

Compendial Deferrals for USP37-NF32 2S

Category	Monograph Title	Monograph Section	Scientific Liaison
Revision	<1> INJECTIONS PF 39(5) Pg. ONLINE	INTRODUCTION, NOMENCLATURE AND DEFINITIONS, INGREDIENTS, LABELS AND LABELING, PACKAGING, FOREIGN AND PARTICULATE MATTER, STERILITY, CONSTITUTED SOLUTIONS, INTRODUCTION, PRODUCT QUALITY TESTS COMMON TO PARENTERAL DOSAGE FORMS, PRODUCT QUALITY TESTS FOR SPECIFIC PARENTERAL DOSAGE FORMS	Desmond Hunt
Revision	<7> LABELING PF 38(6) Pg. ONLINE	DEFINITION, LABELS AND LABELING FOR INJECTABLE PRODUCTS, LABELING FOR PRODUCTS AND OTHER CATEGORIES, GENERAL LABELING	Donna Bohannon
New	<89> ENZYMES USED AS ANCILLARY MATERIALS IN PHARMACEUTICAL MANUFACTURING PF 39(5) Pg. ONLINE	Title, INTRODUCTION/Introduction, DEFINITION/Paragraph Text, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, PURITY/Procedure, SPECIFIC TESTS/Protein Content, SPECIFIC TESTS/Microbial Enumeration Tests <61>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>	Edith Chang
Revision	<111> DESIGN AND ANALYSIS OF BIOLOGICAL ASSAYS PF 39(4) Pg. ONLINE	General	Maura Kibbey
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>	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	<231> HEAVY METALS PF 39(1) Pg. ONLINE	Title, Introduction, SPECIAL REAGENTS, METHOD I, METHOD II, METHOD III	Kahkashan Zaidi
Revision	<341> ANTIMICROBIAL AGENTS--CONTENT PF 39(3) Pg. ONLINE	Introduction, GENERAL GAS CHROMATOGRAPHIC METHOD, POLAROGRAPHIC METHOD	Shankari Shivaprasad
Revision	<659> PACKAGING AND STORAGE REQUIREMENTS PF 39(4) Pg. ONLINE	GENERAL DEFINITIONS, Introduction, PACKAGING, GENERAL DEFINITIONS, INJECTION PACKAGING, STORAGE CONDITIONS	Desmond Hunt
Revision	<661> CONTAINERS -- PLASTICS PF 39(5) Pg. ONLINE	Title, INTRODUCTION, POLYETHYLENE CONTAINERS, POLYPROPYLENE CONTAINERS, POLYETHYLENE TEREPHTHALATE BOTTLES AND POLYETHYLENE TEREPHTHALATE G CONTAINERS, TEST METHODS, SCOPE	Desmond Hunt
New	<661.1> PLASTIC MATERIALS OF CONSTRUCTION PF 39(5) Pg. ONLINE	Title, INTRODUCTION, SCOPE, TEST METHODS, SPECIFICATIONS	Desmond Hunt
New	<661.2> PLASTIC PACKAGING SYSTEMS FOR PHARMACEUTICAL USE PF 39(5) Pg. ONLINE	Title, INTRODUCTION, SCOPE, TEST METHODS, SPECIFICATIONS	Desmond Hunt

New	<697> CONTAINER CONTENT FOR INJECTIONS PF 38(6) Pg. ONLINE	Introduction, DETERMINATION OF VOLUME OF INJECTION IN CONTAINERS	Desmond Hunt
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	<851> SPECTROPHOTOMETRY AND LIGHT-SCATTERING PF 39(3) Pg. ONLINE	Title, ULTRAVIOLET, VISIBLE, INFRARED, ATOMIC ABSORPTION, FLUORESCENCE, TURBIDIMETRY, NEPHELOMETRY, AND RAMAN MEASUREMENTLIGHT-SCATTERING, COMPARATIVE UTILITY OF SPECTRAL RANGES, THEORY AND TERMS, APPARATUS, PROCEDURE	Horacio Pappa
New	<852> ATOMIC ABSORPTION SPECTROSCOPY PF 37(5) Pg. ONLINE	Title, INTRODUCTION, QUALIFICATION OF ATOMIC ABSORPTION SPECTROPHOTOMETERS, PROCEDURE, VALIDATION AND VERIFICATION	Horacio Pappa
New	<853> FLUORESCENCE SPECTROSCOPY PF 39(1) Pg. ONLINE	Title, INTRODUCTION, QUALIFICATION OF FLUORESCENCE INSTRUMENTS, QUALITATIVE AND QUANTITATIVE FLUORESCENCE MEASUREMENTS, GOOD SPECTROSCOPIC PRACTICE, VALIDATION AND VERIFICATION	Horacio Pappa
New	<854> MID-INFRARED SPECTROSCOPY PF 37(5) Pg. ONLINE	Title, INTRODUCTION, QUALIFICATION OF IR SPECTROPHOTOMETERS, PROCEDURE, VALIDATION AND VERIFICATION	Horacio Pappa
New	<857> ULTRAVIOLET-VISIBLE SPECTROSCOPY PF 37(5) Pg. ONLINE	Title, INTRODUCTION, QUALIFICATION OF UV-VIS SPECTROPHOTOMETERS, PROCEDURE, VALIDATION AND VERIFICATION	Horacio Pappa
Revision	<911> VISCOSITY - CAPILLARY VISCOMETER METHODS PF 39(5) Pg. ONLINE	{Title}, ??INTRO??/Introduction, ??INTRO??/Ubbelohde-Type, ??INTRO??/Ostwald-Type	Hong Wang
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	<1663> EXTRACTABLES ASSOCIATED WITH PHARMACEUTICAL PACKAGING SYSTEMS PF 39(5) Pg. ONLINE	Title, 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	Title, 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	Title, 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 - DRUG RELEASE TESTS PF 39(5) Pg. ONLINE	Title, INTRODUCTION, PERFORMANCE TESTS (DISSOLUTION/DRUG RELEASE)	Margareth Marques

New	<1852> ATOMIC ABSORPTION SPECTROSCOPY - THEORY AND PRACTICE PF 37(5) Pg. ONLINE	Title, THEORY, INSTRUMENTATION, SAMPLE CELL DESIGNS, LINE SOURCES, WAVELENGTH SELECTORS, DETECTION SYSTEMS, BACKGROUND CORRECTION, ANALYTICAL CONSIDERATIONS, OTHER SOURCES OF INFORMATION, APPENDIX: ACRONYMS	Horacio Pappa
New	<1853> FLUORESCENCE SPECTROSCOPY - THEORY AND PRACTICE PF 39(1) Pg. ONLINE	Title, THEORY, INSTRUMENTATION, FACTORS THAT AFFECT QUANTITATION, CALIBRATION OF FLUORESCENCE INSTRUMENTS, PROCEDURE VALIDATION, APPENDIX: DEFINITIONS	Horacio Pappa
New	<1854> MIDDLE INFRARED SPECTROSCOPY - THEORY AND PRACTICE PF 37(5) Pg. ONLINE	Title, PRINCIPLES OF MID-INFRARED SPECTROSCOPY, SAMPLING PROCEDURES, MICROSPECTROSCOPY AND IMAGING, INSTRUMENTATION, ANALYTICAL CONSIDERATIONS, FACTORS THAT AFFECT PHOTOMETRIC AND WAVENUMBER ACCURACY	Horacio Pappa
New	<1857> ULTRAVIOLET-VISIBLE SPECTROSCOPY - THEORY AND PRACTICE PF 37(5) Pg. ONLINE	Title, THEORY, INSTRUMENTATION, CALIBRATION, ANALYTICAL CONSIDERATIONS, OTHER SOURCES OF INFORMATION	Horacio Pappa
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
New	24,25-DIHYDROLANOSTEROL PF 39(5) Pg. ONLINE	Reagent Specification, 24,25-Dihydrolanosterol	Hong Wang
Revision	ACETAMINOPHEN SUPPOSITORIES PF 39(3) Pg. ONLINE	IMPURITIES/4-Aminophenol in Acetaminophen-Containing Drug Products <227>	Clydewyn Anthony
Revision	ADENINE PF 38(6) Pg. ONLINE	ASSAY/Procedure, IMPURITIES/Organic Impurities, IMPURITIES/Related Compounds, SPECIFIC TESTS/Nitrogen Content, Method II <461>	Huy Dinh
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	AMANTADINE HYDROCHLORIDE PF 39(3) Pg. ONLINE	ASSAY/Procedure, IMPURITIES/Organic Impurities, IDENTIFICATION/Infrared Absorption <197S>, ASSAY/Procedure	Shankari Shivaprasad
Revision	AMANTADINE HYDROCHLORIDE CAPSULES PF 39(5) Pg. ONLINE	PERFORMANCE TESTS/Dissolution <711>	Shankari Shivaprasad
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	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,	Sujatha Ramakrishna

		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	
New	ARTEMETHER AND LUMEFANTRINE TABLETS PF 39(1) Pg. ONLINE	Title, DEFINITION/Introduction, IDENTIFICATION/A., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Procedure for Artemether, IMPURITIES/Procedure for Lumefantrine, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Artemether RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Artemether Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Artemether Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Lumefantrine RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Lumefantrine Related Compound A RS	Shankari Shivaprasad
Revision	ASCORBYL PALMITATE PF 38(6) Pg. ONLINE	IDENTIFICATION/A. Procedure, IDENTIFICATION/B, IDENTIFICATION/B., ASSAY/Procedure, SPECIFIC TESTS/Melting Range or Temperature <741>	Galina Holloway
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
New	BENZYLPARABEN PF 39(3) Pg. ONLINE	Benzylparaben	Shankari Shivaprasad
New	BETA-PINENE PF 39(4) Pg. ONLINE	Reagent Specification, β-Pinene	Hong Wang
Revision	Brucine Sulfate PF 39(4) Pg. ONLINE	Brucine Sulfate,	Margareth Marques

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	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
New	CHOLESTANOL PF 39(5) Pg. ONLINE	Reagent Specification, Cholesterol	Hong Wang
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, 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
New	CISATRACURIUM BESYLATE PF 39(5) Pg. ONLINE	Chemical Info/Chemical Structure, Chemical Info/C65H82N2O18S2, Chemical Info/1243.48, Chemical Info/Isoquinolinium, 2,2′-[1,5-pentanediy]bis[oxy(3-oxo-3,1-propanediyl)]bis[1-[(3,4-dimethoxyphenyl)methyl]-1,2,3,4-tetrahydro-6,7-dimethoxy-2-methyl-, dibenzenesulfonate, [1R-[1α,2α(1′R*,2′R*)]]-;-, Chemical Info/(1R,2R)-2-(2-Carboxyethyl)-1,2,3,4-tetrahydro-6,7-dimethoxy-2-methyl-1-veratrylisoquinolinium benzenesulfonate, pentamethylene ester, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Limit of Methyl Benzenesulfonate test, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Optical Rotation, Specific Rotation <781>, SPECIFIC TESTS/pH <791>, SPECIFIC TESTS/Water Determination, Method Ia <921>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Cisatracurium Besylate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Cisatracurium Besylate System Suitability Mixture RS	Heather Joyce
New	CISATRACURIUM BESYLATE INJECTION PF 39(5) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., ASSAY/Procedure, OTHER COMPONENTS/Benzyl Alcohol Content (if present), IMPURITIES/Organic Impurities, SPECIFIC TESTS/pH <791>, 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 Benzyl Alcohol RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Cisatracurium Besylate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Cisatracurium Besylate System Suitability Mixture RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Endotoxin RS	Heather Joyce

Revision	CLARITHROMYCIN TABLETS PF 39(4) Pg. ONLINE	ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Clarithromycin Identity RS	Ahalya Wise
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
New	COSYNTROPIN PF 39(2) Pg. ONLINE	Title, Chemical Info/Chemical Structure, Chemical Info/C136H210N4O031S, Chemical Info/2933, Chemical Info/α1-24-Corticotropin, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B. Amino Acid Analysis, ASSAY/Procedure, IMPURITIES/Organic Impurities, Related Peptides, OTHER COMPONENTS/Acetic Acid in Peptides <503>, OTHER COMPONENTS/Trifluoroacetic Acid Content, SPECIFIC TESTS/Absorption <851>, SPECIFIC TESTS/Bacterial Endotoxins <85>, SPECIFIC TESTS/Microbial Enumeration Tests <61> and Tests for Specified Microorganisms <62>, SPECIFIC TESTS/Optical Rotation, Specific Rotation <781S>, SPECIFIC TESTS/Water Determination, Method 1c <921>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Cosyntropin Acetate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Endotoxin RS	Dale Schmidt
Revision	DESCRIPTION AND SOLUBILITY PF 38(2) Pg. ONLINE	Rabeprazole Sodium, Desloratadine, Dutasteride, Entecavir, Topotecan Hydrochloride, Argatroban, Calcipotriene, Eucalyptus Oil, Ibutilide Fumarate, Cisatracurium Besylate, Desonide, Hydrogenated Lanolin	Elena Gonikberg
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
New	DESONIDE PF 39(5) Pg. ONLINE	Chemical Info/Chemical Structure, Chemical Info/C24H32O6, Chemical Info/416.51, Chemical Info/Pregna-1,4-diene-3,20-dione, 11,21-dihydroxy-16,17-[(1-methylethylidene)bis(oxy)]-, (11β,16α)-; , Chemical Info/11β,16α,17,21-Tetrahydroxypregna-1,4-diene-3,20-dione cyclic 16,17-acetal with acetone, 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>, SPECIFIC TESTS/Optical Rotation, Specific Rotation <781S>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Desonide RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Desonide	Domenick Vicchio

		Hydroxy-3-(hydroxymethyl)-2-methylenecyclopentyl]guanine monohydrate., Chemical Info/Anhydrous, Chemical Info/277.28 [142217-69-4]., DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B. Infrared Absorption <197>, ASSAY/Procedure, IMPURITIES/Organic Impurities, IMPURITIES/Limit of Entecavir Related Compound A, SPECIFIC TESTS/Water Determination, Method 1c <921>, SPECIFIC TESTS/Optical Rotation, Specific Rotation <781S>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Entecavir Monohydrate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Entecavir Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Entecavir System Suitability Mixture RS	
New	ENTECAVIR TABLETS PF 39(2) Pg. ONLINE	Title, DEFINITION/Introduction, IDENTIFICATION/A., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Microbial Enumeration Tests <61> and Tests for Specified Microorganisms <62>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Entecavir Monohydrate RS	Shankari Shivaprasad
Revision	ERYTHROMYCIN OPHTHALMIC OINTMENT PF 39(5) Pg. ONLINE	ASSAY/Procedure, 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
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	EVENING PRIMROSE OIL PF 39(4) Pg. ONLINE	IDENTIFICATION/B. Identification of Fixed Oils by Thin-Layer Chromatography <202>	Huy Dinh
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
Revision	FLUCONAZOLE INJECTION PF 39(2) Pg. ONLINE	{Title} Fluconazole in Dextrose Injection, DEFINITION/Introduction, IDENTIFICATION/B. Test for Dextrose, ASSAY/Procedure, IMPURITIES/Introduction, IMPURITIES/Organic Impurities, IMPURITIES/Procedure 2: For Polar Impurities, IMPURITIES/Organic Impurities: Procedure 3, IMPURITIES/Organic Impurities: Procedure 4,	Shankari Shivaprasad

ADDITIONAL REQUIREMENTS/Labeling

Title, Chemical Info/Chemical Structure, Chemical Info/C31H43N3O49S8Na10, Chemical Info/1728.08, Chemical Info/α-d-Glucopyranoside, methyl O-2-deoxy-6-O-sulfo-2-(sulfoamino)-α-d-glucopyranosyl-(1→4)-O-β-d-glucopyranuronosyl-(1→4)-O-2-deoxy-3,6-di-O-sulfo-2-(sulfoamino)-α-d-glucopyranosyl-(1→4)-O-2-O-sulfo-α-l-idopyranuronosyl-(1→4)-2-deoxy-2-(sulfoamino)-, 6-(hydrogen sulfate), decasodium salt; , Chemical Info/Methyl O-2-deoxy-6-O-sulfo-2-(sulfoamino)-α-d-glucopyranosyl-(1→4)-O-β-d-glucopyranuronosyl-(1→4)-O-2-deoxy-3,6-di-O-sulfo-2-(sulfoamino)-α-d-glucopyranosyl-(1→4)-O-2-O-sulfo-α-l-idopyranuronosyl-(1→4)-2-deoxy-6-O-sulfo-2-(sulfoamino)-α-d-glucopyranoside, decasodium salt, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. 13C NMR Spectrum, IDENTIFICATION/B. Chromatographic Identity, IDENTIFICATION/C. Sodium Determination, ASSAY/Procedure, OTHER COMPONENTS/Sodium Determination, IMPURITIES/Heavy Metals, Method I <231>, IMPURITIES/Free Sulfate and Residual Chloride Determination, IMPURITIES/Organic Impurities, IMPURITIES/Pyridine and Ethanol Determination, SPECIFIC TESTS/Bacterial Endotoxins Test <85>, SPECIFIC TESTS/pH <791>, SPECIFIC TESTS/Microbial Enumeration Tests <61>, SPECIFIC TESTS/Water Determination, Method Ic <921>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Endotoxin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Fondaparinux Sodium for Assay RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Fondaparinux Sodium Identification RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Fondaparinux Sodium System Suitability Mixture A RS

New FONDAPARINUX SODIUM PF 39(5) Pg. ONLINE

[Anita Szajek](#)

Title, DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B. Identification Tests-General, Chloride <191>, ASSAY/Procedure, IMPURITIES/Free Sulfate Determination, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Bacterial Endotoxins Test <85>, SPECIFIC TESTS/Particulate Matter in Injections <788>, SPECIFIC TESTS/Sterility Tests <71>, SPECIFIC TESTS/pH <791>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Endotoxin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Fondaparinux Sodium for Assay RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Fondaparinux Sodium System Suitability Mixture B RS

New FONDAPARINUX SODIUM INJECTION PF 39(5) Pg. ONLINE

[Anita Szajek](#)

G## (Octreotide Acetate, PTA-5)

New G##_Octreotide Acetate, PTA-5 PF 36(6) Pg. 1778

[Edith Chang](#)

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

Revision GENTAMICIN AND PREDNISOLONE ACETATE OPHTHALMIC OINTMENT PF 39(5) Pg. ONLINE

[Ahalya Wise](#)

IDENTIFICATION/A. Thin-Layer Chromatography, PERFORMANCE

Revision GENTAMICIN SULFATE OPHTHALMIC OINTMENT PF 39(5) Pg. ONLINE

[Ahalya Wise](#)

		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	
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 HYDROCHLORIDE INJECTION PF 39(5) Pg. ONLINE	IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Limit of 4-Chlorobenzophenone, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP 4-Chlorobenzophenone 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	INSULIN GLARGINE PF 39(4) Pg. ONLINE	Chemical Info/Chemical Structure, Chemical Info/C267H404N72O78S6, Chemical Info/6062.89, Chemical Info/Insulin (human), 21A-glycine-30Ba-l-arginine-30Bb-l-arginine, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B. Peptide Mapping, ASSAY/Procedure, OTHER COMPONENTS/Zinc Determination, IMPURITIES/Related Compounds, IMPURITIES/Limit of High Molecular Weight Proteins, SPECIFIC TESTS/Insulin Assays, Bioidentity Test <121>.,	Edith Chang

SPECIFIC TESTS/Bacterial Endotoxins Test <85>, SPECIFIC TESTS/Microbial Enumeration Tests <61> and Tests For Specified Microorganisms <62>, SPECIFIC TESTS/Water Determination, Method 1c <921>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Endotoxin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Insulin Glargine RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Insulin Glargine for Peak Identification RS

DEFINITION/Introduction, IDENTIFICATION/A., ASSAY/Procedure, OTHER COMPONENTS/Zinc Determination, IMPURITIES/Related Compounds, IMPURITIES/Limit of High Molecular Weight Proteins, SPECIFIC TESTS/pH <791>, SPECIFIC TESTS/Bacterial Endotoxins Test <85>, SPECIFIC TESTS/Sterility Tests <71>, SPECIFIC TESTS/Particulate Matter in Injections <788>, SPECIFIC TESTS/Injections <1>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>:/USP Endotoxin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>:/USP Insulin Glargine RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>:/USP Insulin Glargine for Peak Identification RS

New INSULIN GLARGINE INJECTION PF 39(4) Pg. ONLINE

[Edith Chang](#)

Revision L##_Octreotide Acetate, Synergi Max-RP PF 36(6) Pg. 1779

L## (Octreotide Acetate, Synergi Max-RP)

[Edith Chang](#)

New L81 PF 39(4) Pg. ONLINE

Reagent Specification, L81

[Margareth Marques](#)

Revision L85 PF 39(3) Pg. ONLINE

L## (Adenine, GC <227>, Acclaim Mixed-Mode WCX-1), L## (Adenine, Acclaim Mixed-Mode WCX-1)

[Clydewyn Anthony](#)

New LAMIVUDINE TABLETS PF 39(1) Pg. ONLINE

Title, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197M>, 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 Lamivudine RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Lamivudine Resolution Mixture B RS

[Shankari Shivaprasad](#)

New HYDROGENATED LANOLIN PF 39(5) Pg. ONLINE

Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Chromatographic Profile of Fatty Alcohols, Hydrocarbons, and Sterols, IMPURITIES/Heavy Metals, Method II <231>, IMPURITIES/Residue on Ignition <281>, SPECIFIC TESTS/Melting Range or Temperature <741>, SPECIFIC TESTS/Fats and Fixed Oils, Acid Value <401>, SPECIFIC TESTS/Fats and Fixed Oils, Hydroxyl Value <401>, SPECIFIC TESTS/Fats and Fixed Oils, Saponification Value <401>, SPECIFIC TESTS/Loss on Drying <731>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Cetyl Alcohol RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Hydrogenated Lanolin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Stearyl Alcohol RS

[Hong Wang](#)

Revision LEVOFLOXACIN PF 39(2) Pg. ONLINE

Chemical Info/(−)-(S)-9-Fluoro-2,3-dihydro-3-methyl-10-(4-methyl-

[Shankari](#)

		1-piperaziny)-7-oxo-7H-pyrido[1,2,3-de]-1,4-[1,4]benzoxazine-6-carboxylic acid, hemihydrate, IMPURITIES/Paragraph Text, IMPURITIES/Organic Impurities, Procedure 1, IMPURITIES/Organic Impurities, Procedure 2, IMPURITIES/Organic Impurities (Enantiomeric Purity), Procedure 3, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Levofloxacin Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Levofloxacin Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Levofloxacin Related Compound D RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP R-Ofloxacin RS	Shivaprasad
New	LEVOFLOXACIN INJECTION PF 39(5) Pg. ONLINE	Title, DEFINITION/Introduction, IDENTIFICATION/A. Ultraviolet Absorption <197U>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Bacterial Endotoxins <85>, SPECIFIC TESTS/Sterility Tests <71>, SPECIFIC TESTS/pH <791>, SPECIFIC TESTS/Particulate Matter in Injections <788>, SPECIFIC TESTS/Osmolality and Osmolarity <785>, SPECIFIC TESTS/Other Requirements, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Levofloxacin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Levofloxacin Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Levofloxacin Related Compound B RS	Shankari Shivaprasad
New	(R)-(+)-LIMONENE PF 39(4) Pg. ONLINE	Reagent Specification, (R)-(+)-Limonene	Hong Wang
New	M-CRESOL PF 39(3) Pg. ONLINE	m-Cresol	Shankari Shivaprasad
New	METHYLCOBALAMIN PF 39(5) Pg. ONLINE	Chemical Info/Chemical Structure, Chemical Info/C63H91CoN13O14P, Chemical Info/1344.40, Chemical Info/Coα-[α-5,6-Dimethyl-1H-benzimidazol-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	METOPROLOL TARTRATE PF 39(1) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197M>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Metoprolol Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Metoprolol Related Compound B RS,	Sujatha Ramakrishna

		ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Metoprolol Related Compound C RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Metoprolol Related Compound D RS	
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	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 39(1) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/C., ASSAY/Procedure, IMPURITIES/Ordinary Impurities <466>, IMPURITIES/Related Compounds, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP 6-Hydroxynicotinic Acid RS	Huy Dinh
New	NICARDIPINE HYDROCHLORIDE INJECTION PF 39(4) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/A., ASSAY/Procedure, IMPURITIES/Limit of N-Benzyl-N-methyl-ethanolamine, IMPURITIES/Organic Impurities, OTHER COMPONENTS/Content of Sorbitol, 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 N-Benzyl-N-methyl-ethanolamine RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Endotoxin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Nicardipine Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Sorbitol RS	Sujatha Ramakrishna
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→7)-disulfide acetate (salt);, Chemical Info/d-Phenylalanyl-l-hemicystyl-l-phenylalanyl-d-tryptophyl-l-lysyl-l-threonyl-l-hemicystyl-l-threoninol cyclic (2→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,	Edith Chang

		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	
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	Ahalya Wise
Revision	Pepsin PF 38(3) Pg. ONLINE	Pepsin	Margareth Marques
Revision	Pepsin, Purified PF 38(3) Pg. ONLINE	Reagent Specification, Pepsin, Purified	Margareth Marques
Revision	PROCHLORPERAZINE MALEATE PF 39(4) Pg. ONLINE	Chemical Info/2-Chloro-10-[3-(4-methyl-1-piperazinyl)-4-methylpiperazin-1-yl]propyl]phenothiazine maleate (1:2), DEFINITION/Paragraph Text, IMPURITIES/Ordinary Impurities <466>, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Prochlorperazine Related Compound A RS	Elena Gonikberg
Revision	PROCHLORPERAZINE MALEATE TABLETS PF 39(4) Pg. ONLINE	DEFINITION/Paragraph Text, ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Prochlorperazine Related Compound A RS	Elena Gonikberg
Revision	PROPOXYPHENE NAPSYLATE PF 39(2) Pg. ONLINE	Chemical Info/Chemical Structure, Chemical Info/(αS,1R)-α-[2-(Dimethylamino)-1-methylethyl]-α-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
New	RABEPRAZOLE SODIUM PF 38(2) Pg. ONLINE	Title, Chemical Info/Chemical Structure, Chemical Info/C18H20N3NaO3S, Chemical Info/381.42, Chemical Info/ 1H-Benzimidazole, 2-[[[4-(3-methoxypropoxy)-3-methyl-2-pyridinyl]methyl]sulfinyl]-, sodium salt;, Chemical Info/2-[[[4-(3-Methoxypropoxy)-3-methyl-2-pyridyl]methyl]sulfinyl]benzimidazole sodium salt, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., IDENTIFICATION/C. Identification Tests—General, Sodium <191>, ASSAY/Procedure, IMPURITIES/Heavy Metals, IMPURITIES/Organic Impurities, SPECIFIC	Elena Gonikberg

TESTS/Loss on Drying <731>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Rabeprazole Sodium RS

Title, DEFINITION/Introduction, IDENTIFICATION/A. Ultraviolet Absorption, IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Acid Stage, PERFORMANCE TESTS/Buffer Stage, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Rabeprazole Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Rabeprazole Related Compound C RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Rabeprazole Related Compound D RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Rabeprazole Related Compound E RS

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

DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B. Thin-Layer Chromatography, IDENTIFICATION/C. HPLC, COMPOSITION/Content of Phenolic Diterpenes, COMPOSITION/Volatile Oil Content <561>, 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/Botanic 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, Acid-Insoluble Ash <561>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Carnosic Acid RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Powdered Rosemary Hydrophilic Extract RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Rosmarinic Acid RS

DEFINITION/Introduction, IDENTIFICATION/A. Thin-Layer Chromatography, IDENTIFICATION/B. HPLC, COMPOSITION/Content of Rosmarinic Acid, CONTAMINANTS/Elemental Impurities—Procedures <233>, CONTAMINANTS/Articles of Botanical Origin, General Method for Pesticide

New

RABEPRAZOLE SODIUM DELAYED-RELEASE TABLETS PF 38(2) Pg. ONLINE

[Elena Gonikberg](#)

New

RIVASTIGMINE TRANSDERMAL SYSTEM PF 39(4) Pg. ONLINE

[Elena Gonikberg](#)

New

ROSEMARY PF 39(1) Pg. ONLINE

[Anton Bzhelyansky](#)

New

ROSEMARY LEAF DRY AQUEOUS EXTRACT PF 39(1) Pg. ONLINE

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Residues Analysis <561>, CONTAMINANTS/Microbial Enumeration Tests <2021>, CONTAMINANTS/Absence of Specified Microorganisms <2022>, SPECIFIC TESTS/Loss on Drying <731>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Powdered Rosemary Hydrophilic Extract RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Rosmarinic Acid RS

DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B. Thin-Layer Chromatography, IDENTIFICATION/C. HPLC, COMPOSITION/Content of Phenolic Diterpenes, 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/Botanic Characteristics, SPECIFIC TESTS/Loss on Drying <731>, 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 Carnosic Acid RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Powdered Rosemary Hydrophilic Extract RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Rosmarinic Acid RS

New POWDERED ROSEMARY PF 39(1) Pg. ONLINE

[Anton Bzhelyansky](#)

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](#)

New SEVELAMER CARBONATE PF 38(6) Pg. ONLINE

Title, Chemical Info/Chemical Structure, Chemical Info/[(C3H7N)m(C3H5ClO)n].xCH2O3., Chemical Info/ Carbonic acid, compound with (chloromethyl)oxirane polymer with 2-propen-1-amine; , Chemical Info/Prop-2-en-1-amine polymer with (chloromethyl)oxirane carbonate, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197A>, ASSAY/Total Titratable Amines <541>, ASSAY/Carbonate Content, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Heavy Metals, Method II <231>, IMPURITIES/Limit of Chloride, IMPURITIES/Limit of Epichlorohydrin, IMPURITIES/Limit of Soluble Oligomers, IMPURITIES/Limit of Allyl Amine, SPECIFIC TESTS/Loss on Drying, SPECIFIC TESTS/Swell Index, SPECIFIC TESTS/Particle Size Determination, Light Diffraction Measurement of Particle Size <429>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Polyallylamine Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Sevelamer Carbonate RS

[Sujatha Ramakrishna](#)

New	SEVELAMER CARBONATE FOR ORAL SUSPENSION PF 38(6) Pg. ONLINE	Title, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197A>, ASSAY/Total Titratable Amines, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Limit of Soluble Oligomers, IMPURITIES/Limit of Allylamine, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Polyallylamine RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Sevelamer Carbonate RS	Sujatha Ramakrishna
New	SEVELAMER CARBONATE TABLETS PF 38(6) Pg. ONLINE	Title, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197A>, ASSAY/Total Titratable Amines <541>, PERFORMANCE TESTS/Disintegration <701>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Limit of Soluble Oligomers, IMPURITIES/Limit of Allylamine, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Polyallylamine Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Sevelamer Carbonate RS	Sujatha Ramakrishna
New	SEVELAMER HYDROCHLORIDE PF 38(6) Pg. ONLINE	Title, Chemical Info/Chemical Structure, Chemical Info/(C ₃ H ₇ N) _m (C ₃ H ₅ ClO) _n ·xHCl, Chemical Info/2-Propen-1-amine polymer with (chloromethyl)oxirane, hydrochloride;, Chemical Info/Allylamine polymer with 1-chloro-2,3-epoxypropane, hydrochloride, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197A>, ASSAY/Total Titratable Amines, ASSAY/Chloride Content, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Heavy Metals, Method II <231>, IMPURITIES/Limit of Epichlorohydrin, IMPURITIES/Limit of Soluble Oligomers, IMPURITIES/Limit of Allyl Amine, SPECIFIC TESTS/Loss on Drying <731>, SPECIFIC TESTS/Swell Index, SPECIFIC TESTS/Particle Size Determination, Light Diffraction Measurement of Particle Size <429>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Polyallylamine RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Sevelamer Hydrochloride RS	Sujatha Ramakrishna
New	SEVELAMER HYDROCHLORIDE TABLETS PF 38(6) Pg. ONLINE	Title, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197A>, ASSAY/Total Titratable Amines <541>, PERFORMANCE TESTS/Disintegration <701>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Limit of Soluble Oligomers, IMPURITIES/Limit of Allylamine, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Polyallylamine Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Sevelamer Hydrochloride RS	Sujatha Ramakrishna
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>,	Anton Bzhelyansky

	<p>New SPIRULINA TABLETS PF 37(6) Pg. ONLINE</p>	<p>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</p> <p>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</p>	<p>Anton Bzhelyansky</p>
	<p>Revision SQUALANE PF 38(6) Pg. ONLINE</p>	<p>DEFINITION/Introduction, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Chromatographic Purity</p> <p>ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Sulbactam Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Sulbactam Related Compound C RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Sulbactam Related Compound D RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Sulbactam Related Compound E RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Sulbactam Related Compound F RS</p>	<p>Galina Holloway</p>
	<p>Revision SULBACTAM SODIUM PF 39(4) Pg. ONLINE</p>	<p>ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Sulbactam Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Sulbactam Related Compound C RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Sulbactam Related Compound D RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Sulbactam Related Compound E RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Sulbactam Related Compound F RS</p>	<p>Ahalya Wise</p>
	<p>Revision SULFACETAMIDE SODIUM OPHTHALMIC OINTMENT PF 39(5) Pg. ONLINE</p>	<p>SPECIFIC TESTS/Metal Particles in Ophthalmic Ointments <751>, SPECIFIC TESTS/Other Requirements</p>	<p>Shankari Shivaprasad</p>
	<p>Revision SULFACETAMIDE SODIUM AND PREDNISOLONE ACETATE OPHTHALMIC OINTMENT PF 39(5) Pg. ONLINE</p>	<p>IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Sulfacetamide Sodium, ASSAY/Prednisolone Acetate, PERFORMANCE TESTS/Minimum Fill <755>, SPECIFIC TESTS/Metal Particles in Ophthalmic Ointments <751>, SPECIFIC</p>	<p>Hillary Cai</p>

TESTS/Other Requirements

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	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
New	TETRADECYLAMMONIUM BROMIDE PF 39(4) Pg. ONLINE	Reagent Specification, Tetradecylammonium Bromide	Ahalya Wise
Revision	THIORIDAZINE HYDROCHLORIDE PF 39(1) Pg. ONLINE	Chemical Info/Chemical Structure, DEFINITION/Introduction, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Melting Range or Temperature <741>, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Thioridazine Related Compound F RS	Ravi Ravichandran
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	Chemical Info/Chemical Structure, Chemical Info/C23H23N3O5·HCl, Chemical Info/457.91 (n = 1), Chemical Info/1H-Pyrano[3′ ,4′ : 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′ ,4′ : 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	Feiwen Mao

		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	
New	TOPOTECAN FOR INJECTION PF 39(1) Pg. ONLINE	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	Feiwen Mao
New	TRANDOLAPRIL AND VERAPAMIL HYDROCHLORIDE EXTENDED-RELEASE TABLETS PF 38(6) Pg. ONLINE	Title, DEFINITION/Introduction, IDENTIFICATION/A., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities, Procedure 1, IMPURITIES/Organic Impurities, Procedure 2, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Trandolapril RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Trandolapril Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Verapamil Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Verapamil Related Compound B RS	Sujatha Ramakrishna
Revision	TROPICAMIDE PF 39(5) Pg. ONLINE	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>/	Feiwen Mao
Revision	USP AND NF EXCIPIENTS, LISTED BY CATEGORY PF 39(4) Pg. ONLINE	{Flavors and Perfumes} Eucalyptus Oil, {Emollient} Hydrogenated Lanolin, {Emulsifying agent } Hydrogenated Lanolin, {Humectant} Hydrogenated Lanolin, {Ointment Base} Hydrogenated Lanolin	Hong Wang