

Compendial Deferrals for USP36-NF31, Second 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	Kahkashan Zaidi
New	<7> LABELING PF 38(1) Pg. ONLINE	Title, DEFINITION, LABELS AND LABELING	Donna Bohannon
Revision	<31> VOLUMETRIC APPARATUS PF 37(2) Pg. ONLINE	USE—, STANDARDS OF ACCURACY—	Horacio Pappa
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	Kahkashan Zaidi
Revision	<621> CHROMATOGRAPHY PF 38(2) Pg. ONLINE	GENERAL PROCEDURES, SYSTEM SUITABILITY	Horacio Pappa
New	<735> X-RAY FLUORESCENCE SPECTROMETRY PF 38(5) Pg. ONLINE	Title, INTRODUCTION, QUALIFICATION OF XRF SPECTROMETERS, PROCEDURE, VALIDATION AND VERIFICATION	Kahkashan 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	Rick Schnatz
New	<852> ATOMIC ABSORPTION SPECTROSCOPY PF 37(5) Pg. ONLINE	Title, INTRODUCTION, QUALIFICATION OF ATOMIC ABSORPTION SPECTROPHOTOMETERS, PROCEDURE, VALIDATION AND VERIFICATION	Horacio Pappa
New	<854> MID-INFRARED SPECTROSCOPY PF 37(5) Pg. ONLINE	Title, INTRODUCTION, QUALIFICATION OF IR SPECTROPHOTOMETERS, PROCEDURE, VALIDATION AND VERIFICATION	Horacio Pappa
New	<857> ULTRAVIOLET-VISIBLE SPECTROSCOPY PF 37(5) Pg. ONLINE	Title, INTRODUCTION, QUALIFICATION OF UV-VIS SPECTROPHOTOMETERS, PROCEDURE, VALIDATION AND VERIFICATION	Horacio Pappa

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	Desmond Hunt
New	<1094> 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	Margareth Marques
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	Horacio 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	Horacio Pappa
New	<1857> ULTRAVIOLET-VISIBLE SPECTROSCOPY - THEORY AND PRACTICE PF 37(5) Pg. ONLINE	Title, THEORY, INSTRUMENTATION, CALIBRATION, ANALYTICAL CONSIDERATIONS, OTHER SOURCES OF INFORMATION	Horacio Pappa
Revision	ACYCLOVIR PF 38(4) Pg. ONLINE	IMPURITIES/Ordinary Impurities <466>, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Acyclovir Related Compound A RS 2-[(2-Amino-6-oxo-1,6-dihydro-9H-purin-9-yl)methoxy]ethyl acetate.C10H13N5O4 267.24, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Acyclovir Related Compound F RS N-[9-[(2-Hydroxyethoxy)methyl]-6-oxo-6,9-dihydro-1H-purin-2-yl]acetamide.C10H13N5O4267.24, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Acyclovir Related Compound G RS 2-{ [2-(Acetylamino)-6-oxo-1,6-dihydro-9H-purin-9-yl]methoxy}ethyl acetate.C12H15N5O5309.28, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Acyclovir Related Compound L RS N2,9-Diacetylguanine.C9H9N5O3 235.20	Amanda Martin-Esker
New	ALBUTEROL EXTENDED-RELEASE TABLETS PF 38(4) Pg. ONLINE	Title, DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B. Ultraviolet Absorption <197U>, ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities, Procedure 1, IMPURITIES/Organic Impurities, Procedure 2, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards<11>/USP Albuterol Sulfate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards<11>/USP Albuterol Related Compound B RS, ADDITIONAL REQUIREMENTS/USP	Domenick Vicchio

		Reference Standards<11>/USP Albuterol Related Compound E RS, ADDITIONAL REQUIREMENTS/USP Reference Standards<11>/USP Levalbuterol Related Compound C RS, ADDITIONAL REQUIREMENTS/USP Reference Standards<11>/USP Levalbuterol Related Compound D RS	
New	ANASTROZOLE TABLETS PF 38(3) Pg. ONLINE	Title, DEFINITION/Introduction, 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	Feiwen Mao
New	ASTAXANTHIN ESTERS PF 38(5) Pg. ONLINE	Title, Chemical Info/Astaxanthin esters;, Chemical Info/Astaxanthin fatty acid esters;, Chemical Info/Fatty acid esters of (3S,3'S)-3,3′-dihydroxy-β,β-carotene-4,4′-dione., DEFINITION/Introduction, IDENTIFICATION/A. Thin Layer Chromaography, IDENTIFICATION/B. HPLC, ASSAY/Content of Total Astaxanthin, CONTAMINANTS/Elemental Impurities—Procedures <233>, CONTAMINANTS/Microbial Enumeration Tests <2021>, CONTAMINANTS/Absence of Specified Microorganisms <2022>, CONTAMINANTS/Pheophorbide Content, SPECIFIC TESTS/Water Determination, Method I <921>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Astaxanthin Esters from Haematococcus pluvialis RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Apocarotenal RS	Huy Dinh
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 Gonikberg
New	AZELASTINE HYDROCHLORIDE PF 38(5) Pg. ONLINE	Chemical Info/Chemical Structure, Chemical Info/C ₂₂ H ₂₄ ClN ₃ O·HCl, Chemical Info/418.36, Chemical Info/1(2H)-Phthalazinone, 4-[(4-chlorophenyl)methyl]-2-(hexahydro-1-methyl-1H-azepin-4-yl), monohydrochloride; ,	Domenick Vicchio

		Chemical Info/4-(p-Chlorobenzyl)-2-(hexahydro-1-methyl-1H-azepin-4-yl)-1(2H)-phthalazinone monohydrochloride, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., IDENTIFICATION/C. Identification Tests—General, Chloride <191>, ASSAY, ASSAY/Procedure, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Heavy Metals, Method II <231>, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Loss on Drying <731>, SPECIFIC TESTS/Acidity or Alkalinity, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Azelastine Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Azelastine Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Azelastine Related Compound D RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Azelastine Related Compound E RS	
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	CEFUROXIME AXETIL PF 38(4) Pg. ONLINE	IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Diastereoisomer Ratio, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Cefuroxime Axetil Delta-3 Isomers RS	Ahalya Wise
Revision	CEFUROXIME AXETIL TABLETS PF 38(4) Pg. ONLINE	IDENTIFICATION/A., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Cefuroxime Axetil Delta-3 Isomers RS	Ahalya Wise
Revision	CEPHALEXIN PF 38(5) Pg. ONLINE	ASSAY/Procedure, IMPURITIES/Organic Impurities, Procedure 1, IMPURITIES/Organic Impurities, Procedure 2, IMPURITIES/Procedure 2, ADDITIONAL REQUIREMENTS/Labeling	Ahalya Wise
Revision	CEPHALEXIN CAPSULES PF 38(5) Pg. ONLINE	IMPURITIES/Organic Impurities, Procedure 1, IMPURITIES/Organic Impurities, Procedure 2, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling	Ahalya Wise
Revision	CEPHALEXIN FOR ORAL SUSPENSION PF 38(5) Pg. ONLINE	ASSAY/Procedure, IMPURITIES/Organic Impurities	Ahalya Wise
Revision	CLONIDINE HYDROCHLORIDE PF 37(4) Pg. ONLINE	ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL	Sujatha

		REQUIREMENTS/USP Reference Standards <11>/USP Clonidine Related Compound A RS 1-Acetyl-2-(2,6-dichlorophenylamino)-2-(4,5-dihydroimidazole).C11H11Cl2N3O272.13	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	Sujatha Ramakrishna
Revision	DESCRIPTION AND SOLUBILITY PF 38(2) Pg. ONLINE	Memantine Hydrochloride, Rabeprazole Sodium, Moexipril Hydrochloride, Epoprostenol Sodium, Azelastine Hydrochloride, Starch	Sujatha Ramakrishna
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, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Dorzolamide Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Dorzolamide Related Compound D RS	Feiwen Mao
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,	Domenick Vicchio

		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	
Revision	ETHER PF 38(3) Pg. ONLINE	IMPURITIES/Limit of Low-Boiling Hydrocarbons	Domenick Vicchio
Revision	G##_Octreotide Acetate, PTA-5 PF 36(6) Pg. 1778	G##_ (Octreotide Acetate, PTA-5)	Edith Chang
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/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	Edith Chang
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	Edith Chang
Revision	L-ISOLEUCINE PF 37(6) Pg. ONLINE	Reagent Specification, l-Isoleucine	Behnam Davani
New	KRILL OIL PF 37(5) Pg. ONLINE	Title, DEFINITION/Introduction, IDENTIFICATION/A. Ultraviolet	Huy Dinh

Absorption <197U>, IDENTIFICATION/B. Fatty Acid Profile, IDENTIFICATION/C. Phospholipid profile, COMPOSITION/Content of EPA and DHA, COMPOSITION/Astaxanthin Esterification, COMPOSITION/Content of Astaxanthin, CONTAMINANTS/Fats and Fixed Oils <401>, CONTAMINANTS/Limit of Dioxins, Furans, and Polychlorinated Biphenyls, SPECIFIC TESTS/Fats and Fixed Oils, Acid Value <401>, SPECIFIC TESTS/Fats and Fixed Oils, Anisidine Value <401>, SPECIFIC TESTS/Fats and Fixed Oils, Peroxide Value <401>, SPECIFIC TESTS/Fats and Fixed Oils, Total Oxidation Value (TOTOX) <401>, SPECIFIC TESTS/Fats and Fixed Oils, Unsaponifiable Matter <401>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Astaxanthin Esters from Haematococcus pluvialis RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Astaxanthin (Synthetic) RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Docosahexaenoic Acid Ethyl Ester RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Eicosapentaenoic Acid Ethyl Ester RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Krill Oil RS, 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 COMPOUNDED 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](#)

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 LOPINAVIR AND RITONAVIR ORAL SOLUTION PF 38(4) Pg. ONLINE

Title, DEFINITION/Introduction, IDENTIFICATION/A., ASSAY/Lopinavir and Ritonavir, PERFORMANCE TESTS/Deliverable

[Behnam Davani](#)

Volume <698>, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Alcohol Determination <611>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Alcohol Determination–Alcohol RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Lopinavir RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ritonavir RS

Chemical Info/Chemical Structure, Chemical Info/C₁₂H₂₁NċHCl, Chemical Info/215.76, Chemical Info/Tricyclo[3.3.1.1^{3,7}]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 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

New MEMANTINE HYDROCHLORIDE PF 38(2) Pg. ONLINE

[Ravi Ravichandran](#)

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

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

[Ravi Ravichandran](#)

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

Title, Chemical Info/Chemical Structure, Chemical Info/C₂₇H₃₄N₂O₇·HCl, 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., 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

[Sujatha Ramakrishna](#)

New MOEXIPRIL HYDROCHLORIDE PF 38(3) Pg. ONLINE

Title, DEFINITION/Introduction, IDENTIFICATION/A. Ultraviolet Absorption <197U>, 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 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

[Sujatha Ramakrishna](#)

New MOEXIPRIL HYDROCHLORIDE TABLETS PF 38(4) Pg. ONLINE

		Reference Standards <11>/USP Moexipril Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Moexipril Related Compound G RS	
New	MOEXIPRIL HYDROCHLORIDE AND HYDROCHLOROTHIAZIDE TABLETS PF 38(4) 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 Benzothiadiazine Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Chlorothiazide RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Hydrochlorothiazide 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 G RS	Sujatha Ramakrishna
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	Clydewyn Anthony
Revision	OCTINOXATE PF 38(5) Pg. ONLINE	ASSAY/Procedure, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Benzyl Benzoate RS Benzoic acid, phenylmethyl ester.C14H14O2212.24	Feiwen Mao
New	OCTREOTIDE ACETATE PF 36(6) Pg. 1559	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	Edith Chang

		Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities/Procedure 1: Limit of Octreotide Acetate Related Compounds, IMPURITIES/Organic Impurities/Procedure 2: Limit of Trifluoroacetic acid (TFA), IMPURITIES/Organic Impurities/Procedure 3: Limit of Triethylamine, SPECIFIC TESTS/Amino acid content, SPECIFIC TESTS/Water Determination, Method I <921>, SPECIFIC TESTS/pH <791>, SPECIFIC TESTS/Acetic Acid Content <503>, SPECIFIC TESTS/Optical Rotation, Specific Rotation <781S>, SPECIFIC TESTS/Bacterial Endotoxins <85>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference standards <11>/USP Octreotide Acetate RS, ADDITIONAL REQUIREMENTS/USP Reference standards <11>/USP Octreotide Acetate (Non-Cyclic) System Suitability Marker RS, ADDITIONAL REQUIREMENTS/USP Reference standards <11>/USP Glacial Acetic Acid RS	
Revision	Pepsin PF 38(3) Pg. ONLINE	Pepsin	Margareth Marques
Revision	Pepsin, Purified PF 38(3) Pg. ONLINE	Reagent Specification, Pepsin, Purified	Margareth Marques
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 Reference Standards <11>/USP Powdered Phyllanthus amarus Extract RS	Maged Sharaf
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>	Clydewyn Anthony

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>	Clydewyn Anthony
New	QUETIAPINE TABLETS PF 38(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 Quetiapine Fumarate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Quetiapine System Suitability RS	Ravi Ravichandran
New	RABEPRAZOLE SODIUM PF 38(2) Pg. ONLINE	Title, Chemical Info/Chemical Structure, Chemical Info/C18H20N3NaO3S, Chemical Info/381.42, Chemical Info/ 1H-Benzimidazole, 2-[[[4-(3-methoxypropoxy)-3-methyl-2-pyridinyl]methyl]sulfinyl]-, sodium salt; , Chemical Info/2-[[[4-(3-Methoxypropoxy)-3-methyl-2-pyridyl]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	Elena Gonikberg
New	RABEPRAZOLE SODIUM DELAYED-RELEASE TABLETS PF 38(2) Pg. ONLINE	Title, DEFINITION/Introduction, IDENTIFICATION/A. Ultraviolet Absorption, IDENTIFICATION/B., 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 E RS	Elena Gonikberg

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, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>	Maged Sharaf
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/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
New	SPIRULINA TABLETS PF 37(6) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/A. Fatty Acids Profile,	Maged

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/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

[Sharaf](#)

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](#)