

Compendial Deferrals for USP38-NF33

Category	Monograph Title	Monograph Section	Scientific Liaison
New	<129> ANALYTICAL PROCEDURES FOR RECOMBINANT THERAPEUTIC MONOCLONAL ANTIBODIES PF 39(3) Pg. ONLINE	INTRODUCTION/Paragraph Text, INTRODUCTION/Size-Exclusion Chromatography, INTRODUCTION/Capillary SDS Electrophoresis (Reduced and Nonreduced), INTRODUCTION/Oligosaccharide Analysis—Analysis of N-Linked Oligosaccharides of Monoclonal Antibodies, INTRODUCTION/Oligosaccharide Analysis: Sialic acid Analysis	Anita Szajek
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	<202> IDENTIFICATION OF FIXED OILS BY THIN-LAYER CHROMATOGRAPHY PF 39(1) Pg. ONLINE	Title, Introduction, IDENTIFICATION, USP Reference Standards <11>, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>	Hong Wang
Revision	<341> ANTIMICROBIAL AGENTS--CONTENT PF 39(3) Pg. ONLINE	Introduction, GENERAL GAS CHROMATOGRAPHIC METHOD, POLAROGRAPHIC METHOD	Shankari Shivaprasad
Revision	<751> METAL PARTICLES IN OPHTHALMIC OINTMENTS PF 39(5) Pg. ONLINE	Title, PROCEDURE-	William Brown
Revision	<771> OPHTHALMIC OINTMENTS PF 39(5) Pg. ONLINE	Title, ADDED SUBSTANCES-, CONTAINERS-, METAL PARTICLES-, LEAKAGE-, INTRODUCTION, OPHTHALMIC DOSAGE FORMS, DRUG PRODUCT QUALITY	Margareth Marques
Revision	<1066> PHYSICAL ENVIRONMENTS THAT PROMOTE SAFE MEDICATION USE PF 40(1) Pg. ONLINE	PURPOSE OF THIS CHAPTER, DEFINITIONS, FACTORS TO CONSIDER WHEN ASSESSING PHYSICAL ENVIRONMENT NEEDS, PHYSICAL ENVIRONMENT GUIDELINES FOR MEDICATION SAFETY ZONES, REFERENCES, INTRODUCTION, ORGANIZATIONAL SUPPORT, MEDICATION SAFETY ZONES, SOUND AND NOISE, ACTIVITIES AND TASKS PERFORMED, TOOLS AND TECHNOLOGIES IN THE PHYSICAL ENVIRONMENT, DISTRACTIONS AND DISTRACTIBILITY INDEX, PHYSICAL ENVIRONMENT ELEMENTS, WORK SYSTEM DESIGN, CHALLENGES IN THE PHYSICAL ENVIRONMENT, PHYSICAL ENVIRONMENT FACTORS, METHODS FOR ASSESSING THE PHYSICAL ENVIRONMENT, SUMMARY, GLOSSARY OF TERMS	Donna Bohannon
Revision	<1092> THE DISSOLUTION PROCEDURE -- DEVELOPMENT AND VALIDATION PF 40(1) Pg. ONLINE	Introduction, GENERAL COMMENTS, MEDIUM, APPARATUS/AGITATION, STUDY DESIGN, ASSAY, VALIDATION, ACCEPTANCE CRITERIA, INTRODUCTION, 1. PRELIMINARY ASSESSMENT (FOR EARLY STAGES OF PRODUCT DEVELOPMENT/DISSOLUTION METHOD DEVELOPMENT), 2. METHOD DEVELOPMENT, 3. ANALYTICAL FINISH, 4. AUTOMATION, 5. VALIDATION, 6. ACCEPTANCE CRITERIA, REFERENCES	William Brown
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	<1200> REQUIREMENTS FOR COMPENDIAL VALIDATION PF 39(6) Pg. ONLINE	Title, Introduction, GENERAL CONSIDERATIONS, TYPE 1 STUDY: PRECISION-ACCURACY AND RANGE, TYPE 2 STUDY: SPECIFICITY, TYPE 3 STUDY: ACCURACY, TYPE 4 STUDY: PRECISION, TYPE 5 STUDY: DETECTABILITY	Horacio Pappa

New	<1602> SPACERS AND VALVED HOLDING CHAMBERS USED WITH INHALATION AEROSOLS 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	Kahkashan Zaidi
New	<1663> EXTRACTABLES ASSOCIATED WITH PHARMACEUTICAL PACKAGING SYSTEMS PF 39(5) Pg. ONLINE	PURPOSE, KEY TERMS, SCOPE, BACKGROUND INFORMATION, GENERATING THE EXTRACT, CHARACTERIZING THE EXTRACT, SUMMARY, REFERENCES	Desmond Hunt
New	<1664> ASSESSMENT OF DRUG PRODUCT LEACHABLES ASSOCIATED WITH PHARMACEUTICAL PACKAGING/DELIVERY SYSTEMS PF 39(5) Pg. ONLINE	PURPOSE, KEY TERMS, SCOPE, CONCEPTS, LEACHABLES STUDY DESIGN, LEACHABLES CHARACTERIZATION, ESTABLISHING A LEACHABLES-EXTRACTABLES CORRELATION, CONSIDERATIONS IN DEVELOPING LEACHABLES SPECIFICATIONS AND ACCEPTANCE CRITERIA, ADDITIONAL CONSIDERATIONS, SUMMARY, REFERENCES	Desmond Hunt
New	<1664.1> ORALLY INHALED AND NASAL DRUG PRODUCTS PF 39(5) Pg. ONLINE	INTRODUCTION, LEACHABLES ASSESSMENT RATIONALE FOR ORALLY INHALED AND NASAL DRUG PRODUCTS, ORALLY INHALED AND NASAL DRUG PRODUCTS DOSAGE FORM TYPES, ADDITIONAL CONSIDERATIONS, REFERENCES	Desmond Hunt
New	<1771> OPHTHALMIC PRODUCTS - PERFORMANCE TESTS PF 39(5) Pg. ONLINE	Title, INTRODUCTION, PERFORMANCE TESTS (DISSOLUTION/DRUG RELEASE)	Margareth Marques
Revision	2 PERCENT NINHYDRIN TS PF 39(1) Pg. ONLINE	2% Ninhydrin pH 5.2 TS	Sujatha Ramakrishna
New	2,2,2-TRICHLOROETHANOL PF 39(3) Pg. ONLINE	2,2,2-Trichloroethanol	Shankari Shivaprasad
Revision	ACETAMINOPHEN SUPPOSITORIES PF 39(3) Pg. ONLINE	IMPURITIES/4-Aminophenol in Acetaminophen-Containing Drug Products <227> ASSAY/Procedure, IMPURITIES/Organic Impurities, IMPURITIES/Related Compounds, SPECIFIC TESTS/Nitrogen Content, Method II <461>	Clydewyn Anthony
Revision	ADENINE PF 38(6) Pg. ONLINE		Huy Dinh
New	(R)-(-)-ALPHA-PHELLANDRENE PF 39(4) Pg. ONLINE	Reagent Specification, (R)-(-)-alpha;-Phellandrene	Hong Wang
New	(+)-ALPHA-PINENE PF 39(4) Pg. ONLINE	Reagent Specification, (+)-alpha;-Pinene	Hong Wang
Revision	AMILORIDE HYDROCHLORIDE PF 40(1) Pg. ONLINE	IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Amiloride Related Compound A RS	Sujatha Ramakrishna
Revision	AMINO BENZOATE POTASSIUM PF 39(1) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/B., ASSAY/Procedure	Hillary Cai
Revision	AMINO BENZOATE SODIUM PF 39(1) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/B., ASSAY/Procedure	Hillary Cai

New	AMIODARONE HYDROCHLORIDE INJECTION PF 39(6) Pg. ONLINE	Title, DEFINITION/Introduction, IDENTIFICATION/A., ASSAY/Procedure, IMPURITIES/Organic Impurities, IMPURITIES/Limit of Iodide, OTHER COMPONENTS/Content of Benzyl Alcohol (if present), SPECIFIC TESTS/Bacterial Endotoxins Test <85>, SPECIFIC TESTS/Sterility Tests <71>, SPECIFIC TESTS/pH <791>, SPECIFIC TESTS/Particulate Matter in Injections <788>, SPECIFIC TESTS/Other Requirements, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Amiodarone Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Amiodarone Related Compound D RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Amiodarone Related Compound E RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Benzyl Alcohol RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Endotoxin RS	Sujatha Ramakrishna
Revision	ANETHOLE PF 40(1) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197F>, IDENTIFICATION/B. Chromatographic Identity, ASSAY/Assay for trans-Anethole, IMPURITIES/Limit of cis-Anethole, p-Anisaldehyde, and Other Volatile Impurities, IMPURITIES/Aldehydes and Ketones, SPECIFIC TESTS/Congearing Temperature <651>, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>	Galina Holloway
New	ARGATROBAN PF 39(3) Pg. ONLINE	Title, Chemical Info/Chemical Structure, Chemical Info/C23H36N6O5S-H2O, Chemical Info/526.65, Chemical Info/ 2-Piperidinecarboxylic acid, 1-[(S)-5-[(aminoiminomethyl)amino]-1-oxo-2-[[[1,2,3,4-tetrahydro-3-methyl-8-quinolyl]sulfonyl]amino]pentyl]-4-methyl-, (2R,4R)-monohydrate;, Chemical Info/(2R,4R)-4-Methyl-1-[(N2-[(1,2,3,4-tetrahydro-3-methyl-8-quinolyl)sulfonyl]-l-arginyl]pipercolic acid, monohydrate, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Heavy metals, Method II <231>, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Organic Impurities, IMPURITIES/Content of Argatroban Related Compound C, IMPURITIES/Content of Stereoisomers, SPECIFIC TESTS/Water Determination, Method Ia <921>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Argatroban RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Argatroban Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Argatroban Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Argatroban Related Compound C RS	Sujatha Ramakrishna
Revision	ATROPINE SULFATE OPHTHALMIC OINTMENT PF 39(5) Pg. ONLINE	SPECIFIC TESTS/Metal Particles in Ophthalmic Ointments <751>, SPECIFIC TESTS/Other Requirements	Heather Joyce
New	AZELASTINE HYDROCHLORIDE OPHTHALMIC SOLUTION PF 39(2) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/A., ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/pH <791>, SPECIFIC TESTS/Osmolality and Osmolarity <785>, SPECIFIC TESTS/Particulate Matter in Ophthalmic Solutions <789>, SPECIFIC TESTS/Sterility Tests <71>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Azelastine Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Azelastine Related Compound D RS	Domenick Vicchio

Revision	BACITRACIN OPHTHALMIC OINTMENT PF 39(5) Pg. ONLINE	SPECIFIC TESTS/Water Determination, Method I <921>, SPECIFIC TESTS/Metal Particles in Ophthalmic Ointments <751>, SPECIFIC TESTS/Other Requirements, ADDITIONAL REQUIREMENTS/Packaging and Storage	Ahalya Wise
Revision	BACITRACIN ZINC AND POLYMYXIN B SULFATE OPHTHALMIC OINTMENT PF 39(5) Pg. ONLINE	ASSAY/Bacitracin, PERFORMANCE TESTS/Minimum Fill <755>, SPECIFIC TESTS/Water Determination, Method I <921>, SPECIFIC TESTS/Metal Particles in Ophthalmic Ointments <751>, SPECIFIC TESTS/Sterility Tests <71>, SPECIFIC TESTS/Other Requirements, ADDITIONAL REQUIREMENTS/Packaging and Storage	Ahalya Wise
Revision	BENZOCAINE PF 40(1) Pg. ONLINE	IDENTIFICATION/Ultraviolet Absorption <197U>, IDENTIFICATION/C., IMPURITIES/Ordinary Impurities <466>, IMPURITIES/Organic Impurities, IMPURITIES/Readily Carbonizable Substances Test <271>, SPECIFIC TESTS/Melting Range or Temperature, Class I <741>, SPECIFIC TESTS/Reaction, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Aminobenzoic Acid RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ethyl 4-Nitrobenzoate RS	Domenick Vicchio
Revision	BENZYL BENZOATE PF 39(6) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Limit of Aldehydes, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Benzaldehyde RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Benzoic Acid RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Benzyl Alcohol RS	Shankari Shivaprasad
New	BENZYLPARABEN PF 39(3) Pg. ONLINE	Benzylparaben	Shankari Shivaprasad
New	BETA-PINENE PF 39(4) Pg. ONLINE	Reagent Specification, -beta; -Pinene	Hong Wang
New	BORAGE SEED OIL CAPSULES PF 39(6) Pg. ONLINE	Title, DEFINITION/Introduction, IDENTIFICATION/A. Fatty Acid Profile, STRENGTH/Content of gamma-Linolenic, Linoleic, and Oleic Acids, PERFORMANCE TESTS/Disintegration and Dissolution <2040>, PERFORMANCE TESTS/Weight Variation <2091>, SPECIFIC TESTS/Fats and Fixed Oils, Peroxide Value <401>, CONTAMINANTS/Microbial Enumeration Tests <2021>, CONTAMINANTS/Absence of Specified Microorganisms <2022>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Borage Oil RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methyl Linoleate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methyl Linolenate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methyl Oleate RS	Natalia Davydova
Revision	BUPROPION HYDROCHLORIDE PF 39(4) Pg. ONLINE	ASSAY/Procedure, IMPURITIES/Limit of m-Chlorobenzoic Acid, IMPURITIES/Limit of 3-Chlorobenzoic Acid, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Bupropion Hydrochloride Related Compound C RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Bupropion Hydrochloride Related Compound F RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP 3-Chlorobenzoic Acid RS	Heather Joyce

New	CALCIPOTRIENE PF 39(4) Pg. ONLINE	Title, Chemical Info/Chemical Structure, Chemical Info/C27H40O3, Chemical Info/412.60, Chemical Info/9,10-Secochola-5,7,10(19),22-tetraene-1,3,24-triol, 24-cyclopropyl-, (1α,3β-,5Z,7E,22E,24S)-, Chemical Info/(5Z,7E,22E,24S)-24-Cyclopropyl-9,10-secochola-5,7,10(19),22-tetraene-1α,3β-,24-triol, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities by HPLC, IMPURITIES/Organic Impurities by TLC, SPECIFIC TESTS/Loss on Drying, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Calcipotriene RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Calcipotriene Related Compound C RS	Feiwen Mao
New	CALCIPOTRIENE OINTMENT PF 39(4) Pg. ONLINE	Title, DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B. Ultraviolet Absorption <197U>, ASSAY/Procedure, PERFORMANCE TESTS/Minimum Fill <755>, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Microbial Enumeration Tests <61> and Tests for Specified Microorganisms <62>, SPECIFIC TESTS/pH <791>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Calcipotriene RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Calcipotriene Related Compound C RS	Feiwen Mao
Revision	CALCIUM PANTOTHENATE PF 38(3) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/C. Optical Rotation, Specific Rotation <781S>, COMPOSITION/Nitrogen Determination, Method I <461>, COMPOSITION/Content of Calcium, ASSAY/Procedure, OTHER COMPONENTS/Content of Calcium, IMPURITIES/Related Compounds, SPECIFIC TESTS/Optical Rotation, Specific Rotation <781S>	Huy Dinh
Revision	CEFOTAXIME SODIUM PF 40(1) Pg. ONLINE	ASSAY/Procedure, IMPURITIES/Organic Impurities, Procedure 1, IMPURITIES/Organic Impurities, Procedure 2, SPECIFIC TESTS/Clarity and Color of Solution, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Cefetamet RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Cefotaxime Related Compound E RS	Ahalya Wise
Revision	CETYL ALCOHOL PF 40(1) Pg. ONLINE	Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Chromatographic Identity, ASSAY/Procedure, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Limit of Related Fatty Alcohols, SPECIFIC TESTS/Fats and Fixed Oils, Hydroxyl Value <401>, SPECIFIC TESTS/Water Determination, Method I <921>, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Lauryl Alcohol RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Myristyl Alcohol RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Oleyl Alcohol RS	Galina Holloway
Revision	CHLORAMPHENICOL OPHTHALMIC OINTMENT PF 39(5) Pg. ONLINE	ASSAY/Procedure, SPECIFIC TESTS/Minimum Fill <755>, SPECIFIC TESTS/Metal Particles in Ophthalmic Ointments <751>, SPECIFIC TESTS/Other Requirements	Ahalya Wise
Revision	CHLORAMPHENICOL AND POLYMYXIN B SULFATE OPHTHALMIC OINTMENT PF 39(5) Pg. ONLINE	ASSAY/Chloramphenicol, SPECIFIC TESTS/Metal Particles in Ophthalmic Ointments <751>, SPECIFIC TESTS/Other Requirements	Ahalya Wise
Revision	CHLORTETRACYCLINE HYDROCHLORIDE OPHTHALMIC OINTMENT PF 39(5) Pg. ONLINE	PERFORMANCE TESTS/Minimum Fill <755>, SPECIFIC TESTS/Water Determination, Method I <921>, SPECIFIC TESTS/Metal Particles in Ophthalmic Ointments <751>, SPECIFIC TESTS/Other Requirements	Ahalya Wise

Revision	CHOLESTEROL PF 39(3) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197A> or <197K>, IDENTIFICATION/B., IDENTIFICATION/C., ASSAY/Procedure, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>	Galina Holloway
New	CHONDROITIN SULFATE SODIUM, SHARK PF 38(6) Pg. ONLINE	Chemical Info/Chondroitin, hydrogen sulfate, sodium salt, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B. Identification Tests; General, Sodium <191>, IDENTIFICATION/C. Specific Disaccharides, IDENTIFICATION/D. Specific Rotation, COMPOSITION/Content of Chondroitin Sulfate Sodium, COMPOSITION/Disaccharide Composition, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Chloride and Sulfate, Chloride <221>, IMPURITIES/Chloride and Sulfate, Sulfate <221>, IMPURITIES/Electrophoretic Purity, IMPURITIES/Limit of Protein, CONTAMINANTS/Elemental Impurities; Procedures <233>, CONTAMINANTS/Microbial Enumeration Tests <2021>, CONTAMINANTS/Absence of Specified Microorganisms <2022>, SPECIFIC TESTS/Clarity and Color of Solution, SPECIFIC TESTS/Optical Rotation, Specific Rotation <781S>, SPECIFIC TESTS/pH <791>, SPECIFIC TESTS/Loss on Drying <731>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Chondroitin Sulfate Sodium, Shark RS	Huy Dinh
Revision	CIPROFLOXACIN OPHTHALMIC OINTMENT PF 39(5) Pg. ONLINE	ASSAY/Procedure, PERFORMANCE TESTS/Minimum Fill <755>, SPECIFIC TESTS/Metal Particles in Ophthalmic Ointments <751>, SPECIFIC TESTS/Other Requirements	Shankari Shivaprasad
Revision	CLOTRIMAZOLE PF 39(6) Pg. ONLINE	ASSAY/Procedure, IMPURITIES/Organic Impurities	Shankari Shivaprasad
Revision	CODEINE PHOSPHATE PF 38(6) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/C., ASSAY/Procedure, IMPURITIES/Organic Impurities, IMPURITIES/Limit of Morphine, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Codeine System Suitability Mixture C11 RS	Hillary Cai
Revision	CROMOLYN SODIUM PF 40(1) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, IMPURITIES/Limit of Oxalate, SPECIFIC TESTS/Acidity or Alkalinity, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Cromolyn Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Cromolyn Related Compound B RS	Ravi Ravichandran
Revision	CROMOLYN SODIUM INHALATION SOLUTION PF 40(1) Pg. ONLINE	IDENTIFICATION/A., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Cromolyn Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Cromolyn Related Compound B RS	Ravi Ravichandran
Revision	CROMOLYN SODIUM NASAL SOLUTION PF 40(1) Pg. ONLINE	IDENTIFICATION/A, ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Cromolyn Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Cromolyn Related Compound B RS	Ravi Ravichandran

Revision	CROMOLYN SODIUM OPHTHALMIC SOLUTION PF 40(1) Pg. ONLINE	IDENTIFICATION/A., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Cromolyn Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Cromolyn Related Compound B RS	Domenick Vicchio
Revision	DESCRIPTION AND SOLUBILITY PF 39(2) Pg. ONLINE	Desloratadine, Topotecan Hydrochloride, Argatroban, Calcipotriene, Eucalyptus Oil, Ibutilide Fumarate, Imatinib Mesylate, Norelgestromin, Polyethylene Glycol, Polyethylene Glycol 3350	Domenick Vicchio
New	DESLORATADINE PF 39(2) Pg. ONLINE	Chemical Info/Chemical Structure, Chemical Info/C19H19CIN2, Chemical Info/310.82, Chemical Info/Benzo[5,6]cyclohepta[1,2-b-pyridine, 8-chloro-6,11-dihydro-11-(4-piperidinylidene)-, 5H-; Chemical Info/8-Chloro-6,11-dihydro-11-(piperidin-4-ylidene)-5H-benzo[5,6]cyclohepta[1,2-b]pyridine, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Heavy Metals, Method II <231>, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Loss on Drying <731>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Desloratadine RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Desloratadine Related Compound A RS	Domenick Vicchio
Revision	DEXAMETHASONE TABLETS PF 39(5) Pg. ONLINE	IDENTIFICATION/A. Thin-Layer Chromatography, IDENTIFICATION/A. Infrared Absorption <197>, IDENTIFICATION/B., IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methylprednisolone RS	Domenick Vicchio
Revision	DEXAMETHASONE SODIUM PHOSPHATE OPHTHALMIC OINTMENT PF 39(5) Pg. ONLINE	PERFORMANCE TESTS/Minimum Fill <755>, SPECIFIC TESTS/Metal Particles in Ophthalmic Ointments <751>, SPECIFIC TESTS/Other Requirements	Domenick Vicchio
New	DEXTRAN OF WEIGHT-AVERAGE MOLECULAR WEIGHT 3,500,000 G/MOL PF 40(1) Pg. ONLINE	Dextran, Weight-Average Molecular Weight 3,500,000 g/mol	Hong Wang
Revision	DINOPROSTONE PF 39(6) Pg. ONLINE	ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Dinoprostone Related Compound C RS	Domenick Vicchio
Revision	DIPHENHYDRAMINE HYDROCHLORIDE INJECTION PF 39(6) Pg. ONLINE	ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Diphenhydramine Related Compound A RS	Domenick Vicchio
Revision	DIPIVEFRIN HYDROCHLORIDE PF 40(1) Pg. ONLINE	ASSAY/Procedure, IMPURITIES/Limits of Epinephrine and Dipivefrin Related Compound B, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Melting Range or Temperature <741>, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Epinephrine Bitartrate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Dipivefrin Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Dipivefrin Related Compound E RS	Feiwen Mao
Revision	DIPIVEFRIN HYDROCHLORIDE OPHTHALMIC SOLUTION PF 40(1) Pg. ONLINE	ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Dipivefrin Related Compound E RS	Feiwen Mao
Revision	ENOXAPARIN SODIUM PF 37(1) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/B. 13C NMR Spectrum, IDENTIFICATION/C., IDENTIFICATION/D., IDENTIFICATION/E., IMPURITIES/Heavy Metals, Method I <231>, SPECIFIC TESTS/pH <791>, SPECIFIC TESTS/Bacterial Endotoxins Test <85>	Anita Szajek

Revision	ENOXAPARIN SODIUM INJECTION PF 37(1) Pg. ONLINE	IDENTIFICATION/C. Identification Tests—General Sodium<191> Spectrophotometry and Light-Scattering <851>, OTHER COMPONENTS/Benzyl Alcohol Content (if Present), SPECIFIC TESTS/Bacterial Endotoxins Test <85>, SPECIFIC TESTS/Anti-Factor IIa Activity	Anita Szajek
New	ENROFLOXACIN COMPOUNDED ORAL SUSPENSION, VETERINARY PF 39(4) Pg. ONLINE	DEFINITION/Introduction, ASSAY/Procedure, SPECIFIC TESTS/pH <791>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/Beyond-Use Date, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Enrofloxacin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Enrofloxacin Related Compound Mixture RS	Jeanne Sun
Revision	EPITETRACYCLINE HYDROCHLORIDE PF 40(1) Pg. ONLINE	IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Limit of 4-Epianhydrotetracycline, SPECIFIC TESTS/4-Epianhydrotetracycline <226>, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Anhydrotetracycline Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP 4-Epianhydrotetracycline Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Epitetracycline Hydrochloride RS	Ahalya Wise
Revision	ERYTHROMYCIN OPHTHALMIC OINTMENT PF 39(5) Pg. ONLINE	ASSAY/Procedure, PERFORMANCE TESTS/Minimum Fill </55>, SPECIFIC TESTS/Metal Particles in Ophthalmic Ointments <751>, SPECIFIC TESTS/Water Determination, Method I <921>, SPECIFIC TESTS/Other Requirements, ADDITIONAL REQUIREMENTS/Packaging and Storage	Ahalya Wise
Revision	ESTRADIOL CYPIONATE PF 39(6) Pg. ONLINE	IDENTIFICATION/Ultraviolet Absorption <197U>, ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Melting Range or Temperature <741>, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Estradiol RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Estradiol Cypionate System Suitability Mixture RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/	Domenick Vicchio
New	EUCALYPTUS OIL PF 39(4) Pg. ONLINE	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	Hong Wang
New	FENTANYL TRANSDERMAL SYSTEM PF 38(6) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B. Infrared Absorption <197S>, ASSAY/Procedure, PERFORMANCE TESTS/Drug Release <724>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities, Procedure 1, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Fentanyl RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Fentanyl Citrate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Fentanyl Related Compound E RS	Hillary Cai

New FENUGREEK SEED PF 39(6) Pg. ONLINE

Title, DEFINITION/Introduction, IDENTIFICATION/A. Thin-Layer Chromatography-Amino Acid Profile, IDENTIFICATION/B. Thin-Layer Chromatography-Steroidal Saponins Profile, COMPOSITION/Content of 4-Hydroxyisoleucine, CONTAMINANTS/Elemental Impurities-Procedures <233>, CONTAMINANTS/Articles of Botanical Origin, General Method for Pesticide Residues Analysis <561>, CONTAMINANTS/Microbial Enumeration Tests <2021>, CONTAMINANTS/Absence of Specified Microorganisms <2022>, SPECIFIC TESTS/Presence of Trigonelline, SPECIFIC TESTS/Botanical Characteristics, SPECIFIC TESTS/Articles of Botanical Origin, Foreign Organic Matter <561>, SPECIFIC TESTS/Loss on Drying <731>, SPECIFIC TESTS/Articles of Botanical Origin, Total Ash <561>, SPECIFIC TESTS/Articles of Botanical Origin, Alcohol-Soluble Extractives, Method 1  <561>, SPECIFIC TESTS/Articles of Botanical Origin, Water-Soluble Extractives, Method 1  <561>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP 4-Hydroxyisoleucine RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Trigonella Foenum-graecum Seed Powdered Extract RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Trigonelline Hydrochloride RS

[Anton Bzhelyansky](#)

New FENUGREEK SEED POWDER PF 39(6) Pg. ONLINE

Title, DEFINITION/Introduction, IDENTIFICATION/A. Thin-Layer Chromatography-Amino Acid Profile, IDENTIFICATION/B. Thin-Layer Chromatography-Steroidal Saponins Profile, COMPOSITION/Content of 4-Hydroxyisoleucine, CONTAMINANTS/Elemental Impurities-Procedures <233>, CONTAMINANTS/Articles of Botanical Origin, General Method for Pesticide Residues Analysis <561>, CONTAMINANTS/Microbial Enumeration Tests <2021>, CONTAMINANTS/Absence of Specified Microorganisms <2022>, SPECIFIC TESTS/Presence of Trigonelline, SPECIFIC TESTS/Botanical Characteristics, SPECIFIC TESTS/Articles of Botanical Origin, Foreign Organic Matter <561>, SPECIFIC TESTS/Loss on Drying <731>, SPECIFIC TESTS/Articles of Botanical Origin, Total Ash <561>, SPECIFIC TESTS/Articles of Botanical Origin, Alcohol-Soluble Extractives, Method 1 <561>, SPECIFIC TESTS/Articles of Botanical Origin, Water-Soluble Extractives, Method 1 <561>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP 4-Hydroxyisoleucine RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Trigonella Foenum-graecum Seed Powdered Extract RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Trigonelline Hydrochloride RS

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New	FENUGREEK SEED POWDERED EXTRACT PF 39(6) Pg. ONLINE	Title, DEFINITION/Introduction, IDENTIFICATION/A. Thin-Layer Chromatography-Amino Acid Profile, IDENTIFICATION/B. Thin-Layer Chromatography-Steroidal Saponins Profile, COMPOSITION/Content of 4-Hydroxyisoleucine, CONTAMINANTS/Elemental Impurities-Procedures <233>, CONTAMINANTS/Articles of Botanical Origin, General Method for Pesticide Residues Analysis <561>, CONTAMINANTS/Microbial Enumeration Tests <2021>, CONTAMINANTS/Absence of Specified Microorganisms <2022>, SPECIFIC TESTS/Presence of Trigonelline, SPECIFIC TESTS/Water Determination, Method Ia <921>, SPECIFIC TESTS/Residue on Ignition <281>, SPECIFIC TESTS/Residual Solvents <565>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP 4-Hydroxyisoleucine RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Trigonella Foenum-graecum Seed Powdered Extract RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Trigonelline Hydrochloride RS	Anton Bzhelyansky
New	FLAX SEED OIL CAPSULES PF 39(6) Pg. ONLINE	Title, DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B. Fatty Acid Profile, STRENGTH/Content of Alpha Linolenic, Linoleic, and Oleic Acids, PERFORMANCE TESTS/Disintegration and Dissolution <2040>, PERFORMANCE TESTS/Weight Variation <2091>, SPECIFIC TESTS/Fats and Fixed Oils, Peroxide Value <401>, CONTAMINANTS/Microbial Enumeration Tests <2021>, CONTAMINANTS/Absence of Specified Microorganisms <2022>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Flax Oil RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methyl Linoleate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methyl Linolenate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methyl Oleate RS	Natalia Davydova
Revision	FLUOROMETHOLONE PF 40(1) Pg. ONLINE	IDENTIFICATION/UV Absorption <19/U>, IDENTIFICATION/C. Thin Layer Chromatography, ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Fluorometholone Related Compound A RS	Domenick Vicchio
Revision	FLUOROMETHOLONE OPHTHALMIC SUSPENSION PF 40(1) Pg. ONLINE	IDENTIFICATION/A. Thin-Layer Chromatography, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Fluorometholone Related Compound A RS	Domenick Vicchio
Revision	FORMOTEROL FUMARATE PF 40(1) Pg. ONLINE	IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, IMPURITIES/ Limit of Related Compound I (Diastereomer), Procedure 1, SPECIFIC TESTS/Optical Rotation, Angular Rotation <781A>	Ravi Ravichandran
New	G##_Octreotide Acetate, PTA-5 PF 36(6) Pg. 1778	G## (Octreotide Acetate, PTA-5)	Edith Chang
Revision	GENTAMICIN AND PREDNISOLONE ACETATE OPHTHALMIC OINTMENT PF 39(5) Pg. ONLINE	IDENTIFICATION/A. Thin-Layer Chromatography, ASSAY/Prednisolone Acetate, PERFORMANCE TESTS/Minimum Fill <755>, SPECIFIC TESTS/Water Determination, Method I <921>, SPECIFIC TESTS/Metal Particles in Ophthalmic Ointments <751>, SPECIFIC TESTS/Other Requirements, ADDITIONAL REQUIREMENTS/Packaging and Storage	Ahalya Wise

Revision	GENTAMICIN SULFATE OPHTHALMIC OINTMENT PF 39(5) Pg. ONLINE	IDENTIFICATION/A. Thin-Layer Chromatography, PERFORMANCE TESTS/Minimum Fill <755>, SPECIFIC TESTS/Metal Particles in Ophthalmic Ointments <751>, SPECIFIC TESTS/Water Determination, Method I <921>, SPECIFIC TESTS/Other Requirements, ADDITIONAL REQUIREMENTS/Packaging and Storage	Ahalya Wise
Revision	HYDROCODONE BITARTRATE PF 39(3) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Loss on Drying <731>, SPECIFIC TESTS/Water Determination <921>, Method I, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Dihydrocodeine Bitartrate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Hydrocodone RS	Hillary Cai
Revision	HYDROCORTISONE ACETATE OPHTHALMIC OINTMENT PF 39(5) Pg. ONLINE	SPECIFIC TESTS/Particulate Matter, SPECIFIC TESTS/Other Requirements, SPECIFIC TESTS/Minimum Fill <755>	Domenick Vicchio
Revision	HYDROXOCOBALAMIN PF 39(1) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/Ultraviolet Absorption <197U>, IDENTIFICATION/C., ASSAY/Procedure, IMPURITIES/Limit of Cyanocobalamin, IMPURITIES/Related Compounds, SPECIFIC TESTS/pH-Dependent Cobalamins, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>	Huy Dinh
Revision	HYDROXYZINE PAMOATE PF 39(6) Pg. ONLINE	IDENTIFICATION/B., ASSAY/Procedure, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Hydroxyzine Hydrochloride RS	Heather Joyce
New	IBUTILIDE FUMARATE PF 39(4) Pg. ONLINE	Title, Chemical Info/Chemical Structure, Chemical Info/(C20H36N2O3S)2·C4H4O4, Chemical Info/885.23, Chemical Info/Methanesulfonamide, N-[4-[4-(ethylheptylamino)-1-hydroxybutyl]phenyl]-, (±)-, (E)-2-butenedioate (2:1) (salt);, Chemical Info/(±)-4'-[4-(Ethylheptylamino)-1-hydroxybutyl]methanesulfonanilide fumarate (2:1) (salt), Chemical Info/CAS, Chemical Info/Ibutilide free base, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Heavy Metals, Method II <231>, IMPURITIES/Content of Fumaric Acid, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Water Determination, Method I <921>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Fumaric Acid RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ibutilide Fumarate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ibutilide Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ibutilide Related Compound B RS	Sujatha Ramakrishna
Revision	IDOXURIDINE OPHTHALMIC OINTMENT PF 39(5) Pg. ONLINE	SPECIFIC TESTS/Metal Particles in Ophthalmic Ointments <751>, SPECIFIC TESTS/Other Requirements	Shankari Shivaprasad

New	IMATINIB MESYLATE PF 39(6) Pg. ONLINE	Title, Chemical Info/Chemical Structure, Chemical Info/C29H31N7O-CH4O3S, Chemical Info/589.71, Chemical Info/C29H31N7O, Chemical Info/493.60, Chemical Info/Benzamide, 4 [(4-methyl-1-piperazinyl)methyl]-N-[4-methyl-3-[[4-(3-pyridinyl)-2-pyrimidinyl]aminophenyl]-, methanesulfonate salt;, Chemical Info/N-(4-Methyl-3-[[4-(pyridin-3-yl)pyrimidin-2-yl]amino}phenyl)-4-[[4-methylpiperazin-1-yl)methyl]benzamide mesylate, Chemical Info/CAS, Chemical Info/Imatinib, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197M>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Organic Impurities, IMPURITIES/Limit of Isopentyl Methanesulfonate, IMPURITIES/Limit of Imatinib Related Compound F, IMPURITIES/Limit of 1-Methylpiperazine, IMPURITIES/Limit of 3-Acetylpyridine, IMPURITIES/Limit of Dimethylamine, SPECIFIC TESTS/Water Determination, Method I <921>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP 3-Acetylpyridine RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Cyclizine Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Dimethylamine Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Imatinib Mesylate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Imatinib Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Imatinib Related Compound F RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Imatinib System Suitability Mixture RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Isopentyl Methanesulfonate RS	Feiwen Mao
New	IMATINIB TABLETS PF 39(6) Pg. ONLINE	Title, DEFINITION/Introduction, IDENTIFICATION/A., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities, IMPURITIES/Limit of Imatinib Related Compound F, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Imatinib Mesylate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Imatinib Related Compound F RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Imatinib System Suitability Mixture RS	Feiwen Mao
Revision	INDOMETHACIN PF 40(1) Pg. ONLINE	DEFINITION/Introduction, ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Indomethacin Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Indomethacin Related Compound B RS	Hillary Cai
Revision	ISONIAZID PF 39(6) Pg. ONLINE	IDENTIFICATION/B. Ultraviolet Absorption, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Melting Range or Temperature <741>	Shankari Shivaprasad
New	L##_Polyethylene Glycol 3350, Aquagel OH 40 PF 40(1) Pg. ONLINE	L##_ (Polyethylene Glycol 3350, Aquagel-OH40)	Hong Wang
New	L##_Polyethylene Glycol 3350, TSKgel G-Oligo-PW PF 40(1) Pg. ONLINE	L##_ (Polyethylene Glycol 3350, TSKgel G-Oligo-PW)	Hong Wang
Revision	L##_Octreotide Acetate, Synergi Max-RP PF 36(6) Pg. 1779	L##_ (Octreotide Acetate, Synergi Max-RP)	Edith Chang

New	L85 PF 38(6) Pg. ONLINE	L## (Adenine, Acclaim Mixed-Mode WCX-1)	Huy Dinh
Revision	LIDOCAINE HYDROCHLORIDE TOPICAL SOLUTION PF 39(6) Pg. ONLINE	IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Lidocaine Related Compound H RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methylparaben RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ropivacaine Related Compound A RS	Mary Koleck
Revision	LIDOCAINE HYDROCHLORIDE ORAL TOPICAL SOLUTION PF 39(6) Pg. ONLINE	IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, 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	MAGNESIUM SALICYLATE PF 40(1) Pg. ONLINE	C14H10MgO6, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/Ultraviolet Absorption <197U>, ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, 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	Hillary Cai
New	M-CRESOL PF 39(3) Pg. ONLINE	m-Cresol	Shankari Shivaprasad
New	MENAQUINONE-7 PF 40(1) Pg. ONLINE	Title, Chemical Info/Chemical Structure, Chemical Info/C46H64O2, Chemical Info/649.00, Chemical Info/(all-E)-2-(3,7,11,15,19,23,27-Heptamethyl-2,6,10,14,18,22,26-octacosaeptaenyl)-3-methyl-1,4-naphthalenedione, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197A>, IDENTIFICATION/B. Ultraviolet Absorption <197U>, IDENTIFICATION/C., ASSAY/Procedure, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Elemental Impurities-Procedures <233>, IMPURITIES/Enantiomeric Purity, 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 Menaquinone-7 RS	Huy Dinh
New	MENAQUINONE-7 PREPARATION PF 40(1) Pg. ONLINE	Title, DEFINITION/Introduction, IDENTIFICATION/A. Thin-Layer Chromatography, IDENTIFICATION/B., COMPOSITION/Content of Menaquinone-7, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Elemental Impurities-Procedures <233>, IMPURITIES/Enantiomeric Purity, SPECIFIC TESTS/Microbial Enumeration Tests <2021>, SPECIFIC TESTS/Absence of Specified Microorganisms <2022>, SPECIFIC TESTS/Loss on Drying <731> (for solid Menaquinone-7 Preparations), ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Menaquinone-7 RS	Huy Dinh

Revision	METHIMAZOLE PF 40(1) Pg. ONLINE	IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Ordinary Impurities <466>, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Melting Range or Temperature <741>, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methimazole Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methimazole Related Compound C RS	Elena Gonikberg
New	METHYLCOBALAMIN PF 39(5) Pg. ONLINE	Chemical Info/Chemical Structure, Chemical Info/C63H91CoN13O14P, Chemical Info/1344.40, Chemical Info/Coα-alpha;-5,6-Dimethyl-1H-benzoimidazol-1-yl]-Coβ-methylcobamide, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Ultraviolet Absorption <197U>, IDENTIFICATION/B. Cobalt, IDENTIFICATION/C., ASSAY/Procedure, IMPURITIES/Related Compounds, SPECIFIC TESTS/Water Determination, Method Ia <921>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Cyanocobalamin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Hydroxocobalamin Acetate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methylcobalamin RS	Huy Dinh
Revision	METHYLDOPA PF 39(2) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/B. Ultraviolet Absorption <197U>, IDENTIFICATION/B., IDENTIFICATION/C., ASSAY/Procedure, IMPURITIES/Limit of 3-O-Methylmethyldopa, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP 3-O-Methylmethyldopa RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methyldopa Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methyldopa Related Compound C RS	Sujatha Ramakrishna
Revision	METRONIDAZOLE TABLETS PF 40(1) Pg. ONLINE	PERFORMANCE TESTS/Dissolution <711>, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Tinidazole Related Compound A RS	Shankari Shivaprasad
New	MORPHINE SULFATE EXTENDED-RELEASE TABLETS PF 35(5) Pg. 1164	Title, DEFINITION/Introduction, IDENTIFICATION/A. Identification Tests-General, Sulfate <191>, IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities/Procedure, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>	Clydewyn Anthony
Revision	MYRISTYL ALCOHOL PF 40(1) Pg. ONLINE	Title, Chemical Info, DEFINITION/Introduction, IDENTIFICATION/A. Chromatographic Identity, ASSAY/Procedure, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Limit of Related Fatty Alcohols, SPECIFIC TESTS/Melting Range or Temperature, Class II <741>, SPECIFIC TESTS/Fats and Fixed Oils, Hydroxyl Value <401>, SPECIFIC TESTS/Water Determination, Method I <921>, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Lauryl Alcohol RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Oleyl Alcohol RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Stearyl Alcohol RS	Galina Holloway

Revision	NAPROXEN TABLETS PF 39(5) Pg. ONLINE	IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Naproxen Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Naproxen Related Compound L RS	Hillary Cai
Revision	NAPROXEN SODIUM TABLETS PF 39(5) Pg. ONLINE	IDENTIFICATION/B., IDENTIFICATION/C., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Naproxen Related Compound A, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Naproxen Related Compound L	Hillary Cai
New	NAPROXEN SODIUM AND PSEUDOEPHEDRINE HYDROCHLORIDE EXTENDED-RELEASE TABLETS PF 38(6) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/A., 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/USP Reference Standards <11>/USP Naproxen Sodium RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Pseudoephedrine Hydrochloride RS	Hillary Cai
Revision	NEOMYCIN SULFATE OPHTHALMIC OINTMENT PF 39(5) Pg. ONLINE	PERFORMANCE TESTS/Minimum Fill <755>, SPECIFIC TESTS/Water Determination, Method I <921>, SPECIFIC TESTS/Metal Particles in Ophthalmic Ointments <751>, SPECIFIC TESTS/Other Requirements	Ahalya Wise
Revision	NEOMYCIN SULFATE AND DEXAMETHASONE SODIUM PHOSPHATE OPHTHALMIC OINTMENT PF 39(5) Pg. ONLINE	ASSAY/Dexamethasone Phosphate, PERFORMANCE TESTS/Minimum Fill <755>, SPECIFIC TESTS/Water Determination, Method I <921>, SPECIFIC TESTS/Metal Particles in Ophthalmic Ointments <751>, SPECIFIC TESTS/Other Requirements	Ahalya Wise
Revision	NEOMYCIN AND POLYMYXIN B SULFATES OPHTHALMIC OINTMENT PF 39(5) Pg. ONLINE	PERFORMANCE TESTS/Minimum Fill <755>, SPECIFIC TESTS/Water Determination, Method I <921>, SPECIFIC TESTS/Sterility Tests <71>, SPECIFIC TESTS/Metal Particles in Ophthalmic Ointments <751>, SPECIFIC TESTS/Other Requirements	Ahalya Wise
Revision	NEOMYCIN AND POLYMYXIN B SULFATES AND BACITRACIN OPHTHALMIC OINTMENT PF 39(5) Pg. ONLINE	PERFORMANCE TESTS/Minimum Fill <755>, SPECIFIC TESTS/Water Determination, Method I <921>, SPECIFIC TESTS/Sterility Tests <71>, SPECIFIC TESTS/Metal Particles in Ophthalmic Ointments <751>, SPECIFIC TESTS/Other Requirements	Ahalya Wise
Revision	NEOMYCIN AND POLYMYXIN B SULFATES, BACITRACIN, AND HYDROCORTISONE ACETATE OPHTHALMIC OINTMENT PF 39(5) Pg. ONLINE	ASSAY/Hydrocortisone Acetate, PERFORMANCE TESTS/Minimum Fill <755>, SPECIFIC TESTS/Water Determination, Method I <921>, SPECIFIC TESTS/Sterility Tests <71>, SPECIFIC TESTS/Metal Particles in Ophthalmic Ointments <751>, SPECIFIC TESTS/Other Requirements	Ahalya Wise
Revision	NEOMYCIN AND POLYMYXIN B SULFATES AND BACITRACIN ZINC OPHTHALMIC OINTMENT PF 39(5) Pg. ONLINE	PERFORMANCE TESTS/Minimum Fill <755>, SPECIFIC TESTS/Water Determination, Method I <921>, SPECIFIC TESTS/Metal Particles in Ophthalmic Ointments <751>, SPECIFIC TESTS/Other Requirements, ADDITIONAL REQUIREMENTS/Packaging and Storage	Ahalya Wise
Revision	NEOMYCIN AND POLYMYXIN B SULFATES, BACITRACIN ZINC, AND HYDROCORTISONE OPHTHALMIC OINTMENT PF 39(5) Pg. ONLINE	ASSAY/Hydrocortisone, PERFORMANCE TESTS/Minimum Fill <755>, SPECIFIC TESTS/Water Determination, Method I <921>, SPECIFIC TESTS/Metal Particles in Ophthalmic Ointments <751>, SPECIFIC TESTS/Other Requirements	Ahalya Wise

Revision	NEOMYCIN AND POLYMYXIN B SULFATES, BACITRACIN ZINC, AND HYDROCORTISONE ACETATE OPHTHALMIC OINTMENT PF 39(5) Pg. ONLINE	ASSAY/Hydrocortisone Acetate, PERFORMANCE TESTS/Minimum Fill <755>, SPECIFIC TESTS/Water Determination, Method I <921>, SPECIFIC TESTS/Sterility Tests <71>, SPECIFIC TESTS/Metal Particles in Ophthalmic Ointments <751>, SPECIFIC TESTS/Other Requirements, ADDITIONAL REQUIREMENTS/Packaging and Storage	Ahalya Wise
Revision	NEOMYCIN AND POLYMYXIN B SULFATES AND DEXAMETHASONE OPHTHALMIC OINTMENT PF 39(5) Pg. ONLINE	ASSAY/Dexamethasone, PERFORMANCE TESTS/Minimum Fill <755>, SPECIFIC TESTS/Water Determination, Method Ib <921>, SPECIFIC TESTS/Sterility Tests <71>, SPECIFIC TESTS/Metal Particles in Ophthalmic Ointments <751>, SPECIFIC TESTS/Other Requirements	Ahalya Wise
Revision	NIACIN PF 40(1) Pg. ONLINE	IDENTIFICATION/B. Ultraviolet Absorption <197U>, IMPURITIES/Related Compounds, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP 6-Methylnicotinic Acid RS, DEFINITION/Introduction, IDENTIFICATION/C., ASSAY/Procedure, IMPURITIES/Ordinary Impurities <466>, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP 6-Hydroxynicotinic Acid RS	Huy Dinh
New	NORELGESTROMIN PF 39(6) Pg. ONLINE	Title, Chemical Info/Chemical Structure, Chemical Info/C21H29NO2, Chemical Info/327.46, Chemical Info/18,19-Dinorpregn-4-en-20-yn-3-one, 13-ethyl-17-hydroxy-, oxime, (17α)-, Chemical Info/13-Ethyl-17-hydroxy-18,19-dinor-17-alpha;-pregn-4-en-20-yn-3-one oxime, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Heavy Metals, Method II <231>, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Optical Rotation, Specific Rotation <781S>, SPECIFIC TESTS/Water Determination, Method Ic <921>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Norelgestromin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Norelgestromin Related Compound A RS	Mary Koleck
New	OCTANESULFONIC ACID SODIUM SALT, MONOHYDRATE PF 39(6) Pg. ONLINE	Octanesulfonic Acid Sodium Salt, Monohydrate	Feiwen Mao

New	OCTREOTIDE ACETATE PF 36(6) Pg. 1559	Title, Chemical Info/Chemical Structure, Chemical Info/C49H66N10O10S2·xC2H4O2, Chemical Info/l-Cysteinamide, d-phenylalanyl-l-cysteinyl-l-phenylalanyl-d-tryptophyl-l-lysyl-l-threonyl-N-[2-hydroxy-1-(hydroxymethyl)propyl]-, cyclic (2→7)-disulfide, [R-(R*,R*)]-, acetate (salt);, Chemical Info/d-Phenylalanyl-l-cysteinyl-l-phenylalanyl-d-tryptophyl-l-lysyl-l-threonyl-N-[(1R,2R)-2-hydroxy-1-(hydroxymethyl)propyl]-l-cysteinamide cyclic (2-rarr;7)-disulfide acetate (salt);, Chemical Info/d-Phenylalanyl-l-hemicystyl-l-phenylalanyl-d-tryptophyl-l-lysyl-l-threonyl-l-hemicystyl-l-threoninol cyclic (2-rarr;7)-disulfide acetate (salt)., Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities/Procedure 1: Limit of Octreotide Acetate Related Compounds, IMPURITIES/Organic Impurities/Procedure 2: Limit of Trifluoroacetic acid (TFA), IMPURITIES/Organic Impurities/Procedure 3: Limit of Triethylamine, SPECIFIC TESTS/Amino acid content, SPECIFIC TESTS/Water Determination, Method I <921>, SPECIFIC TESTS/pH <791>, SPECIFIC TESTS/Acetic Acid Content <503>, SPECIFIC TESTS/Optical Rotation, Specific Rotation <781S>, SPECIFIC TESTS/Bacterial Endotoxins <85>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference standards <11>/USP Octreotide Acetate RS, ADDITIONAL REQUIREMENTS/USP Reference standards <11>/USP Octreotide Acetate (Non-Cyclic) System Suitability Marker RS, ADDITIONAL REQUIREMENTS/USP Reference standards <11>/USP Glacial Acetic Acid RS	Edith Chang
Revision	BLAND LUBRICATING OPHTHALMIC OINTMENT PF 39(5) Pg. ONLINE	SPECIFIC TESTS/Homogeneity, SPECIFIC TESTS/Metal Particles in Ophthalmic Ointments <751>, SPECIFIC TESTS/Other Requirements	Feiwen Mao
Revision	OXYTETRACYCLINE HYDROCHLORIDE AND POLYMYXIN B SULFATE OPHTHALMIC OINTMENT PF 39(5) Pg. ONLINE	PERFORMANCE TESTS/Minimum Fill <755>, SPECIFIC TESTS/Metal Particles in Ophthalmic Ointments <751>, SPECIFIC TESTS/Water Determination, Method I <921>, SPECIFIC TESTS/Other Requirements, ADDITIONAL REQUIREMENTS/Packaging and Storage	Aalya Wise
Revision	Pepsin PF 38(3) Pg. ONLINE	Pepsin, Pepsin	Margareth Marques
Revision	Pepsin, Purified PF 38(3) Pg. ONLINE	Reagent Specification, Pepsin, Purified	Margareth Marques
Revision	PHENYTOIN PF 40(1) Pg. ONLINE	IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, IMPURITIES/Limit of benzophenone, SPECIFIC TESTS/Clarity and Color of Solution, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Benzophenone RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Phenytoin Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Phenytoin Related Compound B RS	Ravi Ravichandran
New	POLYETHYLENE GLYCOL STANDARDS WITH MOLECULAR WEIGHTS OF 960, 1960, 3020, 6430, AND 12,300 DALTONS (G/MOL) PF 40(1) Pg. ONLINE	Polyethylene Glycol Standards with Molecular Weights of 960, 1960, 3020, 6430, and 12,300 Daltons (g/mol)	Hong Wang
Revision	POLYETHYLENE GLYCOL PF 39(6) Pg. ONLINE	SPECIFIC TESTS/Viscosity-Capillary Viscometer Methods <911>	Jenny Liu

New	POLYETHYLENE GLYCOL 3350 PF 39(6) Pg. ONLINE	Title, Chemical Info/Poly(oxy-1,2-ethanediyl), -alpha;-hydro-ω-hydroxy-; , Chemical Info/1,2-Ethanediol, homopolymer, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197F>, IDENTIFICATION/B. Chromatographic Identity, ASSAY/Procedure, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Heavy Metals <231>, IMPURITIES/Limit of Ethylene Oxide and Dioxane, IMPURITIES/Limit of Ethylene Glycol and Diethylene Glycol, IMPURITIES/Limit of Formaldehyde and Acetaldehyde, SPECIFIC TESTS/Apparent Weight-Average Molecular Weight and Polydispersity, SPECIFIC TESTS/Acidity and Alkalinity, SPECIFIC TESTS/Water Determination, Method I <921>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Diethylene Glycol RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ethylene Glycol RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Polyethylene Glycol 3350 RS	Hong Wang
Revision	PROPOXYPHENE NAPSYLATE PF 39(2) Pg. ONLINE	Chemical Info/Chemical Structure, Chemical Info/(-alpha;S,1R)-α-[2-(Dimethylamino)1-methylethyl]-alpha;-phenylphenethyl propionate compound with 2-naphthalenesulfonic acid (1:1) monohydrate(2S,3R)-(+)-4-(Dimethylamino)-3-methyl-1,2-diphenyl-2-butanol propionate (ester) 2-naphthalenesulfonate (1:1) monohydrate, IDENTIFICATION/B. Ultraviolet Absorption <197U>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Melting Range or Temperature, Class I <741>, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Propoxyphene Related Compound A RS	Hillary Cai
Revision	PYRIDOSTIGMINE BROMIDE TABLETS PF 39(6) Pg. ONLINE	IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Pyridostigmine Related Compound A RS	Ravi Ravichandran
Revision	REPAGLINIDE PF 39(6) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/B. Ultraviolet Absorption <197U>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, IMPURITIES/Enantiomeric Purity, SPECIFIC TESTS/Optical Rotation, Specific Rotation <781S>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Repaglinide Related Compound E RS	Elena Gonikberg
New	RIVASTIGMINE TRANSDERMAL SYSTEM PF 39(4) Pg. ONLINE	Title, DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, OTHER COMPONENTS/Content of Alpha Tocopherol (if present), PERFORMANCE TESTS/Drug Release <724>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Rivastigmine Related Compound C RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Rivastigmine Related Compound D RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Rivastigmine Related Compound E RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Rivastigmine Related Compound F RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Rivastigmine Tartrate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Alpha Tocopherol RS	Elena Gonikberg
New	SABINENE PF 39(4) Pg. ONLINE	Reagent Specification, Sabinene	Hong Wang

Revision	SAFFLOWER OIL PF 39(5) Pg. ONLINE	Chemical Info, DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B., IMPURITIES/Alkaline Impurities, SPECIFIC TESTS/Fatty Acid Composition, SPECIFIC TESTS/Fats and Fixed Oils, Fatty Acid Composition <401>, SPECIFIC TESTS/Fats and Fixed Oils, Iodine Value, Method II <401>, SPECIFIC TESTS/Limit of Peroxide, SPECIFIC TESTS/Water Determination, Method Ic <921>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>	Galina Holloway
Revision	SODIUM CHLORIDE OPHTHALMIC OINTMENT PF 39(5) Pg. ONLINE	ASSAY/Procedure, PERFORMANCE TESTS/Minimum Fill <755>, SPECIFIC TESTS/Metal Particles in Ophthalmic Ointments <751>, SPECIFIC TESTS/Other Requirements, ADDITIONAL REQUIREMENTS/Packaging and Storage	Mary Koleck
New	SPIRULINA PF 37(6) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B. Fatty Acids Profile, IDENTIFICATION/C. HPLC for Chlorophyll A, IDENTIFICATION/D. HPLC for Carotenoids, COMPOSITION/Content of Beta Carotene and Total Carotenoids, COMPOSITION/Content of C-Phycocyanin, COMPOSITION/Content of Protein, CONTAMINANTS/Limit of Microcystins, CONTAMINANTS/Elemental Contaminants, CONTAMINANTS/Articles of Botanical Origin, General Method for Pesticide Residues Analysis <561>, CONTAMINANTS/Microbial Enumeration Tests <2021>, CONTAMINANTS/Absence of Specified Microorganisms <2022>, SPECIFIC TESTS/Description, SPECIFIC TESTS/Loss on Drying <731>, SPECIFIC TESTS/Articles of Botanical Origin, Total Ash <561>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Beta Carotene RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methyl Linoleate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methyl Linolenate 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 Palmitoleate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methyl Stearate RS	Anton Bzhelyansky

New	SPIRULINA TABLETS PF 37(6) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/A. Fatty Acids Profile, IDENTIFICATION/B. HPLC for Chlorophyll A, IDENTIFICATION/C. HPLC for Carotenoids, STRENGTH/Content of Beta Carotene and Total Carotenoids, STRENGTH/Content of C-Phycocyanin, STRENGTH/Content of Protein, PERFORMANCE TESTS/Weight Variation <2091>, CONTAMINANTS/Limit of Microcystins, CONTAMINANTS/Elemental Contaminants <2233>, CONTAMINANTS/Articles of Botanical Origin, General Method for Pesticide Residues Analysis <561>, CONTAMINANTS/Microbial Enumeration Tests <2021>, CONTAMINANTS/Absence of Specified Microorganisms <2022>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Beta Carotene RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methyl Linoleate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methyl Linolenate 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 Palmitoleate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methyl Stearate RS	Anton Bzhelyansky
Revision	SULFACETAMIDE SODIUM OPHTHALMIC OINTMENT PF 39(5) Pg. ONLINE	SPECIFIC TESTS/Metal Particles in Ophthalmic Ointments <751>, SPECIFIC TESTS/Other Requirements	Shankari Shivaprasad
Revision	SULFACETAMIDE SODIUM AND PREDNISOLONE ACETATE OPHTHALMIC OINTMENT PF 39(5) Pg. ONLINE	IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Sulfacetamide Sodium, ASSAY/Prednisolone Acetate, PERFORMANCE TESTS/Minimum Fill <755>, SPECIFIC TESTS/Metal Particles in Ophthalmic Ointments <751>, SPECIFIC TESTS/Other Requirements	Hillary Cai
Revision	SULFAMETHOXAZOLE PF 39(6) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/B. Ultraviolet Absorption <197U>, IDENTIFICATION/B., IDENTIFICATION/C., ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Melting Range or Temperature, Class I <741>, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Sulfamethoxazole Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Sulfamethoxazole Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Sulfamethoxazole Related Compound C RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Sulfamethoxazole Related Compound F RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Sulfanilic Acid RS	Shankari Shivaprasad
Revision	SULFAMETHOXAZOLE AND TRIMETHOPRIM ORAL SUSPENSION PF 40(1) Pg. ONLINE	IDENTIFICATION/A., IMPURITIES/Limit Of Trimethoprim Degradation Product, IMPURITIES/Limit of Sulfanilamide, Sulfanilic Acid, and Sulfamethoxazole N4-Glucoside, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Sulfamethoxazole Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Sulfamethoxazole Related Compound F RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Trimethoprim Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Trimethoprim Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Trimethoprim Related Compound C RS	Shankari Shivaprasad

Revision	SULINDAC PF 40(1) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/C., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Sulindac Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Sulindac Related Compound B, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Sulindac Related Compound C	Hillary Cai
Revision	SUNFLOWER OIL PF 39(5) Pg. ONLINE	Chemical Info, DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B., IMPURITIES/Alkaline Impurities, SPECIFIC TESTS/Fats and Fixed Oils, Fatty Acid Composition <401>, SPECIFIC TESTS/Fats and Fixed Oils, Saponification Value <401>, SPECIFIC TESTS/Refractive Index <831>, SPECIFIC TESTS/Specific Gravity <841>, SPECIFIC TESTS/Water Determination, Method Ic <921>, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>	Hong Wang
Revision	TETRACAINE PF 39(6) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/A. Procedure, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B. Procedure, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Melting Range or Temperature, Class I <741>, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Aminobenzoic Acid RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Tetracaine Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Tetracaine Related Compound C RS	Mary Koleck
Revision	TETRACAINE HYDROCHLORIDE PF 39(6) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/A. Ultraviolet Absorption <197U>, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B. Procedure, IDENTIFICATION/C, IDENTIFICATION/C., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Aminobenzoic Acid RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Tetracaine Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Tetracaine Related Compound C RS	Mary Koleck
Revision	TETRACYCLINE HYDROCHLORIDE OPHTHALMIC OINTMENT PF 39(5) Pg. ONLINE	IDENTIFICATION/A., PERFORMANCE TESTS/Minimum Fill <755>, SPECIFIC TESTS/Water Determination, Method I <921>, SPECIFIC TESTS/Metal Particles in Ophthalmic Ointments <751>, SPECIFIC TESTS/Other Requirements, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP 4-Epianhydrotetracycline Hydrochloride RS	Ahalya Wise
Revision	TOBRAMYCIN OPHTHALMIC OINTMENT PF 39(5) Pg. ONLINE	IDENTIFICATION/A. Thin-Layer Chromatography, PERFORMANCE TESTS/Minimum Fill <755>, SPECIFIC TESTS/Sterility Tests <71>, SPECIFIC TESTS/Water Determination, Method I <921>, SPECIFIC TESTS/Metal Particles in Ophthalmic Ointments <751>, SPECIFIC TESTS/Other Requirements	Ahalya Wise
Revision	TOBRAMYCIN AND DEXAMETHASONE OPHTHALMIC OINTMENT PF 39(5) Pg. ONLINE	IDENTIFICATION/A. Thin-Layer Chromatography, PERFORMANCE TESTS/Minimum Fill <755>, SPECIFIC TESTS/Metal Particles in Ophthalmic Ointments <751>, SPECIFIC TESTS/Sterility Tests <71>, SPECIFIC TESTS/Water Determination, Method I <921>, SPECIFIC TESTS/Other Requirements	Ahalya Wise

New	TOPOTECAN HYDROCHLORIDE PF 39(1) Pg. ONLINE	<p>Chemical Info/Chemical Structure, Chemical Info/C23H23N3O5·HCl, Chemical Info/457.91 (n = 1), Chemical Info/1H-Pyrano[3-prime;,4-prime::6,7]indolizino[1,2-b]quinoline-3,14(4H,12H)-dione, 10-[(dimethylamino)methyl]-4-ethyl-4,9-dihydroxy-, monohydrochloride, (S)-; , Chemical Info/(S)-10-[(Dimethylamino)methyl]-4-ethyl-4,9-dihydroxy-1H-pyrano[3-prime;,4-prime::6,7]indolizino[1,2-b]quinoline-3,14(4H,12H)-dione monohydrochloride; , Chemical Info/CAS, Chemical Info/5/4 Hydrochloride, Chemical Info/C23H23N3O5·5/4 HCl, Chemical Info/467.02 (n = 5/4), Chemical Info/Topotecan, Chemical Info/C23H23N3O5, Chemical Info/421.45, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., IDENTIFICATION/C., ASSAY/Procedure, OTHER COMPONENTS/Content of Chloride, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Heavy Metals, Method II <231>, IMPURITIES/Organic Impurities, IMPURITIES/Limit of Methanol and Acetone (if it is present in the manufacturing process), IMPURITIES/Limit of Triethylamine (if it is present in the manufacturing process), SPECIFIC TESTS/Water Determination, Method Ia <921>, SPECIFIC TESTS/Specific Rotation <781S>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Topotecan Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Topotecan Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Triethylamine RS</p>	Feiwen Mao
New	TOPOTECAN FOR INJECTION PF 39(1) Pg. ONLINE	<p>DEFINITION/Introduction, IDENTIFICATION/A. Ultraviolet Absorption <197U>, IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Bacterial Endotoxins Test <85>, SPECIFIC TESTS/Sterility Tests <71>, SPECIFIC TESTS/pH <791>, SPECIFIC TESTS/Particulate Matter in Injections <788>, SPECIFIC TESTS/Constituted Solution, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Endotoxin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Irinotecan Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Topotecan Hydrochloride RS</p>	Feiwen Mao
Revision	TROPICAMIDE PF 39(5) Pg. ONLINE	<p>Chemical Info/Chemical Structure, Chemical Info/(±)-N-Ethyl-2-phenyl-N-(4-pyridylmethyl)hydracrylamideN-Ethyl-3-hydroxy-2-phenyl-N-(pyridin-4-ylmethyl)propanamide, DEFINITION/Introduction, IDENTIFICATION/B. Ultraviolet Absorption <197U>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Melting Range or Temperature, Class I <741>, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/</p>	Feiwen Mao
Revision	USP AND NF EXCIPIENTS, LISTED BY CATEGORY PF 39(4) Pg. ONLINE	<p>{Flavors and Perfumes} Eucalyptus Oil, {Coating Agent} Polyethylene Glycol 3350, {Diluent} Polyethylene Glycol 3350, {Film-Forming Agent} Polyethylene Glycol 3350, {Lubricant} Polyethylene Glycol 3350, {Ointment Base} Polyethylene Glycol 3350, {Plasticizer} Polyethylene Glycol 3350, {Solvent} Polyethylene Glycol 3350, {Suppository Base} Polyethylene Glycol 3350</p>	Hong Wang