Compendial Deferrals for USP36-NF31

Category	Monograph Title	Monograph Section	Scientific Liaison
New	<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	<u>Kahkashan</u> Zaidi
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> Zaidi
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	<u>Rick Schna</u>
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> Pappa
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	<1724> SEMI-SOLID DRUG PRODUCTS - PERFORMANCE TESTS PF 37(5) Pg. ONLINE	Title, SCOPE, PURPOSE, INTRODUCTION, IN VITRO PERFORMANCE TESTS	<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> Pappa

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> Pappa
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	<u>Gabriel</u> Giancasprc
Revision	ADENOSINE PF 38(1) Pg. ONLINE	IDENTIFICATION/B., IMPURITIES/Organic Impurities, SPECIFIC TESTS/Melting Range or Temperature <741>	<u>Heather</u> Joyce
Revision	AMIKACIN PF 37(4) Pg. ONLINE	IDENTIFICATION/Thin-Layer Chromatographic Identification Test <201>, ASSAY/Procedure	<u>Ahalya Wis</u>
Revision	AMIKACIN SULFATE PF 37(4) Pg. ONLINE	Chemical Info/C22H43N5O13·H2SO4C22H43N5O13·1.8H2SO4, 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	<u>Ahalya Wis</u>
Revision	AMIKACIN SULFATE INJECTION PF 37(4) Pg. ONLINE	IDENTIFICATION/A. Thin-Layer Chromatographic Identification Test <201>, IDENTIFICATION/B., ASSAY/Procedure	<u>Ahalya Wis</u>
New	AMLODIPINE AND BENAZEPRIL HYDROCHLORIDE CAPSULES PF 38(1) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/A., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution, <711>, PERFORMANCE TESTS/Uniformity of Dosage Units, <905>, IMPURITIES/Procedure, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Amlodipine Besylate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Amlodipine Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Benazepril Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Benazepril Related Compound C RS	<u>Sujatha</u> <u>Ramakrish</u>
Revision	AMOXAPINE TABLETS PF 38(1) Pg. ONLINE	IDENTIFICATION/B., PERFORMANCE TESTS/Dissolution <711>	<u>Heather</u> Joyce
Revision	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](C24H26N407S514.55)	<u>Ahalya Wis</u>

Revision	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](C24H26N407S514.55)	<u>Ahalya Wis</u>
Revision	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)	<u>Ahalya Wis</u>
Revision	AMOXICILLIN AND CLAVULANATE POTASSIUM FOR ORAL SUSPENSION PF 36(4) Pg. 899	IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Amoxicillin Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Amoxicillin Related Compound D RS	<u>Ahalya Wis</u>
Revision	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	<u>Ahalya Wis</u>
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)	<u>Elena</u> Gonikberg
New	CIPROFLOXACIN EXTENDED-RELEASE 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 Ciprofloxacin Ethylenediamine Analog RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ciprofloxacin Hydrochloride RS	<u>Behnam</u> Davani
Revision	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, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Clindamycin Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Lincomycin Hydrochloride RS	<u>Ahalya Wis</u>
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	<u>Sujatha</u> <u>Ramakrish</u>
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	<u>Sujatha</u> <u>Ramakrish</u>

REQUIREMENTS/Packaging and Storage

Revision	DESCRIPTION AND SOLUBILITY PF 37(3) Pg. ONLINE	Quetiapine Fumarate, Epoprostenol Sodium	<u>Hariram</u> <u>Ramanatha</u>
New	DIPHENHYDRAMINE CITRATE AND IBUPROFEN TABLETS PF 37(3) Pg. ONLINE	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	<u>Domenick</u> <u>Vicchio</u>
Revision	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	<u>Domenick</u> <u>Vicchio</u>
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>	<u>Anita Szaj</u> ∉
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	<u>Anita Szaję</u>
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 Sodium RS	<u>Domenick</u> <u>Vicchio</u>
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	<u>Thomas</u> Sigambris

system, IMPURITIES/Procedure 1/System suitability, IMPURITIES/Procedure 1/Analysis, IMPURITIES/Procedure 1/Acceptance criteria, IMPURITIES/Procedure 2: Impurities With Charges Different From Filgrastim/1 M phosphoric acid solution, IMPURITIES/Procedure 2: Impurities With Charges Different From Filgrastim/1 M sodium hydroxide solution, IMPURITIES/Procedure 2: Impurities With Charges Different From Filgrastim/Anolyte solution, IMPURITIES/Procedure 2: Impurities With Charges Different From Filgrastim/Catholyte solution, IMPURITIES/Procedure 2: Impurities With Charges Different From Filgrastim/Initiator, IMPURITIES/Procedure 2: Impurities With Charges Different From Filgrastim/Fixing solution, IMPURITIES/Procedure 2: Impurities With Charges Different From Filgrastim/Gel wash I, IMPURITIES/Procedure 2: Impurities With Charges Different From Filgrastim/Coomassie staining solution, IMPURITIES/Procedure 2: Impurities With Charges Different From Filgrastim/Coomassie destaining solution, IMPURITIES/Procedure 2: Impurities With Charges Different From Filgrastim/Reference solution A, IMPURITIES/Procedure 2: Impurities With Charges Different From Filgrastim/Reference solution B, IMPURITIES/Procedure 2: Impurities With Charges Different From Filgrastim/Reference solution C, IMPURITIES/Procedure 2: Impurities With Charges Different From Filgrastim/Reference solution D. IMPURITIES/Procedure 2: Impurities With Charges Different From Filgrastim/Sample solution, IMPURITIES/Procedure 2: Impurities With Charges Different From Filgrastim/Analysis, IMPURITIES/Procedure 3: Impurities With Molecular Weight Different From That of Filgrastim/4X SDS sample buffer (nonreducing conditions), IMPURITIES/Procedure 3: Impurities With Molecular Weight Different From That of Filgrastim/4X SDS sample buffer (reducing conditions), IMPURITIES/Procedure 3: Impurities 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	
Revision	G##_Octreotide Acetate, PTA-5 PF 36(6) Pg. 1778	G## (Octreotide Acetate, PTA-5)	<u>Thomas</u> Sigambris
Revision	GALANTAMINE HYDROBROMIDE PF 38(1) Pg. ONLINE	IMPURITIES/Enantiomeric Purity	<u>Heather</u> Joyce
Revision	GENTAMICIN SULFATE PF 38(1) Pg. ONLINE	IMPURITIES/Limit of Methanol (if present), SPECIFIC TESTS/Content of Gentamicins, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Sisomicin Sulfate RS	<u>Ahalya Wis</u>
New	GYMNEMA PF 38(1) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B. HPLC, COMPOSITION/Content of Gymnemic Acids, CONTAMINANTS/Heavy Metals, Method III <231>, 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/Botanic Characteristics, SPECIFIC TESTS/Articles of Botanical Origin, Foreign Organic Matter <561>, SPECIFIC TESTS/Articles of Botanical Origin, Alcohol-Soluble Extractives, Method I <561>, SPECIFIC TESTS/Articles of Botanical Origin, Water-Soluble Extractives, Method I <561>, SPECIFIC TESTS/Loss on Drying <731>, SPECIFIC TESTS/Articles of Botanical Origin, Total Ash <561>, SPECIFIC TESTS/Articles of Botanical Origin, Acid-Insoluble Ash <561>, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Gymnemagenin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Native Gymnema Extract RS	<u>Maged</u> Sharaf
New	NATIVE GYMNEMA EXTRACT PF 38(1) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/A. HPLC, COMPOSITION/Content of Gymnemic Acids, CONTAMINANTS/Heavy Metals, Method III <231>, 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/Loss on Drying <731>, SPECIFIC TESTS/Articles of Botanical Origin, Total Ash <561>, SPECIFIC TESTS/Articles of Botanical Origin, Acid-Insoluble Ash <561>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Gymnemagenin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Native Gymnema Extract RS	<u>Maged</u> Sharaf
New	POWDERED GYMNEMA PF 38(1) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B. HPLC, COMPOSITION/Content of Gymnemic Acids, CONTAMINANTS/Heavy Metals, Method III <231>, 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/Botanic Characteristics,	<u>Maged</u> <u>Sharaf</u>

		SPECIFIC TESTS/Articles of Botanical Origin, Alcohol-Soluble Extractives, Method I <561>, SPECIFIC TESTS/Articles of Botanical Origin, Water-Soluble Extractives, Method I <561>, SPECIFIC TESTS/Loss on Drying <731>, SPECIFIC TESTS/Articles of Botanical Origin, Total Ash <561>, SPECIFIC TESTS/Articles of Botanical Origin, Acid-Insoluble Ash <561>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Gymnemagenin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Native Gymnema Extract RS	
New	PURIFIED GYMNEMA EXTRACT PF 38(1) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/A. HPLC, COMPOSITION/Content of Gymnemic Acids, CONTAMINANTS/Heavy Metals, Method III <231>, 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/Loss on Drying <731>, SPECIFIC TESTS/Articles of Botanical Origin, Total Ash <561>, SPECIFIC TESTS/Articles of Botanical Origin, Acid-Insoluble Ash <561>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Gymnemagenin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Native Gymnema Extract RS	<u>Maged</u> <u>Sharaf</u>
New	HYALURONATE SODIUM PF 38(1) Pg. ONLINE	Title, Chemical Info/Chemical Structure, Chemical Info/(C14H20NNaO11)n, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B. Identification Tests—General, Sodium <191>, ASSAY/Procedure, IMPURITIES/Chloride and Sulfate, Chloride <221>, IMPURITIES/Iron <241>, IMPURITIES/Heavy Metals <231>, IMPURITIES/Nucleic Acids, IMPURITIES/Protein, IMPURITIES/Sulfated Glycosaminoglycans, SPECIFIC TESTS/Intrinsic Viscosity, SPECIFIC TESTS/Appearance of the Solution, SPECIFIC TESTS/Loss on Drying <731>, SPECIFIC TESTS/pH <791>, SPECIFIC TESTS/Microbial Enumeration Test <61> and Absence of Specified Microorganisms <62>, SPECIFIC TESTS/Bacterial Endotoxins <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 d-Glucuronic Acid RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Hyaluronate Sodium RS	<u>Thomas</u> <u>Sigambris</u>
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, Chemical Info/28B-I-Aspartic acid-insulin (human), Chemical Info/C256H381N65079S6, 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	<u>Thomas</u> <u>Sigambris</u>

		<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	
New	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	<u>Thomas</u> Sigambris
Revision	ISOPHANE INSULIN HUMAN SUSPENSION PF 36(6) Pg. 1539	SPECIFIC TESTS/Sterility Tests <71>	<u>Thomas</u> Sigambris
Revision	ISOPHANE INSULIN SUSPENSION PF 36(6) Pg. 1538	SPECIFIC TESTS/Sterility Tests <71>	<u>Thomas</u> Sigambris
Revision	L-ISOLEUCINE PF 37(6) Pg. ONLINE	Reagent Specification, I-Isoleucine	<u>Behnam</u> Davani
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.C10H1004194.18, 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 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, Peroxide Value <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 Krill Oil RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Krill Oil RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP	<u>Huy Dinh</u>

		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)	<u>Thomas</u> Sigambris
New	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	<u>Rick Schna</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	<u>Behnam</u> Davani
Omission	MENOTROPINS PF 37(4) Pg. ONLINE	Entire document	<u>Maura</u> Kibbey
Omission	MENOTROPINS FOR INJECTION PF 37(4) Pg. ONLINE	Entire document	<u>Maura</u> <u>Kibbey</u>
New	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	<u>Clydewyn</u> <u>Anthony</u>
Revision	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	<u>Hong Wan</u> ı
New	OCTREOTIDE ACETATE PF 36(6) Pg. 1559	Title, Chemical Info/Chemical Structure, Chemical Info/C49H66N10010S2·xC2H402, 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-lysyl-I-threonyl- N-[(1R,2R)-2-hydroxy-1-(hydroxymethyl)propyl]-I-cysteinamide cyclic	<u>Thomas</u> Sigambris

		(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/D2Rakaging 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	
New	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	<u>Maged</u> <u>Sharaf</u>
Revision	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	<u>Ahalya Wis</u>
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 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,	<u>Hariram</u> <u>Ramanath</u> a

		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/V3P Reference Standards <11>/USP Quetiapine Fumarate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Quetiapine System Suitability RS	
New	QUINAPRIL AND HYDROCHLOROTHIAZIDE TABLETS PF 37(6) Pg. ONLINE	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 Benzothiadiazine Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Hydrochlorothiazide RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Quinapril Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Hydrochlorothiazide RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Quinapril Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Quinapril Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Quinapril Related Compound B RS	<u>Sujatha</u> <u>Ramakrish</u>
New	ROPINIROLE HYDROCHLORIDE PF 36(1) Pg. 133	IMPURITIES/Organic Impurities /Procedure 1, IMPURITIES/Organic Impurities /Procedure 2, ADDITIONAL REQUIREMENTS/Labeling	<u>Hariram</u> <u>Ramanath</u> a
New	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>	<u>Fouad Atoι</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>	<u>Fouad Atoı</u>
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>	<u>Fouad Atoเ</u>
Revision	SENNOSIDES PF 35(2) Pg. 309	SPECIFIC TESTS/Content of Sennosides A and B, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>	<u>Maged</u> Sharaf
New	SERTRALINE HYDROCHLORIDE PF 34(5) Pg. 1189	Related compounds	<u>Hariram</u> <u>Ramanath</u> a

New	SPIRULINA PF 37(6) Pg. ONLINE	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/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/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/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 Palmitate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methyl Palmitoleate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methyl Stearate RS	<u>Maged</u> <u>Sharaf</u>
New	SPIRULINA TABLETS 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, STRENGTH/Content of Protein, PERFORMANCE TESTS/Weight Variation <2091>, CONTAMINANTS/Limit of Microcystins, CONTAMINANTS/Elemental Contaminants <2233>, CONTAMINANTS/Elemental Contaminants <2233>, CONTAMINANTS/Atricles 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 Palmitoleate 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	<u>Maged</u> <u>Sharaf</u>
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	<u>Rick Schna</u>
New	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(C12H2006260.28)	<u>Hariram</u> <u>Ramanath</u> a

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 REQUIREMENTS/USP Reference Standards <11>/USP Torsemide Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Torsemide REQUIREMENTS/USP Reference Standards <11>/USP	<u>Sujatha</u> <u>Ramakrish</u>
Revision	TROSPIUM CHLORIDE PF 38(1) Pg. ONLINE	IMPURITIES/Limit of Trospium Chloride Related Compound C	<u>Elena</u> Gonikberg
Revision	VALGANCICLOVIR HYDROCHLORIDE PF 36(4) Pg. 935	IMPURITIES/Organic Impurities/Procedure 3, SPECIFIC TESTS/Enantiomeric Purity of Valganciclovir	<u>Leonel</u> <u>Santos</u>