## Compendial Deferrals for USP36-NF31, First Supplement

Category	Monograph Title	Monograph Section	Scientific Liaison
New	<5> INHALATION AND NASAL DRUG PRODUCTS GENERAL INFORMATION AND PRODUCT QUALITY TESTS 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	<u>Kahkashan</u> <u>Zaidi</u>
New	<7> LABELING PF 38(1) Pg. ONLINE	Title, DEFINITION, LABELS AND LABELING	<u>Donna</u> <u>Bohannon</u>
Revision	<31> VOLUMETRIC APPARATUS PF 37(2) Pg. ONLINE	USE—, STANDARDS OF ACCURACY—	<u>Horacio</u> <u>Pappa</u>
Revision	<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	<u>Kahkashan</u> <u>Zaidi</u>
Revision	<621> CHROMATOGRAPHY PF 38(2) Pg. ONLINE	GENERAL PROCEDURES, SYSTEM SUITABILITY	<u>Horacio</u> <u>Pappa</u>
Revision	<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
New	<852> ATOMIC ABSORPTION SPECTROSCOPY PF 37(5) Pg. ONLINE	Title, INTRODUCTION, QUALIFICATION OF ATOMIC ABSORPTION SPECTROPHOTOMETERS, PROCEDURE, VALIDATION AND VERIFICATION	<u>Horacio</u> <u>Pappa</u>
New	<854> MID-INFRARED SPECTROSCOPY PF 37(5) Pg. ONLINE	Title, INTRODUCTION, QUALIFICATION OF IR SPECTROPHOTOMETERS, PROCEDURE, VALIDATION AND VERIFICATION	<u>Horacio</u> <u>Pappa</u>

New	<857> ULTRAVIOLET-VISIBLE SPECTROSCOPY PF 37(5) Pg. ONLINE	Title, INTRODUCTION, QUALIFICATION OF UV-VIS SPECTROPHOTOMETERS, PROCEDURE, VALIDATION AND VERIFICATION	<u>Horacio</u> <u>Pappa</u>
New	<1083> GOOD DISTRIBUTION PRACTICES- SUPPLY CHAIN INTEGRITY PF 38(2) Pg. ONLINE	Title, PURPOSE, SCOPE, DEFINITIONS, COUNTERFEIT DRUGS AND MEDICAL DEVICES, BEST PRACTICES TO COMBAT COUNTERFEIT DRUGS AND MEDICAL DEVICES, DIVERSION AND THEFT	<u>Desmond</u> <u>Hunt</u>
New	<1094> LIQUID-FILLED CAPSULES - DISSOLUTION TESTING AND RELATED QUALITY ATTRIBUTES PF 38(1) Pg. ONLINE	Title, 1. INTRODUCTION, 2. CROSS-LINKING IN GELATIN CAPSULES, 3. DISSOLUTION PROCEDURE DEVELOPMENT, 4. METHOD VALIDATION, 5. SUGGESTIONS FOR STARTING POINTS, 6. QUALITY BY DESIGN	<u>Margareth</u> <u>Marques</u>
New	<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	<u>Horacio</u> <u>Pappa</u>
New	<1854> MIDDLE INFRARED SPECTROSCOPY - THEORY AND PRACTICE PF 37(5) Pg. ONLINE	Title, PRINCIPLES OF MID-INFRARED SPECTROSCOPY, SAMPLING PROCEDURES, MICROSPECTROSCOPY AND IMAGING, INSTRUMENTATION, ANALYTICAL CONSIDERATIONS, FACTORS THAT AFFECT PHOTOMETRIC AND WAVENUMBER ACCURACY	<u>Horacio</u> <u>Pappa</u>
New	<1857> ULTRAVIOLET-VISIBLE SPECTROSCOPY - THEORY AND PRACTICE PF 37(5) Pg. ONLINE	Title, THEORY, INSTRUMENTATION, CALIBRATION, ANALYTICAL CONSIDERATIONS, OTHER SOURCES OF INFORMATION	<u>Horacio</u> <u>Pappa</u>
New	<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
New	ANASTROZOLE TABLETS PF 38(3) Pg. ONLINE	Title, DEFINITION/Introduction,	Feiwen Mao

IDENTIFICATION/Introduction, 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 Anastrozole RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Anastrozole Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Anastrozole Related Compound D RS

New ATOMOXETINE CAPSULES PF 38(2) Pg. ONLINE

DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K> or <197A>, IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Atomoxetine Hydrochloride RS

<u>Heather</u> Joyce

New 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 Gonikbera

Revision BUTYL ALCOHOL PF 38(3) Pg. ONLINE

Chemical Info, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197F>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Butyl Ether, IMPURITIES/Limit of Butyraldehyde, 2-Butanol, Isobutyl Alcohol (2-Methyl-1-Propanol), and Butyl Ether, SPECIFIC TESTS/Specific Gravity <841>, SPECIFIC TESTS/Distilling Range,

<u>Galina</u> Holloway

		Method II <721>, SPECIFIC TESTS/Aldehydes, ADDITIONAL REQUIREMENTS/ USP Reference Standards <11>	
Revision	CALCIUM PANTOTHENATE PF 38(3) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/C. Optical Rotation, Specific Rotation <781S>, COMPOSITION/Nitrogen Determination, Method I <461>, COMPOSITION/Content of Calcium, ASSAY/Procedure, OTHER COMPONENTS/Content of Calcium, IMPURITIES/Related Compounds, SPECIFIC TESTS/Optical Rotation, Specific Rotation <781S>	Huy Dinh
Revision	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
Revision	CLOPIDOGREL BISULFATE PF 38(1) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/B., IDENTIFICATION/C., ASSAY/Procedure, IMPURITIES/Organic Impurities, IMPURITIES/Limit of Clopidogrel Related Compound C, ADDITIONAL REQUIREMENTS/Packaging and Storage	<u>Sujatha</u> Ramakrishna
Revision	DESCRIPTION AND SOLUBILITY PF 37(3) Pg. ONLINE	Quetiapine Fumarate, Memantine Hydrochloride, Rabeprazole Sodium, Moexipril Hydrochloride, Epoprostenol Sodium	<u>Ravi</u> <u>Ravichandran</u>
New	DORZOLAMIDE HYDROCHLORIDE AND TIMOLOL MALEATE OPHTHALMIC SOLUTION PF 38(3) Pg. ONLINE	Title, DEFINITION/Introduction, IDENTIFICATION/A. Thin-Layer Chromatographic Identification Test <201>, IDENTIFICATION/B., IDENTIFICATION/C., ASSAY/Dorzolamide, ASSAY/Timolol, IMPURITIES/Organic Impurities: Dorzolamide Hydrochloride, IMPURITIES/Organic Impurities: Timolol Maleate, SPECIFIC TESTS/Sterility Tests <71>, SPECIFIC TESTS/pH <791>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Dorzolamide Related Compound B RS, ADDITIONAL	Feiwen Mao

		REQUIREMENTS/USP Reference Standards <11>/USP Dorzolamide Related Compound D RS	
Revision	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
Revision	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
New	EPOPROSTENOL SODIUM PF 37(6) Pg. ONLINE	Title, Chemical Info/Chemical Structure, Chemical Info/C20H31NaO5, Chemical Info/374.45, Chemical Info/Prosta-5,13-dien-1-oic acid, 6,9-epoxy-11,15-dihydroxy-, sodium salt, (5Z,9α,11α,13E,15S)-;, Chemical Info/Sodium (Z)-(3aR,4R,5R,6aS)-hexahydro-5-hydroxy-4-[(E)-(3S)-3-hydroxy-1-octenyl]-2H-cyclopenta[b]furan-Δ2,Δ-valerate, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., IDENTIFICATION/C. Identification Tests— General, Sodium <191>, ASSAY/Procedure, IMPURITIES/Heavy Metals, Method II <231>, IMPURITIES/Limit of Sodium Hydroxide, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Water, Method I <921>, SPECIFIC TESTS/Optical Rotation, Specific Rotation <781S>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Epoprostenol Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Epoprostenol Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Epoprostenol Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Epoprostenol Sodium RS	Domenick Vicchio

Revision 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/Anolyte solution, IMPURITIES/Procedure 2: Impurities With Charges Different From Filgrastim/Catholyte solution, IMPURITIES/Procedure 2: Impurities With Charges Different From Filgrastim/Initiator. IMPURITIES/Procedure 2: Impurities With Charges Different From Filgrastim/Fixing solution, IMPURITIES/Procedure 2: Impurities With Charges Different From Filgrastim/Gel wash I, IMPURITIES/Procedure 2: Impurities With Charges Different From Filgrastim/Coomassie staining solution, IMPURITIES/Procedure 2: Impurities With Charges Different From Filgrastim/Coomassie destaining solution, IMPURITIES/Procedure 2: Impurities With Charges Different From Filgrastim/Reference solution A, IMPURITIES/Procedure 2: Impurities With Charges

Mary Crivellone

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 Filarastim/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 Filarastim/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

Revision	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	<u>Clydewyn</u> <u>Anthony</u>
New	INSULIN ASPART PF 36(6) Pg. 1535	Title, Chemical Info/Chemical Structure, B., 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/Insulin Assays, Bioidentity Test <121>, 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	Edith Chang
New	INSULIN ASPART INJECTION PF 36(6) Pg. 1537	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	Edith Chang

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

		Storage, 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	
Revision	L-ISOLEUCINE PF 37(6) Pg. ONLINE	Reagent Specification, I-Isoleucine	<u>Behnam</u> <u>Davani</u>
Revision	ISOPROPYL ALCOHOL PF 38(2) Pg. ONLINE	Chemical Info/Isopropyl alcohollsopropanol, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Limit of Volatile Impurities, SPECIFIC TESTS/Water Determination, Method I <921>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP 2-Propanol System Suitability RS It contains isopropyl alcohol with 0.1% each of ethyl ether, acetone, diisopropyl ether, 1-propanol, and 2- butanol.	<u>Galina</u> <u>Holloway</u>
New	KETOPROFEN CAPSULES PF 36(6) Pg. 1541	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	<u>Clydewyn</u> <u>Anthony</u>
New	KRILL OIL PF 37(5) Pg. ONLINE	Title, DEFINITION/Introduction, IDENTIFICATION/A. Ultraviolet Absorption <197U>, IDENTIFICATION/B. Fatty Acid Profile, IDENTIFICATION/C. Phospholipid	<u>Huy Dinh</u>

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, 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

Revision

L##\_Octreotide Acetate, Synergi Max-RP PF 36(6) Pg. 1779

L## (Octreotide Acetate, Synergi Max-RP)

**Edith Chang** 

New

LAMOTRIGINE ORAL SUSPENSION PF 37(1)
Pa. ONLINE

Title, DEFINITION/Introduction, ASSAY/Procedure, SPECIFIC TESTS/pH < 791 > , ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/Beyond-Use Date, ADDITIONAL

Rick Schnatz

		REQUIREMENTS/USP Reference Standards <11>/USP Lamotrigine RS	
Revision	LEVETIRACETAM TABLETS PF 38(2) Pg. ONLINE	IDENTIFICATION/A. Infrared Absorption <197K>, IMPURITIES/Organic Impurities	<u>Ravi</u> <u>Ravichandran</u>
New	LEVOFLOXACIN TABLETS PF 37(6) 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 Levofloxacin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Levofloxacin Related Compound A RS	Behnam Davani
New	MEMANTINE HYDROCHLORIDE PF 38(2) Pg. ONLINE	Title, Chemical Info/Chemical Structure, Chemical Info/C12H21N· HCI, Chemical Info/215.76, Chemical Info/Tricyclo[3.3.1.13,7]decan-1-amine, 3,5-dimethyl-, hydrochloride; Chemical Info/1-Amino-3,5-dimethyladamantane hydrochloride, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., IDENTIFICATION/C. Identification Tests— General, Chloride <191>, ASSAY/Procedure, IMPURITIES/Heavy Metals, Method II, <231>, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Water Determination, Method I <921>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Memantine Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Memantine Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Memantine Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Memantine Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Memantine Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Memantine Related Compound C RS, ADDITIONAL	Ravi Ravichandran

New MEMANTINE HYDROCHLORIDE TABLETS PF 38(3) Pg. ONLINE

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

Title, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Limit of Memantine– Lactose Adduct, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Amantadine Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Memantine Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Memantine Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Memantine Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Memantine Related Compound C RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Memantine Related Compound D RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Memantine Related Compound E RS

Ravi Ravichandran

Title, Chemical Info/Chemical Structure, Chemical Info/C27H34N2O7· HCI, Chemical Info/535.03, Chemical Info/3-Isoquinolinecarboxylic acid, 2-[2-[[1-(ethoxycarbonyl)-3-phenylpropyl]amino]-1-oxopropyl]-1,2,3,4-tetrahydro-6,7-dimethoxy-, monohydrochloride, [3S-[2[R\*(R\*)], 3R\*]]-;, Chemical Info/(3S)-2-[(2S)-[(1S)-1-Carboxy-3-phenylpropyl]alanyl]-1,2,3,4-tetrahydro-6,7-dimethoxy-3-isoquinolinecarboxylic acid, 2-ethyl ester, monohydrochloride., Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B.,

<u>Sujatha</u> <u>Ramakrishna</u>

MOEXIPRIL HYDROCHLORIDE PF 38(3) Pg. ONLINE

New

IDENTIFICATION/C. Identification Tests— General, Chloride <191>, ASSAY/Procedure, IMPURITIES/Heavy Metals, Method II <231>, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Organic Impurities, IMPURITIES/Content of Imidazole, SPECIFIC TESTS/Water Determination, Method Ia < 921>, SPECIFIC TESTS/Optical Rotation, Specific Rotation <781>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Imidazole RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Moexipril Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Moexipril Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Moexipril Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Moexipril Related Compound C RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Moexipril Related Compound D RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Moexipril Related Compound E RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Moexipril Related Compound F RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Moexipril Related Compound G RS

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

<u>Clydewyn</u> <u>Anthony</u>

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

New OCTREOTIDE ACETATE PF 36(6) Pg. 1559

Edith Chang

IDENTIFICATION/A., IMPURITIES/Organic Impurities, Procedure 1, IMPURITIES/Organic Impurities, Procedure 2, SPECIFIC TESTS/Color of Solution, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>,

Marker RS. ADDITIONAL REQUIREMENTS/USP Reference

Title, Chemical Info/Chemical Structure, Chemical Info/C49H66N10O10S2· xC2H4O2, Chemical Info/I-Cysteinamide, d-phenylalanyl-I-cysteinyl-I-phenylalanyl-d-tryptophyl-I-lysyl-I-threonyl-N-[2-hydroxy-1-(hydroxymethyl)propyl]-, cyclic (2→ 7)-disulfide, [R-(R\*,R\*)]-, acetate (salt);, Chemical Info/d-Phenylalanyl-I-cysteinyl-I-phenylalanyl-d-tryptophyl-I-

(hydroxymethyl)propyl]-l-cysteinamide cyclic (2→ 7)-disulfide acetate (salt);, Chemical Info/d-Phenylalanyl-l-hemicystyl-l-phenylalanyl-d-tryptophyl-l-lysyl-l-threonyl-hemicystyl-l-threoninol cyclic (2→ 7)-disulfide

DEFINITION/Introduction, IDENTIFICATION/A. Infrared

Impurities/Procedure 1: Limit of Octreotide Acetate

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

<11>/USP Octreotide Acetate RS, ADDITIONAL REQUIREMENTS/USP Reference standards <11>/USP Octreotide Acetate (Non-Cyclic) System Suitability

SPECIFIC TESTS/Bacterial Endotoxins <85>,

standards <11>/USP Glacial Acetic Acid RS

TESTS/Optical Rotation, Specific Rotation <781S>,

ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference standards

lysyl-I-threonyl-N-[(1R,2R)-2-hydroxy-1-

Absorption <197K>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic

Related Compounds, IMPURITIES/Organic

acetate (salt)., Chemical Info/CAS,

Elena Gonikberg

Revision OMEPRAZOLE PF 38(3) Pg. ONLINE

ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Omeprazole Related Compound E RS Omeprazole N-oxide. 4-Methoxy-2-[[(RS)-(5-methoxy-1H-benzimidazol-2-yl)sulfinyl]methyl]-3,5-dimethylpyridine 1-oxide. C17H19N3O4S361.42, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Omeprazole Related Compound I RS Omeprazole sulfone N-oxide. 4-Methoxy-2-[[(5-methoxy-1H-benzimidazol-2-yl)sulfonyl]methyl]-3,5-dimethylpyridine 1-oxide. C17H19N3O5S377.41

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Revision	Pepsin PF 38(3) Pg. ONLINE	Pepsin	Margareth Marques
Revision	Pepsin, Purified PF 38(3) Pg. ONLINE	Reagent Specification, Pepsin, Purified	<u>Margareth</u> <u>Marques</u>
Revision	PHENYTOIN SODIUM INJECTION PF 38(3) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/, OTHER COMPONENTS/Alcohol and Propylene Glycol Content, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Dehydrated Alcohol RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Propylene Glycol RS	<u>Ravi</u> <u>Ravichandran</u>
New	POWDERED PHYLLANTHUS AMARUS EXTRACT PF 36(6) Pg. 1622	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	Maged Sharaf

		Reference Standards <11>/USP Powdered Phyllanthus amarus Extract RS	
Revision	PRILOCAINE HYDROCHLORIDE PF 38(3) Pg. ONLINE	IDENTIFICATION/B., IDENTIFICATION/C., IMPURITIES/Organic Impurities, SPECIFIC TESTS/Melting Range or Temperature, Class I <741>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Prilocaine Related Compound A RS o-Toluidine hydrochloride.C7H9N· HCI143.62, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Prilocaine Related Compound B RS (RS)-N-(4-Methylphenyl)-2-(propylamino)propanamide.C13H20N2O220.31	Mary Waddell
New	PROMETHAZINE HYDROCHLORIDE AND CODEINE PHOSPHATE ORAL SOLUTION PF 35(2) Pg. 292	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>	<u>Clydewyn</u> <u>Anthony</u>
New	PROMETHAZINE HYDROCHLORIDE AND DEXTROMETHORPHAN HYDROBROMIDE ORAL SOLUTION PF 35(2) Pg. 295	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>	<u>Clydewyn</u> <u>Anthony</u>
New	QUETIAPINE FUMARATE PF 37(3) Pg. ONLINE	Title, Chemical Info/Chemical Structure, Chemical	<u>Ravi</u> <u>Ravichandran</u>

Info/(C21H25N3O2S)2· C4H4O4, Chemical Info/883.09, Chemical Info/Ethanol, 2-[2-(4dibenzo[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-1piperazinyl)ethoxylethanol 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

Title, Chemical Info/Chemical Structure, Chemical Info/C18H20N3NaO3S, Chemical Info/381.42, Chemical Info/ 1H-Benzimidazole, 2-[[[4-(3-methoxypropoxy)-3methyl-2-pyridinyl]methyl]sulfinyl]-, sodium salt;, Chemical Info/2-[[[4-(3-Methoxypropoxy)-3-methyl-2pyridyl]methyl]sulfinyl]benzimidazole sodium salt, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., IDENTIFICATION/C. Identification Tests— General, Sodium <191>, ASSAY/Procedure, IMPURITIES/Heavy Metals, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Loss on Drying <731>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Rabeprazole Sodium RS

New RABEPRAZOLE SODIUM PF 38(2) Pg. ONLINE

RABEPRAZOLE SODIUM DELAYED-RELEASE TABLETS PF 38(2) Pg. ONLINE

Title, DEFINITION/Introduction, IDENTIFICATION/A. Ultraviolet Absorption, IDENTIFICATION/B.,

Elena Gonikbera

Elena

Gonikberg

New

ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Acid Stage, PERFORMANCE TESTS/Buffer Stage, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Rabeprazole Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Rabeprazole Related Compound C RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Rabeprazole Related Compound D RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Rabeprazole Related Compound D RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Rabeprazole Related Compound E RS

		<11>/USP Rabeprazole Related Compound D RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Rabeprazole Related Compound E RS	
Revision	ROCURONIUM BROMIDE PF 38(2) Pg. ONLINE	ADDITIONAL REQUIREMENTS/Packaging and Storage	<u>Ravi</u> <u>Ravichandran</u>
New	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
Revision	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
Revision	SENNOSIDES PF 35(2) Pg. 309	SPECIFIC TESTS/Content of Sennosides A and B,	Maged

<u>Sharaf</u>

DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B. Fatty Acids Profile, IDENTIFICATION/C. HPLC for Chlorophyll A, IDENTIFICATION/D. HPLC for Carotenoids, COMPOSITION/Content of Beta Carotene and Total Carotenoids, COMPOSITION/Content of C-Phycocyanin, COMPOSITION/Content of Protein, CONTAMINANTS/Limit of Microcystins, CONTAMINANTS/Elemental Contaminants, CONTAMINANTS/Articles of Botanical Origin, General Method for Pesticide Residues Analysis <561>, CONTAMINANTS/Microbial Enumeration Tests <2021>, CONTAMINANTS/Absence of Specified Microorganisms < 2022 > , SPECIFIC TESTS/Description, SPECIFIC TESTS/Loss on Drying <731>, SPECIFIC TESTS/Articles of Botanical Origin, Total Ash <561>, 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 Methyl Linoleate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methyl Linolenate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methyl Oleate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methyl Palmitate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methyl Palmitoleate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methyl Stearate RS

Maged Sharaf

SPIRULINA PF 37(6) Pg. ONLINE

DEFINITION/Introduction, IDENTIFICATION/A. Fatty Acids Profile, IDENTIFICATION/B. HPLC for Chlorophyll A, IDENTIFICATION/C. HPLC for Carotenoids, STRENGTH/Content of Beta Carotene and Total Carotenoids, STRENGTH/Content of C-Phycocyanin,

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New

STRENGTH/Content of Protein, PERFORMANCE TESTS/Weight Variation < 2091>, CONTAMINANTS/Limit of Microcystins, CONTAMINANTS/Elemental Contaminants <2233>, CONTAMINANTS/Articles of Botanical Origin, General Method for Pesticide Residues Analysis < 561 > , CONTAMINANTS/Microbial Enumeration Tests < 2021 > , CONTAMINANTS/Absence of Specified Microorganisms < 2022 > , 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 Methyl Linoleate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methyl Linolenate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methyl Oleate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methyl Palmitate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methyl Palmitoleate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methyl Stearate RS

New 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

New TORSEMIDE TABLETS PF 37(6) 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 Torsemide RS, ADDITIONAL

<u>Sujatha</u> Ramakrishna REQUIREMENTS/USP Reference Standards <11>/USP Torsemide Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Torsemide Related Compound E RS