

## Compendial Approvals for USP43-NF38 2S

Date: Tue Mar 31 10:38:35 EDT 2020

Category	Monograph Title	Monograph Section	Scientific Liaison
Revision	<5> INHALATION AND NASAL DRUG PRODUCTS GENERAL INFORMATION AND PRODUCT QUALITY TESTS PF 45(5) Pg. ONLINE	4. DESCRIPTION OF PRODUCT QUALITY TESTS/Valve Delivery	Kahkashan Zaidi
Revision	<121> INSULIN ASSAYS PF 43(4) Pg. ONLINE	??UNKNOWN??/Rabbit Blood Sugar Method-Quantitative, ??UNKNOWN??/In Vivo Biodentity Test, ??UNKNOWN??/In Vitro Cell-Based Biodentity Test for Insulin Glargine and Insulin Lispro, RABBIT BLOOD SUGAR METHOD- QUANTITATIVE	Diane McCarthy
Revision	<232> ELEMENTAL IMPURITIES--LIMITS PF 45(5) Pg. ONLINE	DRUG PRODUCTS/Parenteral Products, DRUG SUBSTANCE AND EXCIPIENTS	Kahkashan Zaidi
Revision	<381> ELASTOMERIC COMPONENTS IN INJECTABLE PHARMACEUTICAL PRODUCT PACKAGING/DELIVERY SYSTEMS PF 45(4) Pg. ONLINE	1. INTRODUCTION, 2. SCOPE, 3. TEST SAMPLES, 4. PROCEDURES, 4.1 Biological REactivity, 4.2 Physicochemical Tests, 4.3 Functionality Tests	Desmond Hunt
Revision	<382> ELASTOMERIC COMPONENT FUNCTIONAL SUITABILITY IN PARENTERAL PRODUCT PACKAGING/DELIVERY SYSTEMS PF 45(4) Pg. ONLINE	1. INTRODUCTION, 2. SCOPE/2.1 Packaging::Delivery Systems, 3. GENERAL TEST REQUIREMENTS/3.1 Test Samples, 3. GENERAL TEST REQUIREMENTS/3.2 Test Sample Population Size, 3. GENERAL TEST REQUIREMENTS/3.3 Acceptance Criteria, 4. PACKAGING::DELIVERY SYSTEM INTEGRITY TESTS/Procedure, 4. PACKAGING::DELIVERY SYSTEM INTEGRITY TESTS/Acceptance criteria, 5. NEEDLE AND SPIKE ACCESS FUNCTIONAL SUITABILITY TESTS/5.1 Fragmentation, 5. NEEDLE AND SPIKE ACCESS FUNCTIONAL SUITABILITY TESTS/5.2 Penetration Force, 5. NEEDLE AND SPIKE ACCESS FUNCTIONAL SUITABILITY TESTS/5.3 Needle Self-Sealing Capacity, 5. NEEDLE AND SPIKE ACCESS FUNCTIONAL SUITABILITY TESTS/5.4 Spike Retention and Sealability Capacity, 6. PLUNGER FUNCTIONAL SUITABILITY TESTS/6.1 Plunger Break-Loose and Glide Forces, 6. PLUNGER FUNCTIONAL SUITABILITY TESTS/6.2 Plunger Seal Integrity, 7. TIP CAP AND NEEDLE SHIELD FUNCTIONAL SUITABILITY TESTS/Procedure A, 7. TIP CAP AND NEEDLE SHIELD FUNCTIONAL SUITABILITY TESTS/Procedure B, 7. TIP CAP AND NEEDLE SHIELD FUNCTIONAL SUITABILITY TESTS/Acceptance criteria	Desmond Hunt
New	<607> PHARMACEUTICAL FOAMS--PRODUCT QUALITY TESTS PF 45(5) Pg. ONLINE	INTRODUCTION, PRODUCT QUALITY TESTS FOR PHARMACEUTICAL FOAMS, QUALITY TESTS FOR FOAM PRODUCTS BY ALL ROUTES OF ADMINISTRATION/Dispersed Content Uniformity Throughout Canister Life, QUALITY TESTS FOR FOAM PRODUCTS BY ALL ROUTES OF ADMINISTRATION/Minimum Fill, OTHER TESTS/Leak Rate (Aerosol Products), OTHER TESTS/Propellant (Aerosol Products), OTHER TESTS/Pressure in Canister (Aerosol Products), OTHER TESTS/pH, OTHER TESTS/Sterility, OTHER TESTS/Microbial Limits, OTHER TESTS/Antimicrobial Preservative Content, OTHER TESTS/Antioxidant Content, OTHER TESTS/Osmolarity and Osmolality, ADDITIONAL QUALITY TESTS APPLICABLE FOR TOPICAL FOAM PRODUCTS/Time to Break, ADDITIONAL QUALITY TESTS APPLICABLE FOR TOPICAL FOAM PRODUCTS/Delivery Rate, ADDITIONAL QUALITY TESTS APPLICABLE FOR TOPICAL FOAM PRODUCTS/Delivered Amount, ADDITIONAL QUALITY TESTS APPLICABLE FOR TOPICAL FOAM PRODUCTS/Relative Density of Uncollapsed Foam, ADDITIONAL QUALITY TESTS APPLICABLE FOR TOPICAL FOAM PRODUCTS/Water Content	Margareth Marques
Revision	<659> PACKAGING AND STORAGE REQUIREMENTS PF 45(5) Pg. ONLINE	POISON PREVENTION PACKAGING ACT, TEMPERATURE AND STORAGE, GENERAL DEFINITIONS, Injection Packaging, ASSOCIATED COMPONENTS, TEMPERATURE AND STORAGE DEFINITIONS	Desmond Hunt
Revision	<671> CONTAINERS--PERFORMANCE TESTING PF 44(3) Pg. ONLINE	INTRODUCTION, MOISTURE VAPOR TRANSMISSION FOR PLASTIC PACKAGING SYSTEMS, CLASSIFICATION SYSTEM FOR PLASTIC PACKAGING SYSTEMS, SPECTRAL TRANSMISSION, GLOSSARY	Desmond Hunt
Omission	<691> COTTON PF 45(4) Pg. ONLINE	Entire document	Desmond Hunt
Revision	<698> DELIVERABLE VOLUME PF 45(4) Pg. ONLINE	SCOPE	Mingyan Chu

Revision	<755> MINIMUM FILL PF 45(4) Pg. ONLINE	SCOPE, PROCEDURE FOR DOSAGE FORMS OTHER THAN AEROSOLS, SPRAYS, AND FOAMS, PROCEDURE FOR AEROSOLS, SPRAYS, AND FOAMS	Mingyan Chu
Revision	<785> OSMOLALITY AND OSMOLARITY PF 45(4) Pg. ONLINE	INTRODUCTION, THEORETICAL BACKGROUND, TYPES OF OSMOLALITY INSTRUMENTS/Freezing-point Depression Osmometer, TYPES OF OSMOLALITY INSTRUMENTS/Vapor Pressure Osmometer, QUALIFICATION OF OSMOLALITY INSTRUMENTS/Installation Qualification (IQ), QUALIFICATION OF OSMOLALITY INSTRUMENTS/Operational Qualification (OQ), QUALIFICATION OF OSMOLALITY INSTRUMENTS/Performance Qualification (PQ), OPERATION AND CALIBRATION OF OSMOMETERS/Standard Solutions, OPERATION AND CALIBRATION OF OSMOMETERS/Calibration, OPERATION AND CALIBRATION OF OSMOMETERS/Test Solutions, OPERATION AND CALIBRATION OF OSMOMETERS/Method 1: Freezing-Point Osmometry, OPERATION AND CALIBRATION OF OSMOMETERS/Method 2: Vapor Pressure Osmometry, REPORTING OF RESULTS/Measurement Result, REPORTING OF RESULTS/Conversion to Osmolarity, REPORTING OF RESULTS/Tonicity, OSMOLARITY/Example 2, MEASUREMENT OF OSMOLALITY/Procedure, REFERENCES, INTRODUCTION, OSMOTIC PRESSUREBACKGROUND, OSMOLALITYOPERATION AND CALIBRATION OF OSMOMETER, OSMOLARITY, MEASUREMENT OF OSMOLALITY	Margareth Marques
Revision	<1079> RISKS AND MITIGATION STRATEGIES FOR THE STORAGE AND TRANSPORTATION OF FINISHED DRUG PRODUCTS PF 45(5) Pg. ONLINE	1. INTRODUCTION, 2. SCOPE, 3. RISK-BASED APPROACH TO THE STORAGE AND TRANSPORTATION OF FINISHED DRUG PRODUCTS, 4. RISK MITIGATION CATEGORIES AS QMS ELEMENTS, 4.1 Documentation and Procedures, 4.2 Training, 4.3 Resources for Storage, Transportation, and Personnel, 4.4 Qualification and Validation, GLOSSARY, ADDITIONAL SOURCES OF INFORMATION	Desmond Hunt
New	<1079.2> MEAN KINETIC TEMPERATURE IN THE EVALUATION OF TEMPERATURE EXCURSIONS DURING STORAGE AND TRANSPORTATION OF DRUG PRODUCTS PF 45(5) Pg. ONLINE	1. INTRODUCTION, 2. SCOPE, 3. MEAN KINETIC TEMPERATURE, 4. APPLICATION OF MKT/Use of MKT for Controlled Cold Temperature Excursions, 5. CONCLUSION	Desmond Hunt
Revision	<1092> THE DISSOLUTION PROCEDURE -- DEVELOPMENT AND VALIDATION PF 44(6) Pg. ONLINE	INTRODUCTION, 1. PRELIMINARY ASSESSMENT (FOR EARLY STAGES OF PRODUCT DEVELOPMENT/DISSOLUTION METHOD DEVELOPMENT), 2. METHOD DEVELOPMENT, 3. ANALYTICAL FINISH, 5. VALIDATION, 6. ACCEPTANCE CRITERIA, REFERENCES, Introduction, Preliminary Assessment, Method Development, Analytical Finish, Automation, Validation, Acceptance	Margareth Marques
Revision	<1105> IMMUNOLOGICAL TEST METHODS-SURFACE PLASMON RESONANCE PF 45(4) Pg. ONLINE	INTRODUCTION, OVERVIEW/Assay Types, SPR ASSAY/Sample and Buffer Preparation, SPR ASSAY/Surface Preparation, SPR ASSAY/Surface Regeneration, SPR ASSAY/Data Analysis and Interpretation, SPR ASSAY/Application 1—Immunogenicity Assessment, SPR ASSAY/Application 2—Concentration Analysis, SPR ASSAY/Application 3—Kinetic and Affinity Analysis, USE OF SPR IN A REGULATED ENVIRONMENT	Li Jing
New	<1108> ASSAYS TO EVALUATE FRAGMENT CRYSTALLIZABLE ( FC)-MEDIATED EFFECTOR FUNCTION PF 45(5) Pg. ONLINE	Opening Section, INTRODUCTION, BACKGROUND, CELL-BASED FUNCTIONAL ASSAYS/Antibody-Dependent Cell-Mediated Cytotoxicity, CELL-BASED FUNCTIONAL ASSAYS/Complement-Dependent Cytotoxicity, CELL-BASED FUNCTIONAL ASSAYS/Antibody-Dependent Cellular Phagocytosis, CELL-BASED FUNCTIONAL ASSAYS/Fc-Dependent Apoptosis, BINDING ASSAY FORMATS/Non-Cell-Based Binding Assays, BINDING ASSAY FORMATS/Cell-Based Binding Assays, CRITICAL REAGENTS/Complement, CRITICAL REAGENTS/Recombinant Fc Receptors, CRITICAL REAGENTS/Quality of Reagents, CRITICAL REAGENTS/Qualification of Reagents, ASSAY VALIDATION, DATA ANALYSIS AND REPORTING	Li Jing

Revision	<1381> ASSESSMENT OF ELASTOMERIC COMPONENT USED IN INJECTABLE PHARMACEUTICAL PRODUCT PACKAGING/DELIVERY SYSTEMS PF 45(4) Pg. ONLINE	Opening Section, 1. INTRODUCTION, 2. SCOPE, 3. DESCRIPTION OF ELASTOMERIC COMPONENTS IN PACKAGING SYSTEMS, 4. ELASTOMERIC COMPONENTS—MATERIALS OF CONSTRUCTION/4.1 Thermoset and Thermoplastic Elastomeric Components, 4. ELASTOMERIC COMPONENTS—MATERIALS OF CONSTRUCTION/4.2 Thermoplastic Composition (Typical), 4. ELASTOMERIC COMPONENTS—MATERIALS OF CONSTRUCTION/4.3 Surface Coatings and Treatments, 4. ELASTOMERIC COMPONENTS—MATERIALS OF CONSTRUCTION/4.4 Compounds of Concern, 5. ELASTOMERIC COMPONENTS—MANUFACTURING TECHNOLOGY AND STERILIZATION PROCEDURES/5.1 Generic Manufacturing, 5. ELASTOMERIC COMPONENTS—MANUFACTURING TECHNOLOGY AND STERILIZATION PROCEDURES/5.2 Sterilization Procedures, 6. IDENTIFICATION TESTS, 7. TEST REQUIREMENTS AND RESPONSIBILITIES, 8. SUMMARY OF 381 PHYSICOCHEMICAL TESTS/8.1 Test Samples, 8. SUMMARY OF 381 PHYSICOCHEMICAL TESTS/8.2 Physicochemical Tests, 8. SUMMARY OF 381 PHYSICOCHEMICAL TESTS/8.3 Biocompatibility Tests, 8. SUMMARY OF 381 PHYSICOCHEMICAL TESTS/8.4 Extractable Elements Method	Desmond Hunt
Revision	<1382> ASSESSMENT OF ELASTOMERIC COMPONENT FUNCTIONAL SUITABILITY IN PARENTERAL PRODUCT PACKAGING/DELIVERY SYSTEMS PF 45(4) Pg. ONLINE	1. INTRODUCTION, 2. EARLY PACKAGING::DELIVERY SYSTEM SELECTION AND DEVELOPMENT: FUNCTIONAL SUITABILITY ASSESSMENT CONSIDERATIONS, 3. FINAL PRODUCT PACKAGING::DELIVERY SYSTEM FITNESS-FOR-INTENDED-USE SUITABILITY ASSESSMENT, 4. GENERAL CHAPTER 382 BACKGROUND AND GUIDANCE/4.1 Test Samples, 4. GENERAL CHAPTER 382 BACKGROUND AND GUIDANCE/4.2 Test Sample Population Size, 4. GENERAL CHAPTER 382 BACKGROUND AND GUIDANCE/4.3 Packaging::Delivery System Integrity Tests, 4. GENERAL CHAPTER 382 BACKGROUND AND GUIDANCE/4.4 Needle and Spike Access Functionality Tests, 4. GENERAL CHAPTER 382 BACKGROUND AND GUIDANCE/4.5 Plunger Functional Suitability Tests, 4. GENERAL CHAPTER 382 BACKGROUND AND GUIDANCE/4.6 Tip Cap and Needle Shield Functional Suitability Tests, 5. CONCLUSION	Desmond Hunt
Revision	<1430.3> ANALYTICAL METHODOLOGIES BASED ON SCATTERING PHENOMENA-DYNAMIC LIGHT SCATTERING PF 45(4) Pg. ONLINE	Opening Section, 1. INTRODUCTION, 2. APPLICATIONS, 3. THEORY/3.1 Correlation Function Analysis, 4. INSTRUMENTATION, 5. MEASUREMENT/5.1 Factors That Affect the Measurement, 5. MEASUREMENT/5.2 Sample Preparation, 5. MEASUREMENT/5.3 Test Procedures, 5. MEASUREMENT/5.4 Data Interpretation, 6. ADVANTAGES AND LIMITATIONS, 7. ADDITIONAL SOURCES OF INFORMATION	Edmond Biba
New	<1430.6> ANALYTICAL METHODOLOGIES BASED ON SCATTERING PHENOMENA-PARTICLE COUNTING VIA LIGHT SCATTERING PF 45(4) Pg. ONLINE	1. INTRODUCTION, 2. Theory, 3. Instrumentation/3.1 Liquid Counters, 3. Instrumentation/3.2 Airborne Counters, 3. Instrumentation/3.3 Light Scattering Aerosol Spectrometers, 4. Factors That Affect the Testing, 5. Qualification of Light Scattering Particle Counting Instruments/5.1 Size Calibration, 5. Qualification of Light Scattering Particle Counting Instruments/5.2 Verification of Size Setting, 5. Qualification of Light Scattering Particle Counting Instruments/5.3 Counting Accuracy, 5. Qualification of Light Scattering Particle Counting Instruments/5.4 Sensor Resolution, 5. Qualification of Light Scattering Particle Counting Instruments/5.5 Sampling Volume (For Liquid Counters Only), 5. Qualification of Light Scattering Particle Counting Instruments/5.6 Sampling Flow Rate, 5. Qualification of Light Scattering Particle Counting Instruments/5.7 Calibration Interval, 6. ADDITIONAL SOURCES OF INFORMATION	Edmond Biba
New	<1430.7> ANALYTICAL METHODOLOGIES BASED ON SCATTERING PHENOMENA-NEPHELOMETRY AND TURBIDIMETRY PF 45(4) Pg. ONLINE	1. INTRODUCTION, 2. THEORY/2.1 Nephelometry and Turbidimetry, 2. THEORY/2.2 Rate Nephelometry, 2. THEORY/2.3 Rate Turbidimetry, 3. Instrumentation/3.1 Rate Nephelometry Instrumental Parameter Settings, 3. Instrumentation/3.2 Calibration of Rate Nephelometric Instruments, 4. APPLICATIONS, 5. METHOD DEVELOPMENT/5.1 Method Design, 5. METHOD DEVELOPMENT/5.2 Sample Considerations, 5. METHOD DEVELOPMENT/5.3 Reagents, 5. METHOD DEVELOPMENT/5.4 Method Specific Reference Standards, 5. METHOD DEVELOPMENT/5.5 Controls, 5. METHOD DEVELOPMENT/5.6 Robustness, 6. METHOD VALIDATION, 7. DATA ANALYSIS, 8. ADDITIONAL SOURCES OF INFORMATION	Edmond Biba

New	<1603> GOOD CASCADE IMPACTOR PRACTICES PF 45(2) Pg. ONLINE	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
New	<1671> THE APPLICATION OF MOISTURE VAPOR TRANSMISSION RATES FOR SOLID ORAL DOSAGE FORMS IN PLASTIC PACKAGING SYSTEMS PF 44(3) Pg. ONLINE	INTRODUCTION, PACKAGING SYSTEMS, DESICCANT VERSUS WATER MVTR METHOD, EQUIVALENCY AND APPLICATION OF MVTR DETERMINATION METHOD, REPACKAGING OF SODFS, GLOSSARY, REFERENCES	Desmond Hunt
Revision	ACETAMINOPHEN AND DIPHENHYDRAMINE CITRATE TABLETS PF 45(5) Pg. ONLINE	ASSAY/Procedure 1: Acetaminophen, ASSAY/Procedure 2: Diphenhydramine Citrate, PERFORMANCE TESTS/Dissolution 711, Procedure, Apparatus 1 and Apparatus 2, Immediate-release dosage forms, Procedure for a pooled sample for immediate-release dosage forms, PERFORMANCE TESTS/Uniformity of Dosage Units 905, Content Uniformity, ADDITIONAL REQUIREMENTS/USP Reference Standards 11	Clydewyn Anthony
Revision	3-Acetylthio-2-methylpropanoic Acid PF 45(4) Pg. ONLINE	3-Acetylthio-2-methylpropanoic Acid	Margareth Marques
Revision	Ammonium Vanadate PF 45(4) Pg. ONLINE	Ammonium Vanadate	Margareth Marques
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
Revision	p-Anisidine PF 45(4) Pg. ONLINE	p-Anisidine	Margareth Marques
Omission	ASPIRIN, CAFFEINE, AND DIHYDROCODEINE BITARTRATE CAPSULES PF 45(4) Pg. ONLINE	Entire document	Wei Yang
Revision	AZTEC MARIGOLD ZEAXANTHIN EXTRACT PF 45(5) Pg. ONLINE	CHEMICAL INFORMATION, DEFINITION, CONTAMINANTS/Botanical Extracts 565, Preparations, General Pharmacopeial Requirements, Pesticide Residues, CONTAMINANTS/Microbial Enumeration Tests 2021, CONTAMINANTS/Absence of Specified Microorganisms 2022, Test Procedures, Test for Absence of Salmonella Species and Test for Absence of Escherichia coli	Maria Monagas
Omission	BARIUM HYDROXIDE LIME PF 45(5) Pg. ONLINE	Entire document	Ravi Ravichandran

		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	
New	BITTER ORANGE FRUIT FLAVONOIDS DRY EXTRACT PF 44(1) Pg. ONLINE		Maria Monagas
New	12 PERCENT BORON TRICHLORIDE SOLUTION IN METHANOL PF 45(5) Pg. ONLINE	12% Boron Trichloride Solution in Methanol	Margareth Marques
Omission	BROMODIPHENHYDRAMINE HYDROCHLORIDE ORAL SOLUTION PF 45(4) Pg. ONLINE	Entire document	Sujatha Ramakrishna
Omission	BROMPHENIRAMINE MALEATE INJECTION PF 45(5) Pg. ONLINE	Entire document	Mary Koleck
		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	
New	BUDESONIDE NASAL SPRAY PF 44(3) Pg. ONLINE		Richard Nguyen
Omission	CALCIUM GLUBIONATE SYRUP PF 45(4) Pg. ONLINE	Entire document	Mary Koleck
Omission	CARBENICILLIN FOR INJECTION PF 45(5) Pg. ONLINE	Entire document	Christine Hiemer
Omission	CARBENICILLIN DISODIUM PF 45(5) Pg. ONLINE	Entire document	Christine Hiemer
Omission	CARBENICILLIN INDANYL SODIUM PF 45(5) Pg. ONLINE	Entire document	Christine Hiemer
Omission	CARBENICILLIN INDANYL SODIUM TABLETS PF 45(5) Pg. ONLINE	Entire document	Christine Hiemer
Omission	CEFOPERAZONE INJECTION PF 45(5) Pg. ONLINE	Entire document	Slavica Shane
Omission	CEFOPERAZONE FOR INJECTION PF 45(5) Pg. ONLINE	Entire document	Slavica Shane
Omission	CEFORANIDE PF 45(4) Pg. ONLINE	Entire document	Slavica Shane
Omission	CEFORANIDE FOR INJECTION PF 45(4) Pg. ONLINE	Entire document	Slavica Shane
Omission	CEFOTIAM HYDROCHLORIDE PF 45(4) Pg. ONLINE	Entire document	Slavica Shane
Omission	CEFOTIAM FOR INJECTION PF 45(4) Pg. ONLINE	Entire document	Slavica Shane
Omission	CEFPYRIMIDE PF 45(4) Pg. ONLINE	Entire document	Slavica Shane
Omission	CEFPYRIMIDE FOR INJECTION PF 45(4) Pg. ONLINE	Entire document	Slavica Shane
Omission	CELLULOSE SODIUM PHOSPHATE PF 45(4) Pg. ONLINE	Entire document	Behnaz Almasi
Omission	CELLULOSE SODIUM PHOSPHATE FOR ORAL SUSPENSION PF 45(4) Pg. ONLINE	Entire document	Behnaz Almasi
Omission	CEPHALOTHIN INJECTION PF 45(5) Pg. ONLINE	Entire document	Slavica Shane
Omission	CEPHALOTHIN FOR INJECTION PF 45(5) Pg. ONLINE	Entire document	Slavica Shane

		CHEMICAL INFORMATION, DEFINITION, IDENTIFICATION/A., IDENTIFICATION/B., IDENTIFICATION/C., ASSAY/Procedure, IMPURITIES/Related Compounds, IMPURITIES/Limit of Fructose and myo-Inositol, IMPURITIES/Chloride and Sulfate <221>, Chloride, IMPURITIES/Residue on Ignition <281>, CONTAMINANTS/Articles of Botanical Origin 561, Test for Aflatoxins, CONTAMINANTS/Articles of Botanical Origin 561, Pesticide Residue Analysis, CONTAMINANTS/Articles of Botanical Origin 561, Limits of Elemental Impurities, SPECIFIC TESTS/Microbial Enumeration Tests 2021, SPECIFIC TESTS/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/Optical Rotation 781S, Procedures, Specific Rotation, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards 11	
New	D-CHIRO-INOSITOL PF 45(4) Pg. ONLINE		Fatkhulla Tadjimukhamedov
Omission	CHLORAMPHENICOL CREAM PF 45(5) Pg. ONLINE	Entire document	Praveen Pabba
Omission	CHLORAMPHENICOL OPHTHALMIC SOLUTION PF 45(5) Pg. ONLINE	Entire document	Praveen Pabba
Omission	CHLORAMPHENICOL FOR OPHTHALMIC SOLUTION PF 45(5) Pg. ONLINE	Entire document	Praveen Pabba
Omission	CHLORAMPHENICOL ORAL SOLUTION PF 45(2) Pg. ONLINE	Entire document	Julie Zhang
Omission	CHLORAMPHENICOL OTIC SOLUTION PF 45(5) Pg. ONLINE	Entire document	Praveen Pabba
Omission	CHLORAMPHENICOL AND HYDROCORTISONE ACETATE FOR OPHTHALMIC SUSPENSION PF 45(5) Pg. ONLINE	Entire document	Praveen Pabba
New	CHLOROMETHYLNITROIMIDAZOLE PF 43(3) Pg. ONLINE	Chloromethylnitroimidazole	Nicholas Garito Jr.
Omission	CHLORPHENIRAMINE MALEATE INJECTION PF 45(4) Pg. ONLINE	Entire document	Mary Koleck
Revision	CIPROFLOXACIN OPHTHALMIC SOLUTION PF 44(3) Pg. ONLINE	IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities	Shankari Shivaprasad
Omission	CLOFIBRATE PF 45(5) Pg. ONLINE	Entire document	Yanyin Yang
Omission	CLOFIBRATE CAPSULES PF 45(5) Pg. ONLINE	Entire document	Yanyin Yang
Revision	COD LIVER OIL PF 45(4) Pg. ONLINE	IDENTIFICATION/B. Fatty Acid Profile, ADDITIONAL REQUIREMENTS/Labeling	Fatkhulla Tadjimukhamedov
Revision	COD LIVER OIL CAPSULES PF 45(4) Pg. ONLINE	IDENTIFICATION/A. Presence of Vitamin A, IDENTIFICATION/B. Fatty Acid Profile, STRENGTH/Vitamin A, STRENGTH/Vitamin D, SPECIFIC TESTS/Fats and Fixed Oils 401, Procedures, Acid Value, SPECIFIC TESTS/Fats and Fixed Oils 401, Procedures, Saponification Value	Natalia Davydova
Omission	CODEINE PHOSPHATE INJECTION PF 45(4) Pg. ONLINE	Entire document	Wei Yang
Revision	PURIFIED COTTON PF 45(4) Pg. ONLINE	IDENTIFICATION/A. Auxiliary Packaging Components 670, Pharmaceutical Coil, Cotton Pharmaceutical Coil, IDENTIFICATION/B. Fluorescence, SPECIFIC TESTS/Loss on Drying 731, SPECIFIC TESTS/Auxiliary Packaging Components 670, SPECIFIC TESTS/Fiber Length, SPECIFIC TESTS/Absorbency, SPECIFIC TESTS/Cotton, 691 Fiber Length and Absorbency Test, SPECIFIC TESTS/Other Foreign Matter	Leslie Furr
Omission	CROMOLYN SODIUM INHALATION POWDER PF 45(5) Pg. ONLINE	Entire document	Ravi Ravichandran
Omission	CYCLANDELATE PF 45(5) Pg. ONLINE	Entire document	Yanyin Yang
Omission	CYROMAZINE PF 45(5) Pg. ONLINE	Entire document	Jane Li
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

Revision	DICYCLOMINE HYDROCHLORIDE CAPSULES 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
Revision	DICYCLOMINE HYDROCHLORIDE INJECTION PF 43(6) Pg. ONLINE	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 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	DIHYDROTACHYSTEROL PF 45(5) Pg. ONLINE	Entire document	Behnaz Almasi
Omission	DIHYDROTACHYSTEROL CAPSULES PF 45(5) Pg. ONLINE	Entire document	Behnaz Almasi
Omission	DIHYDROTACHYSTEROL ORAL SOLUTION PF 45(5) Pg. ONLINE	Entire document	Behnaz Almasi
Omission	DIHYDROTACHYSTEROL TABLETS PF 45(5) Pg. ONLINE	Entire document	Behnaz Almasi
Omission	DIPIVEFRIN HYDROCHLORIDE OPHTHALMIC SOLUTION PF 45(5) Pg. ONLINE	Entire document	Feiwen Mao
Omission	DIRITHROMYCIN PF 45(5) Pg. ONLINE	Entire document	Praveen Pabba
Omission	DIRITHROMYCIN DELAYED-RELEASE TABLETS PF 45(5) Pg. ONLINE	Entire document	Praveen Pabba
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
Omission	ABSORBABLE DUSTING POWDER PF 45(5) Pg. ONLINE	Entire document	Leslie Furr
Omission	DYPHYLLINE INJECTION PF 45(5) Pg. ONLINE	Entire document	Mary Koleck
Omission	DYPHYLLINE ORAL SOLUTION PF 45(5) Pg. ONLINE	Entire document	Mary Koleck
Omission	DYPHYLLINE TABLETS PF 45(5) Pg. ONLINE	Entire document	Mary Koleck
Omission	ERGOLOID MESYLATES CAPSULES PF 45(5) Pg. ONLINE	Entire document	Heather Joyce
Omission	ERGOLOID MESYLATES ORAL SOLUTION PF 45(5) Pg. ONLINE	Entire document	Heather Joyce
Omission	STERILE ERYTHROMYCIN GLUCEPTATE PF 45(1) Pg. ONLINE	Entire document	Julie Zhang
Omission	ESTROPIPATE VAGINAL CREAM PF 45(5) Pg. ONLINE	Entire document	Gerald Hsu
Omission	ETHCHLORVYNOL CAPSULES PF 45(5) Pg. ONLINE	Entire document	Heather Joyce
Revision	ETHYL MALTOL PF 45(4) Pg. ONLINE	DEFINITION, IDENTIFICATION/A. Spectroscopic Identification Tests 197, Infrared Spectroscopy, IDENTIFICATION/B. Chromatographic Identity, ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards 11	Peng Zhang
Revision	FELBAMATE ORAL SUSPENSION PF 45(5) Pg. ONLINE	IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution 711, IMPURITIES/Organic Impurities, SPECIFIC TESTS/pH 791	Heather Joyce
Omission	FERUMOXIL ORAL SUSPENSION PF 45(5) Pg. ONLINE	Entire document	Ravi Ravichandran

New	FISH OIL OMEGA-3 ACID ETHYL ESTERS CONCENTRATE PF 45(4) Pg. ONLINE	DEFINITION, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Content of EPAee, DHAee, and Total Omega-3-Acid Ethyl Esters, IMPURITIES/Oligomers and Partial Glycerides, IMPURITIES/Limit of Dioxins, Furans, and Polychlorinated Biphenyls (PCBs), SPECIFIC TESTS/Fats and Fixed Oils 401, Procedures, Acid Value, SPECIFIC TESTS/Fats and Fixed Oils 401, Procedures, Anisidine Value, SPECIFIC TESTS/Fats and Fixed Oils 401, Procedures, Peroxide Value, SPECIFIC TESTS/Absorbance, ( ) ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards 11	Fatkhulla Tadjimukhamedov
Revision	SODIUM FLUORIDE F 18 INJECTION PF 45(5) Pg. ONLINE	DEFINITION, IDENTIFICATION/A. Radiochemical Identity, IDENTIFICATION/B. Radiochemical Identity, ASSAY/Radioactivity, ASSAY/Radioactive Concentration (Strength), PURITY/Radiochemical Purity, PURITY/Radionuclidic Purity, IMPURITIES/Radionuclidic Impurities, IMPURITIES/Radiochemical Impurities, SPECIFIC TESTS/Appearance, SPECIFIC TESTS/Bacterial Endotoxins Test 85, SPECIFIC TESTS/pH 791, SPECIFIC TESTS/pH, SPECIFIC TESTS/Specific Activity, SPECIFIC TESTS/Other Requirements, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards 11	Ravi Ravichandran
Omission	FLUOROMETHOLONE CREAM PF 45(4) Pg. ONLINE	Entire document	Gerald Hsu
Omission	FURAZOLIDONE ORAL SUSPENSION PF 45(5) Pg. ONLINE	Entire document	Jane Li
Omission	FURAZOLIDONE TABLETS PF 45(5) Pg. ONLINE	Entire document	Jane Li
Revision	0.01 N HYDROCHLORIC ACID VS PF 45(5) Pg. ONLINE	0.01 N Hydrochloric Acid VS	Margareth Marques
New	4-HYDROXY-6-METHYL-2-PYRONE PF 45(4) Pg. ONLINE	4-Hydroxy-6-methyl-2-pyrone	Margareth Marques
New	INDIAN BARBERRY STEM PF 44(5) Pg. ONLINE	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



New	INDIAN BARBERRY STEM DRY EXTRACT PF 44(5) Pg. ONLINE	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 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
New	INDIAN BARBERRY STEM POWDER PF 44(5) Pg. ONLINE	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
Omission	ISOPROPAMIDE IODIDE TABLETS PF 45(4) Pg. ONLINE	Entire document	Behnaz Almasi
Omission	ISOPROTERENOL INHALATION SOLUTION PF 45(4) Pg. ONLINE	Entire document	Ravi Ravichandran
Omission	ISOPROTERENOL HYDROCHLORIDE TABLETS PF 45(4) Pg. ONLINE	Entire document	Gerald Hsu
Omission	ISOPROTERENOL SULFATE PF 45(4) Pg. ONLINE	Entire document	Ravi Ravichandran
Omission	ISOPROTERENOL SULFATE INHALATION AEROSOL PF 45(4) Pg. ONLINE	Entire document	Ravi Ravichandran
Omission	ISOPROTERENOL SULFATE INHALATION SOLUTION PF 45(4) Pg. ONLINE	Entire document	Ravi Ravichandran
New	L114 PF 45(5) Pg. ONLINE	L114	Margareth Marques
Revision	MILK OF MAGNESIA PF 44(3) Pg. ONLINE	IDENTIFICATION/B., ASSAY/Procedure, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>	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	MAGNESIUM CARBONATE PF 44(2) 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>	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>	Michael Chang

Revision	MAGNESIUM HYDROXIDE PASTE PF 44(3) Pg. ONLINE	IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Limit of Calcium, IMPURITIES/Limit of Lead, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>	Michael Chang
Revision	MAGNESIUM OXIDE PF 43(6) Pg. ONLINE	IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Limit of Calcium, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>	Michael Chang
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	MAGNESIUM TRISILICATE PF 44(2) Pg. ONLINE	IDENTIFICATION/B., ASSAY/Content of Magnesium Oxide, IMPURITIES/Soluble Salts, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>, IDENTIFICATION/C	Michael Chang
Omission	MENADIOL SODIUM DIPHOSPHATE PF 44(4) Pg. ONLINE	Entire document	Donald Min
Revision	MONOBENZONE PF 45(4) Pg. ONLINE	IDENTIFICATION/B. Spectroscopic Identification Tests 197, Ultraviolet-Visible Spectroscopy, IDENTIFICATION/C. Melting Range or Temperature, 741 Class I, SPECIFIC TESTS/Melting Range or Temperature, 741 Class I	Sujatha Ramakrishna
Omission	MORICIZINE HYDROCHLORIDE PF 44(4) Pg. ONLINE	Entire document	Donald Min
New	0.2% PHOSPHORIC ACID TS PF 44(3) Pg. ONLINE	0.2% Phosphoric Acid TS-	Nicholas Garito Jr.
Revision	PINDOLOL TABLETS PF 45(3) Pg. ONLINE	IDENTIFICATION/A., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution 711, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards 11	Donald Min
Revision	PIROXICAM PF 44(5) Pg. ONLINE	IDENTIFICATION/B. Ultraviolet Absorption <197U>, IDENTIFICATION/C. Thin-Layer Chromatography <201>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Limit of Piroxicam Related Compound B, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Piroxicam Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Piroxicam Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Piroxicam Related Compound D RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Piroxicam Related Compound G RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Piroxicam Related Compound J RS	Hillary Cai
Revision	POTASSIUM CARBONATE PF 45(1) Pg. ONLINE	ASSAY/Procedure	Michael Chang
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

New	PUMMELO PEEL PF 45(4) Pg. ONLINE	DEFINITION, IDENTIFICATION/A. HPTLC for Articles of Botanical Origin 203 , IDENTIFICATION/B. HPLC, COMPOSITION/Content of Flavonoid 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/Water Determination 921 , Method II, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards 11	Cuiying Ma
New	PUMMELO PEEL FLAVONOIDS DRY EXTRACT PF 45(4) Pg. ONLINE	DEFINITION, IDENTIFICATION/A. HPTLC for Articles of Botanical Origin 203 , IDENTIFICATION/B. HPLC, COMPOSITION/Content of Flavonoid Glycosides, CONTAMINANTS/Botanical Extracts 565 , Preparations, General Pharmacopeial Requirements, Pesticide Residues, CONTAMINANTS/Articles of Botanical Origin 561 , Test for Aflatoxins, CONTAMINANTS/Microbial Enumeration Tests 2021 , CONTAMINANTS/Absence of Specified Microorganisms 2022 , Test Procedures, Test for Absence of Salmonella Species and Test for Absence of Escherichia coli, SPECIFIC TESTS/Articles of Botanical Origin 561 , Methods of Analysis, Total Ash, SPECIFIC TESTS/Loss on Drying 731 , SPECIFIC TESTS/Botanical Extracts 565 , Preparations, General Pharmacopeial Requirements, Residual Solvents, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards 11	Cuiying Ma
New	PUMMELO PEEL POWDER PF 45(4) Pg. ONLINE	DEFINITION, IDENTIFICATION/A. HPTLC for Articles of Botanical Origin 203 , IDENTIFICATION/B. HPLC, COMPOSITION/Content of Flavonoid 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/Water Determination 921 , Method II, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards 11	Cuiying Ma
Revision	PURIFIED RAYON PF 45(4) Pg. ONLINE	IDENTIFICATION/A. Auxiliary Packaging Components 670 , Pharmaceutical Coil, Rayon Pharmaceutical Coil, IDENTIFICATION/B. Fluorescence, SPECIFIC TESTS/Fiber Length, SPECIFIC TESTS/Absorbency, SPECIFIC TESTS/Other Foreign Matter	Leslie Furr
Revision	SODIUM FERROUS CITRATE PF 45(5) Pg. ONLINE	IMPURITIES/Elemental Impurities—Procedures 233	Fatkhulla Tadjimukhamedov
New	0.05 N SODIUM HYDROXIDE VS PF 45(5) Pg. ONLINE	0.05 N Sodium Hydroxide VS	Margareth Marques
Revision	0.5 N SODIUM HYDROXIDE VS PF 45(4) Pg. ONLINE	0.5 N Sodium Hydroxide VS	Margareth Marques

New	0.02 N SODIUM HYDROXIDE VS PF 45(4) Pg. ONLINE	0.02 N Sodium Hydroxide VS	Margareth Marques
New	SODIUM TETRABORATE, ANHYDROUS PF 45(4) Pg. ONLINE	Sodium Tetraborate, Anhydrous	Margareth Marques
New	0.05 N SODIUM THIOSULFATE VS PF 45(5) Pg. ONLINE	0.05 N Sodium Thiosulfate VS	Margareth Marques
Revision	SUCCINYLCOLINE CHLORIDE PF 45(4) Pg. ONLINE	IDENTIFICATION/A. Spectroscopic Identification Tests 197 , Infrared Spectroscopy, IMPURITIES/Limit of Choline, ADDITIONAL REQUIREMENTS/Packaging and Storage	Ren-Hwa Yeh
Omission	TRIPLE SULFA VAGINAL CREAM PF 45(4) Pg. ONLINE	Entire document	Praveen Pabba
Omission	TRIPLE SULFA VAGINAL INSERTS PF 45(4) Pg. ONLINE	Entire document	Praveen Pabba
Omission	SULFABENZAMIDE PF 45(4) Pg. ONLINE	Entire document	Praveen Pabba
Omission	SULFACETAMIDE PF 45(4) Pg. ONLINE	Entire document	Praveen Pabba
Omission	SULFADIAZINE SODIUM INJECTION PF 45(4) Pg. ONLINE	Entire document	Praveen Pabba
Omission	SULFAMETHIZOLE ORAL SUSPENSION PF 45(4) Pg. ONLINE	Entire document	Praveen Pabba
Omission	SULFAMETHOXAZOLE TABLETS PF 45(4) Pg. ONLINE	Entire document	Praveen Pabba
Revision	ABSORBABLE SURGICAL SUTURE PF 45(5) Pg. ONLINE	SPECIFIC TESTS/Sutures—Diameter 861 , SPECIFIC TESTS/Extractable Color (if Suture is dyed)	Leslie Furr
Revision	NONABSORBABLE SURGICAL SUTURE PF 45(5) Pg. ONLINE	SPECIFIC TESTS/Sutures—Diameter 861 , SPECIFIC TESTS/Extractable Color (if Suture is dyed)	Leslie Furr
Revision	TELMISARTAN AND AMLODIPINE TABLETS PF 45(4) Pg. ONLINE	ASSAY/Procedure, PERFORMANCE TESTS/Dissolution 711 , IMPURITIES/Organic Impurities	Donald Min
Omission	TESTOLACTONE PF 45(3) Pg. ONLINE	Entire document	Feiwen Mao
Omission	TESTOLACTONE TABLETS PF 45(4) Pg. ONLINE	Entire document	Feiwen Mao
Revision	THALIDOMIDE PF 45(5) Pg. ONLINE	IDENTIFICATION/A. Spectroscopic Identification Tests 197 , Infrared Spectroscopy, IDENTIFICATION/B., ASSAY/Procedure, SPECIFIC TESTS/Microbial Enumeration Tests 61 and Tests for Specified Microorganisms 62	Feiwen Mao
Omission	THEOPHYLLINE, EPHEDRINE HYDROCHLORIDE, AND PHENOBARBITAL TABLETS PF 45(4) Pg. ONLINE	Entire document	Sujatha Ramakrishna
Revision	TIGECYCLINE FOR INJECTION PF 45(5) Pg. ONLINE	IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Bacterial Endotoxins Test 85	Praveen Pabba
Revision	TRIAMCINOLONE ACETONIDE NASAL SPRAY PF 45(5) Pg. ONLINE	IDENTIFICATION/B., ASSAY/Procedure, OTHER COMPONENTS/Content of Edetate Disodium, OTHER COMPONENTS/Content of Benzalkonium Chloride, PERFORMANCE TESTS/Delivered Dose Uniformity (Between Units), PERFORMANCE TESTS/Delivered Dose Uniformity (Within Unit), SPECIFIC TESTS/Particle Size	Ravi Ravichandran
Revision	TRYPSIN PF 43(6) Pg. ONLINE	{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 Recombinant Porcine RS	Elena Curti
Revision	VINBLASTINE SULFATE PF 45(4) Pg. ONLINE	IDENTIFICATION/A. Spectroscopic Identification Tests 197 , Infrared Spectroscopy, ASSAY/Procedure, ADDITIONAL REQUIREMENTS/USP Reference Standards 11	Feiwen Mao
Revision	VINBLASTINE SULFATE FOR INJECTION PF 45(4) Pg. ONLINE	IDENTIFICATION/A. Spectroscopic Identification Tests 197 , Infrared Spectroscopy, ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards 11	Feiwen Mao
Revision	VINCRISTINE SULFATE PF 45(4) Pg. ONLINE	IDENTIFICATION/A. Spectroscopic Identification Tests 197 , Infrared Spectroscopy, ASSAY/Procedure, ADDITIONAL REQUIREMENTS/USP Reference Standards 11	Feiwen Mao
Revision	VINCRISTINE SULFATE INJECTION PF 45(4) Pg. ONLINE	IDENTIFICATION/A. Thin-Layer Chromatographic Identification Test 201 , ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards 11	Feiwen Mao

Revision	VINCRISTINE SULFATE FOR INJECTION PF 45(4) Pg. ONLINE	IDENTIFICATION/A. Thin-Layer Chromatographic Identification Test 201 , ASSAY/Procedure, PERFORMANCE TESTS/Uniformity of Dosage Units 905 , IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards 11	Feiwen Mao
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