Compendial Deferrals for USP 35–NF 30

Monograph Title	Monograph Section	Scientific Liaison
<17> PRESCRIPTION CONTAINER LABELING PF 37(1) Pg. ONLINE	Title, INTRODUCTION, PRESCRIPTION CONTAINER LABEL STANDARDS TO PROMOTE PATIENT UNDERSTANDING, REFERENCES	Shawn Becker
<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 REFERENCES	Tina Morris
<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
<1119> NEAR-INFRARED SPECTROSCOPY PF 36(2) Pg. 532	INSTRUMENTATION	Horacio Pappa
<1761> APPLICATIONS OF	Title, PRINCIPLES OF NMR, NMR SPECTROMETERS, RELAXATION,	

NUCLEAR MAGNETIC RESONANCE SPECTROSCOPY PF 36(2) Pg. 539	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 CONTAMINANTS IN DIETARY SUPPLEMENTS PF 36(1) Pg. 258	Title, INTRODUCTION, LIMITS OF ELEMENTAL CONTAMINANTS, OPTIONS FOR COMPLIANCE WITH THE LIMITS OF ELEMENTAL CONTAMINANTS, ANALYTICAL PROCEDURES FOR TOTAL ELEMENTAL CONTAMINANTS, ANALYTICAL PROCEDURE FOR INORGANIC ARSENIC, ANALYTICAL PROCEDURE FOR METHYLMERCURY	Gabriel Giancaspro
GENERAL NOTICES TO USP-NF PF 36(6) Pg. 1477	10. PRESERVATION, PACKAGING, STORAGE, AND LABELING	Todd Cecil
AGAR PF 33(4) Pg. 702	Microbial limits <61>	Feiwen Mao
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](C1 4H21N5O2291.35)	Domenick Vicchio
AMIODARONE HYDROCHLORIDE ORAL SUSPENSION PF 37(1) Pg. ONLINE	Title, 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
AMLODIPINE ORAL SUSPENSION PF 37(1) Pg. ONLINE	Title, 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
AMOXICILLIN CAPSULES PF 36(4) Pg. 892	IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Amoxicillin Related Compound C RS [(4S)-2-[5-(4-hydroxyphenyl)-3,6-dioxopiperazin-2-yl]-5,5-dimethylthiazol idine-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-d imethylthiazolidine-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-hydr oxyphenyl)acetamido}-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane -2-carboxylic acid; d-hydroxyphenylglycylamoxicillin](C24H26N4O7S514.55)	Ahalya Wise
	IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP	

AMOXICILLIN FOR ORAL SUSPENSION PF 36(4) Pg. 894	Reference Standards <11>/USP Amoxicillin Related Compound E RS [(4S)-2-{[(R)-2-amino-2-(4-hydroxyphenyl)acetamido]methyl}-5,5-dimethylth iazolidine-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-hydr oxyphenyl)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-d imethylthiazolidine-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-d imethylthiazolidine-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-d imethylthiazolidine-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
	Title, DEFINITION/Introduction, IDENTIFICATION/Introduction,	

ANAGRELIDE CAPSULES PF 36(5) Pg. 1162	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	Sujatha Ramakrishna
ARTEMETHER PF 36(2) Pg. 377	Title, Chemical Info/Chemical Structure, Chemical Info/C16H26O5, Chemical Info/298.37, Chemical Info/(3R,5aS,6R,8aS,9R,10S,12R,12aR)-Decahydro-10-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-ep oxy-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-3,1 2-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-ep oxy-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-3,1 2-epoxy-12H-pyrano[4,3-j]-1,2-benzodioxepin](C16H26O5298.37), 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)	Behnam Davani
BETA CAROTENE PF 36(6) Pg. 1498	DEFINITION/Introduction, IDENTIFICATION/Procedure, ASSAY/Procedure	Huy Dinh
	DEFINITION/Introduction, IDENTIFICATION/Procedure,	

BETA CAROTENE CAPSULES PF 37(1) Pg. ONLINE	IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, ASSAY/Content of Total Beta Carotene, SPECIFIC TESTS/Alpha Carotene and Other Related Compounds, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>	Natalia Davydova
BETA CAROTENE PREPARATION PF 36(6) Pg. 1583	Title, DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B., COMPOSITION/Content of Beta Carotene, COMPOSITION/Alpha Carotene and Other Related Compounds, IMPURITIES/Residue on Ignition <281>, 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 Beta Carotene RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Beta Carotene System Suitability RS	Huy Dinh
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 Lafaver
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
	ASSAY/Procedure, IMPURITIES/Organic Impurities/Procedure 1: Limit of	

CEFEPIME HYDROCHLORIDE PF 36(1) Pg. 76	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
CELECOXIB PF 36(6) Pg. 1519	Title, Chemical Info/C17H14F3N3O2S, Chemical Info/381.4, Chemical Info/4-[5-(4-Methylphenyl)-3-(trifluoromethyl)-1H-pyrazol-1-yl]benzenesulfonamide;, Chemical Info/p-[5-p-Tolyl-3-(trifluoromethyl)pyrazol-1-yl]benzenesulfonamide, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Inorganic Impurities/Heavy Metals, IMPURITIES/Inorganic Impurities/Residue on Ignition <281>, IMPURITIES/Organic Impurities/Procedure, SPECIFIC TESTS/Water Determination, Method I <921>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Celecoxib RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Celecoxib Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Celecoxib Related Compound B RS	Clydewyn Anthony
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
CHLOROQUINE PHOSPHATE ORAL SUSPENSION PF 37(1) Pg. ONLINE	Title, 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
CODEINE PHOSPHATE ORAL SOLUTION PF 37(1) Pg. ONLINE	Title, 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
DAPSONE ORAL SUSPENSION PF 37(1) Pg. ONLINE	Title, 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
DESCRIPTION AND SOLUBILITY PF 36(2) Pg. 578	Artemether, Butyl Stearate, Betadex Sulfobutyl Ether Sodium, Montelukast Sodium, Fosfomycin Tromethamine, Diethyl Sebacate, Lumefantrine, Celecoxib, Estazolam, Anagrelide Hydrochloride, Rosiglitazone Maleate	Behnam Davani
	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	

DIETHYL SEBACATE PF 35(5) Pg. 1203	<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>	Robert Lafaver
DROSPIRENONE AND ETHINYL ESTRADIOL TABLETS PF 36(4) Pg. 914	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(C20H 22O2294.39)	Domenick Vicchio
ENALAPRIL MALEATE ORAL SUSPENSION PF 37(1) Pg. ONLINE	Title, 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
ENOXAPARIN SODIUM PF 37(1) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/B. 13C NMR Spectrum, IDENTIFICATION/C., IDENTIFICATION/D., IDENTIFICATION/E., IMPURITIES/Heavy Metals, Method I <231>, SPECIFIC TESTS/pH <791>, SPECIFIC TESTS/Bacterial Endotoxins Test <85>	Anita Szajek
ENOXAPARIN SODIUM INJECTION PF 37(1) Pg. ONLINE	IDENTIFICATION/C. Identification Tests—General Sodium<191> Spectrophotometry and Light-Scattering <851>, OTHER COMPONENTS/Benzyl Alcohol Content (if Present), SPECIFIC TESTS/Bacterial Endotoxins Test <85>, SPECIFIC TESTS/Anti-Factor IIa Activity	Anita Szajek
ESTAZOLAM PF 36(6) Pg. 1527	Title, Chemical Info/Chemical Structure, Chemical Info/C16H11ClN4, Chemical Info/294.74, Chemical Info/4H-[1,2,4]Triazolo[4,3-a][1,4]benzodiazepine, 8-chloro-6-phenyl-;, Chemical Info/8-Chloro-6-phenyl-4H-s-triazolo[4,3-a][1,4]benzodiazepine, 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/Loss on Drying <731>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Estazolam RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Estazolam Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Nordazepam RS	Ravi Ravichandran
ESTAZOLAM TABLETS PF 36(6) Pg. 1528	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 Estazolam RS	Ravi Ravichandran

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 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	

FILGRASTIM PF 36(5) Pg. 1180	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, 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	Thomas Sigambris
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	Behnam Davani

	Determination, Method Ic <921>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Fosfomycin Tromethamine RS	
G##_Octreotide Acetate, PTA-5 PF 36(6) Pg. 1778	G## (Octreotide Acetate, PTA-5)	Thomas Sigambris
GLUCAGON PF 35(5) Pg. 1148	Chemical Info/Molecular Weight, Chemical Info/Chemical Name, DEFINITION/Introduction, 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
HYDROCHLORIC ACID INJECTION PF 37(1) Pg. ONLINE	Title, DEFINITION/Introduction, ASSAY/Procedure, SPECIFIC TESTS/pH <791>, SPECIFIC TESTS/Sterility Tests <71>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/Beyond-Use Date	Rick Schnatz
INSULIN ASPART PF 36(6) Pg. 1535	Title, Chemical Info/Chemical Structure, Chemical Info/28B-l-Aspartic acid-insulin (human), Chemical Info/C256H381N65O79S6, Chemical Info/5826 daltons, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B. Peptide Mapping, ASSAY/Procedure, IMPURITIES/Organic Impurities/Procedure 1: Related Proteins, IMPURITIES/Organic Impurities/Procedure 2: Limit of High Molecular Weight Proteins, SPECIFIC TESTS/Insulin Assays, Bioidentity Test <121>, SPECIFIC TESTS/Bacterial Endotoxin Test <85>, SPECIFIC TESTS/Microbial Enumeration Tests <61> and Tests for Specified Microorganisms <62>, SPECIFIC TESTS/Loss on Drying <731>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standard <11>/USP Endotoxin RS, ADDITIONAL REQUIREMENTS/USP Reference Standard <11>/USP Insulin Aspart RS	Thomas Sigambris
INSULIN ASPART INJECTION PF 36(6) Pg. 1537	Title, DEFINITION/Introduction, IDENTIFICATION/Introduction, ASSAY/Procedure, IMPURITIES/Organic Impurities/Procedure 1: Related Proteins, IMPURITIES/Organic Impurities/Procedure 2: Limit of High Molecular Weight Proteins, SPECIFIC TESTS/Bacterial Endotoxins Test <85>, SPECIFIC TESTS/Sterility <71>, SPECIFIC TESTS/Particulate Matter <788>, SPECIFIC TESTS/pH <791>, SPECIFIC TESTS/Zinc Content <591>, SPECIFIC TESTS/Injections <1>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standard <11>/USP Endotoxin RS, ADDITIONAL REQUIREMENTS/USP Reference Standard <11>/USP Insulin Aspart RS	Thomas Sigambris
ISOPHANE INSULIN HUMAN SUSPENSION PF	SPECIFIC TESTS/Sterility Tests <71>	Thomas Sigambris

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ISOPHANE INSULIN SUSPENSION PF 36(6) Pg. 1538	SPECIFIC TESTS/Sterility Tests <71>	Thomas Sigambris
ISRADIPINE ORAL SUSPENSION PF 37(1) Pg. ONLINE	Title, 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
KETOPROFEN CAPSULES PF 36(6) Pg. 1541	Title, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., ASSAY/Note, ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, IMPURITIES/Organic Impurities/Procedure, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ketoprofen RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ketoprofen Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ketoprofen Related Compound C RS 2-(3-Carboxyphenyl) propionic acid.C10H10O4194.18, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ketoprofen Related Compound D RS	Clydewyn Anthony
L##_Octreotide Acetate, Synergi Max-RP PF 36(6) Pg. 1779	L## (Octreotide Acetate, Synergi Max-RP)	Thomas Sigambris
LAMOTRIGINE ORAL SUSPENSION PF 37(1) Pg. ONLINE	Title, DEFINITION/Introduction, ASSAY/Procedure, SPECIFIC TESTS/pH <791>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/Beyond-Use Date, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Lamotrigine RS	Rick Schnatz
LAMOTRIGINE TABLETS FOR ORAL SUSPENSION PF 36(6) Pg. 1544	Title, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities /Procedure 1, IMPURITIES/Organic Impurities /Analysis, IMPURITIES/Organic Impurities /Procedure 2, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/ USP Reference Standards <11>/USP Lamotrigine RS, ADDITIONAL REQUIREMENTS/ USP Reference Standards <11>/USP Lamotrigine Related Compound B RS, ADDITIONAL REQUIREMENTS/ USP Reference Standards <11>/USP Lamotrigine Related Compound C RS	Hariram Ramanathan
LISINOPRIL ORAL SUSPENSION PF 37(1) Pg. ONLINE	Title, 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
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
	Title, Chemical Info/Chemical Structure, Chemical Info/C30H32Cl3NO, Chemical Info/528.94, Chemical Info/(±)-2,7-Dichloro-9-[(Z)-p-chlorobenzylidine]-α[(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>,	

LUMEFANTRINE PF 36(2) Pg. 413	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.](C44H 24Cl6O2797.4)	Behnam Davani
MESO-ZEAXANTHIN PF 36(6) Pg. 1617	Title, Chemical Info/Chemical Structure, Chemical 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	Huy Dinh
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
METOLAZONE TABLETS PF 35(6) Pg. 1464	PERFORMANCE TESTS/Dissolution	Margareth Marques
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-met hylethyl)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 Sodium RS, ADDITIONAL REQUIREMENTS/USP	Mary Waddell

	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 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>, PERFORMANCE TESTS/Drug Release <724>Dissolution <711>, ADDITIONAL REQUIREMENTS/Labeling	Clydewyn Anthony
OCTREOTIDE ACETATE PF 36(6) Pg. 1559	Title, Chemical Info/Chemical Structure, Chemical Info/C49H66N10O10S2·xC2H4O2, Chemical Info/l-Cysteinamide, d-phenylalanyl-l-cysteinyl-l-phenylalanyl-d-tryptophyl-l-lysyl-l-threonyl -N-[2-hydroxy-1-(hydroxymethyl)propyl]-, cyclic (2→7)-disulfide, [R-(R*,R*)]-, acetate (salt);, Chemical Info/d-Phenylalanyl-l-cysteinyl-l-phenylalanyl-d-tryptophyl-l-lysyl-l-thr eonyl-N-[(1R,2R)-2-hydroxy-1-(hydroxymethyl)propyl]-l-cysteinamide cyclic (2→7)-disulfide acetate (salt);, Chemical Info/d-Phenylalanyl-l-hemicystyl-l-phenylalanyl-d-tryptophyl-l-lysyl-l-th reonyl-l-hemicystyl-l-threoninol cyclic (2→7)-disulfide acetate (salt)., Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities/Procedure 1: Limit of Octreotide Acetate Related Compounds, IMPURITIES/Organic Impurities/Procedure 2: Limit of Trifluoroacetic acid (TFA), IMPURITIES/Organic Impurities/Procedure 3: Limit of Triethylamine, SPECIFIC TESTS/Amino acid content, SPECIFIC TESTS/Water Determination, Method I <921>, SPECIFIC TESTS/pH <791>, SPECIFIC TESTS/Acetic Acid Content <503>, SPECIFIC TESTS/Optical Rotation, Specific Rotation <781S>, SPECIFIC TESTS/Bacterial Endotoxins <85>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference standards <11>/USP Octreotide Acetate RS, ADDITIONAL REQUIREMENTS/USP Reference standards <11>/USP Octreotide Acetate (Non-Cyclic) System Suitability Marker RS, ADDITIONAL REQUIREMENTS/USP Reference standards <11>/USP Glacial Acetic Acid RS	Thomas Sigambris
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

OMEPRAZOLE ORAL SUSPENSION PF 37(1) Pg. ONLINE	Title, 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
OXCARBAZEPINE PF 34(5) Pg. 1177	Related compounds	Ravi Ravichandran
PENTOXIFYLLINE ORAL SUSPENSION PF 37(1) Pg. ONLINE	Title, 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
PHENOBARBITAL ORAL SUSPENSION PF 37(1) Pg. ONLINE	Title, 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
POWDERED PHYLLANTHUS AMARUS EXTRACT PF 36(6) Pg. 1622	Title, DEFINITION/Introduction, IDENTIFICATION/A. Thin-Layer Chromatographic Identification Test <201>, IDENTIFICATION/B., COMPOSITION/Content of Lignans, CONTAMINANTS/Articles of Botanical Origin, General Method for Pesticide Residues Analysis <561>, CONTAMINANTS/Heavy Metals, Method III <231>, 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/Other Requirements, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Phyllanthin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Powdered Phyllanthus amarus Extract RS	Maged Sharaf
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	Title, DEFINITION/Introduction, IDENTIFICATION/Introduction, ASSAY/Procedure, IMPURITIES/Organic Impurities/Procedure 1, IMPURITIES/Organic Impurities/Procedure 2, SPECIFIC TESTS, SPECIFIC	

DEXTROMETHORPHAN HYDROBROMIDE ORAL SOLUTION PF 35(2) Pg. 295	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
PROPYLTHIOURACIL ORAL SUSPENSION PF 37(1) Pg. ONLINE	Title, 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
PYRAZINAMIDE ORAL SUSPENSION PF 37(1) Pg. ONLINE	Title, 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
PYRIMETHAMINE ORAL SUSPENSION PF 37(1) Pg. ONLINE	Title, 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
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
RIFABUTIN ORAL SUSPENSION PF 37(1) Pg. ONLINE	Title, 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
ROPINIROLE HYDROCHLORIDE PF 36(1) Pg. 133	IMPURITIES/Organic Impurities /Procedure 1, IMPURITIES/Organic Impurities /Procedure 2, ADDITIONAL REQUIREMENTS/Labeling	Ravi Ravichandran
SCAFFOLD EQUINE PERICARDIUM COLLAGEN. PF 36(6) Pg. 1521	Title, DEFINITION/Introduction, SPECIFIC TESTS/Histological Evaluation, SPECIFIC TESTS/Protein Determination, SPECIFIC TESTS/Lipid Analysis, SPECIFIC TESTS/Moisture Determination, SPECIFIC TESTS/Ash Determination, SPECIFIC TESTS/Carbohydrates, SPECIFIC TESTS/Tensile Strength, SPECIFIC TESTS/Burst Strength, SPECIFIC TESTS/Suture Pullout Strength, SPECIFIC TESTS/Pronase Digestion Resistance, SPECIFIC TESTS/Thermal Analysis, SPECIFIC TESTS/Visual Inspection, SPECIFIC TESTS/Bacterial Endotoxin Test <85>, SPECIFIC TESTS/Sterility Tests <71>, SPECIFIC TESTS/Safety, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>	Fouad Atouf
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
SILDENAFIL CITRATE ORAL SUSPENSION PF 37(1) Pg. ONLINE	Title, DEFINITION/Introduction, ASSAY/Procedure, SPECIFIC TESTS/pH <791>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/Beyond-Use Date	Rick Schnatz
SODIUM PHENYLBUTYRATE ORAL SUSPENSION PF 37(1) Pg. ONLINE	Title, 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 Sodium Phenylbutyrate RS	Rick Schnatz
SOTALOL HYDROCHLORIDE ORAL SUSPENSION PF 37(1) Pg. ONLINE	Title, 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
SPIRONOLACTONE ORAL SUSPENSION PF 37(1) Pg. ONLINE	Title, 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
SPIRONOLACTONE AND HYDROCHLOROTHIAZIDE ORAL SUSPENSION PF 37(1) Pg. ONLINE	Title, 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 Hydrochlorothiazide RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Spironolactone RS	Rick Schnatz
	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)-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-m ethoxycyclohexyl)-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/(−)-	

TACROLIMUS PF 35(2) Pg. 310	(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]-14,1 6-dimethoxy-4,10,12,18-tetramethyl-15,19-epoxy-3H-pyrido[2,1-c][1,4]oxaaz acyclotricosine-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>, IMPURITIES/Organic Impurities/Procedure 1, IMPURITIES/Organic Impurities/Procedure 2, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Tacrolimus Related Compound A RS (E)-8-Ethyl-5,6,8,11,12,13,14,15,16,17,18,19,24,25,26,26a-Hexadecahydro-5 ,19-dihydroxy-3-[(E)-2-(4-hydroxy-3-methoxycyclohexyl)-1-methylvinyl]-14, 16-dimethoxy-4,10,12,18-tetramethyl-15,19-epoxy-3H-pyrido[2,1-c][1,4]oxaa zacyclotricosine-1,7,20,21-(4H,23H)-tetrone.C43H69NO12792.01, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Tacrolimus System Suitability Mixture RS—This is a mixture of tacrolimus, ascomycin ((3S,4R,5S,8R,9E,12S,14S,15R,16S,18R,19R,26aS)-8-Ethyl-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-4,10,1 2,18-tetramethyl-15,19-epoxy-3H-pyrido[2,1-c][1,4]oxaazacyclotricosine-1, 7,20,21-(4H,23H)-tetrone; C43H69NO12; 792.01), and tacrolimus 8-propyl analog ((3S,4R,5S,8S,9E,12S,14S,15R,16S,18R,19R,26aS)-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}-14,1 6-dimethoxy-4,10,12,18-tetramethyl-15,19-epoxy-8-propyl-3H-pyrido[2,1-c][1,4]oxaazacyclotricosine-1,7,20,21(4H,23H)-tetrone; C44H71NO12; 806.03)	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>, PERFORMANCE TESTS/Dissolution <711>, IMPURITIES/Organic Impurities/Procedure 1, IMPURITIES/Organic Impurities/Procedure 2, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Tacrolimus Related Compound A RS (E)-8-Ethyl-5,6,8,11,12,13,14,15,16,17,18,19,24,25,26,26a-hexadecahydro-5 ,19-dihydroxy-3-[(E)-2-(4-hydroxy-3-methoxycyclohexyl)-1-methylvinyl]-14, 16-dimethoxy-4,10,12,18-tetramethyl-15,19-epoxy-3H-pyrido[2,1-c][1,4]oxaa zacyclotricosine-1,7,20,21-(4H,23H)-tetrone.C43H69NO12792.01, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Tacrolimus System Suitability Mixture RS It contains tacrolimus, ascomycin ((3S,4R,5S,8R,9E,12S,14S,15R,16S,18R,19R,26aS)-8-Ethyl-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-	Ahalya Wise

	methylvinyl]-14,16-dimethoxy-4,10,1 2,18-tetramethyl-15,19-epoxy-3H-pyrido[2,1-c][1,4]oxaazacyclotricosine-1, 7,20,21-(4H,23H)-tetroneC43H69NO12792.01 and tacrolimus 8-propyl analog, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/ ((3S,4R,5S,8S,9E,12S,14S,15R,16S,18R,19R,26aS)-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-h ydroxy-3-methoxycyclohexyl]-1-methylvinyl}-14,16-dimethoxy-4,10,12,18-tet ramethyl-15,19-epoxy-8-pro-pyl-3H-pyrido[2,1-c][1,4]oxaazacyclotricosine-1,7,20,21(4H,23H)tetrone.C44H71NO12806.03	
TACROLIMUS ORAL SUSPENSION PF 37(1) Pg. ONLINE	Title, 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
TEMAZEPAM PF 36(6) Pg. 1574	IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Temazepam Related Compound A RS 5-Chloro-2-methylaminobenzophenone.C14H12ClNO245.70, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Temazepam Related Compound F RS 7-Chloro-1-methyl-5-phenyl-1H-1,4-benzodiazepine-2,3-dione.C16H11ClN2O2 298.72	Hariram Ramanathan
TEMOZOLOMIDE ORAL SUSPENSION PF 37(1) Pg. ONLINE	Title, 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 Temozolomide RS	Rick Schnatz
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
TRAMADOL HYDROCHLORIDE ORAL SUSPENSION PF 37(1) Pg. ONLINE	Title, 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
TRAMADOL HYDROCHLORIDE AND ACETAMINOPHEN ORAL SUSPENSION PF 37(1) Pg. ONLINE	Title, 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
URSODIOL ORAL SUSPENSION PF 37(1) Pg.	Title, DEFINITION/Introduction, ASSAY/Procedure, SPECIFIC TESTS/pH <791>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL	Rick Schnatz

ONLINE	REQUIREMENTS/Beyond-Use Date, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ursodiol RS	
USP AND NF EXCIPIENTS, LISTED BY CATEGORY PF 35(6) Pg. 1488	{Emollient} Butyl Stearate, {Flavors and Perfumes} Diethyl Sebacate, {Complexing Agent} Betadex Sulfobutyl Ether Sodium, {Sequestering Agent} Betadex Sulfobutyl Ether Sodium, {Wetting and/or Solubilizing Agent} Betadex Sulfobutyl Ether Sodium	Robert Lafaver
VALACYCLOVIR ORAL SUSPENSION PF 37(1) Pg. ONLINE	Title, 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
VALGANCICLOVIR HYDROCHLORIDE PF 36(4) Pg. 935	IMPURITIES/Organic Impurities/Procedure 3, SPECIFIC TESTS/Enantiomeric Purity of Valganciclovir	Leonel Santos
VALSARTAN AND HYDROCHLOROTHIAZIDE TABLETS PF 36(6) Pg. 1580	PERFORMANCE TESTS/Dissolution <711>	Sujatha Ramakrishna
VITAMIN E PF 37(1) Pg. ONLINE	ASSAY/Alpha Tocopherol, ASSAY/Alpha Tocopheryl Acetate, ASSAY/Alpha Tocopheryl Acid Succinate	Huy Dinh