Monograph Title	Monograph Section	Scientific Liaison
<81> ANTIBIOTICS--MICROBIAL ASSAYS PF 36(5) Pg. 1239	Introduction, APPARATUS, MEDIA AND DILUENTS, UNITS AND REFERENCE STANDARDS, PREPARATION OF THE STANDARD, PREPARATION OF THE SAMPLE, ORGANISMS AND INOCULUM, PROCEDURE, CALCULATION, INTRODUCTION AND GENERAL INFORMATION, CYLINDER-PLATE METHOD, TURBIDIMETRIC METHOD, MEDIA AND SOLUTIONS, CALCULATIONS, APPENDIX 1. FORMULAS FOR MANUAL CALCULATIONS OF REGRESSION AND SAMPLE CONCENTRATION, APPENDIX 2. PROCEDURE FOR CHECKING FOR OUTLIERS; REJECTION OF OUTLYING OR ABERRANT MEASUREMENTS	Ahalya Wise
<111> DESIGN AND ANALYSIS OF BIOLOGICAL ASSAYS PF 36(4) Pg. 952	STEPS PRECEDING THE CALCULATION OF POTENCY, EXPERIMENTAL ERROR AND TESTS OF ASSAY VALIDITY	Tina Morris
<232> ELEMENTAL IMPURITIES--LIMITS PF 36(1) Pg. 197	Title, INTRODUCTION, LIMITS OF ELEMENTAL IMPURITIES, OPTIONS FOR DESCRIBING LIMITS OF ELEMENTAL IMPURITIES, ANALYTICAL PROCEDURES	Kahkashan Zaidi
<233> ELEMENTAL IMPURITIES - PROCEDURES PF 36(1) Pg. 201	Title, INTRODUCTION, ALTERNATIVE PROCEDURE VALIDATION REQUIREMENTS, VALIDATION OF LIMIT PROCEDURES, VALIDATION OF QUANTITATIVE PROCEDURES, REFEREE PROCEDURES 1 AND 2, CALCULATIONS AND REPORTING	Kahkashan Zaidi
<761> NUCLEAR MAGNETIC RESONANCE PF 36(2) Pg. 462	Title, Introduction, APPARATUS, THE SPECTRUM, GENERAL METHOD, INTRODUCTION, QUALIFICATION OF NMR INSTRUMENTS, QUALITATIVE AND QUANTITATIVE NMR ANALYSIS, PROCEDURE VALIDATION, GLOSSARY	Kahkashan Zaidi
<797> PHARMACEUTICAL COMPOUNDING--STERILE PREPARATIONS PF 36(3) Pg. 714	DEFINITIONS, IMMEDIATE-USE CSPS, HAZARDOUS DRUGS AS CSPS, RADIOPHARMACEUTICALS AS CSPS, ENVIRONMENTAL QUALITY AND CONTROL	Shawn Becker
<1032> DEVELOPMENT AND DESIGN OF BIOASSAYS PF 36(4) Pg. 956	Title, 1. INTRODUCTION, 2. BIOASSAY FITNESS FOR USE, 3. BIOASSAY FUNDAMENTALS, 4. STATISTICAL ASPECTS OF BIOASSAY FUNDAMENTALS, 5. STAGES IN THE BIOASSAY PROCESS	Tina Morris
<1033> VALIDATION OF BIOLOGICAL ASSAYS PF 36(4) Pg. 986	Title, 1. INTRODUCTION, 2. FUNDAMENTALS OF BIOASSAY VALIDATION, 3. A BIOASSAY VALIDATION EXAMPLE, 4. LITERATURE	Tina Morris
<1034> ANALYSIS OF BIOLOGICAL ASSAYS PF 36(4) Pg. 1005	Title, 1. INTRODUCTION, 2. OVERVIEW OF ANALYSIS OF BIOASSAY DATA, 3. ANALYSIS MODELS, 4. CONFIDENCE INTERVALS, 5. LITERATURE, APPENDIX–GLOSSARY, GLOSSARY	Tina Morris

	REFERENCES	
<1050> VIRAL SAFETY EVALUATION OF BIOTECHNOLOGY PRODUCTS DERIVED FROM CELL LINES OF HUMAN OR ANIMAL ORIGIN PF 36(3) Pg. 726	I. INTRODUCTION, II. POTENTIAL SOURCES OF VIRUSVIRALCONTAMINATION, III. CELL LINE QUALIFICATION: TESTING FOR VIRUSES, IV. TESTING FOR VIRUSES IN UNPROCESSED BULK, V. RATIONALE AND ACTION PLAN FOR VIRAL CLEARANCE STUDIES AND VIRUS TESTS ON PURIFIED BULK, VI. EVALUATION AND CHARACTERIZATION OF VIRAL CLEARANCE PROCEDURESVI. GOALS, PRINCIPLES, DESIGN, AND EVALUATION OF VIRAL CLEARANCE STUDIES, VII. SUMMARY, GLOSSARY, APPENDIX I. GLOSSARY, APPENDIX 1, APPENDIX 2, APPENDIX 4. VIRUS ABBREVIATIONS, APPENDIX 3, APPENDIX 5	Tina Morris
<1113> MICROBIAL IDENTIFICATION PF 35(1) Pg. 167	Title, INTRODUCTION, MICROBIAL ISOLATION, PRELIMINARY SCREENING OF MICROBIAL ISOLATES, MICROBIAL IDENTIFICATION BY PHENOTYPIC METHODS, MICROBIAL IDENTIFICATION BY GENOTYPIC METHODS, VERIFICATION OF MICROBIAL IDENTIFICATION METHODS	Radhakrishna Tirumalai
<1119> NEAR-INFRARED SPECTROSCOPY PF 36(2) Pg. 532	INSTRUMENTATION	Horacio Pappa
<1151> PHARMACEUTICAL DOSAGE FORMS PF 35(5) Pg. 1260	Introduction, BIOAVAILABILITY, TERMINOLOGY, AEROSOLS, BOLUSES, CAPSULES, CONCENTRATE FOR DIP, CREAMS, ELIXIRS, EMULSIONS, EXTRACTS AND FLUIDEXTRACTS, GELS, IMPLANTS (PELLETS), INFUSIONS, INTRAMAMMARY, INHALATIONS, INJECTIONS, IRRIGATIONS, LOTIONS, LOZENGES, OINTMENTS, OPHTHALMIC PREPARATIONS, PASTES, POWDERS, PREMIXES, SOLUTIONS, SUPPOSITORIES, SUSPENSIONS, SYRUPS, SYSTEMS, TABLETS, GENERAL CONSIDERATIONS, PRODUCT QUALITY TESTS, GENERAL, DOSAGE FORMS, DRY POWDER INHALERS, EMULSIONS (CREAMS AND LOTIONS), FEED ADDITIVES, FOAMS, MEDICAL GASES (INHALATION MATERIALS), GRANULES, MEDICATED GUMS, INSERTS, LIQUIDS, LOTIONS (SEE EMULSIONS), TRANSDERMAL SYSTEMS (PATCHES), PILLS, PLASTERS, MEDICATED SOAPS AND SHAMPOOS, SPRAYS (NASAL, PULMONARY, OR SOLUTIONS FOR NEBULIZATION), TAPES, GLOSSARY	William Brown
<1761> APPLICATIONS OF NUCLEAR MAGNETIC RESONANCE SPECTROSCOPY PF 36(2) Pg. 539	Title, 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
<2232> ELEMENTAL	Title, INTRODUCTION, LIMITS OF ELEMENTAL CONTAMINANTS, OPTIONS FOR COMPLIANCE WITH THE LIMITS OF ELEMENTAL CONTAMINANTS,	

CONTAMINANTS IN DIETARY SUPPLEMENTS PF 36(1) Pg. 258	ANALYTICAL PROCEDURES FOR TOTAL ELEMENTAL CONTAMINANTS, ANALYTICAL PROCEDURE FOR INORGANIC ARSENIC, ANALYTICAL PROCEDURE FOR METHYLMERCURY	Gabriel Giancaspro
AGAR PF 33(4) Pg. 702	Chemical Info, Definition, Botanic characteristics, Packaging and storage, USP Reference standards <11>, Identification, Microbial limits <61>, Limit of foreign insoluble matter	Hong Wang
MEDICAL AIR PF 35(4) Pg. 828	IDENTIFICATION/Introduction, ASSAY/Procedure, IMPURITIES/Inorganic Impurities/Carbon Dioxide, IMPURITIES/Inorganic Impurities/Sample, IMPURITIES/Inorganic Impurities/Analysis, IMPURITIES/Inorganic Impurities/Acceptance criteria, IMPURITIES/Inorganic Impurities/Carbon Monoxide, IMPURITIES/Inorganic Impurities/Sulfur Dioxide, IMPURITIES/Inorganic Impurities/Limit of Nitric Oxide and Nitrogen Dioxide, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling	Ravi Ravichandran
ALENDRONATE SODIUM TABLETS PF 36(5) Pg. 1157	PERFORMANCE TESTS/Dissolution <711>	Elena Gonikberg
ALFUZOSIN HYDROCHLORIDE EXTENDED-RELEASE TABLETS PF 36(4) Pg. 889	Title, 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/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
ALPRAZOLAM ORALLY-DISINTEGRATING TABLETS PF 36(4) Pg. 890	Title, DEFINITION/Introduction, IDENTIFICATION/Introduction, ASSAY/Procedure, PERFORMANCE TESTS/Disintegration <701>, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities/Procedure, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Alprazolam RS	Ravi Ravichandran
	IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP	

AMOXICILLIN CAPSULES PF 36(4) Pg. 892	Amoxicillin Related Compound C RS [(4S)-2-[5-(4-hydroxyphenyl)-3,6-dioxopiperazin -2-yl]-5,5-dimethylthiazolidine-4-carboxylic acid; amoxicillin rearrangement product](C16H19N3O5S365.40), ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Amoxicillin Related Compound D RS [(4S)-2-{[(R)-2-amino-2-(4-hydroxyphenyl)acetamido](carboxy)methyl}-5,5-dimethylthiazolidine-4-carboxylic acid; amoxicillin open ring](C16H21N3O6S383.42), ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Amoxicillin Related Compound G RS [(2S,5R,6R)-6-{(R)-2-[(R)-2-Amino-2-(4-hydroxyphenyl)acetamido]-2 -(4-hydroxyphenyl) acetamido}-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid; d-hydroxyphenylglycylamoxicillin](C24H26N4O7S514.55)	Ahalya Wise
AMOXICILLIN FOR ORAL SUSPENSION PF 36(4) Pg. 894	IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Amoxicillin Related Compound E RS [(4S)-2-{[(R)-2-amino-2-(4-hydroxyphenyl)acetamido]methyl}-5,5-dimethylthiazolidine-4-carboxylic acid; amoxicillin penilloic derivatives](C15H21N3O4S339.41), ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/ USP Amoxicillin Related Compound G RS (2S,5R,6R)-6-{(R)-2-[[(R)-2-amino-2-(4-hydroxyphenyl)acetamido]-2-(4-hydroxyphenyl) acetamido}-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid; d-hydroxyphenylglycylamoxicillin](C24H26N4O7S514.55)	Ahalya Wise
AMOXICILLIN TABLETS PF 36(4) Pg. 896	IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Amoxicillin Related Compound A RS [(2S,5R,6R)-6-amino-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0] heptane-2-carboxylic acid; 6-aminopenicillanic acid](C8H12N2O3S216.26), ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Amoxicillin Related Compound D RS [(4S)-2-{[(R)-2-amino-2-(4-hydroxyphenyl)acetamido](carboxy)methyl} -5,5-dimethylthiazolidine-4-carboxylic acid; amoxicillin open ring](C16H21N3O6S383.42)	Ahalya Wise
AMOXICILLIN AND CLAVULANATE POTASSIUM FOR ORAL SUSPENSION PF 36(4) Pg. 899	IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Amoxicillin Related Compound A RS [(2S,5R,6R)-6-amino-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane -2-carboxylic acid; 6-aminopenicillanic acid](C8H12N2O3S216.26), ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Amoxicillin Related Compound D RS [(4S)-2-{[(R)-2-amino-2-(4-hydroxyphenyl)acetamido](carboxy)methyl}-5,5-dimethylthiazolidine-4-carboxylic acid; amoxicillin open ring](C16H21N3O6S383.42)	Ahalya Wise

AMOXICILLIN AND CLAVULANATE POTASSIUM TABLETS PF 36(4) Pg. 901	IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Amoxicillin Related Compound A RS [(2S,5R,6R)-6-amino-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0] heptane-2-carboxylic acid; 6-aminopenicillanic acid](C8H12N2O3S216.26), ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Amoxicillin Related Compound D RS [(4S)-2-{[(R)-2-amino-2-(4-hydroxyphenyl)acetamido](carboxy)methyl}-5,5-dimethylthiazolidine-4-carboxylic acid; amoxicillin open ring](C16H21N3O6S383.42)	Ahalya Wise
ANAGRELIDE HYDROCHLORIDE PF 36(5) Pg. 1160	Title, Chemical Info/Chemical Structure, Chemical Info/C10H7Cl2N3O·HCl·H2O, Chemical Info/310.56, Chemical Info/Anhydrous, Chemical Info/292.55, Chemical Info/CAS, Chemical Info/Imidazo[2,1-b]quinazolin-2(3H)-one, 6,7-dichloro-1,5-dihydro-, monohydrochloride, monohydrate;, Chemical Info/6,7-Dichloro-1,5-dihydroimidazo[2,1-b]-quinazolin-2(3H)-one monohydrochloride, monohydrate, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., IDENTIFICATION/C. Identification Tests—General, Chloride <191>, ASSAY/Procedure, IMPURITIES/Inorganic Impurities/Residue on Ignition <281>, IMPURITIES/Inorganic Impurities/Heavy Metals, Method II <231>, IMPURITIES/Organic Impurities/Procedure, SPECIFIC TESTS/Water Determination, Method I <921>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Anagrelide Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Anagrelide Related Compound A RS [ethyl 2-(6-amino-2,3-dichlorobenzylamino)acetate] (C11H14Cl2N2O2277.15), ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Anagrelide Related Compound B RS [(2-amino-5,6-dichloroquinazolin-3(4H)-yl)acetic acid] (C10H9Cl2N3O2274.10)	Sujatha Ramakrishna
ANAGRELIDE CAPSULES PF 36(5) Pg. 1162	Title, DEFINITION/Introduction, IDENTIFICATION/Introduction, ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities/Procedure, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Anagrelide Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Anagrelide Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Anagrelide Related Compound C RS Title, Chemical Info/Chemical Structure, Chemical Info/C16H26O5, Chemical Info/298.37, Chemical Info/(3R,5aS,6R,8aS,9R,10S,12R,12aR)-Decahydro-10-	Sujatha Ramakrishna

ARTEMETHER PF 36(2) Pg. 377	methoxy-3,6,9- trimethyl-3,12- epoxy-12H-pyrano[4.3-j]-1,2-benzodioxepin, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Inorganic Impurities/Residue on Ignition <281>, IMPURITIES/Inorganic Impurities/Heavy Metals, Method II <231>, IMPURITIES/Organic Impurities/Procedure 1: Analysis of Cyclohexanone Propanal Derivative and Furoisochromen Derivative by TLC, IMPURITIES/Organic Impurities/Procedure 2: Analysis of Artemether Related Compound A, Artemether Related Compound B, and Any Other Individual Impurity by HPLC, SPECIFIC TESTS/Optical Rotation, Specific Rotation <781S>, SPECIFIC TESTS/Color of solution, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Artemether RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Artemether Related Compound A RS [(3R,5aS,6R,8aS,9R,12R,12aR)-Decahydro-10-hydroxy-3,6,9-trimethyl-3, 12-epoxy -12H-pyrano[4,3-j]-1,2-benzodioxepin](C15H24O5284.35), ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Artemether Related Compound B RS [(3R,5aS,6R,8aS,9R,10R,12R,12aR)-Decahydro-10-methoxy-3,6,9-trimethyl-3, 12 -epoxy-12H-pyrano[4,3-j]-1,2- benzodioxepin](C16H26O5298.37)	Behnam Davani
ARTEMETHER AND LUMEFANTRINE TABLETS PF 36(2) Pg. 379	Title, DEFINITION/Introduction, IDENTIFICATION/A. Thin Layer Chromatography, IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities/Procedure 1: Impurities of Artemether, IMPURITIES/Organic Impurities/Procedure 2: Impurities of Lumefantrine, IMPURITIES/Organic Impurities/Acceptance criteria, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Artemether RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Artemether Related Compound A RS [(3R,5aS,6R,8aS,9R,12R,12aR)-Decahydro-10-hydroxy-3,6,9-trimethyl-3,12- epoxy- 12H-pyrano[4,3-j]-1,2-benzodioxepin](C15H24O5284.35), ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Artemether Related Compound B RS [(3R,5aS,6R,8aS,9R,10R,12R,12aR)-Decahydro-10-methoxy-3,6,9-trimethyl-3 ,12-epoxy-12H-pyrano[4,3-j]-1,2- benzodioxepin](C16H26O5298.37), ADDITIONAL	Behnam Davani

	REQUIREMENTS/USP Reference Standards <11>/USP Lumefantrine RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Lumefantrine Related Compound A RS [(RS, Z)-2-(Dibutylamino)-2-(2,7-dichloro-9-(4-chlorobenzylidene) -9H- fluoren-4-yl)ethanol](C30H32Cl3NO528.94)	
BETADEX SULFOBUTYL ETHER SODIUM PF 36(2) Pg. 447	Title, Chemical Info/Chemical Structure, Chemical Info/C42H70-nO35·(C4H8SO3Na)n, Chemical Info/2163 when n = 6.5, Chemical Info/Beta Cyclodextrin Sulfobutyl Ethers, Sodium Salts;, Chemical Info/Beta Cyclodextrin Sulfobutyl Ether Sodium, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., IDENTIFICATION/C., IDENTIFICATION/D. Identification Tests—General, Sodium <191>, ASSAY/Procedure, IMPURITIES/Inorganic Impurities/Heavy Metals, Method II <231>, IMPURITIES/Inorganic Impurities/Limit of Sodium Chloride, IMPURITIES/Organic Impurities/Procedure 1: Limit of Beta Cyclodextrin (Betadex), IMPURITIES/Organic Impurities/Procedure 2: Limit of 4-Hydroxybutane-1-Sulfonic Acid, IMPURITIES/Organic Impurities/Procedure 3: Limit of Bis(4-Sulfobutyl) Ether Disodium, IMPURITIES/Organic Impurities/Procedure 4: Limit of 1,4-Butane Sultone, SPECIFIC TESTS, SPECIFIC TESTS/Bacterial Endotoxins Test <85>, SPECIFIC TESTS/Microbial Enumeration Tests <61> and Tests for Specified Microorganisms <62>, SPECIFIC TESTS/Clarity of Solution, SPECIFIC TESTS/Average Degree of Substitution, SPECIFIC TESTS/pH <791>, SPECIFIC TESTS/Water Determination, Method I <921>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Beta Cyclodextrin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Betadex Sulfobutyl Ether Sodium RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Endotoxin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Sodium Chloride RS	Hong Wang
BUTYL STEARATE PF 35(6) Pg. 1502	Title, Chemical Info/Chemical Structure, Chemical Info/Butyl Octadecanoate, Chemical Info/C22H44O2, Chemical Info/340.59, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/Infrared Absorption <197F>, SPECIFIC TESTS/Solubility in alcohol, SPECIFIC TESTS/Specific Gravity <841>, SPECIFIC TESTS/Fats and Fixed Oils, Iodine Value <401>, SPECIFIC TESTS/Melting Range or Temperature, Class III <741>, SPECIFIC TESTS/Fats and Fixed Oils, Saponification Value <401>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Butyl Stearate RS	Robert Lafayer

CALCITONIN SALMON PF 36(5) Pg. 1174	DEFINITION/Introduction, IMPURITIES/Organic Impurities/Procedure: Related Peptides and Other Related Substances, SPECIFIC TESTS/Bioidentity, SPECIFIC TESTS/Microbial Enumeration Tests <61> and Tests for Specified Microorganisms <62>	Thomas Sigambris
CARBIDOPA AND LEVODOPA EXTENDED-RELEASE TABLETS PF 34(6) Pg. 1433	Title, Definition, Packaging and storage, Labeling, USP Reference standards <11>, Identification, Dissolution <711> - Test 1, Dissolution <711> - Test 2, Dissolution <711> - Test 3, Uniformity of dosage units <905>, Related compounds, Assay	Ravi Ravichandran
CEFEPIME HYDROCHLORIDE PF 36(1) Pg. 76	ASSAY/Procedure, IMPURITIES/Organic Impurities/Procedure 1: Limit of N-Methylpyrrolidine, IMPURITIES/Organic Impurities/Procedure 2: Other Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Cefepime Hydrochloride System Suitability RS	Ahalya Wise
CEFEPIME FOR INJECTION PF 36(1) Pg. 79	ASSAY/Procedure, IMPURITIES/Organic Impurities/Procedure 1: Limit of N-Methylpyrrolidine, IMPURITIES/Organic Impurities/Procedure 2: Other Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Cefepime Hydrochloride System Suitability RS	Ahalya Wise
CETIRIZINE HYDROCHLORIDE TABLETS PF 36(2) Pg. 389	Title, DEFINITION/Introduction, IDENTIFICATION/Introduction, ASSAY/Procedure, PERFORMANCE TESTS, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities/Procedure, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Cetirizine Hydrochloride RS	Domenick Vicchio
DESCRIPTION AND SOLUBILITY PF 36(2) Pg. 578	Artemether, Butyl Stearate, Betadex Sulfobutyl Ether Sodium, Montelukast Sodium, Fosfomycin Tromethamine, Valganciclovir Hydrochloride, Diethyl Sebacate, Lumefantrine, Milbemycin Oxime, Anagrelide Hydrochloride, Polyglyceryl Dioleate, Hydrogenated Starch Hydrolysate, Albumin Human	Behnam Davani
DIETHYL SEBACATE PF 35(5) Pg. 1203	Title, Chemical Info/Chemical Structure, Chemical Info/CH3CH2OOC(CH2)8COOCH2CH3, Chemical Info/C14H26O4, 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	Robert Lafaver

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DROSPIRENONE AND ETHINYL ESTRADIOL TABLETS PF 36(4) Pg. 914	Title, DEFINITION/Introduction, IDENTIFICATION/Introduction, ASSAY/Procedure, PERFORMANCE TESTS, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities/Procedure, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Drospirenone RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ethinyl Estradiol RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ethinyl Estradiol Related Compound B RS 19-Nor-17α-pregna-1,3,5(10),9(11)-tetraen-20-yne-3,17-diol(C20H22O2294.39)	Domenick Vicchio
ESTRADIOL TRANSDERMAL SYSTEM PF 35(5) Pg. 1136	PERFORMANCE TESTS/Drug Release <724>	Margareth Marques
FENTANYL TRANSDERMAL SYSTEM PF 36(2) Pg. 397	Title, DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B. Thin-Layer Chromatography Identification Test <201>, ASSAY/Procedure, PERFORMANCE TESTS, PERFORMANCE TESTS/Drug Release <724>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities /Procedure 1, IMPURITIES/Organic Impurities /Procedure 2, SPECIFIC TESTS/Alcohol Content, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Fentanyl Citrate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/ USP Fentanyl Related Compound E RS 1-phenethyl-N-phenylpiperidine-4-amineC19H24N2 · 2HCl353.33, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/ USP Fentanyl Related Compound G RS N-(1-phenethyl-4-piperidyl)-acetanilide, acetyl fentanylC21H26N2O322.44, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Alcohol RS	Clydewyn Anthony
	Title, Chemical Info/Chemical Structure, Chemical Info/C845H1339N223O243S9, Chemical Info/ 18,800 daltons, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A, IDENTIFICATION/B, IDENTIFICATION/C: Peptide Mapping, ASSAY/Potency, IMPURITIES/Organic Impurities, IMPURITIES/Procedure 1/Solution A, IMPURITIES/Procedure 1/Solution B, IMPURITIES/Procedure 1/Mobile phase, IMPURITIES/Procedure 1/Standard solution, IMPURITIES/Procedure 1/Sample solution, IMPURITIES/Procedure 1/Chromatographic system, IMPURITIES/Procedure 1/System suitability, IMPURITIES/Procedure 1/Analysis, IMPURITIES/Procedure 1/Acceptance criteria, IMPURITIES/Procedure 2: Impurities	

FILGRASTIM PF 36(5) Pg. 1180	With Charges Different From Filgrastim/1 M phosphoric acid solution, IMPURITIES/Procedure 2: Impurities With Charges Different From Filgrastim/1 M sodium hydroxide solution, IMPURITIES/Procedure 2: Impurities With Charges Different From Filgrastim/Anolyte solution, IMPURITIES/Procedure 2: Impurities With Charges Different From Filgrastim/Catholyte solution, IMPURITIES/Procedure 2: Impurities With Charges Different From Filgrastim/Initiator, IMPURITIES/Procedure 2: Impurities With Charges Different From Filgrastim/Fixing solution, IMPURITIES/Procedure 2: Impurities With Charges Different From Filgrastim/Gel wash I, IMPURITIES/Procedure 2: Impurities With Charges Different From Filgrastim/Coomassie staining solution, IMPURITIES/Procedure 2: Impurities With Charges Different From Filgrastim/Coomassie destaining solution, IMPURITIES/Procedure 2: Impurities With Charges Different From Filgrastim/Reference solution A, IMPURITIES/Procedure 2: Impurities With Charges Different From Filgrastim/Reference solution B, IMPURITIES/Procedure 2: Impurities With Charges Different From Filgrastim/Reference solution C, IMPURITIES/Procedure 2: Impurities With Charges Different From Filgrastim/Reference solution D, IMPURITIES/Procedure 2: Impurities With Charges Different From Filgrastim/Sample solution, IMPURITIES/Procedure 2: Impurities With Charges Different From Filgrastim/Analysis, IMPURITIES/Procedure 3: Impurities With Molecular Weight Different From That of Filgrastim/4X SDS sample buffer (nonreducing conditions), IMPURITIES/Procedure 3: Impurities With Molecular Weight Different From That of Filgrastim/4X SDS sample buffer (reducing conditions), IMPURITIES/Procedure 3: Impurities With Molecular Weight Different From That of Filgrastim/1X SDS sample buffer (nonreducing conditions), IMPURITIES/Procedure 3: Impurities With Molecular Weight Different From That of Filgrastim/1X SDS sample buffer (reducing conditions), IMPURITIES/Procedure 3: Impurities With Molecular Weight Different From That of Filgrastim/Gel wash I, IMPURITIES/Procedure 3: Impurities With Molecular Weight Different From That of Filgrastim/Gel wash II, IMPURITIES/Procedure 3: Impurities With Molecular Weight Different From That of Filgrastim/Reducer solution, IMPURITIES/Procedure 3: Impurities With Molecular Weight Different From That of Filgrastim/Silver nitrate solution, IMPURITIES/Procedure 3: Impurities With Molecular Weight Different From That of Filgrastim/Developer, IMPURITIES/Procedure 3: Impurities With Molecular Weight Different From That of Filgrastim/Acetic acid solution, IMPURITIES/Procedure 3: Impurities With Molecular Weight Different From That of Filgrastim/Running buffer, IMPURITIES/Procedure 3: Impurities With Molecular Weight Different From That of Filgrastim/Resolving gel, IMPURITIES/Procedure 3: Impurities With Molecular Weight Different From That of Filgrastim/Reference solution A,	Clydewyn Anthony

	IMPURITIES/Procedure 3: Impurities With Molecular Weight Different From That of Filgrastim/Reference solution B, IMPURITIES/Procedure 3: Impurities With Molecular Weight Different From That of Filgrastim/Reference solution C, IMPURITIES/Procedure 3: Impurities With Molecular Weight Different From That of Filgrastim/Reference solution D, IMPURITIES/Procedure 3: Impurities With Molecular Weight Different From That of Filgrastim/Sample solution, IMPURITIES/Procedure 3: Impurities With Molecular Weight Different From That of Filgrastim/Analysis, IMPURITIES/Procedure 4: Limit of High Molecular Weight Proteins/Mobile phase, IMPURITIES/Procedure 4: Limit of High Molecular Weight Proteins/Column conditioning solution, IMPURITIES/Procedure 4: Limit of High Molecular Weight Proteins/Resolution solution, IMPURITIES/Procedure 4: Limit of High Molecular Weight Proteins/Standard solution, IMPURITIES/Procedure 4: Limit of High Molecular Weight Proteins/Sample solution, IMPURITIES/Procedure 4: Limit of High Molecular Weight Proteins/Chromatographic system, IMPURITIES/Procedure 4: Limit of High Molecular Weight Proteins/System suitability, IMPURITIES/Procedure 4: Limit of High Molecular Weight Proteins/Analysis, IMPURITIES/Procedure 4: Limit of High Molecular Weight Proteins/Acceptance criteria, SPECIFIC TESTS/Protein Concentration, SPECIFIC TESTS/Microbial Enumeration Tests <61>, SPECIFIC TESTS/Bacterial Endotoxins Test <85>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Endotoxin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Filgrastim RS	
FOSFOMYCIN TROMETHAMINE PF 36(2) Pg. 404	Title, Chemical Info/Chemical Structure, Chemical Info/C3H7O4P·C4H11NO3, Chemical Info/259.19, Chemical Info/Phosphonic acid, (3-methyloxiranyl)-, (2R-cis)-, compd. with 2-amino-2-(hydroxymethyl)-1,3-propanediol (1:1);, Chemical Info/(1R,2S)-(1,2-Epoxypropyl)phosphonic acid, compound with 2-amino-2-(hydroxymethyl)-1,3-propanediol (1:1), Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., IDENTIFICATION/C., ASSAY/Procedure, IMPURITIES/Inorganic Impurities/Heavy Metals, Method I <231>, IMPURITIES/Inorganic Impurities/Limit of Inorganic Phosphates, IMPURITIES/Organic Impurities/Procedure, SPECIFIC TESTS/pH <791>, 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 Fosfomycin Tromethamine RS	Behnam Davani
	Chemical Info/Molecular Weight, Chemical Info/Chemical Name, DEFINITION/Introduction,	

GLUCAGON PF 35(5) Pg. 1148	IDENTIFICATION/Introduction, IDENTIFICATION/A, IDENTIFICATION/B, ASSAY/Procedure, OTHER COMPONENTS/Nitrogen Determination, Method II <461>, IMPURITIES/Inorganic Impurities, IMPURITIES/Organic Impurities/Procedure, SPECIFIC TESTS/Water Determination, Method IMethod Ic <921>, SPECIFIC TESTS/Bacterial Endotoxins Test <85>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>	Thomas Sigambris
GLUCAGON FOR INJECTION PF 35(5) Pg. 1152	DEFINITION/Introduction, IDENTIFICATION/Introduction, ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Water Determination, Method Ic <921>, SPECIFIC TESTS/pH and Clarity of solution, SPECIFIC TESTS/Bacterial Endotoxins Test <85>, SPECIFIC TESTS/Sterility Tests <71>, SPECIFIC TESTS/Other Requirements, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>	Thomas Sigambris
HELIUM PF 35(4) Pg. 850	IDENTIFICATION/A., IDENTIFICATION/B., IDENTIFICATION/Introduction, ASSAY/Procedure, IMPURITIES/Inorganic Impurities/Carbon Monoxide, IMPURITIES/Inorganic Impurities/Acceptance criteria, SPECIFIC TESTS/Odor, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling	Ravi Ravichandran
HEPARIN CALCIUM PF 36(5) Pg. 1185	Title, DEFINITION/Introduction, IDENTIFICATION, IDENTIFICATION/A. 1H NMR Spectrum, IDENTIFICATION/B. Identification Tests—General, Calcium <191>, ASSAY/Anti-Factor IIa Potency	Anita Szajek
HYDROMORPHONE HYDROCHLORIDE PF 35(5) Pg. 1156	IMPURITIES/Organic Impurities/Procedure, ADDITIONAL REQUIREMENTS/ USP Reference Standards <11>	Clydewyn Anthony
HYDROXYPROPYL CORN STARCH PF 36(5) Pg. 1229	Title	Hong Wang
LORATADINE ORALLY-DISINTEGRATING TABLETS PF 34(3) Pg. 624	Title, Definition, Packaging and storage, USP Reference standards <11>, Identification, Disintegration <701>, Dissolution <711>, Uniformity of dosage units <905>, Related compounds, Assay	Mary Waddell
LORATADINE AND PSEUDOEPHEDRINE SULFATE EXTENDED-RELEASE TABLETS PF 32(6) Pg. 1715	Title, Definition, Packaging and storage, USP Reference standards <11>, Identification, Dissolution <711>, Uniformity of dosage units <905>, Loss on drying <731>, Loratadine chromatographic purity, Pseudoephedrine sulfate chromatographic purity, Assay for loratadine, Assay for pseudoephedrine sulfate	Mary Waddell
	Title, Chemical Info/Chemical Structure, Chemical Info/C30H32Cl3NO, Chemical Info/528.94, Chemical Info/(±)-2,7-Dichloro-9-[(Z) -p-chlorobenzylidine]-α	

LUMEFANTRINE PF 36(2) Pg. 413	[(dibutylamino)methyl]-fluorene-4-methanol, Chemical Info/CAS, DEFINITION/Paragraph Text, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Inorganic Impurities/Residue on Ignition <281>, IMPURITIES/Inorganic Impurities/Heavy Metals, Method II <231>, IMPURITIES/Organic Impurities/Procedure, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Lumefantrine RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Lumefantrine Related Compound A RS [(RS, Z)-2-(Dibutylamino)-2-(2,7-dichloro-9-(4-chlorobenzylidene) -9H-fluoren-4-yl)ethanol](C30H32Cl3NO528.94), ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Lumefantrine Related Compound B RS Lumefantrine related compound B is a mixture of isomers A and B. [Isomer A is (1S,3R,5R)-1,3-bis[(EZ)-2,7-Dichloro-9-(4-chlorobenzylidene) -9H-fluoren-4-yl]-2,6-dioxabicyclo[3.1.0]hexane.] [Isomer B is 2-((EZ)-2,7-Dichloro-9-(4-chlorobenzylidene)-9H-fluoren-4-yl)-3'-((EZ) -2,7-dichloro-9-(4-chlorobenzylidene)-9H-fluoren-4-yl)-2,2'-bioxirane.](C44H24Cl6O2797.4)	Behnam Davani
METOLAZONE TABLETS PF 35(6) Pg. 1464	PERFORMANCE TESTS/Dissolution Title, Chemical Info/Chemical Structure, Chemical Info/C31H43NO7 (Milbemycin A3 Oxime), Chemical Info/541.68, Chemical Info/Milbemycin B, 5-O-demethyl-28-deoxy-25-methyl-6,28-epoxy-23-hydroxyimino-, [6R,23S,25S(E)]-;, Chemical Info/(2αE,4E,5′S,6R,6′S,8E,11R,13R,15S,17αR,20αR,20βS)-6′-ethyl-3′,4′,5′,6,6′,7,10,11,14,15,17α,20,20α,20β-tetradecahydro-20β-hydroxy-5′,6,8,19-tetramethylspiro[11,15-methano-2H,13H,17H-furo[4,3,2-pq][2,6]benzodioxacyclooctadecin-13,2′-[2H]pyran]-17-one 20-oxime;, Chemical Info/(1R, 4S, 5′S, 6R, 6′R, 8R, 13R, 20R, 24S, 10E, 14E, 16E, 22Z)-24-hydroxy-21-hydroxyimino-2-oxo-11, 13, 22-trimethyl-3, 7, 19-trioxatetracyclo-[15, 6, 1,14,8,020,24] pentacosa-10, 14, 16, 22-tetraene-6-spiro-2′-(5,′6′-dimethyltetrahydropyran), Chemical Info/C32H45NO7 (Milbemycin A4 Oxime), Chemical Info/555.70, Chemical Info/Milbemycin B, 5-O-demethyl-28-deoxy-25-ethyl-6,28-epoxy-23-hydroxyimino-,	Margareth Marques

MILBEMYCIN OXIME PF 36(2) Pg. 417	[6R,23S,25S(E)]-;, Chemical Info/(2αE,4E,5′S,6R,6′S, 8E,11R,13R,15S,17αR, 20αR,20βS)-6′-3′,4′,5′,6,6′,7,10, 11,14,15,17α,20,20α,20β-tetradecahydro-20β-hydroxy-5′,6′,6,8,19-pentamethylspiro [11,15-methano-2H,13H,17H-furo[4,3,2-pq][2,6] benzodioxacyclooctadecin-13,2′-[2H]pyran]-17-one 20-oxime;, Chemical Info/(1R, 4S, 5′S, 6R, 6′R, 8R, 13R, 20R, 24S, 10E, 14E, 16E, 22Z)-24-hydroxy-21 -hydroxyimino-2-oxo-11, 13, 22-trimethyl-3, 7, 19-trioxatetracyclo- [15, 6, 1,14,8,020,24] pentacosa-10, 14, 16, 22-tetraene-6-spiro-2′-(6′-ethyl-5′-methyltetrahydropyran);, Chemical Info/Mixture of milbemycin A3 oxime and milbemycin A4 oxime, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities/Procedure, SPECIFIC TESTS/Water Determination, Method I <921>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Milbemycin Oxime RS	Morgan Puderbaugh
MONTELUKAST SODIUM PF 36(1) Pg. 121	Title, Chemical Info/Chemical Structure, Chemical Info/C35H35ClNNaO3S, Chemical Info/ 608.17, Chemical Info/Cyclopropaneacetic acid, 1-[[[1-[3-[2-(7-chloro-2-quinolinyl)ethenyl]phenyl] -3-[2-(1-hydroxy-1-methylethyl) phenyl]propyl]thio]methyl]-, sodium salt, [R-,(E)]-;, Chemical Info/Sodium 1-[[[(R)-m-[(E)-2-(7-chloro-2-quinolyl)vinyl] -α-[o-(1-hydroxy-1-methylethyl) phenethyl]benzyl]thio]-methyl]cyclopropaneacetate, Chemical Info/CAS, Chemical Info/C35H36ClNO3S, Chemical Info/ 586.18, Chemical Info/Montelukast, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197>, IDENTIFICATION/B. Identification Tests—General, Sodium <191>, IDENTIFICATION/C., ASSAY/Note, ASSAY/Procedure, IMPURITIES/Inorganic Impurities/Heavy Metals, IMPURITIES/Organic Impurities/Procedure, SPECIFIC TESTS/Water Determination, Method Ia <921>, SPECIFIC TESTS/Enantiomeric Purity, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Montelukast	Mary Waddell

	Sodium RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Montelukast Dicyclohexylamine (DCHA) RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/(C35H36ClNO3S·C12H23N767.50), ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Montelukast Racemate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Montelukast for Peak Identification RS	
MORPHINE SULFATE EXTENDED-RELEASE CAPSULES PF 36(2) Pg. 422	PERFORMANCE TESTS/Dissolution <711>	Clydewyn Anthony
MORPHINE SULFATE EXTENDED-RELEASE TABLETS PF 35(5) Pg. 1164	Title, DEFINITION/Introduction, IDENTIFICATION/A. Identification Tests-General, Sulfate <191>, IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS, PERFORMANCE TESTS/Drug Release <724>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities/Procedure, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>	Clydewyn Anthony
NITROGEN PF 35(4) Pg. 910	IDENTIFICATION/Introduction, ASSAY/Procedure, IMPURITIES/Inorganic Impurities/Carbon Monoxide, SPECIFIC TESTS/Odor, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling	Ravi Ravichandran
NITROGEN 97 PERCENT PF 35(4) Pg. 911	DEFINITION/Introduction, IDENTIFICATION/Introduction, ASSAY/Procedure, IMPURITIES/Inorganic Impurities/Carbon Dioxide, IMPURITIES/Inorganic Impurities/Carbon Monoxide, IMPURITIES/Inorganic Impurities/Sulfur Dioxide, IMPURITIES/Inorganic Impurities/Limit of Nitric Oxide and Nitrogen Dioxide, ADDITIONAL REQUIREMENTS/Packaging and Storage	Ravi Ravichandran
NITROUS OXIDE PF 35(4) Pg. 859	DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B., IDENTIFICATION/C., ASSAY/Procedure, IMPURITIES/Inorganic Impurities/Ammonia, IMPURITIES/Inorganic Impurities/Nitric Oxide, IMPURITIES/Inorganic Impurities/Nitrogen Dioxide, IMPURITIES/Inorganic Impurities/Halogens, IMPURITIES/Inorganic Impurities/Carbon Monoxide, IMPURITIES/Inorganic Impurities/Carbon Dioxide, SPECIFIC TESTS/Water, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling	Ravi Ravichandran
NONYLPARABEN PF 36(2) Pg.	Nonylparaben (4-Hydroxybenzoic acid nonyl ester, nonyl 4-	Morgan

575	hydroxybenzoate),	Puderbaugh
OLMESARTAN MEDOXOMIL PF 36(5) Pg. 1197	Title, Chemical Info/Chemical Structure, Chemical Info/C29H30N6O6, Chemical Info/558.59, Chemical Info/1H-Imidazole-5-carboxylic acid, 4-(1-hydroxy-1-methylethyl)-2-propyl-1-[[2′-(1H-tetrazol-5-yl) [1,1′-biphenyl]-4-yl]methyl]-, (5-methyl-2-oxo-1,3-dioxol-4-yl)methyl ester, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Inorganic Impurities/Residue on Ignition <281>, IMPURITIES/Inorganic Impurities/Heavy Metals, Method II <231>, IMPURITIES/Organic Impurities/Procedure, SPECIFIC TESTS/Limit of Acetone (if present), SPECIFIC TESTS/Water Determination, Method Ic <921>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Olmesartan Medoxomil RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Olmesartan Medoxomil Related Compound A RS	Sujatha Ramakrishna
ORLISTAT PF 35(5) Pg. 1166	Title, Chemical Info/Chemical Structure, Chemical Info/C29H53NO5, Chemical Info/495.73, Chemical Info/l-Leucine, N-formyl-, 1-[(3-hexyl-4-oxo-2-oxetanyl)methyl]dodecyl ester, [2S-[2α(R*), 3β]]-;, Chemical Info/N-Formyl-l-leucine, ester with (3S,4S)-3-hexyl-4-[(2S)-2-hydroxytridecyl]-2-oxetanone, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197M>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Inorganic Impurities/Residue on Ignition <281>, IMPURITIES/Inorganic Impurities/Heavy Metals, Method II <231>, IMPURITIES/Organic Impurities/Procedure 1: Limit of Orlistat Related Compound A, IMPURITIES/Organic Impurities/Procedure 2: Limit of Orlistat Related Compound B, IMPURITIES/Organic Impurities/Procedure 3, IMPURITIES/Organic Impurities/Procedure 4: Limit of Orlistat Related Compound D, IMPURITIES/Organic Impurities/Procedure 5: Limit of Orlistat Related Compound E, SPECIFIC TESTS/Optical Rotation, Specific Rotation <781>, SPECIFIC TESTS/Water Determination, Method Ic <921>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>	Clydewyn Anthony
ORLISTAT CAPSULES PF 35(5) Pg. 1169	Title, DEFINITION/Introduction, IDENTIFICATION/Introduction, ASSAY/Procedure, PERFORMANCE TESTS, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities/Procedure, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>	Clydewyn Anthony
OXCARBAZEPINE PF 34(5) Pg. 1177	Related compounds	Ravi Ravichandran

OXCARBAZEPINE TABLETS PF 34(6) Pg. 1478	Title, Definition, Packaging and storage, USP Reference standards <11>, Identification, Uniformity of dosage units <905>, Related compounds, Assay	Ravi Ravichandran
OXYGEN PF 35(4) Pg. 861	IDENTIFICATION/Procedure, IDENTIFICATION/B. Procedure, ASSAY/Procedure, IMPURITIES/Inorganic Impurities/Carbon Dioxide, IMPURITIES/Inorganic Impurities/Carbon Monoxide, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling	Ravi Ravichandran
OXYGEN 93 PERCENT PF 35(4) Pg. 862	IDENTIFICATION/A. Procedure, IDENTIFICATION/B. Procedure, ASSAY/Procedure, IMPURITIES/Inorganic Impurities/Carbon Dioxide, IMPURITIES/Inorganic Impurities/Carbon Monoxide, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling	Ravi Ravichandran
PANCURONIUM BROMIDE INJECTION PF 32(4) Pg. 1097	Title, Definition, Packaging and storage, USP Reference standards <11>, Identification, Bacterial endotoxins <85>, pH <791>, Particulate matter <788>, Related compounds, Other requirements, Assay	Mary Waddell
POLYGLYCERYL DIOLEATE PF 36(5) Pg. 1234	Title, Chemical Info/R–O–(CH2–CH(OR)–CH2–O)3–R, Chemical Info/R = H, or CO–C17H33, Chemical Info/1,2,3-Propanetriol, homopolymer, (9Z)-9-octadecenoate,, Chemical Info/Polyglyceryl 3 Dioleate, Chemical Info/CAS, Chemical Info/R–O–(CH2–CH(OR)–CH2–O)6–R, Chemical Info/Polyglyceryl 6 Dioleate, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197F>, IDENTIFICATION/B., IDENTIFICATION/C., ASSAY/Content of Fatty Acids, IMPURITIES/Inorganic Impurities/Residue on Ignition, IMPURITIES/Inorganic Impurities/Heavy Metals, Method II <231>, SPECIFIC TESTS/Acid Value, SPECIFIC TESTS/Fats and Fixed Oils, Hydroxyl Value <401>, SPECIFIC TESTS/Iodine Value, SPECIFIC TESTS/Fats and Fixed Oils, Peroxide Value <401>, SPECIFIC TESTS/Fats and Fixed Oils, Saponification Value <401>, SPECIFIC TESTS/Water, Method I <921>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methyl Myristate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methyl Palmitate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methyl Palmitoleate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methyl Stearate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methyl Oleate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methyl Linoleate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP	Hong Wang

	Methyl Linolenate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Polyglyceryl 3 Dioleate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Polyglyceryl 6 Dioleate RS	
PROMETHAZINE AND PHENYLEPHRINE HYDROCHLORIDE ORAL SOLUTION PF 35(2) Pg. 298	Title, DEFINITION/Introduction, IDENTIFICATION/Introduction, ASSAY/Procedure, IMPURITIES/Organic Impurities/Procedure 1, IMPURITIES/Organic Impurities/Procedure 2, SPECIFIC TESTS, SPECIFIC TESTS/ pH <791>, SPECIFIC TESTS/ Alcohol Determination (if present), Method II <611>, SPECIFIC TESTS/Deliverable Volume <698>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/ USP Reference Standards <11>	Clydewyn Anthony
PROMETHAZINE AND PHENYLEPHRINE HYDROCHLORIDE AND CODEINE PHOSPHATE ORAL SOLUTION PF 35(2) Pg. 301	Title, DEFINITION/Introduction, IDENTIFICATION/Introduction, ASSAY/Procedure, IMPURITIES/Organic Impurities/Procedure 1, IMPURITIES/Organic Impurities/Procedure 2, SPECIFIC TESTS, SPECIFIC TESTS/pH <791>, SPECIFIC TESTS/Alcohol Determination, Method II <611> (if present), SPECIFIC TESTS/Deliverable Volume <698>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>	Clydewyn Anthony
PROMETHAZINE HYDROCHLORIDE AND CODEINE PHOSPHATE ORAL SOLUTION PF 35(2) Pg. 292	Title, DEFINITION/Introduction, IDENTIFICATION/Introduction, ASSAY/Procedure, IMPURITIES/Organic Impurities/Procedure 1, IMPURITIES/Organic Impurities/Procedure 2, SPECIFIC TESTS, SPECIFIC TESTS/ pH <791>, SPECIFIC TESTS/Alcohol Determination (if present), Method II <611>, SPECIFIC TESTS/ Deliverable Volume <698>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/ USP Reference Standards <11>	Clydewyn Anthony
PROMETHAZINE HYDROCHLORIDE AND DEXTROMETHORPHAN HYDROBROMIDE ORAL SOLUTION PF 35(2) Pg. 295	Title, DEFINITION/Introduction, IDENTIFICATION/Introduction, ASSAY/Procedure, IMPURITIES/Organic Impurities/Procedure 1, IMPURITIES/Organic Impurities/Procedure 2, SPECIFIC TESTS, SPECIFIC TESTS/ pH <791>, SPECIFIC TESTS/Alcohol Determination (if present), Method II <611>, SPECIFIC TESTS/ Deliverable Volume <698>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>	Clydewyn Anthony
RIBAVIRIN CAPSULES PF 35(3) Pg. 576	Title, DEFINITION/Introduction, IDENTIFICATION/Introduction, ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities/Procedure, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>	Leonel Santos

ROPINIROLE HYDROCHLORIDE PF 36(1) Pg. 133	IMPURITIES/Organic Impurities /Procedure 1, IMPURITIES/Organic Impurities /Procedure 2, ADDITIONAL REQUIREMENTS/Labeling	Ravi Ravichandran
SCAFFOLD PORCINE DERMIS PF 36(5) Pg. 1209	Title, DEFINITION/Introduction, SPECIFIC TESTS/Histological Evaluation, SPECIFIC TESTS/Biochemical Analysis, SPECIFIC TESTS/Thermal Analysis, SPECIFIC TESTS/Biomechanical Analysis, SPECIFIC TESTS/Sterility Tests <71>, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Authentic Visual References <11>	Fouad Atouf
SCAFFOLD PORCINE DERMIS CROSS-LINKED PF 36(5) Pg. 1212	Title, DEFINITION/Introduction, SPECIFIC TESTS/Histological Evaluation, SPECIFIC TESTS/Moisture Content, SPECIFIC TESTS/Collagen Content, SPECIFIC TESTS/Fat Content, SPECIFIC TESTS/Tensile Strength, SPECIFIC TESTS/Visual Inspection, SPECIFIC TESTS/Sterility Tests <71>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Visual Reference Standards <11>	Fouad Atouf
SCAFFOLD HUMAN PERIPHERAL NERVE PF 36(5) Pg. 1205	Title, DEFINITION/Introduction, SPECIFIC TESTS/Histological Evaluation, SPECIFIC TESTS/ChABCase Residual Testing, SPECIFIC TESTS/Visual, SPECIFIC TESTS/Safety, SPECIFIC TESTS/Suture Pullout, SPECIFIC TESTS/Sterility Tests <71>, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/Packaging, Sterilization, and Storage, ADDITIONAL REQUIREMENTS/USP Authentic Visual References <11>	Fouad Atouf
SENNOSIDES PF 35(2) Pg. 309	SPECIFIC TESTS/Content of Sennosides A and B, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>	Maged Sharaf
SERTRALINE HYDROCHLORIDE PF 34(5) Pg. 1189	Related compounds	Ravi Ravichandran
HYDROGENATED STARCH HYDROLYSATE PF 35(1) Pg. 136	Title, Chemical Info, Definition, Packaging and storage, Labeling, USP Reference standards <11>, Identification, Microbial limits <61>, pH <791>, Water, Method I <921>, Residue on ignition <281>, Reducing sugars, Limit of chloride, Limit of sulfate <221>, Limit of nickel, Content of maltitol and sorbitol, Hydrogenated polysaccharides	Hong Wang
SUMATRIPTAN TABLETS PF 35(4) Pg. 871	IMPURITIES/Organic Impurities/Procedure	Ravi Ravichandran
	Title, Chemical Info/Chemical Structure, Chemical Info/C44H69NO12·H2O, Chemical Info/822.03, Chemical Info/15,19-Epoxy-3H-pyrido[2,1-c][1,4]oxaazacyclotricosine-1,7,20,21 (4H,23H)-	

TACROLIMUS PF 35(2) Pg. 310	tetrone-5,6,8,11,12,13,14,15, 16,17,18,19,24,25,26,26a-hexadecahydro-5,19-dihydroxy-3-[2-(4-hydroxy-3-methoxycyclohexyl)-1-methylethenyl]-14,16-dimethoxy-4,10,12,18-tetramethyl-8-(2-propenyl)-, monohydrate, [3S-[3R*,E(1S*,3S*,4S*)],4S*,5R*,8S*,9E,12R*,14R*,15S*,16R*,18S*,19S*,26aR*]]-;, Chemical Info/(−)-(3S,4R,5S,8R,9E,12S,14S,15R,16S,18R,19R,26aS)-8-Allyl-5,6,8,11,12,13,14,15,16,17,18,19,24,25,26,26a-hexadecahydro-5,19-dihydroxy-3-[(E)-2-[(1R,3R,4R)-4-hydroxy-3-methoxycyclohexyl]-1-methylvinyl]-14,16-dimethoxy-4,10,12,18-tetramethyl-15,19-epoxy-3H-pyrido[2,1-c][1,4]oxaazacyclotricosine-1,7,20,21(4H,23H)-tetrone, monohydrate, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197M>, IDENTIFICATION/B., IDENTIFICATION/C., ASSAY/Procedure, IMPURITIES/Inorganic Impurities/Residue on Ignition <281>, IMPURITIES/Inorganic Impurities/Heavy Metals, Method II <231>, IMPURITIES/Organic Impurities/Procedure, SPECIFIC TESTS/Optical Rotation, Specific Rotation <781S>, SPECIFIC TESTS/Water Determination, Method I <921>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>	Ahalya Wise
TACROLIMUS CAPSULES PF 35(2) Pg. 312	Title, DEFINITION/Introduction, IDENTIFICATION/A. Procedure, IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities/Procedure, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>	Ahalya Wise
TOPIRAMATE CAPSULES PF 36(4) Pg. 930	DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197F>, IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities/Procedure, SPECIFIC TESTS/Limit of Sulfamate and Sulfate, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Topiramate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Topiramate Related Compound A RS 2,3:4,5-bis-O-(1-methylethylidene)-d-fructopyranose(C12H20O6260.28)	Ravi Ravichandran
USP AND NF EXCIPIENTS,	{Emollient} Butyl Stearate, {Emulsifying and/or Solubilizing Agent} Polyglyceryl Dioleate, {Flavors and Perfumes} Diethyl Sebacate, {Humectant} Hydrogenated Starch Hydrolysate, {Sweetening Agent} Hydrogenated Starch Hydrolysate, {Tablet Binder} Hydrogenated Starch Hydrolysate, {Tablet	

LISTED BY CATEGORY PF 35(6) Pg. 1488	and/or Capsule Diluent} Hydrogenated Starch Hydrolysate, {Complexing Agent} Betadex Sulfobutyl Ether Sodium, {Sequestering Agent} Betadex Sulfobutyl Ether Sodium, {Wetting and/or Solubilizing Agent} Betadex Sulfobutyl Ether Sodium	Robert Lafaver
VALGANCICLOVIR HYDROCHLORIDE PF 36(4) Pg. 935	IMPURITIES/Organic Impurities/Procedure 3, SPECIFIC TESTS/Enantiomeric Purity of Valganciclovir	Leonel Santos