

Compendial Deferrals for USP39-NF34 2S

Category	Monograph Title	Monograph Section	Scientific Liaison
New	<89.1> COLLAGENASE I PF 41(5) Pg. ONLINE	<p>Title, Introduction, DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, PURITY/Procedure, IMPURITIES/Clostripain Activity/Potassium phosphate buffer, IMPURITIES/Clostripain Activity/Dithiothreitol solution, IMPURITIES/Clostripain Activity/Calcium chloride solution, IMPURITIES/Clostripain Activity/Substrate stock solution, IMPURITIES/Clostripain Activity/Substrate solution, IMPURITIES/Clostripain Activity/Sample solution, IMPURITIES/Clostripain Activity/Instrumental conditions, IMPURITIES/Clostripain Activity/Analysis, IMPURITIES/Clostripain Activity/System suitability, IMPURITIES/Clostripain Activity/Acceptance criteria, IMPURITIES/Trypsin Activity/Buffer, IMPURITIES/Trypsin Activity/Substrate stock solution, IMPURITIES/Trypsin Activity/Substrate solution, IMPURITIES/Trypsin Activity/Sample solution, IMPURITIES/Trypsin Activity/Instrumental conditions, IMPURITIES/Trypsin Activity/Analysis, IMPURITIES/Trypsin Activity/System suitability, IMPURITIES/Trypsin Activity/Acceptance criteria, SPECIFIC TESTS/Protein Content, SPECIFIC TESTS/Bacterial Endotoxins Test <85>, SPECIFIC TESTS/Microbial Enumeration Tests <61>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11></p>	Edith Chang

New	<89.2> COLLAGENASE II PF 41(5) Pg. ONLINE	<p>Title, Introduction, DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, PURITY/Procedure, IMPURITIES/Clostripain Activity/Potassium phosphate buffer, IMPURITIES/Clostripain Activity/Dithiothreitol solution, IMPURITIES/Clostripain Activity/Calcium chloride solution, IMPURITIES/Clostripain Activity/Substrate stock solution, IMPURITIES/Clostripain Activity/Substrate solution, IMPURITIES/Clostripain Activity/Sample solution, IMPURITIES/Clostripain Activity/Instrumental conditions, IMPURITIES/Clostripain Activity/Analysis, IMPURITIES/Clostripain Activity/System suitability, IMPURITIES/Clostripain Activity/Acceptance criteria, IMPURITIES/Trypsin Activity/Buffer, IMPURITIES/Trypsin Activity/Substrate stock solution, IMPURITIES/Trypsin Activity/Substrate solution, IMPURITIES/Trypsin Activity/Sample solution, IMPURITIES/Trypsin Activity/Instrumental conditions, IMPURITIES/Trypsin Activity/Analysis, IMPURITIES/Trypsin Activity/System suitability, IMPURITIES/Trypsin Activity/Acceptance criteria, SPECIFIC TESTS/Protein Content, SPECIFIC TESTS/Bacterial Endotoxins Test <85>, SPECIFIC TESTS/Microbial Enumeration Tests <61>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11></p>	Edith Chang
Revision	<123> GLUCAGON BIOIDENTITY TESTS PF 41(2) Pg. ONLINE	<p>INTRODUCTION/Introduction, PROCEDURE/Assay, PROCEDURE/B. In Vitro Cell-Based Bioidentity Test, ADDITIONAL REQUIREMENTS/USP Reference Standards <11></p>	Maura Kibbey
New	<127> FLOW CYTOMETRIC ENUMERATION OF CD34+ CELLS PF 41(5) Pg. ONLINE	<p>Title, INTRODUCTION, IDENTIFICATION OF CD34+ HEMATOPOIETIC STEM CELLS, ENUMERATION CONSIDERATIONS, EQUIPMENT SPECIFICATIONS, FLOW CYTOMETER INSTRUMENT SETUP AND CONSIDERATIONS, REAGENTS, SAMPLE PREPARATION, DATA ACQUISITION AND ANALYSIS, CALCULATION OF ABSOLUTE CD34 NUMBER, ADDITIONAL REQUIREMENTS</p>	Rebecca Potts

New	<165> PREKALLIKREIN ACTIVATOR PF 39(5) Pg. ONLINE	DEFINITION/Introduction, ASSAY/Prekallikrein Assay, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>, Standard Solutions	Kevin Carrick
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
		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>	
New	<327> DRUG PRODUCT IMPURITIES TESTS PF 41(1) Pg. ONLINE		Alan Potts

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

Revision <467> RESIDUAL SOLVENTS PF 41(5) Pg. ONLINE

[Horacio Pappa](#)

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

Revision <476> ORGANIC IMPURITIES IN DRUG SUBSTANCES AND DRUG PRODUCTS PF 41(3) Pg. ONLINE

[Antonio Hernandez-Cardoso](#)

Introduction, PACKAGING, POISON PREVENTION PACKAGING ACT (PPPA), TEMPERATURE AND STORAGE, GENERAL DEFINITIONS, INJECTION PACKAGING, MEDICAL GAS PACKAGING, ASSOCIATED COMPONENTS, TEMPERATURE AND STORAGE DEFINITIONS

Revision <659> PACKAGING AND STORAGE REQUIREMENTS PF 41(3) Pg. ONLINE

[Desmond Hunt](#)

Revision	<821> RADIOACTIVITY PF 41(5) Pg. ONLINE	Introduction, GENERAL CONSIDERATIONS, IDENTIFICATION AND ASSAY OF RADIONUCLIDES, 1. INTRODUCTION, 2. PERSONNEL TRAINING AND DOCUMENTATION, 3. QUALIFICATION OF INSTRUMENTS, 4. ONGOING PERFORMANCE TESTS OF INSTRUMENTS, 5. IDENTIFICATION OF RADIONUCLIDES, 6. ASSAY OF RADIONUCLIDES, 7. GLOSSARY, 8. REFERENCES	Ravi Ravichandran
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
Omission	<1015> AUTOMATED RADIOCHEMICAL SYNTHESIS APPARATUS PF 41(5) Pg. ONLINE	Entire document	Ravi Ravichandran
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-INFRARED 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
New	<1602> SPACERS AND VALVED HOLDING CHAMBERS USED WITH INHALATION AEROSOLS - CHARACTERIZATION TESTS PF 40(1) Pg. ONLINE	Title, INTRODUCTION, MEASUREMENT OF APSD AND SUBFRACTIONS WITH NO DELAY BETWEEN INHALER ACTUATION AND SAMPLING ONSET, MEASUREMENT OF APSD AND SUBFRACTIONS WITH DELAY BETWEEN INHALER ACTUATION AND SAMPLING ONSET, TOTAL MASS OF DRUG DELIVERED FROM A SPACER/VHC WHILE SIMULATING PATIENT TIDAL BREATHING, TOTAL MASS OF DRUG DELIVERED FROM A SPACER/VHC WITH FACEMASK WHILE SIMULATING PATIENT TIDAL BREATHING, Title, Introduction, 1. INTRODUCTION, 2. TEST METHOD SELECTION, 3. MEASUREMENT OF APSD, 4. MASS OF DRUG DELIVERED FROM A SPACER/VHC WHILE SIMULATING PATIENT TIDAL BREATHING	Kahkashan Zaidi

New	<1821> RADIOACTIVITY- THEORY AND PRACTICE PF 41(5) Pg. ONLINE	Title, Introduction, 1. INTRODUCTION, 2. TYPES OF DECAY, 3. GENERAL CONSIDERATIONS, 4. INSTRUMENTATION FOR DETECTION AND MEASUREMENT OF RADIOACTIVE EMISSIONS AND APPLICATIONS, 5. GLOSSARY, 6. REFERENCES	Ravi Ravichandran
New	<1823> POSITRON EMISSION TOMOGRAPHY (PET) DRUGS—INFORMATION PF 41(5) Pg. ONLINE	Title, Introduction, 1. INTRODUCTION, 2. TECHNIQUES FOR PRODUCTION AND QUALITY CONTROL, 3. QUALITY ASSURANCE, 4. PRODUCTION, 5. QUALITY CONTROL, 6. ANALYTICAL METHODOLOGIES, 7. QUALITY ATTRIBUTES, 8. STERILITY ASSURANCE, 9. LABELING, 10. GLOSSARY	Ravi Ravichandran
New	0.1 N HYDROCHLORIC ACID VS PF 41(5) Pg. ONLINE	0.1 N Hydrochloric Acid VS	Margareth Marques
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
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

ALBUTEROL SULFATE PF 41(4) Pg. ONLINE

Chemical Info/Chemical Structure, DEFINITION/Introduction, IDENTIFICATION/B. Ultraviolet Absorption <197U>, IDENTIFICATION/C., IDENTIFICATION/D., ASSAY/Procedure, 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 B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Albuterol Related Compound C RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Levalbuterol Related Compound C RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Levalbuterol Related Compound E RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Levalbuterol Related Compound H RS

[Ravi Ravichandran](#)

		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	
Revision	ALBUTEROL TABLETS PF 41(5) Pg. ONLINE		Mary Koleck
New	(R)-(-)-ALPHA-PHELLANDRENE PF 39(4) Pg. ONLINE	Reagent Specification, (R)-(-)-α-Phellandrene	Hong Wang
New	(+)-ALPHA-PINENE PF 39(4) Pg. ONLINE	Reagent Specification, (+)-α-Pinene	Hong Wang
Revision	ALPRAZOLAM EXTENDED-RELEASE TABLETS PF 41(4) Pg. ONLINE	IDENTIFICATION/B., ASSAY/Procedure, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Chlordiazepoxide Related Compound A RS	Heather Joyce
Revision	ALPRAZOLAM ORALLY-DISINTEGRATING TABLETS PF 41(4) Pg. ONLINE	IDENTIFICATION/, IDENTIFICATION/B., ASSAY/Procedure	Heather Joyce

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

Revision AMINOBENZOATE POTASSIUM PF 41(2) Pg. ONLINE

[Wei Yang](#)

IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Benzocaine RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP 4-Nitrobenzoic Acid RS

Revision AMINOBENZOATE POTASSIUM CAPSULES PF 41(4) Pg. ONLINE

[Wei Yang](#)

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

Revision AMINOBENZOATE SODIUM PF 41(2) Pg. ONLINE

[Wei Yang](#)

New	GAMMA-AMINOBUTYRIC ACID CAPSULES PF 41(4) Pg. ONLINE	Title, DEFINITION/Introduction, IDENTIFICATION/A., STRENGTH/Procedure, PERFORMANCE TESTS/Disintegration and Dissolution <2040>, PERFORMANCE TESTS/Weight Variation <2091>, CONTAMINANTS/Microbial Enumeration Tests <2021>, CONTAMINANTS/Absence of Specified Microorganisms <2022>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Gamma-Aminobutyric Acid RS	Natalia Davydova
Revision	AMINOHIPPURATE SODIUM INJECTION PF 41(5) Pg. ONLINE	IDENTIFICATION/C. Identification Tests-General, Sodium <191>, IDENTIFICATION/C.	Manoj Metta
Revision	AMINOPHYLLINE PF 41(3) Pg. ONLINE	IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., ASSAY/Procedure, OTHER COMPONENTS/Ethylenediamine Content, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Caffeine RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Theophylline Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Theophylline Related Compound C RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Theophylline Related Compound D RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Theophylline Related Compound F RS	Mary Koleck
Revision	AMINOPHYLLINE INJECTION PF 41(3) Pg. ONLINE	IDENTIFICATION/B. Infrared Absorption <197K>, IDENTIFICATION/C., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Theophylline Related Compound D RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Theophylline Related Compound F RS	Mary Koleck

Revision	AMINOPHYLLINE ORAL SOLUTION PF 41(3) Pg. ONLINE	IDENTIFICATION/A. Infrared Absorption <197K>, ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Theophylline Related Compound D RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Theophylline Related Compound F RS	Mary Koleck
Revision	AMINOPHYLLINE TABLETS PF 41(3) Pg. ONLINE	IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Theophylline Related Compound D RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Theophylline Related Compound F RS	Mary Koleck
Revision	ASHWAGANDHA ROOT PF 41(5) Pg. ONLINE	IDENTIFICATION/A. HPTLC for Articles of Botanical Origin <203>, IDENTIFICATION/B. HPLC, COMPOSITION/Content of Withanolides, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP β-Sitosterol RS	Anton Bzhelyansky
Revision	POWDERED ASHWAGANDHA ROOT PF 41(5) Pg. ONLINE	IDENTIFICATION/Thin-Layer Chromatography, IDENTIFICATION/B. HPLC, COMPOSITION/Content of Withanolides, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP β-Sitosterol RS	Anton Bzhelyansky
Revision	POWDERED ASHWAGANDHA ROOT EXTRACT PF 41(5) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/Thin-Layer Chromatographic Identification Test <201>, IDENTIFICATION/B. HPLC, COMPOSITION/Content of Withanolides, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP β-Sitosterol RS	Anton Bzhelyansky

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	BETA-PINENE PF 39(4) Pg. ONLINE	Reagent Specification, β-Pinene	Hong Wang

Revision	BETAMETHASONE VALERATE CREAM PF 41(5) Pg. ONLINE	IDENTIFICATION/A. Thin-Layer Chromatographic Identification Test <201>, 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
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

IDENTIFICATION/A.Thin-Layer Chromatographic Identification Test <201>, 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

Revision BETAMETHASONE VALERATE OINTMENT PF 41(5) Pg. ONLINE

[Mary Koleck](#)

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

New BIVALIRUDIN PF 41(5) Pg. ONLINE

[Anita Szajek](#)

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

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

[Anita Szajek](#)

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

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

[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	CARBAMAZEPINE EXTENDED-RELEASE TABLETS PF 41(2) Pg. ONLINE	ASSAY/Procedure, IMPURITIES/Organic Impurities: Procedure 1, IMPURITIES/Organic Impurities: Procedure 2, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Carbamazepine Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Carbamazepine Related Compound B RS	Heather Joyce
Revision	CASTOR OIL PF 41(5) Pg. ONLINE	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 <401>, 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>	Hong Wang

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>

Revision HYDROGENATED CASTOR OIL PF 41(5) Pg. ONLINE

[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 Standards <11>/USP Endotoxin RS

New CEFTIOFUR HYDROCHLORIDE PF 40(4) Pg. ONLINE

[Morgan Puderbaugh](#)

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 RS

New

CEFTIOFUR SODIUM PF 40(4) Pg. ONLINE

[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-[[carbamoyloxy)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	Domenick Vicchio

Title, DEFINITION/Introduction, IDENTIFICATION/A. Thin-Layer Chromatography, IDENTIFICATION/B. HPLC, COMPOSITION/Content of Phenylpropanoids and Coumarin, COMPOSITION/Total Phenolic Content, CONTAMINANTS/Elemental Impurities-Procedures <233>, CONTAMINANTS/Articles of Botanical Origin, Pesticide Residues Analysis <561>, CONTAMINANTS/Microbial Enumeration Tests <2021>, CONTAMINANTS/Absence of Specified Microorganisms <2022>, SPECIFIC TESTS/Botanical Characteristics, SPECIFIC TESTS/Articles of Botanical Origin, Foreign Organic Matter <561>, SPECIFIC TESTS/Water Determination, Method II <921>, SPECIFIC TESTS/Articles of Botanical Origin, Total Ash <561>, SPECIFIC TESTS/Articles of Botanical Origin, Acid-Insoluble Ash <561>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Cinnamic Acid RS

New

CINNAMOMUM CASSIA BARK PF 40(5) Pg. ONLINE

[Anton Bzhelyansky](#)

Title, DEFINITION/Introduction, IDENTIFICATION/A. Thin-Layer Chromatography, IDENTIFICATION/B. HPLC, COMPOSITION/Content of Phenylpropanoids and Coumarin, COMPOSITION/Total Phenolic Content, CONTAMINANTS/Elemental Impurities-Procedures <233>, CONTAMINANTS/Articles of Botanical Origin, Pesticide Residues Analysis <561>, CONTAMINANTS/Microbial Enumeration Tests <2021>, CONTAMINANTS/Absence of Specified Microorganisms <2022>, SPECIFIC TESTS/Botanical Characteristics, SPECIFIC TESTS/Articles of Botanical Origin, Foreign Organic Matter <561>, SPECIFIC TESTS/Water Determination, Method II <921>, SPECIFIC TESTS/Articles of Botanical Origin, Total Ash <561>, SPECIFIC TESTS/Articles of Botanical Origin, Acid-Insoluble Ash <561>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Cinnamic Acid RS

New

CINNAMOMUM CASSIA BARK POWDER PF 40(5) Pg. ONLINE

[Anton Bzhelyansky](#)

Title, DEFINITION/Introduction, IDENTIFICATION/A. Thin-Layer Chromatography, IDENTIFICATION/B. HPLC, IDENTIFICATION/C. GC, COMPOSITION/Content of Phenylpropanoids and Coumarin, COMPOSITION/Total Phenolic Content, COMPOSITION/Content of Eugenol, CONTAMINANTS/Elemental Impurities-Procedures <233>, CONTAMINANTS/Articles of Botanical Origin, Pesticide Residues Analysis <561>, CONTAMINANTS/Microbial Enumeration Tests <2021>, CONTAMINANTS/Absence of Specified Microorganisms <2022>, SPECIFIC TESTS/Botanical Characteristics, SPECIFIC TESTS/Articles of Botanical Origin, Foreign Organic Matter <561>, SPECIFIC TESTS/Water Determination, Method II <921>, SPECIFIC TESTS/Articles of Botanical Origin, Total Ash <561>, SPECIFIC TESTS/Articles of Botanical Origin, Acid-Insoluble Ash <561>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Cinnamic Acid RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Eugenol RS

New

CINNAMOMUM VERUM BARK PF 40(5) Pg. ONLINE

[Anton Bzhelyansky](#)

New	CINNAMOMUM VERUM BARK POWDER PF 40(5) Pg. ONLINE	Title, DEFINITION/Introduction, IDENTIFICATION/A. Thin-Layer Chromatography, IDENTIFICATION/B. HPLC, IDENTIFICATION/C. GC, COMPOSITION/Content of Phenylpropanoids and Coumarin, COMPOSITION/Total Phenolic Content, COMPOSITION/Content of Eugenol, CONTAMINANTS/Elemental Impurities-Procedures <233>, CONTAMINANTS/Articles of Botanical Origin, Pesticide Residues Analysis <561>, CONTAMINANTS/Microbial Enumeration Tests <2021>, CONTAMINANTS/Absence of Specified Microorganisms <2022>, SPECIFIC TESTS/Botanical Characteristics, SPECIFIC TESTS/Articles of Botanical Origin, Foreign Organic Matter <561>, SPECIFIC TESTS/Water Determination, Method II <921>, SPECIFIC TESTS/Articles of Botanical Origin, Total Ash <561>, SPECIFIC TESTS/Articles of Botanical Origin, Acid-Insoluble Ash <561>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Cinnamic Acid RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Eugenol RS	Anton Bzhelyansky
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 Hydrochloride RS	Jeanne Sun
Revision	CURCUMINOIDS PF 41(5) Pg. ONLINE	IDENTIFICATION/Thin-Layer Chromatographic Identification Test, IDENTIFICATION/B. HPLC, COMPOSITION/Content of Curcuminoids, CONTAMINANTS/Botanical Extracts <565>, Preparations, Residual Solvents	Anton Bzhelyansky

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 Hydrochloride 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
Revision	DESCRIPTION AND SOLUBILITY PF 41(4) Pg. ONLINE	Febantel, Methylene Blue, Ceftiofur Hydrochloride, Ceftiofur Sodium, Milbemycin Oxime, Eucalyptus Oil, Rosuvastatin Calcium, Doxercalciferol, Linezolid, Acamprosate Calcium, Desoxycholic Acid, Frovatriptan Succinate, Methylnaltrexone Bromide, Nebivolol Hydrochloride, Sodium Succinate, Solifenacin Succinate	Morgan Puderbaugh

Revision	DESOXYCHOLIC ACID PF 41(5) Pg. ONLINE	<p>{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></p>	Galina Holloway
Revision	DEXAMETHASONE TABLETS PF 39(5) Pg. ONLINE	<p>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</p>	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</p>	Alan Potts

IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Dipyridamole Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Dipyridamole Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Dipyridamole Related Compound C RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Dipyridamole Related Compound D RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Dipyridamole Related Compound E RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Dipyridamole Related Compound F RS

Revision DIPYRIDAMOLE PF 41(3) Pg. ONLINE

[Sujatha Ramakrishna](#)

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 Dipyridamole Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Dipyridamole Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Dipyridamole Related Compound C RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Dipyridamole Related Compound D RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Dipyridamole Related Compound E RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Dipyridamole Related Compound F RS

Revision DIPYRIDAMOLE TABLETS PF 41(3) Pg. ONLINE

[Sujatha Ramakrishna](#)

Revision DOXYCYCLINE HYCLATE CAPSULES PF 41(4) Pg. ONLINE

IDENTIFICATION/A. Infrared Absorption <197A>, IDENTIFICATION/B., 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 Doxycycline Monohydrate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Doxycycline Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methacycline Hydrochloride RS

[Morgan Puderbaugh](#)

Revision DOXYCYCLINE HYCLATE TABLETS PF 41(4) Pg. ONLINE

IDENTIFICATION/A. Infrared Absorption <197A>, IDENTIFICATION/B., 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 Doxycycline Monohydrate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Doxycycline Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methacycline Hydrochloride RS

[Morgan Puderbaugh](#)

Revision ELEUTHERO PF 41(5) Pg. ONLINE

{Title} Eleuthero Root and Rhizome, DEFINITION/Introduction, IDENTIFICATION/A. HPTLC for Articles of Botanical Origin <203>, COMPOSITION/Content of Eleutherosides B and E

[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

Title, Chemical Info/Chemical Structure, Chemical Info/C809H1301N229O240S5, 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

[Kevin Carrick](#)

Title, Chemical Info/Chemical Structure, Chemical Info/C1982H3054N560O618S28, Chemical Info/INS: (The chemical formula includes the γ -carboxylations and modification of D (Asp) in position 63, and does not include the glycosylations.), Chemical Info/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 (γ -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

New

EPTACOG ALFA PF 41(3) Pg. ONLINE

[Trish Li](#)

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

New

EPTACOG ALFA FOR INJECTION PF 41(3) Pg. ONLINE

[Trish Li](#)

Revision	ESMOLOL HYDROCHLORIDE PF 41(2) Pg. ONLINE	SPECIFIC TESTS/pH <791>	Sujatha Ramakrishna
		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	
New	ETHAMBUTOL HYDROCHLORIDE COMPOUNDED ORAL SUSPENSION PF 41(2) Pg. ONLINE		Jeanne Sun
		Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197F>, IDENTIFICATION/B., ASSAY/Content of Aroma Substances, IMPURITIES/Test for Aldehyde, SPECIFIC TESTS/Specific Gravity <841>, SPECIFIC TESTS/Refractive Index <831>, SPECIFIC TESTS/Optical Rotation <781>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/US Reference Standards <11>/USP Camphor RS, ADDITIONAL REQUIREMENTS/US Reference Standards <11>/USP Eucalyptol RS, ADDITIONAL REQUIREMENTS/US Reference Standards <11>/USP Eucalyptus Oil RS, IDENTIFICATION/B. Identity by Aroma Substance Profile	
New	EUCALYPTUS OIL PF 39(4) Pg. ONLINE		Hong Wang

Title, Chemical Info/Chemical Structure, Chemical Info/C184H282N50O60S, Chemical Info/4186.57, Chemical Info/l-Histidyl-glycyl-l-glutamyl-glycyl-l-threonyl-l-phenylalanyl-l-threonyl-l-seryl-l-aspartyl-l-leucyl-l-seryl-l-lysyl-l-glutamyl-l-methionyl-l-glutamyl-l-glutamyl-l-glutamyl-l-alanyl-l-valyl-l-arginyl-l-leucyl-l-phenylalanyl-l-isoleucyl-l-glutamyl-l-tryptophyl-l-leucyl-l-lysyl-l-asparaginyll-glycyl-glycyl-l-prolyl-l-seryl-l-seryl-glycyl-l-alanyl-l-prolyl-l-prolyl-l-prolyl-l-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

New

EXENATIDE PF 41(5) Pg. ONLINE

[Anita Szajek](#)

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 Fenbendazole RS

New

FEBANTEL PF 41(4) Pg. ONLINE

[Morgan Puderbaugh](#)

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

Revision

FLUORESCIN PF 40(5) Pg. ONLINE

[Feiwen Mao](#)

New

FLUTICASONE PROPIONATE LOTION PF 41(3) Pg. ONLINE

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

[Gerald Hsu](#)

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](#)

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

New

FROVATRIPTAN SUCCINATE PF 41(5) Pg. ONLINE

[Heather Joyce](#)

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

Revision

GONADORELIN ACETATE PF 40(3) Pg. ONLINE

[Trish Li](#)

Chemical Info/Chemical Structure, Chemical Info/C28H34O15, Chemical Info/610.57, Chemical Info/4H-1-Benzopyran-4-one, 7-[[6-O-(6-deoxy-α-l-mannopyranosyl)-β-d-glucopyranosyl]oxy]-2,3-dihydro-5-hydroxy-2-(3-hydroxy-4-methoxyphenyl)-, (2S)-, Chemical Info/(S)-5-Hydroxy-2-(3-hydroxy-4-methoxyphenyl)-4-oxo-3,4-dihydro-2H-chromen-7-yl 6-O-(α-l-rhamnopyranosyl)-β-d-glucopyranoside, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Related Compounds, SPECIFIC TESTS/Loss on Drying <731>, SPECIFIC TESTS/Microbial Enumeration Tests <2021>, SPECIFIC TESTS/Absence of Specified Microorganisms <2022>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Didymine RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Diosmin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Hesperidin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Isonaringin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Neohesperidin RS

New HESPERIDIN PF 41(2) Pg. ONLINE

[Huy Dinh](#)

ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Water-Insoluble Substances, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP 1-Chlorophthalazine RS C8H5N2Cl164.59, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP 2-Formyl Benzoic Acid RSC8H6O3150.13, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Phthalazine RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP 1-Phthalazinone RS

Revision HYDRALAZINE HYDROCHLORIDE PF 41(2) Pg. ONLINE

[Sujatha Ramakrishna](#)

Revision HYDRALAZINE HYDROCHLORIDE TABLETS PF 41(2) Pg. ONLINE

ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Phthalazine RS

[Sujatha Ramakrishna](#)

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.C17H19CIN2286.80	Heather Joyce
		IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, 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	
Revision	HYDROXYZINE HYDROCHLORIDE TABLETS PF 41(1) Pg. ONLINE		Heather Joyce
		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	
Revision	IMIPRAMINE HYDROCHLORIDE TABLETS PF 41(2) Pg. ONLINE		Heather Joyce
		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	
Revision	INDAPAMIDE PF 41(2) Pg. ONLINE		Sujatha Ramakrishna

Revision INDAPAMIDE TABLETS PF 41(2) Pg. ONLINE

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

[Suatha Ramakrishna](#)

Title, DEFINITION/Introduction, IDENTIFICATION/A. HPTLC for Articles of Botanical Origin <203>, IDENTIFICATION/B. Caffeoylquinic Acids HPLC Profile, IDENTIFICATION/C. Iridoids HPLC Profile, COMPOSITION/Content of Caffeoylquinic Acids, COMPOSITION/Content of Iridoids, 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/Limit of Triterpenoid Saponins, SPECIFIC TESTS/Articles of Botanical Origin <561>, Methods of Analysis, Foreign Organic Matter, SPECIFIC TESTS/Articles of Botanical Origin <561>, Methods of Analysis, Alcohol-Soluble Extractives, Method 1, SPECIFIC TESTS/Articles of Botanical Origin <561>, Methods of Analysis, Water-Soluble Extractives, Method 2, SPECIFIC TESTS/Loss on Drying <731>, SPECIFIC TESTS/Articles of Botanical Origin <561>, Methods of Analysis, Total Ash, SPECIFIC TESTS/Articles of Botanical Origin <561>, Methods of Analysis, Acid-Insoluble Ash, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Chlorogenic Acid RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Lonicera japonica Flower Dry Extract RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Lonicera macranthoides Flower Dry Extract RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Luteolin-7-O-glucoside RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Rutin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Secoxyloganin RS

Title, DEFINITION/Introduction, IDENTIFICATION/A. HPTLC for Articles of Botanical Origin <203>, IDENTIFICATION/B. Caffeoylquinic Acids HPLC Profile, IDENTIFICATION/C. Iridoids HPLC Profile, COMPOSITION/Content of Caffeoylquinic Acids, COMPOSITION/Content of Iridoids, CONTAMINANTS/Articles of Botanical Origin <561>, Pesticide Residue Analysis, CONTAMINANTS/Microbial Enumeration Tests <2021>, CONTAMINANTS/Absence of Specified Microorganisms <2022>, Test Procedures, Test for Absence of Salmonella species and Test for Absence of Escherichia coli, SPECIFIC TESTS/Limit of Triterpenoid Saponins, SPECIFIC TESTS/Loss on Drying <731>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Chlorogenic Acid RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Lonicera japonica Flower Dry Extract RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Lonicera macranthoides Flower Dry Extract RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Luteolin-7-O-glucoside RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Rutin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Secoxyloganin RS

JAPANESE HONEYSUCKLE FLOWER DRY EXTRACT PF 41(5) Pg.
ONLINE

New

[Cuiying Ma](#)

New	JAPANESE HONEYSUCKLE FLOWER POWDER PF 41(5) Pg. ONLINE	<p>Title, DEFINITION/Introduction, IDENTIFICATION/A. HPTLC for Articles of Botanical Origin <203>, IDENTIFICATION/B. Caffeoylquinic Acids HPLC Profile, IDENTIFICATION/C. Iridoids HPLC Profile, COMPOSITION/Content of Caffeoylquinic Acids, COMPOSITION/Content of Iridoids, 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/Limit of Triterpenoid Saponins, SPECIFIC TESTS/Articles of Botanical Origin <561>, Methods of Analysis, Alcohol-Soluble Extractives, Method 1, SPECIFIC TESTS/Articles of Botanical Origin <561>, Methods of Analysis, Water-Soluble Extractives, Method 2, SPECIFIC TESTS/Loss on Drying <731>, SPECIFIC TESTS/Articles of Botanical Origin <561>, Methods of Analysis, Total Ash, SPECIFIC TESTS/Articles of Botanical Origin <561>, Methods of Analysis, Acid-Insoluble Ash, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Chlorogenic Acid RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Lonicera japonica Flower Dry Extract RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Lonicera macranthoides Flower Dry Extract RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Luteolin-7-O-glucoside RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Rutin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Secoxyloganin RS</p>	Cuiying Ma
Revision	KRILL OIL CAPSULES PF 41(3) Pg. ONLINE	<p>IDENTIFICATION/A. Fatty Acid Profile, IDENTIFICATION/B. Phospholipid Profile, STRENGTH/Content of Total Phospholipids</p>	Natalia Davydova
Revision	KRILL OIL DELAYED-RELEASE CAPSULES PF 41(3) Pg. ONLINE	<p>IDENTIFICATION/A. Fatty Acid Profile, IDENTIFICATION/B. Phospholipid Profile, STRENGTH/Content of Total Phospholipids</p>	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	L90 PF 41(5) Pg. ONLINE	L90	Heather Joyce
New	L91 PF 41(5) Pg. ONLINE	L91	Edith Chang
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	LIDOCAINE PF 40(4) Pg. ONLINE	IMPURITIES/Organic Impurities, SPECIFIC TESTS/Melting Range or Temperature <741>, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Lidocaine Related Compound H RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ropivacaine Related Compound A RS	Mary Koleck
New	(R)-(+)-LIMONENE PF 39(4) Pg. ONLINE	Reagent Specification, (R)-(+)-Limonene	Hong Wang
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

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 Megestrol Acetate RS	Gerald Hsu
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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 Megestrol Acetate RS	Gerald Hsu
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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
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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
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Chemical Info/C₁₆H₁₈N₃S·xH₂O, Chemical Info/Phenothiazin-5-ium, 3,7-bis(dimethylamino)-, chloride; trihydrate., Chemical Info/Chemical Name 3,7-Bis(dimethylamino)phenothiazin-5-ium chloride; Pentahydrate409.9332680-41-4Chemical Info/CAS, Chemical Info/C.I. Basic Blue 9Trihydrate, 373.90, Chemical Info/Chemical Name Monohydrate337.90122965-43-9Chemical 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/Arsenic, Method I <211>, IMPURITIES/Copper or Zinc, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Loss on Drying <731>, SPECIFIC TESTS/Bacterial Endotoxins Test <85>, SPECIFIC TESTS/Microbial Enumeration Tests <61>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Azure B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Endotoxin RS

Title, Chemical Info/Chemical Structure, Chemical Info/C₂₁H₂₆BrNO₄, Chemical Info/436.34, Chemical Info/Morphinanum, 17-(cyclopropylmethyl)-4,5-epoxy-3,14-dihydroxy-17-methyl-6-oxo-, bromide, (5 α);-, Chemical Info/(17RS)-17-(Cyclopropylmethyl)-4,5 α -epoxy-3,14-dihydroxy-17-methyl-6-oxomorphinanum bromide, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., IDENTIFICATION/C. Identification Tests-General <191>, Bromide, ASSAY/Procedure, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Organic Impurities, SPECIFIC TESTS/pH <791>, SPECIFIC TESTS/Water Determination <921>, Method Ic, SPECIFIC TESTS/Optical Rotation <781S>, Specific Rotation, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methylnaltrexone Bromide RS

New METHYLNALTREXONE BROMIDE PF 41(5) Pg. ONLINE

[Elena Gonikberg](#)

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

Revision METHYLPREDNISOLONE PF 41(2) Pg. ONLINE

[Gerald Hsu](#)

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

Revision METHYLPREDNISOLONE TABLETS PF 41(2) Pg. ONLINE

[Gerald Hsu](#)

Revision METOPROLOL FUMARATE PF 41(1) Pg. ONLINE

DEFINITION/Introduction, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Melting Range or Temperature <741>, 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, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Metoprolol Related Compound D RS

[Sujatha Ramakrishna](#)

Revision METOPROLOL SUCCINATE PF 41(3) Pg. ONLINE

IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., IMPURITIES/Organic Impurities, Procedure 1, IMPURITIES/Content of Metoprolol Related Compound H and Metoprolol Related Compound I, IMPURITIES/, Procedure 2, SPECIFIC TESTS/Clarity and Color of Solution, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Metoprolol Related Compound H RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Metoprolol Related Compound I RS

[Donald Min](#)

Revision MICONAZOLE PF 41(5) Pg. ONLINE

IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/A. Infrared Absorption <197>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Econazole Nitrate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Miconazole Related Compound C RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Miconazole Related Compound F RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Miconazole Related Compound I 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

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 \prime ;S,6R,6 \prime ;S,8E,11R,13R,15S,17 α ;R,20 α ;R,20 β ;S)-6 \prime ;-ethyl-3 \prime ;4 \prime ;;5 \prime ;;6,6 \prime ;;7,10,11,14,15,17 α ;;20,20 α ;;20 β ;-tetradecahydro-20 β ;-hydroxy-5 \prime ;;6,8,19-tetramethylspiro[11,15-methano-2H,13H,17H-furo[4,3,2-pq][2,6]benzodioxacyclooctadecin-13,2 \prime ;-[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 \prime ;S,6R,6 \prime ;S,8E,11R,13R,15S,17 α ;R,20 α ;R,20 β ;S)-6 \prime ;-ethyl-3 \prime ;4 \prime ;;5 \prime ;;6,6 \prime ;;7,10,11,14,15,17 α ;;20,20 α ;;20 β ;-tetradecahydro-20 β ;-hydroxy-5 \prime ;;6,8,19-tetramethylspiro[11,15-methano-2H,13H,17H-furo[4,3,2-pq][2,6]benzodioxacyclooctadecin-13,2 \prime ;-[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 Reference Standards <11>/USP Milbemycin Oxime RS

New

MILBEMYCIN OXIME PF 40(4) Pg. ONLINE

[Morgan Puderbaugh](#)

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](#)

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/(1R, 1′R;S)-1, 1′-[(2R, 2′S)-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 Nebivolol Related Compound E 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 <11>/USP Verbascoside RS

New

OLIVE LEAF PF 41(5) Pg. ONLINE

[Anton Bzhelyansky](#)

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 Verbascoside RS

New

OLIVE LEAF DRY EXTRACT PF 41(5) Pg. ONLINE

[Anton Bzhelyansky](#)

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 Verbascoside RS

New

OLIVE LEAF POWDER PF 41(5) Pg. ONLINE

[Anton Bzhelyansky](#)

New	PALONOSETRON INJECTION PF 41(1) Pg. ONLINE	<p>Title, DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Limit of Specified Impurities, IMPURITIES/Limit of Unspecified Impurities, SPECIFIC TESTS/pH <791>, SPECIFIC TESTS/Particulate Matter in Injections <788>, SPECIFIC TESTS/Bacterial Endotoxins Test <85>, SPECIFIC TESTS/Sterility Tests <71>, 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 Palonosetron Enantiomer RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Palonosetron Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Palonosetron Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Palonosetron Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Palonosetron Related Compound C RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Palonosetron Related Compound D RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Palonosetron Related Compound E RS</p>	Elena Gonikberg
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	<p>IDENTIFICATION/A., IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage</p>	Hillary Cai

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
New	QUETIAPINE EXTENDED-RELEASE TABLETS PF 41(5) Pg. ONLINE	Title, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197F>, 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 Quetiapine Fumarate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Quetiapine Related Compound H RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Quetiapine System Suitability RS	K. Seela

New	RED CLOVER AERIAL PARTS ISOFLAVONE AGLYCONES DRY EXTRACT PF 41(5) Pg. ONLINE	<p>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</p>	Anton Bzhelyansky
New	ROSUVASTATIN TABLETS PF 40(6) 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 Rosuvastatin Calcium RS</p>	Sujatha Ramakrishna

		<p>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</p>	
New	ROSUVASTATIN CALCIUM PF 40(2) Pg. ONLINE		Sujatha Ramakrishna
New	SABINENE PF 39(4) Pg. ONLINE	Reagent Specification, Sabinene	Hong Wang
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

Revision	SALICYLIC ACID GEL PF 40(4) Pg. ONLINE	IDENTIFICATION/A. Procedure, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>	Ren-Hwa Yeh
Revision	SODIUM NITRITE PF 40(5) Pg. ONLINE	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>	Sujatha Ramakrishna
Revision	SODIUM NITRITE INJECTION PF 40(5) Pg. ONLINE	IDENTIFICATION/C., ASSAY/Procedure, IMPURITIES/Limit of Sodium Nitrate, IMPURITIES/Limit of Nitrogen Oxide (NO _x) Related Impurities, SPECIFIC TESTS/Bacterial Endotoxins Test <85>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Sodium Nitrite RS	Sujatha Ramakrishna

Title, Chemical Info/Chemical Structure, Chemical Info/INS: x = 0 or 6, Chemical Info/NaOOC-CH₂CH₂-COONa (C₄H₄Na₂O₄), Chemical Info/162.05, Chemical Info/Anhydrous disodium 1,4-butanedioate;, Chemical Info/Anhydrous butanedioic acid disodium salt, Chemical Info/CAS, Chemical Info/NaOOC-CH₂CH₂-COONa·6H₂O (C₄H₄Na₂O₄·6H₂O), Chemical Info/270.14, Chemical Info/Disodium 1,4-butanedioate hexahydrate;, Chemical Info/Butanedioic acid disodium salt hexahydrate, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K> or <197A>, IDENTIFICATION/B. Chromatographic Identity, IDENTIFICATION/C. Sodium, ASSAY/Procedure, IMPURITIES/Limit of Sodium Acetate, Sodium Maleate, and Sodium Fumarate, IMPURITIES/Limit of Sulfate, SPECIFIC TESTS/Acidity and Alkalinity, SPECIFIC TESTS/Loss on Drying <731>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Anhydrous Sodium Succinate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Fumaric Acid RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Glacial Acetic Acid RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Maleic Acid RS

[Hong Wang](#)

New	SOLIFENACIN SUCCINATE PF 41(5) Pg. ONLINE	<p>Title, Chemical Info/Chemical Structure, Chemical Info/C₂₃H₂₆N₂O₂·C₄H₆O₄, Chemical Info/480.55, Chemical Info/Butanedioic acid, compound with (1S)-(3R)-1-azabicyclo[2.2.2]oct-3-yl 3,4-dihydro-1-phenyl-2(1H)-isoquinolinecarboxylate (1:1),, Chemical Info/(R)-Quinuclidin-3-yl (S)-1-phenyl-3,4-dihydroisoquinoline-2(1H)-carboxylate succinate salt (1:1)., Chemical Info/CAS, Chemical Info/Solifenacin, Chemical Info/C₂₃H₂₆N₂O₂, Chemical Info/362.46, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., IDENTIFICATION/C. Identification for Succinate, ASSAY/Procedure, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Organic Impurities, IMPURITIES/Stereoisomer Impurities, SPECIFIC TESTS/Loss on Drying <731>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Solifenacin Succinate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Solifenacin Identification Mixture A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Solifenacin Identification Mixture B RS</p>	Elena Gonikberg
New	SULFAGUANIDINE PF 41(4) Pg. ONLINE	Sulfaguanidine	Sridevi Ramachandran
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	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	Ren-Hwa Yeh
Revision	TINIDAZOLE PF 41(4) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/B. Ultraviolet Absorption <197U>, IDENTIFICATION/B., IDENTIFICATION/C., ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Melting Range or Temperature <741>	Praveen Pabba
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	TURMERIC PF 41(5) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/A. Thin-Layer Chromatography, IDENTIFICATION/A. HPTLC for Articles of Botanical Origin <203>, IDENTIFICATION/B., IDENTIFICATION/B. HPLC, COMPOSITION/Content of Curcuminoids	Anton Bzhelyansky
Revision	POWDERED TURMERIC PF 41(5) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/A. Thin-Layer Chromatography, IDENTIFICATION/A. HPTLC for Articles of Botanical Origin <203>, IDENTIFICATION/B., IDENTIFICATION/B. HPLC, COMPOSITION/Content of Curcuminoids, SPECIFIC TESTS/Articles of Botanical Origin, Foreign Organic Matter <561>	Anton Bzhelyansky

Revision	POWDERED TURMERIC EXTRACT PF 41(5) Pg. ONLINE	IDENTIFICATION/A. Thin-Layer Chromatography, IDENTIFICATION/A. HPTLC for Articles of Botanical Origin <203>, IDENTIFICATION/B., IDENTIFICATION/B. HPLC, COMPOSITION/Content of Curcuminoids	Anton Bzhelyansky
Revision	USP AND NF EXCIPIENTS, LISTED BY CATEGORY PF 39(4) Pg. ONLINE	{Flavors and Perfumes} Eucalyptus Oil, {Emulsifying Agent} Desoxycholic Acid, {Flavors and Fragrance} Sodium Succinate	Hong Wang
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	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	Jeanne Sun
New	ZIPRASIDONE CAPSULES 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 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	Sridevi Ramachandran