

Compendial Deferrals for USP35-NF30, First Supplement

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
<31> VOLUMETRIC APPARATUS PF 37(2) Pg. ONLINE	USE—; STANDARDS OF ACCURACY—	Horacio Pappa
<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 37(3) Pg. ONLINE	INTRODUCTION, LIMITS OF ELEMENTAL IMPURITIES, OPTIONS FOR DESCRIBING LIMITS OF ELEMENTAL IMPURITIES, ANALYTICAL PROCEDURES, SPECIATION, ROUTES OF EXPOSURE, DRUG PRODUCTS, DRUG SUBSTANCE AND EXCIPIENTS, ANALYTICAL TESTING, Title	Kahkashan Zaidi
<233> ELEMENTAL IMPURITIES - PROCEDURES PF 37(3) Pg. ONLINE	INTRODUCTION, COMPENDIAL PROCEDURES 1 AND 2, ALTERNATE PROCEDURE VALIDATION, LIMIT PROCEDURES, QUANTITATIVE PROCEDURES, Title, ALTERNATIVE PROCEDURE VALIDATION REQUIREMENTS, VALIDATION OF LIMIT PROCEDURES, VALIDATION OF QUANTITATIVE PROCEDURES, REFEREE PROCEDURES 1 AND 2, CALCULATIONS AND REPORTING	Kahkashan Zaidi
<621> CHROMATOGRAPHY PF 37(3) Pg. ONLINE	SYSTEM SUITABILITY	Horacio Pappa
<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
<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-	Domenick Vicchio

amino-6,7-dimethoxyquinazolin-2-yl)-N-methylpropane-1,3-diamine](C14H21N5O2291.35)

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

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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 Reference Standards <11>/USP Amoxicillin Related Compound D RS [(4S)-2-{{(R)-2-amino-2-(4-hydroxyphenyl)acetamido}(carboxy)methyl}-5,5-dimethylthiazolidine-4-carboxylic acid; amoxicillin open ring](C16H21N3O6S383.42), ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Amoxicillin Related Compound G RS [(2S,5R,6R)-6-{{(R)-2-[(R)-2-Amino-2-(4-hydroxyphenyl)acetamido]-2-(4-hydroxyphenyl)acetamido}-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid; d-hydroxyphenylglycylamoxicillin](C24H26N4O7S514.55)

[Ahalya Wise](#)

AMOXICILLIN FOR ORAL SUSPENSION PF 36(4) Pg. 894

IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Amoxicillin Related Compound 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)

[Ahalya Wise](#)

AMOXICILLIN TABLETS PF 36(4) Pg. 896

IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Amoxicillin Related Compound A RS [(2S,5R,6R)-6-amino-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid; 6-aminopenicillanic acid](C8H12N2O3S216.26), ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Amoxicillin Related Compound D RS [(4S)-2-{{(R)-2-amino-2-(4-hydroxyphenyl)acetamido}(carboxy)methyl}-5,5-dimethylthiazolidine-4-carboxylic acid; amoxicillin open ring](C16H21N3O6S383.42)

[Ahalya Wise](#)

IMPURITIES/Organic Impurities, ADDITIONAL

AMOXICILLIN AND CLAVULANATE
POTASSIUM FOR ORAL SUSPENSION
PF 36(4) Pg. 899

REQUIREMENTS/USP Reference Standards <11>/USP
Amoxicillin Related Compound A RS, ADDITIONAL
REQUIREMENTS/USP Reference Standards <11>/USP
Amoxicillin Related Compound D RS

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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, ADDITIONAL
REQUIREMENTS/USP Reference Standards <11>/USP
Amoxicillin Related Compound D RS

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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-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)

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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-

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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)

Title, DEFINITION/Introduction, IDENTIFICATION/A., ASSAY/Articaine Hydrochloride, ASSAY/Epinephrine, PERFORMANCE TESTS/Deliverable Volume <698>, IMPURITIES/Organic Impurities, Limit of Articaine Related Compounds, IMPURITIES/Organic Impurities, Limit of Epinephrine Related Compounds, SPECIFIC TESTS/pH <791>, SPECIFIC TESTS/Bacterial Endotoxin Test <85>, SPECIFIC TESTS/Sterility <71>, SPECIFIC TESTS/Particulate Matter in Injections <788>, SPECIFIC TESTS/Other Requirements, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Articaine Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Articaine Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Endotoxin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Epinephrine Bitartrate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Norepinephrine Bitartrate RS

ASSAY/Procedure, IMPURITIES/Organic Impurities, Procedure 1: Limit of Azithromycin N-oxide, IMPURITIES/Introduction, IMPURITIES/Limit of Azithromycin N-Oxide, Desosaminylazithromycin and N-Demethylazithromycin, IMPURITIES/Organic Impurities, Procedure 2: Limit of Aminoazithromycin, Formamido Analog, Methylformamido Analog, and 3′-De(dimethylamino)-3′-oxoazithromycin (if present), ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Desosaminylazithromycin RS

DEFINITION/Introduction, IDENTIFICATION/Procedure, ASSAY/Procedure

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>

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

ARTICAINE HYDROCHLORIDE AND EPINEPHRINE INJECTION PF 37(3) Pg. ONLINE

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AZITHROMYCIN FOR INJECTION PF 37(3) Pg. ONLINE

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BETA CAROTENE PF 36(6) Pg. 1498

[Huy Dinh](#)

BETA CAROTENE CAPSULES PF 37(1) Pg. ONLINE

[Natalia Davydova](#)

BETA CAROTENE PREPARATION PF 36(6) Pg. 1583

[Huy Dinh](#)

CARISOPRODOL PF 37(3) Pg. ONLINE	Standards <11>/USP Beta Carotene System Suitability RS IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Melting Range or Temperature, Class I <741>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Carisoprodol Related Compound A RS 2-Hydroxymethyl-2-methylpentyl carbamate.C8H17NO3 175.23	Ravi Ravichandran
CARISOPRODOL TABLETS PF 37(3) Pg. ONLINE	ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Carisoprodol Related Compound A RS 2-Hydroxymethyl-2-methylpentyl carbamate.C8H17NO3175.23	Ravi Ravichandran
CEFEPIME HYDROCHLORIDE PF 36(1) Pg. 76	ASSAY/Procedure, IMPURITIES/Organic Impurities/Procedure 1: Limit of N-Methylpyrrolidine, IMPURITIES/Organic Impurities/Procedure 2: Other Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Cefepime Hydrochloride System Suitability RS	Ahalya Wise
CEFEPIME FOR INJECTION PF 36(1) Pg. 79	ASSAY/Procedure, IMPURITIES/Organic Impurities/Procedure 1: Limit of N-Methylpyrrolidine, IMPURITIES/Organic Impurities/Procedure 2: Other Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Cefepime Hydrochloride System Suitability RS	Ahalya Wise
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
CICLOPIROX TOPICAL SOLUTION PF 37(3) Pg. ONLINE	Title, DEFINITION/Introduction, IDENTIFICATION/A., ASSAY/Procedure, PERFORMANCE TESTS/Minimum Fill <755>, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Microbial Enumeration Tests <61> and Tests For Specified Microorganisms <62>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ciclopirox RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ciclopirox Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ciclopirox Related Compound C RS	Behnam Davani
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
	Title, DEFINITION/Introduction, ASSAY/Procedure,	

DAPSONE ORAL SUSPENSION PF 37(1) Pg. ONLINE	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, Olmesartan Medoxomil, Quetiapine Fumarate, Sildenafil Citrate, Fosfomycin Tromethamine, Diethyl Sebacate, Lumefantrine, Rosiglitazone Maleate	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·HCl 277.79	Domenick Vicchio
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-	Domenick Vicchio

Nor-17 α ; -pregna-1,3,5(10),9(11)-tetraen-20-yne-3,17-diol(C₂₀H₂₂O₂294.39)

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

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ESTAZOLAM PF 36(6) Pg. 1527

IMPURITIES/Organic Impurities/Procedure, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Estazolam Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Nordazepam RS

[Ravi Ravichandran](#)

Title, Chemical Info/Chemical Structure, Chemical Info/C₈₄H₅₁N₃O₂S₉, 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 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

Title, Chemical Info/Chemical Structure, Chemical Info/C₃H₇O₄P·C₄H₁₁NO₃, Chemical Info/259.19, Chemical Info/Phosphonic acid, (3-methyloxiranyl)-, (2R-cis)-, compd. with 2-amino-2-(hydroxymethyl)-1,3-propanediol (1:1);, Chemical Info/(1R,2S)-(1,2-Epoxypropyl)phosphonic acid, compound with 2-amino-2-(hydroxymethyl)-1,3-propanediol (1:1), Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., IDENTIFICATION/C., ASSAY/Procedure, IMPURITIES/Inorganic Impurities/Heavy Metals, Method I <231>, IMPURITIES/Inorganic Impurities/Limit of Inorganic Phosphates, IMPURITIES/Organic Impurities/Procedure, SPECIFIC TESTS/pH <791>, SPECIFIC TESTS/Optical Rotation, Specific Rotation <781S>, SPECIFIC TESTS/Water Determination, Method Ic <921>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Fosfomycin Tromethamine RS

FOSFOMYCIN TROMETHAMINE PF 36(2)
Pg. 404

[Behnam Davani](#)

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

G## (Octreotide Acetate, PTA-5)

[Thomas Sigambris](#)

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 I Method Ic <921>, SPECIFIC TESTS/Bacterial Endotoxins Test <85>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>

GLUCAGON PF 35(5) Pg. 1148

[Thomas Sigambris](#)

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>

GLUCAGON FOR INJECTION PF 35(5)
Pg. 1152

[Thomas Sigambris](#)

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

HYDROCHLORIC ACID INJECTION PF
37(1) Pg. ONLINE

[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 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

[Clydewyn Anthony](#)

Reference Standards <11>/USP Ketoprofen Related Compound D RS

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](#)

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](#)

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-fluoren-4-yl)ethanol](C₃₀H₃₂Cl₃NO528.94), ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Lumefantrine Related Compound B RS Lumefantrine related compound B is a mixture of isomers A and B. [Isomer A is (1S,3R,5R)-1,3-bis[(EZ)-2,7-Dichloro-9-(4-chlorobenzylidene)-9H-fluoren-4-yl]-2,6-dioxabicyclo[3.1.0]hexane.] [Isomer B is 2-((EZ)-2,7-Dichloro-9-(4-chlorobenzylidene)-9H-fluoren-4-yl)-3'-((EZ)-2,7-dichloro-9-(4-chlorobenzylidene)-9H-fluoren-4-yl)-2,2'-bioxirane.](C₄₄H₂₄Cl₆O₂797.4)

[Behnam Davani](#)

MESO-ZEAXANTHIN PF 36(6) Pg. 1617

Title, Chemical Info/Chemical Structure, Chemical Info/C₄₀H₅₆O₂, Chemical Info/568.88, Chemical Info/ββ-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

[Huy Dinh](#)

<281>, SPECIFIC TESTS/Water Determination, Method I
<921>, ADDITIONAL REQUIREMENTS/Packaging and
Storage, ADDITIONAL REQUIREMENTS/USP Reference
Standards <11>/USP meso-Zeaxanthin RS

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](#)

MESO-ZEAXANTHIN PREPARATION PF
36(6) Pg. 1619

METOLAZONE TABLETS PF 35(6) Pg.
1464

PERFORMANCE TESTS/Dissolution

[Sujatha
Ramakrishna](#)

MORPHINE SULFATE INJECTION PF
37(3) Pg. ONLINE

IDENTIFICATION/A. Thin-Layer Chromatography,
ASSAY/Procedure, SPECIFIC TESTS/Bacterial Endotoxins
Test <85>, ADDITIONAL REQUIREMENTS/Labeling

[Clydewyn
Anthony](#)

MORPHINE SULFATE EXTENDED-
RELEASE TABLETS PF 35(5) Pg. 1164

Title, DEFINITION/Introduction, IDENTIFICATION/A.
Identification Tests-General, Sulfate <191>,
IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE
TESTS, PERFORMANCE TESTS/Drug Release <724>,
PERFORMANCE TESTS/Uniformity of Dosage Units <905>,
IMPURITIES/Organic Impurities/Procedure, ADDITIONAL
REQUIREMENTS/Packaging and Storage, ADDITIONAL
REQUIREMENTS/USP Reference Standards <11>,
PERFORMANCE TESTS/Drug Release <724>Dissolution
<711>, ADDITIONAL REQUIREMENTS/Labeling

[Clydewyn
Anthony](#)

Title, Chemical Info/Chemical Structure, Chemical
Info/C49H66N10O10S2·x2H4O2, 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
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

[Thomas
Sigambris](#)

OCTREOTIDE ACETATE PF 36(6) Pg.
1559

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

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

OLMESARTAN MEDOXOMIL PF 36(5)
Pg. 1197

[Sujatha Ramakrishna](#)

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

OMEPRAZOLE ORAL SUSPENSION PF 37(1) Pg. ONLINE

[Rick Schnatz](#)

Related compounds

OXCARBAZEPINE PF 34(5) Pg. 1177

[Hariram Ramanathan](#)

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

PENTOXIFYLLINE ORAL SUSPENSION PF 37(1) Pg. ONLINE

[Rick Schnatz](#)

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

PHENOBARBITAL ORAL SUSPENSION PF 37(1) Pg. ONLINE

[Rick Schnatz](#)

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

POWDERED PHYLLANTHUS AMARUS

[Maged](#)

EXTRACT PF 36(6) Pg. 1622

<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

[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 AND PHENYLEPHRINE HYDROCHLORIDE ORAL SOLUTION PF 35(2) Pg. 298

Title, DEFINITION/Introduction, IDENTIFICATION/Introduction, ASSAY/Procedure, IMPURITIES/Organic Impurities/Procedure 1, IMPURITIES/Organic Impurities/Procedure 2, SPECIFIC TESTS, SPECIFIC TESTS/ pH <791>, SPECIFIC TESTS/ Alcohol Determination (if present), Method II <611>, SPECIFIC TESTS/Deliverable Volume <698>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/ USP Reference Standards <11>

[Clydewyn Anthony](#)

PROMETHAZINE AND PHENYLEPHRINE HYDROCHLORIDE AND CODEINE PHOSPHATE ORAL SOLUTION PF 35(2) Pg. 301

Title, DEFINITION/Introduction, IDENTIFICATION/Introduction, ASSAY/Procedure, IMPURITIES/Organic Impurities/Procedure 1, IMPURITIES/Organic Impurities/Procedure 2, SPECIFIC TESTS, SPECIFIC TESTS/pH <791>, SPECIFIC TESTS/Alcohol Determination, Method II <611> (if present), SPECIFIC TESTS/Deliverable Volume <698>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>

[Clydewyn Anthony](#)

PROMETHAZINE HYDROCHLORIDE AND CODEINE PHOSPHATE ORAL SOLUTION PF 35(2) Pg. 292

Title, DEFINITION/Introduction, IDENTIFICATION/Introduction, ASSAY/Procedure, IMPURITIES/Organic Impurities/Procedure 1, IMPURITIES/Organic Impurities/Procedure 2, SPECIFIC TESTS, SPECIFIC TESTS/ pH <791>, SPECIFIC TESTS/Alcohol Determination (if present), Method II <611>, SPECIFIC TESTS/ Deliverable Volume <698>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/ USP Reference Standards <11>

[Clydewyn Anthony](#)

PROMETHAZINE HYDROCHLORIDE AND DEXTROMETHORPHAN HYDROBROMIDE ORAL SOLUTION PF 35(2) Pg. 295

Title, DEFINITION/Introduction, IDENTIFICATION/Introduction, ASSAY/Procedure, IMPURITIES/Organic Impurities/Procedure 1, IMPURITIES/Organic Impurities/Procedure 2, SPECIFIC TESTS, SPECIFIC TESTS/ pH <791>, SPECIFIC TESTS/Alcohol Determination (if present), Method II <611>, SPECIFIC TESTS/ Deliverable Volume <698>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>

[Clydewyn Anthony](#)

Title, DEFINITION/Introduction, ASSAY/Procedure, SPECIFIC TESTS/pH <791>, ADDITIONAL

PROPYLTHIOURACIL ORAL SUSPENSION PF 37(1) Pg. ONLINE	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
QUETIAPINE FUMARATE PF 37(3) Pg. ONLINE	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	Hariram Ramanathan
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	Hariram Ramanathan

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/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>

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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](#)

Title, Chemical Info/Chemical Structure, Chemical Info/C22H30N6O4S·C6H8O7, Chemical Info/666.70, Chemical Info/Piperazine, 1-[[3-(6,7-dihydro-1-methyl-7-oxo-3-propyl-1H-pyrazolo[4,3-d]pyrimidin-5-yl)-4-ethoxyphenyl]sulfonyl]-4-methyl-, 2-hydroxy-1,2,3-propanetricarboxylate (1:1);, Chemical Info/1-[[3-(6,7-Dihydro-1-methyl-7-oxo-3-propyl-1H-pyrazolo[4,3-d]pyrimidin-5-yl)-4-ethoxyphenyl]sulfonyl]-4-methylpiperazine citrate (1:1), Chemical Info/CAS, Chemical Info/Sildenafil, Chemical Info/474.58,

SILDENAFIL CITRATE PF 37(3) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, ASSAY/Procedure, IMPURITIES/Heavy Metals, Method II <231>, IMPURITIES/Limit of Imidazole, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Water Determination, Method I <921>, SPECIFIC TESTS/Residue on Ignition <281>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Imidazole RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Sildenafil Citrate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Sildenafil Related Compound A RS	Mary Waddell
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
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
	Title, DEFINITION/Introduction, ASSAY/Procedure, SPECIFIC TESTS/pH <791>, ADDITIONAL	

TEMOZOLOMIDE ORAL SUSPENSION PF 37(1) Pg. ONLINE	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

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](#)