

Compendial Deferrals for USP37-NF32 1S

Category	Monograph Title	Monograph Section	Scientific Liaison
Revision	<7> LABELING PF 38(6) Pg. ONLINE	DEFINITION, LABELS AND LABELING FOR INJECTABLE PRODUCTS, LABELING FOR PRODUCTS AND OTHER CATEGORIES, GENERAL LABELING	Donna Bohannon
New	<129> ANALYTICAL PROCEDURES FOR RECOMBINANT THERAPEUTIC MONOCLONAL ANTIBODIES PF 39(3) Pg. ONLINE	Title, INTRODUCTION/Paragraph Text, INTRODUCTION/Size-Exclusion Chromatography, INTRODUCTION/Capillary SDS Electrophoresis (Reduced and Nonreduced), INTRODUCTION/Oligosaccharide Analysis—Analysis of N-Linked Oligosaccharides of Monoclonal Antibodies, INTRODUCTION/Oligosaccharide Analysis—Sialic acid Analysis	Anita Szajek
New	<202> IDENTIFICATION OF FIXED OILS BY THIN-LAYER CHROMATOGRAPHY PF 39(1) Pg. ONLINE	Title, Introduction, IDENTIFICATION, USP Reference Standards <11>, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>	Hong Wang
New	<227> 4-AMINOPHENOL IN ACETAMINOPHEN-CONTAINING DRUG PRODUCTS PF 39(3) Pg. ONLINE	INTRODUCTION/Introduction, INTRODUCTION/SOLUTION PREPARATIONS, INTRODUCTION/CHROMATOGRAPHIC METHOD, INTRODUCTION/ANALYSIS, INTRODUCTION/CHROMATOGRAPHIC ADJUSTMENTS	Clydewyn Anthony
Revision	<231> HEAVY METALS PF 39(1) Pg. ONLINE	Title, Introduction, SPECIAL REAGENTS, METHOD I, METHOD II, METHOD III	Kahkashan Zaidi
Revision	<341> ANTIMICROBIAL AGENTS--CONTENT PF 39(3) Pg. ONLINE	Introduction, GENERAL GAS CHROMATOGRAPHIC METHOD, POLAROGRAPHIC METHOD	Shankari Shivaprasad
Revision	<659> PACKAGING AND STORAGE REQUIREMENTS PF 38(6) Pg. ONLINE	GENERAL DEFINITIONS, INJECTION PACKAGING	Desmond Hunt
Revision	<671> CONTAINERS--PERFORMANCE TESTING PF 39(2) Pg. ONLINE	Introduction, MOISTURE PERMEATION, LIGHT TRANSMISSION TEST, INTRODUCTION, MOISTURE VAPOR TRANSMISSION, SPECTRAL TRANSMISSION	Desmond Hunt
New	<697> CONTAINER CONTENT FOR INJECTIONS PF 38(6) Pg. ONLINE	Introduction, DETERMINATION OF VOLUME OF INJECTION IN CONTAINERS	Desmond Hunt
Revision	<851> SPECTROPHOTOMETRY AND LIGHT-SCATTERING PF 39(3) Pg. ONLINE	Title, ULTRAVIOLET, VISIBLE, INFRARED, ATOMIC ABSORPTION, FLUORESCENCE, TURBIDIMETRY, NEPHELOMETRY, AND RAMAN MEASUREMENTLIGHT-SCATTERING, COMPARATIVE UTILITY OF SPECTRAL RANGES,	Horacio Pappa

THEORY AND TERMS, APPARATUS, PROCEDURE

New	<852> ATOMIC ABSORPTION SPECTROSCOPY PF 37(5) Pg. ONLINE	Title, INTRODUCTION, QUALIFICATION OF ATOMIC ABSORPTION SPECTROPHOTOMETERS, PROCEDURE, VALIDATION AND VERIFICATION	Horacio Pappa
New	<853> FLUORESCENCE SPECTROSCOPY PF 39(1) Pg. ONLINE	Title, INTRODUCTION, QUALIFICATION OF FLUORESCENCE INSTRUMENTS, QUALITATIVE AND QUANTITATIVE FLUORESCENCE MEASUREMENTS, GOOD SPECTROSCOPIC PRACTICE, 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	<1094> CAPSULES - DISSOLUTION TESTING AND RELATED QUALITY ATTRIBUTES PF 38(1) Pg. ONLINE	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	<1853> FLUORESCENCE SPECTROSCOPY - THEORY AND PRACTICE PF 39(1) Pg. ONLINE	Title, THEORY, INSTRUMENTATION, FACTORS THAT AFFECT QUANTITATION, CALIBRATION OF FLUORESCENCE INSTRUMENTS, PROCEDURE VALIDATION, APPENDIX: DEFINITIONS	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	GENERAL NOTICES TO USP-NF PF 39(1) Pg. ONLINE	5. MONOGRAPH COMPONENTS/5.60.30: Elemental Impurities	Todd Cecil

Revision	2 PERCENT NINHYDRIN TS PF 39(1) Pg. ONLINE	2% Ninhydrin pH 5.2 TS	Sujatha Ramakrishna
New	2,2,2-TRICHLOROETHANOL PF 39(3) Pg. ONLINE	2,2,2-Trichloroethanol	Shankari Shivaprasad
Revision	ACETAMINOPHEN CAPSULES PF 39(3) Pg. ONLINE	IMPURITIES/4-Aminophenol in Acetaminophen-Containing Drug Products <227>	Clydewyn Anthony
Revision	ACETAMINOPHEN ORAL SOLUTION PF 39(3) Pg. ONLINE	IMPURITIES/4-Aminophenol in Acetaminophen-Containing Drug Products <227>	Clydewyn Anthony
Revision	ACETAMINOPHEN FOR EFFERVESCENT ORAL SOLUTION PF 39(3) Pg. ONLINE	IMPURITIES/4-Aminophenol in Acetaminophen-Containing Drug Products <227>	Clydewyn Anthony
Revision	ACETAMINOPHEN SUPPOSITORIES PF 39(3) Pg. ONLINE	IMPURITIES/4-Aminophenol in Acetaminophen-Containing Drug Products <227>	Clydewyn Anthony
Revision	ACETAMINOPHEN ORAL SUSPENSION PF 39(3) Pg. ONLINE	IMPURITIES/Limit of 4-Aminophenol, IMPURITIES/4-Aminophenol in Acetaminophen-Containing Drug Products <227>	Clydewyn Anthony
Revision	ACETAMINOPHEN TABLETS PF 39(3) Pg. ONLINE	IMPURITIES/4-Aminophenol in Acetaminophen-Containing Drug Products <227>	Clydewyn Anthony
Revision	ACETAMINOPHEN EXTENDED-RELEASE TABLETS PF 39(3) Pg. ONLINE	IMPURITIES/ 4-Aminophenol in Acetaminophen-Containing Drug Products <227>	Clydewyn Anthony
Revision	ACETAMINOPHEN AND TRAMADOL HYDROCHLORIDE TABLETS PF 39(3) Pg. ONLINE	{Title} Tramadol Hydrochloride and Acetaminophen Tablets, DEFINITION/Introduction	Clydewyn Anthony
Revision	ADENINE PF 38(6) Pg. ONLINE	ASSAY/Procedure, IMPURITIES/Organic Impurities, IMPURITIES/Related Compounds, SPECIFIC TESTS/Nitrogen Content, Method II <461>	Huy Dinh
Revision	AMANTADINE HYDROCHLORIDE PF 39(3) Pg. ONLINE	ASSAY/Procedure, IMPURITIES/Organic Impurities	Shankari Shivaprasad
Revision	AMINO BENZOATE POTASSIUM PF 39(1) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/B., ASSAY/Procedure	Hillary Cai
Revision	AMINO BENZOATE SODIUM PF 39(1) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/B., ASSAY/Procedure	Hillary Cai
New	ARGATROBAN PF 39(3) Pg. ONLINE	Title, Chemical Info/Chemical Structure, Chemical Info/C23H36N6O5SċH2O, Chemical Info/526.65, Chemical Info/ 2-Piperidinecarboxylic acid, 1-[(S)-5-[(aminoiminomethyl)amino]-1-oxo-2-[[1,2,3,4-tetrahydro-3-	Sujatha Ramakrishna

methyl-8-quinoliny]sulfonyl]amino}pentyl]-4-methyl-, (2R,4R)-monohydrate; , Chemical Info/(2R,4R)-4-Methyl-1-{N2-[(1,2,3,4-tetrahydro-3-methyl-8-quinolyl)sulfonyl]-l-arginyl}pipercolic acid, monohydrate, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Heavy metals, Method II <231>, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Organic Impurities, IMPURITIES/Content of Argatroban Related Compound C, IMPURITIES/Content of Stereoisomers, SPECIFIC TESTS/Water Determination, Method Ia <921>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Argatroban RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Argatroban Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Argatroban Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Argatroban Related Compound C RS

Title, DEFINITION/Introduction, IDENTIFICATION/A., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Procedure for Artemether, IMPURITIES/Procedure for Lumefantrine, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Artemether RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Artemether Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Artemether Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Lumefantrine RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Lumefantrine Related Compound A RS

IDENTIFICATION/A. Procedure, IDENTIFICATION/B, IDENTIFICATION/B., ASSAY/Procedure, SPECIFIC TESTS/Melting Range or Temperature <741>

PERFORMANCE TESTS/Dissolution <711>, ADDITIONAL REQUIREMENTS/Labeling

Chemical Info/Chemical Structure, Chemical Info/C22H24CIN3O&middledot;HCl, Chemical Info/418.36,

New

ARTEMETHER AND LUMEFANTRINE TABLETS PF 39(1)
Pg. ONLINE

[Shankari Shivaprasad](#)

Revision

ASCORBYL PALMITATE PF 38(6) Pg. ONLINE

[Galina Holloway](#)

Revision

ASPIRIN DELAYED-RELEASE TABLETS PF 39(3) Pg.
ONLINE

[Hillary Cai](#)

New

AZELASTINE HYDROCHLORIDE PF 38(5) Pg. ONLINE

[Domenick Vicchio](#)

Chemical Info/1(2H)-Phthalazinone, 4-[(4-chlorophenyl)methyl]-2-(hexahydro-1-methyl-1H-azepin-4-yl), monohydrochloride; , 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

DEFINITION/Introduction, IDENTIFICATION/A., ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/pH <791>, SPECIFIC TESTS/Osmolality and Osmolarity <785>, SPECIFIC TESTS/Particulate Matter in Ophthalmic Solutions <789>, SPECIFIC TESTS/Sterility Tests <71>, 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 D RS

New

AZELASTINE HYDROCHLORIDE OPHTHALMIC SOLUTION PF 39(2) Pg. ONLINE

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New

BENZYLPARABEN PF 39(3) Pg. ONLINE

Benzylparaben

[Shankari Shivaprasad](#)

Revision

BROMPHENIRAMINE MALEATE PF 38(6) Pg. ONLINE

DEFINITION/Introduction, IDENTIFICATION/Ultraviolet Absorption <197U>, ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Melting Range or Temperature <741>, SPECIFIC TESTS/Optical Rotation, Specific Rotation <781>, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Chlorpheniramine Maleate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Chlorpheniramine Related Compound B RS,

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ADDITIONAL REQUIREMENTS/USP Reference Standards
<11>/USP Pheniramine Maleate RS

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>

DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197A> or <197K>, IDENTIFICATION/B., IDENTIFICATION/C., ASSAY/Procedure, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>

Chemical Info/Chondroitin, hydrogen sulfate, sodium salt, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B. Identification Tests—General, Sodium <191>, IDENTIFICATION/C. Specific Disaccharides, IDENTIFICATION/D. Specific Rotation, COMPOSITION/Content of Chondroitin Sulfate Sodium, COMPOSITION/Disaccharide Composition, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Chloride and Sulfate, Chloride <221>, IMPURITIES/Chloride and Sulfate, Sulfate <221>, IMPURITIES/Electrophoretic Purity, IMPURITIES/Limit of Protein, CONTAMINANTS/Elemental Impurities—Procedures <233>, CONTAMINANTS/Microbial Enumeration Tests <2021>, CONTAMINANTS/Absence of Specified Microorganisms <2022>, SPECIFIC TESTS/Clarity and Color of Solution, SPECIFIC TESTS/Optical Rotation, Specific Rotation <781S>, SPECIFIC TESTS/pH <791>, SPECIFIC TESTS/Loss on Drying <731>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Chondroitin Sulfate Sodium, Shark RS

DEFINITION/Introduction, IDENTIFICATION/C., ASSAY/Procedure, IMPURITIES/Organic Impurities, IMPURITIES/Limit of Morphine, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Codeine System Suitability Mixture C11 RS

Revision CALCIUM PANTOTHENATE PF 38(3) Pg. ONLINE

[Huy Dinh](#)

Revision CHOLESTEROL PF 39(3) Pg. ONLINE

[Galina Holloway](#)

New CHONDROITIN SULFATE, SHARK PF 38(6) Pg. ONLINE

[Huy Dinh](#)

Revision CODEINE PHOSPHATE PF 38(6) Pg. ONLINE

[Hillary Cai](#)

New	COSYNTROPIN PF 39(2) Pg. ONLINE	Title, Chemical Info/Chemical Structure, Chemical Info/C136H210N40O31S, Chemical Info/2933, Chemical Info/α1-24-Corticotropin, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B. Amino Acid Analysis, ASSAY/Procedure, IMPURITIES/Organic Impurities, Related Peptides, OTHER COMPONENTS/Acetic Acid in Peptides <503>, OTHER COMPONENTS/Trifluoroacetic Acid Content, SPECIFIC TESTS/Absorption <851>, SPECIFIC TESTS/Bacterial Endotoxins <85>, SPECIFIC TESTS/Microbial Enumeration Tests <61> and Tests for Specified Microorganisms <62>, SPECIFIC TESTS/Optical Rotation, Specific Rotation <781S>, SPECIFIC TESTS/Water Determination, Method 1c <921>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Cosyntropin Acetate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Endotoxin RS	Dale Schmidt
Revision	DESCRIPTION AND SOLUBILITY PF 38(2) Pg. ONLINE	Rabeprazole Sodium, Desloratadine, Dutasteride, Entecavir, Topotecan Hydrochloride, Epoprostenol Sodium, Argatroban, Mandelic Acid, Azelastine Hydrochloride	Elena Gonikberg
New	DESLORATADINE PF 39(2) Pg. ONLINE	Chemical Info/Chemical Structure, Chemical Info/C19H19CIN2, Chemical Info/310.82, Chemical Info/Benzo[5,6]cyclohepta[1,2-b]pyridine, 8-chloro-6,11-dihydro-11-(4-piperidinylidene)-, 5H-; , Chemical Info/8-Chloro-6,11-dihydro-11-(piperidin-4-ylidene)-5H-benzo[5,6]cyclohepta[1,2-b]pyridine, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Heavy Metals, Method II <231>, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Loss on Drying <731>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Desloratadine RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Desloratadine Related Compound A RS	Domenick Vicchio
Revision	DIETHYLTOLUAMIDE PF 39(2) Pg. ONLINE	IDENTIFICATION/A. Infrared Absorption <197S><197F>, IDENTIFICATION/B., ASSAY/Procedure	Shankari Shivaprasad
Revision	DIETHYLTOLUAMIDE TOPICAL SOLUTION PF 39(2) Pg.	IDENTIFICATION/B., ASSAY/Procedure	Shankari Shivaprasad

ONLINE

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](#)

New DUTASTERIDE PF 39(2) Pg. ONLINE

Chemical Info/Chemical Structure, Chemical Info/C27H30F6N2O2, Chemical Info/528.53, Chemical Info/(5 α ; ,17 β ;)-N-[2,5-Bis(trifluoromethyl)phenyl]-3-oxo-4-azaandrost-1-ene-17-carboxamide; , Chemical Info/ α ; , α ; , α ; , α ; \', α ; \', α ; \'-Hexafluoro-3-oxo-4-aza-5 α ; -androst-1-ene-17 β ; -carboxy-2\',5\'-xylidide, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K> or <197M>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Limit of Platinum, IMPURITIES/Limit of Residual solvents, IMPURITIES/Organic Impurities, Procedure 1, IMPURITIES/Organic Impurities, Procedure 2, SPECIFIC TESTS/Water Determination, Method Ic <921>, SPECIFIC TESTS/Optical Rotation, Specific Rotation <781S>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Dutasteride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Dutasteride Resolution Mixture RS

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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

[Anita Szajek](#)

<851>, OTHER COMPONENTS/Benzyl Alcohol Content (if Present), SPECIFIC TESTS/Bacterial Endotoxins Test <85>, SPECIFIC TESTS/Anti-Factor IIa Activity

Title, Chemical Info/Chemical Structure, Chemical Info/C₁₂H₁₅N₅O₃·H₂O, Chemical Info/295.29, Chemical Info/CAS, Chemical Info/6H-Purin-6-one, 2-amino-1,9-dihydro-9-[(1S,3R,4S)-4-hydroxy-3-(hydroxymethyl)-2-methylenecyclopentyl]-, monohydrate;, Chemical Info/9-[(1S,3R,4S)-4-Hydroxy-3-(hydroxymethyl)-2-methylenecyclopentyl]guanine monohydrate., Chemical Info/Anhydrous, Chemical Info/277.28 [142217-69-4]., DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B. Infrared Absorption <197>, ASSAY/Procedure, IMPURITIES/Organic Impurities, IMPURITIES/Limit of Entecavir Related Compound A, SPECIFIC TESTS/Water Determination, Method 1c <921>, SPECIFIC TESTS/Optical Rotation, Specific Rotation <781S>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Entecavir Monohydrate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Entecavir Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Entecavir System Suitability Mixture RS

[Shankari Shivaprasad](#)

New ENTECAVIR PF 39(2) Pg. ONLINE

Title, DEFINITION/Introduction, IDENTIFICATION/A., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Microbial Enumeration Tests <61> and Tests for Specified Microorganisms <62>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Entecavir Monohydrate RS

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New ENTECAVIR TABLETS PF 39(2) Pg. ONLINE

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;Δ²-valerate, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K> ,

[Domenick Vicchio](#)

New EPOPROSTENOL SODIUM PF 37(6) Pg. ONLINE

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

DEFINITION/Introduction, IDENTIFICATION/A., ASSAY/Procedure, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Water Determination, Method I <921>, SPECIFIC TESTS/Particulate Matter in Injections <788>, SPECIFIC TESTS/pH <791>, SPECIFIC TESTS/Bacterial Endotoxins Test <85>, SPECIFIC TESTS/Sterility Tests <71>, SPECIFIC TESTS/Constituted solution, SPECIFIC TESTS/Other requirements, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Epoprostenol Sodium RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Epoprostenol Related Compound A RS

DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B. Infrared Absorption <197S>, ASSAY/Procedure, PERFORMANCE TESTS/Drug Release <724>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities, Procedure 1, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Fentanyl RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Fentanyl Citrate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Fentanyl Related Compound E RS

Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A., IMPURITIES/Fats and Fixed Oils, Trace Metals <401>, SPECIFIC TESTS/Fats and Fixed Oils, Acid Value <401>, SPECIFIC TESTS/Fats and Fixed Oils, Peroxide Value

New EPOPROSTENOL FOR INJECTION PF 38(6) Pg. ONLINE

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New FENTANYL TRANSDERMAL SYSTEM PF 38(6) Pg. ONLINE

[Hillary Cai](#)

New FLAX OIL PF 39(1) Pg. ONLINE

[Huy Dinh](#)

<401>, SPECIFIC TESTS/Fats and Fixed Oils, Iodine Value
<401>, SPECIFIC TESTS/Fats and Fixed Oils, Saponification
Value <401>, SPECIFIC TESTS/Fats and Fixed Oils,
Unsaponifiable Matter <401>, SPECIFIC TESTS/Fats and Fixed
Oils, Fatty Acid Composition <401>, SPECIFIC
TESTS/Refractive Index <831>, ADDITIONAL
REQUIREMENTS/Packaging and Storage

{Title} Fluconazole in Dextrose Injection,
DEFINITION/Introduction, IDENTIFICATION/B. Test for
Dextrose, ASSAY/Procedure, IMPURITIES/Introduction,
IMPURITIES/Organic Impurities, IMPURITIES/Procedure 2: For
Polar Impurities, IMPURITIES/Organic Impurities: Procedure 3,
IMPURITIES/Organic Impurities: Procedure 4, ADDITIONAL
REQUIREMENTS/Labeling

[Shankari
Shivaprasad](#)

Revision FLUCONAZOLE INJECTION PF 39(2) Pg. ONLINE

Title, DEFINITION/Introduction, IDENTIFICATION/A.,
IDENTIFICATION/B. Identification Tests—General,
Sodium <191> and Chloride <191>, ASSAY/Procedure,
IMPURITIES/Organic Impurities, SPECIFIC TESTS/Sterility Tests
<71>, SPECIFIC TESTS/Bacterial Endotoxins Test <85>,
SPECIFIC TESTS/Other Requirements, ADDITIONAL
REQUIREMENTS/Packaging and Storage, ADDITIONAL
REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP
Reference Standards <11>/USP Endotoxin RS, ADDITIONAL
REQUIREMENTS/USP Reference Standards <11>/USP
Fluconazole RS

[Shankari
Shivaprasad](#)

New FLUCONAZOLE IN SODIUM CHLORIDE INJECTION PF
39(2) Pg. ONLINE

IMPURITIES/Limit of Urea, ADDITIONAL REQUIREMENTS/USP
Reference Standards <11>/USP Urea RS

[Feiwen Mao](#)

Revision FLUOROURACIL INJECTION PF 39(3) Pg. ONLINE

G## (Octreotide Acetate, PTA-5)

[Edith Chang](#)

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

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

[Hillary Cai](#)

Revision HYDROCODONE BITARTRATE PF 39(3) Pg. ONLINE

DEFINITION/Introduction, IDENTIFICATION/Ultraviolet
Absorption <197U>, IDENTIFICATION/C., ASSAY/Procedure,
IMPURITIES/Limit of Cyanocobalamin, IMPURITIES/Related

[Huy Dinh](#)

Revision HYDROXOCOBALAMIN PF 39(1) Pg. ONLINE

Compounds, SPECIFIC TESTS/pH-Dependent Cobalamins, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>

IDENTIFICATION/B., IDENTIFICATION/C. Thin-Layer Chromatographic Identification Test <201>, IDENTIFICATION/D. Procedure, ASSAY/Procedure, IMPURITIES/ Limit of Ionic Compounds, IMPURITIES/Free Iodine, IMPURITIES/Limit of Free Iodide, IMPURITIES/Organic Impurities, IMPURITIES/ Limit of methanol, isopropyl alcohol, and methoxyethanol, IMPURITIES/Limit of 3-Chloro-1,2-propanediol, IMPURITIES/Limit of 3-Chloropropane-1,2-diol, IMPURITIES/Limit of Free Aromatic amine, SPECIFIC TESTS/Optical Rotation, Specific Rotation <781S>, ADDITIONAL REQUIREMENTS/Packaging and Storage

[Ravi Ravichandran](#)

Revision IOHEXOL PF 39(3) Pg. ONLINE

Revision L##_Adenine, GC <227>, Acclaim Mixed-Mode WCX-1 PF 39(3) Pg. ONLINE

L##_ (Adenine, GC <227>, Acclaim Mixed-Mode WCX-1), L##_ (Adenine, Acclaim Mixed-Mode WCX-1)

[Clydewyn Anthony](#)

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

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

[Edith Chang](#)

Title, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197M>, 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 Lamivudine RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Lamivudine Resolution Mixture B RS

[Shankari Shivaprasad](#)

New LAMIVUDINE TABLETS PF 39(1) Pg. ONLINE

Chemical Info/(−)-(S)-9-Fluoro-2,3-dihydro-3-methyl-10-(4-methyl-1-piperazinyl)-7-oxo-7H-pyrido[1,2,3-de]-1,4-[1,4]benzoxazine-6-carboxylic acid, hemihydrate, IMPURITIES/Paragraph Text, IMPURITIES/Organic Impurities, Procedure 1, IMPURITIES/Organic Impurities, Procedure 2, IMPURITIES/Organic Impurities (Enantiomeric Purity), Procedure 3, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Levofloxacin Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Levofloxacin Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Levofloxacin Related Compound D RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP R-

[Shankari Shivaprasad](#)

Revision LEVOFLOXACIN PF 39(2) Pg. ONLINE

Ofloxacin RS

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

[Shankari Shivaprasad](#)

Title, Chemical Info/Chemical Structure, Chemical Info/C8H8O3, Chemical Info/152.15, Chemical Info/Benzeneacetic acid, α-hydroxy-; , Chemical Info/(RS)-2-Hydroxy-2-phenylacetic acid; , Chemical Info/(±)-α-Hydroxyphenylacetic acid; , Chemical Info/2-Hydroxy-2-phenylacetic acid, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Heavy Metals, Method II <231>, IMPURITIES/Limit of Benzoylformic Acid, Benzaldehyde, Benzoic Acid, and Acetophenone, IMPURITIES/Limit of Chloride, SPECIFIC TESTS/Melting Range or Temperature <741>, SPECIFIC TESTS/Water Determination, Method Ia <921>, SPECIFIC TESTS/Turbidity, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Benzaldehyde RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Benzoic Acid RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Mandelic Acid RS

[Hong Wang](#)

m-Cresol

DEFINITION/Introduction, IDENTIFICATION/B. Ultraviolet Absorption <197U>, IDENTIFICATION/B., IDENTIFICATION/C., ASSAY/Procedure, IMPURITIES/Limit of 3-O-Methylmethyldopa, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP 3-O-Methylmethyldopa RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methyldopa Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards

[Shankari Shivaprasad](#)

[Sujatha Ramakrishna](#)

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

New MANDELIC ACID PF 38(6) Pg. ONLINE

New M-CRESOL PF 39(3) Pg. ONLINE

Revision METHYLDOPA PF 39(2) Pg. ONLINE

<11>/USP Methyldopa Related Compound C RS

DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197M>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Metoprolol Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Metoprolol Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Metoprolol Related Compound C RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Metoprolol Related Compound D RS

[Sujatha Ramakrishna](#)

Revision METOPROLOL TARTRATE PF 39(1) Pg. ONLINE

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](#)

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

DEFINITION/Introduction, IDENTIFICATION/A., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Naproxen Sodium Related Impurities, IMPURITIES/Pseudoephedrine Hydrochloride Related Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Naproxen Sodium RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Pseudoephedrine Hydrochloride RS

[Hillary Cai](#)

New NAPROXEN SODIUM AND PSEUDOEPHEDRINE HYDROCHLORIDE EXTENDED-RELEASE TABLETS PF 38(6) Pg. ONLINE

DEFINITION/Introduction, IDENTIFICATION/C., ASSAY/Procedure, IMPURITIES/Ordinary Impurities <466>, IMPURITIES/Related Compounds, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP 6-Hydroxynicotinic Acid RS

[Huy Dinh](#)

Revision NIACIN PF 39(1) Pg. ONLINE

Title, Chemical Info/Chemical Structure, Chemical Info/C49H66N10O10S2·xC2H4O2, Chemical Info/I-

[Edith Chang](#)

New OCTREOTIDE ACETATE PF 36(6) Pg. 1559

Cysteinamide, d-phenylalanyl-l-cysteinyl-l-phenylalanyl-d-tryptophyl-l-lysyl-l-threonyl-N-[2-hydroxy-1-(hydroxymethyl)propyl]-, cyclic (2→7)-disulfide, [R-(R*,R*)]-, acetate (salt);, Chemical Info/d-Phenylalanyl-l-cysteinyl-l-phenylalanyl-d-tryptophyl-l-lysyl-l-threonyl-N-[(1R,2R)-2-hydroxy-1-(hydroxymethyl)propyl]-l-cysteinamide cyclic (2→7)-disulfide acetate (salt);, Chemical Info/d-Phenylalanyl-l-hemicystyl-l-phenylalanyl-d-tryptophyl-l-lysyl-l-threonyl-l-hemicystyl-l-threoninol cyclic (2→7)-disulfide acetate (salt)., Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities/Procedure 1: Limit of Octreotide Acetate Related Compounds, IMPURITIES/Organic Impurities/Procedure 2: Limit of Trifluoroacetic acid (TFA), IMPURITIES/Organic Impurities/Procedure 3: Limit of Triethylamine, SPECIFIC TESTS/Amino acid content, SPECIFIC TESTS/Water Determination, Method I <921>, SPECIFIC TESTS/pH <791>, SPECIFIC TESTS/Acetic Acid Content <503>, SPECIFIC TESTS/Optical Rotation, Specific Rotation <781S>, SPECIFIC TESTS/Bacterial Endotoxins <85>, ADDITIONAL REQUIREMENTS/Packaging 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](#)

Revision PHENYTOIN SODIUM PF 39(2) Pg. ONLINE

IDENTIFICATION/A. Procedure, IDENTIFICATION/A. Infrared Absorption—General <197K>, IDENTIFICATION/B. Identification Tests—General, Sodium <191>, IDENTIFICATION/C., IMPURITIES/Organic Impurities, SPECIFIC TESTS/Clarity and Color of Solution, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Phenytoin Sodium RS

[Ravi Ravichandran](#)

New POWDERED PHYLLANTHUS AMARUS EXTRACT PF 36(6) Pg. 1622

DEFINITION/Introduction, IDENTIFICATION/A. Thin-Layer Chromatographic Identification Test <201>,

[Anton Bzhelyansky](#)

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

Revision PRAZOSIN HYDROCHLORIDE PF 39(3) Pg. ONLINE

IMPURITIES/Heavy Metals, Method II <231>

[Sujatha Ramakrishna](#)

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>

[Hillary Cai](#)

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>

[Hillary Cai](#)

Revision PROPOXYPHENE NAPSYLATE PF 39(2) Pg. ONLINE

Chemical Info/Chemical Structure, Chemical Info/(αS,1R)-α-[2-(Dimethylamino)-1-methylethyl]-α-phenylphenethyl propionate compound with 2-naphthalenesulfonic acid (1:1) monohydrate(2S,3R)-(+)-4-(Dimethylamino)-3-methyl-1,2-diphenyl-2-butanol propionate (ester) 2-naphthalenesulfonate (1:1) monohydrate, IDENTIFICATION/B. Ultraviolet Absorption <197U>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Melting Range or Temperature, Class I <741>, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Propoxyphene Related Compound A RS

[Hillary Cai](#)

New	RABEPRAZOLE SODIUM PF 38(2) Pg. ONLINE	<p>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&mdash;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</p>	Elena Gonikberg
New	<p>RABEPRAZOLE SODIUM DELAYED-RELEASE TABLETS PF 38(2) Pg. ONLINE</p>	<p>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</p>	Elena Gonikberg
New	RHODIOLA ROSEA PF 39(3) Pg. ONLINE	<p>DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B. Thin-Layer Chromatography, IDENTIFICATION/C. HPLC, COMPOSITION/Content of Phenylpropanoid Glycosides and Salidroside, CONTAMINANTS/Elemental Impurities&mdash;Procedures <233>, CONTAMINANTS/Articles of Botanical Origin, General Method for Pesticide Residues Analysis <561>, CONTAMINANTS/Microbial Enumeration Tests <2021>, CONTAMINANTS/Absence of Specified Microorganisms <2022>, CONTAMINANTS/Articles of Botanical Origin, Test for Aflatoxins <561>, SPECIFIC TESTS/Botanic Characteristics, SPECIFIC TESTS/Articles of Botanical Origin, Foreign Organic Matter</p>	Anton Bzhelyansky

<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 Powdered Rhodiola rosea Extract RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Rosavin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Salidroside RS

DEFINITION/Introduction, IDENTIFICATION/A. Thin-Layer Chromatography, IDENTIFICATION/C. HPLC, COMPOSITION/Content of Phenylpropenoid Glycosides and Salidroside, OTHER COMPONENTS/Alcohol Determination, Method I <611>, CONTAMINANTS/Articles of Botanical Origin, General Method for Pesticide Residues Analysis <561>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Powdered Rhodiola rosea Extract RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Rosavin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Salidroside RS

DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B. Thin-Layer Chromatography, IDENTIFICATION/C. HPLC, COMPOSITION/Content of Phenylpropenoid Glycosides and Salidroside, CONTAMINANTS/Elemental Impurities—Procedures <233>, CONTAMINANTS/Articles of Botanical Origin, General Method for Pesticide Residues Analysis <561>, CONTAMINANTS/Microbial Enumeration Tests <2021>, CONTAMINANTS/Absence of Specified Microorganisms <2022>, CONTAMINANTS/Articles of Botanical Origin, Test for Aflatoxins <561>, SPECIFIC TESTS/Botanic Characteristics, 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 Powdered Rhodiola rosea Extract RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Rosavin RS

New RHODIOLA ROSEA TINCTURE PF 39(3) Pg. ONLINE

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New POWDERED RHODIOLA ROSEA PF 39(3) Pg. ONLINE

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New

POWDERED RHODIOLA ROSEA EXTRACT PF 39(3) Pg. ONLINE

DEFINITION/Introduction, IDENTIFICATION/A. Thin-Layer Chromatography, IDENTIFICATION/B. HPLC, COMPOSITION/Content of Phenylpropanoid Glycosides and Salidroside, CONTAMINANTS/Elemental Impurities—Procedures <233>, CONTAMINANTS/Articles of Botanical Origin, General Method for Pesticide Residues Analysis <561>, CONTAMINANTS/Microbial Enumeration Tests <2021>, CONTAMINANTS/Absence of Specified Microorganisms <2022>, CONTAMINANTS/Articles of Botanical Origin, Test for Aflatoxins <561>, SPECIFIC TESTS/Loss on Drying <731>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Powdered Rhodiola rosea Extract RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Rosavin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Salidroside RS

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Revision

RISPERIDONE PF 39(3) Pg. ONLINE

ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Risperidone Related Compound G RS

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New

ROSEMARY PF 39(1) Pg. ONLINE

DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B. Thin-Layer Chromatography, IDENTIFICATION/C. HPLC, COMPOSITION/Content of Phenolic Diterpenes, COMPOSITION/Volatile Oil Content <561>, CONTAMINANTS/Elemental Impurities—Procedures <233>, 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/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 Carnosic Acid RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Powdered Rosemary Hydrophilic Extract RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Rosmarinic Acid RS

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DEFINITION/Introduction, IDENTIFICATION/A. Thin-Layer Chromatography, IDENTIFICATION/B. HPLC, COMPOSITION/Content of Rosmarinic Acid, CONTAMINANTS/Elemental Impurities—Procedures <233>, 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>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Powdered Rosemary Hydrophilic Extract RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Rosmarinic Acid RS

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DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B. Thin-Layer Chromatography, IDENTIFICATION/C. HPLC, COMPOSITION/Content of Phenolic Diterpenes, CONTAMINANTS/Elemental Impurities—Procedures <233>, 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/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 Carnosic Acid RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Powdered Rosemary Hydrophilic Extract RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Rosmarinic Acid RS

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IDENTIFICATION/C. Identification Tests—General, Chloride <191>, ASSAY/Procedure, IMPURITIES/Limit of (R,R) Sertraline Hydrochloride, IMPURITIES/Organic Impurities, Procedure 1, IMPURITIES/Organic Impurities, Procedure 2, IMPURITIES/Limit of Mandelic Acid, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Benzoic Acid RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Mandelic Acid RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP

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New

POWDERED ROSEMARY HYDROPHILIC EXTRACT PF 39(1) Pg. ONLINE

New

POWDERED ROSEMARY PF 39(1) Pg. ONLINE

Revision

SERTRALINE HYDROCHLORIDE PF 39(3) Pg. ONLINE

Sertraline Hydrochloride Related Compound A RS

Title, Chemical Info/Chemical Structure, Chemical Info/[(C3H7N)m(C3H5ClO)n]ċxCH2O3., Chemical Info/Carbonic acid, compound with (chloromethyl)oxirane polymer with 2-propen-1-amine;, Chemical Info/Prop-2-en-1-amine polymer with (chloromethyl)oxirane carbonate, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197A>, ASSAY/Total Titratable Amines <541>, ASSAY/Carbonate Content, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Heavy Metals, Method II <231>, IMPURITIES/Limit of Chloride, IMPURITIES/Limit of Epichlorohydrin, IMPURITIES/Limit of Soluble Oligomers, IMPURITIES/Limit of Allyl Amine, SPECIFIC TESTS/Loss on Drying, SPECIFIC TESTS/Swell Index, SPECIFIC TESTS/Particle Size Determination, Light Diffraction Measurement of Particle Size <429>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Polyallylamine Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Sevelamer Carbonate RS

[Sujatha Ramakrishna](#)

Title, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197A>, ASSAY/Total Titratable Amines, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Limit of Soluble Oligomers, IMPURITIES/Limit of Allylamine, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Polyallylamine RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Sevelamer Carbonate RS

[Sujatha Ramakrishna](#)

Title, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197A>, ASSAY/Total Titratable Amines <541>, PERFORMANCE TESTS/Disintegration <701>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Limit of Soluble Oligomers, IMPURITIES/Limit of Allylamine, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Polyallylamine Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Sevelamer Carbonate RS

[Sujatha Ramakrishna](#)

Title, Chemical Info/Chemical Structure, Chemical

[Sujatha Ramakrishna](#)

New	SEVELAMER CARBONATE PF 38(6) Pg. ONLINE
New	SEVELAMER CARBONATE FOR ORAL SUSPENSION PF 38(6) Pg. ONLINE
New	SEVELAMER CARBONATE TABLETS PF 38(6) Pg. ONLINE
New	SEVELAMER HYDROCHLORIDE PF 38(6) Pg. ONLINE

Info/(C3H7N)m(C3H5ClO)n·xHCl, Chemical Info/2-Propen-1-amine polymer with (chloromethyl)oxirane, hydrochloride; , Chemical Info/Allylamine polymer with 1-chloro-2,3-epoxypropane, hydrochloride, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197A>, ASSAY/Total Titratable Amines, ASSAY/Chloride Content, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Heavy Metals, Method II <231>, IMPURITIES/Limit of Epichlorohydrin, IMPURITIES/Limit of Soluble Oligomers, IMPURITIES/Limit of Allyl Amine, SPECIFIC TESTS/Loss on Drying <731>, SPECIFIC TESTS/Swell Index, SPECIFIC TESTS/Particle Size Determination, Light Diffraction Measurement of Particle Size <429>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Polyallylamine RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Sevelamer Hydrochloride RS

Title, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197A>, ASSAY/Total Titratable Amines <541>, PERFORMANCE TESTS/Disintegration <701>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Limit of Soluble Oligomers, IMPURITIES/Limit of Allylamine, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Polyallylamine Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Sevelamer Hydrochloride RS

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

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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

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/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

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New SPIRULINA TABLETS PF 37(6) Pg. ONLINE

DEFINITION/Introduction, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Chromatographic Purity

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Revision SQUALANE PF 38(6) Pg. ONLINE

IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., ASSAY/Procedure, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Fumaric Acid RS

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Revision SUCCINIC ACID PF 39(2) Pg. ONLINE

Revision	THIORIDAZINE HYDROCHLORIDE PF 39(1) Pg. ONLINE	Chemical Info/Chemical Structure, DEFINITION/Introduction, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Melting Range or Temperature <741>, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Thioridazine Related Compound F RS	Ravi Ravichandran
New	TOPOTECAN HYDROCHLORIDE PF 39(1) Pg. ONLINE	Chemical Info/Chemical Structure, Chemical Info/C23H23N3O5·HCl, Chemical Info/457.91 (n = 1), Chemical Info/1H-Pyrano[3′,4′:6,7]indolizino[1,2-b]quinoline-3,14(4H,12H)-dione, 10-[(dimethylamino)methyl]-4-ethyl-4,9-dihydroxy-, monohydrochloride, (S)-; , Chemical Info/(S)-10-[(Dimethylamino)methyl]-4-ethyl-4,9-dihydroxy-1H-pyrano[3′,4′:6,7]indolizino[1,2-b]quinoline-3,14(4H,12H)-dione monohydrochloride; , Chemical Info/CAS, Chemical Info/5/4 Hydrochloride, Chemical Info/C23H23N3O5·5/4 HCl, Chemical Info/467.02 (n = 5/4), Chemical Info/Topotecan, Chemical Info/C23H23N3O5, Chemical Info/421.45, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., IDENTIFICATION/C., ASSAY/Procedure, OTHER COMPONENTS/Content of Chloride, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Heavy Metals, Method II <231>, IMPURITIES/Organic Impurities, IMPURITIES/Limit of Methanol and Acetone (if it is present in the manufacturing process), IMPURITIES/Limit of Triethylamine (if it is present in the manufacturing process), SPECIFIC TESTS/Water Determination, Method Ia <921>, SPECIFIC TESTS/Specific Rotation <781S>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Topotecan Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Topotecan Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Triethylamine RS	Feiwen Mao
New	TOPOTECAN FOR INJECTION PF 39(1) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/A. Ultraviolet Absorption <197U>, IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Bacterial Endotoxins Test <85>, SPECIFIC TESTS/Sterility Tests <71>, SPECIFIC TESTS/pH <791>, SPECIFIC TESTS/Particulate Matter in Injections <788>, SPECIFIC TESTS/Constituted	Feiwen Mao

Solution, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Endotoxin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Irinotecan Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Topotecan Hydrochloride RS

Title, DEFINITION/Introduction, IDENTIFICATION/A., 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 Trandolapril RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Trandolapril Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Verapamil Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Verapamil Related Compound B RS

New TRANDOLAPRIL AND VERAPAMIL HYDROCHLORIDE EXTENDED-RELEASE TABLETS PF 38(6) Pg. ONLINE

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Revision USP AND NF EXCIPIENTS, LISTED BY CATEGORY PF 38(6) Pg. ONLINE

{Antimicrobial Preservative} Mandelic Acid

[Hong Wang](#)

Revision WARFARIN SODIUM PF 39(2) Pg. ONLINE

IMPURITIES/Organic Impurities

[Feiwen Mao](#)