

Compendial Deferrals for USP35–NF30, Second Supplement

Monograph Title	Monograph Section	Scientific Liaison
<5> GENERAL QUALITY TESTS FOR INHALATION AND NASAL DRUG PRODUCTS PF 37(4) Pg. ONLINE	Title, I. INTRODUCTION, II. PRODUCT QUALITY TESTS FOR INHALATION DRUG PRODUCTS, III. PRODUCT QUALITY TESTS FOR NASAL DRUG PRODUCTS, IV. DESCRIPTION OF PRODUCT QUALITY TESTS	Kahkashan Zaidi
<17> PRESCRIPTION CONTAINER LABELING PF 37(1) Pg. ONLINE	Title, INTRODUCTION, PRESCRIPTION CONTAINER LABEL STANDARDS TO PROMOTE PATIENT UNDERSTANDING, REFERENCES	Donna Bohannon
<31> VOLUMETRIC APPARATUS PF 37(2) Pg. ONLINE	USE—, STANDARDS OF ACCURACY—;	Horacio Pappa
<601> AEROSOLS, METERED-DOSE INHALERS, AND DRY POWDER INHALERS PF 37(4) Pg. ONLINE	Title, Introduction, PROPELLANTS, AEROSOLS, TOPICAL AEROSOLS, NASAL SPRAYS, METERED-DOSE INHALERS AND DRY POWDER INHALERS, TABLE OF CONTENTS, INTRODUCTION, A. DELIVERED DOSE UNIFORMITY, B. DROPLET/PARTICLE SIZE DISTRIBUTION—NASAL AEROSOLS, SPRAYS, AND POWDERS, C. AERODYNAMIC SIZE DISTRIBUTION—INHALATION AEROSOLS, SPRAYS, AND POWDERS, D. DATA ANALYSIS	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	Rick Schnatz
<852> ATOMIC ABSORPTION SPECTROSCOPY PF 37(5) Pg. ONLINE	Title, INTRODUCTION, QUALIFICATION OF ATOMIC ABSORPTION SPECTROPHOTOMETERS, PROCEDURE, VALIDATION AND VERIFICATION	Horacio Pappa
<854> MID-IRRED SPECTROSCOPY PF 37(5) Pg. ONLINE	Title, INTRODUCTION, QUALIFICATION OF IR SPECTROPHOTOMETERS, PROCEDURE, VALIDATION AND VERIFICATION	Horacio Pappa
<857> ULTRAVIOLET-VISIBLE SPECTROSCOPY PF 37(5) Pg. ONLINE	Title, INTRODUCTION, QUALIFICATION OF UV-VIS SPECTROPHOTOMETERS, PROCEDURE, VALIDATION AND VERIFICATION	Horacio Pappa
<1724> SEMI-SOLID DRUG PRODUCTS - PERFORMANCE TESTS PF 37(5) Pg. ONLINE	Title, SCOPE, PURPOSE, INTRODUCTION, IN VITRO PERFORMANCE TESTS	Margareth Marques
<1852> ATOMIC ABSORPTION SPECTROSCOPY - THEORY AND PRACTICE PF 37(5) Pg. ONLINE	Title, THEORY, INSTRUMENTATION, SAMPLE CELL DESIGNS, LINE SOURCES, WAVELENGTH SELECTORS, DETECTION SYSTEMS, BACKGROUND CORRECTION, ANALYTICAL CONSIDERATIONS, OTHER SOURCES OF INFORMATION, APPENDIX: ACRONYMS	Horacio Pappa
<1854> MIDDLE INFRARED SPECTROSCOPY - THEORY AND PRACTICE	Title, PRINCIPLES OF MID-IRRED SPECTROSCOPY, SAMPLING PROCEDURES, MICROSPECTROSCOPY AND IMAGING, INSTRUMENTATION, ANALYTICAL CONSIDERATIONS, FACTORS THAT AFFECT PHOTOMETRIC AND WAVENUMBER ACCURACY	Horacio Pappa

PF 37(5) Pg. ONLINE

<1857> ULTRAVIOLET-VISIBLE SPECTROSCOPY - THEORY AND PRACTICE PF 37(5) Pg. ONLINE

Title, THEORY, INSTRUMENTATION, CALIBRATION, ANALYTICAL CONSIDERATIONS, OTHER SOURCES OF INFORMATION

[Horacio Pappa](#)

<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](#)

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](#)

AMIKACIN PF 37(4) Pg. ONLINE

IDENTIFICATION/Thin-Layer Chromatographic Identification Test <201>, ASSAY/Procedure

[Ahalya Wise](#)

AMIKACIN SULFATE PF 37(4) Pg. ONLINE

Chemical Info/C22H43N5O13&middledot;H2SO4C22H43N5O13&middledot;1.8H2SO4, IDENTIFICATION/Thin-Layer Chromatographic Identification Test <201>, IDENTIFICATION/C. Identification Tests—General, Sulfate <191>, ASSAY/Procedure, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Amikacin Sulfate RS

[Ahalya Wise](#)

AMIKACIN SULFATE INJECTION PF 37(4) Pg. ONLINE

IDENTIFICATION/A. Thin-Layer Chromatographic Identification Test <201>, IDENTIFICATION/B., ASSAY/Procedure

[Ahalya Wise](#)

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](#)

AMOXAPINE PF 37(5) Pg. ONLINE

IMPURITIES/Organic Impurities

[Ravi Ravichandran](#)

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-dimethylthiazolidine-4-carboxylic acid; amoxicillin rearrangement product](C16H19N3O5S365.40), ADDITIONAL REQUIREMENTS/USP

[Ahalya Wise](#)

<p>AMOXICILLIN FOR ORAL SUSPENSION PF 36(4) Pg. 894</p>	<p>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)</p>	<p>Ahalya Wise</p>
<p>AMOXICILLIN TABLETS PF 36(4) Pg. 896</p>	<p>IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Amoxicillin Related Compound D and E Mixture RS, 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)</p>	<p>Ahalya Wise</p>
<p>AMOXICILLIN AND CLAVULANATE POTASSIUM FOR ORAL SUSPENSION PF 36(4) Pg. 899</p>	<p>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)</p>	<p>Ahalya Wise</p>
<p>AMOXICILLIN AND CLAVULANATE POTASSIUM TABLETS PF 36(4) Pg. 901</p>	<p>IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Amoxicillin Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Amoxicillin Related Compound D RS</p>	<p>Ahalya Wise</p>
<p>ARTEMETHER PF 36(2) Pg. 377</p>	<p>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-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-</p>	<p>Behnam Davani</p>

trimethyl-3,12-epoxy-12H-pyrano[4,3-j]-1,2-benzodioxepin](C16H26O5298.37)

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 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](#)

ATORVASTATIN
CALCIUM TABLETS PF
37(5) Pg. ONLINE

Title, DEFINITION/Introduction, IDENTIFICATION/A., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Atorvastatin Calcium RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Atorvastatin Related Compound H RS (lactone impurity)

[Elena Gonikberg](#)

BETA CAROTENE
CAPSULES PF 37(1) Pg.
ONLINE

DEFINITION/Introduction, IDENTIFICATION/Procedure, 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>/USP Beta Carotene RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Beta Carotene System Suitability RS

[Natalia Davydova](#)

BETA CAROTENE
PREPARATION PF 36(6)
Pg. 1583

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](#)

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](#)

CLINDAMYCIN
PHOSPHATE PF 37(5) Pg.
ONLINE

IDENTIFICATION/A. Infrared Absorption <197M><197K>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage,

[Ahalya Wise](#)

	ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Clindamycin Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Lincomycin Hydrochloride RS	
CLONIDINE HYDROCHLORIDE PF 37(4) Pg. ONLINE	ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Clonidine Related Compound A RS 1-Acetyl-2-(2,6-dichlorophenylamino)-2-(4,5-dihydroimidazole).C11H11Cl2N3O272.13	Sujatha Ramakrishna
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, Quetiapine Fumarate, Fosfomycin Tromethamine, Diethyl Sebacate, Lumefantrine	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 <11>	Robert Lafaver
DIPHENHYDRAMINE CITRATE AND IBUPROFEN TABLETS PF 37(3) Pg. ONLINE	Title, DEFINITION/Introduction, IDENTIFICATION/A., ASSAY/Procedure, PERFORMANCE TESTS, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities, IMPURITIES/Limit of Ibuprofen Related Compound C, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Diphenhydramine Citrate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Diphenhydramine Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ibuprofen RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ibuprofen Related Compound C RS	Domenick Vicchio
DIPHENHYDRAMINE HYDROCHLORIDE PF 37(3) Pg. ONLINE	IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Diphenhydramine Related Compound A RS 2-(Diphenylmethoxy)-N-methylethanamine hydrochloride.C16H19NO&middledot;HCl 277.79	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](#)

FILGRASTIM PF 36(5)
Pg. 1180

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/Analyte 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

[Thomas
Sigambris](#)

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

G##_Octreotide Acetate, PTA-5 PF 36(6) Pg. 1778

G## (Octreotide Acetate, PTA-5)

[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](#)

HYDROCODONE BITARTRATE PF 37(4) Pg. ONLINE

DEFINITION/Introduction, ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Loss on Drying <731>, SPECIFIC TESTS/Water Determination, Method I <921>, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Dihydrocodeine Bitartrate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Hydrocodone Bitartrate Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Hydrocodone RS

[Clydewyn Anthony](#)

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, Biodentity 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,

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INSULIN ASPART INJECTION PF 36(6) Pg. 1537	ADDITIONAL REQUIREMENTS/USP Reference Standard <11>/USP Insulin Aspart RS	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 36(6) Pg. 1539	SPECIFIC TESTS/Sterility Tests <71>		Thomas Sigambris
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
KRILL OIL PF 37(5) Pg. ONLINE		Title, DEFINITION/Introduction, IDENTIFICATION/A. Ultraviolet Absorption <197U>, IDENTIFICATION/B. Fatty Acid Profile, IDENTIFICATION/C. Phospholipid profile, COMPOSITION/Content of EPA and DHA, COMPOSITION/Astaxanthin Esterification, COMPOSITION/Content of Astaxanthin, CONTAMINANTS/Fats and Fixed Oils <401>, CONTAMINANTS/Limit of Dioxins, Furans, and Polychlorinated Biphenyls, SPECIFIC TESTS/Fats and Fixed Oils, Acid Value <401>, SPECIFIC TESTS/Fats and Fixed Oils, Anisidine Value <401>, SPECIFIC TESTS/Fats and Fixed Oils, Peroxide Value <401>, SPECIFIC TESTS/Fats and Fixed Oils, Total Oxidation Value (TOTOX) <401>, SPECIFIC TESTS/Fats and Fixed Oils, Unsaponifiable Matter <401>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Astaxanthin Esters from Haematococcus pluvialis RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Astaxanthin (Synthetic) RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Docosahexaenoic Acid Ethyl Ester RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Eicosapentaenoic Acid Ethyl Ester RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Krill Oil RS,	Huy Dinh

	ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Lysophosphatidylcholine RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methyl Tricosanoate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Phosphatidylcholine RS	
L##_Ocreotide Acetate, Synergi Max-RP PF 36(6) Pg. 1779	L##_ (Ocreotide 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
LISINAPRIL 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
LUMEFANTRINE PF 36(2) Pg. 413	Title, Chemical Info/Chemical Structure, Chemical Info/C30H32Cl3NO, Chemical Info/528.94, Chemical Info/(±)-2,7-Dichloro-9-[(Z)-p-chlorobenzylidene]-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>, 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-fluorene-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-fluorene-4-yl]-2,6-dioxabicyclo[3.1.0]hexane.] [Isomer B is 2-((EZ)-2,7-Dichloro-9-(4-chlorobenzylidene)-9H-fluorene-4-yl)-3'-((EZ)-2,7-dichloro-9-(4-chlorobenzylidene)-9H-fluorene-4-yl)-2,2'-bioxirane.](C44H24Cl6O2797.4)	Behnam Davani
MENOTROPINS PF 37(4) Pg. ONLINE	Title, DEFINITION/Introduction, ASSAY/Luteinizing Hormone, ASSAY/Follicle-Stimulating Hormone, SPECIFIC TESTS/Bacterial Endotoxins Test <85>, SPECIFIC TESTS/Safety, SPECIFIC TESTS/Water Determination, Method I <921>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Endotoxin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Human Chorionic Gonadotropin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Menotropins RS	Maura Kibbey
MENOTROPINS FOR INJECTION PF 37(4) Pg. ONLINE	Title, DEFINITION/Introduction, ASSAY/Luteinizing Hormone, ASSAY/Follicle-Stimulating Hormone, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, SPECIFIC TESTS/Bacterial Endotoxins Test <85>, SPECIFIC TESTS/Constituted Solution, SPECIFIC TESTS/pH <791>, SPECIFIC TESTS/Sterility Tests <71>, SPECIFIC TESTS/Other Requirements, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Endotoxin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP	Maura Kibbey

Human Chorionic Gonadotropin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Menotropins RS

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](#)

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

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OCTOXYNOL 9 PF 37(5) Pg. ONLINE

Poly(oxy-1,2-ethanediyl), α-(octylphenyl)-ω-hydroxy-; Polyethylene glycol mono(octylphenyl) ether, Chemical Info/ Poly(oxy-1,2-ethanediyl), α-[4-(1,1,3,3-tetramethylbutyl)phenyl]-ω-hydroxy-; Chemical Info/ α-[4-(1,1,3,3-Tetramethylbutyl)phenyl]-ω-hydroxypoly(oxy-1,2-ethanediyl);, Chemical Info/ Polyethylene glycol mono[p-(1,1,3,3-tetramethylbutyl)phenyl] ether; , Chemical Info/ Polyethylene glycol mono(4-tert-octylphenyl) ether, DEFINITION/Introduction, IDENTIFICATION/B., ASSAY/Procedure, ASSAY/Content of Free Polyethylene Glycols, SPECIFIC TESTS/Cloud Point, SPECIFIC TESTS/Fats and Fixed Oils, Acid Value <401>, SPECIFIC TESTS/Fats and Fixed Oils, Peroxide Value <401>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Nonoxynol 9 RS

[Hong Wang](#)

OCTREOTIDE ACETATE PF 36(6) Pg. 1559

Title, Chemical Info/Chemical Structure, Chemical Info/C49H66N10O10S2ċx2H4O2, 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-threonyl-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-threonyl-l-hemicystyl-l-threoninol cyclic (2→7)-disulfide acetate (salt)., Chemical

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	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	
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
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
PIPERACILLIN AND TAZOBACTAM FOR INJECTION PF 37(2) Pg. ONLINE	ASSAY/Procedure, IMPURITIES/Organic Impurities, Procedure 1, IMPURITIES/Organic Impurities, Procedure 2, ADDITIONAL REQUIREMENTS/Labeling, 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.C8H12N2O3S216.26	Ahalya Wise
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

<p>PROMETHAZINE HYDROCHLORIDE AND DEXTROMETHORPHAN HYDROBROMIDE ORAL SOLUTION PF 35(2) Pg. 295</p>	<p>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></p>	<p>Clydewyn Anthony</p>
<p>PROPYLTHIOURACIL ORAL SUSPENSION PF 37(1) Pg. ONLINE</p>	<p>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</p>	<p>Rick Schnatz</p>
<p>PYRAZINAMIDE ORAL SUSPENSION PF 37(1) Pg. ONLINE</p>	<p>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</p>	<p>Rick Schnatz</p>
<p>PYRIMETHAMINE ORAL SUSPENSION PF 37(1) Pg. ONLINE</p>	<p>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</p>	<p>Rick Schnatz</p>
<p>QUETIAPINE FUMARATE PF 37(3) Pg. ONLINE</p>	<p>Title, Chemical Info/Chemical Structure, Chemical Info/(C₂₁H₂₅N₃O₂S)₂·C₄H₄O₄, Chemical Info/883.09, Chemical Info/Ethanol, 2-[2-(4-dibenzo[b,f][1,4]thiazepin-11-yl-1-piperazinyl)ethoxy]-, (E)-2-butenedioate (2:1) (salt);, Chemical Info/2-[2-(4-Dibenzo[b,f][1,4]thiazepin-11-yl-1-piperazinyl)ethoxy]ethanol fumarate (2:1) salt, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., ASSAY/Procedure, OTHER COMPONENTS/Content of Fumaric Acid, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Heavy Metals, Method II <231>, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Loss on Drying <731>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Quetiapine Fumarate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Quetiapine System Suitability RS</p>	<p>Hariram Ramanathan</p>
<p>RIFABUTIN ORAL SUSPENSION PF 37(1) Pg. ONLINE</p>	<p>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</p>	<p>Rick Schnatz</p>
<p>ROPINIROLE HYDROCHLORIDE PF 36(1) Pg. 133</p>	<p>IMPURITIES/Organic Impurities /Procedure 1, IMPURITIES/Organic Impurities /Procedure 2, ADDITIONAL REQUIREMENTS/Labeling</p>	<p>Hariram Ramanathan</p>
<p>SCAFFOLD EQUINE PERICARDIUM COLLAGEN. PF 36(6) Pg. 1521</p>	<p>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,</p>	<p>Fouad Atouf</p>

	ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>	
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/ChABC Case 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	Hariram Ramanathan
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	Rick Schnatz

	REQUIREMENTS/USP Reference Standards <11>/USP Spironolactone RS	
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
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)	Hariram Ramanathan
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. 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 Ursodiol RS	Rick Schnatz
USP AND NF EXCIPIENTS, LISTED BY CATEGORY PF 35(5) Pg. 1197	{Flavors and Perfumes} Diethyl Sebacate	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

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