Compendial Approvals for USP37-NF32 2S

Category	Monograph Title	Monograph Section	Scientific Liaison
New	<124> ERYTHROPOIETIN BIOASSAYS PF 39(5) Pg. ONLINE	Introduction, NORMOCYTHEMIC MICE ASSAY	Fouad Atouf
New	<126>SOMATROPIN BIOIDENTITY TESTS PF 39(5) Pg. ONLINE	Introduction, PROCEDURE/In Vivo Bioidentity Test, PROCEDURE/In Vitro Cell-Based Bioidentity Test	<u>Maura</u> <u>Kibbey</u>
New	<227> 4-AMINOPHENOL IN ACETAMINOPHEN-CONTAINING DRUG PRODUCTS PF 39(3) Pg. ONLINE	INTRODUCTION/Introduction, INTRODUCTION/SOLUTION PREPARATIONS, INTRODUCTION/CHROMATOGRAPHIC METHOD, INTRODUCTION/ANALYSIS, INTRODUCTION/CHROMATOGRAPHIC ADJUSTMENTS	<u>Clydewyn</u> <u>Anthony</u>
Revision	<441> NIACIN OR NIACINAMIDE ASSAY PF 39(5) Pg. ONLINE	CHEMICAL METHOD, MICROBIOLOGICAL METHOD, CHROMATOGRAPHIC METHODS	Huy Dinh
New	<469> ETHYLENE GLYCOL, DIETHYLENE GLYCOL, AND TRIETHYLENE GLYCOL IN ETHOXYLATED SUBSTANCES PF 39(4) Pg. ONLINE	??INTRO??/Introduction, IMPURITIES/Procedure/Diluent, IMPURITIES/Procedure/Standard solution, IMPURITIES/Procedure/Sample solution, IMPURITIES/Procedure/Chromatographic system, IMPURITIES/Procedure/System suitability, IMPURITIES/Procedure/Analysis, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>	Hong Wang
Revision	<563> IDENTIFICATION OF ARTICLES OF BOTANICAL ORIGIN PF 39(5) Pg. ONLINE	DNA-BASED METHODS FOR AUTHENTICATION OF ARTICLES OF BOTANICAL ORIGIN	<u>Christopher</u> <u>Okunji</u>
Revision	<671> CONTAINERSPERFORMANCE TESTING PF 39(2) Pg. ONLINE	INTRODUCTION, MOISTURE VAPOR TRANSMISSION, SPECTRAL TRANSMISSION	<u>Desmond</u> <u>Hunt</u>
New	<705> QUALITY ATTRIBUTES OF TABLETS LABELED AS HAVING A FUNCTIONAL SCORE PF 39(4) Pg. ONLINE	PURPOSE, SCOPE, SPLITTING TABLETS WITH FUNCTIONAL SCORING, DISSOLUTION, DISINTEGRATION	<u>William</u> <u>Brown</u>
Revision	<724> DRUG RELEASE PF 39(4) Pg. ONLINE	Introduction, TRANSDERMAL DELIVERY SYSTEMS-GENERAL DRUG RELEASE STANDARDS, SCOPE, GENERAL DRUG RELEASE STANDARDS	<u>William</u> <u>Brown</u>
Revision	<736> MASS SPECTROMETRY PF 39(5) Pg. ONLINE	Title, SAMPLE INTRODUCTION, IONIZATION TECHNIQUES, ANALYZERS, TANDEM MASS SPECTROMETRY, DATA ANALYSIS AND INTERPRETATION, INTRODUCTION, QUALITATIVE ANALYSIS, QUANTITATIVE ANALYSIS, QUALIFICATION OF MASS SPECTROMETRY INSTRUMENTS, VALIDATION AND VERIFICATION OF MASS SPECTROMETRY ANALYTICAL PROCEDURES	Alan Potts
Revision	<741> MELTING RANGE OR TEMPERATURE PF 39(5) Pg. ONLINE	Introduction, APPARATUS, PROCEDURES	Antonio Hernandez- Cardoso
Revision	<781> OPTICAL ROTATION PF 39(5) Pg. ONLINE	INTRODUCTION, PROCEDURES	Antonio Hernandez- Cardoso
Revision	<791> pH PF 39(5) Pg. ONLINE	Introduction, BUFFER SOLUTIONS FOR STANDARDIZATION OF THE PH METER, INTRODUCTION, pH MEASUREMENT SYSTEM, INSTRUMENT REQUIREMENTS, BUFFER SOLUTIONS FOR STANDARDIZATION OF THE PH MEASUREMENT SYSTEM, CALIBRATION, OPERATION	Antonio Hernandez- Cardoso

Omission	<1081> GEL STRENGTH OF GELATIN PF 39(5) Pg. ONLINE	Entire document	Hong Wang
New	<1115> BIOBURDEN CONTROL OF NONSTERILE DRUG SUBSTANCES AND PRODUCTS PF 39(4) Pg. ONLINE	Introduction, US REGULATORY GUIDANCE DOCUMENTS, MICROBIAL CONTROL CONSIDERATIONS DURING PRODUCT DEVELOPMENT, MICROBIAL CONTROL CONSIDERATIONS DURING MANUFACTURING, MICROBIAL CONTROL OF DRUG SUBSTANCE MANUFACTURING, MICROBIAL ASSESSMENT OF NONSTERILE PRODUCT MANUFACTURING ENVIRONMENTS, OVERALL MANAGEMENT OF A MICROBIOLOGICAL CONTROL PROGRAM, REFERENCES	<u>Radhakrishna</u> <u>Tirumalai</u>
Revision	<1151> PHARMACEUTICAL DOSAGE FORMS PF 39(5) Pg. ONLINE	GENERAL CONSIDERATIONS, PRODUCT QUALITY TESTS, GENERAL, DOSAGE FORMS, GLOSSARY	<u>William</u> <u>Brown</u>
Revision	<1181> SCANNING ELECTRON MICROSCOPY PF 39(4) Pg. ONLINE	Introduction, ELECTRON BEAM-SAMPLE INTERACTION, APPARATUS, PROCEDURE, INTRODUCTION, UTILITY OF THE TECHNIQUE, ELECTRON BEAM GENERATION, SAMPLE PREPARATION, X-RAY GENERATION AND ELEMENTAL COMPOSITIONAL ANALYSIS, IMAGE OPTIMIZATION, FORENSIC ANALYSIS OF PARTICLES, GENERAL REFERENCES	<u>Kahkashan</u> <u>Zaidi</u>
Omission	<1196> PHARMACOPEIAL HARMONIZATION PF 39(5) Pg. ONLINE	Entire document	Kevin Moore
New	<1229.6> LIQUID-PHASE STERILIZATION PF 39(4) Pg. ONLINE	INTRODUCTION, VALIDATION OF STERILIZATION BY LIQUIDS, REFERENCE	<u>Radhakrishna</u> <u>Tirumalai</u>
New	<1234> VACCINES FOR HUMAN USE- POLYSACCHARIDE AND GLYCOCONJUGATE VACCINES PF 39(4) Pg. ONLINE	INTRODUCTION, BACKGROUND, KEY QUALITY PARAMETERS FOR BULK POLYSACCHARIDES, KEY QUALITY PARAMETERS FOR BULK FORMULATED POLYSACCHARIDE VACCINE, KEY QUALITY PARAMETERS FOR POLYSACCHARIDE VACCINES: FINAL FILLS, KEY QUALITY PARAMETERS FOR CARRIER PROTEIN, KEY QUALITY PARAMETERS FOR ACTIVATED INTERMEDIATES, KEY QUALITY PARAMETERS FOR MONOVALENT BULK CONJUGATE (DRUG SUBSTANCE), FORMULATED AND ADJUVANTED (IF APPROPRIATE) CONJUGATE BULKS, KEY QUALITY PARAMETERS FOR CONJUGATE VACCINE DRUG PRODUCT	<u>Maura</u> <u>Kibbey</u>
New	<1240> VIRUS TESTING OF HUMAN PLASMA FOR FURTHER MANUFACTURE PF 39(4) Pg. ONLINE	SCOPE, INTRODUCTION, RATIONALE FOR VIRUS TESTING OF PLASMA FOR FURTHER MANUFACTURE, APPROACHES TO TESTING, REGULATORY ENVIRONMENT, CONCLUSIONS, APPENDIX	<u>Maura</u> <u>Kibbey</u>
New	<1736> APPLICATIONS OF MASS SPECTROMETRY PF 39(5) Pg. ONLINE	I. INTRODUCTION, 2. MASS SPECTROMETERS, 3. MASS ANALYSIS, 4. MS-MS/MSN SPECTROMETRY INSTRUMENTATION, 5. QUALITATIVE ANALYSIS, 6. QUANTITATIVE ANALYSIS, 7. EMERGING MS APPLICATIONS	Alan Potts
Revision	<2232> ELEMENTAL CONTAMINANTS IN DIETARY SUPPLEMENTS PF 39(5) Pg. ONLINE	LIMITS OF ELEMENTAL CONTAMINANTS, OPTIONS FOR COMPLIANCE WITH THE LIMITS OF ELEMENTAL CONTAMINANTS, ANALYTICAL PROCEDURES FOR TOTAL ELEMENTAL CONTAMINANTS	Christopher Okunji
New	<2250> DETECTION OF IRRADIATED DIETARY SUPPLEMENTS PF 39(5) Pg. ONLINE	INTRODUCTION, PRINCIPLES OF PHOTOSTIMULATED LUMINESCENCE AND THERMOLUMINESCENCE, GENERAL PROCEDURE FOR DETECTION OF IRRADIATION IN DIETARY INGREDIENTS AND DIETARY SUPPLEMENTS	Christopher Okunji
New	4-HYDROXY-2-BUTANONE PF 39(5) Pg. ONLINE	Reagent Specification, 4-Hydroxy-2-butanone	Hong Wang
Revision	ACARBOSE PF 39(5) Pg. ONLINE	ASSAY/Procedure	Mary Crivellone

Revision	ACETAMINOPHEN CAPSULES PF 39(3) Pg. ONLINE	IMPURITIES/4-Aminophenol in Acetaminophen-Containing Drug Products <227>	<u>Clydewyn</u> <u>Anthony</u>
Revision	ACETAMINOPHEN ORAL SOLUTION PF 39(3) Pg. ONLINE	IMPURITIES/4-Aminophenol in Acetaminophen-Containing Drug Products <227>	<u>Clydewyn</u> <u>Anthony</u>
Revision	ACETAMINOPHEN FOR EFFERVESCENT ORAL SOLUTION PF $39(3)$ Pg. ONLINE	IMPURITIES/4-Aminophenol in Acetaminophen-Containing Drug Products <227>	<u>Clydewyn</u> <u>Anthony</u>
Revision	ACETAMINOPHEN ORAL SUSPENSION PF 39(3) Pg. ONLINE	IMPURITIES/Limit of 4-Aminophenol, IMPURITIES/4-Aminophenol in Acetaminophen-Containing Drug Products <227>	<u>Clydewyn</u> <u>Anthony</u>
Revision	ACETAMINOPHEN TABLETS PF 39(3) Pg. ONLINE	IMPURITIES/4-Aminophenol in Acetaminophen-Containing Drug Products <227>	<u>Clydewyn</u> <u>Anthony</u>
Revision	ACETAMINOPHEN EXTENDED-RELEASE TABLETS PF 39(3) Pg. ONLINE	IMPURITIES/ 4-Aminophenol in Acetaminophen-Containing Drug Products <227>	<u>Clydewyn</u> <u>Anthony</u>
Revision	ACETAMINOPHEN AND TRAMADOL HYDROCHLORIDE TABLETS PF 39(3) Pg. ONLINE	{Title} Tramadol Hydrochloride and Acetaminophen Tablets, DEFINITION/Introduction	<u>Clydewyn</u> <u>Anthony</u>
New	L-ALANYL-L-GLUTAMINE PF 39(4) Pg. ONLINE	Chemical Info/Chemical Structure, Chemical Info/C8H15N3O4, Chemical Info/217.23, Chemical Info/I-2-(1-Oxo-2-amino-propylamino)-4-amino-4-oxobutanoic acid, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197A>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Chloride and Sulfate, Chloride <221>, IMPURITIES/Chloride and Sulfate, Sulfate <221>, IMPURITIES/Iron <241>, IMPURITIES/Residual Solvents <467>, IMPURITIES/Limit of Ammonium, IMPURITIES/Related Compounds, SPECIFIC TESTS/Optical Rotation, Specific Rotation <781S>, SPECIFIC TESTS/Water Determination, Method Ia <921>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Alanine RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP I-Alanyl-I-Alanine RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Reference Standards <11>/USP I-Alanyl-I-Glutamine RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Glutamine RS	Huy Dinh
Revision	ALCOHOL Stage 6 Harmonization	Entire Document	<u>Jenny Liu</u>
Revision	DEHYDRATED ALCOHOL Stage 6 Harmonization	Entire Document	<u>Jenny Liu</u>
Revision	ASPIRIN DELAYED-RELEASE TABLETS PF 39(3) Pg. ONLINE	PERFORMANCE TESTS/Dissolution <711>, ADDITIONAL REQUIREMENTS/Labeling	<u>Hillary Cai</u>
New	ATENOLOL COMPOUNDED ORAL SUSPENSION PF 39(5) 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 Atenolol RS	Jeanne Sun
New	ATENOLOL COMPOUNDED ORAL SUSPENSION, VETERINARY PF 39(5) 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	Jeanne Sun

Atenolol RS

New	AZELASTINE HYDROCHLORIDE PF 38(5) Pg. ONLINE	Chemical Info/Chemical Structure, Chemical Info/C22H24ClN3O·HCl, Chemical Info/418.36, Chemical Info/1(2H)-Phthalazinone, 4-[(4-chlorophenyl)methyl]-2-(hexahydro-1-methyl-1H-azepin-4-yl), monohydrochloride;, Chemical Info/4-(p-Chlorobenzyl)-2-(hexahydro-1-methyl-1H-azepin-4-yl)-1(2H)-phthalazinone monohydrochloride, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., IDENTIFICATION/C. Identification Tests—General, Chloride <191>, ASSAY, ASSAY/Procedure, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Heavy Metals, Method II <231>, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Loss on Drying <731>, SPECIFIC TESTS/Acidity or Alkalinity, 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 B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Azelastine Related Compound D RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Azelastine Related Compound D RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Azelastine Related Compound E RS	Domenick Vicchio
New	BENAZEPRIL HYDROCHLORIDE COMPOUNDED ORAL SUSPENSION, VETERINARY PF 39(5) 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 Benazepril Hydrochloride RS	Jeanne Sun
New	BORAGE SEED OIL PF 39(4) Pg. ONLINE	Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A., IMPURITIES/Heavy Metals, Method II <231>, SPECIFIC TESTS/Fats and Fixed Oils, Acid Value <401>, SPECIFIC TESTS/Fats and Fixed Oils, Peroxide Value <401>, SPECIFIC TESTS/Fats and Fixed Oils, Saponification Value <401>, SPECIFIC TESTS/Fats and Fixed Oils, Unsaponifiable Matter <401>, SPECIFIC TESTS/Fats and Fixed Oils, Fatty Acid Composition <401>, SPECIFIC TESTS/Refractive Index <831>, ADDITIONAL REQUIREMENTS/Packaging and Storage	Huy Dinh
Revision	BROMPHENIRAMINE MALEATE PF 38(6) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/Ultraviolet Absorption <197U>, ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Melting Range or Temperature <741>, SPECIFIC TESTS/Optical Rotation, Specific Rotation <781>, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Chlorpheniramine Maleate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Chlorpheniramine Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Pheniramine Maleate RS	<u>Domenick</u> <u>Vicchio</u>
New	BUTANE-1,4-DIOL PF 39(5) Pg. ONLINE	Reagent Specification, Butane-1,4-diol	Hong Wang
New	BUTANE-1,2-DIOL PF 39(5) Pg. ONLINE	Reagent Specification, Butane-1,2-diol	Hong Wang
New	BUTANE-2,3-DIOL PF 39(5) Pg. ONLINE	Reagent Specification, Butane-2,3-diol	Hong Wang
New	BUTYLENE GLYCOL PF 39(5) Pg. ONLINE	Chemical Info/Chemical Structure, Chemical Info/C4H10O2 (HOCH2CH2CH(OH)CH3), Chemical Info/90.12, Chemical Info/Butane-1,3-diol;, Chemical Info/1,3-Butylene glycol, Chemical Info/CAS,	Hong Wang

DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197F>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Limit of Lead, IMPURITIES/Limit of 4-Hydroxy-2-butanone, Butane-2,3-diol, Ethylene Glycol, Butane-1,2-diol, Butane-1,4-diol, Diethylene Glycol, and Other Organic Impurities, SPECIFIC TESTS/Acidity and Alkalinity, SPECIFIC TESTS/Water Determination, Method I <921>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Butane-1,3-diol RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Diethylene Glycol RS, ADDITIONAL REQUIREMENTS/USP Reference Glycol RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ethylene Glycol RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Propylene Glycol RS

		Propylene Glycol RS	
Revision	CARBAMAZEPINE EXTENDED-RELEASE TABLETS PF 39(4) Pg. ONLINE	IDENTIFICATION/A. Ultraviolet Absorption <197U>, ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities: Procedure 1, Residual Solvents, IMPURITIES/Procedure 2, IMPURITIES/Procedure 3, SPECIFIC TESTS/Water Determination, Method Ia <921>	Heather Joyce
Omission	CHLORAMPHENICOL, POLYMYXIN B SULFATE, AND HYDROCORTISONE ACETATE OPHTHALMIC OINTMENT PF 39(5) Pg. ONLINE	Entire document	Ahalya Wise
Omission	CHLORAMPHENICOL AND PREDNISOLONE OPHTHALMIC OINTMENT PF 39(5) Pg. ONLINE	Entire document	Ahalya Wise
Revision	CHLOROXYLENOL PF 39(5) Pg. ONLINE	IMPURITIES/Limit of Tetrachloroethylene	<u>Shankari</u> <u>Shivaprasad</u>
New	CLOPIDOGREL COMPOUNDED ORAL SUSPENSION PF 39(5) 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 Clopidogrel Bisulfate RS	Jeanne Sun
New	CUPRIC TARTRATE, ALKALINE, SOLUTION (FEHLING'S SOLUTION) PF 39(5) Pg. ONLINE	Cupric Tartrate, Alkaline, Solution (Fehling\'s Solution)	<u>Galina</u> <u>Holloway</u>
Revision	CUPRIC SULFATE PF 39(4) Pg. ONLINE	DEFINITION/Introduction, SPECIFIC TESTS/Loss on Drying <731>, ADDITIONAL REQUIREMENTS/Labeling	<u>Shankari</u> <u>Shivaprasad</u>
Revision	CYSTINE PF 39(5) Pg. ONLINE	IDENTIFICATION/B. Optical Rotation, Specific Rotation <781S>	Huy Dinh
Omission	CARBON MONOXIDE C 11 PF 39(4) Pg. ONLINE	Entire document	<u>Ravi</u> <u>Ravichandran</u>
Omission	FLUMAZENIL C 11 INJECTION PF 39(4) Pg. ONLINE	Entire document	<u>Ravi</u> <u>Ravichandran</u>
Omission	MESPIPERONE C 11 INJECTION PF 39(4) Pg. ONLINE	Entire document	<u>Ravi</u> <u>Ravichandran</u>
Omission	METHIONINE C 11 INJECTION PF 39(4) Pg. ONLINE	Entire document	<u>Ravi</u> <u>Ravichandran</u>

Omission	RACLOPRIDE C 11 INJECTION PF 39(4) Pg. ONLINE	Entire document	<u>Ravi</u> <u>Ravichandran</u>
Omission	SODIUM ACETATE C 11 INJECTION PF 39(4) Pg. ONLINE	Entire document	<u>Ravi</u> <u>Ravichandran</u>
Revision	CRYOPRESERVED HUMAN FIBROBLAST-DERIVED DERMAL SUBSTITUTE PF 39(5) Pg. ONLINE	{Title} Construct Human Fibroblasts in Polyglactin Scaffold, DEFINITION/Introduction, SPECIFIC TESTS/Histological Evaluation, SPECIFIC TESTS/Metabolic Activity Assessment, SPECIFIC TESTS/DNA Content, SPECIFIC TESTS/Total Collagen Content, SPECIFIC TESTS/Sterility Tests <71>, SPECIFIC TESTS/Bacterial Endotoxins Test <85>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards Authentic Visual References<11>/ USP Construct Human Fibroblasts in Polyglactin Scaffold	Rebecca Potts
Revision	DESCRIPTION AND SOLUBILITY PF 39(4) Pg. ONLINE	Fexofenadine Hydrochloride, Glyceryl Behenate, Lauroyl Polyoxylglycerides, Mandelic Acid, Butylene Glycol, Cabergoline, Invert Sugar, Isoflurophate, Sodium Picosulfate, Sunflower Oil, Azelastine Hydrochloride	<u>Domenick</u> <u>Vicchio</u>
Revision	DEXAMETHASONE ORAL SOLUTION PF 39(4) Pg. ONLINE	IDENTIFICATION/Thin-Layer Chromatography Identification Test <201>, ASSAY/Procedure, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methylparaben RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Prednisolone RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Propylparaben RS	<u>Domenick</u> <u>Vicchio</u>
Revision	DEXTRAN 40 IN DEXTROSE INJECTION PF 39(5) Pg. ONLINE	DEFINITION/Introduction, ASSAY/Dextran 40	Kevin Carrick
Revision	DEXTRAN 70 IN DEXTROSE INJECTION PF 39(5) Pg. ONLINE	DEFINITION/Introduction, ASSAY/Dextran 70	Kevin Carrick
		ASSAY/Procedure, PERFORMANCE TESTS/Dissolution, Procedure for a	<u>Heather</u>
Revision	DEXTROAMPHETAMINE SULFATE TABLETS PF 39(5) Pg. ONLINE	Pooled Sample <711>, SPECIFIC TESTS/Isomeric purity, ADDITIONAL REQUIREMENTS/Packaging and Storage	<u>Joyce</u>
Revision Revision	DEXTROAMPHETAMINE SULFATE TABLETS PF 39(5) Pg. ONLINE DEXTROSE INJECTION PF 39(4) Pg. ONLINE		
		REQUIREMENTS/Packaging and Storage IMPURITIES/Heavy Metals <231>, ADDITIONAL	Joyce Domenick

		REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/Beyond-Use Date, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Doxycycline Hyclate RS	
New	ENALAPRIL MALEATE 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 Enalapril Maleate RS	<u>Jeanne Sun</u>
Revision	ENZACAMENE PF 39(5) Pg. ONLINE	Chemical Info/3-(4-Methylbenzylidene)-camphor Bicyclo[2.2.1]heptan-2-one, 1,7,7-trimethyl-3-[(4-methylphenyl)methylene]-; (±)-3-(p-Methylbenzylidene)camphor, ASSAY/Procedure, IMPURITIES/Procedure, SPECIFIC TESTS/Melting Range or Temperature, Class 1a <741>, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methyl Benzylidene Camphor RS	<u>Feiwen Mao</u>
New	EVENING PRIMROSE OIL PF 39(4) Pg. ONLINE	Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A., IMPURITIES/Heavy Metals, Method II <231>, SPECIFIC TESTS/Fats and Fixed Oils, Acid Value <401>, SPECIFIC TESTS/Fats and Fixed Oils, Peroxide Value <401>, SPECIFIC TESTS/Fats and Fixed Oils, Saponification Value <401>, SPECIFIC TESTS/Fats and Fixed Oils, Unsaponifiable Matter <401>, SPECIFIC TESTS/Fats and Fixed Oils, Fatty Acid Composition <401>, SPECIFIC TESTS/Refractive Index <831>, ADDITIONAL REQUIREMENTS/Packaging and Storage	<u>Huy Dinh</u>
Revision	FELBAMATE PF 39(4) Pg. ONLINE	ASSAY/Procedure, IMPURITIES/Organic Impurities, Early Eluting, IMPURITIES/Organic Impurities, Late Eluting	<u>Heather</u> <u>Joyce</u>
Revision	FISH OIL CONTAINING OMEGA-3 ACIDS CAPSULES PF 39(4) Pg. ONLINE	IDENTIFICATION/A., STRENGTH/Content of EPA and DHA, STRENGTH/Content of Total Omega-3 Acids	<u>Natalia</u> Davydova
Revision	FISH OIL CONTAINING OMEGA-3 ACIDS DELAYED-RELEASE CAPSULES PF 39(4) Pg. ONLINE	IDENTIFICATION/A., STRENGTH/Content of EPA and DHA, STRENGTH/Content of Total Omega-3 Acids	<u>Natalia</u> <u>Davydova</u>
New	FLAX SEED OIL PF 39(1) Pg. ONLINE	Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A., IMPURITIES/Fats and Fixed Oils, Trace Metals <401>, SPECIFIC TESTS/Fats and Fixed Oils, Acid Value <401>, SPECIFIC TESTS/Fats and Fixed Oils, Peroxide Value <401>, SPECIFIC TESTS/Fats and Fixed Oils, Iodine Value <401>, SPECIFIC TESTS/Fats and Fixed Oils, Saponification Value <401>, SPECIFIC TESTS/Fats and Fixed Oils, Unsaponifiable Matter <401>, SPECIFIC TESTS/Fats and Fixed Oils, Fatty Acid Composition <401>, SPECIFIC TESTS/Refractive Index <831>, ADDITIONAL REQUIREMENTS/Packaging and Storage	Huy Dinh
Revision	FLUNIXIN MEGLUMINE PF 39(4) Pg. ONLINE	Chemical Info/1-Deoxy-1-(methylamino)-D-glucitol 2-{[2-methyl-3-(trifluoromethyl)phenyl]amino}nicotinate, DEFINITION/Introduction, IDENTIFICATION/Ultraviolet Absorption <197U>, ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Melting Range or Temperature <741>, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Flunixin Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Flunixin Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Flunixin Related Compound C RS	Morgan Puderbaugh

Omission	FLUORODOPA F 18 INJECTION PF 39(4) Pg. ONLINE	Entire document	<u>Ravi</u> <u>Ravichandran</u>
Revision	FLUPHENAZINE DECANOATE INJECTION PF 39(5) Pg. ONLINE	Limit of Fluphenazine and Late-Eluting Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage	<u>Heather</u> <u>Joyce</u>
Revision	GABAPENTIN PF 39(4) Pg. ONLINE	IMPURITIES/Early-Eluting Impurities	<u>Heather</u> <u>Joyce</u>
New	GANODERMA LUCIDUM FRUITING BODY PF 39(5) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/A. Thin-Layer Chromatography, IDENTIFICATION/B. HPLC, IDENTIFICATION/C. HPLC, COMPOSITION/Content of Triterpenoic Acids, 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/Content of Water-Soluble Polysaccharides, 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 Dextrose RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP I-Fucose RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Galactose RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ganoderic Acid A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ganoderma Lucidum Fruiting Body Powdered Extract RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ganoderma Standards <11>/USP Reference Standards <11>/USP Mannose RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Mannose RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Mannose RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP	Anton Bzhelyansky
New	GANODERMA LUCIDUM FRUITING BODY POWDER PF 39(5) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/A. Thin-Layer Chromatography, IDENTIFICATION/B. HPLC, IDENTIFICATION/C. HPLC, COMPOSITION/Content of Triterpenoic Acids, 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/Content of Water-Soluble Polysaccharides, 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 Dextrose RS, ADDITIONAL REQUIREMENTS/USP	Anton Bzhelyansky

Revision POWDERED GINKGO EXTRACT PF 39(4) Pg. ONLINE GLYCERYL BEHENATE PF 39(4) Pg. ONLINE Revision New GLYCYL-L-GLUTAMINE PF 39(4) Pg. ONLINE GLYCYL-L-TYROSINE PF 39(4) Pg. ONLINE New

Reference Standards <11>/USP Ergosterol RS, ADDITIONAL
REQUIREMENTS/USP Reference Standards <11>/USP I-Fucose RS,
ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP
Galactose RS, ADDITIONAL REQUIREMENTS/USP Reference Standards
<11>/USP Ganoderic Acid A RS, ADDITIONAL REQUIREMENTS/USP
Reference Standards <11>/USP d-Glucuronic Acid RS, ADDITIONAL
REQUIREMENTS/USP Reference Standards <11>/USP Mannose RS,
ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP
Ganoderma Lucidum Fruiting Body Powdered Extract RS

SPECIFIC TESTS/Limit of Rutin and Ouercetin

Anton Bzhelyansky

DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B., IDENTIFICATION/C. Melting Range or Temperature, Class II <741>, ASSAY/Procedure, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Heavy Metals, Method II <231>, IMPURITIES/Limit of Free Glycerin, SPECIFIC TESTS/Fats and Fixed Oils, Acid Value, Method I <401>, SPECIFIC TESTS/Fats and Fixed Oils, Fatty Acid Composition <401>, SPECIFIC TESTS/Water Determination, Method Ia <921>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Glycerin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Glyceryl Dibehenate RS, DEFINITION/Introduction, IDENTIFICATION/A. Thin-Laver Chromatographic Identification Test, IMPURITIES/Content of 1-Monoglycerides, SPECIFIC TESTS/Fats and Fixed Oils, Saponification Value <401>, SPECIFIC TESTS/Fats and Fixed Oils, Iodine Value, Method II <401>

Galina Holloway

Chemical Info/Chemical Structure, Chemical Info/C7H13N3O4·H2O, Chemical Info/221.21, Chemical Info/I-2-(Amino acetamide)-4-amino-4oxo-butanoic acid monohydrate;, Chemical Info/Glycyl-l-glutamine hydrate, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197A>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Chloride and Sulfate, Chloride <221>, IMPURITIES/Chloride and Sulfate, Sulfate <221>, IMPURITIES/Iron <241>, IMPURITIES/Residual Solvents <467>, IMPURITIES/Limit of Ammonium, IMPURITIES/Related Compounds, SPECIFIC TESTS/Optical Rotation, Specific Rotation <781S>, SPECIFIC TESTS/Water Determination, Method Ia <921>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP I-Alanyl-I-Alanine RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP I-AlanyI-I-Glutamine RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Glutamine RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Glycine RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Glycyl-I-Glutamine RS

Chemical Info/Chemical Structure, Chemical Info/C11H14N2O4·2H2O, Chemical Info/274.27, Chemical Info/I-2-Aminoacetamide-3-(parahydroxyphenyl) propionic acide dihydrate;, Chemical Info/Glycyl-tyrosine dihydrate, Chemical Info/CAS, DEFINITION/Introduction,

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IDENTIFICATION/A. Infrared Absorption <197A>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Chloride and Sulfate, Chloride <221>, IMPURITIES/Chloride and Sulfate, Sulfate <221>, IMPURITIES/Iron <241>, IMPURITIES/Residual Solvents <467>, IMPURITIES/Limit of Ammonium, IMPURITIES/Related Compounds, SPECIFIC TESTS/Optical Rotation, Specific Rotation <781S>, SPECIFIC TESTS/Water Determination, Method Ia <921>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Alanyl-I-Alanine RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP I-Alanyl-I-Glutamine RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Tyrosine RS

		Reference Standards <11>/USP Glycine RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Glycyl-I-Tyrosine RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Tyrosine RS	
Revision	CHORIONIC GONADOTROPIN PF 39(5) Pg. ONLINE	Chemical Info, ASSAY/Procedure, SPECIFIC TESTS/Acute Toxicity	<u>Maura</u> <u>Kibbey</u>
Revision	CHORIONIC GONADOTROPIN FOR INJECTION PF 39(5) Pg. ONLINE	ASSAY/Procedure, PERFORMANCE TESTS/Uniformity of Dosage Units <905>	<u>Maura</u> <u>Kibbey</u>
Revision	GUAR GUM PF 39(5) Pg. ONLINE	Chemical Info, DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B., IDENTIFICATION/A. Indication for a Polymeric Compound and Distinction from Locust Bean Gum, IDENTIFICATION/B. Identification of Constituting Mannose and Galactose by Thin-Layer Chromatography, SPECIFIC TESTS/Acid-Insoluble Matter, SPECIFIC TESTS/Microbial Enumeration Tests <61> and Tests for Specified Microorganisms <62>, SPECIFIC TESTS/Starch, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>	Hong Wang
Revision	HYDRALAZINE HYDROCHLORIDE PF 39(5) Pg. ONLINE	IDENTIFICATION/B. Ultraviolet Absorption <197U>, IDENTIFICATION/B.	<u>Sujatha</u> <u>Ramakrishna</u>
Revision	HYDROXYPROPYL CELLULOSE Stage 6 Harmonization	Entire Document	<u>Jenny Liu</u>
Revision	HYDROXYZINE HYDROCHLORIDE PF 39(5) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/Ultraviolet Absorption <197U>, ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Loss on Drying <731>, SPECIFIC TESTS/Water Determination <921>, ADDITIONAL REQUIREMENTS/Packaging and Storage	<u>Heather</u> <u>Joyce</u>
New	IMIPRAMINE PAMOATE PF 39(5) Pg. ONLINE	Chemical Info/Chemical Structure, Chemical Info/(C19H24N2)2·C23H16O6, Chemical Info/949.18, Chemical Info/Naphthalenecarboxylic acid, 4,4\'-methylenebis[3-hydroxy-, compd. with 5H-dibenz[b,f]azepine-5-propanamine, 10,11-dihydro-N,N-dimethyl-, 2- (1:2);, Chemical Info/5-[3-(Dimethylamino)propyl]-10,11-dihydro-5H-dibenz[b,f]azepine compound (2:1) with 4,4\'-methylenebis(3-hydroxy-2-naphthoic acid);, Chemical Info/3-[10,11-Dihydro-5H-dibenzo[b,f]azepin-5-yl)-N,N-dimethylpropan-1-amine 4,4\'-methylenebis(3-hydroxy-2-naphthoate) salt (2:1), 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/Water Determination, Method I <921>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL	<u>Heather</u> <u>Joyce</u>

REQUIREMENTS/USP Reference Standards <11>/USP Depramine RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Iminodibenzyl RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Imipramine Pamoate RS

Chemical Info/Invert Sugar Syrup, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A., ASSAY/Procedure, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Heavy Metals<231>, SPECIFIC TESTS/pH<791>, SPECIFIC TESTS/Total Solids, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Dextrose RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Fructose RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Sucrose RS

Galina Holloway

Heather

<u>Joyce</u> Heather

<u>Joyce</u> Galina

Holloway

Suiatha

Ramakrishna

Omission ISOFLUROPHATE PF 39(5) Pg. ONLINE

New

Omission ISOFLUROPHATE OPHTHALMIC OINTMENT PF 39(5) Pg. ONLINE

Revision ISOPROPYL MYRISTATE PF 39(5) Pg. ONLINE

INVERT SUGAR PF 39(5) Pq. ONLINE

Revision ISRADIPINE PF 39(4) Pg. ONLINE

Revision KRILL OIL PF 39(4) Pg. ONLINE

Entire document

Entire document

ASSAY/Procedure

IDENTIFICATION/A: Infrared Absorption <197K>, IDENTIFICATION/B, SPECIFIC TESTS/Melting Range or Temperature <741>

DEFINITION/Introduction, IDENTIFICATION/A. Fatty Acid Profile, IDENTIFICATION/B. Phospholipid Profile, COMPOSITION/Content of EPA and DHA, COMPOSITION/Content of Total Phospholipids, COMPOSITION/Content of Astaxanthin, CONTAMINANTS/Fats and Fixed Oils <401>, CONTAMINANTS/Limit of Dioxins, Furans, and Polychlorinated Biphenvls, SPECIFIC TESTS/Astaxanthin Esterification, SPECIFIC TESTS/Fats and Fixed Oils, Acid Value <401>, SPECIFIC TESTS/Fats and Fixed Oils, Peroxide Value <401>, SPECIFIC TESTS/Fats and Fixed Oils, Unsaponifiable Matter <401>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REOUIREMENTS/USP Reference Standards <11>/USP Astaxanthin Esters from Haematococcus pluvialis RS, ADDITIONAL REOUIREMENTS/USP Reference Standards <11>/USP Astaxanthin (Synthetic) RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Docosahexaenoic Acid Ethyl Ester RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Eicosapentaenoic Acid Ethyl Ester RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Krill Oil RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methyl Tricosanoate RS

DEFINITION/Introduction, IDENTIFICATION/A. Fatty Acid Profile, IDENTIFICATION/B. Phospholipid Profile, STRENGTH/Content of Krill Oil, STRENGTH/Content of EPA and DHA, STRENGTH/Content of Total Phospholipids, STRENGTH/Content of Astaxanthin, PERFORMANCE TESTS/Disintegration and Dissolution <2040>, PERFORMANCE TESTS/Weight Variation <2091>, CONTAMINANTS/Limit of Dioxins, Furans, and Polychlorinated Biphenyls, CONTAMINANTS/Microbial Enumeration Tests <2021>, CONTAMINANTS/Absence of Specified

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New KRILL OIL CAPSULES PF 39(5) Pg. ONLINE

		Microorganisms <2022>, SPECIFIC TESTS/Astaxanthin Esterification, SPECIFIC TESTS/Fats and Fixed Oils, Peroxide Value <401>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Astaxanthin Esters from Haematococcus pluvialis RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Astaxanthin (Synthetic) RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Docosahexaenoic Acid Ethyl Ester RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Eicosapentaenoic Acid Ethyl Ester RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Krill Oil RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methyl Tricosanoate RS	
New	KRILL OIL DELAYED-RELEASE CAPSULES PF 39(5) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/A. Fatty Acid Profile, IDENTIFICATION/B. Phospholipid Profile, STRENGTH/Content of Krill Oil, STRENGTH/Content of EPA and DHA, STRENGTH/Content of Total Phospholipids, STRENGTH/Content of Astaxanthin, PERFORMANCE TESTS/Disintegration and Dissolution <2040>, PERFORMANCE TESTS/Weight Variation <2091>, CONTAMINANTS/Limit of Dioxins, Furans, and Polychlorinated Biphenyls, CONTAMINANTS/Microbial Enumeration Tests <2021>, CONTAMINANTS/Absence of Specified Microorganisms <2022>, SPECIFIC TESTS/Astaxanthin Esterification, SPECIFIC TESTS/Fats and Fixed Oils, Peroxide Value <401>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Astaxanthin Esters from Haematococcus pluvialis RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Astaxanthin (Synthetic) RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Docosahexaenoic Acid Ethyl Ester RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Reference Standa	Natalia Davydova
New	L82 PF 39(5) Pg. ONLINE	Reagent Specification, L82	Margareth Marques
New	LAMOTRIGINE COMPOUNDED ORAL SUSPENSION 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 Lamotrigine RS	Jeanne Sun
New	LANSOPRAZOLE COMPOUNDED ORAL SUSPENSION PF 39(5) 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 Lansoprazole RS	Jeanne Sun
Revision	LEVOBUNOLOL HYDROCHLORIDE PF 39(5) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/Ultraviolet Absorption <197U>, IDENTIFICATION/C. Identification Tests-General, Chloride <191>, ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Melting Range or Temperature <741>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL	<u>Feiwen Mao</u>

		REQUIREMENTS/USP Reference Standards <11>/USP Atenolol RS	
Revision	LEVOBUNOLOL HYDROCHLORIDE OPHTHALMIC SOLUTION PF 39(5) Pg. ONLINE	ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Edetate Disodium RS	<u>Feiwen Mao</u>
Revision	LITHIUM CITRATE PF 39(4) Pg. ONLINE	IDENTIFICATION/A., ASSAY/Procedure	<u>Ravi</u> <u>Ravichandran</u>
Revision	LITHIUM ORAL SOLUTION PF 39(4) Pg. ONLINE	IDENTIFICATION/A., ASSAY/Procedure, ADDITIONAL REQUIREMENTS/Packaging and Storage	<u>Ravi</u> <u>Ravichandran</u>
New	MANDELIC ACID PF 38(6) Pg. ONLINE	Chemical Info/Chemical Structure, Chemical Info/C8H8O3, Chemical Info/152.15, Chemical Info/Benzeneacetic acid, α-hydroxy-;, Chemical Info/(RS)-2-Hydroxy-2-phenylacetic acid;, Chemical Info/(±)-α-Hydroxyphenylacetic acid;, Chemical Info/2-Hydroxy-2-phenylacetic acid, 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/Limit of Benzoylformic Acid, Benzaldehyde, Benzoic Acid, and Acetophenone, IMPURITIES/Limit of Chloride, SPECIFIC TESTS/Melting Range or Temperature <741>, SPECIFIC TESTS/Water Determination, Method Ia <921>, SPECIFIC TESTS/Turbidity, ADDITIONAL REQUIREMENTS/Packaging and Storage, 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 Reference Standards <11>/USP Mandelic Acid RS	Hong Wang
Revision	MANNITOL Stage 6 Harmonization	Entire Document	<u>Jenny Liu</u>
Revision	MEBENDAZOLE PF 39(4) Pg. ONLINE	IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Mebendazole Related Compound D RS	<u>Shankari</u> <u>Shivaprasad</u>
Revision	MEPHENYTOIN PF 39(4) Pg. ONLINE	IDENTIFICATION/Ultraviolet Absorption <197U>, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Melting Range or Temperature <741>, ADDITIONAL REQUIREMENTS/Packaging and Storage	<u>Ravi</u> <u>Ravichandran</u>
Revision	MEPHENYTOIN TABLETS PF 39(4) Pg. ONLINE	IDENTIFICATION/A, ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage	<u>Ravi</u> <u>Ravichandran</u>
New	METHYL P-TOLUENESULFONATE PF 39(5) Pg. ONLINE	Reagent Specification, Methyl p-Toluenesulfonate	<u>Heather</u> <u>Joyce</u>
Revision	METHYLPARABEN SODIUM PF 39(5) Pg. ONLINE	Chemical Info, DEFINITION/Introduction, ASSAY/Procedure, IMPURITIES/Related Compounds	<u>Galina</u> <u>Holloway</u>
New	METRONIDAZOLE BENZOATE COMPOUNDED ORAL SUSPENSION PF 39(4) Pg. ONLINE	DEFINITION/Introduction, ASSAY/Procedure, SPECIFIC TESTS/pH <791>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Beyond-Use Date, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP	<u>Jeanne Sun</u>

Metronidazole Benzoate RS

Revision	MEXILETINE HYDROCHLORIDE PF 39(5) Pg. ONLINE	IDENTIFICATION/Thin-Layer Chromatography	<u>Sujatha</u> <u>Ramakrishna</u>
Revision	MITOMYCIN PF 39(4) Pg. ONLINE	IMPURITIES/Organic Impurities	Ahalya Wise
Revision	MORICIZINE HYDROCHLORIDE PF 39(5) Pg. ONLINE	Chemical Info/Carbamic acid, [10-[3-(4-morpholinyl)-11-oxopropyl]-10H-phenothiazin-2yl]-, ethyl ester, hydrochloride;, Chemical Info/CAS, IDENTIFICATION/B. Ultraviolet Absorption <197U>, IDENTIFICATION/B., IDENTIFICATION/C. Thin-Layer Chromatography, IDENTIFICATION/C. Identification Tests-General, Chloride <191>	<u>Sujatha</u> Ramakrishna
Revision	NAPHAZOLINE HYDROCHLORIDE OPHTHALMIC SOLUTION PF 39(5) Pg. ONLINE	IDENTIFICATION/Melting Range or Temperature, Class Ia <741>, IDENTIFICATION/B., ASSAY/Procedure	<u>Feiwen Mao</u>
Omission	NEOMYCIN SULFATE AND HYDROCORTISONE ACETATE OPHTHALMIC OINTMENT PF 39(5) Pg. ONLINE	Entire document	Ahalya Wise
Omission	NEOMYCIN SULFATE AND PREDNISOLONE ACETATE OPHTHALMIC OINTMENT PF 39(5) Pg. ONLINE	Entire document	Ahalya Wise
Omission	NEOMYCIN SULFATE AND PREDNISOLONE SODIUM PHOSPHATE OPHTHALMIC OINTMENT PF 39(5) Pg. ONLINE	Entire document	Ahalya Wise
Omission	NEOMYCIN SULFATE, SULFACETAMIDE SODIUM, AND PREDNISOLONE ACETATE OPHTHALMIC OINTMENT PF 39(5) Pg. ONLINE	Entire document	Ahalya Wise
Omission	NEOMYCIN SULFATE AND TRIAMCINOLONE ACETONIDE OPHTHALMIC OINTMENT PF 39(5) Pg. ONLINE	Entire document	Ahalya Wise
Revision	NICARDIPINE HYDROCHLORIDE PF 39(4) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/Ultraviolet Absorption <197U>, ASSAY/Procedure, IMPURITIES/Organic Impurities	<u>Sujatha</u> <u>Ramakrishna</u>
Revision	OLEOVITAMIN A AND D CAPSULES PF 39(5) Pg. ONLINE	ASSAY/Vitamin A Assay <571>, ASSAY/Vitamin D Assay <581>, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Retinyl Acetate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Retinyl Palmitate RS	<u>Natalia</u> <u>Davydova</u>
Revision	OXAPROZIN PF 39(4) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/B. Ultraviolet Absorption <197U>, ASSAY/Procedure	Hillary Cai
Revision	OXYMETAZOLINE HYDROCHLORIDE OPHTHALMIC SOLUTION PF 39(5) Pg. ONLINE	IDENTIFICATION/A. Procedure, IDENTIFICATION/A., IDENTIFICATION/B.	<u>Feiwen Mao</u>
Omission	WATER O 15 INJECTION PF 39(4) Pg. ONLINE	Entire document	<u>Ravi</u> <u>Ravichandran</u>
New	PAROXETINE EXTENDED-RELEASE TABLETS PF 39(5) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/A., 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 Paroxetine Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Paroxetine Related Compound B RS, ADDITIONAL	<u>Ravi</u> <u>Ravichandran</u>

		REQUIREMENTS/USP Reference Standards <11>/USP Paroxetine Related Compound F RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Paroxetine System Suitability Mixture A RS	
Revision	PENTOXIFYLLINE PF 39(4) Pg. ONLINE	IDENTIFICATION/Ultraviolet Absorption <197U>, SPECIFIC TESTS/Melting Range or Temperature, Class I <741>	<u>Sujatha</u> <u>Ramakrishna</u>
New	PHENOXYBENZAMINE HYDROCHLORIDE COMPOUNDED ORAL SUSPENSION PF 39(4) Pg. ONLINE	DEFINITION/Introduction, ASSAY/Procedure, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Beyond-Use Date, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Phenoxybenzamine Hydrochloride RS	Jeanne Sun
Omission	PHYSOSTIGMINE PF 39(5) Pg. ONLINE	Entire document	<u>Ravi</u> <u>Ravichandran</u>
Omission	PHYSOSTIGMINE SULFATE PF 39(5) Pg. ONLINE	Entire document	<u>Ravi</u> <u>Ravichandran</u>
Omission	PHYSOSTIGMINE SULFATE OPHTHALMIC OINTMENT PF $39(5)$ Pg. ONLINE	Entire document	<u>Ravi</u> <u>Ravichandran</u>
Revision	PINDOLOL PF 39(5) Pg. ONLINE	IDENTIFICATION/B. Ultraviolet Absorption <197U>, IDENTIFICATION/C., SPECIFIC TESTS/Melting Range or Temperature <741>	<u>Sujatha</u> <u>Ramakrishna</u>
New	PIROXICAM COMPOUNDED ORAL SUSPENSION PF 39(4) Pg. ONLINE	DEFINITION/Introduction, ASSAY/Procedure, SPECIFIC TESTS/pH <791>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Beyond-Use Date, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Piroxicam RS	Jeanne Sun
Omission	PLICAMYCIN PF 39(4) Pg. ONLINE	Entire document	Ahalya Wise
Omission	PLICAMYCIN FOR INJECTION PF 39(4) Pg. ONLINE	Entire document	Ahalya Wise
Revision	POLYSORBATE 80 PF 39(5) Pg. ONLINE	IDENTIFICATION/A., IDENTIFICATION/B. Infrared Absorption <197F>, IMPURITIES/⧫Heavy Metals, Method II <231>, SPECIFIC TESTS/⧫Viscosity-Capillary Viscometer Methods <911> and Rotational Rheometer Methods <912>, ADDITIONAL REQUIREMENTS/⧫USP Reference Standards <11>/USP Polysorbate 80 RS	<u>Kevin Moore</u>
Revision	PRAZOSIN HYDROCHLORIDE PF 39(3) Pg. ONLINE	Organic Impurities, Reference Standards	<u>Sujatha</u> <u>Ramakrishna</u>
New	PREDNISOLONE 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 Hydrocortisone RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Prednisolone RS	Jeanne Sun
New	PREDNISOLONE SODIUM PHOSPHATE COMPOUNDED ORAL SOLUTION PF 39(5) Pg. ONLINE	DEFINITION/Introduction, ASSAY/Procedure, SPECIFIC TESTS/pH <791>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/Beyond-Use Date,	<u>Jeanne Sun</u>

		ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Prednisolone Sodium Phosphate RS	
Revision	PROGUANIL HYDROCHLORIDE PF 39(4) Pg. ONLINE	ASSAY/Procedure, IMPURITIES/Organic Impurities, Procedure 1, IMPURITIES/Organic Impurities, Procedure 2, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Proguanil Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Proguanil Related Compound E RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Proguanil Related Compound F RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Proguanil Related Compound G RS	<u>Shankari</u> <u>Shivaprasad</u>
Omission	PROPRANOLOL HYDROCHLORIDE AND HYDROCHLOROTHIAZIDE EXTENDED-RELEASE CAPSULES PF 39(4) Pg. ONLINE	Entire document	<u>Sujatha</u> <u>Ramakrishna</u>
Revision	PROPYLPARABEN SODIUM PF 39(5) Pg. ONLINE	Chemical Info, DEFINITION/Introduction, ASSAY/Procedure, IMPURITIES/Related Compounds, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ethylparaben RS	<u>Galina</u> <u>Holloway</u>
Revision	RAMIPRIL PF 39(5) Pg. ONLINE	IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B, SPECIFIC TESTS/Melting Range or Temperature <741>	<u>Sujatha</u> <u>Ramakrishna</u>
Omission	RESERPINE, HYDRALAZINE HYDROCHLORIDE, AND HYDROCHLOROTHIAZIDE TABLETS PF 39(4) Pg. ONLINE	Entire document	<u>Sujatha</u> <u>Ramakrishna</u>
New	RHODIOLA ROSEA PF 39(3) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B. Thin-Layer Chromatography, IDENTIFICATION/C. HPLC, COMPOSITION/Content of Phenylpropenoid Glycosides and Salidroside, 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>, CONTAMINANTS/Articles of Botanical Origin, Test for Aflatoxins <561>, 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 Rosavin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Rosavin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Salidroside RS	Anton Bzhelyansky
New	RHODIOLA ROSEA TINCTURE PF 39(3) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/A. Thin-Layer Chromatography, IDENTIFICATION/C. HPLC, COMPOSITION/Content of Phenylpropenoid Glycosides and Salidroside, OTHER COMPONENTS/Alcohol Determination, Method I <611>, CONTAMINANTS/Articles of Botanical Origin, General Method for Pesticide Residues Analysis <561>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Powdered Rhodiola rosea Extract RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Rosavin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP	<u>Anton</u> Bzhelyansky

		Salidroside RS
New	POWDERED RHODIOLA ROSEA PF 39(3) Pg. ONLINE	DEFINITION/Introduction, IDEN Layer Chromatography, IDENTI of Phenylpropenoid Glycosides a Impurities—Procedures < Botanical Origin, General Metho CONTAMINANTS/Microbial Enun CONTAMINANTS/Articles of Sp. CONTAMINANTS/Articles of Bota SPECIFIC TESTS/Botanic Charac <731>, SPECIFIC TESTS/Articles SPECIFIC TESTS/Articles SPECIFIC TESTS/Articles of Bota ADDITIONAL REQUIREMENTS/P REQUIREMENTS/Labeling, ADDI Standards <11>/USP Powdered REQUIREMENTS/USP Reference
New	POWDERED RHODIOLA ROSEA EXTRACT PF 39(3) Pg. ONLINE	DEFINITION/Introduction, IDEN Chromatography, IDENTIFICATI Phenylpropenoid Glycosides and Impurities— Procedures < Botanical Origin, General Metho CONTAMINANTS/Microbial Enum CONTAMINANTS/Absence of Spc CONTAMINANTS/Articles of Bota SPECIFIC TESTS/Loss on Drying REQUIREMENTS/Packaging and REQUIREMENTS/Labeling, ADDI Standards <11>/USP Powdered REQUIREMENTS/USP Reference ADDITIONAL REQUIREMENTS/U Salidroside RS
Revision	RISPERIDONE PF 39(3) Pg. ONLINE	ASSAY/Procedure, IMPURITIES/ REQUIREMENTS/USP Reference Compound G RS
Revision	SACCHARIN Stage 6 Harmonization	Entire Document
New	SALMETEROL INHALATION POWDER PF 39(4) Pg. ONLINE	DEFINITION/Introduction, IDEN PERFORMANCE TESTS/Particle SPERFORMANCE TESTS/Delivered Impurities, SPECIFIC TESTS/Mic for Specified Microorganisms < 6 Matter, Method 2 <788>, ADDI Storage, ADDITIONAL REQUIRE <11>/USP Salmeterol Related CREQUIREMENTS/USP Reference Compound H RS, ADDITIONAL F<11>/USP Salmeterol Resolutio REQUIREMENTS/USP Reference REQUIREMENTS/USP Reference REQUIREMENTS/USP Reference

Salidroside RS

DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B. Thin-Layer Chromatography, IDENTIFICATION/C. HPLC, COMPOSITION/Content of Phenylpropenoid Glycosides and Salidroside, 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>, CONTAMINANTS/Articles of Botanical Origin, Test for Aflatoxins <561>, 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 Rosavin RS

Anton Bzhelyansky

DEFINITION/Introduction, IDENTIFICATION/A. Thin-Layer Chromatography, IDENTIFICATION/B. HPLC, COMPOSITION/Content of Phenylpropenoid Glycosides and Salidroside, 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>, CONTAMINANTS/Articles of Botanical Origin, Test for Aflatoxins <561>, SPECIFIC TESTS/Loss on Drying <731>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Powdered Rhodiola rosea Extract RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Rosavin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Salidroside RS

Anton Bzhelyansky

ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Risperidone Related Compound G RS

<u>Ravi</u> Ravichandran

Jenny Liu

DEFINITION/Introduction, IDENTIFICATION/A., ASSAY/Procedure, PERFORMANCE TESTS/Particle Size Distribution by Cascade Impaction, PERFORMANCE TESTS/Delivered Dose Uniformity, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Microbial Enumeration Tests <61> and Tests for Specified Microorganisms <62>, SPECIFIC TESTS/Foreign Particulate Matter, Method 2 <788>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Salmeterol Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Salmeterol Resolution Check RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Salmeterol Resolution Check RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Salmeterol Resolution Check RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Salmeterol System Suitability RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Salmeterol Xinafoate RS

<u>Ravi</u> Ravichandran

Omission	SCOPOLAMINE HYDROBROMIDE OPHTHALMIC OINTMENT PF 39(5) Pg. ONLINE	Entire document	<u>Feiwen Mao</u>
Revision	SERTRALINE HYDROCHLORIDE PF 39(3) Pg. ONLINE	IDENTIFICATION/C. Identification Tests—General, Chloride <191>, ASSAY/Procedure, IMPURITIES/Limit of (R,R) Sertraline Hydrochloride, IMPURITIES/Organic Impurities, Procedure 1, IMPURITIES/Organic Impurities, Procedure 2, IMPURITIES/Limit of Mandelic Acid, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Benzoic Acid RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Mandelic Acid RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Sertraline Hydrochloride Related Compound A RS	<u>Ravi</u> <u>Ravichandran</u>
Revision	HUMAN FIBROBLAST-DERIVED TEMPORARY SKIN SUBSTITUTE PF 39(5) Pg. ONLINE	{Title} Construct Human Fibroblasts in Bilayer Synthetic Scaffold, DEFINITION/Introduction, SPECIFIC TESTS/Histological Characterization, SPECIFIC TESTS/Metabolic Activity Assessment, SPECIFIC TESTS/DNA Content, SPECIFIC TESTS/Total Collagen Content, SPECIFIC TESTS/Bacterial Endotoxins Test <85>, SPECIFIC TESTS/Sterility Tests <71>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards, Authentic Visual References <11>/Construct Human Fibroblasts in Bilayer Synthetic Scaffold	Rebecca Potts
New	SODIUM PHENYLBUTYRATE PF 39(4) Pg. ONLINE	Chemical Info/Chemical Structure, Chemical Info/C10H11NaO2, Chemical Info/186.18, Chemical Info/Benzenebutanoic acid, sodium salt;, Chemical Info/Sodium 4-phenylbutyrate;, Chemical Info/Sodium 4-phenylbutanoate., Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B. Identification Tests-General, Sodium <191>, ASSAY/Procedure, IMPURITIES/Heavy Metals, Method I <231>, IMPURITIES/Corganic Impurities, SPECIFIC TESTS/Water Determination, Method Ia <921>, SPECIFIC TESTS/Water Determination, Method Ia <921>, SPECIFIC TESTS/PH <791>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Sodium Phenylbutyrate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Phenylbutyrate Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Phenylbutyrate Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Phenylbutyrate Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Phenylbutyrate Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Phenylbutyrate Related Compound C RS	Elena Gonikberg
New	SODIUM PICOSULFATE PF 39(5) Pg. ONLINE	Chemical Info/Chemical Structure, Chemical Info/C18H13NNa2O8S2·H2O, Chemical Info/499.42, Chemical Info/C18H13NNa2O8S2, Chemical Info/481.41, Chemical Info/4,4′-(2-Pyridylmethylene)diphenyl bis(hydrogen sulfate) disodium salt, monohydrate;, Chemical Info/Disodium 4,4′-(pyridin-2-ylmethanediyl)dibenzenesulfonate;, Chemical Info/ 4,4′-(Pyridin-2-ylmethylene)bisphenyl bis (sodium sulfate), monohydrate, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197>, IDENTIFICATION/B. Identification Tests-General, Sodium <191>, ASSAY/Procedure, IMPURITIES/Chloride and Sulfate, Chloride <221>, IMPURITIES/Chloride and Sulfate, Sulfate <221>, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Color of Solution, SPECIFIC TESTS/Acidity and Alkalinity, SPECIFIC TESTS/Water Determination, Method Ia <921>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL	Elena Gonikberg

		REQUIREMENTS/USP Reference Standards <11>/USP Sodium Picosulfate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Sodium Picosulfate Related Compound A RS	
Revision	SODIUM STARCH GLYCOLATE Stage 6 Harmonization	Entire Document	Jenny Liu
Revision	SOMATROPIN PF 39(5) Pg. ONLINE	IDENTIFICATION/B. Peptide Mapping, IDENTIFICATION/C. Somatropin Bioidentity Tests<126>, ASSAY/Somatropin Content	<u>Maura</u> <u>Kibbey</u>
Revision	SOMATROPIN FOR INJECTION PF 39(5) Pg. ONLINE	IDENTIFICATION/B. Somatropin Bioidentity Tests <126>, ASSAY/Somatropin Content	<u>Maura</u> <u>Kibbey</u>
New	SPIRONOLACTONE COMPOUNDED ORAL SUSPENSION PF 39(5) 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 Spironolactone RS	<u>Jeanne Sun</u>
Revision	SPIRONOLACTONE ORAL SUSPENSION PF 39(5) Pg. ONLINE	{Title} Compounded Oral Suspension, Veterinary, DEFINITION/Introduction, ASSAY/Procedure, ADDITIONAL REQUIREMENTS/Labeling	Jeanne Sun
Revision	SUCCINIC ACID PF 39(2) Pg. ONLINE	IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., ASSAY/Procedure, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Fumaric Acid RS	<u>Galina</u> <u>Holloway</u>
Revision	SUCROSE PF 39(5) Pg. ONLINE	IDENTIFICATION/A. Infrared Absorption <197K>, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>	Kevin Moore
Omission	TETRACAINE OPHTHALMIC OINTMENT PF 39(5) Pg. ONLINE	Entire document	Mary Koleck
New	TOPIRAMATE COMPOUNDED ORAL SUSPENSION 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 Topiramate RS	<u>Jeanne Sun</u>
Revision	TRAZODONE HYDROCHLORIDE TABLETS PF 39(4) Pg. ONLINE	ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Trazodone Related Compound C RS	<u>Ravi</u> <u>Ravichandran</u>
Revision	USP AND NF EXCIPIENTS, LISTED BY CATEGORY PF 39(4) Pg. ONLINE	{Coating Agent} Glyceryl Behenate, {Coating Agent} Glyceryl Dibehenate, {Lubricant} Glyceryl Behenate, {Lubricant} Glyceryl Behenate, {Suspending and/or Viscosity-Increasing Agent} Glyceryl Behenate, {Suspending and/or Viscosity-Increasing Agent} Glyceryl Dibehenate, {Wet Binder} Glyceryl Behenate, {Wet Binder} Glyceryl Dibehenate, {Antimicrobial Preservative} Mandelic Acid, {Coating Agent} Sunflower Oil, {Diluent} Invert Sugar, {Diluent} Sunflower Oil, {Emollient} Sunflower Oil, {Solvent} Butylene Glycol, {Solvent} Sunflower Oil, {Sweetening Agent} Invert Sugar, {Vehicle (Oleaginous)} {} Sunflower Oil, {Wet Binder} Invert Sugar, {Wetting and/or Solubilizing Agent} Butylene Glycol	Galina Holloway
Revision	VALPROIC ACID CAPSULES PF 39(4) Pg. ONLINE	ASSAY/Procedure	<u>Ravi</u>

			<u>Ravichandran</u>
Omission	VIDARABINE PF 39(5) Pg. ONLINE	Entire document	<u>Shankari</u> <u>Shivaprasad</u>
Omission	VIDARABINE OPHTHALMIC OINTMENT PF 39(5) Pg. ONLINE	Entire document	<u>Shankari</u> <u>Shivaprasad</u>
New	VINPOCETINE CAPSULES PF 39(4) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/A. Ultraviolet Absorption <197U>, IDENTIFICATION/B. HPLC, STRENGTH/Procedure, PERFORMANCE TESTS/Disintegration and Dissolution <2040>, PERFORMANCE TESTS/Weight Variation <2091>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Vinpocetine RS	<u>Natalia</u> <u>Davydova</u>
New	VINPOCETINE TABLETS PF 39(4) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/A. Ultraviolet Absorption <197U>, IDENTIFICATION/B. HPLC, STRENGTH/Procedure, PERFORMANCE TESTS/Disintegration and Dissolution <2040>, PERFORMANCE TESTS/Weight Variation <2091>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Vinpocetine RS	<u>Natalia</u> <u>Davydova</u>
Revision	VITAMIN A PF 39(5) Pg. ONLINE	IDENTIFICATION/B. Thin-Layer Chromatography, ASSAY/Vitamin A Assay <571>, SPECIFIC TESTS/Absorbance Ratio, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/	Huy Dinh
Revision	VITAMIN A CAPSULES PF 39(5) Pg. ONLINE	IDENTIFICATION/A., IDENTIFICATION/B. Thin-Layer Chromatographic Identification Test, ASSAY/Content of Vitamin A, SPECIFIC TESTS/Absorbance Ratio, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Retinyl Acetate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Retinyl Palmitate RS	<u>Natalia</u> <u>Davydova</u>