

Compendial Approvals for USP38-NF33 1S

Category	Monograph Title	Monograph Section	Scientific Liaison
Revision	<161> TRANSFUSION AND INFUSION ASSEMBLIES AND SIMILAR MEDICAL DEVICES PF 40(3) Pg. ONLINE	Introduction, STERILITY-, BACTERIAL ENDOTOXINS-, PYROGEN-, OTHER REQUIREMENTS-, INTRODUCTION, BACTERIAL ENDOTOXINS, DEFINITIONS, REAGENTS AND TEST SOLUTIONS, DEMONSTRATION OF CONTINUED SUITABILITY, PYROGENS, REFERENCES	Radhakrishna Tirumalai
New	<202> IDENTIFICATION OF FIXED OILS BY THIN-LAYER CHROMATOGRAPHY PF 39(1) Pg. ONLINE	Introduction, IDENTIFICATION, USP Reference Standards <11>, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>, IDENTIFICATION/Procedure	Hong Wang
New	<203> HIGH PERFORMANCE THIN-LAYER CHROMATOGRAPHY PROCEDURE FOR IDENTIFICATION OF ARTICLES OF BOTANICAL ORIGIN PF 40(3) Pg. ONLINE	INTRODUCTION, REQUIRED EQUIPMENT, PROCEDURE	Nandakumara Sarma
Omission	<361> BARBITURATE ASSAY PF 40(3) Pg. ONLINE	Entire document	Ravi Ravichandran
Revision	<616> BULK DENSITY AND TAPPED DENSITY Stage 6 Harmonization	Entire Document	Jenny Liu
Revision	<789> PARTICULATE MATTER IN OPHTHALMIC SOLUTIONS PF 40(3) Pg. ONLINE	Introduction, LIGHT OBSCURATION PARTICLE COUNT TEST	Desmond Hunt
Revision	<1010> ANALYTICAL DATA -- INTERPRETATION AND TREATMENT PF 40(3) Pg. ONLINE	INTRODUCTION, PREREQUISITE LABORATORY PRACTICES AND PRINCIPLES, MEASUREMENT PRINCIPLES AND VARIATION, OUTLYING RESULTS, COMPARISON OF ANALYTICAL METHODS/PROCEDURES, APPENDIX B: PRECISION STUDY, APPENDIX C: EXAMPLES OF OUTLIER TESTS FOR ANALYTICAL DATA, APPENDIX D: COMPARISON OF METHODS/PROCEDURES-PRECISION, APPENDIX E: COMPARISON OF METHODS/PROCEDURES-DETERMINING THE LARGEST ACCEPTABLE DIFFERENCE, δ, BETWEEN TWO METHODS/PROCEDURES, APPENDIX F: EQUIVALENCE TESTING AND TOST, APPENDIX FG: ADDITIONAL SOURCES OF INFORMATION	Horacio Pappa
New	<1064> IDENTIFICATION OF ARTICLES OF BOTANICAL ORIGIN USING HIGH-PERFORMANCE THIN-LAYER CHROMATOGRAPHY PROCEDURE PF 40(3) Pg. ONLINE	INTRODUCTION, VARIABLES OF HPTLC, CONCLUSIONS	Nandakumara Sarma
Revision	<1066> PHYSICAL ENVIRONMENTS THAT PROMOTE SAFE MEDICATION USE PF 40(1) Pg. ONLINE	DEFINITIONS, FACTORS TO CONSIDER WHEN ASSESSING PHYSICAL ENVIRONMENT NEEDS, PHYSICAL ENVIRONMENT GUIDELINES FOR MEDICATION SAFETY ZONES, REFERENCES, INTRODUCTION, ORGANIZATIONAL SUPPORT, MEDICATION SAFETY ZONES, SOUND AND NOISE, ACTIVITIES AND TASKS PERFORMED, TOOLS AND TECHNOLOGIES IN THE PHYSICAL ENVIRONMENT, DISTRACTIONS AND DISTRACTIBILITY INDEX, PHYSICAL ENVIRONMENT ELEMENTS, WORK SYSTEM DESIGN, CHALLENGES IN THE PHYSICAL ENVIRONMENT, PHYSICAL ENVIRONMENT FACTORS, METHODS FOR ASSESSING THE PHYSICAL ENVIRONMENT, SUMMARY, GLOSSARY OF TERMS	Donna Bohannon
Revision	<1092> THE DISSOLUTION PROCEDURE -- DEVELOPMENT AND VALIDATION PF 40(1) Pg. ONLINE	Introduction, GENERAL COMMENTS, MEDIUM, APPARATUS/AGITATION, STUDY DESIGN, ASSAY, VALIDATION, ACCEPTANCE CRITERIA,	William Brown

		INTRODUCTION, 1. PRELIMINARY ASSESSMENT (FOR EARLY STAGES OF PRODUCT DEVELOPMENT/DISSOLUTION METHOD DEVELOPMENT), 2. METHOD DEVELOPMENT, 3. ANALYTICAL FINISH, 4. AUTOMATION, 5. VALIDATION, 6. ACCEPTANCE CRITERIA, REFERENCES	
New	<1106.1> IMMUNOGENICITY ASSAYS— DESIGN AND VALIDATION OF ASSAYS TO DETECT ANTI-DRUG NEUTRALIZING ANTIBODY PF 40(3) Pg. ONLINE	INTRODUCTION AND SCOPE, FACTORS THAT INFLUENCE THE DEVELOPMENT OF NEUTRALIZING ANTIBODIES, DETERMINATION OF PRECLINICAL AND CLINICAL IMMUNOGENICITY, RISK-BASED APPROACH TO ASSESSING NEUTRALIZING ANTIBODIES AND THEIR CONSEQUENCES, DESIGN OF NAB TEST METHODS, VALIDATION OF NAB ASSAYS, LIFE CYCLE MANAGEMENT, APPENDIX: ADDITIONAL SOURCES OF INFORMATION	Maura Kibbey
Revision	<1160> PHARMACEUTICAL CALCULATIONS IN PRESCRIPTION COMPOUNDING PF 40(3) Pg. ONLINE	INTRODUCTION, BASIC MATHEMATICAL CONCEPTS, BASIC PHARMACEUTICAL CALCULATIONS, TABLE OF CONTENTS, INTRODUCTION, CALCULATING AMOUNTS OF ACTIVE INGREDIENTS, DOSAGE CALCULATIONS, USE OF POTENCY UNITS, VOLUME AND WEIGHT SUMS, DENSITY AND SPECIFIC GRAVITY, MILLIEQUIVALENTS AND MILLIMOLES, CONCENTRATION EXPRESSIONS (WITH TABLE 1), ALCOHOL, ALLIGATION ALTERNATE AND ALGEBRA, ALIQUOT CALCULATIONS, POWDER VOLUME CALCULATIONS, INTRAVENOUS FLOW OR INFUSION RATES, ISOOSMOTIC SOLUTIONS, PH AND BUFFER CALCULATION, TEMPERATURE, ENDOTOXINS, STABILITY AND EXPIRATION DATE CALCULATIONS, APPENDIX 1: LOGARITHMS (WITH TABLE 9 AND TABLE 10), 1. INTRODUCTION, 2. CALCULATING AMOUNTS OF ACTIVE INGREDIENTS, 3. DOSAGE CALCULATIONS, 4. USE OF POTENCY UNITS, 5. VOLUME AND WEIGHT SUMS, 6. DENSITY AND SPECIFIC GRAVITY, 7. MILLIEQUIVALENTS AND MILLIMOLES, 8. CONCENTRATION EXPRESSIONS, 9. ALCOHOL, 10. ALLIGATION ALTERNATE AND ALGEBRA METHODS, 11. ALIQUOT CALCULATIONS, 12. POWDER VOLUME CALCULATIONS, 13. INTRAVENOUS FLOW OR INFUSION RATES, 14. ISOOSMOTIC SOLUTIONS, 15. PH AND BUFFER CALCULATIONS, 16. TEMPERATURE, 17. ENDOTOXINS, 18. STABILITY AND EXPIRATION DATE CALCULATIONS, APPENDIX 1: LOGARITHMS	Jeanne Sun
New	<1229.11> VAPOR PHASE STERILIZATION PF 40(2) Pg. ONLINE	INTRODUCTION, HYDROGEN PEROXIDE, PERACETIC ACID, VALIDATION OF VAPOR STERILIZATION, ROUTINE PROCESS CONTROL	Radhakrishna Tirumalai
New	<1663> EXTRACTABLES ASSOCIATED WITH PHARMACEUTICAL PACKAGING SYSTEMS PF 39(5) Pg. ONLINE	PURPOSE, KEY TERMS, SCOPE, BACKGROUND INFORMATION, GENERATING THE EXTRACT, CHARACTERIZING THE EXTRACT, SUMMARY, REFERENCES	Desmond Hunt
New	<1664> ASSESSMENT OF DRUG PRODUCT LEACHABLES ASSOCIATED WITH PHARMACEUTICAL PACKAGING/DELIVERY SYSTEMS PF 39(5) Pg. ONLINE	PURPOSE, KEY TERMS, SCOPE, CONCEPTS, LEACHABLES STUDY DESIGN, LEACHABLES CHARACTERIZATION, ESTABLISHING A LEACHABLES-EXTRACTABLES CORRELATION, CONSIDERATIONS IN DEVELOPING LEACHABLES SPECIFICATIONS AND ACCEPTANCE CRITERIA, ADDITIONAL CONSIDERATIONS, SUMMARY, REFERENCES	Desmond Hunt
New	<1664.1> ORALLY INHALED AND NASAL DRUG PRODUCTS PF 39(5) Pg. ONLINE	INTRODUCTION, KEY TERMS, LEACHABLES ASSESSMENT RATIONALE FOR ORALLY INHALED AND NASAL DRUG PRODUCTS, ORALLY INHALED AND NASAL DRUG PRODUCTS DOSAGE FORM TYPES, ADDITIONAL CONSIDERATIONS, REFERENCES	Desmond Hunt
Revision	ACEBUTOLOL HYDROCHLORIDE PF 40(3) Pg. ONLINE	IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Melting Range or Temperature <741>, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Acebutolol Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards	Sujatha Ramakrishna

		<11>/USP Acebutolol Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Acebutolol Related Compound I RS	
Revision	ADENINE PF 38(6) Pg. ONLINE	ASSAY/Procedure, IMPURITIES/Organic Impurities, IMPURITIES/Related Compounds, SPECIFIC TESTS/Nitrogen Content, Method II <461>	Huy Dinh
Revision	ALANINE PF 40(2) Pg. ONLINE	IMPURITIES/Organic Impurities, IMPURITIES/Related Compounds, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Fumaric Acid RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Maleic Acid RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Malic Acid RS	Huy Dinh
New	ALMOTRIPTAN MALATE PF 40(3) Pg. ONLINE	Chemical Info/Chemical Structure, Chemical Info/C17H25N3O2S.C4H6O5, Chemical Info/469.55, Chemical Info/Pyrrolidine, 1-[[[3-[2-(dimethylamino)ethyl]-1H-indol-5-yl]methyl]sulfonyl]-, hydroxybutanedioate (1:1);, Chemical Info/1-[(3-[2-(Dimethylamino)ethyl]indol-5-yl)methyl]sulfonyl]pyrrolidine malate (1:1), Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Limit of Almotriptan Related Compound D and Almotriptan Dimer Derivative, IMPURITIES/Organic Impurities, IMPURITIES/Limit of Fumaric Acid, SPECIFIC TESTS/Water Determination, Method Ia <921>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Almotriptan Malate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Almotriptan Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Almotriptan Related Compound C RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Almotriptan Related Compound D RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Fumaric Acid RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Maleic Acid RS	Heather Joyce
New	ALMOTRIPTAN TABLETS PF 40(3) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197F>, IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Almotriptan Malate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Almotriptan Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Almotriptan Related Compound C RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Almotriptan Related Compound D RS	Heather Joyce
New	AMLODIPINE, VALSARTAN AND HYDROCHLOROTHIAZIDE TABLETS PF 40(2) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Amlodipine Besylate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Amlodipine Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Benzothiadiazine Related Compound A RS, ADDITIONAL	Sujatha Ramakrishna

		REQUIREMENTS/USP Reference Standards <11>/USP Hydrochlorothiazide RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Valsartan RS	
Revision	AMLODIPINE BESYLATE TABLETS PF 40(3) Pg. ONLINE	ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, IMPURITIES/Organic Impurities	Sujatha Ramakrishna
Revision	AMOBARBITAL SODIUM FOR INJECTION PF 40(2) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B. Identification Tests-General, Sodium <191>, SPECIFIC TESTS/Other Requirements	Heather Joyce
New	ANASTROZOLE TABLETS PF 40(3) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Anastrozole RS	Feiwen Mao
Revision	ANTIPYRINE PF 40(3) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/Ultraviolet Absorption <197U>, IDENTIFICATION/C., ASSAY/Procedure	Hillary Cai
New	BACILLUS SUBTILIS SUBSP. SUBTILIS MENAQUINONE-7 EXTRACT PF 40(3) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/A. Thin-Layer Chromatography, IDENTIFICATION/B., COMPOSITION/Content of Menaquinone-7 and Menaquinone-6, IMPURITIES/Elemental Impurities-Procedures <233>, IMPURITIES/Isomeric Purity, SPECIFIC TESTS/Microbial Enumeration Tests <2021>, SPECIFIC TESTS/Absence of Specified Microorganisms <2022>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Menaquinone-7 RS	Huy Dinh
Revision	BENZOCAINE PF 40(1) Pg. ONLINE	IDENTIFICATION/Ultraviolet Absorption <197U>, IDENTIFICATION/C., IMPURITIES/Ordinary Impurities <466>, IMPURITIES/Organic Impurities, IMPURITIES/Readily Carbonizable Substances Test <271>, SPECIFIC TESTS/Melting Range or Temperature, Class I <741>, SPECIFIC TESTS/Reaction, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Aminobenzoic Acid RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ethyl 4-Nitrobenzoate RS	Domenick Vicchio
Revision	BENZOCAINE CREAM PF 40(3) Pg. ONLINE	IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Aminobenzoic Acid RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ethyl 4-Nitrobenzoate RS, Identification/A	Domenick Vicchio
Revision	BENZOCAINE GEL PF 40(3) Pg. ONLINE	IDENTIFICATION/A., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Aminobenzoic Acid RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ethyl 4-Nitrobenzoate RS, Identification/A	Domenick Vicchio
New	BORAGE SEED OIL CAPSULES PF 39(6) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/A. Fatty Acid Profile, STRENGTH/Content of gamma-Linolenic, Linoleic, and Oleic Acids, PERFORMANCE TESTS/Disintegration and Dissolution <2040>, PERFORMANCE TESTS/Weight Variation <2091>, SPECIFIC TESTS/Fats and Fixed Oils, Peroxide Value <401>, CONTAMINANTS/Microbial Enumeration	Natalia Davydova

		Tests <2021>, CONTAMINANTS/Absence of Specified Microorganisms <2022>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Borage Oil RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methyl Linoleate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methyl Linolenate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methyl Oleate RS	
New	BUPRENORPHINE COMPOUNDED BUCCAL SOLUTION, VETERINARY PF 40(2) 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 Buprenorphine Hydrochloride RS	Jeanne Sun
Revision	BUTABARBITAL SODIUM ORAL SOLUTION PF 40(3) Pg. ONLINE	IDENTIFICATION/B., ASSAY/Procedure, ADDITIONAL REQUIREMENTS/Packaging and Storage	Heather Joyce
Revision	BUTABARBITAL SODIUM TABLETS PF 40(3) Pg. ONLINE	IDENTIFICATION/Infrared Absorption <197K>, ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, ADDITIONAL REQUIREMENTS/Packaging and Storage	Heather Joyce
Revision	CEFOTAXIME SODIUM PF 40(1) Pg. ONLINE	ASSAY/Procedure, IMPURITIES/Organic Impurities, Procedure 1, IMPURITIES/Organic Impurities, Procedure 2, SPECIFIC TESTS/Clarity and Color of Solution, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Cefetamet RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Cefotaxime Related Compound E RS	Ahalya Wise
Revision	CROMOLYN SODIUM INHALATION SOLUTION PF 40(1) Pg. ONLINE	IDENTIFICATION/A., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Cromolyn Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Cromolyn Related Compound B RS	Ravi Ravichandran
Revision	CROMOLYN SODIUM NASAL SOLUTION PF 40(1) Pg. ONLINE	IDENTIFICATION/A, ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Cromolyn Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Cromolyn Related Compound B RS	Ravi Ravichandran
Revision	UREA C 13 FOR ORAL SOLUTION PF 40(3) Pg. ONLINE	IDENTIFICATION/A., IDENTIFICATION/B, ASSAY/Procedure, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, SPECIFIC TESTS/Other Requirements, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>	Ravi Ravichandran
New	DICLOFENAC SODIUM AND MISOPROSTOL DELAYED-RELEASE TABLETS PF 40(2) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/A. Ultraviolet Absorption <197U>, IDENTIFICATION/B., ASSAY/Misoprostol, ASSAY/Diclofenac Sodium, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities: Misoprostol, IMPURITIES/Organic Impurities: Diclofenac Sodium, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Diclofenac Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards	Elena Gonikberg

		<11>/USP Diclofenac Sodium RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Misoprostol RS	
Revision	DINOPROSTONE PF 39(6) Pg. ONLINE	ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Dinoprostone Related Compound C RS	Domenick Vicchio
Revision	DIPHENOXYLATE HYDROCHLORIDE PF 40(2) Pg. ONLINE	Chemical Info/4-Piperidinecarboxylic acid, 1-(3-cyano-3,3-diphenylpropyl)-4-phenyl-, ethyl ester, monohydrochloride ; hydrochloride; , Chemical Info/Ethyl 1-(3-cyano-3,3-diphenylpropyl)-4-phenylisonipecotate monohydrochlorideEthyl 1-(3-cyano-3,3-diphenylpropyl)-4-phenylpiperidine-4-carboxylate hydrochloride, IDENTIFICATION/B. Ultraviolet Absorption <197U>, IDENTIFICATION/C., ASSAY/Procedure, IMPURITIES/Ordinary Impurities <466>, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Melting Range or Temperature <741>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Diphenoxylate Related Compound A RS	Elena Gonikberg
Revision	DIPIVEFRIN HYDROCHLORIDE PF 40(1) Pg. ONLINE	ASSAY/Procedure, IMPURITIES/Limits of Epinephrine and Dipivefrin Related Compound B, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Melting Range or Temperature <741>, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Epinephrine Bitartrate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Dipivefrin Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Dipivefrin Related Compound E RS	Feiwen Mao
Revision	DIPIVEFRIN HYDROCHLORIDE OPHTHALMIC SOLUTION PF 40(1) Pg. ONLINE	ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Dipivefrin Related Compound E RS	Feiwen Mao
Revision	DONEPEZIL HYDROCHLORIDE PF 40(2) Pg. ONLINE	Chemical Info/Chemical NameC24H29NO3·HCl·H2O 433.97 5,6-Dimethoxyindan-1-one, 2-[(1-benzyl-4-piperidyl)methyl]-, (±)-, hydrochloride; , Chemical Info/Chemical Name Monohydrate 884740-09-4 Chemical Info/CAS, IMPURITIES/, Procedure 2, SPECIFIC TESTS/Water Determination, Method Ia <921>, ADDITIONAL REQUIREMENTS/Labeling	Heather Joyce
Revision	DOXAZOSIN MESYLATE PF 40(3) Pg. ONLINE	ASSAY/Procedure, IMPURITIES/Organic Impurities	Sujatha Ramakrishna
Revision	EPIRUBICIN HYDROCHLORIDE PF 40(2) Pg. ONLINE	ASSAY/Procedure, IMPURITIES/Procedure 1, IMPURITIES/Procedure 2, SPECIFIC TESTS/Sterility Tests <71>, ADDITIONAL REQUIREMENTS/Labeling	Ahalya Wise
New	EPIRUBICIN HYDROCHLORIDE INJECTION PF 40(2) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/pH <791>, SPECIFIC TESTS/Sterility Tests <71>, SPECIFIC TESTS/Bacterial Endotoxins Test <85>, SPECIFIC TESTS/Other Requirements, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Doxorubicin Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Endotoxin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Epirubicin Hydrochloride RS	Ahalya Wise
Revision	ESMOLOL HYDROCHLORIDE PF 40(3) Pg. ONLINE	ASSAY/Procedure, ADDITIONAL REQUIREMENTS/Packaging and Storage	Sujatha Ramakrishna

Revision	ESTRADIOL CYPIONATE PF 39(6) Pg. ONLINE	IDENTIFICATION/Ultraviolet Absorption <197U>, ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Melting Range or Temperature <741>, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Estradiol RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Estradiol Cypionate System Suitability Mixture RS	Domenick Vicchio
Revision	ETHYL ACETATE PF 40(3) Pg. ONLINE	IDENTIFICATION/A. Infrared Absorption <197F>, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>	Galina Holloway
New	FLAX SEED OIL CAPSULES PF 39(6) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B. Fatty Acid Profile, STRENGTH/Content of Alpha Linolenic, Linoleic, and Oleic Acids, PERFORMANCE TESTS/Disintegration and Dissolution <2040>, PERFORMANCE TESTS/Weight Variation <2091>, SPECIFIC TESTS/Fats and Fixed Oils, Peroxide Value <401>, CONTAMINANTS/Microbial Enumeration Tests <2021>, CONTAMINANTS/Absence of Specified Microorganisms <2022>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Flax Oil RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methyl Linoleate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methyl Linolenate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methyl Oleate RS	Natalia Davydova
Revision	FLUMAZENIL PF 40(3) Pg. ONLINE	ASSAY/Procedure, IMPURITIES/Organic Impurities, Procedure 1, IMPURITIES/Organic Impurities, Procedure 2, SPECIFIC TESTS/Melting Range or Temperature, Class Ia <741>, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Flumazenil Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Flumazenil Related Compound C RS	Heather Joyce
Revision	FLUMAZENIL INJECTION PF 40(3) Pg. ONLINE	IDENTIFICATION/A. Thin-Layer Chromatographic Identification Test <201>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Flumazenil Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Flumazenil Related Compound B RS	Heather Joyce
Revision	FORMOTEROL FUMARATE PF 40(1) Pg. ONLINE	IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, IMPURITIES/ Limit of Related Compound I (Diastereomer), Procedure 1, SPECIFIC TESTS/Optical Rotation, Angular Rotation <781A>	Ravi Ravichandran
New	GALANTAMINE ORAL SOLUTION PF 40(3) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/A., ASSAY/Procedure, PERFORMANCE TESTS/Deliverable Volume <698>, 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 Galantamine Hydrobromide RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Galantamine Hydrobromide Related Compounds Mixture RS	Heather Joyce
New	GALANTAMINE EXTENDED-RELEASE CAPSULES PF 40(2) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES,	Heather Joyce

		IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Galantamine Hydrobromide RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Galantamine Hydrobromide Related Compounds Mixture RS	
Revision	HYDROXOCOBALAMIN PF 39(1) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/Ultraviolet Absorption <197U>, IDENTIFICATION/C., ASSAY/Procedure, IMPURITIES/Limit of Cyanocobalamin, IMPURITIES/Related Compounds, SPECIFIC TESTS/pH-Dependent Cobalamins, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>	Huy Dinh
Revision	HYDROXYZINE PAMOATE PF 39(6) Pg. ONLINE	IDENTIFICATION/B., ASSAY/Procedure, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Hydroxyzine Hydrochloride RS, â€¢ ADDITIONAL REQUIREMENTS/Reference Standards/USP Pamoic Acid RS	Heather Joyce
New	IBUTILIDE FUMARATE PF 39(4) Pg. ONLINE	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	Suiatha Ramakrishna
New	IMIQUIMOD CREAM PF 40(3) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/A. Ultraviolet Absorption <197U>, IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Minimum Fill <755>, IMPURITIES/Organic Impurities, SPECIFIC TESTS/pH <791>, SPECIFIC TESTS/Microbial Enumeration Tests <61> and Tests For Specified Microorganisms <62>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Imiquimod RS	Shankari Shivaprasad
Revision	INDOMETHACIN PF 40(1) Pg. ONLINE	DEFINITION/Introduction, ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Indomethacin Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Indomethacin Related Compound B RS	Hillary Cai
Revision	INDOMETHACIN SUPPOSITORIES PF 40(3) Pg. ONLINE	IDENTIFICATION/A. Thin-Layer Chromatography, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Indomethacin Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Indomethacin Related Compound B RS	Hillary Cai

Revision	ISONIAZID PF 39(6) Pg. ONLINE	IDENTIFICATION/B. Ultraviolet Absorption, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Melting Range or Temperature <741>	Shankari Shivaprasad
Revision	LEVALBUTEROL HYDROCHLORIDE PF 40(3) Pg. ONLINE	IMPURITIES/Organic Impurities	Ravi Ravichandran
New	LEVETIRACETAM INJECTION PF 40(3) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/A., ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/pH <791>, SPECIFIC TESTS/Bacterial Endotoxins Test <85>, SPECIFIC TESTS/Sterility Tests <71>, SPECIFIC TESTS/Particulate Matter in Injections <788>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Bacterial Endotoxin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Levetiracetam RS	Ravi Ravichandran
Revision	LEVOCARNITINE INJECTION PF 40(2) Pg. ONLINE	ASSAY/Procedure	Natalia Davydova
New	LEVOCETIRIZINE DIHYDROCHLORIDE PF 40(2) Pg. ONLINE	Title, Chemical Info/Chemical Structure, Chemical Info/C ₂₁ H ₂₅ CIN ₂ O ₃ ·2HCl, Chemical Info/461.81, Chemical Info/Acetic acid, [2-[4-[(R)-(4-chlorophenyl)phenylmethyl]-1-piperazinyl]ethoxy]-, dihydrochloride;, Chemical Info/(2-{4-[(R)-(4-Chlorophenyl)phenylmethyl]piperazin-1-yl}ethoxy)acetic acid dihydrochloride, Chemical Info/CAS, Chemical Info/Levocetirizine free base, Chemical Info/C ₂₁ H ₂₅ CIN ₂ O ₃ , Chemical Info/388.89, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., IDENTIFICATION/C. Identification Tests-General, Chloride <191>, ASSAY/Procedure, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Organic Impurities, IMPURITIES/Enantiomeric Purity, SPECIFIC TESTS/Loss on Drying <731>, SPECIFIC TESTS/pH <791>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Cetirizine Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Chlorobenzhydryl Piperazine RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Levocetirizine Amide RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Levocetirizine Dihydrochloride RS	Mary Koleck
Revision	LIDOCAINE HYDROCHLORIDE TOPICAL SOLUTION PF 39(6) Pg. ONLINE	IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Lidocaine Related Compound H RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methylparaben RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ropivacaine Related Compound A RS	Mary Koleck
Revision	LIDOCAINE HYDROCHLORIDE ORAL TOPICAL SOLUTION PF 39(6) Pg. ONLINE	IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Lidocaine Related Compound H RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ropivacaine Related Compound A RS	Mary Koleck
Revision	MANNITOL Stage 6 Harmonization	Entire Document	Jenny Liu
New	MENAQUINONE-7 PF 40(1) Pg. ONLINE	Chemical Info/Chemical Structure, Chemical Info/C ₄₆ H ₆₄ O ₂ , Chemical	Huy Dinh

Info/649.00, Chemical Info/(all-E)-2-(3,7,11,15,19,23,27-Heptamethyl-2,6,10,14,18,22,26-octacosaeptaenyl)-3-methyl-1,4-naphthalenedione, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197A>, IDENTIFICATION/B. Ultraviolet Absorption <197U>, IDENTIFICATION/C., ASSAY/Procedure, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Elemental Impurities-Procedures <233>, IMPURITIES/Enantiomeric Purity, SPECIFIC TESTS/Microbial Enumeration Tests <2021>, SPECIFIC TESTS/Absence of Specified Microorganisms <2022>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Menaquinone-7 RS

DEFINITION/Introduction, IDENTIFICATION/A., STRENGTH/Content of Menaquinone-7, Method 1, STRENGTH/Content of Menaquinone-7, Method 2, PERFORMANCE TESTS/Disintegration and Dissolution <2040>, PERFORMANCE TESTS/Weight Variation <2091>, CONTAMINANTS/Microbial Enumeration Tests <2021>, CONTAMINANTS/Absence of Specified Microorganisms <2022>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Menaquinone-7 RS

DEFINITION/Introduction, IDENTIFICATION/A. Thin-Layer Chromatography, IDENTIFICATION/B., COMPOSITION/Content of Menaquinone-7, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Elemental Impurities-Procedures <233>, IMPURITIES/Enantiomeric Purity, SPECIFIC TESTS/Microbial Enumeration Tests <2021>, SPECIFIC TESTS/Absence of Specified Microorganisms <2022>, SPECIFIC TESTS/Loss on Drying <731> (for solid Menaquinone-7 Preparations), ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Menaquinone-7 RS

DEFINITION/Introduction, IDENTIFICATION/A., STRENGTH/Content of Menaquinone-7, Method 1, STRENGTH/Content of Menaquinone-7, Method 2, PERFORMANCE TESTS/Disintegration and Dissolution <2040>, PERFORMANCE TESTS/Weight Variation <2091>, CONTAMINANTS/Microbial Enumeration Tests <2021>, CONTAMINANTS/Absence of Specified Microorganisms <2022>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Menaquinone-7 RS

Chemical Info/Chemical Structure, Chemical Info/C₁₂H₁₅NO₃, Chemical Info/221.25, Chemical Info/2-Oxazolidinone, 5-[(3,5-dimethylphenoxy)methyl]-; , Chemical Info/5-[(3,5-Xylyloxy)methyl]-2-oxazolidinone; , Chemical Info/5-[(3,5-Dimethylphenoxy)methyl]-1,3-oxazolidin-2-one, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197A> or <197K>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Organic Impurities, Procedure 1, IMPURITIES/Organic Impurities, Procedure 2, SPECIFIC TESTS/Loss on Drying <731>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Metaxalone RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Metaxalone Related Compound B RS,

New MENAQUINONE-7 CAPSULES PF 40(2) Pg. ONLINE

[Natalia Davydova](#)

New MENAQUINONE-7 PREPARATION PF 40(1) Pg. ONLINE

[Huy Dinh](#)

New MENAQUINONE-7 TABLETS PF 40(2) Pg. ONLINE

[Natalia Davydova](#)

New METAXALONE PF 40(3) Pg. ONLINE

[Ravi Ravichandran](#)

		ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Metaxalone Related Compound C RS	
New	METAXALONE TABLETS PF 40(3) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/A., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, PERFORMANCE TESTS/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Metaxalone RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Metaxalone Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Metaxalone Related Compound C RS	Ravi Ravichandran
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	METRONIDAZOLE INJECTION PF 40(3) Pg. ONLINE	IDENTIFICATION/A., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Tinidazole Related Compound A RS	Shankari Shivaprasad
Revision	METRONIDAZOLE TABLETS PF 40(1) Pg. ONLINE	PERFORMANCE TESTS/Dissolution <711>, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Tinidazole Related Compound A RS	Shankari Shivaprasad
Revision	MILRINONE PF 40(3) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/B., ASSAY/Procedure	Sujatha Ramakrishna
New	MINOCYCLINE HYDROCHLORIDE EXTENDED-RELEASE TABLETS PF 40(3) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Minocycline Hydrochloride RS	Ahalya Wise
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	Hillary Cai

		Reference Standards <11>/USP Naproxen Related Compound A, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Naproxen Related Compound L	
Revision	NIACIN PF 40(1) Pg. ONLINE	IDENTIFICATION/B. Ultraviolet Absorption <197U>, IMPURITIES/Related Compounds, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP 6-Methylnicotinic Acid RS, DEFINITION/Introduction, IDENTIFICATION/C., ASSAY/Procedure, IMPURITIES/Ordinary Impurities <466>, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP 6-Hydroxynicotinic Acid RS	Huy Dinh
New	NORELGESTROMIN PF 39(6) Pg. ONLINE	Chemical Info/Chemical Structure, Chemical Info/C21H29NO2, Chemical Info/327.46, Chemical Info/18,19-Dinorpregn-4-en-20-yn-3-one, 13-ethyl-17-hydroxy-, oxime, (17α)-, Chemical Info/13-Ethyl-17-hydroxy-18,19-dinor-17α-pregn-4-en-20-yn-3-one oxime, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Optical Rotation, Specific Rotation <781S>, SPECIFIC TESTS/Water Determination, Method Ic <921>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Norelgestromin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Norelgestromin Related Compound A RS	Mary Koleck
Revision	NORFLOXACIN PF 40(2) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/Ultraviolet Absorption <197U>, ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Norfloxacin Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Norfloxacin Related Compound E RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Norfloxacin Related Compound H RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Norfloxacin Related Compound K RS	Shankari Shivaprasad
Revision	PHENYTOIN SODIUM PF 40(2) Pg. ONLINE	IDENTIFICATION/A. Procedure, IDENTIFICATION/A. Infrared Absorption-General <197K>, IDENTIFICATION/B. Identification Tests-General, Sodium <191>, IDENTIFICATION/C., ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Clarity and Color of Solution, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Phenytoin Sodium RS	Ravi Ravichandran
Revision	POTASSIUM METAPHOSPHATE PF 40(2) Pg. ONLINE	(KPO3) _n , Chemical Info/Chemical Name Potassium polymetaphosphate, SPECIFIC TESTS/or Rotational Rheometer Methods <912>	Galina Holloway
Revision	REPAGLINIDE PF 39(6) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/B. Ultraviolet Absorption <197U>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, IMPURITIES/Enantiomeric Purity, SPECIFIC TESTS/Optical Rotation, Specific Rotation <781S>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Repaglinide Related Compound E RS	Elena Gonikberg
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	Galina Holloway

		REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>	
New	SELEGILINE COMPOUNDED TOPICAL GEL PF 40(2) 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 Methamphetamine Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Selegiline Hydrochloride RS	Jeanne Sun
Revision	RICE STARCH Stage 6 Harmonization	Entire Document	Jenny Liu
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
New	TADALAFIL COMPOUNDED ORAL SUSPENSION PF 40(2) 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 Tadalafil RS	Jeanne Sun
Revision	TEMAZEPAM PF 40(2) Pg. ONLINE	ASSAY/Procedure, IMPURITIES/Organic Impurities	Ravi Ravichandran
Revision	TETRACAINE PF 39(6) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/A. Procedure, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B. Procedure, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Melting Range or Temperature, Class I <741>, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Aminobenzoic Acid RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Tetracaine Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Tetracaine Related Compound C RS	Mary Koleck
Revision	TETRACAINE HYDROCHLORIDE PF 39(6) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/A. Ultraviolet Absorption <197U>, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B. Procedure, IDENTIFICATION/C, IDENTIFICATION/C., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Aminobenzoic Acid RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Tetracaine Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Tetracaine Related Compound C RS	Mary Koleck
Revision	TICARCILLIN DISODIUM PF 40(3) Pg. ONLINE	IDENTIFICATION/A. Ultraviolet Absorption <197U>, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., IDENTIFICATION/C., IDENTIFICATION/B, ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Content of Ticarcillin, ADDITIONAL REQUIREMENTS/Packaging and Storage	Ahalya Wise

Revision	TICARCILLIN MONOSODIUM PF 40(3) Pg. ONLINE	Chemical Info/Chemical Structure, IDENTIFICATION/B. Ultraviolet Absorption <197U>, IDENTIFICATION/B., IDENTIFICATION/C., IDENTIFICATION/C, ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Clavulanate Lithium RS	Ahalya Wise
New	TIENCHI GINSENG ROOT AND RHIZOME PF 40(2) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B. Thin-Layer Chromatography, IDENTIFICATION/C. HPLC, COMPOSITION/Content of Saponins, 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/Articles of Botanical Origin, Alcohol-Soluble Extractives, Method 2 <561>, SPECIFIC TESTS/Articles of Botanical Origin, Water-Soluble Extractives, Method 2 <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 Aflatoxins RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ginsenoside Rg1 RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Panax notoginseng Dry Extract RS	Christopher Okunji
New	TIENCHI GINSENG ROOT AND RHIZOME DRY EXTRACT PF 40(2) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B. Thin-Layer Chromatography, IDENTIFICATION/C. HPLC, COMPOSITION/Content of Saponins, 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 Aflatoxins RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ginsenoside Rg1 RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Panax notoginseng Dry Extract RS	Christopher Okunji
New	TIENCHI GINSENG ROOT AND RHIZOME POWDER PF 40(2) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B. Thin-Layer Chromatography, IDENTIFICATION/C. HPLC, COMPOSITION/Content of Saponins, 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/Articles of Botanical Origin, Alcohol-Soluble Extractives, Method 2 <561>, SPECIFIC TESTS/Articles of Botanical Origin, Water-Soluble Extractives, Method 2 <561>, SPECIFIC TESTS/Loss on Drying <731>, SPECIFIC TESTS/Articles of Botanical Origin, Total Ash <561>, SPECIFIC TESTS/Articles of Botanical	Christopher Okunji

		Origin, Acid-Insoluble Ash <561>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Aflatoxins RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ginsenoside Rg1 RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Panax notoginseng Dry Extract RS	
New	TRAMADOL HYDROCHLORIDE COMPOUNDED ORAL SUSPENSION, VETERINARY PF 40(2) 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 Tramadol Hydrochloride RS	Jeanne Sun
Revision	TROPICAMIDE PF 39(5) Pg. ONLINE	Chemical Info/Chemical Structure, N-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
New	VORICONAZOLE COMPOUNDED OPHTHALMIC SOLUTION, VETERINARY PF 40(2) Pg. ONLINE	DEFINITION/Introduction, ASSAY/Procedure, SPECIFIC TESTS/pH <791>, SPECIFIC TESTS/Sterility Tests <71>, SPECIFIC TESTS/Particulate Matter in Ophthalmic Solutions <789>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/Beyond-Use Date, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Voriconazole RS	Jeanne Sun
New	ZONISAMIDE COMPOUNDED ORAL SUSPENSION PF 40(2) 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 Zonisamide RS	Jeanne Sun