CONCLUSION, GLOSSARY, REFERENCES INTRODUCTION, GLOSSARY/Unspecified impurities and unspecified degradation products:, INTRODUCTION, APPENDICES/Appendix 2: Additional Sources of Information and Guidance	Rebecca Potts  Antonio Hernandez-Cardoso

INTRODUCTION, 1. PRELIMINARY ASSESSMENT (FOR EARLY STAGES OF PRODUCT <1092> THE DISSOLUTION PROCEDURE -- DEVELOPMENT AND VALIDATION PF 44(6) DEVELOPMENT/DISSOLUTION METHOD DEVELOPMENT), 2. METHOD DEVELOPMENT, 3. Revision Pa. ONLINE ANALYTICAL FINISH, 5. VALIDATION, 6. ACCEPTANCE CRITERIA, REFERENCES William Brown INTRODUCTION, KEY CONSIDERATIONS IN TIM DEVELOPMENT/Reagent Selection, KEY CONSIDERATIONS IN ITM DEVELOPMENT/Development of Immunoassays, <1102> IMMUNOLOGICAL TEST METHODS -- GENERAL CONSIDERATIONS PF 45(2) Pg. VALIDATION/System Suitability or Assay Acceptance Criteria, DATA Revision ONLINE REPORTING/Trending, DATA REPORTING/Data Tracking Shvamosree Bhattacharva Untitled Section, INTRODUCTION/Regulations and Standards, OVERALL MANUFACTURING PLAN/Manufacturing Facilities and Systems, OVERALL MANUFACTURING PLAN/Manufacturing Process, OVERALL MANUFACTURING PLAN/Manufacturing Surveillance, SEED LOT SYSTEMS/Systems for Biotechnology-Engineered Vaccines, RAW MATERIALS, FERMENTATION, AND CELL CULTURE MEDIA/Untitled Section, MATERIALS OF ANIMAL ORIGIN, SEED LOT SYSTEMS AND CELL BANKING, PROPAGATION AND HARVEST/Propagation and Harvest for Bacterial Vaccines, PROPAGATION AND HARVEST/Propagation and Harvest for Viral Vaccines, PROPAGATION AND HARVEST/Untitled Section, VACCINES PRODUCED BY RECOMBINANT TECHNOLOGY/cell substrate growth phase, VACCINES PRODUCED BY RECOMBINANT TECHNOLOGY/virus production phase, VACCINES PRODUCED BY RECOMBINANT TECHNOLOGY/Untitled Section, PURIFICATION/Bacterial Fermentation, PURIFICATION/Untitled Section, PURIFICATION/Biotechnology-Engineered Cells, PURIFICATION/Viral Vaccines Derived from Chicken Eggs, INTERMEDIATES/Production of Intermediates, INTERMEDIATES/Tests for Intermediates, STERILE FILTERED BULK, FINAL BULK/Tests for Final Bulk, FINAL CONTAINER/Excipients and Other Additives, EVALUATING THE STABILITY OF VACCINES/Stability Protocols, EVALUATING THE STABILITY OF VACCINES/Analytical Measurements, EVALUATING THE STABILITY OF VACCINES/Formal Evaluation of Stability Data and Product Expiry Dating, CONTAINER, LABELING/Container Label, LOT RELEASE TESTING/General Principles, LOT RELEASE TESTING/Common Tests, LOT RELEASE TESTING/Ouality, RETENTION SAMPLES AND <1235> VACCINES FOR HUMAN USE -- GENERAL CONSIDERATIONS PF 45(1) Pg. OTHER REOUIREMENTS, Appendix/Appendix 1: Types of Vaccines Currently Licensed in Revision ONLINE the U.S. (examples), Appendix/Selected Regulatory Documents Dibvendu Saha Untitled Section, INTRODUCTION, RAW MATERIALS AND MATERIALS OF ANIMAL ORIGIN, CELL BANKS/Source and History, CELL BANKS/Cell Bank Lineage and Genealogy, CELL BANKS/Cell Bank Manufacture, CELL BANKS/Cell Bank Validation, CELL BANKS/Cell Bank Testing, CELL BANKS/Cell Bank Storage, CELL BANKS/Storage Stability, PROPAGATION AND HARVEST/Fermentation Hardware, PROPAGATION AND HARVEST/Product Requirements, PROPAGATION AND HARVEST/Early Development Considerations, PROPAGATION AND HARVEST/Scale-Up, PURIFICATION/Polysaccharide Purification, PURIFICATION/In-Process Controls, PURIFICATION/Untitled Section, PURIFICATION/Protein Purification, INTERMEDIATES, DRUG SUBSTANCE, DRUG PRODUCT AND LOT RELEASE/Other Vaccine Components and Vaccine Properties, DRUG PRODUCT AND LOT RELEASE/Information Insert (Label), DRUG PRODUCT AND LOT <1238> VACCINES FOR HUMAN USE -- BACTERIAL VACCINES PF 45(1) Pg. ONLINE RELEASE/Untitled Section, OTHER REQUIREMENTS Revision Dibyendu Saha

INTRODUCTION/General Categories of Viral Vaccines, RAW MATERIALS AND MATERIALS OF ANIMAL ORIGIN, EGGS AND PRIMARY CELL LINES USED IN VIRAL VACCINE PRODUCTION/Maintenance of Flocks, EGGS AND PRIMARY CELL LINES USED IN VIRAL VACCINE PRODUCTION/Handling of Eggs, EGGS AND PRIMARY CELL LINES USED IN VIRAL VACCINE PRODUCTION/Primary Avian Embryo Cell Lines, EGGS AND PRIMARY CELL LINES USED IN VIRAL VACCINE PRODUCTION/Primary Cell Lines from Other Animal Sources, CELL BANKS AND SEED LOT SYSTEMS/Viral Seed Lots, CELL BANKS AND SEED LOT SYSTEMS/Seed Storage, CELL BANKS AND SEED LOT SYSTEMS/Recombinant Cell Lines, PROPAGATION AND HARVEST, CELL SUBSTRATE GROWTH PHASE, VIRUS PRODUCTION PHASE/In Ovo Cultivation, VIRUS PRODUCTION PHASE/Establishment of Primary Cell Cultures, VIRUS PRODUCTION PHASE/Cell Culture, VIRUS PRODUCTION PHASE/Virus Culture, VIRUS PRODUCTION PHASE/Control Cells During Production, VIRUS PRODUCTION PHASE/Culture Process Technologies and Facility, PURIFICATION/Viral Inactivation, PURIFICATION/Live, Attenuated, and Nonreplicating Viral Vaccines, PURIFICATION/Virus-Derived Subunit Vaccines, PURIFICATION/Recombinant or VLP Vaccines, PURIFICATION/In-Process Controls, INTERMEDIATES/Tests for Intermediates, DRUG SUBSTANCE, DRUG PRODUCT, LOT RELEASE TESTS/Potency Assays, LOT RELEASE TESTS/Common Tests, LOT RELEASE TESTS/Manufacturing Residuals, LOT RELEASE TESTS/Preservatives, LOT RELEASE TESTS/Excipients, LOT RELEASE TESTS/Adjuvants, OTHER INFORMATION, APPENDIX/Selected Regulatory Documents

Dibyendu Saha

Untitled Section, INTRODUCTION, PEPTIDE DEFINITION, MANUFACTURING METHODS, RAW MATERIALS, PEPTIDE GENERAL CHARACTERISTICS AND SPECIFICATION/Color and Appearance, PEPTIDE GENERAL CHARACTERISTICS AND SPECIFICATION/Identification, PEPTIDE GENERAL CHARACTERISTICS AND SPECIFICATION/Bioassays, PEPTIDE GENERAL CHARACTERISTICS AND SPECIFICATION/Peptide Content and Assay, PEPTIDE GENERAL CHARACTERISTICS AND SPECIFICATION/Impurities and Related Compounds, PEPTIDE GENERAL CHARACTERISTICS AND SPECIFICATION/Microbiological Contamination, PEPTIDE GENERAL CHARACTERISTICS AND SPECIFICATION/Macterial Endotoxins, PEPTIDE

GENERAL CHARACTERISTICS AND SPECIFICATION/Specific Tests

<1503> QUALITY ATTRIBUTES OF SYNTHETIC PEPTIDE DRUG SUBSTANCES PF 45(3)
Pg. ONLINE

<1239> VACCINES FOR HUMAN USE -- VIRAL VACCINES PF 45(1) Pq. ONLINE

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Elena Curti

Untitled Section, 1. INTRODUCTION/1.1 Background and Rationale, 1. INTRODUCTION/1.2 Purpose and Scope, 1. INTRODUCTION/1.3 Specific Information Regarding Impactor Stage Mensuration, 2. Definitions of Key Terms Relating to this Chapter, 3. CASCADE IMPACTOR OPERATING PRINCIPLES, 4. APPARATUS MAINTENANCE/4.1 Stage Mensuration, Measurement Traceability, and Mensuration Interval, 4. APPARATUS MAINTENANCE/4.2 Internal Losses, 4. APPARATUS MAINTENANCE/4.3 Inspection of Damaged/Deformed Collection Surfaces, 5. CASCADE IMPACTOR METHOD DEVELOPMENT/5.1 Initial Considerations, 5, CASCADE IMPACTOR METHOD DEVELOPMENT/5.2 Number of Inhaler Actuations/Inhalations per Determination, 5. CASCADE IMPACTOR METHOD DEVELOPMENT/5.3 Number of Replicate APSD Determinations, 5, CASCADE IMPACTOR METHOD DEVELOPMENT/5,4 Mitigation of Particle Bounce and Re-Entrainment, 5. CASCADE IMPACTOR METHOD DEVELOPMENT/5.5 Mitigation of Electrostatic Charge Accumulation, 6. IN-USE ASPECTS/6.1 Initial Considerations, 6. IN-USE ASPECTS/6.2 Inspection of Cascade Impactor Components Susceptible to Deterioration, 6. IN-USE ASPECTS/6.3 Assurance of Stage Collection Surface Coating, 6. IN-USE ASPECTS/6.4 Assertion of Correct Assembly, 6. IN-USE ASPECTS/6.5 Mitigation of Air Leakage into the Apparatus, 6. IN-USE ASPECTS/6.6 Setting of Flow Rate, 6. IN-USE ASPECTS/6.7 Cleaning and Storage Between Uses, 6. IN-USE ASPECTS/6.8 Assertion that Individual Cascade Impactor Assemblies of the Same Type (i.e., Andersen Cascade Impactor or Next Generation Impactor) are Interchangeable

Kahkashan Zaidi

INTRODUCTION/Choice of CI and Sampling Flow Rate for the APSD Measurement, PHARMACOPEIAL APSD DATA ANALYSIS/The Deposition Profile, PHARMACOPEIAL APSD DATA ANALYSIS/The APSD: Sized Deposition Profile, PHARMACOPEIAL APSD DATA ANALYSIS/Stage Grouping of the Deposition Data, OTHER TREATMENTS OF APSD DATA/The APSD: Cumulative Distribution Profile, OTHER TREATMENTS OF APSD DATA/Sized Fractions

Kahkashan Zaidi

INTRODUCTION, PACKAGING SYSTEMS, DESICCANT VERSUS WATER MVTR METHOD, EQUIVALENCY AND APPLICATION OF MVTR DETERMINATION METHOD, REPACKAGING OF SODFS, GLOSSARY, REFERENCES

Desmond Hunt

Title, INTRODUCTION, DISSOLUTION PROCEDURE DEVELOPMENT, REFERENCES

Margareth Margues

Title, DEFINITION/Introduction, 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>/USP Abacavir Sulfate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Lamivudine RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Lamivudine RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Reference Standards <11>/USP Zidovudine RS

Shankari Shivaprasad

IDENTIFICATION/A. Spectroscopic Identification Tests 197 , Infrared Spectroscopy:, IDENTIFICATION/C. Identification Tests—General 191 , Chemical Identification Tests, Chloride:, ASSAY/Procedure, IMPURITIES/Organic Impurities
IDENTIFICATION/B. Inin-Layer Chromatographic Identification Test 201 , ASSAY/Procedure, PERFORMANCE TESTS/Dissolution 711 , IMPURITIES/Organic Impurities
IDENTIFICATION/Thin-Layer Chromatographic Identification Test <201>, ASSAY/Procedure, IMPURITIES/Limit of c-c Dimer
IDENTIFICATION/B. Thin-Layer Chromatographic Identification Test <201>,

IDENTIFICATION/B., ASSAY/Procedure

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<1603> GOOD CASCADE IMPACTOR PRACTICES PF 45(2) Pq. ONLINE

<1604> DATA INTERPRETATION OF AERODYNAMIC PARTICLE SIZE DISTRIBUTION MEASUREMENTS FOR ORALLY INHALED PRODUCTS PF 45(2) Pg. ONLINE

<1671> THE DETERMINATION AND APPLICATION OF MOISTURE VAPOR

TRANSMISSION RATE PF 44(3) Pg. ONLINE

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New <1711> ORAL DOSAGE FORMS - PERFORMANCE TESTS PF 44(5) Pa. ONLINE

New ABACAVIR, LAMIVUDINE AND ZIDOVUDINE TABLETS PF 44(5) Pg. ONLINE

Revision ACEBUTOLOL HYDROCHLORIDE PF 45(2) Pg. ONLINE

Revision ACETAMINOPHEN CAPSULES PF 45(3) Pg. ONLINE

Revision ACETAMINOPHEN ORAL SOLUTION PF 44(4) Pg. ONLINE

Revision ACETAMINOPHEN TABLETS PF 42(3) Pg. ONLINE

New	ALBUTEROL INHALATION AEROSOL PF 44(1) Pg. ONLINE	Title, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K> or <197A>, IDENTIFICATION/B., ASSAY/Procedure, OTHER COMPONENTS/Alcohol Content, PERFORMANCE TESTS/Inhalation and Nasal Drug Products: Aerosols, Sprays, and Powders-Performance Quality Tests <601>, C. Aerodynamic Size Distribution-Inhalation Aerosols, Sprays, and Powders, PERFORMANCE TESTS/Delivered-Dose Uniformity (Between Units), PERFORMANCE TESTS/Delivered-Dose Uniformity (Within Unit), IMPURITIES/Organic Impurities, SPECIFIC TESTS/Microbial Enumeration Tests <61> and Tests for Specified Microorganisms <62>, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Albuterol Sulfate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Alcohol Determination-Alcohol RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Albuterol Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Albuterol Related Compound F RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Reference Standards <11	Ravi Ravichandran
		DEFINITION, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Uniformity of Dosage Units 905:, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Sterility Tests 71:, SPECIFIC TESTS/pH 791:, SPECIFIC TESTS/Particulate Matter in Injections 788, Method 1 Light Obscuration Particle Count Test, ADDITIONAL REQUIREMENTS/Packaging and Storage:, ADDITIONAL	
New	ALBUTEROL INHALATION SOLUTION PF 45(3) Pg. ONLINE	REQUIREMENTS/USP Reference Standards 11	Ravi Ravichandran
Revision	ALBUTEROL TABLETS PF 44(4) Pg. ONLINE	IDENTIFICATION/A., IDENTIFICATION/Identification Tests-General, Sulfate <191>, ASSAY/Procedure, PERFORMANCE TESTS/, Procedure, Apparatus 1 and Apparatus 2, Immediate-Release Dosage Forms, Procedure for a pooled sample, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Albuterol Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Albuterol Related Compound E RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Levalbuterol Related Compound C RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Levalbuterol Related Compound D RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Levalbuterol Related Compound H RS	Mary Koleck
Revision	ALCLOMETASONE DIPROPIONATE CREAM PF 45(3) Pg. ONLINE	IDENTIFICATION/B, Thin-Layer Chromatographic Identification Test 201, ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Microbial Enumeration Tests 61 and Tests for Specified Microorganisms 62:, ADDITIONAL REQUIREMENTS/USP Reference Standards 11, IDENTIFICATION/B. Thin-Layer Chromatographic Identification Test 201	Mary Koleck
Revision	ALCLOMETASONE DIPROPIONATE OINTMENT PF 45(3) Pg. ONLINE	IDENTIFICATION/B, Thin-Layer Chromatographic Identification Test 201, ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Microbial Enumeration Tests 61 and Tests for Specified Microorganisms 62:, ADDITIONAL REQUIREMENTS/USP Reference Standards 11, IDENTIFICATION/B. Thin-Layer Chromatographic Identification Test 201	Mary Koleck
Omission	AMINOBENZOATE SODIUM PF 44(4) Pg. ONLINE	Entire document	Wei Yang
New	AMLODIPINE, OLMESARTAN MEDOXOMIL, AND HYDROCHLOROTHIAZIDE TABLETS PF 45(3) Pg. ONLINE	DEFINITION, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, PERFÖRMANCE TESTS/Dissolution 711, PERFORMANCE TESTS/Uniformity, of Dosage Units 905:, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage:, ADDITIONAL REQUIREMENTS/USP Reference Standards 11	Edith Chang
Omission	AMPHOTERICIN B CREAM PF 45(2) Pg. ONLINE	Entire document	Julie Zhang
Omission	AMPHOTERICIN B LOTION PF 45(2) Pg. ONLINE	Entire document	Julie Zhang
Omission	AMPHOTERICIN B OINTMENT PF 45(2) Pg. ONLINE	Entire document	Julie Zhang

Omission	AMPICILLIN AND PROBENECID FOR ORAL SUSPENSION PF 45(2) Pg. ONLINE	Entire document	Christine Hiemer
Omission	ANTHRALIN PF 45(3) Pg. ONLINE	Entire document	Jane Li
Omission	ANTHRALIN CREAM PF 45(3) Pg. ONLINE	Entire document	Jane Li
Omission	ANTHRALIN OINTMENT PF 45(3) Pg. ONLINE	Entire document	Jane Li
Revision	ARGININE PF 44(5) Pg. ONLINE	IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., IMPURITIES/Organic Impurities, IMPURITIES/Related Compounds, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP L-Citrulline RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Glutamic Acid RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP L-Ornithine Hydrochloride RS	Fatkhulla Tadjimukhamedov
Revision	ARGININE HYDROCHLORIDE PF 44(5) Pg. ONLINE	IDENTIFICATION/B., IMPURITIES/Chromatographic Purity, IMPURITIES/Related Compounds, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP L-Citrulline RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Glutamic Acid RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP L-Ornithine Hydrochloride RS	<u>Fatkhulla Tadjimukhamedov</u>
Revision	ATOMOXETINE HYDROCHLORIDE PF 45(2) Pg. ONLINE	CHEMICAL INFORMATION, IDENTIFICATION/A. Spectroscopic Identification Tests 197, Infrared Spectroscopy:, IDENTIFICATION/C. Identification Tests—General 191, Chemical Identification Tests, Chloride:, ASSAY/Procedure, IMPURITIES/Organic Impurities, Procedure 1, IMPURITIES/Organic Impurities, Procedure 2, ADDITIONAL REQUIREMENTS/USP Reference Standards 11	<u>Heather Joyce</u>
Revision	ATOMOXETINE CAPSULES PF 44(1) Pg. ONLINE	IDENTIFICATION/A. Infrared Absorption <197K> or <197A>, ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, IMPURITIES/Organic Impurities	<u>Heather Joyce</u>
New	ATOVAQUONE AND PROGUANIL HYDROCHLORIDE TABLETS PF 44(5) Pg. ONLINE	Title, DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY, ASSAY/Procedure, PERFORMANCE TESTS, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Atovaquone Related Impurities, IMPURITIES/Proguanil Related Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Atovaquone RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Atovaquone Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Proguanil Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Proguanil Related Compound G RS	Shankari Shivaprasad
Revision	ATROPINE SULFATE OPHTHALMIC SOLUTION PF 45(2) Pq. ONLINE	IDENTIFICATION/C., ASSAY/Procedure, IMPURITIES/Organic Impurities	Heather Joyce
Omission	AUROTHIOGLUCOSE PF 44(6) Pg. ONLINE	Entire document	Wei Yang
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Revision	AZITHROMYCIN FOR ORAL SUSPENSION PF 44(5) Pg. ONLINE	IDENTIFICATION/B. Spectroscopic Identification Tests <197>, Infrared Spectroscopy	<u>Praveen Pabba</u>
New	BACLOFEN INJECTION PF 44(5) Pg. ONLINE	Title, DEFINITION/Introduction, 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/Osmolality and Osmolarity <785>, Osmolality, SPECIFIC TESTS/Bacterial Endotoxins Test <85>, SPECIFIC TESTS/Other Requirements, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Baclofen RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Baclofen Related Compound A RS	

New BAEL TREE FRUIT PF 44(5) Pg. ONLINE

New

Omission

BAEL TREE FRUIT DRY EXTRACT PF 44(5) Pg. ONLINE

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BELLADONNA EXTRACT TABLETS PF 44(3) Pg. ONLINE

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/Limit of Aegeline, 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/Loss on Drying <731>, SPECIFIC TESTS/Articles of Botanical Origin <561>, Methods of Analysis, Total Ash, 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, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Aegle marmelos Fruit Dry Extract RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Marmelosin RS

Title, DEFINITION/Introduction, IDENTIFICATION/A. HPTLC for Articles of Botanical Origin <203>, IDENTIFICATION/B. HPLC, COMPOSITION/Content of Marmelosin, CONTAMINANTS/Articles of Botanical Origin <561>, Limits of Elemental Impurities.

Nam-Cheol Kim

Title, DEFINITION/Introduction, IDENTIFICATION/A. HPTLC for Articles of Botanical Origin <203>, IDENTIFICATION/B. HPLC, COMPOSITION/Content of Marmelosin, 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/Limit of Aegeline, SPECIFIC TESTS/Loss on Drying <731>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Aegle marmelos Fruit Dry Extract RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Marmelosin RS

Nam-Cheol Kim

Title, DEFINITION/Introduction, IDENTIFICATION/A. HPTLC for Articles of Botanical Origin <203>, IDENTIFICATION/B. HPLC, COMPOSITION/Content of Marmelosin, 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/Limit of Aegeline, 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/Loss on Drving <731>, 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, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Aegle marmelos Fruit Dry Extract RS, ADDITIONAL REOUIREMENTS/USP Reference Standards <11>/USP Marmelosin RS

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Entire document

Nam-Cheol Kim Nam-Cheol Kim Nam-Cheol Kim

Nam-Cheol Kim

Omission	BELLADONNA TINCTURE PF 44(3) Pg. ONLINE	Entire document	Nam-Cheol Kim
New	BENAZEPRIL HYDROCHLORIDE AND HYDROCHLOROTHIAZIDE TABLETS PF 45(3) 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	Edith Chang
Revision	BENZONATATE PF 44(1) Pg. ONLINE	Chemical Info/Chemical NameChemical Info/Chemical StructureChemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/Ultraviolet Absorption <197U>, ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Tetracaine Related Compound B RS	Wei Yang
Revision	BENZTROPINE MESYLATE PF 44(3) Pg. ONLINE	Chemical Info/403.53403.54, (1R,3r,5S)-3-(Benzhydryloxy)-8-methyl-8-azabicyclo[3.2.1]octane methanesulfonate, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K> or <197A>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Melting Range or Temperature <741>, SPECIFIC TESTS/Loss on Drying <731>, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Benzhydrol RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Benzophenone RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Benztropine Related Compound A RS	<u>Heather Joyce</u>
Revision	BENZTROPINE MESYLATE INJECTION PF 44(3) Pg. ONLINE	IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Bacterial Endotoxins Test <85>, SPECIFIC TESTS/Sterility Tests <71>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Benzhydrol RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Benzophenone RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Benztropine Related Compound A RS	<u>Heather Joyce</u>
Revision Revision	BENZTROPINE MESYLATE TABLETS PF 44(3) Pg. ONLINE BETAXOLOL HYDROCHLORIDE PF 45(2) 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>/USP Benzhydrol RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Benzophenone RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Benztropine Related Compound A RS IDENTIFICATION/A. Spectroscopic Identification Tests 197, Infrared Spectroscopy:, IDENTIFICATION/B. Identification Tests—General 191, Chemical Identification Tests, Chloride	Heather Joyce Feiwen Mao
Revision	BISOPROLOL FUMARATE PF 44(5) Pg. ONLINE	IDENTIFICATION/Infrared Absorption <197K>, ASSAY/Procedure, IMPURITIES/Organic Impurities, OTHER COMPONENTS/Content of Fumaric Acid, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Bisoprolol Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Bisoprolol Related Compound C RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Bisoprolol Related Compound D RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Bisoprolol Related Compound E RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Metoprolol Related Compound C RS	Edith Chang

IDENTIFICATION/Thin-Layer Chromatographic Identification Test <201>, IDENTIFICATION/B, ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Bisoprolol Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Bisoprolol Related Compound D RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Bisoprolol Related Compound F RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Bisoprolol Related Compound G RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Metoprolol Related Compound C RS

Edith Chang

BISOPROLOL FUMARATE TABLETS PF 44(5) Pg. ONLINE

Revision

Revision

New

IDENTIFICATION/A. Thin-Layer Chromatographic Identification Test ,201 , ASSAY/Procedure, PERFORMANCE TESTS/Dissolution 711 , IMPURITIES/Organic Impurities. ADDITIONAL REQUIREMENTS/USP Reference Standards 11

**Edith Chang** 

BISOPROLOL FUMARATE AND HYDROCHLOROTHIAZIDE TABLETS PF 45(2) Pg. ONLINE Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards 11

Title, DEFINITION/Introduction, IDENTIFICATION/A. HPTLC for Articles of Botanical Origin <203>, IDENTIFICATION/B. HPLC, COMPOSITION/Content of Flavonoids, 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/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>/USP Bitter Orange Fruit Flavonoids Dry Extract RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Naringin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Neohesperidin RS

Maria Monagas

BITTER ORANGE FRUIT FLAVONOIDS DRY EXTRACT PF 44(1) Pg. ONLINE

Title, Chemical Info/Chemical Structure, Chemical Info/C98H138N24O33, Chemical Info/2180.29 (free base), Chemical Info/I-Leucine, d-phenylalanyl-I-prolyl-I-arginyl-Iprolylglycylglycylglycyl-l-asparaginylglycyl-l-α-aspartyl-l-phenylalanyl-lα-qlutamyl-l-α-qlutamyl-l-isoleucyl-l-prolyl-l-α-qlutamyl-l-αglutamyl-l-tyrosyl-;, Chemical Info/d-Phenylalanyl-l-prolyl-l-arginyl-lprolylglycylglycylglycyl-l-asparaginylglycyl-l-α-aspartyl-l-phenylalanyl-lα-qlutamyl-l-α-qlutamyl-l-isoleucyl-l-prolyl-l-α-qlutamyl-l-αglutamyl-I-tyrosyl-I-leucine, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B., IDENTIFICATION/C. Amino Acid Content, IDENTIFICATION/D. Bioidentity, ASSAY/Procedure, ??UNKNOWN??/Procedure 1, ??UNKNOWN??/Procedure 2, OTHER COMPONENTS/Trifluoroacetic Acid (TFA) in Peptides <503.1>, SPECIFIC TESTS/Microbial Enumeration Tests <61>, SPECIFIC TESTS/Bacterial Endotoxins Test <85>, SPECIFIC TESTS/Water Determination <921>, Method I, Method Ic, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Bivalirudin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP [Asp9]-Bivalirudin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP [des-Glu13]-Bivalirudin RS

Elena Curti

New BIVALIRUDIN PF 44(2) Pg. ONLINE

New BIVALIRUDIN FOR INJECTION PF 44(2) Pg. ONLINE Revision BROMOCRIPTINE MESYLATE CAPSULES PF 43(6) Pg. ONLINE BUDESONIDE NASAL SPRAY PF 44(3) Pg. ONLINE New Revision BUMETANIDE PF 44(1) Pg. ONLINE BUMETANIDE INJECTION PF 44(1) Pg. ONLINE Revision Revision BUMETANIDE TABLETS PF 43(6) Pg. ONLINE

BUPROPION HYDROCHLORIDE PF 44(4) Pg. ONLINE

Revision

Title, DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B. Bioidentity, ASSAY/Procedure, ??UNKNOWN??/Procedure, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, SPECIFIC TESTS/Completeness of Solution <641>, SPECIFIC TESTS/Constituted Solution, SPECIFIC TESTS/Bacterial Endotoxins Test <85>, SPECIFIC TESTS/Sterility Tests <71>, SPECIFIC TESTS/Water Determination <921>, Method I., Method Ic., SPECIFIC TESTS/Particulate Matter in Injections <788>, SPECIFIC TESTS/pH <791>, SPECIFIC TESTS/Other Requirements, ADDITIONAL REOUIREMENTS/Packaging and Storage, ADDITIONAL REOUIREMENTS/Labeling, ADDITIONAL REOUIREMENTS/USP Reference Standards <11>/USP Bivalirudin RS. ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP [Asp9]-Bivalirudin

Elena Curti

IDENTIFICATION/A., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage Mary Koleck

Title, DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, OTHER COMPONENTS/Content of Potassium Sorbate, OTHER COMPONENTS/Content of Edetate Disodium, PERFORMANCE TESTS/Delivered-Dose Uniformity, PERFORMANCE TESTS/Minimum Fill <755>, IMPURITIES/Organic Impurities, 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>/USP Budesonide RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Edetate Disodium RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Potassium Sorbate RS

Richard Nguven

IDENTIFICATION/A. Infrared Absorption <197M><197>, IDENTIFICATION/Ultraviolet Absorption <197U>, IDENTIFICATION/C., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Butyl 3-(butylamino)-4-phenoxy-5-sulfamoylbenzoate RS

**Edith Chang** 

IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Bumetanide Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Butyl 3-(butylamino)-4-phenoxy-5-sulfamoylbenzoate RS

**Edith Chang** 

IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Bumetanide Related Compound B RS

**Edith Chang** 

IDENTIFICATION/C. Identification Tests-General <191>, Chemical Identification Tests, Chloride, ASSAY/Procedure, IMPURITIES/Limit of 3-Chlorobenzoic Acid, IMPURITIES/Limit of Bupropion Related Compound G, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Bupropion Hydrochloride Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Bupropion Hydrochloride Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Bupropion Hydrochloride Related Compound C RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/ USP Bupropion Hydrochloride Related Compound F RS 1-(3-Chlorophenyl)-1hydroxypropan-2-one, C9H9O2Cl 184.62, ADDITIONAL REOUIREMENTS/USP Reference Standards <11>/USP Bupropion Related Compound G RS

Heather Joyce

Revision	BUPROPION HYDROCHLORIDE TABLETS PF 44(4) Pg. ONLINE	ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Bupropion Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Bupropion Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP 3-Chlorobenzoic Acid RS	Heather Joyce
Revision	BUPROPION HYDROCHLORIDE EXTENDED-RELEASE TABLETS PF 44(4) Pg. ONLINE	ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Bupropion Hydrochloride Related Compound C RS Note-May also be labeled as USP Bupropion Hydrochloride Related Compound C RS., ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Bupropion Hydrochloride Related Compound F RS Note-May also be labeled as USP Bupropion Hydrochloride Related Compound F RS.	Heather Joyce
	, , , <u>, , , , , , , , , , , , , , , , </u>	,	
Omission	BUTABARBITAL PF 45(3) Pg. ONLINE	Entire document IDENTIFICATION/C., ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Color and Clarity, SPECIFIC TESTS/Sterility Tests <71>, SPECIFIC TESTS/Particulate Matter in Injections <788>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Theophylline RS	Heather Joyce
Revision	CAFFEINE CITRATE INJECTION PF 43(6) Pg. ONLINE	ASSAY/Procedure, OTHER COMPONENTS/Isopropyl Alcohol Content, IMPURITIES/Organic Impurities, 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>/USP Calcipotriene RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Calcipotriene Related Compound	<u>Heather Joyce</u>
New	CALCIPOTRIENE TOPICAL SOLUTION PF 43(6) Pg. ONLINE	C RS	Feiwen Mao
Revision	CARBACHOL PF 45(2) Pg. ONLINE	IDENTIFICATION/A. Spectroscopic Identification Tests 197 , Infraçed Spectroscopy:, IDENTIFICATION/B. Identification Tests—General 191 , Chemical Identification Tests, Chloride, ASSAY/Procedure, IMPURITIES/Ordinary Impurities 466	Heather Joyce
Omission	CARBACHOL OPHTHALMIC SOLUTION PF 45(3) Pg. ONLINE	Entire document	Heather Joyce
Revision	CARBIDOPA AND LEVODOPA TABLETS PF 44(4) Pg. ONLINE	IMPURITIES/Organic Impurities	Heather Joyce
Revision	CARBIDOPA AND LEVODOPA ORALLY DISINTEGRATING TABLETS PF 44(1) Pg. ONLINE	IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, IMPURITIES/Organic Impurities	Heather Joyce
Revision	CEFEPIME FOR INJECTION PF 44(2) Pg. ONLINE	IDENTIFICATION/C., ASSAY/Procedure, IMPURITIES/Organic Impurities, IMPURITIES/Procedure 2, SPECIFIC TESTS/Bacterial Endotoxins Test <85>, SPECIFIC TESTS/Sterility Tests <71>, SPECIFIC TESTS/Water Determination <921>, Method I, ADDITIONAL REQUIREMENTS/Packaging and Storage	Slavica Shane
Revision	CEFIXIME PF 44(1) Pg. ONLINE	IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Microbial Enumeration Tests <61> and Tests for Specified Microorganisms <62>, SPECIFIC TESTS/Optical Rotation <781S>, Procedures, Specific Rotation	Slavica Shane
New	CEFIXIME CAPSULES PF 44(1) Pg. ONLINE	Title, DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B. Ultraviolet Absorption <197U>, ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Microbial Enumeration Tests <61> and Tests for Specified Microorganisms <62>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Cefixime RS	Slavica Shane
Revision	CEFIXIME FOR ORAL SUSPENSION PF 44(1) Pg. ONLINE	IDENTIFICATION/ A., IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Microbial Enumeration Tests <61> and Tests for Specified Microorganisms <62>	Slavica Shane

CEFIXIME TABLETS PF 44(1) Pg. ONLINE	IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Water Determination, Method I <921>, SPECIFIC TESTS/Microbial Enumeration Tests <61> and Tests for Specified Microorganisms <62>, ADDITIONAL REQUIREMENTS/Packaging and Storage	Slavica Shane
CEFOTETAN DISODIUM PE 43(6) Pg. ONLINE	ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Bacterial Endotoxins Test <85>, SPECIFIC TESTS/Sterility Tests <71>, SPECIFIC TESTS/Other Requirements, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling <7>, Labels and Labeling for Injectable Products, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Endotoxin RS IDENTIFICATION/C., ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Sterility Tests <71>, SPECIFIC TESTS/Bacterial Endotoxins Test <85>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards	Slavica Shane Slavica Shane
CETOTETAN DISODION IT 43(0) 19. ONLINE	,	
CEFTAZIDIME PF 45(3) Pg. ONLINE	CHEMICAL INFORMATION, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, IMPURITIES/Limit of Pyridine, SPECIFIC TESTS/Bacterial Endotoxins Test 85:, ADDITIONAL REQUIREMENTS/USP Reference Standards 11	Slavica Shane
CEFTAZIDIME FOR INJECTION PF 45(3) Pg. ONLINE	IDENTIFICATION/B., ASSAY/Procedure, OTHER COMPONENTS/Sodium Carbonate (Where Present), OTHER COMPONENTS/Content of Arginine (Where Present), IMPURITIES/Organic Impurities, IMPURITIES/Limit of Pyridine, SPECIFIC TESTS/Bacterial Endotoxins Test 85:, SPECIFIC TESTS/Sterility Tests 71:, SPECIFIC TESTS/Loss on Drying 731, ADDITIONAL REQUIREMENTS/Packaging and Storage:, ADDITIONAL REQUIREMENTS/USP Reference Standards 11  ASSAY/Procedure, IMPURITIES/Organic Impurities, Procedure 1, IMPURITIES/Organic Impurities, Procedure 2, IMPURITIES/Procedure 2, ADDITIONAL  REQUIREMENTS/I abeling	Slavica Shane
CETTIPLEMINT 43(0) 19. ONLINE		Slavica Silane
CEPHALEXIN CAPSULES PF 43(6) Pg. ONLINE CEPHALEXIN FOR ORAL SUSPENSION PF 43(6) Pg. ONLINE	Impurities, Procedure 2, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling	Slavica Shane Slavica Shane
	,,	Stavica Share
CETIRIZINE HYDROCHLORIDE CAPSULES PF 44(6) Pg. ONLINE	Title, DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, 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>/USP Cetirizine Hydrochloride RS	Richard Nguyen
	IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference	
CETYLPYRIDINIUM CHLORIDE PF 44(5) Pg. ONLINE	Standards <11>/USP Myristylpyridinium Chloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Stearylpyridinium Chloride RS	Sujatha Ramakrishna
CHLORAMPHENICOL ORAL SOLUTION PF 45(2) Pg. ONLINE	Entire document	Julie Zhang
CHLORDIAZEPOXIDE PF 44(5) Pg. ONLINE	IDENTIFICATION/Infrared Absorption <197K>, IDENTIFICATION/C., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP 2-Amino-5-chlorobenzophenone RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Chlordiazepoxide Related Compound A RS	<u>Heather Joyce</u>
	CEFOTETAN FOR INJECTION PF 43(6) Pg. ONLINE  CEFTAZIDIME PF 45(3) Pg. ONLINE  CEFTAZIDIME FOR INJECTION PF 45(3) Pg. ONLINE  CEPHALEXIN PF 43(6) Pg. ONLINE  CEPHALEXIN CAPSULES PF 43(6) Pg. ONLINE  CEPHALEXIN FOR ORAL SUSPENSION PF 43(6) Pg. ONLINE  CETIRIZINE HYDROCHLORIDE CAPSULES PF 44(6) Pg. ONLINE  CETYLPYRIDINIUM CHLORIDE PF 44(5) Pg. ONLINE  CHLORAMPHENICOL ORAL SOLUTION PF 45(2) Pg. ONLINE	IMPURITIES/Organic Impurities, SPECIFIC TESTS/Water Determination, Method I

Revision CHLORDIAZEPOXIDE HYDROCHLORIDE PF 44(5) Pg. ONLINE
New CHLOROMETHYLNITROIMIDAZOLE PF 43(3) Pg. ONLINE

CHLOROTHIAZIDE SODIUM FOR INJECTION PF 44(2) Pg. ONLINE

Revision

Revision CHRYSANTHEMUM FLOWER PF 45(1) Pg. ONLINE

Revision CHRYSANTHEMUM FLOWER DRY EXTRACT PF 45(1) Pg. ONLINE

IDENTIFICATION/Infrared Absorption <197K>, IDENTIFICATION/C., IDENTIFICATION/C. Identification Tests-General <191>, Chloride, ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Melting Range or Temperature, Class I <741>, SPECIFIC TESTS/Sterility Tests <71>, SPECIFIC TESTS/Bacterial Endotoxins Test <85>, SPECIFIC TESTS/Other Requirements, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP 2-Amino-5-chlorobenzophenone RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Chlordiazepoxide Related Compound A RS

Chloromethylnitroimidazole
IDENTIFICATION/A., IDENTIFICATION/Ultraviolet Absorption <197U>,
ASSAY/Procedure, IMPURITIES/Organic Impurities

Heather Joyce
Sridevi Ramachandran

**Edith Chang** 

DEFÍNITION/Untitled Section, IDENTIFICATION/A. HPTLC for Articles of Botanical Origin 203 , IDENTIFICATION/B. HPLC, COMPOSITION/Content of Caffeoylquinic Acids and Flavone 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 REOUIREMENTS/Packaging and Storage: ADDITIONAL REOUIREMENTS/Labeling: ADDITIONAL REQUIREMENTS/USP Reference Standards 11

Cuiying Ma

DEFINITION/Untitled Section, IDENTIFICATION/A. HPTLC for Articles of Botanical Origin 203, IDENTIFICATION/B. HPLC, COMPOSITION/Content of Caffeoylquinic Acids and Flavone 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/Loss on Drying 731, SPECIFIC TESTS/Articles of Botanical Origin 561, Methods of Analysis, Total Ash:, SPECIFIC TESTS/Botanical Extracts 565, Preparations, General Pharmacopeial Requirements, Residual Solvents:, ADDITIONAL REQUIREMENTS/Packaging and Storage:, ADDITIONAL REQUIREMENTS/Labeling:, ADDITIONAL REQUIREMENTS/Labeling:

**Cuiying Ma** 

Revision	CHRYSANTHEMUM FLOWER POWDER PF 45(1) Pg. ONLINE
Revision	CILOSTAZOL TABLETS PF 45(2) Pg. ONLINE
Revision	CIPROFLOXACIN OPHTHALMIC SOLUTION PF 44(3) Pg. ONLINE
New	CITICOLINE PF 45(2) Pg. ONLINE
Revision	CLARITHROMYCIN EXTENDED-RELEASE TABLETS PF 44(4) Pg. ONLINE
Revision	CLOBETASOL PROPIONATE OINTMENT PF 44(2) Pg. ONLINE
New	CLOBETASOL PROPIONATE TOPICAL SPRAY PF 45(1) Pg. ONLINE
Revision	CLONAZEPAM PF 44(3) Pg. ONLINE
Revision	CLONAZEPAM TABLETS PF 44(3) Pg. ONLINE

DEFINITION/Untitled Section, IDENTIFICATION/A. HPTLC for Articles of Botanical Origin 203 , IDENTIFICATION/B. HPLC, COMPOSITION/Content of Caffeoylquinic Acids and Flavone 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 IDENTIFICATION/A. Intrared Absorption 19/S, IDENTIFICATION/A., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution 711, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards 11,	<u>Cuiying Ma</u>
IDENTIFICATION/A. Infrared Absorption 197S IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities	Edith Chang Shankari Shivaprasad
CHEMICAL INFORMÁTION, DEFINITION, IDENTIFICATION/A. Spectroscopic	<u>Silalikali Silivapiasau</u>
Identification Tests 197 , Infrared, Spectroscopy: , IDENTIFICATION/B. , ASSAY/Procedure, IMPURITIES/Chloride and Sulfate 221 , Chloride, IMPURITIES/Chloride and Sulfate 221 , Sulfate, IMPURITIES/Limit of Phosphate, IMPURITIES/Related Compounds, SPECIFIC TESTS/Loss on Drying 731 , ADDITIONAL	
REQUIREMENTS/Packaging and Storage:, ADDITIONAL REQUIREMENTS/USP Reference Standards 11 PERFORMANCE TESTS/Dissolution <711>, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Clarithromycin	Fatkhulla Tadjimukhamedov
Identity RS	Praveen Pabba
IDENTIFICATION/A. Thin-Layer Chromatographic Identification Test <201>, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Beclomethasone Dipropionate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Clobetasol Propionate Related Compound A RS	Mary Koleck
DEFINITION, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, OTHER COMPONENTS/Content of Alcohol, OTHER COMPONENTS/Content of Isopropyl Myristate, PERFORMANCE TESTS/Delivered-Dose Uniformity, PERFORMANCE TESTS/Minimum Fill 755:, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Microbial Enumeration Tests 61 and Tests for Specified Microorganisms 62:, ADDITIONAL	THUI Y NOICEN
REQUIREMENTS/Packaging and Storage:, ADDITIONAL REQUIREMENTS/USP Reference Standards 11	Mary Koleck
IDENTIFICATION/A. Infrared Absorption <197K> or <197A>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Limit of Clonazepam Related Compound C, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Melting Range or Temperature <741>, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP	
Clonazepam Related Compound C RS IDENTIFICATION/Infrared Absorption, ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, IMPURITIES/Organic Impurities, ADDITIONAL	<u>Heather Joyce</u>
REQUIREMENTS/Packaging and Storage	Heather Joyce

New	CLONIDINE HYDROCHLORIDE EXTENDED-RELEASE TABLETS PF 44(6) Pg. ONLINE	Title, DEFINITION/Introduction, IDENTIFICATION/A. Thin-Layer Chromatographic Identification Test <201>, 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>/USP Clonidine Hydrochloride RS	Edith Chang
Revision	CLOZAPINE PF 44(5) Pg. ONLINE	IDENTIFICATION/A. Infrared Absorption <197K> or <197A>, ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Loss on Drying <731>, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Clozapine Resolution Mixture RS	Heather Joyce
Revision	CLOZAPINE TABLETS PF 44(5) Pg. ONLINE	IDENTIFICATION/A., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Clozapine Resolution Mixture RS DEFINITION/Introduction, IDENTIFICATION/Intrared Absorption <19/K>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Limit of Morphine, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference	<u>Heather Joyce</u>
Revision	CODEINE PHOSPHATE PF 44(6) Pg. ONLINE	Standards <11>/USP Codeine System Suitability Mixture RS	Wei Yang
		Title, DEFINITION/Introduction, IDENTIFICATION/A., 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>/USP Cyclophosphamide RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP	
New	CYCLOPHOSPHAMIDE CAPSULES PF 44(6) Pg. ONLINE  DACARBAZINE PF 44(2) Pg. ONLINE	Cyclophosphamide Related Compound A RS  Chemical Info/1H-Imidazole-4-carboxamide, 5-(3,3-dimethyl-1-triazenyl)-;1H-Imidazole-4-carboxamide, 5-(3,3-dimethyltriaz-1-enyl)-;, Chemical Info/5-(3,3-Dimethyl-1-triazeno)imidazole-4-carboxamide5-(3,3-Dimethyltriaz-1-enyl)-1H-imidazole-4-carboxamide, IDENTIFICATION/A. Infrared Absorption <197>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, IMPURITIES/Limit of Dimethylamine, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/ 5-Aminoimidazole-4-carboxamide hydrochloride.C4H6N4O·HCl 162.58, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Dimethylamine Solution RS	Jane Li Feiwen Mao
Revision	DACARBAZINE FOR INJECTION PF 44(2) Pg. ONLINE	IDENTIFICATION/A., IDENTIFICATION/B., IDENTIFICATION/C., ASSAY/Procedure, IMPURITIES/Limit of 2-Azahypoxanthine, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Particulate Matter in Injections <788>, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/	Feiwen Mao
		Title, DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY, ASSAY/Procedure, PERFORMANCE TESTS, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES, IMPURITIES, IMPURITIES, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Desvenlafaxine RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Desvenlafaxine Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Desvenlafaxine Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Desvenlafaxine Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Desvenlafaxine Succinate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards	
New	DESVENLAFAXINE EXTENDED-RELEASE TABLETS PF 44(1) Pg. ONLINE	<11>/USP Venlafaxine Hydrochloride RS IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference	<u>Heather Joyce</u>
Revision	DEXAMETHASONE ELIXIR PF 43(6) Pg. ONLINE	Standards <11>/USP Betamethasone RS	Mary Koleck

Revision	DEXAMETHASONE ORAL SOLUTION PF 43(6) Pg. ONLINE	IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Betamethasone RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methylparaben RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Prednisolone RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Propylparaben RS	Mary Koleck
Revision	DEXAMETHASONE SODIUM PHOSPHATE OPHTHALMIC SOLUTION PF 43(6) Pg. ONLINE	IDENTIFICATION/A. Thin-Layer Chromatography, IDENTIFICATION/A., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Betamethasone Sodium Phosphate RS	Mary Koleck
Revision	DIAZEPAM PF 45(2) Pg. ONLINE	IDENTIFICATION/A. Spectroscopic Identification Tests 197, Infrared Spectroscopy:, IDENTIFICATION/B. Thin-Layer Chromatographic Identification Test 201, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Melting Range or Temperature, Class I 741:, ADDITIONAL REQUIREMENTS/USP Reference Standards 11	<u>Heather Joyce</u>
Revision	DIAZEPAM INJECTION PF 45(2) Pg. ONLINE	IDENTIFICATION/A., IDENTIFICATION/B. Infrared Absorption, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Bacterial Endotoxins Test 85:, ADDITIONAL REQUIREMENTS/Packaging and Storage:, ADDITIONAL REQUIREMENTS/USP Reference Standards 11	Heather Joyce
Revision	DIAZEPAM TABLETS PF 45(2) Pg. ONLINE	IDENTIFICATION/B. Thin-Layer Chromatographic Identification Test 201, ( ) IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution 711, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage:, ADDITIONAL REQUIREMENTS/USP Reference Standards 11	<u>Heather Joyce</u>
Revision	DIAZOXIDE PF 45(1) Pg. ONLINE	IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities	Edith Chang
Revision	DIBUCAINE HYDROCHLORIDE PF 45(2) Pg. ONLINE	IDENTIFICATION/C. Identification Tests—General 191 , Chemical Identification Tests, Chloride: , ASSAY/Procedure, IMPURITIES/Organic Impurities	Mary Koleck
Revision	DICYCLOMINE HYDROCHLORIDE PF 43(6) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B., IDENTIFICATION/C., ASSAY/Procedure, IMPURITIES/Readily Carbonizable Substances Test <271>, IMPURITIES/Organic Impurities, IMPURITIES/Limit of Dicyclomine Related Compound A, SPECIFIC TESTS/Melting Range or Temperature, Class I <741>, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Dicyclomine Related Compound A RS	Behnaz Almasi
		ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, IMPURITIES/Limit of Dicyclomine Related Compound A, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP	
Revision	DICYCLOMINE HYDROCHLORIDE CAPSULES PF 43(6) Pg. ONLINE	Dicyclomine Related Compound A RS  ASSAY/Procedure, IMPURITIES/Limit of Dicyclomine Related Compound A, SPECIFIC TESTS/Bacterial Endotoxins Test <85>, SPECIFIC TESTS/Sterility Tests <71>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL	<u>Behnaz Almasi</u>
Revision	DICYCLOMINE HYDROCHLORIDE INJECTION PF 43(6) Pg. ONLINE	REQUIREMENTS/USP Reference Standards <11>/USP Dicyclomine Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Endotoxin RS	Behnaz Almasi
Revision	DICYCLOMINE HYDROCHLORIDE ORAL SOLUTION PF 43(6) Pg. ONLINE	ASSAY/Procedure, IMPURITIES/Limit of Dicyclomine Related Compound A, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Dicyclomine Related Compound A RS	Behnaz Almasi
Revision	DICYCLOMINE HYDROCHLORIDE TABLETS PF 43(6) Pg. ONLINE	ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, IMPURITIES/Limit of Dicyclomine Related Compound A, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Dicyclomine Related Compound A RS	Behnaz Almasi

Omission	DIGITALIS PF 44(3) Pg. ONLINE	Entire document	Nam-Cheol Kim
Omission	POWDERED DIGITALIS PF 44(3) Pg. ONLINE	Entire document	Nam-Cheol Kim
Omission	DIGITALIS CAPSULES PF 44(3) Pg. ONLINE	Entire document	Nam-Cheol Kim
Omission	DIGITALIS TABLETS PF 44(3) Pg. ONLINE	Entire document	Nam-Cheol Kim
Omission Revision	DIMENHYDRINATE ORAL SOLUTION PF 45(3) Pg. ONLINE  DISULFIRAM PF 43(6) Pg. ONLINE	Entire document Chemical Into/296.54296.52, DEFINITION/Introduction, IDENTIFICATION/A. Intrared Absorption <197K><197>, ASSAY/Procedure, IMPURITIES/<291>, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Melting Range or Temperature, Class I <741>	Behnaz Almasi Heather Joyce
Revision	DOXAZOSIN TABLETS PF 44(5) Pg. ONLINE	IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Doxazosin Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Doxazosin Related Compound G RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Terazosin Related Compound A RS	Edith Chang
Revision	DOXEPIN HYDROCHLORIDE PF 45(2) Pg. ONLINE	IDENTIFICATION/A. Spectroscopic Identification Tests 197 , Infrared Spectroscopy: , IDENTIFICATION/B., IDENTIFICATION/C. Identification Tests—General 191 , Chemical Identification Tests, Chloride, ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards 11	<u>Heather Joyce</u>
Revision	DOXEPIN HYDROCHLORIDE CAPSULES PF 44(6) Pg. ONLINE	DEFINITION/Introduction, 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>/USP Doxepin Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Doxepin Related Compound C RS	Heather Joyce
New	DROMETRIZOLE TRISILOXANE PF 45(2) Pg. ONLINE	CHEMICAL INFORMÀTION, DEFINITION, IDENTIFICATION/A. Spectroscopic Identification Tests 197, Infrared Spectroscopy:, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Limit of Platinum, IMPURITIES/Organic Impurities, IMPURITIES/Limit of Heptamethyl Trisiloxane, ADDITIONAL REQUIREMENTS/Packaging and Storage:, ADDITIONAL REQUIREMENTS/USP Reference Standards 11	Sujatha Ramakrishna
Revision	DRONABINOL CAPSULES PF 44(6) Pg. ONLINE	IDENTIFICATION/A., ASSAY/Procedure, IMPURITIES/Limit of Δ8-Tetrahydrocannabinol, ADDITIONAL REQUIREMENTS/Packaging and Storage	Behnaz Almasi
Revision	EDETATE DISODIUM COMPOUNDED OPHTHALMIC SOLUTION PF 44(4) Pg. ONLINE	Title, DEFINITION/Introduction, ASSAY/Procedure, SPECIFIC TESTS/pH <791>, SPECIFIC TESTS/Sterility Tests <71>, Test for Sterility of the Product to be Examined, Membrane Filtration, SPECIFIC TESTS/Particulate Matter in Ophthalmic Solutions <789>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Beyond-Use Date, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Edetate Disodium RS	Brian Serumaga
Revision	EPINEPHRINE INJECTION PF 44(6) Pg. ONLINE	IDENTIFICATION/A., ASSAY/Procedure, IMPURITIES/Enantiomeric Purity, SPECIFIC TESTS/Particulate Matter in Injections <788>, SPECIFIC TESTS/Sterility Tests <71>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Dopamine Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Epinephrine RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Racepinephrine Hydrochloride RS	<u>Gerald Hsu</u>

DEFINITION/Introduction, IDENTIFICATION/Procedure, IDENTIFICATION/A. Spectroscopic Identification Tests <197>, Infrared Spectroscopy, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Limit of Adrenalone, IMPURITIES/Limit of Norepinephrine Bitartrate, IMPURITIES/Organic Impurities, IMPURITIES/Enantiomeric Purity, SPECIFIC TESTS/Melting Range or Temperature <741>, SPECIFIC TESTS/Loss on Drying <731>, SPECIFIC TESTS/Optical Rotation, Specific Rotation <781S>, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Adrenalone Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Racepinephrine Hydrochloride RS

Suiatha Ramakrishna

New Omission	EPOPROSTENOL SODIUM PF 44(2) Pg. ONLINE STERILE ERYTHROMYCIN GLUCEPTATE PF 45(1) Pg. ONLINE
Revision	ESCITALOPRAM ORAL SOLUTION PF 44(2) Pg. ONLINE
Revision	ESTRADIOL VAGINAL INSERTS PF 45(3) Pg. ONLINE
Revision	ESTRADIOL AND NORETHINDRONE ACETATE TABLETS PF 44(6) Pg. ONLINE
New	ETOPOSIDE PHOSPHATE PF 45(2) Pg. ONLINE

EPINEPHRINE BITARTRATE PF 44(5) Pg. ONLINE

Revision

Title, Chemical Info/Chemical Structure, Chemical Info/C20H31NaO5, Chemical Info/374.45, Chemical Info/Prosta-5,13-dien-1-oic acid, 6,9-epoxy-11,15-dihydroxy-, sodium salt, (5Z,9α,11α,13E,15S)-;, Chemical Info/Sodium (Z)-(3aR,4R,5R,6aS)-hexahydro-5-hydroxy-4-[(E)-(3S)-3-hydroxy-1-octenyl]-2Hcyclopenta[b]furan-Δ 2-valerate;, Chemical Info/Sodium (Z)-5-{(3aR,4R,5R,6aS)-5-hydroxy-4-[(S,E)-3-hydroxyoct-1-en-1-yl]hexahydro-2H-cyclopenta[b]furan-2vlidene \ pentanoate, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K> or <197A>, IDENTIFICATION/B., IDENTIFICATION/C. Identification Tests-General <191>, Chemical Identification Tests, Sodium, ASSAY/Procedure, IMPURITIES/Limit of Sodium Hydroxide, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Water Determination <921>, Method I, Method Ic, SPECIFIC TESTS/Optical Rotation <781S>, Procedures, Specific Rotation, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Epoprostenol Sodium RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Epoprostenol Sodium System Suitability Mixture RS Entire document

IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/LIMIT OF CITAIOPRAM Related Compound B, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP CitaIopram Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP CitaIopram Related Compound C RS

Heather Joyce

Gerald Hsu

Julie Zhang

IDENTIFICATION/A. Thin-Layer Chromatographic Identification Test 201:, ASSAY/Procedure, PERFORMANCE TESTS/Dissolution 711, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards 11 IDENTIFICATION/Inin-Layer Chromatographic Identification Test <201>, ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, IMPURITIES/Organic Impurities

Gerald Hsu

**Gerald Hsu** 

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

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/PARTICULATE Requirements:, ADDITIONAL REQUIREMENTS/Packaging and Storage:, ADDITIONAL REQUIREMENTS/USP Reference Standards 11

Jane Li

New ETOPOSIDE PHOSPHATE FOR INJECTION PF 45(2) Pg. ONLINE

New Revision	EXEMESTANE TABLETS PF 44(6) Pg. ONLINE  EXENATIDE PF 45(3) Pg. ONLINE	Title, DEFINITION/Introduction, 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>/USP Exemestane RS DEFINITION/UNITITIES SECTION, IDENTIFICATION/B. AMINIO ACID ANALYSIS, ASSAY/Procedure, IMPURITIES/Procedure 1: Exenatide Related Substances and Impurities, IMPURITIES/Procedure 2: N-Acqtyl, His1-Exenatide, IMPURITIES/Procedure 3: Limit of d-His1 Exenatide, PROCESS-RELATED IMPURITIES/Limit of Phosphate, SPECIFIC TESTS/Bacterial Endotoxins Test 85:, ADDITIONAL REQUIREMENTS/Labeling:	Jane Li Manoj Metta
Revision	FELODIPINE PF 44(5) Pg. ONLINE	Chemical Info/(±)-Ethyl methyl 4-(2,3-dichlorophenyl)-1,4-dihydro-2,6-dimethyl-3,5-pyridinedicarboxylateEthyl methyl 4-(2,3-dichlorophenyl)-2,6-dimethyl-1,4-dihydropyridine-3,5-dicarboxylate, Chemical Info/CAS, IDENTIFICATION/A. Infrared Absorption <197K>Spectroscopic Identification Tests <197>, Infrared Spectroscopy, ASSAY/Procedure, IMPURITIES/Limit of Ethyl 3-Aminocrotonate, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Color of Solution, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ethyl 3-Aminocrotonate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Felodipine Related Compound A RS	Edith Chang
New	FEXOFENADINE HYDROCHLORIDE ORAL SUSPENSION PF 43(6) Pg. ONLINE	Title, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, PERFORMANCE TESTS/Deliverable Volume <698>, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Deliverable Volume <698>, IMPURITIES/Organic Impurities, 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>/USP Fexofenadine RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Fexofenadine Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Fexofenadine Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Fexofenadine Related Compound C RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Propylparaben RS	<u>Gerald Hsu</u>
New	FEXOFENADINE HYDROCHLORIDE ORALLY DISINTEGRATING TABLETS PF 44(6) Pg. ONLINE	Title, DEFINITION/Introduction, IDENTIFICATION/A. Spectroscopic Identification Tests <197>, Infrared Spectroscopy, IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Disintegration <701>, 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>/USP Fexofenadine Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Fexofenadine Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Fexofenadine Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Fexofenadine Related Compound C RS	Richard Nguyen
Revision	FLAVOXATE HYDROCHLORIDE PF 45(2) Pg. ONLINE	CHEMICAL INFORMATION, DEFINITION/Untitled Section, IDENTIFICATION/A. Spectroscopic Identification Tests 197, Infrared Spectroscopy:, IDENTIFICATION/C. Identification Tests—General 191, Chemical Identification Tests, Chloride:, ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Loss on Drying 731:, ADDITIONAL REQUIREMENTS/USP Reference Standards 11	<u>Heather Joyce</u>

		IDENTIFICATION/ A., IDENTIFICATION/B., ASSAT/PROCEDURE, IMPURITIES/ORGANIC Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Fluconazole Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Fluconazole Related Compound B RS, ADDITIONAL	
Revision	FLUCONAZOLE TABLETS PF 44(3) Pg. ONLINE	REQUIREMENTS/USP Reference Standards <11>/USP Fluconazole Related Compound C RS	Shankari Shivaprasad
		IDENTIFICATION/INTRAFED ADSORPTION < 19/N>, IDENTIFICATION/B. UITRAVIOLET Absorption <197U>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Ordinary Impurities <466>, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Fluphenazine Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Fluphenazine Related Compound	
Revision	FLUPHENAZINE HYDROCHLORIDE PF 44(6) Pg. ONLINE	B RS	Heather Joyce
		IDENTIFICATION/A. ININ-Layer CHROMATOGRAPHY, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Fluphenazine Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Fluphenazine	
Revision	FLUPHENAZINE HYDROCHLORIDE ELIXIR PF 44(6) Pg. ONLINE	Related Compound B RS	Heather Joyce
		IDENTIFICATION/A. Inin-Layer Chromatography, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Fluphenazine Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Fluphenazine Related Compound RD REQUIREMENTS/USP Reference Standards <11>/USP Fluphenazine Related Compound RD ROMANDE REQUIREMENTS/USP RESERVED TO THE RESERVED RESERV	
Revision	FLUPHENAZINE HYDROCHLORIDE INJECTION PF 44(6) Pg. ONLINE	B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methylparaben RS	Heather Joyce
		IDENTIFICATION/A. ININ-Layer CHROMATOGRAPHY, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Fluphenazine Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Fluphenazine Related Compound	neutrici soyee
Revision	FLUPHENAZINE HYDROCHLORIDE ORAL SOLUTION PF 44(6) Pg. ONLINE	B RS	Heather Joyce
Revision	FLUPHENAZINE HYDROCHLORIDE TABLETS PF 44(6) Pg. ONLINE FORMOTEROL FUMARATE PF 45(3) Pg. ONLINE	IDENTIFICATION/A. Thin-Layer Chromatography, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Fluphenazine Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Fluphenazine Related Compound B RS CHEMICAL INFORMATION, IDENTIFICATION/A. Spectroscopic Identification Tests 197, Infrared Spectroscopy:, ASSAY/Procedure, IMPURITIES/Organic Impurities, IMPURITIES/Limit of Formoterol Related Compound I, ADDITIONAL REQUIREMENTS/USP Reference Standards 11	Heather Joyce  Ravi Ravichandran
		Chemical Info/Chemical Structure, Chemical Info/C16H25GdN4O8·C7H17NO5, Chemical Info/753.86, Chemical Info/d-Glucitol, 1-deoxy-1-(methylamino)-, [1,4,7,10-tetraazacyclododecane-1,4,7,10-tetraacetato(4-)- &kgrN1,&kgrN4,&kgrN7,&kgrN10,&kgrO1,&kgrO4,&kgrO7,&kgrO10]gadolinate(1) (1:1);, Chemical Info/1-Deoxy-1-(methylamino)-d-glucitol hydrogen [1,4,7,10-tetraazacyclododecane-1,4,7,10-tetraacetato(4-)- &kgrN1,&kgrN4,&kgrN7,&kgrN10,&kgrO1,&kgrO4,&kgrO7,&kgrO10]gadolinate(1), Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Ultraviolet Absorption <197U>, IDENTIFICATION/B., ASSAY/Procedure, OTHER COMPONENTS/Content of Meglumine, IMPURITIES/Limit of Free Gadolinium, IMPURITIES/Limit of Free Tetraxetan, SPECIFIC TESTS/PH <791>, SPECIFIC TESTS/Particulate Matter in Injections <788>, SPECIFIC TESTS/Sterility Tests <71>, SPECIFIC TESTS/Bacterial Endotoxins Test <85>, SPECIFIC TESTS/Container Content for Injections <697>, ADDITIONAL REQUIREMENTS/Packaging and Storage,	-
New	GADOTERATE MEGILIMINE INJECTION PE 44(3) Pg. ONLINE	ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Gadoterate Mealumine RS	Pavi Pavichandran

Meglumine RS

Ravi Ravichandran

GADOTERATE MEGLUMINE INJECTION PF 44(3) Pg. ONLINE

New

Revision Revision	GALANTAMINE TABLETS PF 44(3) Pg. ONLINE HARD GELATIN CAPSULE SHELL PF 44(5) Pg. ONLINE	Content Uniformity, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Galantamine Hydrobromide Related Compounds Mixture RS DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B., SPECIFIC TESTS/Loss on Drying <731>	Heather Joyce  Margareth Marques
New	GLIPIZIDE EXTENDED-RELEASE TABLETS PF 45(1) Pg. ONLINE	DEFINITION, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution 711, PERFORMANCE TESTS/Uniformity of Dosage Units 905:, IMPURITIES/Organic Impurities, Procedure 1, IMPURITIES/Organic Impurities, Procedure 2, ADDITIONAL REQUIREMENTS/Packaging and Storage:, ADDITIONAL REQUIREMENTS/USP Reference Standards 11	Behnaz Almasi
Revision	GLYCINE PF 45(1) Pg. ONLINE	IDENTIFICATION/A. Spectroscopic Identification Tests 197 , Infrared Spectroscopy:, IMPURITIES/Related Compounds, ADDITIONAL REQUIREMENTS/Labeling:	<u>Fatkhulla Tadjimukhamedov</u>
		Chemical Info/1374.461182.3 (acetic acid free, anhydrous), Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, OTHER COMPONENTS/Acetic Acid in Peptides <503>, ??UNKNOWN??/Gonadorelin-Related Impurities, Procedure 1, ??UNKNOWN??/Gonadorelin-Related Impurities, Procedure 2, ??UNKNOWN??/Acetic Acid and Trifluoroacetic Acid, ??UNKNOWN??/Limit of Fluoride, SPECIFIC TESTS/Optical Rotation, Specific Rotation <781S>, SPECIFIC TESTS/Bacterial Endotoxins Test <85>, SPECIFIC TESTS/Microbial Enumeration Tests <61> and Tests for Specified Microorganisms <62>, SPECIFIC TESTS/Amino Acid Analysis, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP	
Revision	GONADORELIN ACETATE PF 44(2) Pg. ONLINE	Reference Standards <11>/USP [D-His2]-Gonadorelin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP [D-Tyr5]-Gonadorelin RS IDENTIFICATION/A. Ihin-Layer Chromatographic Identification Test 201, IDENTIFICATION/A., ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Bacterial Endotoxins Test 85:, ADDITIONAL REQUIREMENTS/USP Reference	Michael Huang
Revision	GRANISETRON HYDROCHLORIDE INJECTION PF 45(2) Pg. ONLINE	Standards 11  IDENTIFICATION/A., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution 711, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference	Behnaz Almasi
Revision	GRANISETRON HYDROCHLORIDE TABLETS PF 45(2) Pg. ONLINE	Standards 11	Behnaz Almasi
Revision	HALOPERIDOL TABLETS PF 45(1) Pg. ONLINE	IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCÉ TESTS/Dissolution 711, PERFORMANCE TESTS/Uniformity of Dosage Units 905:, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage:, ADDITIONAL REQUIREMENTS/USP Reference Standards 11  CHEMICAL INFORMATION, DEFINITION, IDENTIFICATION/A. Spectroscopic	Heather Joyce
Revision	HALOPERIDOL DECANOATE PF 45(2) Pg. ONLINE	Identification Tests 197 , Infrared Spectroscopy: , IDENTIFICATION/B., IDENTIFICATION/C. Identification Tests—General 191 , Chloride, ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Loss on Drying 731 , ADDITIONAL REQUIREMENTS/USP Reference Standards 11	Heather Joyce
Revision	HISTIDINE PF 43(6) Pg. ONLINE	IDENTIFICATION/B., IMPURITIES/Related Compounds, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP I-Alanine RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP I-Arginine RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP I-Lysine Hydrochloride RS	<u>Fatkhulla Tadjimukhamedov</u>

IDENTIFICATION/Ultraviolet Absorption <197U>, ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>,

Revision	HYDROCORTISONE CREAM PF 44(6) Pg. ONLINE	IDENTIFICATION/A. Thin-Layer Chromatographic Identification Test <201>, IDENTIFICATION/A., 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>/USP Prednisolone RS	Gerald Hsu
Revision	HYDROCORTISONE LOTION PF 45(3) Pg. ONLINE	IDENTIFICATION/A. Thin-Layer Chromatographic Identification Test 201, IDENTIFICATION/A., 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	<u>Gerald Hsu</u>
Revision	HYDROCORTISONE OINTMENT PF 44(6) Pg. ONLINE	IDENTIFICATION/A. Thin-Layer Chromatographic Identification Test <201>, IDENTIFICATION/A., 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>/USP Prednisolone RS	Gerald Hsu
Revision	HYDROCORTISONE RECTAL SUSPENSION PF 45(3) Pg. ONLINE	IDENTIFICATION/Thin-Layer Chromatographic Identification Test 201, IDENTIFICATION/A, 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	Gerald Hsu
Revision	HYDROCORTISONE TABLETS PF 44(6) Pg. ONLINE	IDENTIFICATION/A. Infrared Absorption <197M>, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, 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>/USP Prednisolone RS	Gerald Hsu
	· / -	IDENTIFICATION/Thin-Layer Chromatographic Identification Test <201>, 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>/USP Cortisone Acetate RS,	3333
Revision	HYDROCORTISONE ACETATE CREAM PF 44(3) Pg. ONLINE	ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Hydrocortisone RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Prednisolone Acetate RS IDENTIFICATION/A. Intrared Absorption, IDENTIFICATION/A., IDENTIFICATION/B.,	Gerald Hsu
Revision	HYDROMORPHONE HYDROCHLORIDE INJECTION PF 45(3) Pg. ONLINE	ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage:, ADDITIONAL REQUIREMENTS/USP Reference Standards 11  IDENTIFICATION/Ultraviolet Absorption <19/U>, IDENTIFICATION/B. Intrared  Absorption <107(c, 107), ASSAY/Pacadure, IMPURITIES/Ordinary Impurities	<u>Wei Yang</u>
Revision	HYDROXYCHLOROQUINE SULFATE PF 44(2) Pg. ONLINE	Absorption <197K><197>, ASSAY/Procedure, IMPURITIES/Ordinary Impurities <466>, IMPURITIES/Organic Impurities	Shankari Shivaprasad
Revision	HYDROXYCHLOROQUINE SULFATE TABLETS PF 44(3) Pg. ONLINE	ASSAY/Procedure, PERFORMANCE TESTS/Organic Impurities	Shankari Shivaprasad
	• • • • • • • • • • • • • • • • • • • •	DEFINITION/Introduction, IDENTIFICATION/A., SPECIFIC TESTS/Loss on Drying	
Revision	HARD HYPROMELLOSE CAPSULE SHELL PF 44(5) Pg. ONLINE	<731>, ADDITIONAL REQUIREMENTS/Packaging and Storage	Margareth Marques

INDIAN BARBERRY STEM PF 44(5) Pg. ONLINE New

New

New

INDIAN BARBERRY STEM DRY EXTRACT PF 44(5) Pg. ONLINE

Title, DEFINITION/Introduction, IDENTIFICATION/A. HPTLC for Articles of Botanical Origin <203>, IDENTIFICATION/B. HPLC, COMPOSITION/Content of Berberine, 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 1, SPECIFIC TESTS/Articles of Botanical Origin <561>, Methods of Analysis, Water-Soluble Extractives, Method 2, SPECIFIC TESTS/Loss on Drying <731>, 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, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling. ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Berberine Chloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Berberis aristata Stem Dry Extract RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Palmatine Chloride RS

Nam-Cheol Kim

Title, DEFINITION/Introduction, IDENTIFICATION/A. HPTLC for Articles of Botanical Origin <203>, IDENTIFICATION/B, HPLC, COMPOSITION/Content of Berberine, 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/Loss on Drying <731>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REOUIREMENTS/Labeling, ADDITIONAL REOUIREMENTS/USP Reference Standards <11>/USP Berberine Chloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Berberis aristata Stem Dry Extract RS, ADDITIONAL REOUIREMENTS/USP Reference Standards <11>/USP Palmatine Chloride RS

Nam-Cheol Kim

Nam-Cheol Kim

Title, DEFINITION/Introduction, IDENTIFICATION/A. HPTLC for Articles of Botanical Origin <203>, IDENTIFICATION/B, HPLC, COMPOSITION/Content of Berberine, 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 1, SPECIFIC TESTS/Articles of Botanical Origin <561>, Methods of Analysis, Water-Soluble Extractives, Method 2, SPECIFIC TESTS/Loss on Drying <731>, 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, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REOUIREMENTS/USP Reference Standards <11>/USP Berberine Chloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Berberis aristata Stem Dry Extract RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Palmatine Chloride RS

Revision INSULIN HUMAN PF 44(4) Pa. ONLINE

New ISCOTRIZINOL PF 43(5) Pg. ONLINE

Omission ISOMETHEPTENE MUCATE PF 45(2) Pg. ONLINE

OTHER COMPONENTS/Zinc Determination <591>, SPECIFIC TESTS/Bacterial Endotoxins Test <85>, SPECIFIC TESTS/Microbial Enumeration Tests <61> and Tests for Specified Microorganisms <62>, ADDITIONAL REOUIREMENTS/Labeling

Manoj Metta

Title, Chemical Info/Chemical Structure, Chemical Info/C44H59N7O5, Chemical Info/765.98, Chemical Info/Benzoic acid, 4,4′-[[6-[[4-[[(1,1dimethylethyl)amino]carbonyl]phenyl]amino]-1,3,5-triazine-2,4-diyl]diimino]bis-, bis(2ethylhexyl) ester:, Chemical Info/Bis(2-ethylhexyl) 4.4&prime:-[(6-{[4-(tertbutylcarbamoyl)phenyl]amino}-1,3,5-triazine-2,4-diyl)diimino]dibenzoate, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Residue on Ignition <281>. IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage. ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ethylhexyl Triazone Related Compound A RS, ADDITIONAL REOUIREMENTS/USP Reference Standards <11>/USP Ethylhexyl Triazone Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ethylhexyl Triazone Related Compound C RS, ADDITIONAL REOUIREMENTS/USP Reference Standards <11>/USP Iscotrizinol RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Iscotrizinol Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Iscotrizinol Related Compound C RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Iscotrizinol Related Compound D RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Iscotrizinol Related Compound F.RS. ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Iscotrizinol Related Compound G RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Iscotrizinol Related Compound I RS Entire document

<u>Feiwen Mao</u> Heather Joyce

Title, DEFINITION/Introduction, IDENTIFICATION/A. HPTLC for Articles of Botanical Origin <203>, IDENTIFICATION/B. HPLC, COMPOSITION/Content of Flavonol Glycosides and Quercetin, 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>/USP Isorhamnetin-3-O-Rutinoside RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Quercetin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Rutin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Sophora japonica Flower Dry Extract RS

JAPANESE SOPHORA FLOWER DRY EXTRACT PF 44(6) Pg. ONLINE

JAPANESE SOPHORA FLOWER POWDER PF 44(6) Pg. ONLINE

Title, DEFINITION/Introduction, IDENTIFICATION/A, HPTLC for Articles of Botanical Origin <203>, IDENTIFICATION/B. HPLC, COMPOSITION/Content of Flavonol Glycosides and Quercetin, 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>/USP Isorhamnetin-3-O-Rutinoside RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ouercetin RS, ADDITIONAL REOUIREMENTS/USP Reference Standards <11>/USP Rutin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Sophora japonica Flower Dry Extract RS

Cuiving Ma

Title, DEFINITION/Introduction, IDENTIFICATION/A. HPTLC for Articles of Botanical Origin <203>, IDENTIFICATION/B. HPLC, COMPOSITION/Content of Flavonol Glycosides and Ouercetin, 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 Drving <731>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Isorhamnetin-3-O-Rutinoside RS, ADDITIONAL REOUIREMENTS/USP Reference Standards <11>/USP Ouercetin RS. ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Rutin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Sophora japonica Flower Dry Extract RS

Cuiying Ma

CHEMICAL INFORMATION, DEFINITION, IDENTIFICATION/A. Spectroscopic Identification Tests 197, Infrared Spectroscopy:, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Residue on Ignition 281:, IMPURITIES/Limit of Lacosamide S-Enantiomer, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Water Determination 921, Method I:, ADDITIONAL REQUIREMENTS/Packaging and Storage:, ADDITIONAL REQUIREMENTS/USP Reference Standards 11 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:, ADDITIONAL REQUIREMENTS/Packaging and Storage:, ADDITIONAL REQUIREMENTS/USP Reference Standards 11

Ren-Hwa Yeh

Ren-Hwa Yeh

New LACOSAMIDE PF 45(3) Pg. ONLINE

New

New

New LACOSAMIDE INJECTION PF 45(3) Pg. ONLINE

New	LACOSAMIDE ORAL SOLUTION PF 45(3) Pg. ONLINE	PERFORMANCE TESTS/Deliverable Volume 698; 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	Ren-Hwa Yeh
New	LACOSAMIDE TABLETS PF 45(3) 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	Ren-Hwa Yeh
New Revision Revision	LEVETIRACETAM COMPOUNDED ORAL SUSPENSION PF 45(3) Pg. ONLINE LEVOFLOXACIN TABLETS PF 44(5) Pg. ONLINE LEVOTHYROXINE SODIUM PF 45(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  IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities IMPURITIES/Organic Impurities, Procedure 2, ADDITIONAL REQUIREMENTS/USP Reference Standards 11	Brian Serumaga Shankari Shivaprasad Andrea Carney
New Revision	LEVOTHYROXINE SODIUM COMPOUNDED ORAL SUSPENSION PF 45(1) Pg. ONLINE LIDOCAINE AND PRILOCAINE CREAM PF 45(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 IDENTIFICATION/A., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage:	Brian Serumaga Richard Nguyen
		Title, DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, 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>/USP Loratadine RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Loratadine Related Compound A	
New Revision	LORATADINE CAPSULES PF 44(6) Pg. ONLINE  MILK OF MAGNESIA PF 44(3) Pg. ONLINE	RS IDENTIFICATION/B., ASSAY/Procedure, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>	Richard Nguyen  Michael Chang
Revision	MAGNESIA TABLETS PF 44(4) Pg. ONLINE	IDENTIFICATION/B., ASSAY/Procedure, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>	Michael Chang
Revision Revision	MAGNESIUM CARBONATE PF 44(2) Pg. ONLINE  MAGNESIUM CITRATE PF 44(5) Pg. ONLINE	IDENTIFICATION/B., IDENTIFICATION/C. Identification Tests-General <191>, Chemical Identification Tests, Carbonate, ASSAY/Procedure, IMPURITIES/Limit of Calcium, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11> IDENTIFICATION/Identification Tests-General <191>, Chemical Identification Tests, Magnesium, ASSAY/Procedure, IMPURITIES/Limit of Calcium, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>	Michael Chang  Michael Chang
Revision	MAGNESIUM HYDROXIDE PF 44(1) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Soluble Salts, IMPURITIES/Limit of Calcium, IMPURITIES/Limit of Lead, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Limit of Calcium,	Michael Chang
Revision	MAGNESIUM HYDROXIDE PASTE PF 44(3) Pg. ONLINE	IMPURITIES/Limit of Lead, ADDITIONAL REQUIREMENTS/USP Reference Standards <11> IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Limit of Calcium, ADDITIONAL	Michael Chang
Revision	MAGNESIUM OXIDE PF 43(6) Pg. ONLINE	REQUIREMENTS/USP Reference Standards <11>	Michael Chang

DEFINITION, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/PROCEDURE,

Revision	MAGNESIUM OXIDE CAPSULES PF 43(6) Pg. ONLINE	IDENTIFICATION/B., ASSAY/Procedure, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>	Michael Chang
Revision	MAGNESIUM OXIDE TABLETS PF 43(6) Pg. ONLINE	IDENTIFICATION/B., ASSAY/Procedure, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>	Michael Chang
Revision Revision	MAGNESIUM SULFATE PF 45(2) Pg. ONLINE  MAGNESIUM TRISILICATE PF 44(2) Pg. ONLINE	DEFINITION/Untitled Section, IDENTIFICATION/A. Identification Tests—General 191, Chemical Identification Tests, Sulfate, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Iron 241, ADDITIONAL REQUIREMENTS/Packaging and Storage:, ADDITIONAL REQUIREMENTS/USP Reference Standards 11 IDENTIFICATION/B., ASSAY/Content of Magnesium Oxide, IMPURITIES/Soluble Salts, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>	Michael Chang  Michael Chang
Revision	MAPROTILINE HYDROCHLORIDE PF 45(2) Pg. ONLINE	IDENTIFICATION/A. Spectroscopic Identification Tests 197 , Infrared Spectroscopy: , IDENTIFICATION/C. Identification Test—General 191 , Chemical Identification Tests, Chloride, IMPURITIES/Organic Impurities, Procedure 1	Ren-Hwa Yeh
New	MEMANTINE HYDROCHLORIDE EXTENDED RELEASE CAPSULES PF 44(6) Pg. ONLINE	Title, DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, 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>/USP Amantadine Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Memantine Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Memantine Related Compound E RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Memantine Related Compound F RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Memantine Related Compound G RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Memantine Related Compound H RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Memantine Related Compound I RS Related Compound H RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Memantine Related Compound I RS	Mary Koleck
New	MEMANTINE HYDROCHLORIDE ORAL SOLUTION PF 44(5) Pg. ONLINE	Title, DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Deliverable Volume <698>, IMPURITIES/Limit of Memantine Related Compound F, IMPURITIES/Organic Impurities, 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>/USP Amantadine Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Memantine Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Memantine Related Compound E RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Memantine Related Compound F RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Memantine Related Compound F RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Memantine Related Compound H RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Memantine Related Compound H RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Memantine Related Compound I RS	Mary Koleck
Omission	MENADIOL SODIUM DIPHOSPHATE PF 44(4) Pq. ONLINE	Entire document	Donald Min
Omission	METHYLCELLULOSE ORAL SOLUTION PF 44(3) Pg. ONLINE	Entire document	Feiwen Mao
		DEFINITION/Untitled Section, ASSAY/Procedure, IMPURITIES/Organic Impurities, IMPURITIES/Limit of Azure B, SPECIFIC TESTS/Bacterial Endotoxins Test 85:,	
Revision	METHYLENE BLUE INJECTION PF 45(1) Pg. ONLINE	SPECIFIC TESTS/Sterility Tests 71:	<u>Donald Min</u>

Revision	METHYLPHENIDATE HYDROCHLORIDE PF 45(2) Pg. ONLINE	IDENTIFICATION/A. Spectroscopic Identification Tests 197, Infrared Spectroscopy:, IDENTIFICATION/B. Identification Tests—General 191, Chemical Identification Tests, Chloride:, ASSAY/Procedure, IMPURITIES/Organic Impurities, Procedure 1, IMPURITIES/Organic Impurities, Procedure 2	Mary Koleck
Revision Omission	METHYLPREDNISOLONE SODIUM SUCCINATE FOR INJECTION PF 44(4) Pg. ONLINE METHYSERGIDE MALEATE PF 44(3) Pg. ONLINE	IDENTIFICATION/Infrared Absorption, IDENTIFICATION/B., ASSAY/Procedure, OTHER COMPONENTS/Free Methylprednisolone, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Fluorometholone RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methylprednisolone Hemisuccinate Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methylprednisolone Hemisuccinate Related Compound D RS Entire document	Gerald Hsu Mary Koleck
	, , , <del>,</del>	IDENTIFICATION/Infrared Absorption <197>, IDENTIFICATION/B., ASSAY/Procedure,	mary moreon
Revision	MINOXIDIL TABLETS PF 44(2) Pg. ONLINE	PERFORMANCE TESTS/Dissolution <711>, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage	Donald Min
Omission	MORICIZINE HYDROCHLORIDE PF 44(4) Pg. ONLINE	Entire document	Donald Min
Revision	MORPHINE SULFATE COMPOUNDED INJECTION PF 45(2) Pg. ONLINE	ASSAY/Procedure	Tiffany Chan
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
		IDENTIFICATION/A, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Microbial Enumeration Tests 61 and Tests for Specified Microorganisms 62:, ADDITIONAL REQUIREMENTS/Packaging and Storage:,	
Revision	MUPIROCIN CREAM PF 45(3) Pg. ONLINE	ADDITIONAL REQUIREMENTS/USP Reference Standards 11 IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL	Slavica Shane
Revision	MUPIROCIN NASAL OINTMENT PF 45(3) Pg. ONLINE	REQUIREMENTS/USP Reference Standards 11	Slavica Shane
Revision	NADOLOL PF 45(3) Pg. ONLINE	IDENTIFICATION/A. Spectroscopic Identification Tests 197, Infrared Spectroscopy:, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards 11	Donald Min
Revision	NARATRIPTAN HYDROCHLORIDE PF 45(2) Pg. ONLINE	DEFINITION, IDENTIFICATION/A. Spectroscopic Identification Tests 197, Infrared Spectroscopy:, IDENTIFICATION/C. Identification Tests—General 191, Chloride:, IDENTIFICATION/C. Chloride, ASSAY/Procedure, IMPURITIES/Organic Impurities	Gerald Hsu

New NEBIVOLOL HYDROCHLORIDE PF 44(6) Pg. ONLINE

Revision NEOMYCIN SULFATE PF 44(6) Pg. ONLINE

Title, Chemical Info/Chemical Structure, Chemical Info/C22H25F2NO4·HCl, Chemical Info/441.90, Chemical Info/2H-1-Benzopyran-2-methanol, α α ′ [iminobis(methylene)]bis[6-fluoro-3,4-dihydro]-, hydrochloride, (αR,α′R,2R,2′S)-rel-;, Chemical Info/(1RS,1′RS)-1,1′-[(2RS,2′SR)-Bis(6-fluoro-3,4-dihydro-2H-1-benzopyran-2-yl)]-2.2&prime:-iminodiethanol hydrochloride, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Spectroscopic Identification Tests <197>, Infrared Spectroscopy, IDENTIFICATION/B., IDENTIFICATION/C. Identification Tests-General <191>, Chemical Identification Tests, Chloride, ASSAY/Procedure, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Organic Impurities, IMPURITIES/Stereoisomeric Purity, IMPURITIES/Content of Nebivolol Related Compound C and Nebivolol Related Compound D (if present), SPECIFIC TESTS/Water Determination <921>, Method I, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Nebivolol Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Nebivolol Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Nebivolol Related Compound C RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Nebivolol Related Compound D RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Nebivolol Related Compound E RS, ADDITIONAL REOUIREMENTS/USP Reference Standards <11>/USP Nebivolol Stereoisomers Mixture RS

**Donald Min** 

Chemical Info/Chemical NameChemical Info/Chemical StructureChemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B., IDENTIFICATION/C., SPECIFIC TESTS/Composition of Neomycin Sulfate, SPECIFIC TESTS/Sterility Tests <71>, SPECIFIC TESTS/Bacterial Endotoxins Test <85>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Neomycin A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Neomycin B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Neomycin Sulfate System Suitability Mixture RS

Julie Zhang

Title, Chemical Info/Chemical Structure, Chemical Info/C28H22F3N7O·HCI·H2O, Chemical Info/584.00, Chemical Info/Benzamide, 4-methyl-N-[3-(4-methyl-1H-imidazol-1-vl)-5-(trifluoromethyl)phenyll-3-[[4-(3-pyridinyl)-2-pyrimidinyl]amino, monohydrochloride, monohydrate;, Chemical Info/4-Methyl-N-[3-(4-methyl-1Himidazol-1-yl)-5-(trifluoromethyl)phenyl]-3-{[4-(pyridin-3-yl)pyrimidin-2yl]amino}benzamide hydrochloride monohydrate, Chemical Info/CAS, Chemical Info/C28H22F3N7O, Chemical Info/529.52, Chemical Info/Free base, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197M>, IDENTIFICATION/B., IDENTIFICATION/C. Identification Tests-General <191>, Chemical Identification Tests, Chloride, ASSAY/Procedure, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Limit of Nilotinib Related Compound A, Nilotinib Related Compound B, and Nilotinib Related Compound C, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Water Determination <921>, Method I, Method Ia, ADDITIONAL REOUIREMENTS/Packaging and Storage, ADDITIONAL REOUIREMENTS/USP Reference Standards <11>/USP Nilotinib RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Nilotinib Related Compound A RS, ADDITIONAL REOUIREMENTS/USP Reference Standards <11>/USP Nilotinib Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Nilotinib Related Compound C RS, ADDITIONAL REOUIREMENTS/USP Reference Standards <11>/USP Nilotinib System Suitability Mixture RS

Revision NISOLDIPINE PF 43(6) Pg. ONLINE New NITAZOXANIDE PF 44(4) Pg. ONLINE DILUTED NITROGLYCERIN PF 44(3) Pg. ONLINE Revision NITROGLYCERIN INJECTION PF 44(3) Pg. ONLINE Revision Revision NITROGLYCERIN OINTMENT PF 44(3) Pg. ONLINE Title, Chemical Info/Chemical Structure, Chemical Info/C20H24N2O6, Chemical Info/388.41, Chemical Info/3,5-Pyridinedicarboxylic acid, 1,4-dihydro-2,6-dimethyl-4-(2-nitrophenyl)-, methyl 2-methylpropyl ester, (±)-;, Chemical Info/(±)-Isobutyl methyl 1,4-dihydro-2,6-dimethyl-4-(o-nitrophenyl)-3,5-pyridinedicarboxylate, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Loss on Drying <731>, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Nifedipine RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Nisoldipine RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Nisoldipine Related Compound C RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Reference Standards <11>/USP Nisoldipine Related Compound D RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Nisoldipine Related Compound D RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Nisoldipine Related Compound D RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Nisoldipine Related Compound D RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Nisoldipine Related Compound G RS

Donald Min

Title, Chemical Info/Chemical Structure, Chemical Info/C12H9N3O5S, Chemical Info/307.28, Chemical Info/2-(Acetyloxy)-N-(5-nitro-2-thiazolyl) benzamide;, Chemical Info/N-(5-Nitrothiazol-2-yl)salicylamide acetate ester, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Loss on Drying <731>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Aspirin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Nitazoxanide RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Nitazoxanide Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Nitazoxanide Related Compound B RS

Shankari Shivaprasad

IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Bacterial Endotoxins Test <85>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP 1,2-Dinitroglycerin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP 1,3-Dinitroglycerin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP 1-Mononitroglycerin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP 2-Mononitroglycerin RS

Donald Min

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>/USP 1,2-Dinitroglycerin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP 1,3-Dinitroglycerin RS, ADDITIONAL REQUIREMENTS/USP REQUIREMENTS/USP Reference Standards <11>/USP 1-Mononitroglycerin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP 2-Mononitroglycerin RS

**Donald Min** 

IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP 1,2-Dinitroglycerin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP 1,3-Dinitroglycerin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP 1-Mononitroglycerin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP 2-Mononitroglycerin RS

**Donald Min** 

Revision	NITROGLYCERIN SUBLINGUAL TABLETS PF 44(3) Pg. ONLINE	IDENTIFICATION/A. Thin-Layer Chromatographic Identification Test <201>, IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP 1,2-Dinitroglycerin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP 1,3-Dinitroglycerin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP 1-Mononitroglycerin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP 2-Mononitroglycerin RS	Donald Min
Revision	NORETHINDRONE AND ETHINYL ESTRADIOL TABLETS PF 43(6) Pg. ONLINE	IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ethinyl Estradiol Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Norethindrone Related Compound B RS IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE IESTS/DISSOlution 11 , IMPURITIES/Organic Impurities, Procedure 1: Norethindrone Acetate Related Compounds, IMPURITIES/Organic Impurities, Procedure 2: Ethinyl Estradiol Related Compounds, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP	Ren-Hwa Yeh
Revision	NORETHINDRONE ACETATE AND ETHINYL ESTRADIOL TABLETS PF 44(3) Pg. ONLINE	Estrone RS	Ren-Hwa Yeh
Revision	NORGESTIMATE AND ETHINYL ESTRADIOL TABLETS PF 44(6) Pg. ONLINE	IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Disintegration <701>, PERFORMANCE TESTS/Dissolution <711>, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage	Ren-Hwa Yeh
Revision	NORGESTREL PF 43(6) Pg. ONLINE	IDENTIFICATION/A. Infrared Absorption <197K><197>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Melting Range or Temperature<741>, Class I, SPECIFIC TESTS/Limit of Ethynyl Group, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Norgestrel Related Compound L RS IDENTIFICATION/A. Spectroscopic Identification Tests 19/, Infrared Spectroscopy:, IDENTIFICATION/C. Identification Tests—General 191, Chemical Identification Tests, Chemical Identification Tests, Infrared Spectroscopy:	Ren-Hwa Yeh
Revision	NORTRIPTYLINE HYDROCHLORIDE PF 45(2) Pg. ONLINE	Chloridè:, ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Loss on Drying 731	Gerald Hsu
Revision	NORTRIPTYLINE HYDROCHLORIDE CAPSULES PF 45(2) Pg. ONLINE	IDENTIFICATION/A. Infrared Absorption, IDENTIFICATION/B. Identification Tests—General 191, Chemical Identification Tests, Chloride, ASSAY/Procedure, PERFORMANCE TESTS/Dissolution 711, ADDITIONAL REQUIREMENTS/Packaging and Storage:	Gerald Hsu
Revision	NORTRIPTYLINE HYDROCHLORIDE ORAL SOLUTION PF 45(2) Pg. ONLINE	IDENTIFICATION/A. Spectroscopic Identification Tests 197, Infrared Spectroscopy:, IDENTIFICATION/B. Identification Tests—General 191, Chemical Identification Tests, Chloride:, ASSAY/Procedure, ADDITIONAL REQUIREMENTS/Packaging and Storage:	Gerald Hsu

Title, DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B., IDENTIFICATION/C. Identification Tests-General <191>. Chemical Identification Tests. Sodium, IDENTIFICATION/D. Identification Tests-General <191>, Chemical Identification Tests, Bicarbonate, ASSAY/Procedure for Omeprazole, ASSAY/Procedure for Sodium Bicarbonate, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, Content Uniformity, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Acid-Neutralizing Capacity <301>, SPECIFIC TESTS/Microbial Enumeration Tests <61> and Tests for Specified Microorganisms <62>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Omeprazole RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Omeprazole Related Compound A RS, ADDITIONAL REOUIREMENTS/USP Reference Standards <11>/USP Omeprazole Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Omeprazole Related Compound E RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Omeprazole Related Compound F and G Mixture RS. ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Omeprazole Related Compound I RS

Richard Nguven

OMEPRAZOLE AND SODIUM BICARBONATE CAPSULES PF 44(4) Pg. ONLINE

OMEPRAZOLE AND SODIUM BICARBONATE FOR ORAL SUSPENSION PF 44(3) Pg.

Title, DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B., IDENTIFICATION/C. Identification Tests-General <191>, Chemical Identification Tests, Sodium, IDENTIFICATION/D. Identification Tests-General <191>, Chemical Identification Tests, Bicarbonate, ASSAY/Procedure for Omeprazole, ASSAY/Procedure for Sodium Bicarbonate, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, Content Uniformity, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Acid-Neutralizing Capacity <301>, 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/USP Reference Standards <11>/USP Omeprazole RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Omeprazole Related Compound A RS, ADDITIONAL REOUIREMENTS/USP Reference Standards <11>/USP Omeprazole Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Omeprazole Related Compound E RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Omeprazole Related Compound F and G Mixture RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Omeprazole Related Compound I RS

IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, IMPURITIES/Organic Impurities

IDENTIFICATION/A. Intrared Absorption 19/K, ASSAY/Procedure, IMPURITIES/Organic Impurities, Procedure 1, IMPURITIES/Organic Impurities, Procedure 2

CHEMICAL INFORMATION, DEFINITION/Untitled Section, 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 , SPECIFIC TESTS/pH 791 ,
ADDITIONAL REQUIREMENTS/Packaging and Storage: , ADDITIONAL
REQUIREMENTS/USP Reference Standards 11

DEFINITION, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, PERFORMANCE TESTS/Minimum Fill 755:, 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

Richard Nguyen

Gerald Hsu

Gerald Hsu

Shankari Shiyaprasad

Shankari Shivaprasad

New OXICONAZOLE NITRATE PF 45(2) Pg. ONLINE

New OXICONAZOLE NITRATE CREAM PF 45(2) Pq. ONLINE

OXAZEPAM CAPSULES PF 43(6) Pg. ONLINE

OXCARBAZEPINE TABLETS PF 45(3) Pg. ONLINE

New

Revision

Revision

ONLINE

New

New	OXICONAZOLE NITRATE LOTION PF 45(2) Pg. ONLINE	DEFINITION, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, PERFORMANCE TESTS/Minimum Fill 755:, 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	Shankari Shivaprasad
Revision	OXYCODONE HYDROCHLORIDE ORAL SOLUTION PF 44(4) Pg. ONLINE	IDENTIFICATION/A., IDENTIFICATION/B. Thin-Layer Chromatography, IDENTIFICATION/C., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/ USP Oxycodone Related Compound A RS IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/DISSOIUTION 11 , IMPURITIES/Limit of Oxycodone Related Compound B (Oxycodone N-Oxide), ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Oxycodone Related	Hillary Cai
Revision	OXYCODONE HYDROCHLORIDE EXTENDED-RELEASE TABLETS PF 44(5) Pg. ONLINE	Compound B RS	<u>Hillary Cai</u>
Revision	OXYMETHOLONE PF 44(6) Pg. ONLINE  OXYMETHOLONE TABLETS PF 44(6) Pg. ONLINE	IDENTIFICATION/A. Infrared Absorption <197K>Spectroscopic Identification Tests <197>, Infrared Spectroscopy, IDENTIFICATION/B. Ultraviolet Absorption <197U>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Melting Range or Temperature <741>, SPECIFIC TESTS/Completeness of Solution, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Oxymetholone Related Compound B RS  IDENTIFICATION/A. Intrared Absorption, 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/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Oxymetholone Related Compound B RS	Ren-Hwa Yeh
Revision	PACLITAXEL INJECTION PF 44(6) Pg. ONLINE	IDENTIFICATION/A., ASSAY/Procedure, IMPURITIES/Procedure: Limit of Degradation Products, SPECIFIC TESTS/Bacterial Endotoxins Test <85>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Paclitaxel Related Compound B RS	Feiwen Mao
Revision	PAMABROM PF 43(2) Pg. ONLINE	IDENTIFICATION/A. Thin-Layer Chromatographic Identification Test <201>, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/8-Bromotheophylline, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Pamabrom Related Compound A RS	Clydewyn Anthony
Revision	PENTAZOCINE AND NALOXONE TABLETS PF 45(1) Pg. ONLINE	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: Petrolatum/IDENTIFICATION, Petrolatum/IMPURITIES, Petrolatum/SPECIFIC TESTS,	
Revision	PETROLATUM PF 45(3) Pg. ONLINE	Petrolatum/ADDITIONAL REQUIREMENTS	<u>Kevin Moore</u>
Revision	WHITE PETROLATUM PF 45(3) Pg. ONLINE	White Petrolatum/IDENTIFICATION, White Petrolatum/IMPURITIES, White Petrolatum/SPECIFIC TESTS, White Petrolatum/ADDITIONAL REQUIREMENTS	Kevin Moore
Revision Revision	PHENOBARBITAL SODIUM PF 45(3) Pg. ONLINE  PHENOBARBITAL SODIUM INJECTION PF 45(3) Pg. ONLINE	IDENTIFICATION/A. Procedure, IDENTIFICATION/A., IDENTIFICATION/B., IDENTIFICATION/C.Identification Tests—General 191, Chemical Identification Tests, Sodium, ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Bacterial Endotoxins Test 85:, ADDITIONAL REQUIREMENTS/Labeling:, ADDITIONAL REQUIREMENTS/USP Reference Standards 11 IDENTIFICATION/A. Procedure, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Bacterial Endotoxins Test 85:, ADDITIONAL REQUIREMENTS/USP Reference Standards 11	Claire Chisolm  Claire Chisolm
Omission	PHENOBARBITAL SODIUM FOR INJECTION PF 45(3) Pg. ONLINE	Entire document	Claire Chisolm

ASSAY/Procedure, IMPURITIES/Ordinary Impurities 466,, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Melting Range or Temperature 741, Class I:, ADDITIONAL REQUIREMENTS/USP Reference Standards 11 Revision PHENOXYBENZAMINE HYDROCHLORIDE PF 45(2) Pg. ONLINE ASSAY/Procedure, PERFORMANCE TESTS/Dissolution 711, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage:, ADDITIONAL PHENOXYBENZAMINE HYDROCHLORIDE CAPSULES PF 45(2) Pg. ONLINE REQUIREMENTS/USP Reference Standards 11 Revision DEFINITION/Untitled Section, IDENTIFICATION/A, Spectroscopic Identification Tests 197, Infrared Spectroscopy:, IDENTIFICATION/B. Ultraviolet Absorption 197U, ASSAY/Procedure, IMPURITIES/Organic Impurities, IMPURITIES/Limit of Phentermine Related Compound C, ADDITIONAL REQUIREMENTS/Packaging and Storage:, ADDITIONAL REQUIREMENTS/USP Reference Standards 11 Revision PHENTERMINE HYDROCHLORIDE PF 45(3) Pg. ONLINE New 0.2% PHOSPHORIC ACID TS PF 44(3) Pg. ONLINE 0.2% Phosphoric Acid TS-( ) DEFINITION, IDENTIFICATION/A. HPTLC for Articles of Botanical Origin 203, IDENTIFICATION/B. HPLC, COMPOSITION/Content of Iridoid Glycosides, 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 Analysi's, Alcohol-Soluble Extractives, Method 1:, SPECIFIC TESTS/Articles of Botanical Origin 561, Methods of Analysis, Water-Soluble Extractives, Method 1:, 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:,,AQDITIONAL REQUIREMENTS/Packaging and Storage:, ADDITIONAL REQUIREMENTS/Labeling:, ADDITIONAL REQUIREMENTS/USP Reference Standards 11 PICRORHIZA SPECIES ROOT AND RHIZOME PF 45(1) Pg. ONLINE New ( ) DEFINITION, IDENTIFICATION/A. HPTLC for Articles of Botanical Origin 203, IDENTIFICATION/B. HPLC, COMPOSITION/Content of Iridoid Glycosides, 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/Water Determination 921, Method II:, ADDITIONAL REQUIREMENTS/Packaging and Storage:, ADDITIONAL REQUIREMENTS/Labeling:, ADDITIONAL REQUIREMENTS/USP Reference Standards 11 Nam-Cheol Kim New PICRORHIZA SPECIES ROOT AND RHIZOME DRY EXTRACT PF 45(1) Pg. ONLINE

DEFINITION/Untitled Section, IDENTIFICATION/A. Spectroscopic Identification Tests 197, Infrared Spectroscopy:, IDENTIFICATION/B. Ultraviolet Absorption 197U,

Donald Min

**Donald Min** 

Hillary Cai

Nam-Cheol Kim

Sridevi Ramachandran

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DEFINITION, IDENTIFICATION/A, HPTLC for Articles of Botanical Origin 203, IDENTIFICATION/B. HPLC, COMPOSITION/Content of Iridoid Glycosides, 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 1:, SPECIFIC TESTS/Articles of Botanical Origin 561, Methods of Analysis, Water-Soluble Extractives, Method 1:, 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 IDENTIFICATION/A. Spectroscopic Identification Tests 197, Infrared Spectroscopy; ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards 11

Nam-Cheol Kim

Donald Min

IDENTIFICATION/A., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution 711, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage:, ADDITIONAL REQUIREMENTS/USP Reference Standards 11

Donald Min

Hillary Cai

Michael Chang
Michael Chang

Ren-Hwa Yeh Claire Chisolm

ASSAY/Procedure

IDENTIFICATION/B. Identification Tests—General 191 , Chemical Identification Tests, Chloride and Calcium:, ASSAY/Lactate, IMPURITIES/Limit of 5-Hydroxymethylfurfural and Related Substances

Entire document

Title, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities, Procedure 1, IMPURITIES/Organic Impurities, Procedure 2, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Pramipexole Dihydrochloride Monohydrate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Pramipexole Related Compound F RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Pramipexole Related Compound G RS

Revision Omission

New

Revision

Revision

Revision

Revision

Revision

POTASSIUM PERCHLORATE PF 44(6) Pg. ONLINE

POTASSIUM CARBONATE PF 45(1) Pg. ONLINE

PINDOLOL PF 45(3) Pg. ONLINE

PIROXICAM PF 44(5) Pg. ONLINE

Pg. ONLINE

Pg. ONLINE

PINDOLOL TABLETS PF 45(3) Pg. ONLINE

New

PRAMIPEXOLE DIHYDROCHLORIDE TABLETS PF 44(1) Pg. ONLINE

PICRORHIZA SPECIES ROOT AND RHIZOME POWDER PF 45(1) Pg. ONLINE

POTASSIUM BICARBONATE EFFERVESCENT TABLETS FOR ORAL SOLUTION PF 45(2)

POTASSIUM CHLORIDE IN LACTATED RINGER'S AND DEXTROSE INJECTION PF 45(2)

Ravi Ravichandran

Revision	PREDNISOLONE ACETATE PF 44(6) Pg. ONLINE	Cnemical Info/Cnemical Structure, Cnemical Info/402.48402.49, IDENTIFICATION/Infrared Absorption <197K>, IDENTIFICATION/B. Ultraviolet Absorption <197U>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Hydrocortisone Acetate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Prednisolone RS	Ren-Hwa Yeh
Revision  Revision	PREDNISOLONE ACETATE OPHTHALMIC SUSPENSION PF 44(6) Pg. ONLINE  PREDNISONE TABLETS PF 45(3) Pg. ONLINE	IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Hydrocortisone Acetate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Prednisolone RS IDENTIFICATION/A. INTRAGE ADSORPTION 19/K, 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/PSCACAGING ADDITIONAL REQUIREMENTS/PSCACAGING ADDITIONAL REQUIREMENTS/PSCACAGING ADDITIONAL REQUIREMENTS/PSCACAGING ADDITIONAL REQUIREMENTS/PSCACAGING ADDITIONAL REQUIREMENTS/USP Reference Standards 11, IDENTIFICATION/A. Infrared Absorption 197K	Ren-Hwa Yeh
New Revision	PREGABALIN CAPSULES PF 44(5) Pg. ONLINE PRIMIDONE TABLETS PF 44(1) Pg. ONLINE	Title, DEFINITION/Introduction, IDENTIFICATION/A. Spectrophotometric Identification Tests <197>, Infrared Absorption, IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, 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>/USP Pregabalin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Pregabalin Related Compound C RS IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, IMPURITIES/Organic Impurities	Hillary Cai Claire Chisolm
Revision	PROGESTERONE PF 43(6) Pg. ONLINE	IDENTIFICATION/A. Infrared Absorption <197K> <197>, IDENTIFICATION/Ultraviolet Absorption <197U>, ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Melting Range or Temperature <741>, ADDITIONAL REQUIREMENTS/PACKAGING and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Progesterone Related Compound H RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Progesterone System Suitability Mixture RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/	Ren-Hwa Yeh
Revision Revision	PROGESTERONE INJECTION PF 43(6) Pg. ONLINE PROPARACAINE HYDROCHLORIDE PF 45(2) Pg. ONLINE	Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Progesterone Related Compound H RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Progesterone System Suitability Mixture RS IDENTIFICATION/C. Identification Tests—General 191, Chemical Identification Tests, Chloride	Ren-Hwa Yeh
Revision	PROPRANOLOL HYDROCHLORIDE INJECTION PF 44(1) Pg. ONLINE	IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Bacterial Endotoxins Test <85>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Propranolol Related Compound A RS	Donald Min
Revision	PROTRIPTYLINE HYDROCHLORIDE PF 45(2) Pg. ONLINE	DEFÍNITION/Untitled Section, IDENTIFICATION/A. Spectroscopic Identification Tests 197, Infrared Spectroscopy:, IDENTIFICATION/B. Ultraviolet Absorption, 197U, IDENTIFICATION/B., IDENTIFICATION/C., IDENTIFICATION/D. X-Ray Diffraction 941:, ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/pH 791	Claire Chisolm

Revision	PSEUDOEPHEDRINE HYDROCHLORIDE PF 44(4) Pg. ONLINE	IDENTIFICATION/A. Infrared Absorption <197K><197>, IDENTIFICATION/C., ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Melting Range or Temperature <741>, Class I	Clydewyn Anthony
Revision	PSEUDOEPHEDRINE HYDROCHLORIDE ORAL SOLUTION PF 45(1) Pg. ONLINE	IDENTIFICATION/A. Melting Range or Temperature 741, Class I, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Reaction, ADDITIONAL REQUIREMENTS/USP Reference Standards 11	Yanyin Yang
Revision	PSEUDOEPHEDRINE HYDROCHLORIDE EXTENDED-RELEASE TABLETS PF 44(4) Pg. ONLINE	IDENTIFICATION/Infrared Absorption <197K>, ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ephedrine Sulfate RS	Yanyin Yang
Revision	PYRIDOSTIGMINE BROMIDE ORAL SOLUTION PF 44(2) Pg. ONLINE	IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Pyridostigmine Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Pyridostigmine Related Compound B RS, IIIIE, DETINITION/INTRODUCTION, 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>/USP Pyridostigmine Bromide RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Pyridostigmine	Claire Chisolm
New Revision	PYRIDOSTIGMINE BROMIDE EXTENDED-RELEASE TABLETS PF 44(2) Pg. ONLINE  QUINAPRIL TABLETS PF 44(4) Pg. ONLINE	Related Compound B RS  IDENTIFICATION/Thin-Layer Chromatographic Identification Test <201>, ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Quinapril Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Quinapril Related Compound B RS	Claire Chisolm  Donald Min
Revision	QUININE SULFATE CAPSULES PF 44(5) Pg. ONLINE	IDENTIFICATION/B., IDENTIFICATION/C., IDENTIFICATION/D., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities, IMPURITIES/Organic Impurities, Procedure 1, IMPURITIES/Organic Impurities, Procedure 2, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Quininone RS Cinchonan-9-one, 6′-methoxy-, (8α). C20H22N2O2322.40	<u>Praveen Pabba</u>

Chemical Info/Chemical Name (15,25)-2-(Methylamino)-1-phenylpropan-1-ol,

Title, Chemical Info/Chemical Structure, Chemical Info/C21H15ClF4N4O3·H2O, Chemical Info/500.83, Chemical Info/2-Pyridinecarboxamide, 4-[4-[[[4-chloro-3-(trifluoromethyl)phenyllaminolcarbonyllaminol-3-fluorophenoxyl-N-methyl-, monohydrate;, Chemical Info/4-[4-({[4-Chloro-3-(trifluoromethyl)phenyl]carbamoyl}amino)-3-fluorophenoxy]-N-methylpyridine-2carboxamide monohydrate, Chemical Info/CAS, Chemical Info/Anhydrous, Chemical Info/C21H15ClF4N4O3, Chemical Info/482.82, DEFINITION/Introduction, IDENTIFICATION/A. Spectroscopic Identification Tests <197>, Infrared Spectroscopy, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, IMPURITIES/Limit of Regorafenib Related Compound A, SPECIFIC TESTS/Water Determination <921>, Method I, Method Ic, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Regorafenib RS, ADDITIONAL REOUIREMENTS/USP Reference Standards <11>/USP Regorafenib Related Compound A RS 4-(4-Amino-3-fluorophenoxy)-Nmethylpicolinamide.C13H12FN3O2261.26, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Sorafenib Tosylate RS 1-[4-Chloro-3-(trifluoromethyl)phenyl]-3-(4-{[2-(methylcarbamoyl)pyridin-4-yl]oxy}phenyl}urea mono(4methylbenzenesulfonate).C21H16ClF3N4O3·C7H8O3S637.03

Feiwen Mao

New	REPAGLINIDE AND METFORMIN HYDROCHLORIDE TABLETS PF 44(5) Pg. ONLINE
Revision	RIFABUTIN PF 44(4) Pg. ONLINE
Revision	RIFABUTIN CAPSULES PF 44(4) Pg. ONLINE
Revision	RIFAMPIN PF 44(5) Pg. ONLINE
Revision	LACTATED RINGER'S INJECTION PF 45(2) Pg. ONLINE
Revision	LACTATED RINGER'S AND DEXTROSE INJECTION PF 45(2) Pg. ONLINE
Revision	HALF-STRENGTH LACTATED RINGER'S AND DEXTROSE INJECTION PF 45(2) Pg. ONLINE

MODIFIED LACTATED RINGER'S AND DEXTROSE INJECTION PF 45(2) Pg. ONLINE

REGORAFENIB PF 44(6) Pg. ONLINE

New

Revision

Title, DEFINITION/Introduction, IDENTIFICATION/A. Repaglinide, IDENTIFICATION/B. Repaglinide, IDENTIFICATION/C. Metformin Hydrochloride, IDENTIFICATION/D. Metformin Hydrochloride, ASSAY/Procedure 1: Repaglinide, ASSAY/Procedure 2: Metformin Hydrochloride, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Uniformity of Dosage Units < 905>, IMPURITIES/Organic Impurities, Procedure 1: Repaglinide, IMPURITIES/Organic Impurities, Procedure 2: Metformin Hydrochloride, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Metformin Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Repaglinide RS ASSAY/Procedure, IMPURITIES/Chromatographic Purity, IMPURITIES/Organic Impurities, Procedure 2 ASSAY/Procedure, PERFORMANCE TESTS/Dissolution, IMPURITIES/Chromatographic Purity, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and

Ramanuiam Prasad

Ramanujam Prasad

Behnaz Almasi

IDENTIFICATION/Infrared Absorption <197M>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Rifampin Quinone RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Rifampin-N-Oxide RS

Storage

Ramanujam Prasad

IDENTIFICATION/A. Identification Tests—General 191, Chemical Identification Tests, Chloride and Calcium:, ASSAY/Chloride, SPECIFIC TESTS/Sterility Tests 71:

Gerald Hsu

IDENTIFICATION/B. Identification Tests—General 191, Chemical Identification Tests, Chloride and Calcium:, ASSAY/Chloride, ASSAY/Dextrose, IMPURITIES/Limit of 5-Hydroxymethylfurfural and Related Substances, SPECIFIC TESTS/Sterility Tests 71: IDENIJFICATION/B. Identification Tests—General 191, Chemical Identification Tests, Chloride and Calcium:, ASSAY/Chloride, ASSAY/Dextrose, SPECIFIC TESTS/Sterility Tests 71:

Gerald Hsu

**Gerald Hsu** 

IDENTIFICATION/B. Identification Tests—General 191, Chemical Identification Tests, Chloride and Calcium:,, ASSAY/Calcium, ASSAY/Chloride, ASSAY/Dextrose, IMPURITIES/Limit of 5-Hydroxymethylfurfural and Related Substances, SPECIFIC TESTS/Sterility Tests 71:

Gerald Hsu

Revision	RISEDRONATE SODIUM TABLETS PF 45(1) Pg. ONLINE	IDENTIFICATION/A. Spectroscopic Identification Tests 197, Infrared Spectroscopy: ASSAY/Procedure, PERFORMANCE TESTS/Dissolution 711, PERFORMANCE TESTS/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards 11 IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Risperidone Related Compounds	Andrea Carney
Revision	RISPERIDONE ORAL SOLUTION PF 44(6) Pg. ONLINE	Mixture RS	Claire Chisolm
Revision	ROPINIROLE HYDROCHLORIDE PF 45(2) Pg. ONLINE	IDENTIFICATION/A. Spectroscopic Identification Tests $\rangle$ 197 , Infrared Spectroscopy:, IDENTIFICATION/C. Identification Tests—General 191 , Chemical Identification Tests, Chloride, ASSAY/Procedure, IMPURITIES/Limit of Palladium, IMPURITIES/Organic Impurities, Procedure 3	<u>Claire Chisolm</u>
Revision	ROPIVACAINE HYDROCHLORIDE PF 44(4) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, Procedure 1, IMPURITIES/Organic Impurities, Procedure 2: Limit of Ropivacaine Related Compound A, IMPURITIES/Enantiomeric Purity, SPECIFIC TESTS/Color, SPECIFIC TESTS/Clarity, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ropivacaine Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ropivacaine Related Compound B RS	Don Llura Vola
Revision	ROFIVACAINE HIDROCHEORIDE FI 44(4) Fg. ONLINE	IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>,	Ren-Hwa Yeh
Revision	RUFINAMIDE TABLETS PF 44(4) Pg. ONLINE	IMPURITIES/Organic Impurities	Claire Chisolm
Revision	SELEGILINE HYDROCHLORIDE CAPSULES PF 45(2) Pg. ONLINE	IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities	Claire Chisolm
Revision	SELENIUM SULFIDE PF 44(6) Pg. ONLINE	IDENTIFICATION/A. Selenium, IDENTIFICATION/B. Sulfur, ASSAY/Procedure, IMPURITIES/Soluble Selenium Compounds, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>	Michael Chang
Revision Revision	SERTRALINE HYDROCHLORIDE PF 45(2) Pg. ONLINE  SERTRALINE HYDROCHLORIDE TABLETS PF 44(1) Pg. ONLINE	IDENTIFICATION/A. Spectroscopic Identification Tests 197, Infrared Spectroscopy:, IDENTIFICATION/C. Identification Tests—General 191, Chemical Identification Tests, Chloride, ASSAY/Procedure, IMPURITIES/Limit of (R,R) Sertraline Hydrochloride, IMPURITIES/Organic Impurities, Procedure 1, IMPURITIES/Organic Impurities, Procedure 2, IMPURITIES/Limit of Mandelic Acid IDENTIFICATION/A. Infrared Absorption <197A> or <197K>, IDENTIFICATION/A., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, IMPURITIES/Organic Impurities	Claire Chisolm  Claire Chisolm
New	SEVELAMER CARBONATE PF 45(2) Pg. ONLINE	CHEMICAL INFORMATION, DEFINITION, IDENTIFICATION/A. Spectroscopic (Identification Tests 197, Infrared Spectroscopy:, ASSAY/Total Titratable Amines, OTHER COMPONENTS/Carbonate Content, IMPURITIES/Residue on Ignition 281:, IMPURITIES/Limit of Chloride, IMPURITIES/Limit of Epichlorohydrin, IMPURITIES/Limit of Soluble Oligomers:, IMPURITIES/Limit of Allylamine, SPECIFIC TESTS/Loss on Drying, SPECIFIC TESTS/Swelling Index, SPECIFIC TESTS/Light Diffraction Measurement of Particle Size 429, ADDITIONAL REQUIREMENTS/Packaging and Storage:, ADDITIONAL REQUIREMENTS/USP Reference Standards 11	Donald Min
New	SEVELAMER CARBONATE FOR ORAL SUSPENSION PF 45(3) Pg. ONLINE	DEFINITION/Untitled Section, IDENTIFICATION/A. Spectroscopic Identification Tests 197, Infrared Spectroscopy:, ASSAY/Total Titratable Amines, PERFORMANCE TESTS/Uniformity of Dosage Units 905:, IMPURITIES/Limit of Soluble Oligomers:, IMPURITIES/Limit of Allylamine, ADDITIONAL REQUIREMENTS/Packaging and Storage:, ADDITIONAL REQUIREMENTS/USP Reference Standards 11  PERMITION, IDENTIFICATION/A. Spectroscopic Identification, 1ests 197, Infrared Spectroscopy:, ASSAY/Total Titratable Amines, PERFORMANCE TESTS/Disintegration 701, PERFORMANCE TESTS/Uniformity of Dosage Units 905:, IMPURITIES/Limit of Soluble Oligomers:, IMPURITIES/Limit of Allylamine, ADDITIONAL	<u>Donald Min</u>
New	SEVELAMER CARBONATE TABLETS PF 45(3) Pg. ONLINE	REQUIREMENTS/Packaging and Storage:, ADDITIONAL REQUIREMENTS/USP Reference Standards 11	<u>Donald Min</u>

Omission	SODIUM ACETATE SOLUTION PF 44(6) Pg. ONLINE	Entire document	Ren-Hwa Yeh
Revision	SODIUM FLUORIDE PF 45(3) Pg. ONLINE	IDENTIFICATION/A. Fluoride:, IDENTIFICATION/B. Identification Tests—General 191 , Chemical Identification Tests, Sodium, ASSAY/Procedure, IMPURITIES/Chloride, ADDITIONAL REQUIREMENTS/USP Reference Standards 11	Michael Chang
New	SODIUM PHENYLBUTYRATE ORAL POWDER PF 44(2) Pg. ONLINE	Title, DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, 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>/USP Sodium Phenylbutyrate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Phenylbutyrate Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Phenylbutyrate Related Compound B RS	Behnaz Almasi
New	SODIUM PHENYLBUTYRATE TABLETS PF 44(2) Pg. ONLINE	Title, DEFINITION/Introduction, 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>/USP Sodium Phenylbutyrate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Phenylbutyrate Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Phenylbutyrate Related Compound B RS	Behnaz Almasi
New	SORAFENIB TABLETS PF 45(3) Pg. ONLINE	DEFINITION, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution 711, PERFORMANCE TESTS/Uniformity of Dosage Units 905:, 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	<u>Feiwen Mao</u>
		Title, Chemical Info/Chemical Structure, Chemical Info/C21H16ClF3N4O3·C7H8O3S, Chemical Info/637.03, Chemical Info/2-Pyridinecarboxamide, 4-[4-[[[4-chloro-3-(trifluoromethyl)phenyl]amino]carbonyl]amino]phenoxy]-N-methyl-, mono(4-methylbenzenesulfonate);, Chemical Info/4-(4-{3-[4-Chloro-3-(trifluoromethyl)phenyl]ureido}phenoxy)-N2-methylpyridine-2-carboxamide mono(4-methylbenzenesulfonate), Chemical Info/CAS, Chemical Info/Sorafenib (free base), Chemical Info/C21H16ClF3N4O3, Chemical Info/464.83, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Water Determination <921>, Method I, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Sorafenib Tosylate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Sorafenib	
New Revision	SORAFENIB TOSYLATE PF 44(3) Pg. ONLINE  SULFASALAZINE PF 45(2) Pg. ONLINE	Related Compound H RS  DEFINITION/Untitled Section, IDENTIFICATION/A. Spectroscopic Identification Tests ,197, Infrared Spectroscopy:, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Chloride, and Sulfate 221, Chloride, IMPURITIES/Chloride and Sulfate 221, Sulfate, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards 11	Feiwen Mao Praveen Pabba
Revision	SULFASALAZINE TABLETS PF 45(3) Pg. ONLINE	IDENTIFICATION/Procedure, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution 711, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage:, ADDITIONAL REQUIREMENTS/USP Reference Standards 11	Praveen Pabba

Revision	SULFASALAZINE DELAYED-RELEASE TABLETS PF 45(3) Pg. ONLINE	IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage:, ADDITIONAL REQUIREMENTS/USP Reference Standards 11	Praveen Pabba
		IDENTIFICATION/A. Infrared Absorption <197K>or <197A>, IDENTIFICATION/C. Identification Tests-General <191>, Chemical Identification Tests, Sulfate, ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Terbutaline Related Compound A RS, ADDITIONAL	
Revision	TERBUTALINE SULFATE PF 44(1) Pg. ONLINE	REQUIREMENTS/USP Reference Standards <11>/USP Terbutaline Related Compound D RS IDENTIFICATION/A. Inin Layer Chromatography, IDENTIFICATION/A., ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Bacterial	Ren-Hwa Yeh
Revision	TERBUTALINE SULFATE INJECTION PF 44(1) Pg. ONLINE	Endotoxins Test <85>, SPECIFIC TESTS/Sterility Tests <71>, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Terbutaline Related Compound A RS	Ren-Hwa Yeh
Revision	TERRUITALINE CUI EATE TARLETC DE 44/1) Do ONUINE	IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, Procedure, Apparatus 1 and Apparatus 2, Immediate-Release Dosage Forms, Procedure for a pooled sample, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Terbutaline Related Compound A RS	Dec Heer Velo
	TERBUTALINE SULFATE TABLETS PF 44(1) Pg. ONLINE	·	Ren-Hwa Yeh
Omission	TESTOLACTONE PF 45(3) Pg. ONLINE	Entire document	<u>Feiwen Mao</u>
		Title, Chemical Info/Chemical Structure, Chemical Info/C19H27NO3, Chemical Info/317.42, Chemical Info/2-H-Benzo[a]quinolizin-2-one, 1,3,4,6,7,11b-hexahydro-9,10-dimethoxy-3-(2-methylpropyl)-;, Chemical Info/(3RS,11bRS)-3-Isobutyl-9,10-dimethoxy-1,3,4,6,7,11b-hexahydro-2H-pyrido[2,1-a]isoquinolin-2-one., Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Loss on Drying <731>, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Tetrabenazine RS, ADDITIONAL REQUIREMENTS/USP Reference	
New	TETRABENAZINE PF 44(3) Pg. ONLINE	Standards <11>/USP Tetrabenazine Related Compound C RS IDENTIFICATIONA. Spectroscopic Identification Tests 197, Infrared Spectroscopy:, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference	<u>Sridevi Ramachandran</u>
Revision	TETRAHYDROZOLINE HYDROCHLORIDE PF 45(3) Pg. ONLINE	Standards 11 IDENTIFICATION/A. Ultraviolet Absorption 197U , ASSAY/Procedure,	Sujatha Ramakrishna
Revision	TETRAHYDROZOLINE HYDROCHLORIDE OPHTHALMIC SOLUTION PF 45(3) Pg. ONLINE	IMPURITIES/Órganic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards 11	Sujatha Ramakrishna
Nou	TETDAVETAN DE 44/2) Do. ONI INE	Chemical Info/Chemical Structure, Chemical Info/C16H28N4O8, Chemical Info/404.42, Chemical Info/1,4,7,10-Tetraazacyclododecane-1,4,7,10-tetraacetic acid;, Chemical Info/2,2′′′′-(1,4,7,10-Tetraazacyclododecane-1,4,7,10-tetryl)tetraacetic acid., Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197A> or <197K>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Water Determination <921>, Method I, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Tetraxetan RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Tetraxetan Related Compound A	David Davidhav dava
New	TETRAXETAN PF 44(3) Pg. ONLINE	RS	Ravi Ravichandran
Omission	THIORIDAZINE PF 44(6) Pg. ONLINE	Entire document	<u>Sridevi Ramachandran</u>
Revision	THIORIDAZINE HYDROCHLORIDE PF 45(2) Pg. ONLINE	IDENTIFICATION/B. Identification Tests—General 191 , Chemical Identification Tests, Chloride, ASSAY/Procedure, IMPURITIES/Organic Impurities	Nicholas Garito Jr.

[(1R,2S)-2-(3,4-Difluorophenyl)cyclopropylamino]-5-(propylthio)-3H-[1.2.3]triazolo[4,5-d]pvrimidin-3-vl}-5-(2-hvdroxyethoxy)cvclopentane-1,2-diol, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A, Spectroscopic Identification Tests <197>, Infrared Spectroscopy, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Limit of Ticagrelor Related Compound A (if present), IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage Requirements <659>, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ticagrelor RS. ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ticagrelor Related Compound A RS, ADDITIONAL REOUIREMENTS/USP Reference Standards <11>/USP Ticagrelor Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference TICAGRELOR PF 44(6) Pg. ONLINE Standards <11>/ **Donald Min** New Title, DEFINITION/Introduction, 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 REOUIREMENTS/USP Reference Standards <11>/USP Tizanidine Hydrochloride RS. ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Tizanidine Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP TIZANIDINE CAPSULES PF 44(4) Pg. ONLINE Tizanidine Related Compound C RS New Sridevi Ramachandran IDENTIFICATION/A. Spectroscopic Identification Tests 197, Infrared Spectroscopy; IDENTIFICATION/C. Identification Tests—General 191, Chemical Identification Tests, Chloride, ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL Revision TIZANIDINE HYDROCHLORIDE PF 45(2) Pg. ONLINE REQUIREMENTS/USP Reference Standards 11 Nicholas Garito Jr. DEFINITION/Untitled Section, IDENTIFICATION/A. Spectroscopic Identification Tests 197, Infrared Spectroscopy:, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference TRANEXAMIC ACID PF 45(3) Pa. ONLINE Standards 11 Revision Donald Min IDENTIFICATION/A., 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>/USP Triamcinolone Acetonide Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference TRIAMCINOLONE ACETONIDE CREAM PF 44(5) Pg. ONLINE Revision Standards <11>/USP Triamcinolone Acetonide Related Compound C RS Ren-Hwa Yeh IDENTIFICATION/A., 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 REOUIREMENTS/USP Reference Standards <11>/USP Triamcinolone Acetonide Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Triamcinolone Acetonide Related Compound C RS TRIAMCINOLONE ACETONIDE LOTION PF 44(3) Pg. ONLINE Revision Ren-Hwa Yeh IDENTIFICATION/A., 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 REOUIREMENTS/USP Reference Standards <11>/USP Triamcinolone Acetonide Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference TRIAMCINOLONE ACETONIDE DENTAL PASTE PF 44(5) Pg. ONLINE Standards <11>/USP Triamcinolone Acetonide Related Compound C RS Revision Ren-Hwa Yeh

Title, Chemical Info/Chemical Structure, Chemical Info/C23H28F2N6O4S, Chemical Info/522.57, Chemical Info/1,2-Cyclopentanediol, 3-[7-[[(1R,2S)-2-(3,4-

difluorophenyl)cyclopropyl]amino]-5-(propylthio)-3H-1,2,3-triazolo[4,5-d]pyrimidin-3-yl]-5-(2-hydroxyethoxy)-, (1S,2S,3R,5S)-;, Chemical Info/(1S,2S,3R,5S)-3-{7-

Revision	TRIAMCINOLONE ACETONIDE INJECTABLE SUSPENSION PF 44(3) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/Infrared Absorption <197K>, IDENTIFICATION/Ultraviolet Absorption <197U>, ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Bacterial Endotoxins Test <85>, SPECIFIC TESTS/Sterility Tests <71>, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Triamcinolone Acetonide Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Triamcinolone Acetonide Related Compound C RS	Ren-Hwa Yeh
Davisian	TRUENVOUENTOVI, HVDDOCIII ODVDE ODAL COLLITION DE 4E/3) D., ONI INE	DEFINITION/Untitled Section, IDENTIFICATION/A, Spectroscopic Identification Tests 197, Infrared Spectroscopy:, ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Microbial Enumeration Tests 61 and Tests for Specified	
Revision	TRIHEXYPHENIDYL HYDROCHLORIDE ORAL SOLUTION PF 45(3) Pg. ONLINE	Microorganisms 62:, ADDITIONAL REQUIREMENTS/Packaging and Storage:  {Title}, Chemical Info, DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities: Limit of Chymotrypsin, SPECIFIC TESTS/Solubility Test, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Trypsin Crystallized RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Trypsin Bovine RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Trypsin	Nicholas Garito Jr.
Revision	CRYSTALLIZED TRYPSIN PF 43(6) Pg. ONLINE	Recombinant Porcine RS  Title, DEFINITION/Introduction, IDENTIFICATION/A. Spectroscopic Identification Tests <197K>, 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>/USP	Elena Curti
New	VENLAFAXINE EXTENDED-RELEASE TABLETS PF 44(6) Pg. ONLINE	Venlafaxine Hydrochloride RS	Sridevi Ramachandran
New	OIL- AND WATER-SOLUBLE VITAMINS WITH MINERALS CHEWABLE GELS PF 45(2) Pg. ONLINE	DEFINITION, IDENTIFICATION/A., IDENTIFICATION/B., IDENTIFICATION/C., STRENGTH/Vitamin A (as Retinyl Acetate), Method 1, STRENGTH/Vitamin D (as Cholecalciferol), Method 1, STRENGTH/Vitamin E (as Alpha Tocopheryl Acetate), Method 1, STRENGTH/Vitamin A (as Retinyl Acetate or Retinyl Palmitate), Vitamin D (as Cholecalciferol), and Vitamin E (as Alpha Tocopheryl Acetate), Method 2, STRENGTH/Vitamin C, Method 1, STRENGTH/Vitamins B3 (as Niacinamide), B6, Pantothenic Acid, and Folic Acid, Method 1, STRENGTH/Vitamins B1 (as Thiamine Ion) and B2 (as Riboflavin), Method 1; Vitamin C (as Ascorbic Acid), Vitamins B3 (as Niacinamide), B6 (as Pyridoxine), Pantothenic Acid, and Folic Acid, Method 2, STRENGTH/Vitamin B12, STRENGTH/Biotin, Method 12AOAC certified VitaFast microbiological microtiter plate test to quantitate biotin, Art. No P1003, is available, STRENGTH/Biotin, Method 2, STRENGTH/Calcium, Chromium, Magnesium, Molybdenum, Phosphorus, Selenium, and Zinc, STRENGTH/Iodide, PERFORMANCE TESTS/Disintegration and Dissolution 2040, Dissolution: PERFORMANCE TESTS/Weight Variation 2091:, SPECIFIC TESTS/PH 791, SPECIFIC TESTS/Water Activity, 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	Natalia Davydova
		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	
New	VORICONAZOLE TABLETS PF 45(3) Pg. ONLINE	REQUIREMENTS/USP Reference Standards 11 , DEFINITION	<u>Shankari Shivaprasad</u>

Revision WILD CHRYSANTHEMUM FLOWER PF 45(1) Pg. ONLINE

WILD CHRYSANTHEMUM FLOWER DRY EXTRACT PF 45(1) Pg. ONLINE

Revision WILD CHRYSANTHEMUM FLOWER POWDER PF 45(1) Pg. ONLINE

Revision ZIDOVUDINE PF 45(1) Pg. ONLINE

Revision

DEFINITION/Untitled Section, IDENTIFICATION/A. HPTLC for Articles of Botanical Origin 203, IDENTIFICATION/B. HPLC, COMPOSITION/Content of Caffeoylquinic Acids and Flavone 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

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DEFINITION/Untitled Section, IDENTIFICATION/A. HPTLC for Articles of Botanical Origin 203, IDENTIFICATION/B. HPLC, COMPOSITION/Content of Caffeoylquinic Acids and Flavone 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/Loss on Drying 731, SPECIFIC TESTS/Articles of Botanical Origin 561, Methods of Analysis, Total Ash:, SPECIFIC TESTS/Botanical Extracts 565, Preparations, General Pharmacopeial Requirements, Residual Solvents:, ADDITIONAL REQUIREMENTS/Packaging and Storage:, ADDITIONAL REQUIREMENTS/Labeling:, ADDITIONAL REQUIREMENTS/Labeling:,

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DEFINITION, IDENTIFICATION/A. HPTLC for Articles of Botanical Origin 203, IDENTIFICATION/B. HPLC, COMPOSITION/Content of Caffeoylquinic Acids and Flavone 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-Soluple 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

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IDENTIFICATION/A. Spectroscopic Identification Tests 197, Infrared Spectroscopy:, ASSAY/Procedure, IMPURITIES/Limit of Triphenylmethanol and Other Impurities, IMPURITIES/Limit of Zidovudine Related Compounds B and C, IMPURITIES/Organic Impurities, IMPURITIES/Limit of Triphenylmethanol, ADDITIONAL REQUIREMENTS/USP Reference Standards 11

Shankari Shivaprasad

Revision ZIDOVUDINE ORAL SOLUTION PF 45(2) Pg. ONLINE

IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, Procedure 2, SPECIFIC TESTS/Microbial Enumeration Tests 61 and Tests for Specified Microorganisms 62:, ADDITIONAL REQUIREMENTS/Packaging and Storage:, ADDITIONAL REQUIREMENTS/USP Reference Standards 11

Shankari Shivaprasad