

Compendial Approvals for USP35–NF30, Second Supplement

Category	Monograph Title	Monograph Section	Scientific Liaison
Revision	<85> BACTERIAL ENDOTOXINS TEST Stage 6 Harmonization	Entire Document	Radhakrishna Tirumalai
New	<123> GLUCAGON BIOIDENTITY TESTS PF 37(4) Pg. ONLINE	DEFINITION/Introduction, ASSAY/Primary Liver Cell Assay, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>	Maura Kibbey
Revision	<232> ELEMENTAL IMPURITIES--LIMITS PF 37(3) Pg. ONLINE	INTRODUCTION, SPECIATION, ROUTES OF EXPOSURE, DRUG PRODUCTS, DRUG SUBSTANCE AND EXCIPIENTS, ANALYTICAL TESTING	Kahkashan Zaidi
Revision	<233> ELEMENTAL IMPURITIES - PROCEDURES PF 37(3) Pg. ONLINE	INTRODUCTION, COMPENDIAL PROCEDURES 1 AND 2, ALTERNATE PROCEDURE VALIDATION, LIMIT PROCEDURES, QUANTITATIVE PROCEDURES	Kahkashan Zaidi
Revision	<616> BULK DENSITY AND TAPPED DENSITY Stage 6 Harmonization	Entire Document	Kevin Moore
Revision	<696> CRYSTALLINITY DETERMINATION BY SOLUTION CALORIMETRY Stage 6 Harmonization	Entire Document	Kahkashan Zaidi
Revision	<911> VISCOSITY PF 37(4) Pg. ONLINE	{Title} Viscosity-CAPILLARY VISCOMETER METHODS, Introduction, Measurement of Viscosity, Procedure for Cellulose Derivatives, Calibration of Capillary-Type Viscosimeters, Calculations, Method I. Ubbelohde-Type Capillary Viscometer, Method II. Ostwald-Type Capillary Viscometer	Hong Wang
Revision	<912> ROTATIONAL RHEOMETER METHODS PF 37(4) Pg. ONLINE	Introduction, Method I. Spindle Rheometers (Relative Rheometers—Spindle Viscometers), Method II. Concentric Cylinder Rheometers, Method III. Cone-and-Plate Rheometers	Hong Wang
New	<913> ROLLING BALL VISCOMETER METHOD PF 37(5) Pg. ONLINE	Introduction, APPARATUS, MEASURING PRINCIPLE, PROCEDURE, CALCULATION AND CALIBRATION	Hong Wang
Revision	<1079> GOOD STORAGE AND SHIPPING PRACTICES PF 37(4) Pg. ONLINE	Introduction, PACKAGING AND STORAGE STATEMENT IN MONOGRAPHS, STORAGE IN WAREHOUSES, PHARMACIES, TRUCKS, SHIPPING DOCKS, AND OTHER LOCATIONS, DISTRIBUTION AND SHIPMENT OF PHARMACOPEIAL ARTICLES, SPECIAL HANDLING, SHIPMENT FROM MANUFACTURER TO WHOLESALER, SHIPMENT FROM MANUFACTURER OR WHOLESALER TO PHARMACY, SHIPMENT FROM PHARMACY TO PATIENT OR CUSTOMER, RETURNS OF PHARMACEUTICAL ARTICLES FROM PATIENTS OR CUSTOMERS, STORAGE OF PHYSICIAN SAMPLES	Desmond Hunt

		HANDLED BY SALES REPRESENTATIVES IN AUTOMOBILES, STABILITY, STORAGE, AND LABELING, STATEMENTS/LABELING OF THE IMMEDIATE CONTAINERS OR PACKAGE INSERT, INTRODUCTION, SCOPE, BACKGROUND INFORMATION, RESPONSIBILITIES, LABELING CONSIDERATIONS FOR DRUG PRODUCTS, QUALITY MANAGEMENT SYSTEM, CONCLUSION	
Revision	<1088> IN VITRO AND IN VIVO EVALUATION OF DOSAGE FORMS PF 37(5) Pg. ONLINE	Introduction, IN VITRO EVALUATION, IN VIVO EVALUATION OF MODIFIED-RELEASE DOSAGE FORMS, IN VITRO–IN VIVO CORRELATIONS, CORRELATION LEVELS, PURPOSE, SCOPE, BACKGROUND INFORMATION, IN VIVO EVALUATION OF DOSAGE FORMS, CHARACTERIZATION OF DRUG SUBSTANCE, CHARACTERIZATION OF THE DOSAGE FORM	William Brown
New	<1102> IMMUNOLOGICAL TEST METHODS -- GENERAL CONSIDERATIONS PF 37(4) Pg. ONLINE	INTRODUCTION, GENERAL CHARACTERISTICS OF ITMS, TYPES OF ITMS, CHOICE OF ITM, KEY CONSIDERATIONS IN ITM DEVELOPMENT, VALIDATION, DATA REPORTING	Maura Kibbey
New	<1103> IMMUNOLOGICAL TEST METHODS -- ENZYME-LINKED IMMUNOSORBENT ASSAY (ELISA) PF 37(5) Pg. ONLINE	INTRODUCTION, ASSAY DESIGN, CHOICE OF ASSAY, PROCEDURES, ASSAY DEVELOPMENT AND VALIDATION PLAN, DATA ANALYSIS, APPENDIX 1, APPENDIX 2	Maura Kibbey
Omission	<1150> PHARMACEUTICAL STABILITY PF 37(4) Pg. ONLINE	Entire document	Desmond Hunt
New	<1238> VACCINES FOR HUMAN USE -- BACTERIAL VACCINES PF 37(4) Pg. ONLINE	INTRODUCTION, RAW MATERIALS, CELL BANKS, FERMENTATION, PURIFICATION, INTERMEDIATES, DRUG SUBSTANCE, DRUG PRODUCT AND LOT RELEASE, OTHER REQUIREMENTS	Tina Morris
Revision	AMOXAPINE PF 37(5) Pg. ONLINE	IDENTIFICATION/A.Infrared Absorption <197K>, IDENTIFICATION/B., ASSAY/Procedure, SPECIFIC TESTS/Melting Range or Temperature, Class I <741>, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Loxapine Succinate RS	Ravi Ravichandran
New	ARTICAINE HYDROCHLORIDE AND EPINEPHRINE INJECTION PF 37(3) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/A., ASSAY/Articaine Hydrochloride, ASSAY/Epinephrine, PERFORMANCE TESTS/Deliverable Volume <698>, IMPURITIES/Organic Impurities, Limit of Articaine Related Compounds, IMPURITIES/Organic Impurities, Limit of Epinephrine Related Compounds, SPECIFIC TESTS/pH <791>, SPECIFIC TESTS/Bacterial Endotoxin Test <85>, SPECIFIC TESTS/Sterility <71>, SPECIFIC TESTS/Particulate Matter in Injections <788>, SPECIFIC TESTS/Other Requirements, ADDITIONAL REQUIREMENTS/Packaging and	Domenick Vicchio

		Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Articaine Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Articaine Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Endotoxin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Epinephrine Bitartrate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Norepinephrine Bitartrate RS	
Revision	ATRACURIUM BESYLATE PF 37(4) Pg. ONLINE	ASSAY/Procedure, IMPURITIES/Organic Impurities, IMPURITIES/Limit of Impurity J (Methyl Benzenesulfonate), IMPURITIES/Limit of Toluene	Ravi Ravichandran
Revision	ATRACURIUM BESYLATE INJECTION PF 37(4) Pg. ONLINE	ASSAY/Procedure, IMPURITIES/Organic Impurities	Ravi Ravichandran
Revision	AZITHROMYCIN FOR INJECTION PF 37(3) Pg. ONLINE	ASSAY/Procedure, IMPURITIES/Organic Impurities, Procedure 1: Limit of Azithromycin N-oxide, IMPURITIES/Introduction, IMPURITIES/Limit of Azithromycin N-Oxide, Desosaminylazithromycin and N-Demethylazithromycin, IMPURITIES/Organic Impurities, Procedure 2: Limit of Aminoazithromycin, Formamido Analog, Methylformamido Analog, and 3′-De(dimethylamino)-3′-oxoazithromycin (if present), ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Desosaminylazithromycin RS	Ahalya Wise
Revision	BENZYL ALCOHOL Stage 6 Harmonization	Entire Document	Kevin Moore
Revision	BETA CAROTENE PF 36(6) Pg. 1498	DEFINITION/Introduction, IDENTIFICATION/Procedure A., ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Beta Carotene System Suitability RS USP Beta Carotene RS (all-E)-1,1ε-(3,7,12,16-Tetramethyl-1,3,5,7,9,11,13,15,17-octadecanonaene-1,18-diyl)bis[2,6,6-trimethylcyclohexene], ASSAY/Procedure, COMPOSITION/Alpha Carotene and other Related Compounds, COMPOSITION/Content of Beta Carotene, COMPOSITION/Content of Total Carotenoids, Identification/Procedure B.	Huy Dinh
Revision	BETA CAROTENE CAPSULES PF 37(1) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/Procedure, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, ASSAY/Content of Total Beta Carotene, SPECIFIC TESTS/Alpha Carotene and Other Related Compounds, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Beta Carotene RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Beta Carotene System Suitability RS	Natalia Davydova

New	BETA CAROTENE PREPARATION PF 36(6) Pg. 1583	DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B., COMPOSITION/Content of Beta Carotene, COMPOSITION/Alpha Carotene and Other Related Compounds, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Heavy Metals, Method II <231>, SPECIFIC TESTS/Water Determination, Method I <921>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Beta Carotene RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Beta Carotene System Suitability RS	Huy Dinh
New	BETA GLUCAN PF 37(5) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/Nuclear Magnetic Resonance <761>, COMPOSITION/Content of Beta Glucan, COMPOSITION/Content of Protein, COMPOSITION/Content of Fat, CONTAMINANTS/Elemental Impurities—Procedures <233>, CONTAMINANTS/Microbial Enumeration Tests <2021>, CONTAMINANTS/Absence of Specified Microorganisms <2022>, SPECIFIC TESTS/Glycogen, SPECIFIC TESTS/Mannose, SPECIFIC TESTS/Residue on Ignition <281>, SPECIFIC TESTS/Loss on Drying <731>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Beta Glucan RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Dextrose RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Inositol RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Mannose RS	Huy Dinh
Revision	BIOTIN PF 37(5) Pg. ONLINE	ASSAY/Procedure, IMPURITIES/Related Compounds	Huy Dinh
Revision	BUFFER SOLUTIONS PF 37(4) Pg. ONLINE	BUFFER SOLUTIONS	Margareth Marques
Revision	CARISOPRODOL PF 37(3) Pg. ONLINE	IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Melting Range or Temperature, Class I <741>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Carisoprodol Related Compound A RS 2-Hydroxymethyl-2-methylpentyl carbamate.C8H17NO3 175.23	Ravi Ravichandran
Revision	CARISOPRODOL TABLETS PF 37(3) Pg. ONLINE	ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Carisoprodol Related Compound A RS 2-Hydroxymethyl-2-methylpentyl carbamate.C8H17NO3175.23	Ravi Ravichandran
Revision	CEFEPIME	ASSAY/Procedure, IMPURITIES/Organic	Ahalya Wise

	HYDROCHLORIDE PF 36(1) Pg. 76	Impurities/Procedure 1: Limit of N-Methylpyrrolidine, IMPURITIES/Organic Impurities/Procedure 2: Other Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Cefepime Hydrochloride Related Compound D RS and USP Cefepime Hydrochloride Related Compound E RS	
Revision	CEFEPIME FOR INJECTION PF 36(1) Pg. 79	ASSAY/Procedure, IMPURITIES/Organic Impurities/Procedure 1: Limit of N-Methylpyrrolidine, IMPURITIES/Organic Impurities/Procedure 2: Other Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Cefepime Hydrochloride Related Compound D RS and USP Cefepime Hydrochloride Related Compound E RS	Ahalya Wise
Revision	CELLACEFATE Stage 6 Harmonization	Entire Document	Kevin Moore
New	CICLOPIROX TOPICAL SOLUTION PF 37(3) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/A., ASSAY/Procedure, PERFORMANCE TESTS/Minimum Fill <755>, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Microbial Enumeration Tests <61> and Tests For Specified Microorganisms <62>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ciclopirox RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ciclopirox Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ciclopirox Related Compound C RS	Behnam Davani
Revision	CLOZAPINE PF 37(5) Pg. ONLINE	IDENTIFICATION/B., ASSAY/Procedure, SPECIFIC TESTS/Melting Range or Temperature, Class I <741>	Ravi Ravichandran
Revision	COPOVIDONE PF 37(4) Pg. ONLINE	IMPURITIES/Heavy Metals <231>, IMPURITIES/Procedure 4: Limit of Monomers, IMPURITIES/Limit of Monomers (1-Vinyl-2-Pyrrolidone, Vinyl Acetate, and 2-Pyrrolidone)	Robert Lafaver
Revision	CYANOCOBALAMIN PF 37(5) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/C. HPLC, ASSAY/Procedure, IMPURITIES/Pseudocyanocobalamin	Huy Dinh
New	D-10-CAMPHORSULFONIC ACID PF 37(4) Pg. ONLINE	Reagent Specification, d-10-Camphorsulfonic Acid	Margareth Marques
Revision	DESCRIPTION AND SOLUBILITY PF 37(3) Pg. ONLINE	Olmesartan Medoxomil, Sildenafil Citrate, Ferrousferic Oxide, Rosiglitazone Maleate, Atracurium Besylate, Duloxetine Hydrochloride, Esmolol Hydrochloride, Polyoxyl Stearate, Sertraline Hydrochloride, Pregelatinized Hydroxypropyl Corn Starch, Pregelatinized Hydroxypropyl Pea Starch, Pregelatinized Hydroxypropyl Potato Starch, Voriconazole	Sujatha Ramakrishna
Revision	Diatomaceous Earth,	Diatomaceous Earth, Flux-Calcined	Margareth

	Flux-Calcined PF 37(4) Pg. ONLINE		Marques
Revision	Diatomaceous Silica, Calcined PF 37(4) Pg. ONLINE	Diatomaceous Silica, Calcined	Margareth Marques
New	DIOSMIN PF 37(5) Pg. ONLINE	Chemical Info/Chemical Structure, Chemical Info/C28H32O15, Chemical Info/608.55, Chemical Info/5-Hydroxy-2-(3-hydroxy-4-methoxyphenyl)-7-[(2S,3R,4S,5S,6R)-3,4,5-trihydroxy-6-[[[(2R,3R,4R,5R,6S)-3,4,5-trihydroxy-6-methyloxan-2-yl]oxymethyl]oxan-2-yl]oxychromen-4-one;, Chemical Info/7-[[6-O-(6-Deoxy-α-l-mannopyranosyl)-β-d-glucopyranosyl]oxy]-5-hydroxy-2-(3-hydroxy-4-methoxyphenyl)-4H-1-benzopyran-4-one, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Heavy Metals, Method II <231>, IMPURITIES/Limit of Iodine, IMPURITIES/Related Compounds, SPECIFIC TESTS/Water Determination, Method Ia <921>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Diosmin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Diosmin for System Suitability RS	Huy Dinh
Revision	dl-10-Camphorsulfonic Acid PF 37(4) Pg. ONLINE	dl-10-Camphorsulfonic Acid	Margareth Marques
Revision	DROSPIRENONE AND ETHINYL ESTRADIOL TABLETS PF 37(5) Pg. ONLINE	DEFINITION/Introduction, ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Labeling, IDENTIFICATION/Introduction, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities/Procedure, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Drospirenone RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ethinyl Estradiol RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ethinyl Estradiol Related Compound B RS 19-Nor-17α-pregna-1,3,5(10),9(11)-tetraen-20-yne-3,17-diol(C20H22O2294.39)	Domenick Vicchio
New	DULOXETINE HYDROCHLORIDE PF 37(4) Pg. ONLINE	Chemical Info/Chemical Structure, Chemical Info/C18H19NOSċHCl, Chemical Info/333.88, Chemical Info/2-Thiophenepropanamine, N-methyl-γ-(1-naphthalenyloxy)-, hydrochloride, (S)-;-, Chemical Info/(+)-(S)-N-Methyl-γ-(1-naphthyloxy)-2-thiophenpropylamine hydrochloride, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., IDENTIFICATION/C.	Ravi Ravichandran

		<p>Identification Tests&mdash;General, Chloride <191>, ASSAY/Procedure, IMPURITIES/Heavy Metals, Method II <231>, IMPURITIES/Residue On Ignition <281>, IMPURITIES/Organic Impurities, IMPURITIES/Limit of Duloxetine Related Compound A, SPECIFIC TESTS/ Loss On Drying <731>, ADDITIONAL REQUIREMENTS/Packaging And Storage, ADDITIONAL REQUIREMENTS/ USP Reference Standards <11>:/USP Duloxetine Hydrochloride RS, ADDITIONAL REQUIREMENTS/ USP Reference Standards <11>:/USP Duloxetine Related Compound A RS</p>	
New	DULOXETINE DELAYED-RELEASE CAPSULES PF 37(4) Pg. ONLINE	<p>DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197S>, 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 Duloxetine Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>:/USP Duloxetine Related Compound F RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>:/USP Duloxetine Related Compound H RS</p>	<p>Ravi Ravichandran</p>
New	ESMOLOL HYDROCHLORIDE PF 37(4) Pg. ONLINE	<p>Chemical Info/Chemical Structure, Chemical Info/C16H25NO4&middot;HCl, Chemical Info/331.83, Chemical Info/Benzenepropanoic acid, 4-[2-hydroxy-3-[(1-methylethyl)amino]propoxy]-, methyl ester, hydrochloride, (&plusmn;);, Chemical Info/(&plusmn;)-Methyl p-[2-hydroxy-3-(isopropylamino)propoxy]hydrocinnamate hydrochloride, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Heavy Metals <231>, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Organic Impurities, SPECIFIC TESTS/pH <791>, SPECIFIC TESTS/Water Determination <921>, Method Ia, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Esmolol Hydrochloride RS</p>	<p>Sujatha Ramakrishna</p>
Revision	ESTRADIOL CYPIONATE PF 37(5) Pg. ONLINE	<p>Chemical Info/Chemical Structure, ASSAY/Procedure</p>	<p>Domenick Vicchio</p>
Revision	ESTRADIOL CYPIONATE INJECTION PF 37(5) Pg. ONLINE	<p>ASSAY/Procedure</p>	<p>Domenick Vicchio</p>
Revision	Edetate Disodium, Twentieth-Molar (0.05 M) PF 37(5) Pg. ONLINE	<p>Edetate Disodium, Twentieth-Molar (0.05 M)</p>	<p>Margareth Marques</p>
New	FENOFIBRATE TABLETS PF 37(5) Pg. ONLINE	<p>DEFINITION/Introduction, IDENTIFICATION/A., ASSAY/Procedure, PERFORMANCE</p>	<p>Elena Gonikberg</p>

		TESTS/Dissolution <711>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Fenofibrate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Fenofibrate Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Fenofibrate Related Compound B RS	
New	FERROSO FERRIC OXIDE PF 37(5) Pg. ONLINE	Chemical Info/Fe ₃ O ₄ (FeO·Fe ₂ O ₃), Chemical Info/231.54, Chemical Info/Magnetite;, Chemical Info/ Ferrous-ferric oxide;, Chemical Info/Iron (II, III) oxide, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Limit of Arsenic (As) and Antimony (Sb), IMPURITIES/Limit of Cadmium (Cd) and Chromium (Cr), IMPURITIES/Limit of Lead (Pb), IMPURITIES/Limit of Mercury (Hg) and Nickel (Ni), SPECIFIC TESTS/Water-Soluble Substances, SPECIFIC TESTS/Acid-Insoluble Substances, SPECIFIC TESTS/Organic Colors and Lakes, SPECIFIC TESTS/Microbial Enumeration Tests <61> and Tests for Specified Microorganisms <62>, SPECIFIC TESTS/pH <791>, SPECIFIC TESTS/Loss on Drying <731>, ADDITIONAL REQUIREMENTS/Packaging and Storage	Hong Wang
New	FOSFOMYCIN TROMETHAMINE PF 36(2) Pg. 404	Title, Chemical Info/Chemical Structure, Chemical Info/C ₃ H ₇ O ₄ P·C ₄ H ₁₁ NO ₃ , Chemical Info/259.19, Chemical Info/Phosphonic acid, (3-methyloxiranyl)-, (2R-cis)-, compd. with 2-amino-2-(hydroxymethyl)-1,3-propanediol (1:1);, Chemical Info/(1R,2S)-(1,2-Epoxypropyl)phosphonic acid, compound with 2-amino-2-(hydroxymethyl)-1,3-propanediol (1:1), Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., IDENTIFICATION/C., ASSAY/Procedure, IMPURITIES/Inorganic Impurities/Heavy Metals, Method I <231>, IMPURITIES/Inorganic Impurities/Limit of Inorganic Phosphates, IMPURITIES/Organic Impurities/Procedure, SPECIFIC TESTS/pH <791>, SPECIFIC TESTS/Optical Rotation, Specific Rotation <781S>, SPECIFIC TESTS/Water Determination, Method Ic <921>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Fosfomycin Tromethamine RS	Behnam Davani
Revision	GLUCAGON PF 35(5) Pg. 1148	Chemical Info/Molecular Weight, Chemical Info/Chemical Name, DEFINITION/Introduction, IDENTIFICATION/Introduction, IDENTIFICATION/A, IDENTIFICATION/B, ASSAY/Procedure, OTHER COMPONENTS/Nitrogen Determination, Method II <461>, IMPURITIES/Inorganic Impurities, IMPURITIES/Organic Impurities/Procedure,	Thomas Sigambris

		SPECIFIC TESTS/Water Determination, Method I Method Ic <921>, SPECIFIC TESTS/Bacterial Endotoxins Test <85>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>	
Revision	GLUCAGON FOR INJECTION PF 35(5) Pg. 1152	DEFINITION/Introduction, IDENTIFICATION/Introduction, ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Water Determination, Method Ic <921>, SPECIFIC TESTS/pH and Clarity of solution, SPECIFIC TESTS/Bacterial Endotoxins Test <85>, SPECIFIC TESTS/Sterility Tests <71>, SPECIFIC TESTS/Other Requirements, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>, IDENTIFICATION/B. Glucogen Bioidentity Tests <123>, SPECIFIC TESTS/pH and Clarity of Solution	Thomas Sigambris
Revision	GOSERELIN ACETATE PF 37(4) Pg. ONLINE	Chemical Info/Chemical Structure, Chemical Info/C59H84N18O14·x2H4O2, Chemical Info/Luteinizing hormone-releasing factor (pig), 6-[O-(1,1-dimethylethyl)-d-serine]-10-deglycinamide-, 2-(aminocarbonyl)hydrazide, acetate (salt), Chemical Info/CAS, Chemical Info/1-(5-Oxo-l-prolyl-l-histidyl-l-tryptophyl-l-seryl-l-tyrosyl-O-tert-butyl-d-seryl-l-leucyl-l-arginyl-l-prolyl)semicarbazide (Goserelin), Chemical Info/1269.41, DEFINITION/Introduction, IDENTIFICATION/A., ASSAY/Procedure, OTHER COMPONENTS/Limit of Acetic Acid, IMPURITIES/Organic Impurities: Related Compounds, SPECIFIC TESTS/Amino Acid Content, Nuclear Magnetic Resonance <761>, SPECIFIC TESTS/Optical Rotation, Specific Rotation <781>, SPECIFIC TESTS/Bacterial Endotoxins Test <85>, SPECIFIC TESTS/Water Determination, Method I <921>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Goserelin Acetate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Goserelin Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Goserelin System Suitability Mixture RS	Thomas Sigambris
Revision	HYDROCORTISONE PF 37(5) Pg. ONLINE	IMPURITIES/Residue on Ignition <281>	Domenick Vicchio
Revision	HYDROCORTISONE ACETATE PF 37(5) Pg. ONLINE	ASSAY/Procedure, Impurities/Residue on Ignition <281>	Domenick Vicchio
New	PREGELATINIZED HYDROXYPROPYL CORN STARCH PF 37(4) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/A. Test for Pregelatinized State, IDENTIFICATION/B. Test for Starch, IDENTIFICATION/C. Ninhydrin Test, ASSAY/Assay for Hydroxypropyl Groups, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Limit of Iron, IMPURITIES/Limit of Sulfur Dioxide, Method IV <525>,	Hong Wang

		IMPURITIES/Limit of Propylene Glycol, IMPURITIES/Limit of Oxidizing Substances, SPECIFIC TESTS/Microbial Enumeration Tests <61> and Tests for Specified Microorganisms <62>, SPECIFIC TESTS/pH <791>, SPECIFIC TESTS/Loss on Drying <731>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Propylene Glycol RS	
New	PREGELATINIZED HYDROXYPROPYL PEA STARCH PF 37(4) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/A. Test for Pregelatinized State, IDENTIFICATION/B. Test for Starch, IDENTIFICATION/C. Ninhydrin Test, ASSAY/Assay for Hydroxypropyl Groups, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Limit of Iron, IMPURITIES/Limit of Sulfur Dioxide, Method IV <525>, IMPURITIES/Limit of Propylene Glycol, IMPURITIES/Limit of Oxidizing Substances, SPECIFIC TESTS/Microbial Enumeration Tests <61> and Tests for Specified Microorganisms <62>, SPECIFIC TESTS/pH <791>, SPECIFIC TESTS/Loss on Drying <731>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Propylene Glycol RS	Hong Wang
New	PREGELATINIZED HYDROXYPROPYL POTATO STARCH PF 37(4) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/A. Test for Pregelatinized State, IDENTIFICATION/B. Test for Starch, IDENTIFICATION/C. Ninhydrin Test, ASSAY/Assay for Hydroxypropyl Groups, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Limit of Iron, IMPURITIES/Limit of Sulfur Dioxide, Method IV <525>, IMPURITIES/Limit of Propylene Glycol, IMPURITIES/Limit of Oxidizing Substances, SPECIFIC TESTS/Microbial Enumeration Tests <61> and Tests for Specified Microorganisms <62>, SPECIFIC TESTS/pH <791>, SPECIFIC TESTS/Loss on Drying <731>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Propylene Glycol RS	Hong Wang
Revision	Hydrochloric Acid, Half-Normal (0.5 N) in Methanol PF 37(4) Pg. ONLINE	Hydrochloric Acid, Half-Normal (0.5 N) in Methanol	Margareth Marques
Revision	Hydrochloric Acid, Half-Normal(0.5 N) PF 37(4) Pg. ONLINE	Hydrochloric Acid, Half-Normal (0.5 N)	Margareth Marques
Revision	Hydrochloric Acid, Normal (1 N) PF 37(4) Pg. ONLINE	Hydrochloric Acid, Normal (1 N)	Margareth Marques
Revision	AZEOTROPIC ISOPROPYL ALCOHOL PF 37(5) Pg. ONLINE	IMPURITIES/Volatile Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>	Behnam Davani
Revision	L10 PF 37(4) Pg. ONLINE	L10	Margareth Marques

Revision	L43 PF 37(4) Pg. ONLINE	L43	Margareth Marques
Revision	L72 PF 37(4) Pg. ONLINE	L72	Margareth Marques
Revision	L8 PF 37(4) Pg. ONLINE	L8	Margareth Marques
Revision	ANHYDROUS LACTOSE Stage 6 Harmonization	Entire Document	Kevin Moore
Revision	LEAD ACETATE COTTON PF 37(4) Pg. ONLINE	Reagent Specification	Margareth Marques
New	LEVETIRACETAM ORAL SOLUTION PF 37(5) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/A., ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/pH <791>, SPECIFIC TESTS/Microbial Enumeration Tests <61> and Tests for Specified Microorganisms <62>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Levetiracetam RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Levetiracetam Related Compound A RS	Hariram Ramanathan
Revision	MECLIZINE HYDROCHLORIDE PF 37(4) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/B. Ultraviolet Absorption <197U>, IDENTIFICATION/C., ASSAY/Procedure, IMPURITIES/Organic Impurities Procedure 1, IMPURITIES/Organic Impurities Procedure 2, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Meclizine Related Compound A RS 4-Chlorobenzhydrol C13H11ClO 218.68, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Meclizine Related Compound B RS Isomeclizine 1-[(4-Chlorophenyl)(phenyl)methyl]-4-(2-methylbenzyl)piperazine dihydrochloride monohydrate C25H27ClN2·2HCl·H2O481.88	Elena Gonikberg
New	MELATONIN PF 37(4) Pg. ONLINE	Chemical Info/Chemical Structure, Chemical Info/C13H16N2O2, Chemical Info/232.28, Chemical Info/N-Acetyl-5-methoxytryptamine;, Chemical Info/N-(2-(5'-Methoxy-1H-indol-3'yl)ethyl) acetamide, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B. Ultraviolet Absorption <197U>, IDENTIFICATION/C. HPLC Identification Test, ASSAY/Procedure, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Chloride and Sulfate, Chloride <221>, IMPURITIES/Heavy Metals <231>, IMPURITIES/Related Compounds, SPECIFIC TESTS/Loss on Drying <731>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Melatonin RS, ADDITIONAL REQUIREMENTS/USP Reference	Huy Dinh

		Standards <11>/USP Melatonin Related Compound A RS	
Revision	METACRESOL PF 37(4) Pg. ONLINE	IMPURITIES/Organic Impurities	Feiwen Mao
Revision	METHYLBENZETHONIUM CHLORIDE PF 37(5) Pg. ONLINE	ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Benzethonium Chloride RS	Leonel Santos
Revision	MORPHINE SULFATE INJECTION PF 37(3) Pg. ONLINE	IDENTIFICATION/A. Thin-Layer Chromatography, ASSAY/Procedure, SPECIFIC TESTS/Bacterial Endotoxins Test <85>, ADDITIONAL REQUIREMENTS/Labeling	Clydewyn Anthony
New	NIACIN EXTENDED- RELEASE TABLETS PF 37(4) 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 6-Hydroxynicotinic Acid RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Niacin RS	Natalia Davydova
Revision	NYSTATIN VAGINAL INSERTS PF 37(4) Pg. ONLINE	PERFORMANCE TESTS/Disintegration <701>	Ahalya Wise
New	OLMESARTAN MEDOXOMIL PF 36(5) Pg. 1197	Chemical Info/Chemical Structure, Chemical Info/C29H30N6O6, Chemical Info/558.59, Chemical Info/1H-Imidazole-5-carboxylic acid, 4-(1-hydroxy-1-methylethyl)-2-propyl-1-[[2′-;(1H-tetrazol-5-yl) [1,1′-biphenyl]-4-yl]methyl]-, (5-methyl-2-oxo-1,3-dioxol-4-yl)methyl ester, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Inorganic Impurities/Residue on Ignition <281>, IMPURITIES/Inorganic Impurities/Heavy Metals, Method II <231>, IMPURITIES/Organic Impurities/Procedure, SPECIFIC TESTS/Limit of Acetone (if present), SPECIFIC TESTS/Water Determination, Method Ic <921>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Olmesartan Medoxomil RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Olmesartan Medoxomil Related Compound A RS	Sujatha Ramakrishna
Revision	OMEPRAZOLE DELAYED- RELEASE CAPSULES PF 37(5) Pg. ONLINE	IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Omeprazole Related Compounds F and G Mixture RS 1,3-Dimethyl-8-methoxy-12-thioxopyrido[1′;2′;3,4]imidazo[1,2-a]benzimidazol-2(12H)-one and 1,3-dimethyl-9-methoxy-12-thioxopyrido[1′;2′;3,4]imidazo[1,2-a]benzimidazol-2(12H)-one.	Elena Gonikberg

Revision	OXYCODONE HYDROCHLORIDE TABLETS PF 37(4) Pg. ONLINE	IDENTIFICATION/B. Thin-Layer Chromatographic Identification Test <201>	Clydewyn Anthony
Revision	OXYCODONE AND ACETAMINOPHEN CAPSULES PF 37(4) Pg. ONLINE	PERFORMANCE TESTS/Uniformity of Dosage Units <905>	Clydewyn Anthony
Revision	OXYCODONE AND ACETAMINOPHEN TABLETS PF 37(4) Pg. ONLINE	PERFORMANCE TESTS/Uniformity of Dosage Units <905>	Clydewyn Anthony
Revision	Papaic Digest of Soybean Meal PF 37(4) Pg. ONLINE	Papaic Digest of Soybean Meal	Margareth Marques
Revision	Peptic Digest of Animal Tissue PF 37(4) Pg. ONLINE	Peptic Digest of Animal Tissue	Margareth Marques
Revision	Peptone, Dried PF 37(4) Pg. ONLINE	Peptone, Dried	Margareth Marques
New	POLYOXYL STEARATE PF 37(4) Pg. ONLINE	Chemical Info/R-CO-(OCH ₂ CH ₂) _n -OH, Chemical Info/R-CO-(OCH ₂ CH ₂) _n -OOC-R, Chemical Info/R = CH ₃ (CH ₂) ₁₆ or CH ₃ (CH ₂) ₁₄ , Chemical Info/n = 6–100, Chemical Info/Polyethylene glycol stearate;, Chemical Info/Polyethylene glycol monostearate;, Chemical Info/Poly(oxy- 1,2-ethanediyl), α-hydro-ω- hydroxyoctadecanoate, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197A>, IDENTIFICATION/B., ASSAY/Content of Stearic Acid and Palmitic Acid, ASSAY/Content of Free Polyethylene Glycols, IMPURITIES/Heavy Metals, Method II <231>, IMPURITIES/Articles of Botanical Origin, Total Ash <561>, IMPURITIES/Limit of Ethylene Oxide and Dioxane, SPECIFIC TESTS/Alkalinity, SPECIFIC TESTS/Fats and Fixed Oils, Acid Value <401>, SPECIFIC TESTS/Fats and Fixed Oils, Hydroxyl Value <401>, SPECIFIC TESTS/Fats and Fixed Oils, Iodine Value <401>, SPECIFIC TESTS/Fats and Fixed Oils, Peroxide Value <401>, SPECIFIC TESTS/Fats and Fixed Oils, Saponification Value <401>, SPECIFIC TESTS/Melting Range Or Temperature <741>, SPECIFIC TESTS/Congearing Temperature <651>, SPECIFIC TESTS/Water Determination, Method I <921>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Polyoxyl 6 Stearate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Polyoxyl 8 Stearate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Polyoxyl 32 Stearate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Polyoxyl 40 Stearate RS, ADDITIONAL REQUIREMENTS/USP Reference	Hong Wang

		Standards <11>/USP Polyoxyl 75 Stearate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Polyoxyl 100 Stearate RS	
Revision	POLYSORBATE 20 PF 37(4) Pg. ONLINE	Chemical Info/The ratio of the OH group to the (C11H23COO) group is mainly 3:1., Polyethylene glycol 20 sorbitan ether monolaurate; Polyoxyethylene 20 sorbitan monododecanoate;; DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Composition of Fatty Acids, IMPURITIES/Limit of Ethylene Oxide and Dioxane, SPECIFIC TESTS/Bacterial Endotoxins Test <85>, SPECIFIC TESTS/Acid Value, SPECIFIC TESTS/Fats and Fixed Oils, Peroxide Value <401>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Polysorbate 20 RS	Hong Wang
Revision	POLYSORBATE 40 PF 37(4) Pg. ONLINE	The ratio of OH group to C15H31COO group is mainly 3:1. Polyethylene glycol 20 sorbitan ether monopalmitate; Polyoxyethylene 20 sorbitan monohexadecanoate;; Chemical Info/[Compound usually contains also associated fatty acids.], DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197F>, IDENTIFICATION/B., IDENTIFICATION/C., ASSAY/Composition of Fatty Acids, IMPURITIES/Ethylene Oxide and Dioxane, Method II <228>, SPECIFIC TESTS/Bacterial Endotoxins Test <85>, SPECIFIC TESTS/Acid Value, SPECIFIC TESTS/Fats and Fixed Oils, Peroxide Value <401>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Polysorbate 40 RS	Hong Wang
Revision	POLYSORBATE 60 PF 37(4) Pg. ONLINE	Chemical Info/Chemical Structure, Chemical Info/The ratio of OH group to the sum of C15H31COO and C17H35COO groups is mainly 3:1., Polyethylene glycol 20 sorbitan ether monostearate; Polyoxyethylene 20 sorbitan monooctadecanoate;; Chemical Info/[Compound usually also contains associated fatty acids.], DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197F>, IDENTIFICATION/B., IDENTIFICATION/C., ASSAY/Composition of Fatty Acids, IMPURITIES/Limit of Ethylene Oxide and Dioxane, SPECIFIC TESTS/Acid Value, SPECIFIC TESTS/Fats and Fixed Oils, Peroxide Value <401>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Polysorbate 60 RS	Hong Wang
Revision	RIBAVIRIN TABLETS PF 37(5) Pg. ONLINE	IMPURITIES/Organic Impurities: Procedure 2, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ribavirin Related Compound A RS 1-β-d-Ribofuranosyl-1H-1,2,4-triazole-3-carboxylic acid.C8H11N3O6245.19, ADDITIONAL REQUIREMENTS/USP Reference Standards	Leonel Santos

		<11>/USP Ribavirin Related Compound D RS 1H-1,2,4-Triazole-3-carboxamide.C3H4N4O112.09, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Uracil RS Pyrimidine-2,4(1H,3H)-dione.C4H4N2O2112.09, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Uridine RS 1-β-d-Ribofuranosylpyrimidine-2,4(1H,3H)-dione.C9H12N2O6244.20	
Revision	RITONAVIR PF 37(4) Pg. ONLINE	ASSAY/Procedure, IMPURITIES/Organic Impurities	Leonel Santos
New	SILDENAFIL CITRATE PF 37(3) Pg. ONLINE	Chemical Info/Chemical Structure, Chemical Info/C22H30N6O4S&middledot;C6H8O7, Chemical Info/666.70, Chemical Info/Piperazine, 1-[[3-(6,7-dihydro-1-methyl-7-oxo-3-propyl-1H-pyrazolo[4,3-d]pyrimidin-5-yl)-4-ethoxyphenyl]sulfonyl]-4-methyl-, 2-hydroxy-1,2,3-propanetricarboxylate (1:1);, Chemical Info/1-[[3-(6,7-Dihydro-1-methyl-7-oxo-3-propyl-1H-pyrazolo[4,3-d]pyrimidin-5-yl)-4-ethoxyphenyl]sulfonyl]-4-methylpiperazine citrate (1:1), Chemical Info/CAS, Chemical Info/Sildenafil, Chemical Info/474.58, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, ASSAY/Procedure, IMPURITIES/Heavy Metals, Method II <231>, IMPURITIES/Limit of Imidazole, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Water Determination, Method I <921>, IMPURITIES/Residue on Ignition <281>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Imidazole RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Sildenafil Citrate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Sildenafil Related Compound A RS	Mary Waddell
Revision	POTATO STARCH Stage 6 Harmonization	Entire Document	Kevin Moore
Revision	WHEAT STARCH Stage 6 Harmonization	Entire Document	Kevin Moore
Revision	SULFAQUINOXALINE PF 37(4) Pg. ONLINE	IDENTIFICATION/C., ASSAY/Procedure	Morgan Puderbaugh
New	SUMATRIPTAN INJECTION PF 37(5) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/A., ASSAY/Procedure, SPECIFIC TESTS/pH <791>, SPECIFIC TESTS/Osmolality and Osmolarity <785>, SPECIFIC TESTS/Particulate Matter in Injections <788>, SPECIFIC TESTS/Bacterial Endotoxins Test <85>, SPECIFIC TESTS/Sterility Tests <71>, SPECIFIC TESTS/Other Requirements, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Endotoxin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Sumatriptan Succinate RS	Hariram Ramanathan

Revision	Sulfuric Acid, Normal (1 N) PF 37(4) Pg. ONLINE	Sulfuric Acid, Normal (1 N)	Margareth Marques
New	Tetrabutylammonium Hydroxide, 40 Percent in Water PF 37(4) Pg. ONLINE	Reagent Specification, Tetrabutylammonium Hydroxide, 40 Percent in Water,	Margareth Marques
Revision	Tetrabutylammonium Hydrogen Sulfate Ion Pairing Reagent PF 37(4) Pg. ONLINE	Tetrabutylammonium Hydrogen Sulfate Ion Pairing Reagent	Margareth Marques
Revision	USP AND NF EXCIPIENTS, LISTED BY CATEGORY PF 37(5) Pg. ONLINE	{Color} Ferrosoferric Oxide, {Emulsifying and/or Solubilizing Agent} Polyoxyl Stearate, {Suspending and/or Viscosity-Increasing Agent} Pregelatinized Hydroxypropyl Corn Starch, {Suspending and/or Viscosity-Increasing Agent} Pregelatinized Hydroxypropyl Pea Starch, {Suspending and/or Viscosity-Increasing Agent} Pregelatinized Hydroxypropyl Potato Starch, {Tablet Binder} Pregelatinized Hydroxypropyl Corn Starch, {Tablet Binder} Pregelatinized Hydroxypropyl Pea Starch, {Tablet Binder} Pregelatinized Hydroxypropyl Potato Starch, {Tablet and/or Capsule Diluent} Pregelatinized Hydroxypropyl Corn Starch, {Tablet and/or Capsule Diluent} Pregelatinized Hydroxypropyl Pea Starch, {Tablet and/or Capsule Diluent} Pregelatinized Hydroxypropyl Potato Starch, {Tablet Disintegrant} Pregelatinized Hydroxypropyl Corn Starch, {Tablet Disintegrant} Pregelatinized Hydroxypropyl Pea Starch, {Tablet Disintegrant} Pregelatinized Hydroxypropyl Potato Starch, {Wetting and/or Solubilizing Agent} Polyoxyl Stearate	Robert Lafaver
Revision	VALSARTAN AND HYDROCHLOROTHIAZIDE TABLETS PF 37(4) Pg. ONLINE	PERFORMANCE TESTS/Dissolution <711>	Sujatha Ramakrishna
Revision	VITAMIN E PF 37(1) Pg. ONLINE	ASSAY/Alpha Tocopherol, ASSAY/Alpha Tocopheryl Acetate, ASSAY/Alpha Tocopheryl Acid Succinate	Huy Dinh
New	VORICONAZOLE PF 37(4) Pg. ONLINE	Chemical Info/Chemical Structure, Chemical Info/C16H14F3N5O, Chemical Info/349.31, Chemical Info/4-Pyrimidineethanol, α-(2,4-difluorophenyl)-5-fluoro-β-methyl-α-(1H-1,2,4-triazol-1-ylmethyl)-, (αR,βS)-, Chemical Info/(αR,βS)-α-(2,4-Difluorophenyl)-5-fluoro-β-methyl-α-(1H-1,2,4-triazol-1-ylmethyl)-4-pyrimidineethanol, 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/Voriconazole Related Compounds C and D, IMPURITIES/Voriconazole Related Compound F, IMPURITIES/Voriconazole Related	Leonel Santos

Compound B, SPECIFIC TESTS/ Bacterial Endotoxins Test <85>, SPECIFIC TESTS/Sterility Tests <71>, SPECIFIC TESTS/Water Determination, Method I <921>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Endotoxin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Voriconazole RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Voriconazole Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Voriconazole Related Compound C RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Voriconazole Related Compound D RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Voriconazole Related Compound F RS

Revision	XYLITOL PF 37(4) Pg. ONLINE	IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Limit of Other Polyols, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>	Robert Lafaver
Revision	Yeast Extract PF 37(4) Pg. ONLINE	Yeast Extract	Margareth Marques