

Compendial Approvals for USP36–NF31

Category	Monograph Title	Monograph Section	Scientific Liaison
Revision	<1> INJECTIONS PF 37(6) Pg. ONLINE	FOREIGN AND PARTICULATE MATTER	Desmond Hunt
New	<17> PRESCRIPTION CONTAINER LABELING PF 37(1) Pg. ONLINE	INTRODUCTION, PRESCRIPTION CONTAINER LABEL STANDARDS TO PROMOTE PATIENT UNDERSTANDING	Donna Bohannon
Revision	<681> REPACKAGING INTO SINGLE-UNIT CONTAINERS AND UNIT-DOSE CONTAINERS FOR NONSTERILE SOLID AND LIQUID DOSAGE FORMS PF 37(6) Pg. ONLINE	Title, Introduction, CUSTOMIZED PATIENT MEDICATION PACKAGES	Desmond Hunt
Revision	<761> NUCLEAR MAGNETIC RESONANCE SPECTROSCOPY PF 37(6) Pg. ONLINE	Introduction, INTRODUCTION, QUALIFICATION OF NMR INSTRUMENTS, QUALITATIVE AND QUANTITATIVE NMR ANALYSIS, VALIDATION AND VERIFICATION OF NMR ANALYTICAL PROCEDURES, GLOSSARY	Kahkashan Zaidi
Revision	<788> PARTICULATE MATTER IN INJECTIONS PF 37(6) Pg. ONLINE	METHOD 1 LIGHT OBSCURATION PARTICLE COUNT TEST	Desmond Hunt
Revision	<921> WATER DETERMINATION PF 38(1) Pg. ONLINE	METHOD I (TITRIMETRIC)	Antonio Hernandez-Cardoso
Revision	<1051> CLEANING GLASS APPARATUS PF 37(6) Pg. ONLINE	APPENDIX	Antonio Hernandez-Cardoso
Revision	<1136> PACKAGING -- UNIT OF USE PF 37(6) Pg. ONLINE	INTRODUCTION, TYPES OF CONTAINERS FOR UNIT-OF-USE, PACKAGING FABRICATION MATERIALS, PACKAGING CLOSURE TYPES, LABELING, REPACKAGING AND REPROCESSING, INFORMATION FROM MANUFACTURERS, RESPONSIBILITY OF THE DISPENSER, QUALITY CONTROL OF PACKAGING SYSTEM, SCOPE, SINGLE-UNIT CONTAINER, PACKAGING MATERIALS, REPACKAGING A SINGLE SOLID ORAL DRUG PRODUCT INTO A UNIT-DOSE CONTAINER, PERFORMANCE, BEYOND-USE-DATE, MINIMUM REQUIREMENTS, REPACKAGING NONSTERILE SOLID AND LIQUID DOSAGE FORMS INTO SINGLE-UNIT CONTAINERS AND UNIT-DOSE CONTAINERS, CUSTOMIZED PATIENT MEDICATION PACKAGES	Desmond Hunt
Revision	<1146> PACKAGING PRACTICE--REPACKAGING A SINGLE SOLID ORAL DRUG PRODUCT INTO A UNIT-DOSE CONTAINER PF 37(6) Pg. ONLINE	Title, INTRODUCTION, NOMENCLATURE AND DEFINITIONS, MATERIALS, PROCESS, PERFORMANCE, BEYOND-USE DATE, MINIMUM REQUIREMENTS	Desmond Hunt
New	<1197> GOOD DISTRIBUTIONS	SECTION 1. INTRODUCTION AND SCOPE, SECTION 2: QUALITY, ORGANIZATION, AND DOCUMENTATION,	Catherine Sheehan

	PRACTICES FOR BULK PHARMACEUTICAL EXCIPIENTS PF 37(6) Pg. ONLINE	SECTION 3: PREMISES, STORAGE, REPACKAGING, AND STABILITY, SECTION 4: RETURNED GOODS, DISPATCH, TRANSPORT, IMPORTATION, ADULTERATION, AND TRACEABILITY, SECTION 5: EXCIPIENTS USED IN PHARMACY COMPOUNDING, APPENDIX: DEFINITIONS AND ACRONYMS	
Revision	<1761> APPLICATIONS OF NUCLEAR MAGNETIC RESONANCE SPECTROSCOPY PF 37(6) Pg. ONLINE	PRINCIPLES OF NMR, NMR SPECTROMETERS, RELAXATION, TIP ANGLE, RELAXATION DELAY, RESOLUTION, POSTACQUISITION DATA PROCESSING, GENERAL PROCEDURE FOR STRUCTURE IDENTIFICATION, QUANTITATIVE APPLICATIONS, SOLID-STATE NMR, LOW-FIELD NMR	Kahkashan Zaidi
Revision	<2040> DISINTEGRATION AND DISSOLUTION OF DIETARY SUPPLEMENTS PF 37(6) Pg. ONLINE	INTRODUCTION, DISINTEGRATION, DISSOLUTION	Natalia Davydova
Revision	ABACAVIR TABLETS PF 37(6) Pg. ONLINE	IMPURITIES/Organic Impurities	Behnam Davani
Revision	ADENOSINE PF 38(1) Pg. ONLINE	IMPURITIES/Limit of Ammonia, IMPURITIES/Limit of Chloride, IMPURITIES/Limit of Sulfate, SPECIFIC TESTS/Acidity or Alkalinity	Heather Joyce
Revision	ADENOSINE INJECTION PF 38(1) Pg. ONLINE	ASSAY/Procedure, IMPURITIES/Organic Impurities	Heather Joyce
Revision	ALFUZOSIN HYDROCHLORIDE EXTENDED-RELEASE TABLETS PF 38(1) Pg. ONLINE	IDENTIFICATION/A. Infrared Absorption <197>, ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Alfuzosin System Suitability Mixture A RS Impurity A: N-{3-[(4-Amino-6,7-dimethoxyquinazolin-2-yl)(methyl)amino]propyl}furan-2-carboxamide.C19H23N5O4385.42 Impurity D: N-(4-Amino-6,7-dimethoxyquinazolin-2-yl)-N-methylpropane-1,3-diamine.C14H21N5O2291.35 Impurity E: N-[3-[(4-Amino-6,7-dimethoxyquinazolin-2-yl)(methyl)amino]propyl]formamide.C15H21N5O3319.36, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities/Procedure, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Alfuzosin Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Alfuzosin System Suitability Mixture RS—Alfuzosin hydrochloride containing approximately 0.4% of each of the following impurities: Impurity A: [N-{3-[(4-amino-6,7-dimethoxyquinazolin-2-yl)(methyl)amino]propyl}furan-2-carboxamide](C19H23N5O4385.42) Impurity D: [N-(4-amino-6,7-dimethoxyquinazolin-2-yl)-N-methylpropane-1,3-diamine](C14H21N5O2291.35)	Domenick Vicchio
Revision	AMMONIUM ALUM PF 37(6) Pg. ONLINE	IDENTIFICATION/C. Identification Tests—General, Sulfate <191>, ASSAY/Procedure	Feiwen Mao

New	AMIODARONE HYDROCHLORIDE ORAL SUSPENSION PF 37(1) 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 Amiodarone Hydrochloride RS	Rick Schnatz
Revision	AMITRIPTYLINE HYDROCHLORIDE PF 38(1) Pg. ONLINE	IMPURITIES/Organic Impurities, SPECIFIC TESTS/Melting Range or Temperature <741>, Assay	Heather Joyce
Revision	AMITRIPTYLINE HYDROCHLORIDE INJECTION PF 38(1) Pg. ONLINE	IDENTIFICATION/C. Identification—Organic Nitrogenous Bases <181>	Heather Joyce
New	AMLODIPINE ORAL SUSPENSION PF 37(1) 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 Amlodipine Besylate RS	Rick Schnatz
Revision	AMODIAQUINE HYDROCHLORIDE TABLETS PF 37(6) Pg. ONLINE	ASSAY/Procedure	Behnam Davani
Revision	BENZALDEHYDE PF 38(1) Pg. ONLINE	Chemical Info/Benzaldehyde, Chemical Info/ Benzoic aldehyde;, Chemical Info/ Phenyl formaldehyde, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197F>, ASSAY/Procedure, IMPURITIES/Limit of Ethylbenzene, Cyclohexylmethanol, Benzyl Alcohol, and Benzoic Acid, SPECIFIC TESTS/Specific Gravity <841>, SPECIFIC TESTS/Refractive Index <831>, SPECIFIC TESTS/Water Determination, Method I <921>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>	Hong Wang
New	BETA CYCLODEXTRIN PF 38(1) Pg. ONLINE	Reagent Specification, β-Cyclodextrin	Hariram Ramanathan
Revision	BETAXOLOL HYDROCHLORIDE PF 38(1) Pg. ONLINE	Chemical Info/2-Propanol, 1-4-2-(cyclopropylmethoxy)ethylphenoxy-3-(1-methylethyl)amino-, hydrochloride, (±)-. 2-Propanol, 1-[4-[2-(cyclopropylmethoxy)ethyl]phenoxy]-3-[(1-methylethyl)amino]-, hydrochloride, (±)-;-, DEFINITION/Introduction, ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Melting Range or Temperature, Class I <741>, ADDITIONAL REQUIREMENTS/Packaging and Storage	Feiwen Mao
New	BLACK PEPPER PF 37(6) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B. Thin-Layer Chromatography, IDENTIFICATION/C. HPLC, COMPOSITION/Content of Piperine, CONTAMINANTS/Heavy Metals, Method III <231>, CONTAMINANTS/Articles of Botanical Origin, General Method for Pesticide Residues Analysis <561>, CONTAMINANTS/Microbial Enumeration Tests <2021>, CONTAMINANTS/Absence of Specified Microorganisms	Maged Sharaf

		<2022>, SPECIFIC TESTS/Botanic Characteristics, SPECIFIC TESTS/Articles of Botanical Origin, Foreign Organic Matters <561>, SPECIFIC TESTS/Articles of Botanical Origin, Alcohol-Soluble Extractives, Method I <561>, SPECIFIC TESTS/Articles of Botanical Origin, Water-Soluble Extractives, Method I <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 Piperine RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Powdered Pepper Extract RS	
New	POWDERED BLACK PEPPER PF 37(6) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B. Thin-Layer Chromatography, IDENTIFICATION/C. HPLC, COMPOSITION/Content of Piperine, CONTAMINANTS/Heavy Metals, Method III <231>, CONTAMINANTS/Articles of Botanical Origin, General Method for Pesticide Residues Analysis <561>, CONTAMINANTS/Microbial Enumeration Tests <2021>, CONTAMINANTS/Absence of Specified Microorganisms <2022>, SPECIFIC TESTS/Botanic Characteristics, SPECIFIC TESTS/Articles of Botanical Origin, Alcohol-Soluble Extractives, Method I <561>, SPECIFIC TESTS/Articles of Botanical Origin, Water-Soluble Extractives, Method I <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 Piperine RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Powdered Pepper Extract RS	Maged Sharaf
New	POWDERED BLACK PEPPER EXTRACT PF 37(6) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/A. Thin-Layer Chromatography, IDENTIFICATION/B. HPLC, COMPOSITION/Content of Piperine, CONTAMINANTS/Heavy Metals, Method III <231>, 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/Loss on Drying <731>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Piperine RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Powdered Pepper Extract RS	Maged Sharaf
Revision	BUPROPION HYDROCHLORIDE PF 38(1) Pg. ONLINE	ASSAY/Procedure, IMPURITIES/Limit of m-Chlorobenzoic Acid, IMPURITIES/Procedure 2, ADDITIONAL REQUIREMENTS/Packaging and Storage	Heather Joyce
Revision	CALCIUM PANTOTHENATE TABLETS PF 38(1) Pg. ONLINE	ASSAY/Calcium Pantothenate Assay <91>, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Calcium Pantothenate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Racemic Panthenol RS	Natalia Davydova
New	CAPRYLIC ACID PF 38(1)	Chemical Info/Chemical Structure, Chemical	Hong Wang

	Pg. ONLINE	Info/C8H16O2, Chemical Info/144.21, Chemical Info/Octanoic acid;, Chemical Info/1-Heptanecarboxylic acid, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197F>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Heavy Metals <231>, IMPURITIES/Limit of Related Linear and Branched Alkyl Carboxylic Acids, Related Esters, Cyclic Esters and Ketone, SPECIFIC TESTS/Bacterial Endotoxins Test <85>, SPECIFIC TESTS/Fats and Fixed Oils, Peroxide Value <401>, SPECIFIC TESTS/Water Determination, Method Ia <921>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Caprylic Acid RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Endotoxin RS	
Revision	CAPRYLOCAPROYL POLYOXYLGLYCERIDES PF 38(1) Pg. ONLINE	IMPURITIES/Limit of Free Ethylene Oxide and Dioxane, SPECIFIC TESTS/Fats and Fixed Oils, Hydroxyl Value <401>, SPECIFIC TESTS/Fats and Fixed Oils, Saponification Value <401>, ADDITIONAL REQUIREMENTS/Labeling	Hong Wang
New	CHLOROQUINE PHOSPHATE ORAL SUSPENSION PF 37(1) 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 Chloroquine Phosphate RS	Rick Schnatz
Revision	CLARITHROMYCIN PF 37(6) Pg. ONLINE	ASSAY/Procedure, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Heavy Metals <231>, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Clarithromycin Identity RS	Ahalya Wise
Revision	CLARITHROMYCIN FOR ORAL SUSPENSION PF 37(6) Pg. ONLINE	ASSAY/Procedure	Ahalya Wise
Revision	CLARITHROMYCIN EXTENDED-RELEASE TABLETS PF 37(6) Pg. ONLINE	ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, SPECIFIC TESTS/Loss on Drying <731>	Ahalya Wise
New	CODEINE PHOSPHATE ORAL SOLUTION PF 37(1) 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 Codeine Phosphate RS	Rick Schnatz
New	DAPSONE ORAL SUSPENSION PF 37(1) 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 Dapsone RS	Rick Schnatz

Revision	DESCRIPTION AND SOLUBILITY PF 35(5) Pg. 1343	Diethyl Sebacate, Benzaldehyde, Caprylic Acid, Clopidogrel Bisulfate, Fexofenadine Hydrochloride, Rosiglitazone Maleate, Tadalafil, Citalopram Hydrobromide, Dantrolene Sodium, Glyceryl Tristearate, Rufinamide	Hong Wang
New	DIDANOSINE DELAYED-RELEASE CAPSULES PF 38(1) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B. Infrared Absorption <197>, ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Microbial Enumeration Tests <61> and Tests for Specified Microorganisms <62>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Didanosine RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Didanosine Related Compound A RS	Behnam Davani
New	DIETHYL SEBACATE PF 35(5) Pg. 1203	Chemical Info/Chemical Structure, Chemical Info/CH ₃ CH ₂ OOC(CH ₂) ₈ COOCH ₂ CH ₃ , Chemical Info/C ₁₄ H ₂₆ O ₄ , Chemical Info/258.35, Chemical Info/Decanedioic acid, 1,10-diethyl ester;, Chemical Info/Diethyl 1,10-decanedioate, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197F>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Inorganic Impurities/Residue on Ignition <281>, IMPURITIES/Inorganic Impurities/Heavy Metals, Method II <231>, SPECIFIC TESTS/Specific Gravity <841>, SPECIFIC TESTS/Refractive Index <831>, SPECIFIC TESTS/Fats and Fixed Oils, Acid Value <401>, SPECIFIC TESTS/Fats and Fixed Oils, Iodine Value <401>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>	Hong Wang
New	DOXYCYCLINE TABLETS PF 37(6) 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 Doxycycline Hyclate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Doxycycline Related Compound A RS	Ahalya Wise
New	ENALAPRIL MALEATE ORAL SUSPENSION PF 37(1) 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	Rick Schnatz
Revision	ESCITALOPRAM OXALATE PF 38(1) Pg. ONLINE	IMPURITIES/Organic Impurities	Heather Joyce
Omission	ESTRADIOL INJECTABLE SUSPENSION PF 37(6) Pg. ONLINE	Entire document	Domenick Vicchio
New	GLYCERYL TRISTEARATE	Chemical Info/Chemical Structure, Chemical	Hong Wang

	PF 37(6) Pg. ONLINE	Info/C57H11006, Chemical Info/891.49, Chemical Info/Octadecanoic acid, 1,1',1''-(1,2,3-propanetriyl) ester;, Chemical Info/ Octadecanoic acid, 1,2,3-propanetriyl ester;, Chemical Info/ Glycerol trioctadecanoate;, Chemical Info/Tristearoylglycerol, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/Fatty Acid Composition, ASSAY/Content of Triglycerides, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Heavy Metals, Method II <231>, IMPURITIES/Alkaline Impurities, IMPURITIES/Limit of Nickel, SPECIFIC TESTS/Melting Range, Class II <741>, SPECIFIC TESTS/Fats and Fixed Oils, Acid Value <401>, SPECIFIC TESTS/Fats and Fixed Oils, Hydroxyl Value <401>, SPECIFIC TESTS/Fats and Fixed Oils, Saponification Value <401>, SPECIFIC TESTS/Fats and Fixed Oils, Peroxide Value <401>, SPECIFIC TESTS/Fats and Fixed Oils, Unsaponifiable Matter <401>, SPECIFIC TESTS/Water Determination, Method Ia <921>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Glyceryl Distearate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methyl Myristate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methyl Oleate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methyl Stearate RS	
New	HYDROCHLORIC ACID INJECTION PF 37(1) Pg. ONLINE	DEFINITION/Introduction, ASSAY/Procedure, SPECIFIC TESTS/pH <791>, SPECIFIC TESTS/Sterility Tests <71>, SPECIFIC TESTS/Bacterial Endotoxin Test <85>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/Beyond-Use Date, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Endotoxin RS	Rick Schnatz
New	IRON, CARBONYL PF 37(6) Pg. ONLINE	Chemical Info/Fe, Chemical Info/55.85, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Acid-Insoluble Substances, IMPURITIES/Elemental Impurities, Procedures <233>, SPECIFIC TESTS/ Particle Size Distribution Estimation By Analytical Sieving, Test Sieves <786>, ADDITIONAL REQUIREMENTS/Packaging and Storage	Huy Dinh
New	ISRADIPINE ORAL SUSPENSION PF 37(1) 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 Isradipine RS	Rick Schnatz
Revision	KETOROLAC TROMETHAMINE TABLETS PF 38(1) Pg. ONLINE	IDENTIFICATION/Procedure, IDENTIFICATION/Introduction, ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ketorolac Related Compound A RS 5-Benzoyl-N-(1,3-dihydroxy-2-(hydroxymethyl)propan-2-yl)-2,3-dihydro-1H-pyrrolizine-1-carboxamide.C19H22N2O5358.39, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ketorolac Related Compound B RS 5-Benzoyl-2,3-dihydro-1H-pyrrolizin-1-ol.C14H13NO2227.26, ADDITIONAL REQUIREMENTS/USP Reference Standards	Clydewyn Anthony

		<11>/USP Ketorolac Related Compound C RS 5-Benzoyl-2,3-dihydro-1H-pyrrolizin-1-one.C14H11NO2225.24, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ketorolac Related Compound D RS 5-Benzoyl-2,3-dihydro-1H-pyrrolizine.C14H13NO211.26	
Revision	LEVOCARNITINE TABLETS PF 37(6) Pg. ONLINE	ASSAY/Procedure	Natalia Davydova
Revision	LEVODOPA PF 38(1) Pg. ONLINE	ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP 3-Methoxytyrosine RSUSP Levodopa Related Compound B RS 3-Methoxytyrosine.C10H13NO4211.22	Haram Ramanathan
Revision	LEVODOPA CAPSULES PF 38(1) Pg. ONLINE	IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP 3-Methoxytyrosine RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Levodopa Related Compound B RS 3-Methoxytyrosine.C10H13NO4211.22	Haram Ramanathan
Revision	LEVODOPA TABLETS PF 38(1) Pg. ONLINE	ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP 3-Methoxytyrosine RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Levodopa Related Compound B RS 3-Methoxytyrosine.C10H13NO4211.22	Haram Ramanathan
Revision	LEVOTHYROXINE SODIUM PF 38(1) Pg. ONLINE	IDENTIFICATION/A. Infrared Absorption <197>: Note— Methods described in Infrared Absorption <197K> or <197A> may be used., IDENTIFICATION/B., IDENTIFICATION/C., IDENTIFICATION/D., ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Levothyroxine Sodium RS	Elena Gonikberg
New	LISINOPRIL ORAL SUSPENSION PF 37(1) 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 Lisinopril RS	Rick Schnatz
Revision	LITHIUM ORAL SOLUTION PF 38(1) Pg. ONLINE	ASSAY/Procedure, PERFORMANCE TESTS/Uniformity of Dosage Units <905>	Haram Ramanathan
Revision	LOPINAVIR PF 37(6) Pg. ONLINE	IDENTIFICATION/A. Infrared Absorption <197S><197A>, IMPURITIES/Organic Impurities: Procedure 2	Behnam Davani
New	MELATONIN TABLETS PF 37(6) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/A., STRENGTH/Procedure, PERFORMANCE TESTS/Disintegration and Dissolution of Dietary Supplements <2040>, PERFORMANCE TESTS/Weight Variation of Dietary Supplements <2091>, IMPURITIES/Related Compounds, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Melatonin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Melatonin Related Compound A RS	Natalia Davydova
New	MESO-ZEAXANTHIN PF	Title, Chemical Info/Chemical Structure, Chemical	Huy Dinh

	36(6) Pg. 1617	Info/C40H56O2, Chemical Info/568.88, Chemical Info/β, β-carotene-3,3′-diol (3R,3′S)-, Chemical Info/(3R,3′S meso)-Zeaxanthin, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B., IDENTIFICATION/C., COMPOSITION/Content of Total Carotenoids, COMPOSITION/Content of Zeaxanthin, COMPOSITION/Lutein and Other Related Compounds, COMPOSITION/Stereoisomeric Composition, IMPURITIES/Inorganic Impurities/Lead <251>, IMPURITIES/Inorganic Impurities/Residue on Ignition <281>, SPECIFIC TESTS/Water Determination, Method I <921>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP meso-Zeaxanthin RS	
New	MESO-ZEAXANTHIN PREPARATION PF 36(6) Pg. 1619	Title, DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B., IDENTIFICATION/C., COMPOSITION/Content of Total Carotenoids, COMPOSITION/Content of Zeaxanthin, COMPOSITION/Lutein and Other Related Compounds, COMPOSITION/Stereoisomeric Composition, IMPURITIES/Inorganic Impurities/Residue on Ignition <281>, IMPURITIES/Inorganic Impurities/Heavy Metals, Method II <231>, SPECIFIC TESTS/Water Determination, Method I <921>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP meso-Zeaxanthin RS	Huy Dinh
New	5-METHOXY-1H-BENZIMIDAZOLE-2-THIOL PF 38(1) Pg. ONLINE	Reagent Specification, 5-Methoxy-1H-benzimidazole-2-thiol	Elena Gonikberg
Revision	MINOXIDIL TABLETS PF 38(1) Pg. ONLINE	IMPURITIES/Organic Impurities	Sujatha Ramakrishna
Revision	MIRTAZAPINE PF 37(6) Pg. ONLINE	IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Mirtazapine Resolution Mixture RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/ Impurity A: 1,2,3,4,10,14b-Hexahydro-2-methylpyrazino[2,1-a]pyrido[2,3-c][2]benzazepine 2-oxide. Impurity B: (2-(4-Methyl-2-phenylpiperazin-1-yl)pyridin-3-yl)methanol. Impurity C: (2-Methyl-3,4,10,14b-tetrahydrobenzo[c]pyrazino[1,2-a]pyrido[3,2-f]azepin-1(2H)-one. Impurity D: 1,2,3,4,10,14b-Hexahydropyrazino[2,1-a]pyrido[2,3-c][2]benzazepine. Impurity E: 4-Methyl-1-(3-methylpyridin-2-yl)-2-phenylpiperazine. Impurity F: 2-Methyl-1,2,3,4-tetrahydrobenzo[c]pyrazino[1,2-a]pyrido[3,2-f]azepin-10(14bH)-one.	Haram Ramanathan
Revision	MYCOPHENOLATE MOFETIL PF 37(6) Pg. ONLINE	Chemical Info/4-Hexenoic acid, 6-(1,3-dihydro-4-hydroxy-6-methoxy-7-methyl-3-oxo-5-isobenzofuranyl)-4-methyl-, 2-(4-morpholinyl)ethyl ester, (E)-, Chemical Info/CAS, ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Mycophenolate Mofetil Related Compound B RS	Feiwen Mao

Revision	MYRISTIC ACID PF 38(1) Pg. ONLINE	Chemical Info/Chemical Structure, 1-Tetradecanoic acid; 1-Tridecanecarboxylic acid, IDENTIFICATION/A. Infrared Absorption <197F>, IDENTIFICATION/B., IMPURITIES/Limit of Mineral Acids, SPECIFIC TESTS/Fats and Fixed Oils, Saponification Value <401>, SPECIFIC TESTS/Fats and Fixed Oils, Peroxide Value <401>	Hong Wang
Revision	OLANZAPINE PF 38(1) Pg. ONLINE	ASSAY/Procedure, IMPURITIES/Organic Impurities	Hariram Ramanathan
Revision	OLANZAPINE TABLETS PF 37(6) Pg. ONLINE	IDENTIFICATION/A. Infrared Absorption <197S>, IMPURITIES/Organic Impurities	Hariram Ramanathan
Revision	OLEIC ACID PF 38(1) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/B., ASSAY/Procedure, SPECIFIC TESTS/Specific Gravity <841>, SPECIFIC TESTS/Content of Fatty Acids, SPECIFIC TESTS/Fats and Fixed Oils, Iodine Value <401>, SPECIFIC TESTS/Fats and Fixed Oils, Peroxide Value <401>, SPECIFIC TESTS/Water Determination, Method I <921>, SPECIFIC TESTS/Neutral Fat or Mineral Oil, ADDITIONAL REQUIREMENTS/Packaging and Storage	Hong Wang
New	OMEPRAZOLE ORAL SUSPENSION PF 37(1) 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 Omeprazole RS	Rick Schnatz
Revision	PARICALCITOL PF 38(1) Pg. ONLINE	ASSAY/Procedure, IMPURITIES/Organic Impurities	Elena Gonikberg
Revision	PENTAFLUOROPROPIONIC ACID PF 38(1) Pg. ONLINE	Reagent Specification, Pentafluoropropanoic Acid	Ahalya Wise
New	PENTOXIFYLLINE ORAL SUSPENSION PF 37(1) 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 Pentoxifylline RS	Rick Schnatz
New	PHENOBARBITAL ORAL SUSPENSION PF 37(1) 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 Phenobarbital RS	Rick Schnatz
Revision	POTASSIUM IODIDE ORAL SOLUTION PF 37(6) Pg. ONLINE	ASSAY/Procedure	Leonel Santos
Revision	POTASSIUM IODIDE TABLETS PF 37(6) Pg. ONLINE	ASSAY/Procedure	Leonel Santos
Revision	POTASSIUM IODIDE	ASSAY/Procedure	Leonel

	DELAYED-RELEASE TABLETS PF 37(6) Pg. ONLINE		Santos
New	PROPYLTHIOURACIL ORAL SUSPENSION PF 37(1) 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 Propylthiouracil RS	Rick Schnatz
New	PYRAZINAMIDE ORAL SUSPENSION PF 37(1) 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 Pyrazinamide RS	Rick Schnatz
New	PYRIMETHAMINE ORAL SUSPENSION PF 37(1) 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 Phenacetin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Pyrimethamine RS	Rick Schnatz
Revision	RALOXIFENE HYDROCHLORIDE PF 37(6) Pg. ONLINE	ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Raloxifene Related Compound C RS 1-(2-{4-[6-Hydroxy-2-(4-hydroxyphenyl)benzothiophene-3-carbonyl]phenoxy}ethyl)piperidine 1-oxide.C28H27NO5S489.58	Mary Waddell
Revision	RALOXIFENE HYDROCHLORIDE TABLETS PF 37(6) Pg. ONLINE	ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Raloxifene Related Compound C RS 1-(2-{4-[6-Hydroxy-2-(4-hydroxyphenyl)benzothiophene-3-carbonyl]phenoxy}ethyl)piperidine 1-oxide.C28H27NO5S489.58	Mary Waddell
New	RIFABUTIN ORAL SUSPENSION PF 37(1) 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 Rifabutin RS	Rick Schnatz
New	RUFINAMIDE PF 37(6) Pg. ONLINE	Chemical Info/Chemical Structure, Chemical Info/C10H8F2N4O, Chemical Info/238.19, Chemical Info/1H-1,2,3-Triazole-4-carboxamide, 1-[(2,6-difluorophenyl)methyl]-, Chemical Info/1-(2,6-Difluorobenzyl)-1H-1,2,3-triazole-4-carboxamide, 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, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL	Hariram Ramanathan

		REQUIREMENTS/USP Reference Standards <11>/USP Rufinamide RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Rufinamide Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Rufinamide Related Compound B RS	
New	RUFINAMIDE TABLETS PF 37(6) 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 Rufinamide RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Rufinamide Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Rufinamide Related Compound B RS	Haram Ramanathan
New	SERTRALINE HYDROCHLORIDE ORAL SOLUTION PF 38(1) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/A., ASSAY/Procedure, PERFORMANCE TESTS/Deliverable Volume <698>, 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 Sertraline Hydrochloride RS	Haram Ramanathan
New	SILDENAFIL CITRATE ORAL SUSPENSION PF 37(1) Pg. ONLINE	DEFINITION/Introduction, ASSAY/Procedure, SPECIFIC TESTS/pH <791>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/Beyond-Use Date	Rick Schnatz
New	SODIUM PHENYLBUTYRATE ORAL SUSPENSION PF 37(1) Pg. ONLINE	DEFINITION/Introduction, ASSAY/Procedure, SPECIFIC TESTS/pH <791>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/Beyond-Use Date	Rick Schnatz
New	SOTALOL HYDROCHLORIDE ORAL SUSPENSION PF 37(1) 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 Sotalol Hydrochloride RS	Rick Schnatz
New	SPIRONOLACTONE ORAL SUSPENSION PF 37(1) 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	Rick Schnatz
New	SPIRONOLACTONE AND HYDROCHLOROTHIAZIDE ORAL SUSPENSION PF 37(1) 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	Rick Schnatz

		Hydrochlorothiazide RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Spironolactone RS	
New	TACROLIMUS ORAL SUSPENSION PF 37(1) 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 Tacrolimus RS	Rick Schnatz
New	TADALAFIL PF 38(1) Pg. ONLINE	Chemical Info/Chemical Structure, Chemical Info/C22H19N3O4, Chemical Info/389.40, Chemical Info/Pyrazino[1′;2′;:1,6]pyrido[3,4-b]indole-1,4-dione, 6-(1,3-benzodioxol-5-yl)-2,3,6,7,12,12a-hexahydro-2-methyl-, (6R-12aR)-; Chemical Info/(6R,12aR)-2,3,6,7,12,12a-Hexahydro-2-methyl-6-[3,4-(methylenedioxy)phenyl]pyrazino[1′;2′;:1,6]pyrido[3,4-b]indole-1,4-dione, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Organic Impurities, IMPURITIES/Enantiomeric and Diastereomeric Purity, SPECIFIC TESTS/Loss on Drying <731>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Tadalafil RS	Mary Waddell
New	TADALAFIL TABLETS PF 38(1) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197>, 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 Tadalafil RS	Mary Waddell
New	TRAMADOL HYDROCHLORIDE ORAL SUSPENSION PF 37(1) 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 Tramadol Hydrochloride RS	Rick Schnatz
New	TRAMADOL HYDROCHLORIDE AND ACETAMINOPHEN ORAL SUSPENSION PF 37(1) Pg. ONLINE	DEFINITION/Introduction, ASSAY/Procedure for Tramadol Hydrochloride, ASSAY/Procedure for Acetaminophen, SPECIFIC TESTS/pH <791>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/Beyond-Use Date, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Acetaminophen RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Tramadol Hydrochloride RS	Rick Schnatz
New	TROSPIUM CHLORIDE TABLETS PF 38(1) 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,	Elena Gonikberg

		ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Trospium Chloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Trospium Chloride Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Trospium Chloride Related Compound B RS	
New	URSODIOL ORAL SUSPENSION PF 37(1) 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 Ursodiol RS	Rick Schnatz
Revision	USP AND NF EXCIPIENTS, LISTED BY CATEGORY PF 35(5) Pg. 1197	{Flavors and Perfumes} Diethyl Sebacate, {Emulsifying and/or Solubilizing Agent} Caprylic Acid, {Emulsifying and/or Solubilizing Agent} Glycerol Tristearate, {Tablet and/or Capsule Lubricant} Glycerol Tristearate	Hong Wang
New	VALACYCLOVIR ORAL SUSPENSION PF 37(1) 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 Valacyclovir Hydrochloride RS	Rick Schnatz
Revision	VITAMIN E CAPSULES PF 38(1) Pg. ONLINE	ASSAY/Alpha Tocopherol, ASSAY/Alpha Tocopheryl Acetate, ASSAY/Alpha Tocopheryl Acid Succinate, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Alpha Tocopherol RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Alpha Tocopheryl Acetate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/Alpha Tocopheryl Acid Succinate RS	Natalia Davydova
Revision	VITAMIN E PREPARATION PF 38(1) Pg. ONLINE	ASSAY/Alpha Tocopherol, ASSAY/Alpha Tocopheryl Acetate, ASSAY/Alpha Tocopheryl Acid Succinate, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Alpha Tocopherol RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Alpha Tocopheryl Acetate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/Alpha Tocopheryl Acid Succinate RS	Huy Dinh
New	OIL-SOLUBLE VITAMINS ORAL SOLUTION PF 37(6) Pg. ONLINE	DEFINITION/Introduction, STRENGTH/Vitamin A, STRENGTH/Vitamin D, STRENGTH/Vitamin E, STRENGTH/Phytonadione (Vitamin K1), STRENGTH/Beta Carotene, OTHER COMPONENTS/Alcohol Determination, Method I <611> (if present), CONTAMINANTS/Microbial Enumeration Tests <2021>, CONTAMINANTS/Absence of Specified Microorganisms <2022>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling1 1  USP Units of activity for vitamins, where such exist or formerly existed, are equivalent to the corresponding international units, where such formerly existed. The USP Unit for Vitamin E has been discontinued. International units (IU) for vitamins also have been discontinued; however, the use of IU on the labels of vitamin products continues. Where articles are labeled in terms of Units in addition to the required labeling, the relationship of the USP Units or IU to mass	Natalia Davydova

is as follows. One USP Vitamin A Unit = 0.3 µg of all-trans-retinol (vitamin A alcohol) or 0.344 µg of all-trans-retinyl acetate (vitamin A acetate) or 0.55 µg of all-trans-retinyl palmitate (vitamin A palmitate), and 1 µg of retinol (3.3 USP Vitamin A Units) = 1 retinol equivalent (RE); 1 IU of beta carotene = 0.6 µg of all-trans-beta carotene; 1 USP Vitamin D Unit = 0.025 µg of ergocalciferol or cholecalciferol; and 1 mg of dl-alpha tocopherol = 1.1 former U, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Alpha Tocopherol RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Alpha Tocopheryl Acetate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Alpha Tocopheryl Acid Succinate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Beta Carotene RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Beta Carotene System Suitability RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Cholecalciferol RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ergocalciferol RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Phytonadione RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Retinyl Acetate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Retinyl Palmitate RS

DEFINITION/Introduction, STRENGTH/Vitamin A, STRENGTH/Vitamin D, STRENGTH/Vitamin E, STRENGTH/Phytonadione (Vitamin K1), STRENGTH/Beta Carotene, STRENGTH/Calcium, Method 1, STRENGTH/Chromium, Method 1, STRENGTH/Copper, Method 1, STRENGTH/Fluoride, Method 1, STRENGTH/Fluoride, Method 2, STRENGTH/Iodide, Method 1, STRENGTH/Iodide, Method 2, STRENGTH/Iron, Method 1, STRENGTH/Magnesium, Method 1, STRENGTH/Manganese, Method 1, STRENGTH/Molybdenum, Method 1, STRENGTH/Molybdenum, Method 2, STRENGTH/Phosphorus, Method 1, STRENGTH/Potassium, STRENGTH/Selenium, Method 1, STRENGTH/Selenium, Method 2, STRENGTH/Zinc, Method 1, STRENGTH/Boron, Nickel, Tin, and Vanadium, Method 1; Calcium, Chromium, Copper, Iron, Magnesium, Manganese, Phosphorus, and Zinc, Method 2; Molybdenum and Selenium, Method 3, 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: 1  USP Units of activity for vitamins, where such exist or formerly existed, are equivalent to the corresponding international units, where such formerly existed. The USP Unit for Vitamin E has been discontinued. International units (IU) for vitamins also have been discontinued; however, the use of IU on the labels of vitamin products continues. Where articles are labeled in terms of Units in addition to the required labeling, the relationship of the USP Units or IU to mass is as follows. One USP Vitamin A Unit = 0.3 µg of all-trans-retinol (vitamin A alcohol) or 0.344 µg of all-trans-retinyl acetate (vitamin A acetate) or 0.55

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µg of all-trans-retinyl palmitate (vitamin A palmitate), and 1 µg of retinol (3.3 USP Vitamin A Units) = 1 retinol equivalent (RE); 1 IU of beta carotene = 0.6 µg of all-trans-beta carotene; 1 USP Vitamin D Unit = 0.025 µg of ergocalciferol or cholecalciferol; and 1 mg of dl-alpha tocopherol = 1.1 former , ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Alpha Tocopherol RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Alpha Tocopheryl Acetate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Alpha Tocopheryl Acid Succinate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Beta Carotene RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Beta Carotene System Suitability RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Cholecalciferol RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ergocalciferol RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Phytonadione RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Retinyl Palmitate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Sodium Fluoride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Vitamin A RS

DEFINITION/Introduction, STRENGTH/Vitamin A, STRENGTH/Vitamin D, STRENGTH/Vitamin E, STRENGTH/Phytonadione (Vitamin K1), STRENGTH/Beta Carotene, STRENGTH/Chromium, STRENGTH/Fluoride, STRENGTH/Iodide, Method 1, STRENGTH/Iodide, Method 2, STRENGTH/Iron, STRENGTH/Magnesium, STRENGTH/Manganese, STRENGTH/Molybdenum, STRENGTH/Zinc, OTHER COMPONENTS/Alcohol Determination, Method I <611> (if present), CONTAMINANTS/Microbial Enumeration Tests <2021>, CONTAMINANTS/ Absence of Specified Microorganisms <2022>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling1: 1  USP Units of activity for vitamins, where such exist or formerly existed, are equivalent to the corresponding international units, where such formerly existed. The USP Unit for Vitamin E has been discontinued. International units (IU) for vitamins also have been discontinued. However, the use of IU on the labels of vitamin products continues. Where articles are labeled in terms of Units in addition to the required labeling, the relationship of the USP Units or IU to mass is as follows. One USP Vitamin A Unit = 0.3 µg of all-trans-retinol (vitamin A alcohol) or 0.344 µg of all-trans-retinyl acetate (vitamin A acetate) or 0.55 µg of all-trans-retinyl palmitate (vitamin A palmitate), and 1 µg of retinol (3.3 USP Vitamin A Units) = 1 retinol equivalent (RE); 1 IU of beta carotene = 0.6 µg of all-trans-beta carotene; 1 USP Vitamin D Unit = 0.025 µg of ergocalciferol or cholecalciferol; and 1 mg of dl-alpha tocopherol = 1.1 former , ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Alpha Tocopherol RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Alpha Tocopheryl Acetate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Alpha Tocopheryl Acid Succinate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP

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Beta Carotene RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Beta Carotene System Suitability RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Cholecalciferol RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ergocalciferol RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Phytonadione RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Retinyl Acetate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Retinyl Palmitate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Sodium Fluoride RS

DEFINITION/Introduction, STRENGTH/Vitamin A, STRENGTH/Vitamin D, STRENGTH/Vitamin E, STRENGTH/Phytonadione (Vitamin K1), STRENGTH/Beta Carotene, STRENGTH/Calcium, Method 1, STRENGTH/Chromium, Method 1, STRENGTH/Copper, Method 1, STRENGTH/Fluoride, Method 1, STRENGTH/Fluoride, Method 2, STRENGTH/Iodide, Method 1, STRENGTH/Iodide, Method 2, STRENGTH/Iron, Method 1, STRENGTH/Magnesium, Method 1, STRENGTH/Manganese, Method 1, STRENGTH/Molybdenum, Method 1, STRENGTH/Molybdenum, Method 2, STRENGTH/Phosphorus, Method 1, STRENGTH/Potassium, STRENGTH/Selenium, Method 1, STRENGTH/Selenium, Method 2, STRENGTH/Zinc, Method 1, STRENGTH/Boron, Nickel, Tin, and Vanadium, Method 1; Calcium, Chromium, Copper, Iron, Magnesium, Manganese, Phosphorus, and Zinc, Method 2; Molybdenum and Selenium, Method 3, PERFORMANCE TESTS/Disintegration and Dissolution of Dietary Supplements <2040>, Dissolution, PERFORMANCE TESTS/Weight Variation of Dietary Supplements <2091>, CONTAMINANTS/Microbial Enumeration Tests <2021>, CONTAMINANTS/Absence of Specified Microorganisms <2022>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling: 1
1  USP Units of activity for vitamins, where such exist or formerly existed, are equivalent to the corresponding international units, where such formerly existed. The USP Unit for Vitamin E has been discontinued. International units (IU) for vitamins also have been discontinued; however, the use of IU on the labels of vitamin products continues. Where articles are labeled in terms of Units in addition to the required labeling, the relationship of the USP Units or IU to mass is as follows. One USP Vitamin A Unit = 0.3 µg of all-trans-retinol (vitamin A alcohol) or 0.344 µg of all-trans-retinyl acetate (vitamin A acetate) or 0.55 µg of all-trans-retinyl palmitate (vitamin A palmitate), and 1 µg of retinol (3.3 USP Vitamin A Units) = 1 retinol equivalent (RE); 1 IU of beta carotene = 0.6 µg of all-trans-beta carotene; 1 USP Vitamin D Unit = 0.025 µg of ergocalciferol or cholecalciferol; and 1 mg of dl-alpha tocopherol = 1.1 former , ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Alpha Tocopherol RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Alpha Tocopheryl Acetate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Alpha Tocopheryl Acid Succinate RS, ADDITIONAL

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REQUIREMENTS/USP Reference Standards <11>/USP
Cholecalciferol RS, ADDITIONAL REQUIREMENTS/USP
Reference Standards <11>/USP Ergocalciferol RS,
ADDITIONAL REQUIREMENTS/USP Reference Standards
<11>/USP Phytonadione RS, ADDITIONAL
REQUIREMENTS/USP Reference Standards <11>/USP
Retinyl Acetate RS, ADDITIONAL REQUIREMENTS/USP
Reference Standards <11>/USP Retinyl Palmitate RS,
ADDITIONAL REQUIREMENTS/USP Reference Standards
<11>/USP Sodium Fluoride RS