

Compendial Deferrals for USP40-NF35

Category	Monograph Title	Monograph Section	Scientific Liaison
Revision	<123> GLUCAGON BIOIDENTITY TESTS PF 41(2) Pg. ONLINE	INTRODUCTION/Introduction, PROCEDURE/Assay, PROCEDURE/B. In Vitro Cell-Based Bioidentity Test, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>	Maura Kibbey
New	<321> DRUG PRODUCT ASSAY TESTS - ORGANIC CHEMICAL MEDICINES PF 41(1) Pg. ONLINE	Title, INTRODUCTION/Paragraph Text, ASSAY/Procedure 1, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>	Alan Potts
New	<327> DRUG PRODUCT IMPURITIES TESTS PF 41(1) Pg. ONLINE	Title, INTRODUCTION/Introduction, IMPURITIES/Salicylic Acid in Aspirin-Containing Drug Products/Solution A, IMPURITIES/Salicylic Acid in Aspirin-Containing Drug Products/Solution B, IMPURITIES/Salicylic Acid in Aspirin-Containing Drug Products/Mobile phase, IMPURITIES/Salicylic Acid in Aspirin-Containing Drug Products/Diluent, IMPURITIES/Salicylic Acid in Aspirin-Containing Drug Products/System suitability solution A, IMPURITIES/Salicylic Acid in Aspirin-Containing Drug Products/System suitability solution B, IMPURITIES/Salicylic Acid in Aspirin-Containing Drug Products/Standard solution, IMPURITIES/Salicylic Acid in Aspirin-Containing Drug Products/Sample solution, IMPURITIES/Salicylic Acid in Aspirin-Containing Drug Products/Chromatographic system, IMPURITIES/Salicylic Acid in Aspirin-Containing Drug Products/System suitability, IMPURITIES/Salicylic Acid in Aspirin-Containing Drug Products/Analysis, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>	Alan Potts
Revision	<467> RESIDUAL SOLVENTS PF 41(5) Pg. ONLINE	INTRODUCTION, CLASSIFICATION OF RESIDUAL SOLVENTS BY RISK ASSESSMENT, METHODS FOR ESTABLISHING EXPOSURE LIMITS, OPTIONS FOR DESCRIBING LIMITS OF CLASS 2 RESIDUAL SOLVENTS, ANALYTICAL PROCEDURES, REPORTING LEVELS OF RESIDUAL SOLVENTS, LIMITS OF RESIDUAL SOLVENTS, IDENTIFICATION, CONTROL, AND QUANTIFICATION OF RESIDUAL SOLVENTS, GLOSSARY, APPENDIX 1. LIST, APPENDIX 2. ADDITIONAL BACKGROUND, APPENDIX 3. PROCEDURES FOR ESTABLISHING EXPOSURE LIMITS, INTRODUCTION, CONTROL STRATEGY, OPTIONS FOR DESCRIBING LIMITS FOR RESIDUAL SOLVENTS, SCREENING FOR WATER-SOLUBLE ARTICLES, PROCEDURE A, PROCEDURE B, SCREENING FOR WATER-INSOLUBLE ARTICLES, CLASS 3 RESIDUAL SOLVENTS, LIMIT TESTS WHEN SOLVENTS LTBP ARE KNOWN, QUANTITATIVE TESTS, QUANTIFICATION FOR WATER-INSOLUBLE ARTICLES, PROCEDURE C, VERIFICATION AND VALIDATION, VERIFICATION OF COMPENDIAL PROCEDURES, VALIDATION OF ALTERNATIVE PROCEDURES, APPENDICES	Horacio Pappa

Revision	<476> ORGANIC IMPURITIES IN DRUG SUBSTANCES AND DRUG PRODUCTS PF 41(3) Pg. ONLINE	Title, INTRODUCTION, IDENTIFICATION OF IMPURITIES IN DRUG SUBSTANCES AND DRUG PRODUCTS, ANALYTICAL PROCEDURES FOR IMPURITIES AND DEGRADATION PRODUCTS, REPORTING IMPURITIES AND DEGRADATION PRODUCTS, SETTING ACCEPTANCE CRITERIA FOR IMPURITIES AND DEGRADATION PRODUCTS, QUALIFICATION OF IMPURITIES AND DEGRADATION PRODUCTS, IDENTIFICATION OF IMPURITIES AND DEGRADATION PRODUCTS	Antonio Hernandez-Cardoso
New	<797> PHARMACEUTICAL COMPOUNDING--STERILE PREPARATIONS PF 41(6) Pg. ONLINE	INTRODUCTION, ORGANIZATION OF THIS CHAPTER, RESPONSIBILITY OF COMPOUNDING PERSONNEL, CSP MICROBIAL CONTAMINATION RISK LEVELS, PERSONNEL TRAINING AND EVALUATION IN ASEPTIC MANIPULATION SKILLS, IMMEDIATE-USE CSPS, SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS, HAZARDOUS DRUGS AS CSPS, RADIOPHARMACEUTICALS AS CSPS, ALLERGEN EXTRACTS AS CSPS, VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY, ENVIRONMENTAL QUALITY AND CONTROL, SUGGESTED STANDARD OPERATING PROCEDURES (SOPS), ELEMENTS OF QUALITY CONTROL, VERIFICATION OF AUTOMATED COMPOUNDING DEVICES (ACDS) FOR PARENTERAL NUTRITION COMPOUNDING, FINISHED PREPARATION RELEASE CHECKS AND TESTS, STORAGE AND BEYOND-USE DATING, MAINTAINING STERILITY, PURITY, AND STABILITY OF DISPENSED AND DISTRIBUTED CSPS, PATIENT OR CAREGIVER TRAINING, PATIENT MONITORING AND ADVERSE EVENTS REPORTING, QUALITY ASSURANCE (QA) PROGRAM, ABBREVIATIONS AND ACRONYMS, GLOSSARY, *No Head*, 1. INTRODUCTION AND SCOPE, 2. PERSONNEL QUALIFICATIONS-TRAINING, EVALUATION, AND REQUALIFICATION, 3. PERSONAL HYGIENE AND PERSONAL PROTECTIVE EQUIPMENT, 4. BUILDINGS AND FACILITIES, 5. ENVIRONMENTAL MONITORING, 6. CLEANING AND DISINFECTING COMPOUNDING AREAS, 7. EQUIPMENT AND COMPONENTS, 8. STERILIZATION AND DEPYROGENATION, 9. SOPS AND MASTER FORMULATION AND COMPOUNDING RECORDS, 10. RELEASE TESTING, 11. LABELING, 12. ESTABLISHING BEYOND-USE DATES AND IN-USE TIMES, 13. QUALITY ASSURANCE AND QUALITY CONTROL, 14. CSP STORAGE, HANDLING, PACKAGING, AND TRANSPORT, 15. COMPLAINT HANDLING AND ADVERSE EVENT REPORTING, 16. DOCUMENTATION, 17. RADIOPHARMACEUTICALS AS CSPS, APPENDICES	Jeanne Sun
New	<856> NEAR-INFRARED SPECTROSCOPY PF 41(1) Pg. ONLINE	Title, 1. INTRODUCTION, 2. QUALIFICATION OF NIR SPECTROMETERS, 3. PROCEDURE, 4. VALIDATION AND VERIFICATION, USP REFERENCE STANDARDS <11>	Kahkashan Zaidi
New	<858> RAMAN SPECTROSCOPY PF 40(6) Pg. ONLINE	Title, Introduction, QUALIFICATION OF RAMAN SPECTROMETERS, PROCEDURE, VALIDATION AND VERIFICATION, VERIFICATION	Kahkashan Zaidi
New	<909> UNIFORMITY OF DOSE FROM ORAL SUSPENSIONS IN MULTIPLE-UNIT CONTAINERS PF 40(4) Pg. ONLINE	Title, PURPOSE, PROCEDURE, ACCEPTANCE CRITERIA	William Brown

Revision	<1058> ANALYTICAL INSTRUMENT QUALIFICATION PF 41(3) Pg. ONLINE	INTRODUCTION, ANALYTICAL INSTRUMENT QUALIFICATION PROCESS, ROLES AND RESPONSIBILITIES, SOFTWARE VALIDATION, CHANGE CONTROL, AIQ DOCUMENTATION, INSTRUMENT CATEGORIES, GLOSSARY	Horacio Pappa
Revision	<1086> IMPURITIES IN DRUG SUBSTANCES AND DRUG PRODUCTS PF 41(3) Pg. ONLINE	INTRODUCTION, DRUG SUBSTANCE, DRUG PRODUCT, DEFINITIONS, INTRODUCTION, ORGANIC IMPURITIES IN DRUG SUBSTANCES, ORGANIC IMPURITIES IN DRUG PRODUCTS, ORGANIC IMPURITIES DECISION TREE, APPENDIX 1: DEFINITIONS, APPENDIX 2: ADDITIONAL SOURCES OF INFORMATION AND GUIDANCE	Antonio Hernandez-Cardoso
Revision	<1119> NEAR-IR SPECTROSCOPY PF 41(1) Pg. ONLINE	Title, INTRODUCTION, INSTRUMENTATION, METHOD VALIDATION, GLOSSARY, *No Head*, 1. THEORY, 2. TRANSMISSION, REFLECTION, AND TRANSFLECTION MODES, 3. FACTORS THAT AFFECT NIR SPECTRA, 4. PRETREATMENT OF NIR SPECTRAL DATA, 5. INSTRUMENTATION, 6. APPLICATIONS, 7. PROCEDURE VALIDATION. 8. APPENDIX: GLOSSARY	Kahkashan Zaidi
Revision	<1120> RAMAN SPECTROSCOPY PF 40(6) Pg. ONLINE	Title, INTRODUCTION, QUALITATIVE AND QUANTITATIVE RAMAN MEASUREMENTS, FACTORS AFFECTING QUANTIFICATION, APPARATUS, QUALIFICATION AND VERIFICATION OF RAMAN SPECTROMETERS, METHOD VALIDATION, DEFINITION OF TERMS AND SYMBOLS, THEORY, SAMPLING FACTORS, SPECIALIZED TECHNIQUES, CALIBRATION, FACTORS THAT AFFECT MEASUREMENT PERFORMANCE. PROCEDURE VALIDATION	Kahkashan Zaidi
New	<1168> COMPOUNDING FOR INVESTIGATIONAL STUDIES PF 39(5) Pg. ONLINE	I. INTRODUCTION, II. REGULATORY ENVIRONMENT AND GUIDANCE, III. FACILITIES, IV. EQUIPMENT, V. PERSONNEL, VI. MATERIALS MANAGEMENT-PREPARATION, VII. MATERIALS MANAGEMENT-FINISHED PREPARATION, VIII. COMPOUNDING, IX. PACKAGING, LABELING, AND LABELS, X. QUALITY ASSURANCE PROGRAM MANAGEMENT, XI. STABILITY, STORAGE, AND DISTRIBUTION, XII. PROCEDURES AND DOSAGE FORMS, XIII. MISCELLANEOUS. XIV. CONCLUSIONS	Rick Schnatz
New	<1210> STATISTICAL TOOLS FOR PROCEDURE VALIDATION PF 40(5) Pg. ONLINE	Title, *No Head*, 1. INTRODUCTION, 2. WORK DONE BEFORE VALIDATION, 3. ACCURACY AND PRECISION, 4. RANGE DEFINITIONS, 5. LIMITS OF DETECTION AND QUANTITATION, 6. MODELLING THE CALIBRATION RELATIONSHIP (LINEARITY), 7. APPENDIX, 8. REFERENCES	Steven Walfish
Revision	<1790> VISUAL INSPECTION OF INJECTIONS PF 41(6) Pg. ONLINE	Introduction, 1. SCOPE, 2. INTRODUCTION, 3. TYPICAL INSPECTION PROCESS FLOW, 4. INSPECTION LIFE-CYCLE, 5. INTERPRETATION OF INSPECTION RESULTS, 6. INSPECTION METHODS AND TECHNOLOGIES, 7. QUALIFICATION AND VALIDATION OF INSPECTION PROCESSES, 8. PRODUCTS IN DISTRIBUTION, 9. CONCLUSIONS AND RECOMMENDATIONS, REFERENCES	Desmond Hunt
New	2,6-DIAMINOPYRIDINE PF 41(3) Pg. ONLINE	2,6-Diaminopyridine,	Sridevi Ramachandran

New	ACAMPROSATE CALCIUM PF 41(5) Pg. ONLINE	Title, Chemical Info/Chemical Structure, Chemical Info/C ₁₀ H ₂₀ CaN ₂ O ₈ S ₂ , Chemical Info/400.48, Chemical Info/1-Propanesulfonic acid, 3-(acetylamino)-, calcium salt (2:1);, Chemical Info/Calcium 3-(acetylamino)propane-1-sulfonate, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., IDENTIFICATION/C. Identification Tests-General <191>, Calcium, ASSAY/Procedure, IMPURITIES/Limit of Acamprosate Related Compound A, IMPURITIES/Organic Impurities, SPECIFIC TESTS/pH <791>, SPECIFIC TESTS/Loss on Drying <731>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Acamprosate Calcium RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Acamprosate Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Acamprosate Related Compound B RS	Heather Joyce
New	ACAMPROSATE DELAYED-RELEASE TABLETS PF 41(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>, IMPURITIES/Limit of Acamprosate Related Compound A, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Acamprosate Calcium RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Acamprosate Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Acamprosate Related Compound B RS	Heather Joyce
Revision	ACETAZOLAMIDE PF 41(3) Pg. ONLINE	IMPURITIES/Silver-Reducing Substances, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Acetazolamide Related Compound D RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Acetazolamide Related Compound E RS	Ramanujam Prasad
New	ACETYLCYSTEINE COMPOUNDED SOLUTION PF 41(2) Pg. ONLINE	Title, DEFINITION/Introduction, ASSAY/Procedure, SPECIFIC TESTS/pH <791>, SPECIFIC TESTS/Sterility Tests <71>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Beyond-Use Date, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Acetylcysteine RS	Jeanne Sun

Revision	ALBUMIN HUMAN PF 41(6) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/A. Immunodiffusion, IDENTIFICATION/B. Protein Composition by Zone Electrophoresis, ASSAY/Procedure, OTHER COMPONENTS/Content of Sodium Caprylate, OTHER COMPONENTS/Content of N-Acetyl-dl-tryptophan, IMPURITIES/Prekallikrein Activator <165>, SPECIFIC TESTS/Bacterial Endotoxins Test <85>, SPECIFIC TESTS/Biological Reactivity tests <88>, In Vivo, Safety Tests-Biologicals, SPECIFIC TESTS/Sterility Tests <71>, SPECIFIC TESTS/pH <791>, SPECIFIC TESTS/Molecular Weight Distribution, SPECIFIC TESTS/Heat Stability, SPECIFIC TESTS/Content of Sodium, SPECIFIC TESTS/Limit of Potassium, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>	Kevin Carrick
Revision	ALBUTEROL TABLETS PF 41(5) Pg. ONLINE	IDENTIFICATION/A., IDENTIFICATION/B. Identification Tests-General, Sulfate <191>, IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Albuterol Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Albuterol Related Compound C 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 E RS	Mary Koleck
Revision	ALPRAZOLAM TABLETS PF 41(6) Pg. ONLINE	IDENTIFICATION/A. Infrared Absorption, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Alprazolam Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Chlordiazepoxide Related Compound A RS	Heather Joyce
Revision	AMINOBENZOATE SODIUM PF 41(2) Pg. ONLINE	Chemical Info, DEFINITION/Introduction, IDENTIFICATION/A. Ultraviolet Absorption <197U>, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Chloride and Sulfate, Chloride <221>, IMPURITIES/Chloride and Sulfate, Sulfate <221>, IMPURITIES/Volatile Diazotizable Substances, IMPURITIES/Limit of Aniline and p-Toluidine, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Aniline RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Benzocaine RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP 4-Nitrobenzoic Acid RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP p-Toluidine RS	Wei Yang

Revision	AMINOHIPPURATE SODIUM INJECTION PF 41(5) Pg. ONLINE	IDENTIFICATION/C. Identification Tests-General, Sodium <191>, IDENTIFICATION/C.	Manoj Metta
New	AMLODIPINE AND ATORVASTATIN TABLETS PF 42(1) 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 Related to Amlodipine, IMPURITIES/Organic Impurities Related to Atorvastatin, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Amlodipine Besylate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Amlodipine Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Amlodipine Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Amlodipine Related Compound E RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Amlodipine Related Compound F RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Atorvastatin Calcium RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Atorvastatin Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Atorvastatin Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Atorvastatin Related Compound C RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Atorvastatin Related Compound H RS	Sujatha Ramakrishna
Revision	ASPIRIN PF 41(6) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B. Infrared Absorption <197K> or <197A>, ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Readily Carbonizable Substances Test <271>, SPECIFIC TESTS/Substances Insoluble in Sodium Carbonate TS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Salicylic Acid RS	Clydewyn Anthony
Revision	ASPIRIN CAPSULES PF 41(1) Pg. ONLINE	IDENTIFICATION/A. Procedure, IDENTIFICATION/A., ASSAY/Procedure, ASSAY/Drug Product Assay Tests-Organic Chemical Medicines, Procedure 1 <321>, IMPURITIES/Organic Impurities, IMPURITIES/Limit of Free Salicylic Acid, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Caffeine RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Dextromethorphan Hydrobromide RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Diphenhydramine Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Doxylamine Succinate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Pseudoephedrine Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Salicylic Acid RS	Hillary Cai

New	ATORVASTATIN CALCIUM TABLETS PF 42(1) Pg. ONLINE	Title, DEFINITION/Introduction, IDENTIFICATION, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY, ASSAY/Procedure, PERFORMANCE TESTS, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Atorvastatin Calcium RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Atorvastatin Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Atorvastatin Related Compound D RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Atorvastatin Related Compound H _{DC}	Sujatha Ramakrishna
Revision	BETAMETHASONE VALERATE LOTION PF 41(5) Pg. ONLINE	IDENTIFICATION/A. Thin-Layer Chromatography, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Betamethasone RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Betamethasone Valerate Related Compound A RS	Mary Koleck
New	BIVALIRUDIN PF 41(5) Pg. ONLINE	Title, Chemical Info/Chemical Structure, Chemical Info/C98H138N24O33, Chemical Info/2180.29 (free base), Chemical Info/l-Leucine, d-phenylalanyl-l-prolyl-l-arginyl-l-prolylglycylglycylglycylglycyl-l-asparaginylglycyl-l-α-aspartyl-l-phenylalanyl-l-α-glutamyl-l-α-glutamyl-l-isoleucyl-l-prolyl-l-α-glutamyl-l-α-glutamyl-l-tyrosyl-; , Chemical Info/d-Phenylalanyl-l-prolyl-l-arginyl-l-prolylglycylglycylglycylglycyl-l-asparaginylglycyl-l-α-aspartyl-l-phenylalanyl-l-α-glutamyl-l-α-glutamyl-l-isoleucyl-l-prolyl-l-α-glutamyl-l-α-glutamyl-l-tyrosyl-l-leucine, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A, IDENTIFICATION/B., IDENTIFICATION/C. Amino Acid Content, IDENTIFICATION/D. Bioidentity, ASSAY/Procedure, ASSAY/Product-Related Substances and Impurities, 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 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, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Endotoxin RS	Anita Szajek

New BIVALIRUDIN FOR INJECTION PF 41(5) Pg. ONLINE

Title, DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B. Bioidentity, ASSAY/Procedure, ASSAY/Product-Related Substances and Impurities, 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>, Test for Sterility of the Product to Be Examined, Membrane Filtration, SPECIFIC TESTS/Water Determination <921>, Method Ic, SPECIFIC TESTS/Particulate Matter in Injections <788>, SPECIFIC TESTS/pH <791>, SPECIFIC TESTS/Other Requirements, 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 Endotoxin RS

[Anita Szajek](#)

Revision BROMPHENIRAMINE MALEATE ORAL SOLUTION PF 41(1) Pg. ONLINE

IDENTIFICATION/Identification-Organic Nitrogenous Bases <181>, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, OTHER COMPONENTS/Alcohol Determination, Method I <611>, PERFORMANCE TESTS/Deliverable Volume <698>, SPECIFIC TESTS/Microbial Enumeration Tests <61> and Tests for Specified Microorganisms <62>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Caffeine RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Dextromethorphan Hydrobromide RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Diphenhydramine Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Doxylamine Succinate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Pseudoephedrine Hydrochloride RS

[Domenick Vicchio](#)

Revision BROMPHENIRAMINE MALEATE TABLETS PF 41(1) Pg. ONLINE

DEFINITION/Introduction, IDENTIFICATION/Identification-Organic Nitrogenous Bases <181>, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Caffeine RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Dextromethorphan Hydrobromide RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Diphenhydramine Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Doxylamine Succinate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Pseudoephedrine Hydrochloride RS

[Domenick Vicchio](#)

Revision	BUPIVACAINE HYDROCHLORIDE PF 41(3) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197S>, IDENTIFICATION/A., ASSAY/Procedure, IMPURITIES/Chromatographic Purity, IMPURITIES/Organic Impurities, IMPURITIES/Limit of Ropivacaine Related Compound A, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Bupivacaine Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Bupivacaine Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ropivacaine Related Compound A RS	Mary Koleck
Revision	BUPIVACAINE HYDROCHLORIDE INJECTION PF 41(3) Pg. ONLINE	IDENTIFICATION/A. Identification-Organic Nitrogenous Bases <181>, IDENTIFICATION/A., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Bupivacaine Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Bupivacaine Related Compound B RS	Mary Koleck
Revision	BUPIVACAINE HYDROCHLORIDE IN DEXTROSE INJECTION PF 41(3) Pg. ONLINE	IDENTIFICATION/C., ASSAY/Bupivacaine Hydrochloride, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Bupivacaine Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Bupivacaine Related Compound B RS	Mary Koleck
Revision	BUPRENORPHINE HYDROCHLORIDE PF 41(6) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/B., IDENTIFICATION/C. Identification Tests-General <191>, Chloride, ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/pH <791>, SPECIFIC TESTS/Acidity or Alkalinity, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Buprenorphine Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Buprenorphine System Suitability Mixture RS	Wei Yang

New	CARGLUMIC ACID PF 41(6) Pg. ONLINE	<p>Title, Chemical Info/Chemical Structure, Chemical Info/C6H10N2O5, Chemical Info/190.15, Chemical Info/I-Glutamic acid, N-(aminocarbonyl)-; , Chemical Info/N-Carbamoyl-I-glutamic acid, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Organic Impurities, IMPURITIES/Limit of d-Carglumic acid, SPECIFIC TESTS/Loss on Drying <731>, SPECIFIC TESTS/Optical Rotation <781>, Procedures, Specific Rotation, SPECIFIC TESTS/pH <791>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Carglumic Acid RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP d-Carglumic Acid RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Carglumic Acid Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Carglumic Acid Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Carglumic Acid Related Compound C RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP I-Glutamic Acid RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Pyroglutamic Acid RS</p>	Sujatha Ramakrishna
Revision	CASTOR OIL PF 41(5) Pg. ONLINE	<p>Chemical Info, DEFINITION/Introduction, IDENTIFICATION/A. Identity by Fatty Acid Composition, IDENTIFICATION/B. Distinction from Most Other Fixed Oils, ASSAY/Triglyceride Composition, SPECIFIC TESTS/Distinction from Most Other Fixed Oils, SPECIFIC TESTS/Fats and Fixed Oils <401>, Free Fatty Acids, SPECIFIC TESTS/Fats and Fixed Oils <401>, Acid Value, SPECIFIC TESTS/Fats and Fixed Oils <401>, Hydroxyl Value, SPECIFIC TESTS/Fats and Fixed Oils <401>, Peroxide Value, SPECIFIC TESTS/Fats and Fixed Oils, Iodine Value <401>, SPECIFIC TESTS/Fats and Fixed Oils <401>, Unsaponifiable Matter, SPECIFIC TESTS/Water Determination <921>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/Other Requirements, ADDITIONAL REQUIREMENTS/USP Reference Standards <11></p>	
Revision	HYDROGENATED CASTOR OIL PF 41(5) Pg. ONLINE	<p>Chemical Info, DEFINITION/Introduction, IDENTIFICATION/A. Identity by Fatty Acid Composition, IDENTIFICATION/B. Melting Range or Temperature <741>, Class II, ASSAY/Triglyceride Composition, IMPURITIES/Limit of Nickel, IMPURITIES/Alkaline Impurity, SPECIFIC TESTS/Melting Range or Temperature, Class II <741>, SPECIFIC TESTS/Fats and Fixed Oils, <401>, Acid Value (Free Fatty Acids), ADDITIONAL REQUIREMENTS/USP Reference Standards <11></p>	Hong Wang

Chemical Info/Chemical Structure, Chemical Info/C19H17N5O7S3·HCl, Chemical Info/560.02, Chemical Info/5-Thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid, 7-[[[(2-amino-4-thiazolyl)(methoxyimino)acetyl]amino]-3-[[[(2-furanylcarbonyl)thio]methyl]-8-oxo-, monohydrochloride, [6R-[6α, 7β(Z)]]-, Chemical Info/(6R,7R)-7-[2-(2-Amino-4-thiazolyl)glyoxylamido]-3-(mercaptomethyl)-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid, 72-(Z)-(O-methyloxime), 2-furoate (ester), monohydrochloride, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197M>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Low Molecular Weight Impurities, IMPURITIES/High Molecular Weight Impurities (Ceftiofur Polymers), SPECIFIC TESTS/Optical Rotation, Specific Rotation <781S>, SPECIFIC TESTS/Bacterial Endotoxins <85>, SPECIFIC TESTS/Water Determination, Method I <921>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Cefotaxime Sodium RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ceftiofur Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ceftiofur System Suitability Mixture RS, ADDITIONAL REQUIREMENTS/USP Reference

[Morgan Puderbaugh](#)

New	CEFTIOFUR SODIUM PF 40(4) Pg. ONLINE	Chemical Info/Chemical Structure, Chemical Info/C19H16N5NaO7S3, Chemical Info/545.54, Chemical Info/C19H16N5NaO7S3·H2O, Chemical Info/563.55, Chemical Info/C19H16N5NaO7S3·3H2O, Chemical Info/599.59, Chemical Info/5-Thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid, 7-[[[2-amino-4-thiazolyl](methoxyimino)acetyl]amino]-3-[[[2-furanylcarbonyl)thio]methyl]-8-oxo-, monosodium salt, [6R-[6α,7β(Z)]]-, Chemical Info/Sodium (6R,7R)-7-[2-(2-amino-4-thiazolyl)glyoxylamido]-3-(mercaptomethyl)-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylate, 72-(Z)-(O-methyloxime), 2-furoate (ester), Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197M>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Low Molecular Weight Impurities, IMPURITIES/High Molecular Weight Impurities (Ceftiofur Polymers), IMPURITIES/Residual Solvents <467>, SPECIFIC TESTS/pH <791>, SPECIFIC TESTS/Optical Rotation, Specific Rotation <781S>, SPECIFIC TESTS/Bacterial Endotoxins <85>, SPECIFIC TESTS/Water Determination, Method I <921>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Cefotaxime Sodium RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ceftiofur Sodium Trihydrate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ceftiofur System Suitability Mixture RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Endotoxin	Morgan Puderbaugh
Revision	CEFUROXIME AXETIL PF 41(2) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Diastereoisomer Ratio, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Cefuroxime Axetil Delta-3 Isomers RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Cefuroxime Axetil E-Isomers RS (1RS,6R,7R)-1-Acetoxyethyl 3-[[[carbamoxyloxy)methyl]-7-[(E)-2-(furan-2-yl)-2-(methoxyimino)acetamido]-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylate.C20H22N4O10S510.47	Morgan Puderbaugh
Revision	CEFUROXIME AXETIL TABLETS PF 41(2) Pg. ONLINE	IDENTIFICATION/A., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Water Determination, Method I <921>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Cefuroxime Axetil Delta-3 Isomers RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Cefuroxime Axetil E-Isomers RS	Morgan Puderbaugh
New	CHELATING ION EXCHANGE RESIN PF 41(3) Pg. ONLINE	Chelating Ion-Exchange Resin	Trish Li

Revision CHLORPHENIRAMINE MALEATE TABLETS PF 41(1) Pg. ONLINE

DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, ASSAY/Drug Product Assay Tests-Organic Chemical Medicines , Procedure 1 <321>, PERFORMANCE TESTS/Dissolution <711>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Caffeine RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Dextromethorphan Hydrobromide RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Diphenhydramine Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Doxylamine Succinate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Pseudoephedrine Hydrochloride RS, Title, DEFINITION/Introduction, IDENTIFICATION/A. HPTLC for Articles of Botanical Origin <203>, IDENTIFICATION/B. HPLC, COMPOSITION/Content of Total Phenylpropanoids and Coumarin, 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>, Alcohol-Soluble Extractives, Method 1, SPECIFIC TESTS/Water Determination <921>, Method II, SPECIFIC TESTS/Articles of Botanical Origin <561>, Total Ash, SPECIFIC TESTS/Articles of Botanical Origin <561>, Acid-Insoluble Ash, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Cinnamaldehyde RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Cinnamic Acid RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Cinnamomum cassia Twig Powder RS

[Domenick Vicchio](#)

New CINNAMOMUM CASSIA TWIG PF 42(1) Pg. ONLINE

[Cuiying Ma](#)

New	CINNAMOMUM CASSIA TWIG POWDER PF 42(1) Pg. ONLINE	Title, DEFINITION/Introduction, IDENTIFICATION/A. HPTLC for Articles of Botanical Origin <203>, IDENTIFICATION/B. HPLC, COMPOSITION/Content of Total Phenylpropanoids and Coumarin, 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>, Alcohol-Soluble Extractives, Method 1, SPECIFIC TESTS/Water Determination <921>, Method II, SPECIFIC TESTS/Articles of Botanical Origin <561>, Total Ash, SPECIFIC TESTS/Articles of Botanical Origin <561>, Acid-Insoluble Ash, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Cinnamaldehyde RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Cinnamic Acid RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Cinnamomum cassia Twig Powder RS	
Revision	CIPROFLOXACIN TABLETS PF 42(1) Pg. ONLINE	IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage	Cuiying Ma
New	CLOMIPRAMINE COMPOUNDED ORAL SUSPENSION, VETERINARY PF 41(2) Pg. ONLINE	Title, DEFINITION/Introduction, 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>/USP Clomipramine Hvdrochloride RS	Shankari Shivaprasad
New	CREATINE PF 41(6) Pg. ONLINE	Title, Chemical Info/Chemical Structure, Chemical Info/C4H9N3O2.H2O, Chemical Info/149.15, Chemical Info/2-[Carbamimidoyl(methyl)amino]acetic acid;, Chemical Info/ Hydrate, Chemical Info/CAS, Chemical Info/C4H9N3O2, Chemical Info/131.13, Chemical Info/Anhydrous, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Chloride and Sulfate <221>, Sulfate, IMPURITIES/Related Compounds, SPECIFIC TESTS/Loss on Drying <731>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Creatine RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Creatinine RS	Jeanne Sun Huy Dinh

Revision	CROMOLYN SODIUM PF 42(1) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., IDENTIFICATION/C. Identification Tests-General <191>, Sodium, ASSAY/Procedure, IMPURITIES/Organic Impurities, IMPURITIES/Limit of Oxalate, SPECIFIC TESTS/Acidity or Alkalinity, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Cromolyn Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Cromolyn Related Compound B RS	Ravi Ravichandran
New	DALFAMPRIDINE PF 42(1) Pg. ONLINE	Title, Chemical Info/Chemical Structure, Chemical Info/C5H6N2, Chemical Info/94.11, Chemical Info/4-Pyridinamine;, Chemical Info/4-Aminopyridine, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Limit of Dalfampridine Related Compound B and Dalfampridine Related Compound C, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Water Determination <921>, Method Ia, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Dalfampridine RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Dalfampridine Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Dalfampridine Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Dalfampridine Related Compound C RS	Heather Joyce
Revision	DAUNORUBICIN HYDROCHLORIDE PF 40(6) Pg. ONLINE	IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/C. Identification Tests-General, Chloride <191>, ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Daunorubicinone RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Dihydrodaunorubicin Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Doxorubicin Hvdrochloride RS	Ahalya Wise
Revision	DAUNORUBICIN HYDROCHLORIDE FOR INJECTION PF 41(1) Pg. ONLINE	IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Water Determination, Method I <921>, SPECIFIC TESTS/Sterility Tests <71>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Daunorubicinone RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Dihydrodaunorubicin Hydrochloride RS	Ahalya Wise
New	DESCHLOROCLOTRIMAZOLE PF 42(1) Pg. ONLINE	Deschloroclotrimazole	Ramanujam Prasad
Revision	DESCRIPTION AND SOLUBILITY PF 41(4) Pg. ONLINE	Febantel, Ceftiofur Hydrochloride, Ceftiofur Sodium, Milbemycin Oxime, Carglumic Acid, Pregabalin, Dalfampridine, Iloperidone, Rosuvastatin Calcium, Linezolid, Acamprosate Calcium, Desoxycholic Acid, Frovatriptan Succinate, Methylnaltrexone Bromide. Nebivolol Hvdrochloride. Solifenacin Succinate	Morgan Puderbaugh

New	DESOGESTREL PF 41(6) Pg. ONLINE	Title, Chemical Info/Chemical Structure, Chemical Info/C22H30O, Chemical Info/310.47, Chemical Info/18,19-Dinorpregn-4-en-20-yn-17-ol, 13-ethyl-11-methylene-, (17α)-, Chemical Info/13-Ethyl-11-methylene-18,19-dinor-17α-pregn-4-en-20-yn-17-ol, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Optical Rotation <781S>, Procedure, Specific Rotation, SPECIFIC TESTS/Loss on Drying <731>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Desogestrel RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Desogestrel Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Desogestrel Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Desogestrel Related Compound C RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Desogestrel Related Compound D RS	Mary Koleck
Revision	DESOXIMETASONE PF 42(1) Pg. ONLINE	IDENTIFICATION/B. Thin-Layer Chromatography, IDENTIFICATION/B., ASSAY/Procedure	Mary Koleck
Revision	DESOXIMETASONE CREAM PF 42(1) Pg. ONLINE	IDENTIFICATION/A. Thin-Layer Chromatography, IDENTIFICATION/A.	Mary Koleck
Revision	DESOXIMETASONE GEL PF 42(1) Pg. ONLINE	IDENTIFICATION/A. Thin-Layer Chromatography, IDENTIFICATION/A., ASSAY/Procedure	Mary Koleck
Revision	DESOXIMETASONE OINTMENT PF 42(1) Pg. ONLINE	IDENTIFICATION/A. Thin-Layer Chromatography, IDENTIFICATION/A.	Mary Koleck
Revision	DESOXYCHOLIC ACID PF 41(5) Pg. ONLINE	{Title} Deoxycholic, DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/A. Infrared Absorption <197A>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Limit of Lead, IMPURITIES/Heavy Metals <231>, Method II, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Optical Rotation <781S>, Specific Rotation, SPECIFIC TESTS/Melting Range or Temperature <741>, Class I, SPECIFIC TESTS/Loss on Drying <731>, SPECIFIC TESTS/Water Determination <921>, Method Ic, SPECIFIC TESTS/Clarity of Solution, SPECIFIC TESTS/Color of Solution, SPECIFIC TESTS/Bacterial Endotoxins Test <85>, SPECIFIC TESTS/Microbial Enumeration Tests <61> and Tests for Specified Microorganisms <62>, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>	Galina Holloway
Revision	DEXAMETHASONE TABLETS PF 39(5) Pg. ONLINE	IDENTIFICATION/A. Thin-Layer Chromatography, IDENTIFICATION/A. Infrared Absorption <197>, IDENTIFICATION/B., IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methylprednisolone RS	Domenick Vicchio

Revision	DEXCHLORPHENIRAMINE MALEATE TABLETS PF 41(2) Pg. ONLINE	<p>IDENTIFICATION/A. Identification-Organic Nitrogenous Bases <181>, IDENTIFICATION/A., IDENTIFICATION/C., ASSAY/Procedure, ASSAY/Drug Product Assay Tests-Organic Chemical Medicines, Procedure 1 <321>, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Caffeine RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Dextromethorphan Hydrobromide RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Diphenhydramine Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Doxylamine Succinate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Pseudoephedrine Hydrochloride RS, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Dipyrnidamole Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Dipyrnidamole Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Dipyrnidamole Related Compound C RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Dipyrnidamole Related Compound D RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Dipyrnidamole Related Compound E RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Dipyrnidamole Related Compound F RS</p>	Alan Potts
Revision	DIPYRIDAMOLE PF 41(3) Pg. ONLINE	<p>IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Dipyrnidamole Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Dipyrnidamole Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Dipyrnidamole Related Compound C RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Dipyrnidamole Related Compound D RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Dipyrnidamole Related Compound E RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Dipyrnidamole Related Compound F RS</p>	Sujatha Ramakrishna
Revision	DIPYRIDAMOLE TABLETS PF 41(3) Pg. ONLINE	<p>{Title} Eleuthero Root and Rhizome, DEFINITION/Introduction, IDENTIFICATION/A. HPTLC for Articles of Botanical Origin <203>, COMPOSITION/Content of Eleutherosides B and E</p>	Sujatha Ramakrishna Anton Bzhelyansky

New	ELEUTHERO ROOT AND RHIZOME DRY EXTRACT CAPSULES PF 41(5) Pg. ONLINE	Title, DEFINITION/Introduction, IDENTIFICATION/A. HPLC, STRENGTH/Content of Eleutherosides B and E, PERFORMANCE TESTS/Disintegration and Dissolution <2040>, Disintegration, PERFORMANCE TESTS/Weight Variation <2091>, CONTAMINANTS/Microbial Enumeration Tests <2021>, CONTAMINANTS/Absence of Specified Microorganisms <2022>, Test Procedures, Test for Absence of Salmonella Species and Test Procedures, Test for Absence of Escherichia coli, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Powdered Eleuthero Extract RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Eleutheroside B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Eleutheroside E RS	Natalia Davydova
New	ELEUTHERO ROOT AND RHIZOME DRY EXTRACT TABLETS PF 41(5) Pg. ONLINE	Title, DEFINITION/Introduction, IDENTIFICATION/A. HPLC, STRENGTH/Content of Eleutherosides B and E, PERFORMANCE TESTS/Disintegration and Dissolution <2040>, Disintegration, PERFORMANCE TESTS/Weight Variation <2091>, CONTAMINANTS/Microbial Enumeration Tests <2021>, CONTAMINANTS/Absence of Specified Microorganisms <2022>, Test Procedures, Test for Absence of Salmonella Species and Test Procedures, Test for Absence of Escherichia coli, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Powdered Eleuthero Extract RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Eleutheroside B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Eleutheroside E RS	Natalia Davydova
Revision	POWDERED ELEUTHERO PF 41(5) Pg. ONLINE	{Title} Eleuthero Root and Rhizome Powder, DEFINITION/Introduction, IDENTIFICATION/A. HPTLC for Articles of Botanical Origin <203>, COMPOSITION/Content of Eleutherosides B and E	Anton Bzhelyansky
Revision	POWDERED ELEUTHERO EXTRACT PF 41(5) Pg. ONLINE	{Title} Eleuthero Root and Rhizome Dry Extract, DEFINITION/Introduction, IDENTIFICATION/Thin-Layer Chromatographic Identification Test <201>, COMPOSITION/Content of Eleutherosides B and E, SPECIFIC TESTS/Alcohol Determination <611>, Method II, SPECIFIC TESTS/Other Requirements, ADDITIONAL REQUIREMENTS/Labeling	Anton Bzhelyansky

New	EPOETIN PF 41(5) Pg. ONLINE	<p>Title, Chemical Info/Chemical Structure, Chemical Info/C809H1301N229O24O55, Chemical Info/18,236.06 Da (amino acid sequence), DEFINITION/Introduction, IDENTIFICATION/A. Erythropoietin Bioassays <124>, IDENTIFICATION/B. Peptide Mapping, ASSAY/ Erythropoietin Bioassays <124>, IMPURITIES/Limit of High Molecular Weight Proteins, SPECIFIC TESTS/N-Glycan Profiling, SPECIFIC TESTS/Isoform Distribution, SPECIFIC TESTS/Protein Content, SPECIFIC TESTS/Sterility Tests <71>, SPECIFIC TESTS/Bacterial Endotoxins Test <85>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Endotoxin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Erythropoietin RS</p>	Kevin Carrick
New	EPTACOG ALFA PF 41(3) Pg. ONLINE	<p>Title, Chemical Info/Chemical Structure, Chemical Info/C1982H3054N560O618S28, Chemical Info/INS: (The chemical formula includes the &gamma;-carboxylations and modification of D (Asp) in position 63, and does not include the glycosylations.), Chemical Info/&ape;50,000 (The molecular weight includes the glycosylation.), Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B. Peptide Mapping, ASSAY/Concentration of Eptacog Alfa, ASSAY/Potency, IMPURITIES/Degraded Heavy Chain and Oxidized Forms, IMPURITIES/Gla-Domainless Eptacog Alfa (&gamma;-Carboxylation), IMPURITIES/Dimer and Related Substances of Higher Molecular Mass, IMPURITIES/Non-Activated Factor VII (Single Chain), SPECIFIC TESTS/Glycan Analysis, SPECIFIC TESTS/Bacterial Endotoxins Test <85>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Coagulation Factor VIIa RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Coagulation Factor VIIa for Bioassay RS</p>	
New	EPTACOG ALFA FOR INJECTION PF 41(3) Pg. ONLINE	<p>Title, DEFINITION/Introduction, IDENTIFICATION/A., ASSAY/Content of Eptacog Alfa, ASSAY/Potency, IMPURITIES/Degraded Heavy Chain and Oxidized Forms, IMPURITIES/Dimer and Related Substances of Higher Molecular Mass, SPECIFIC TESTS/Water Determination <921>, Method 1c, SPECIFIC TESTS/Bacterial Endotoxins Test <85>, SPECIFIC TESTS/pH <791>, SPECIFIC TESTS/Sterility Tests <71>, Test for Sterility of the Product to Be Examined, Membrane Filtration, SPECIFIC TESTS/Constituted Solution, ADDITIONAL REQUIREMENTS/Packaging and Storage Requirements <659>, Injection Packaging, Sterile solids packaging, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Coagulation Factor VIIa RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Coagulation Factor VIIa for Bioassay RS</p>	Kevin Carrick

Revision	ESMOLOL HYDROCHLORIDE PF 41(2) Pg. ONLINE	SPECIFIC TESTS/pH <791>	Sujatha Ramakrishna
New	ETHAMBUTOL HYDROCHLORIDE COMPOUNDED ORAL SUSPENSION PF 41(2) Pg. ONLINE	Title, DEFINITION/Introduction, 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>/USP Ethambutol Hydrochloride RS	Jeanne Sun
New	EXENATIDE PF 41(5) Pg. ONLINE	Title, Chemical Info/Chemical Structure, Chemical Info/C184H282N50O60S, Chemical Info/4186.57, Chemical Info/I-Histidyl-glycyl-I-glutamyl-glycyl-I-threonyl-I-phenylalanyl-I-threonyl-I-seryl-I-aspartyl-I-leucyl-I-seryl-I-lysyl-I-glutamyl-I-methionyl-I-glutamyl-I-glutamyl-I-glutamyl-I-alanyl-I-valyl-I-arginyl-I-leucyl-I-phenylalanyl-I-isoleucyl-I-glutamyl-I-tryptophyl-I-leucyl-I-lysyl-I-asparaginyI-glycyl-glycyl-I-prolyl-I-seryl-I-seryl-glycyl-I-alanyl-I-prolyl-I-prolyl-I-prolyl-I-serinamide, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. HPLC, IDENTIFICATION/B. Amino Acid Analysis, IDENTIFICATION/C., ASSAY/Procedure, ??UNKNOWN??/Procedure 1: Exenatide Related Substances and Impurities, ??UNKNOWN??/Procedure 2: N-Acetyl His1-Exenatide, ??UNKNOWN??/Procedure 3: Limit of d-His1 Exenatide, ??UNKNOWN??/Procedure 4: Limit of Phosphate, ??UNKNOWN??/Procedure 5, Trifluoroacetic Acid (TFA) in Peptides <503.1>, OTHER COMPONENTS/Acetic Acid In Peptides <503>, SPECIFIC TESTS/Bacterial Endotoxins Test <85>, SPECIFIC TESTS/Microbial Enumeration Tests <61> and Tests for Specified Microorganisms <62>, SPECIFIC TESTS/Water Determination <921>, Method Ic, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP [N-Acetyl-His1]-Exenatide RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Endotoxin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Exenatide RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP [Glu13]-Exenatide RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP [Met(O)14]-Exenatide RS	Anita Szajek

New	FEBANTEL PF 41(4) Pg. ONLINE	<p>Title, Chemical Info/Chemical Structure, Chemical Info/C₂₀H₂₂N₄O₆S, Chemical Info/446.48, Chemical Info/Carbamic acid, [[2-[(methoxyacetyl)amino]-4-(phenylthio)phenyl]carbonimidoyl]bis-, dimethyl ester;, Chemical Info/Dimethyl { [2-(2-methoxyacetamido)-4-(phenylthio)phenyl]imidocarbonyl} dicarbamate, 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/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Febantel RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Febantel Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Febantel Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Febantel Related Compound C RS</p>	Morgan Puderbaugh
Revision	FLUORESCEIN PF 40(5) Pg. ONLINE	<p>IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Fluorescein Related Compound C RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Phthalic Acid RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Resorcinol RS</p>	Feiwen Mao
New	FLUTICASONE PROPIONATE LOTION PF 41(3) Pg. ONLINE	<p>Title, DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, 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 Fluticasone Propionate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Fluticasone Propionate Related Compound D RS</p>	Gerald Hsu

Revision FLUTICASONE PROPIONATE NASAL SPRAY PF 41(6) Pg. ONLINE

ASSAY/Procedure, OTHER COMPONENTS/Content of Benzalkonium Chloride, PERFORMANCE TESTS/Delivered Dose Uniformity (within container), PERFORMANCE TESTS/Delivered Dose Uniformity (within batch), IMPURITIES/Organic Impurities, SPECIFIC TESTS/Foreign Particulates, SPECIFIC TESTS/Droplet Size Distribution, SPECIFIC TESTS/Spray Pattern, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Benzalkonium Bromide RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Docusate Sodium RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Fluticasone Propionate Related Compound D RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Fluticasone Propionate Related Compounds Mixture RS This Reference Standard is a mixture of fluticasone propionate and fluticasone propionate related compounds D and F, and the chemical names for all are given below: Fluticasone propionate: S-Fluoromethyl 6 α ; 9 α ; -difluoro-11 β ; -hydroxy-16 α ; -methyl-3-oxo-17 α ; -propionyloxyandrosta-1,4-diene-17 β ; -carbothioate. Fluticasone propionate related compound D: S-Methyl6 α ; 9 α ; -difluoro-11 β ; -hydroxy-16 α ; -methyl-3-oxo-17 α ; -propionyloxy-androsta-1,4-diene-17 β ; -carbothioate. Fluticasone propionate related compound F: 6 α ; 9 α ; -Difluoro-11 β ; 17 α ; -dihydroxy-16 α ; -methyl-3-oxoandrosta-1,4-diene-17 β ; -carboxylic acid.

[Ravi Ravichandran](#)

New FROVATRIPTAN TABLETS PF 41(5) 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 Frovatriptan Succinate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Frovatriptan Related Compound A RS

[Heather Joyce](#)

New FROVATRIPTAN SUCCINATE PF 41(5) Pg. ONLINE

Title, Chemical Info/Chemical Structure, Chemical Info/C₁₄H₁₇N₃O·C₄H₆O₄·H₂O, Chemical Info/379.41, Chemical Info/(+)-(R)-2,3,4,9-Tetrahydro-3-(methylamino)-1H-carbazole-6-carboxamide butanedioate (1:1), monohydrate, Chemical Info/(+)-(R)-5,6,7,8-Tetrahydro-6-(methylamino)carbazole-3-carboxamide succinate (1:1), monohydrate, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Limit of Palladium, IMPURITIES/Limit of d-Camphor Sulfonic Acid, IMPURITIES/Organic Impurities, IMPURITIES/Enantiomeric Purity, SPECIFIC TESTS/Water Determination <921>, Method I, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP d-Camphor Sulfonic Acid RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Frovatriptan Racemate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Frovatriptan Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Frovatriptan Succinate RS

[Heather Joyce](#)

Revision HARD GELATIN CAPSULE SHELL PF 41(6) Pg. ONLINE

Title, DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B., SPECIFIC TESTS/Loss on Drying <731>, SPECIFIC TESTS/Disintegration <701>, SPECIFIC TESTS/Microbial Enumeration Tests <61> and Tests for Specified Microorganisms <62>, ADDITIONAL REQUIREMENTS/Packaging and Storage

[Margareth Marques](#)

Revision GONADORELIN ACETATE PF 40(3) Pg. ONLINE

DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, OTHER COMPONENTS/Acetic Acid in Peptides <503>, IMPURITIES/Gonadorelin Related Impurities, IMPURITIES/Acetic Acid and, IMPURITIES/Limit of Fluoride, SPECIFIC TESTS/Optical Rotation, Specific Rotation <781S>, SPECIFIC TESTS/Bacterial Endotoxins <85>, SPECIFIC TESTS/Microbial Enumeration Tests <61> and Tests for Specified Microorganisms <62>, SPECIFIC TESTS/Amino Acid Analysis, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Endotoxin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Glacial Acetic Acid RS

[Trish Li](#)

Revision	HISTIDINE PF 41(6) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Heavy Metals <231>, Method I, 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 Biotin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP I-Lysine Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Thiamine Hydrochloride RS	
Revision	HYDROXYZINE HYDROCHLORIDE INJECTION PF 41(1) Pg. ONLINE	ASSAY/Procedure, IMPURITIES/Limit of 4-Chlorobenzophenone, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Hydroxyzine Related Compound A RS 1-[4-Chlorophenyl]phenylmethyl]piperazine.C17H19ClN2286.80	Huy Dinh
Revision	HYDROXYZINE HYDROCHLORIDE ORAL SOLUTION PF 42(1) Pg. ONLINE	IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP 4-Chlorobenzophenone RS 4-Chlorobenzophenone.C13H9ClO216.66, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Hydroxyzine Related Compound A RS p-Chlorobenzhydrylpiperazine; Also known as 1-[4-Chlorophenyl]phenylmethyl]piperazine.C17H19ClN2286.80	Heather Joyce
Revision	HYDROXYZINE PAMOATE PF 42(1) Pg. ONLINE	IDENTIFICATION/Infrared Absorption <197K>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP 4-Chlorobenzophenone RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Hydroxyzine Related Compound A RS	Heather Joyce
Revision	HYDROXYZINE PAMOATE CAPSULES PF 42(1) 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 4-Chlorobenzophenone RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Hydroxyzine Related Compound A RS	Heather Joyce

New	ILOPERIDONE PF 42(1) Pg. ONLINE	<p>Title, Chemical Info/Chemical Structure, Chemical Info/C24H27FN2O4, Chemical Info/426.48, Chemical Info/Ethanone, 1-[4-[3-[4-(6-fluoro-1,2-benzisoxazol-3-yl)-1-piperidinyl]propoxy]-3-methoxyphenyl]-; , Chemical Info/4&prime;-[3-[4-(6-Fluoro-1,2-benzisoxazol-3-yl)piperidino]propoxy]-3&prime;-methoxyacetophenone, 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/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Chloropropyl Vanillin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Iloperidone RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Iloperidone Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Paliperidone Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Vanillin RS</p>	Heather Joyce
Revision	IMIPRAMINE HYDROCHLORIDE TABLETS PF 41(2) Pg. ONLINE	<p>IDENTIFICATION/A. Infrared Absorption <197K>, 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 Depramine RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Desipramine Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Iminodibenzyl RS</p>	Heather Joyce
Revision	INDAPAMIDE PF 41(2) Pg. ONLINE	<p>DEFINITION/Introduction, IDENTIFICATION/B. Ultraviolet Absorption <197U>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Chromatographic Purity, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Indapamide Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Indapamide Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Indapamide Related Compound C RS</p>	Sujatha Ramakrishna
Revision	INDAPAMIDE TABLETS PF 41(2) Pg. ONLINE	<p>ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Indapamide Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Indapamide Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Indapamide Related Compound C RS</p>	Sujatha Ramakrishna

Revision	INDOMETHACIN ORAL SUSPENSION PF 42(1) Pg. ONLINE	IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, OTHER COMPONENTS/Content of Sorbic Acid (if present), IMPURITIES/Limit of 4-Chlorobenzoic Acid, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Indomethacin Related Compound B RS	Wei Yang
Revision	IRON SUCROSE INJECTION PF 41(6) Pg. ONLINE	ASSAY/Iron, ADDITIONAL REQUIREMENTS/Labeling	Sujatha Ramakrishna
Revision	KRILL OIL CAPSULES PF 41(3) Pg. ONLINE	IDENTIFICATION/A. Fatty Acid Profile, IDENTIFICATION/B. Phospholipid Profile, STRENGTH/Content of Total Phospholipids	Natalia Davydova
Revision	KRILL OIL DELAYED-RELEASE CAPSULES PF 41(3) Pg. ONLINE	IDENTIFICATION/A. Fatty Acid Profile, IDENTIFICATION/B. Phospholipid Profile, STRENGTH/Content of Total Phospholipids	Natalia Davydova
New	L##_EPTACOG alfa, Dionex CarboPac PA100 PF 41(3) Pg. ONLINE	L##_ (Eptacog Alfa, Dionex CarboPac PA100)	Trish Li
New	L##_Rosuvastatin Calcium, Chiracel OJ-RH PF 40(6) Pg. ONLINE	L##_ (Rosuvastatin Calcium, CHIRALCEL OJ-RH)	Sujatha Ramakrishna
New	L##_Sodium Nitrite, IonPac AS12A PF 40(6) Pg. ONLINE	L##_ (Sodium Nitrite, IonPac AS12A)-	Sujatha Ramakrishna
New	L##_EPTACOG alfa, Dionex DNAPac PA100 PF 41(3) Pg. ONLINE	L##_ (Eptacog Alfa, Dionex DNAPac PA100)	Trish Li
Revision	L85 PF 39(3) Pg. ONLINE	L##_ (Adenine, GC <227>, Acclaim Mixed-Mode WCX-1)	Clydewyn Anthony
New	LEUCOVORIN CALCIUM COMPOUNDED ORAL SUSPENSION PF 41(2) Pg. ONLINE	Title, DEFINITION/Introduction, 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>/USP Leucovorin Calcium RS	Jeanne Sun
Revision	LEVAMISOLE HYDROCHLORIDE PF 41(3) Pg. ONLINE	IDENTIFICATION/A., IDENTIFICATION/A. Infrared Absorption <197>, IDENTIFICATION/B., IMPURITIES/Organic Impurities, SPECIFIC TESTS/Melting Range or Temperature <741>, SPECIFIC TESTS/Light Absorption, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Levamisole System Suitability Mixture RS	Morgan Puderbaugh
Revision	LEVONORGESTREL PF 41(5) Pg. ONLINE	IDENTIFICATION/C., ASSAY/Procedure, IMPURITIES/Limit of Ethynyl Group, IMPURITIES/Organic Impurities	Gerald Hsu
Revision	LITHIUM CARBONATE PF 41(3) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Calcium, IMPURITIES/Sodium, IMPURITIES/Calcium and Sodium, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>	Ren-Hwa Yeh
New	MARFEY'S REAGENT PF 41(6) Pg. ONLINE	Marfey's Reagent	Hillary Cai
Revision	MEDROXYPROGESTERONE ACETATE INJECTABLE SUSPENSION PF 41(3) Pg. ONLINE	IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Medroxyprogesterone Acetate Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Medroxyprogesterone Acetate Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Meaestrol Acetate RS	Gerald Hsu

Revision	MEDROXYPROGESTERONE ACETATE TABLETS PF 41(3) Pg. ONLINE	IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Medroxyprogesterone Acetate Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Medroxyprogesterone Acetate Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Medroxyprogesterone Acetate RS	Gerald Hsu
Revision	METHOTREXATE INJECTION PF 41(4) Pg. ONLINE	IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methotrexate Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methotrexate Related Compound C RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methotrexate Related Compound E RS	Feiwen Mao
Revision	METHOTREXATE TABLETS PF 41(4) Pg. ONLINE	IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methotrexate Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methotrexate Related Compound C RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methotrexate Related Compound E RS	Feiwen Mao
New	METHYL CIS-11-EICOSENOATE PF 41(6) Pg. ONLINE	Methyl cis-11-eicosenoate	Hong Wang
New	METHYL 12-KETOSTEARATE PF 41(6) Pg. ONLINE	Methyl 12-Ketostearate	Hong Wang
Revision	METHYLENE BLUE INJECTION PF 42(1) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B. Thin-Layer Chromatographic Identification Test <201>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, IMPURITIES/Limit of Azure B, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Azure B RS, DEFINITION/Introduction	Donald Min
Revision	METHYLPREDNISOLONE PF 41(2) Pg. ONLINE	IDENTIFICATION/B. Ultraviolet Absorption <197U>, IDENTIFICATION/C., IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methylprednisolone Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methylprednisolone Related Compound C RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methylprednisolone Related Compound D RS	Gerald Hsu

Revision	METHYLPREDNISOLONE TABLETS PF 41(2) Pg. ONLINE	IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methylprednisolone Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methylprednisolone Related Compound C RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methylprednisolone Related Compound D RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Prednisone RS	Gerald Hsu
Revision	METHYLPREDNISOLONE ACETATE PF 41(6) Pg. ONLINE	IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/A. Infrared Absorption <197>, IDENTIFICATION/B. Ultraviolet Absorption <197U>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Dexamethasone Acetate RS 9-Fluoro-11β,17,21-trihydroxy-16α-methylpregna-1,4-diene-3,20-dione 21-acetate.C24H31FO64.34.51	Gerald Hsu
Revision	METHYLPREDNISOLONE ACETATE INJECTABLE SUSPENSION PF 41(6) Pg. ONLINE	IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/A. Infrared Absorption <197>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Dexamethasone Acetate RS 9-Fluoro-11β,17,21-trihydroxy-16α-methylpregna-1,4-diene-3,20-dione 21-acetate.C24H31FO64.34.51	Gerald Hsu
Revision	METOPROLOL TARTRATE INJECTION PF 42(1) Pg. ONLINE	IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Metoprolol Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Metoprolol Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Metoprolol Related Compound C RS	Donald Min
Revision	MICONAZOLE PF 41(5) Pg. ONLINE	ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Miconazole Related Compound C RS	Clydewyn Anthony
New	MICONAZOLE COMPOUNDED OPHTHALMIC SOLUTION PF 41(2) Pg. ONLINE	Title, DEFINITION/Introduction, ASSAY/Procedure, SPECIFIC TESTS/pH <791>, SPECIFIC TESTS/Sterility Tests <71>, 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 Miconazole RS	Jeanne Sun
Revision	MICONAZOLE NITRATE TOPICAL POWDER PF 41(2) Pg. ONLINE	IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Miconazole Related Compound F RS	Alan Potts

New	MILBEMYCIN OXIME PF 40(4) Pg. ONLINE	Chemical Info/Chemical Structure, Chemical Info/Mixture of milbemycin A3 oxime and milbemycin A4 oxime, Chemical Info/CAS, Chemical Info/Milbemycin A3 Oxime, Chemical Info/C31H43NO7, Chemical Info/541.68, Chemical Info/Milbemycin B, 5-O-demethyl-28-deoxy-25-methyl-6,28-epoxy-23-hydroxyimino-, [6R,23S,25S(E)]-; (2 α ;E,4E,5 β ;S,6R,6 β ;S,8E,11R,13R,15S,17 α ;R,20 α ;R,20 β ;S)-6 β ; -ethyl-3 β ;4 β ;5 β ;6,6 β ;7,10,11,14,15,17 α ;20,20 α ;20 β ; -tetradecahydro-20 β ; -hydroxy-5 β ;6,8,19-tetramethylspiro[11,15-methano-2H,13H,17H-furo[4,3,2-pq][2,6]benzodioxacyclooctadecin-13,2 β ; -[2H]pyran]-17-one 20-oxime., Chemical Info/Milbemycin A4 Oxime, Chemical Info/C32H45NO7, Chemical Info/555.70, Chemical Info/Milbemycin B, 5-O-demethyl-28-deoxy-25-ethyl-6,28-epoxy-23-hydroxyimino-, [6R,23S,25S(E)]-; (2 α ;E,4E,5 β ;S,6R,6 β ;S,8E,11R,13R,15S,17 α ;R,20 α ;R,20 β ;S)-6 β ; -ethyl-3 β ;4 β ;5 β ;6,6 β ;7,10,11,14,15,17 α ;20,20 α ;20 β ; -tetradecahydro-20 β ; -hydroxy-5 β ;6,8,19-tetramethylspiro[11,15-methano-2H,13H,17H-furo[4,3,2-pq][2,6]benzodioxacyclooctadecin-13,2 β ; -[2H]pyran]-17-one 20-oxime., DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Water Determination, Method I <921>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP IDENTIFICATION/Infrared Absorption <197K>, ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, IMPURITIES/Organic Impurities	Morgan Puderbaugh
Revision	MORPHINE SULFATE EXTENDED-RELEASE CAPSULES PF 41(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, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Moxifloxacin Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Moxifloxacin Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Moxifloxacin Related Compound F RS	Hillary Cai
New	MOXIFLOXACIN TABLETS PF 42(1) Pg. ONLINE		Shankari Shivaprasad

New	NAPROXEN SODIUM AND PSEUDOEPHEDRINE HYDROCHLORIDE EXTENDED-RELEASE TABLETS PF 40(5) Pg. ONLINE	Title, DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Naproxen Sodium Related Impurities, IMPURITIES/Pseudoephedrine Hydrochloride Related Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ephedrine Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Naproxen Related Compound K RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Naproxen Related Compound L RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Naproxen Sodium RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Pseudoephedrine Hydrochloride RS	Hillary Cai
New	NEBIVOLOL TABLETS PF 41(5) 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 Nebivolol Hydrochloride RS	Donald Min

New	NEBIVOLOL HYDROCHLORIDE PF 41(5) 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′; -iminodiethanol hydrochloride, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., IDENTIFICATION/C. Identification Tests-General <191>, Chloride, ASSAY/Procedure, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Organic Impurities, IMPURITIES/Content of Nebivolol Related Compound C and Nebivolol Related Compound D, SPECIFIC TESTS/Water Determination <921>, Method I, SPECIFIC TESTS/Optical Rotation <781S>, Procedures, Specific Rotation, 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 B 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	Donald Min
Revision	NORETHINDRONE PF 42(1) Pg. ONLINE	IDENTIFICATION/<197K>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Chromatographic Purity, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Melting Range or Temperature <741>, SPECIFIC TESTS/Completeness of Solution, SPECIFIC TESTS/Limit of Ethynyl Group, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Norethindrone Related Compound B RS	Ren-Hwa Yeh
Revision	NORETHINDRONE TABLETS PF 42(1) Pg. ONLINE	IDENTIFICATION/A. Infrared Absorption, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Norethindrone Related Compound B RS	Ren-Hwa Yeh
Revision	NORETHINDRONE ACETATE PF 42(1) Pg. ONLINE	IDENTIFICATION/Infrared Absorption <197K>, IDENTIFICATION/B., IDENTIFICATION/C., ASSAY/Procedure, IMPURITIES/Chromatographic Purity, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Limit of Ethynyl Group, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Norethindrone RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Norethindrone Related Compound B RS	Ren-Hwa Yeh

Revision NORETHINDRONE ACETATE TABLETS PF 42(1) Pg. ONLINE

IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, Content Uniformity, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Norethindrone RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Norethindrone Related Compound B RS Title, DEFINITION/Introduction, IDENTIFICATION/A. HPTLC for Articles of Botanical Origin <203>, IDENTIFICATION/B. HPTLC for Articles of Botanical Origin <203>, COMPOSITION/Content of Oleuropein, 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>, Foreign Organic Matter, SPECIFIC TESTS/Loss on Drying <731>, SPECIFIC TESTS/Articles of Botanical Origin <561>, Total Ash, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Oleanolic Acid RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Oleuropein RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Olive Leaf Dry Extract RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Rutin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards

[Ren-Hwa Yeh](#)

New OLIVE LEAF PF 41(5) Pg. ONLINE

[Anton Bzhelyansky](#)

New	OLIVE LEAF DRY EXTRACT PF 41(5) Pg. ONLINE	<p>Title, DEFINITION/Introduction, IDENTIFICATION/A. HPTLC for Articles of Botanical Origin <203>, IDENTIFICATION/B. HPTLC for Articles of Botanical Origin <203>, COMPOSITION/Content of Oleuropein, CONTAMINANTS/Articles of Botanical Origin <561>, Pesticide Residue Analysis, CONTAMINANTS/Botanical Extracts <565>, Residual Solvents, 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 Oleanolic Acid RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Oleuropein RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Olive Leaf Dry Extract RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Rutin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP</p>	Anton Bzhelyansky
New	OLIVE LEAF POWDER PF 41(5) Pg. ONLINE	<p>Title, DEFINITION/Introduction, IDENTIFICATION/A. HPTLC for Articles of Botanical Origin <203>, IDENTIFICATION/B. HPTLC for Articles of Botanical Origin <203>, COMPOSITION/Content of Oleuropein, 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/Loss on Drying <731>, SPECIFIC TESTS/Articles of Botanical Origin <561>, Total Ash, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Oleanolic Acid RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Oleuropein RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Olive Leaf Dry Extract RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Rutin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP</p>	Anton Bzhelyansky Sujatha Ramakrishna
New	PAIRED ION CHROMATOGRAPHY REAGENT PF 42(1) Pg. ONLINE	Paired Ion Chromatography Reagent	Anton Bzhelyansky Sujatha Ramakrishna
Revision	PHENAZOPYRIDINE HYDROCHLORIDE PF 41(2) Pg. ONLINE	<p>DEFINITION/Introduction, IDENTIFICATION/C., IDENTIFICATION/D. Identification Tests-General, Chloride <191>, ASSAY/Procedure, IMPURITIES/Ordinary Impurities <466>, IMPURITIES/Organic Impurities</p>	Hillary Cai

Revision	PHENAZOPYRIDINE HYDROCHLORIDE TABLETS PF 41(2) Pg. ONLINE	IDENTIFICATION/A., IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage	Hillary Cai
New	PIMOBENDAN PF 42(1) Pg. ONLINE	Title, Chemical Info/Chemical Structure, Chemical Info/C19H18N4O2, Chemical Info/334.37, Chemical Info/3(2H)-Pyridazinone, 4,5-dihydro-6-[2-(4-methoxyphenyl)-1H-benzimidazol-5-yl]-5-methyl-, (\pm)-; , Chemical Info/(\pm)-4,5-Dihydro-6-[2-(p-methoxyphenyl)-5-benzimidazolyl]-5-methyl-3(2H)-pyridazinone; , Chemical Info/6-[2-(4-Methoxyphenyl)-1H-benzimidazol-5-yl]-5-methyl-4,5-dihydropyridazin-3(2H)-one, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197>, 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/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Pimobendan RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Pimobendan Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Pimobendan Related Compound B	Morgan Puderbaugh
Revision	POLYOXYL 35 CASTOR OIL PF 41(5) Pg. ONLINE	Chemical Info, IDENTIFICATION/C., IDENTIFICATION/C. Identity by Fatty Acid Composition, IMPURITIES/Ethylene Oxide and Dioxane <228>, Method I, IMPURITIES/Ethylene Glycol, Diethylene Glycol, and Triethylene Glycol in Ethoxylated Substances <469>, SPECIFIC TESTS/Viscosity-Capillary Methods <911>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methyl Linoleate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methyl Oleate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methyl Palmitate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methyl Ricinoleate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methyl Stearate RS	Hong Wang
Revision	POLYOXYL 40 HYDROGENATED CASTOR OIL PF 41(5) Pg. ONLINE	Chemical Info, DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/A. Identity by Fatty Acid Composition, IMPURITIES/Ethylene Oxide and Dioxane <228>, Method I, IMPURITIES/Limit of Nickel, SPECIFIC TESTS/Fats and Fixed Oils <401>, Hydroxyl Value, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>	Hong Wang
Revision	POTASSIUM CITRATE EXTENDED-RELEASE TABLETS PF 42(1) Pg. ONLINE	ASSAY/Procedure	Natalia Davydova

Revision PREGABALIN PF 41(6) Pg. ONLINE

Title, Chemical Info/Chemical Structure, Chemical Info/C8H17NO2, Chemical Info/159.23, Chemical Info/(S)-3-(Aminomethyl)-5-methylhexanoic acid, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., ASSAY, ASSAY/Procedure, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Chloride and Sulfate <221>, Chloride, IMPURITIES/Organic Impurities, IMPURITIES/Enantiomeric Purity, SPECIFIC TESTS/Loss on Drying <731>, ADDITIONAL REQUIREMENTS, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Mandelic Acid RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Pregabalin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Pregabalin Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Pregabalin Related Compound C RS

[Hillary Cai](#)

New RED CLOVER AERIAL PARTS ISOFLAVONE AGLYCONES DRY EXTRACT PF 41(5) Pg. ONLINE

DEFINITION/Introduction, IDENTIFICATION/A. HPTLC for Articles of Botanical Origin <203>, IDENTIFICATION/B. HPLC, COMPOSITION/Content of Isoflavones, CONTAMINANTS/Articles of Botanical Origin <561>, Pesticide Residue Analysis, CONTAMINANTS/Botanical Extracts <565>, Preparations, General Pharmacopeial Requirements, Residual Solvents, 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/Residue on Ignition <281>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Biochanin A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Daidzein RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Formononetin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Genistein RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Red Clover Aerial Parts Isoflavone Aglycones Dry Extract RS

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New ROSUVASTATIN TABLETS PF 40(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, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Rosuvastatin Calcium RS

[Sujatha Ramakrishna](#)

New ROSUVASTATIN CALCIUM PF 40(2) Pg. ONLINE

Title, Chemical Info/Chemical Structure, Chemical Info/(C₂₂H₂₇FN₃O₆S)₂ · Ca, Chemical Info/1001.14, Chemical Info/6-Heptenoic acid, 7-[4-(4-fluorophenyl)-6-(1-methylethyl)-2-[methyl(methylsulfonyl)amino]-5-pyrimidinyl]-3,5-dihydroxy-, calcium salt (2:1), (3R, 5S, 6E);, Chemical Info/[S-[R*,S*-(E)]]-7-[4-(4-Fluorophenyl)-6-(1-methylethyl)-2-[methyl(methylsulfonyl)amino]-5-pyrimidinyl]-3,5-dihydroxy-6-heptenoic acid, calcium salt (2:1);, Chemical Info/Calcium (3R,5S,E)-7-(4-(4-fluorophenyl)-6-isopropyl-2-(N-methylmethylsulfonamido)pyrimidin-5-yl)-3,5-dihydroxyhept-6-enoate salt (2:1), Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., IDENTIFICATION/C. Identification Tests-General, Calcium <191>, ASSAY/Procedure, IMPURITIES/Organic Impurities, IMPURITIES/Enantiomeric Purity, IMPURITIES/Limit of Chloride, SPECIFIC TESTS/Water Determination, Method Ic <921>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Rosuvastatin Calcium RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Rosuvastatin Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Rosuvastatin Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Rosuvastatin Related Compound C RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Rosuvastatin Related Compound D RS

[Sujatha Ramakrishna](#)

Revision SALICYLIC ACID TOPICAL FOAM PF 41(2) Pg. ONLINE

IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Phenol RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Salicylic Acid Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Salicylic Acid Related Compound B RS

[Alan Potts](#)

New SALIX SPECIES BARK PF 42(1) Pg. ONLINE

Title, DEFINITION/Introduction, IDENTIFICATION/A. HPTLC for Articles of Botanical Origin <203>, IDENTIFICATION/B. HPLC, COMPOSITION/Content of Salicin, 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/Salicylates Profile, SPECIFIC TESTS/Botanical Characteristics, SPECIFIC TESTS/Articles of Botanical Origin <561>, Methods of Analysis, Foreign Organic Matter, 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, SPECIFIC TESTS/Articles of Botanical Origin <561>, Methods of Analysis, Water-Soluble Extractives, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Salicin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Salix Species

[Anton Bzhelyansky](#)

New SALIX SPECIES BARK DRY EXTRACT PF 42(1) Pg. ONLINE

Title, DEFINITION/Introduction, IDENTIFICATION/A. HPTLC for Articles of Botanical Origin <203>, IDENTIFICATION/B. HPLC, COMPOSITION/Content of Salicin, CONTAMINANTS/Articles of Botanical Origin <561>, Pesticide Residue Analysis, CONTAMINANTS/Botanical Extracts <565>, Preparations, General Pharmacopeial Requirements, Residual Solvents, 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/Salicylates Profile and Limit of Free Salicin, SPECIFIC TESTS/Water Determination <921>, Method Ia, 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 Salicin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Salix Species

[Anton Bzhelyansky](#)

New	SALIX SPECIES BARK POWDER PF 42(1) Pg. ONLINE	<p>Title, DEFINITION/Introduction, IDENTIFICATION/A. HPTLC for Articles of Botanical Origin <203>, IDENTIFICATION/B. HPLC, COMPOSITION/Content of Salicin, 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/Salicylates Profile and Limit of Free Salicin, SPECIFIC TESTS/Botanical Characteristics, 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, SPECIFIC TESTS/Articles of Botanical Origin <561>, Methods of Analysis, Water-Soluble Extractives, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Salicin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Salix Species</p>	Anton Bzhelyansky
Revision	SODIUM NITRITE PF 40(5) Pg. ONLINE	<p>DEFINITION/Introduction, IDENTIFICATION/C., ASSAY/Procedure, IMPURITIES/Limit of Aluminum, Iron, and Selenium, IMPURITIES/Limit of Sodium Nitrate, IMPURITIES/Limit of Calcium and Potassium, IMPURITIES/Limit of Alkyl Naphthalene Sulfonates (if present), IMPURITIES/Limit of Carbonate, IMPURITIES/Total Non-Purgeable Organic Content, IMPURITIES/Limit of Sulfate, IMPURITIES/Limit of Chloride, SPECIFIC TESTS/Bacterial Endotoxins Test <85>, SPECIFIC TESTS/Microbial Enumeration Tests <61>, SPECIFIC TESTS/pH <791>, SPECIFIC TESTS/Insoluble Matter, ADDITIONAL REQUIREMENTS/USP Reference Standards <11></p>	Sujatha Ramakrishna
Revision	SODIUM NITRITE INJECTION PF 40(5) Pg. ONLINE	<p>IDENTIFICATION/C., ASSAY/Procedure, IMPURITIES/Limit of Sodium Nitrate, IMPURITIES/Limit of Nitrogen Oxide (NOx) Related Impurities, SPECIFIC TESTS/Bacterial Endotoxins Test <85>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Sodium Nitrite RS</p>	Sujatha Ramakrishna

Revision	SPIRONOLACTONE PF 42(1) Pg. ONLINE	<p>IDENTIFICATION/A. Infrared Absorption <197K><197>, IDENTIFICATION/B. Ultraviolet Absorption <197U>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Ordinary Impurities <466>, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Spironolactone Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Spironolactone Related Compound C RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Spironolactone Related Compound D RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Spironolactone Epimer Mixture RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Spironolactone Related Compound I RS</p>	Donald Min
Revision	SILVER SULFADIAZINE CREAM PF 42(1) Pg. ONLINE	<p>IDENTIFICATION/A. Thin-Layer Chromatographic Identification Test <201>, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Sulfadiazine RS</p>	Praveen Pabba Sridevi Ramachandran
New	SULFAGUANIDINE PF 41(4) Pg. ONLINE	Sulfaguanidine	
New	TERIPARATIDE INJECTION PF 41(4) Pg. ONLINE	<p>Title, DEFINITION/Introduction, IDENTIFICATION/A., ASSAY/Procedure, Product-Related Impurities, SPECIFIC TESTS/pH <791>, SPECIFIC TESTS/Bacterial Endotoxins Test <85>, SPECIFIC TESTS/Sterility Tests <71>, Test for Sterility of the Product to Be Examined, Membrane Filtration, SPECIFIC TESTS/Particulate Matter in Injections <788>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Endotoxin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Teriparatide RS</p>	Edith Chang
Revision	TESTOSTERONE PF 41(4) Pg. ONLINE	<p>IDENTIFICATION/Infrared Absorption <197K>, IDENTIFICATION/B. Ultraviolet Absorption <197U>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Melting Range or Temperature <741>, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Exemestane Related Compound C RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Testosterone Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Testosterone Related Compound C RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Testosterone Related Compound I RS</p>	Ren-Hwa Yeh

New	TESTOSTERONE TOPICAL GEL PF 41(6) Pg. ONLINE	Title, DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Viscosity-Rotational Methods <912>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Testosterone RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Testosterone Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Testosterone Related Compound C RS	Ren-Hwa Yeh
New	TRANEXAMIC ACID INJECTION PF 42(1) Pg. ONLINE	Title, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/pH <791>, SPECIFIC TESTS/Particulate Matter in Injections <788>, SPECIFIC TESTS/Sterility Tests <71>, SPECIFIC TESTS/Bacterial Endotoxins Test <85>, SPECIFIC TESTS/Other Requirements, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Endotoxin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Tranexamic Acid RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Tranexamic Acid Related Compound C RS	Donald Min
Revision	TRETINOIN PF 41(4) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/B. Ultraviolet Absorption <197U>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Limit of Isotretinoin, IMPURITIES/Organic Impurities	Feiwen Mao
Revision	TRETINOIN CREAM PF 41(4) Pg. ONLINE	IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Isotretinoin RS	Feiwen Mao
Revision	TRETINOIN GEL PF 42(1) Pg. ONLINE	IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Isotretinoin RS	Feiwen Mao
Revision	USP AND NF EXCIPIENTS, LISTED BY CATEGORY PF 41(5) Pg. ONLINE	{Emulsifying Agent} Desoxycholic Acid	Galina Holloway
Revision	STERILE PURIFIED WATER PF 41(3) Pg. ONLINE	SPECIFIC TESTS/Oxidizable Substances, SPECIFIC TESTS/Total Organic Carbon <643>, Sterile Water	Antonio Hernandez-Cardoso
Revision	STERILE WATER FOR INHALATION PF 41(3) Pg. ONLINE	SPECIFIC TESTS/Oxidizable Substances, SPECIFIC TESTS/Total Organic Carbon <643>, Sterile Water	Antonio Hernandez-Cardoso
Revision	STERILE WATER FOR INJECTION PF 41(3) Pg. ONLINE	SPECIFIC TESTS/Oxidizable Substances, SPECIFIC TESTS/Total Organic Carbon <643>, Sterile Water	Antonio Hernandez-Cardoso
Revision	STERILE WATER FOR IRRIGATION PF 41(3) Pg. ONLINE	SPECIFIC TESTS/Oxidizable Substances, SPECIFIC TESTS/Total Organic Carbon <643>, Sterile Water	Antonio Hernandez-Cardoso
Revision	CARNAUBA WAX PF 41(5) Pg. ONLINE	IDENTIFICATION/A. Infrared Absorption <197F> or <197A>	Jenny Liu

New	ZINC SULFATE COMPOUNDED INJECTION PF 41(2) Pg. ONLINE	<p>Title, DEFINITION/Introduction, ASSAY/Procedure, SPECIFIC TESTS/pH <791>, SPECIFIC TESTS/Sterility Tests <71>, SPECIFIC TESTS/Bacterial Endotoxins Test <85>, SPECIFIC TESTS/Particulate Matter in Injections <788>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Beyond-Use Date, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Endotoxin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Zinc Sulfate RS</p>	Jeanne Sun
Revision	ZIPRASIDONE HYDROCHLORIDE PF 42(1) Pg. ONLINE	<p>IDENTIFICATION/A. Infrared Absorption <197K> <197>, ASSAY/Procedure, IMPURITIES/Limit of Early-Eluting Impurities, IMPURITIES/Limit of Late-Eluting Impurities, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ziprasidone Related Compound F RS</p>	Sridevi Ramachandran
New	ZIPRASIDONE CAPSULES PF 41(5) Pg. ONLINE	<p>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 Ziprasidone Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ziprasidone Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ziprasidone Related Compound F RS</p>	Sridevi Ramachandran