

Compendial Deferrals for USP 34-NF 29, First Supplement

Monograph Title	Monograph Section	Scientific Liaison
<41> WEIGHTS AND BALANCES PF 33(4) Pg. 716	INTRODUCTION, REPEATABILITY, VERIFICATION OF ACCURACY, WEIGHT CHECK, CALIBRATION CHECK, CALIBRATION CHECK WEIGHT CHECK	Horacio Pappa
<232> ELEMENTAL IMPURITIES--LIMITS PF 36(1) Pg. 197	Title, INTRODUCTION, LIMITS OF ELEMENTAL IMPURITIES, OPTIONS FOR DESCRIBING LIMITS OF ELEMENTAL IMPURITIES, ANALYTICAL PROCEDURES	Kahkashan Zaidi
<233> ELEMENTAL IMPURITIES - PROCEDURES PF 36(1) Pg. 201	Title, INTRODUCTION, ALTERNATIVE PROCEDURE VALIDATION REQUIREMENTS, VALIDATION OF LIMIT PROCEDURES, VALIDATION OF QUANTITATIVE PROCEDURES, REFEREE PROCEDURES 1 AND 2, CALCULATIONS AND REPORTING	Kahkashan Zaidi
<413> IMPURITIES TESTING IN MEDICAL GASES PF 35(4) Pg. 920	Title, INTRODUCTION, CONTINUOUS FLOW SYSTEM, HAND PUMP-FIXED VOLUME	Kahkashan Zaidi
<415> MEDICAL GASES ASSAY PF 35(4) Pg. 921	Title, INTRODUCTION, METHODS, QUALIFICATION, VALIDATION, PROCEDURE, SAMPLING, CERTIFIED STANDARDS FOR MEDICAL GAS ANALYSIS	Kahkashan Zaidi
<761> NUCLEAR MAGNETIC RESONANCE PF 36(2) Pg. 462	Title, Introduction, APPARATUS, THE SPECTRUM, GENERAL METHOD, INTRODUCTION, QUALIFICATION OF NMR INSTRUMENTS, QUALITATIVE AND QUANTITATIVE NMR ANALYSIS, PROCEDURE VALIDATION, GLOSSARY	Kahkashan Zaidi
<797> PHARMACEUTICAL COMPOUNDING--STERILE PREPARATIONS PF 36(3) Pg. 714	DEFINITIONS, IMMEDIATE-USE CSPS, HAZARDOUS DRUGS AS CSPS, RADIOPHARMACEUTICALS AS CSPS, ENVIRONMENTAL QUALITY AND CONTROL	Shawn Becker
<1050> VIRAL SAFETY EVALUATION OF BIOTECHNOLOGY PRODUCTS DERIVED FROM CELL LINES OF HUMAN OR ANIMAL ORIGIN PF 36(3) Pg. 726	I. INTRODUCTION, II. POTENTIAL SOURCES OF VIRUSVIRALCONTAMINATION, III. CELL LINE QUALIFICATION: TESTING FOR VIRUSES, IV. TESTING FOR VIRUSES IN UNPROCESSED BULK, V. RATIONALE AND ACTION PLAN FOR VIRAL CLEARANCE STUDIES AND VIRUS TESTS ON PURIFIED BULK, VI. EVALUATION AND CHARACTERIZATION OF VIRAL CLEARANCE PROCEDURESVI. GOALS, PRINCIPLES, DESIGN, AND EVALUATION OF VIRAL CLEARANCE STUDIES, VII. SUMMARY, GLOSSARY, APPENDIX I. GLOSSARY, APPENDIX 1, APPENDIX 2, APPENDIX 4. VIRUS ABBREVIATIONS, APPENDIX 3, APPENDIX 5	Tina Morris
<1079> GOOD STORAGE AND SHIPPING PRACTICES PF 36(1) Pg. 226	Title, 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 HANDLED BY SALES REPRESENTATIVES IN AUTOMOBILES, STABILITY, STORAGE, AND LABELING, STATEMENTS/LABELING OF THE IMMEDIATE CONTAINERS OR PACKAGE INSERT, PURPOSE, DEFINITIONS, SCOPE,	Desmond Hunt

BACKGROUND INFORMATION, LABELING CONSIDERATIONS FOR DRUG PRODUCTS, RESPONSIBILITIES, QUALITY AGREEMENTS, THE STORAGE MANAGEMENT SYSTEM (SMS): PRACTICES AND CONTROLS, THE TRANSPORTATION MANAGEMENT SYSTEM (TMS): PRACTICES AND CONTROLS, GOOD DOCUMENTATION PRACTICES, CONCLUSION, REFERENCES

Title, INTRODUCTION, MICROBIAL ISOLATION, PRELIMINARY SCREENING OF MICROBIAL ISOLATES, MICROBIAL IDENTIFICATION BY PHENOTYPIC METHODS, MICROBIAL IDENTIFICATION BY GENOTYPIC METHODS, VERIFICATION OF MICROBIAL IDENTIFICATION METHODS

[Radhakrishna Tirumalai](#)

<1113> MICROBIAL IDENTIFICATION PF 35(1) Pg. 167

INSTRUMENTATION

[Horacio Pappa](#)

<1119> NEAR-INFRARED SPECTROSCOPY PF 36(2) Pg. 532

Introduction, BIOAVAILABILITY, TERMINOLOGY, AEROSOLS, BOLUSES, CAPSULES, CONCENTRATE FOR DIP, CREAMS, ELIXIRS, EMULSIONS, EXTRACTS AND FLUIDEXTRACTS, GELS, IMPLANTS (PELLETS), INFUSIONS, INTRAMAMMARY, INHALATIONS, INJECTIONS, IRRIGATIONS, LOTIONS, LOZENGES, OINTMENTS, OPHTHALMIC PREPARATIONS, PASTES, POWDERS, PREMIXES, SOLUTIONS, SUPPOSITORIES, SUSPENSIONS, SYRUPS, SYSTEMS, TABLETS, GENERAL CONSIDERATIONS, PRODUCT QUALITY TESTS, GENERAL, DOSAGE FORMS, DRY POWDER INHALERS, EMULSIONS (CREAMS AND LOTIONS), FEED ADDITIVES, FOAMS, MEDICAL GASES (INHALATION MATERIALS), GRANULES, MEDICATED GUMS, INSERTS, LIQUIDS, LOTIONS (SEE EMULSIONS), TRANSDERMAL SYSTEMS (PATCHES), PILLS, PLASTERS, MEDICATED SOAPS AND SHAMPOOS, SPRAYS (NASAL, PULMONARY, OR SOLUTIONS FOR NEBULIZATION), TAPES, GLOSSARY

[William Brown](#)

<1151> PHARMACEUTICAL DOSAGE FORMS PF 35(5) Pg. 1260

Title, PRINCIPLES OF NMR, NMR SPECTROMETERS, RELAXATION, TIP ANGLE, RELAXATION DELAY, RESOLUTION, POSTACQUISITION DATA PROCESSING, GENERAL PROCEDURE FOR STRUCTURE IDENTIFICATION, QUANTITATIVE APPLICATIONS, SOLID-STATE NMR, LOW-FIELD NMR

[Kahkashan Zaidi](#)

<1761> APPLICATIONS OF NUCLEAR MAGNETIC RESONANCE SPECTROSCOPY PF 36(2) Pg. 539

DISSOLUTION

[Natalia Davydova](#)

<2040> DISINTEGRATION AND DISSOLUTION OF DIETARY SUPPLEMENTS PF 36(2) Pg. 567

Title, INTRODUCTION, LIMITS OF ELEMENTAL CONTAMINANTS, OPTIONS FOR COMPLIANCE WITH THE LIMITS OF ELEMENTAL CONTAMINANTS, ANALYTICAL PROCEDURES FOR TOTAL ELEMENTAL CONTAMINANTS, ANALYTICAL PROCEDURE FOR INORGANIC ARSENIC, ANALYTICAL PROCEDURE FOR METHYLMERCURY

[Yoshiyuki Tokiwa](#)

<2232> ELEMENTAL CONTAMINANTS IN DIETARY SUPPLEMENTS PF 36(1) Pg. 258

93.0% Oxygen Certified Standard

[Kahkashan Zaidi](#)

93.0 PERCENT OXYGEN CERTIFIED STANDARD PF 35(4) Pg. 991

Chemical Info, Definition, Botanic characteristics, Packaging and storage, USP Reference standards <11>, Identification, Microbial limits <61>, Limit of foreign insoluble matter

[Hong Wang](#)

AGAR PF 33(4) Pg. 702

IDENTIFICATION/Introduction, ASSAY/Procedure, IMPURITIES/Inorganic Impurities/Carbon Dioxide, IMPURITIES/Inorganic Impurities/Sample,

MEDICAL AIR PF 35(4) Pg. 828

IMPURITIES/Inorganic Impurities/Analysis, IMPURITIES/Inorganic Impurities/Acceptance criteria, IMPURITIES/Inorganic Impurities/Carbon Monoxide, IMPURITIES/Inorganic Impurities/Sulfur Dioxide, IMPURITIES/Inorganic Impurities/Limit of Nitric Oxide and Nitrogen Dioxide, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling

[Kahkashan Zaidi](#)

ALBUMIN HUMAN PF 31(5) Pg. 1338

Definition, Packaging and storage, Expiration date, Labeling, USP Reference standards, Identification A, B, pH, Molecular size distribution, Heat stability, Incubation, Prekallikrein activator, Protein content, Heme content, Potassium content, Sodium content, Safety, Bacterial endotoxins, Sterility

[Anita Szajek](#)

AMMONIUM CARBONATE TS2 PF 36(3) Pg. 782

Ammonium Carbonate TS 2

[Antonio Hernandez-Cardoso](#)

ARTEMETHER PF 36(2) Pg. 377

Title, Chemical Info/Chemical Structure, Chemical Info/C₁₆H₂₆O₅, Chemical Info/298.37, Chemical Info/(3R,5aS,6R,8aS,9R,10S,12R,12aR)-Decahydro-10-methoxy-3,6,9-trimethyl-3,12-epoxy-12H-pyrano[4.3-j]-1,2-benzodioxepin, 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 1: Analysis of Cyclohexanone Propanal Derivative and Furoisochromen Derivative by TLC, IMPURITIES/Organic Impurities/Procedure 2: Analysis of Artemether Related Compound A, Artemether Related Compound B, and Any Other Individual Impurity by HPLC, SPECIFIC TESTS/Optical Rotation, Specific Rotation <781S>, SPECIFIC TESTS/Color of solution, 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 [(3R,5aS,6R,8aS,9R,12R,12aR)-Decahydro-10-hydroxy-3,6,9-trimethyl-3,12-epoxy-12H-pyrano[4,3-j]-1,2-benzodioxepin](C₁₅H₂₄O₅284.35), ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Artemether Related Compound B RS [(3R,5aS,6R,8aS,9R,10R,12R,12aR)-Decahydro-10-methoxy-3,6,9-trimethyl-3,12-epoxy-12H-pyrano[4,3-j]-1,2-benzodioxepin](C₁₆H₂₆O₅298.37)

[Behnam Davani](#)

ARTEMETHER AND LUMEFANTRINE TABLETS PF 36(2) Pg. 379

Title, DEFINITION/Introduction, IDENTIFICATION/A. Thin Layer Chromatography, IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities/Procedure 1: Impurities of Artemether, IMPURITIES/Organic Impurities/Procedure 2: Impurities of Lumefantrine, IMPURITIES/Organic Impurities/Acceptance criteria, 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 [(3R,5aS,6R,8aS,9R,12R,12aR)-Decahydro-10-hydroxy-3,6,9-trimethyl-3,12-epoxy-12H-pyrano[4,3-j]-1,2-benzodioxepin](C₁₅H₂₄O₅284.35), ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Artemether Related Compound B RS [(3R,5aS,6R,8aS,9R,10R,12R,12aR)-Decahydro-10-methoxy-3,6,9-trimethyl-3,12-epoxy-12H-pyrano[4,3-j]-1,2-benzodioxepin](C₁₆H₂₆O₅298.37), ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Lumefantrine RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Lumefantrine Related Compound A RS [(RS, Z)-2-(Dibutylamino)-2-(2,7-dichloro-9-(4-chlorobenzylidene)-9H-fluoren-4-yl)ethanol](C₃₀H₃₂Cl₃NO₅28.94)

[Behnam Davani](#)

Title, DEFINITION/Introduction, IDENTIFICATION/A. Thin-Layer Chromatographic Identification Test <201>, IDENTIFICATION/B., COMPOSITION/Content of Triterpene Glycosides, IMPURITIES/Inorganic Impurities/Articles of Botanical Origin, Acid-Insoluble Ash <561>, IMPURITIES/Inorganic Impurities/Heavy Metals, Method III <231>, IMPURITIES/Organic Impurities/Procedure 1: Articles of Botanical Origin, Foreign Organic Matters <561>, IMPURITIES/Organic Impurities/Procedure 2: Articles of Botanical Origin, General Method for Pesticide Residues Analysis <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, Alcohol-Soluble Extractives, Method 2 <561>, SPECIFIC TESTS/Microbial Enumeration Tests—Nutritional and Dietary Supplements <2021>, SPECIFIC TESTS/Absence of Specified Microorganisms—Nutritional and Dietary Supplements <2022>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Bacoside A3 RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Powdered Bacopa Extract RS

BACOPA PF 36(3) Pg. 691

[Maged Sharaf](#)

Title, DEFINITION/Introduction, IDENTIFICATION/A. Thin-Layer Chromatographic Identification Test <201>, IDENTIFICATION/B., COMPOSITION/Content of Triterpene Glycosides, IMPURITIES/Inorganic Impurities/Heavy Metals, Method III <231>, IMPURITIES/Organic Impurities/Procedure: Articles of Botanical Origin, General Method for Pesticide Residues Analysis <561>, SPECIFIC TESTS/Loss on Drying <731>, SPECIFIC TESTS/Microbial Enumeration Tests <2021>, SPECIFIC TESTS/Microbiological Procedures for Absence of Specified Microorganisms <2022>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/Other Requirements, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Bacoside A3 RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Powdered Bacopa Extract RS

POWDERED BACOPA EXTRACT PF 36(3) Pg. 694

[Maged Sharaf](#)

Title, DEFINITION/Introduction, IDENTIFICATION/A. Thin-Layer Chromatographic Identification Test <201>, IDENTIFICATION/B., COMPOSITION/Content of Triterpene Glycosides, IMPURITIES/Inorganic Impurities/Articles of Botanical Origin, Acid-Insoluble Ash <561>, IMPURITIES/Inorganic Impurities/Heavy Metals, Method III <231>, IMPURITIES/Organic Impurities/Procedure: Articles of Botanical Origin, General Method for Pesticide Residues Analysis <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, Alcohol-Soluble Extractives, Method 2 <561>, SPECIFIC TESTS/Microbial Enumeration Tests—Nutritional and Dietary Supplements <2021>, SPECIFIC TESTS/Absence of Specified Microorganisms—Nutritional and Dietary Supplements <2022>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Bacoside A3 RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Powdered Bacopa Extract RS

POWDERED BACOPA PF 36(3) Pg. 692

[Maged Sharaf](#)

Title, Chemical Info/Chemical Structure, Chemical Info/C₄₂H₇₀-nO₃₅·(C₄H₈SO₃Na)_n, Chemical Info/2163 when n 6.5, Chemical Info/Beta Cyclodextrin Sulfobutyl Ethers, Sodium Salts;, Chemical Info/Beta Cyclodextrin Sulfobutyl Ether Sodium, Chemical Info/CAS,

<p>BETADEX SULFOBUTYL ETHER SODIUM PF 36(2) Pg. 447</p>	<p>DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., IDENTIFICATION/C., IDENTIFICATION/D. Identification Tests&mdash;General, Sodium <191>, ASSAY/Procedure, IMPURITIES/Inorganic Impurities/Heavy Metals, Method II <231>, IMPURITIES/Inorganic Impurities/Limit of Sodium Chloride, IMPURITIES/Organic Impurities/Procedure 1: Limit of Beta Cyclodextrin (Betadex), IMPURITIES/Organic Impurities/Procedure 2: Limit of 4-Hydroxybutane-1-Sulfonic Acid, IMPURITIES/Organic Impurities/Procedure 3: Limit of Bis(4-Sulfobutyl) Ether Disodium, IMPURITIES/Organic Impurities/Procedure 4: Limit of 1,4-Butane Sultone, SPECIFIC TESTS, SPECIFIC TESTS/Bacterial Endotoxins Test <85>, SPECIFIC TESTS/Microbial Enumeration Tests <61> and Tests for Specified Microorganisms <62>, SPECIFIC TESTS/Clarity of Solution, SPECIFIC TESTS/Average Degree of Substitution, SPECIFIC TESTS/pH <791>, SPECIFIC TESTS/Water Determination, Method I <921>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Beta Cyclodextrin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Betadex Sulfobutyl Ether Sodium RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Endotoxin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Sodium Chloride RS</p>	<p>Hong Wang</p>
<p>BUTYL STEARATE PF 35(6) Pg. 1502</p>	<p>Title, Chemical Info/Chemical Structure, Chemical Info/Butyl Octadecanoate, Chemical Info/C22H44O2, Chemical Info/340.59, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/Infrared Absorption <197F>, SPECIFIC TESTS/Solubility in alcohol, SPECIFIC TESTS/Specific Gravity <841>, SPECIFIC TESTS/Fats and Fixed Oils, Iodine Value <401>, SPECIFIC TESTS/Melting Range or Temperature, Class III <741>, SPECIFIC TESTS/Fats and Fixed Oils, Saponification Value <401>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Butyl Stearate RS</p>	<p>Robert Lafaver</p>
<p>CARBIDOPA AND LEVODOPA EXTENDED- RELEASE TABLETS PF 34(6) Pg. 1433</p>	<p>Title, Definition, Packaging and storage, Labeling, USP Reference standards <11>, Identification, Dissolution <711> - Test 1, Dissolution <711> - Test 2, Dissolution <711> - Test 3, Uniformity of dosage units <905>, Related compounds, Assay</p>	<p>Ravi Ravichandran</p>
<p>CEFEPIME HYDROCHLORIDE PF 36(1) Pg. 76</p>	<p>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 System Suitability RS</p>	<p>Ahalya Wise</p>
<p>CEFEPIME FOR INJECTION PF 36(1) Pg. 79</p>	<p>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 System Suitability RS</p>	<p>Ahalya Wise</p>
<p>CETIRIZINE HYDROCHLORIDE TABLETS PF 36(2) Pg. 389</p>	<p>Title, DEFINITION/Introduction, IDENTIFICATION/Introduction, ASSAY/Procedure, PERFORMANCE TESTS, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities/Procedure, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Cetirizine Hydrochloride RS</p>	<p>Domenick Vicchio</p>
<p>CHITOSAN PF 35(1) Pg. 115</p>	<p>Title, Chemical Info, Definition, Packaging and storage, Labeling, USP Reference standards <11>, Identification, Bacterial endotoxins <85>, Microbial limits <61>, Loss on drying <731>, Residue on ignition <281>, Heavy metals,</p>	<p>Hong Wang</p>

Method III <231>, Limit of lead, mercury, chromium, nickel, cadmium, and arsenic, Limit of iron, Degree of deacetylation, Limit of protein content, Average molecular weight and molecular weight distribution

Title, DEFINITION/Introduction, IDENTIFICATION/Fatty Acid Profile, COMPOSITION/Content of DHA, IMPURITIES/Inorganic Impurities/Limit of Arsenic, IMPURITIES/Inorganic Impurities/Limit of Lead, IMPURITIES/Inorganic Impurities/Limit of Cadmium, IMPURITIES/Inorganic Impurities/Limit of Mercury, SPECIFIC TESTS/Fats and Fixed Oils, Anisidine Value <401>, SPECIFIC TESTS/Fats and Fixed Oils, Acid Value (Free Fatty Acids) <401>, SPECIFIC TESTS/Fats and Fixed Oils, Peroxide Value <401>, SPECIFIC TESTS/Fats and Fixed Oils, Total Oxidation Value (TOTOX) <401>, SPECIFIC TESTS/Fats and Fixed Oils, Unsaponifiable Matter <401>, SPECIFIC TESTS/Specific Gravity <841>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>

CRYPTHECODINIUM
COHNII OIL PF 35(4) Pg. 892

[Gabriel
Giancaspro](#)

Title, DEFINITION/Introduction, IDENTIFICATION/Fatty Acid Profile, OTHER COMPONENTS/Content of Crypthecodinium cohnni Oil, OTHER COMPONENTS/Content of DHA, IMPURITIES/Inorganic Impurities/Limit of Arsenic, IMPURITIES/Inorganic Impurities/Limit of Lead, IMPURITIES/Inorganic Impurities/Limit of Cadmium, IMPURITIES/Inorganic Impurities/Limit of Mercury, SPECIFIC TESTS/Fats and Fixed Oils, Anisidine Value <401>, SPECIFIC TESTS/Fats and Fixed Oils, Free Fatty Acids <401>, SPECIFIC TESTS/Fats and Fixed Oils, Peroxide Value <401>, SPECIFIC TESTS/Fats and Fixed Oils, Total Oxidation Value (TOTOX) <401>, SPECIFIC TESTS/Fats and Fixed Oils, Unsaponifiable Matter <401>, SPECIFIC TESTS/Specific Gravity <841>, PERFORMANCE TESTS, PERFORMANCE TESTS/Disintegration and Dissolution of Dietary Supplements <2040>, PERFORMANCE TESTS/Weight Variation of Dietary Supplements <2091>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>

CRYPTHECODINIUM
COHNII OIL CAPSULES PF
35(5) Pg. 1187

[Natalia
Davydova](#)

Title, Chemical structure, CAS number, Definition, Packaging and storage, USP Reference standards, Labeling (not NL), Identification A, B, C, pH, Loss on drying, Heavy metals, Nitrogen, Limit of nitrite, Limit of boron, Sodium content, Molar ratio of sulphate to carboxylate, Anti-factor IIa activity, Assay (anti-factor Xa activity)

DALTEPARIN SODIUM PF
30(5) Pg. 1598

[Anita Szajek](#)

Title, Chemical Info/Chemical Structure, Chemical Info/CH₃CH₂OOC(CH₂)₈COOCH₂CH₃, Chemical Info/C₁₄H₂₆O₄, Chemical Info/258.35, Chemical Info/Decanedioic acid, 1,10-diethyl ester;, Chemical Info/Diethyl 1,10-decanedioate, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197F>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Inorganic Impurities/Residue on Ignition <281>, IMPURITIES/Inorganic Impurities/Heavy Metals, Method II <231>, SPECIFIC TESTS/Specific Gravity <841>, SPECIFIC TESTS/Refractive Index <831>, SPECIFIC TESTS/Fats and Fixed Oils, Acid Value <401>, SPECIFIC TESTS/Fats and Fixed Oils, Iodine Value <401>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>

DIETHYL SEBACATE PF
35(5) Pg. 1203

[Robert
Lafaver](#)

PERFORMANCE TESTS/Drug Release <724>

ESTRADIOL
TRANSDERMAL SYSTEM
PF 35(5) Pg. 1136

[Margareth
Marques](#)

Title, DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B. Thin-Layer Chromatography Identification Test <201>,

FENTANYL
TRANSDERMAL SYSTEM
PF 36(2) Pg. 397

ASSAY/Procedure, PERFORMANCE TESTS, PERFORMANCE TESTS/Drug Release <724>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities /Procedure 1, IMPURITIES/Organic Impurities /Procedure 2, SPECIFIC TESTS/Alcohol Content, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Fentanyl Citrate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/ USP Fentanyl Related Compound E RS 1-phenethyl-N-phenylpiperidine-4-amineC19H24N2 ċ 2HCl353.33, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/ USP Fentanyl Related Compound G RS N-(1-phenethyl-4-piperidyl)-acetanilide, acetyl fentanylC21H26N2O322.44, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Alcohol RS

[Clydewyn Anthony](#)

FOSFOMYCIN
TROMETHAMINE PF 36(2)
Pg. 404

Title, Chemical Info/Chemical Structure, Chemical Info/C3H7O4PċC4H11NO3, 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](#)

GARCINIA CAMBOGIA PF
36(3) Pg. 699

Title, DEFINITION/Introduction, IDENTIFICATION/Introduction, COMPOSITION/Content of (–)-Hydroxycitric Acid and (–)-Hydroxycitric Acid Lactone, IMPURITIES/Inorganic Impurities/Articles of Botanical Origin, Acid-Insoluble Ash <561>, IMPURITIES/Inorganic Impurities/Heavy Metals, Method III <231>, IMPURITIES/Organic Impurities/Procedure 1: Articles of Botanical Origin, Foreign Organic Matter <561>, IMPURITIES/Organic Impurities/Procedure 2: Articles of Botanical Origin, General Method for Pesticide Residues Analysis <561>, SPECIFIC TESTS/Botanic Characteristics, SPECIFIC TESTS/Limit of Citric Acid, SPECIFIC TESTS/Loss on Drying <731>, SPECIFIC TESTS/Articles of Botanical Origin, Total Ash <561>, SPECIFIC TESTS/Microbial Enumeration Tests—Nutritional and Dietary Supplements <2021>, SPECIFIC TESTS/Absence of specified microorganisms—Nutritional and Dietary Supplements <2022>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Calcium (-)-Hydroxycitrate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Citric Acid RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Powdered Garcinia Hydroxycitrate Extract RS

[Maged Sharaf](#)

POWDERED GARCINIA
CAMBOGIA PF 36(3) Pg.

Title, DEFINITION/Introduction, IDENTIFICATION/Introduction, COMPOSITION/Content of (–)-Hydroxycitric Acid and (–)-Hydroxycitric Acid Lactone, IMPURITIES/Inorganic Impurities/Articles of Botanical Origin, Acid-Insoluble Ash <561>, IMPURITIES/Inorganic Impurities/Heavy Metals, Method III <231>, IMPURITIES/Organic Impurities/Procedure: Articles of Botanical Origin, General Method for Pesticide Residues Analysis <561>, SPECIFIC TESTS/Botanic Characteristics, SPECIFIC TESTS/Limit of Citric Acid, SPECIFIC TESTS/Loss on Drying <731>, SPECIFIC TESTS/Articles of Botanical Origin, Total Ash <561>,

[Maged Sharaf](#)

SPECIFIC TESTS/Microbial Enumeration Tests <2021>, SPECIFIC TESTS/Absence of Specified Microorganisms <2022>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Calcium (–)-Hydroxycitrate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Citric Acid RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Powdered Garcinia Hydroxycitrate Extract RS

Title, DEFINITION/Introduction, IDENTIFICATION/Introduction, COMPOSITION/Content of (–)-Hydroxycitric Acid and Limit of (–)-Hydroxycitric Acid Lactone, IMPURITIES/Inorganic Impurities/Articles of Botanical Origin, Acid-Insoluble Ash <561>, IMPURITIES/Inorganic Impurities/Heavy Metals, Method III <231>, IMPURITIES/Organic Impurities/Procedure: Articles of Botanical Origin, Pesticide Residues <561>, SPECIFIC TESTS/Limit of Citric Acid, SPECIFIC TESTS/Identification Tests—General <191>, SPECIFIC TESTS/Loss on Drying <731>, SPECIFIC TESTS/Microbial Enumeration Tests—Nutritional and Dietary Supplements <2021>, SPECIFIC TESTS/Absence of Specified Microorganisms—Nutritional and Dietary Supplements <2022>, SPECIFIC TESTS/Other Requirements, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Calcium (–)-Hydroxycitrate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Citric Acid RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Powdered Garcinia Hydroxycitrate Extract RS

POWDERED GARCINIA
HYDROXYCITRATE
EXTRACT PF 36(3) Pg. 702

[Maged Sharaf](#)

Title, DEFINITION/Introduction, IDENTIFICATION/A. Thin-Layer Chromatographic Identification Test <201>, IDENTIFICATION/B., COMPOSITION/Content of (–)-Hydroxycitric Acid and (–)-Hydroxycitric Acid Lactone, IMPURITIES/Inorganic Impurities/ Articles of Botanical Origin, Acid-Insoluble Ash <561>, IMPURITIES/Inorganic Impurities/Heavy Metals, Method III <231>, IMPURITIES/Organic Impurities/Procedure 1: Articles of Botanical Origin, Foreign Organic Matter <561>, IMPURITIES/Organic Impurities/Procedure 2: Articles of Botanical Origin, General Method for Pesticide Residues Analysis <561>, SPECIFIC TESTS/Botanic Characteristics, SPECIFIC TESTS/Limit of Citric Acid, SPECIFIC TESTS/Loss on Drying <731>, SPECIFIC TESTS/Articles of Botanical Origin, Total Ash <561>, SPECIFIC TESTS/Microbial Enumeration Tests—Nutritional and Dietary Supplements <2021>, SPECIFIC TESTS/Absence of Specified Microorganisms—Nutritional and Dietary Supplements <2022>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Calcium (–)-Hydroxycitrate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Citric Acid RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Powdered Garcinia Hydroxycitrate Extract RS

GARCINIA INDICA PF 36(3)
Pg. 703

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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, 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>

GLUCAGON PF 35(5) Pg.
1148

[Thomas Sigambris](#)

DEFINITION/Introduction, IDENTIFICATION/Introduction,

GLUCAGON FOR INJECTION PF 35(5) Pg. 1152	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>	Thomas Sigambris
GOSERELIN ACETATE PF 32(3) Pg. 792	Title, Chemical info, Definition, Packaging and storage, USP Reference standards, Specific rotation, Water, Method I, Limit of acetic acid, Related compounds, Amino acid content, Assay	Thomas Sigambris
HELIUM PF 35(4) Pg. 850	IDENTIFICATION/A., IDENTIFICATION/B., IDENTIFICATION/Introduction, ASSAY/Procedure, IMPURITIES/Inorganic Impurities/Carbon Monoxide, IMPURITIES/Inorganic Impurities/Acceptance criteria, SPECIFIC TESTS/Odor, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling	Kabkashan Zaidi
HYDROMORPHONE HYDROCHLORIDE PF 35(5) Pg. 1156	IMPURITIES/Organic Impurities/Procedure, ADDITIONAL REQUIREMENTS/ USP Reference Standards <11>	Clydewyn Anthony
LORATADINE ORALLY-DISINTEGRATING TABLETS PF 34(3) Pg. 624	Title, Definition, Packaging and storage, USP Reference standards <11>, Identification, Disintegration <701>, Dissolution <711>, Uniformity of dosage units <905>, Related compounds, Assay	Mary Waddell
LORATADINE AND PSEUDOEPHEDRINE SULFATE EXTENDED-RELEASE TABLETS PF 32(6) Pg. 1715	Title, Definition, Packaging and storage, USP Reference standards <11>, Identification, Dissolution <711>, Uniformity of dosage units <905>, Loss on drying <731>, Loratadine chromatographic purity, Pseudoephedrine sulfate chromatographic purity, Assay for loratadine, Assay for pseudoephedrine sulfate	Mary Waddell
LUMEFANTRINE PF 36(2) Pg. 413	Title, Chemical Info/Chemical Structure, Chemical Info/C30H32Cl3NO, Chemical Info/528.94, Chemical Info/(±)-2,7-Dichloro-9-[(Z)-p-chlorobenzylidene]-α[(dibutylamino)methyl]-fluorene-4-methanol, Chemical Info/CAS, DEFINITION/Paragraph Text, 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, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Lumefantrine RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Lumefantrine Related Compound A RS [(RS, Z)-2-(Dibutylamino)-2-(2,7-dichloro-9-(4-chlorobenzylidene)-9H-fluoren-4-yl)ethanol](C30H32Cl3NO528.94), ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Lumefantrine Related Compound B RS Lumefantrine related compound B is a mixture of isomers A and B. [Isomer A is (1S,3R,5R)-1,3-bis[(EZ)-2,7-Dichloro-9-(4-chlorobenzylidene)-9H-fluoren-4-yl]-2,6-dioxabicyclo[3.1.0]hexane.] [Isomer B is 2-((EZ)-2,7-Dichloro-9-(4-chlorobenzylidene)-9H-fluoren-4-yl)-3'-((EZ)-2,7-dichloro-9-(4-chlorobenzylidene)-9H-fluoren-4-yl)-2,2'-bioxirane.](C44H= 24Cl6O2797.4)	Behnam Davani
METHOXYPHENYLACETIC TS PF 36(3) Pg. 782	Methoxyphenylacetic TS	Antonio Hernandez-Cardoso
METOLAZONE TABLETS PF 35(6) Pg. 1464	PERFORMANCE TESTS/Dissolution	Margareth Marques
	Title, Chemical Info/Chemical Structure, Chemical Info/C31H43NO7	

(Milbemycin A3 Oxime), Chemical Info/541.68, Chemical Info/Milbemycin B, 5-O-demethyl-28-deoxy-25-methyl-6,28-epoxy-23-hydroxyimino-, [6R,23S,25S(E)]-, Chemical Info/(2 α ;E,4E,5 \prime ;S,6R,6 \prime ;S,8E,11R,13R,15S,17 α =mp; α ;R,20 α ;R,20 β ;S)-6 \prime ;-ethyl-3 \prime ;;=4 \prime ;;5 \prime ;;6,6 \prime ;;7,10,11,14,15,17 α ;;20,2=0 α ;;20 β ;-tetradecahydro-20 β ;-hydroxy-5 \prime = ;,6,8,19-tetramethylspiro[11,15-methano-2H,13H,17H-furo[4,3,2-pq][2,6]benzodioxacyclooctadecin-13,2 \prime ;-[2H]pyran]-17-one 20-oxime;; Chemical Info/(1R, 4S, 5 \prime ;S, 6R, 6 \prime ;R, 8R, 13R, 20R, 24S, 10E, 14E, 16E, 22Z)-24-hydroxy-21-hydroxyimino-2-oxo-11, 13, 22-trimethyl-3, 7, 19-trioxatetracyclo-[15, 6, 1,14,8,020,24] pentacosa-10, 14, 16, 22-tetraene-6-spiro-2 \prime ;- (5, \prime ;6 \prime ;-dimethyltetra= hydropyran), Chemical Info/C32H45NO7 (Milbemycin A4 Oxime), Chemical Info/555.70, Chemical Info/Milbemycin B, 5-O-demethyl-28-deoxy-25-ethyl-6,28-epoxy-23-hydroxyimino-, [6R,23S,25S(E)]-, Chemical Info/(2 α ;E,4E,5 \prime ;S,6R,6 \prime ;S,8E,11R,13R,15S,17 α =mp; α ;R,20 α ;R,20 β ;S)-6 \prime ;-3 \prime ;;4 \prime =prime;;5 \prime ;;6,6 \prime ;;7,10,11,14,15,17 α ;;20,20 α =alpha;;20 β ;-tetradecahydro-20 β ;-hydroxy-5 \prime ;;6 α =p;prime;;6,8,19-pentamethylspiro[11,15-methano-2H,13H,17H-furo[4,3,2-pq][= 2,6]benzodioxacyclooctadecin-13,2 \prime ;-[2H]pyran]-17-one 20-oxime;; Chemical Info/(1R, 4S, 5 \prime ;S, 6R, 6 \prime ;R, 8R, 13R, 20R, 24S, 10E, 14E, 16E, 22Z)-24-hydroxy-21-hydroxyimino-2-oxo-11, 13, 22-trimethyl-3, 7, 19-trioxatetracyclo-[15, 6, 1,14,8,020,24] pentacosa-10, 14, 16, 22-tetraene-6-spiro-2 \prime ;- (6 \prime ;-ethyl-5 \prime ;-methyl=etrahydropyran);, Chemical Info/Mixture of milbemycin A3 oxime and milbemycin A4 oxime, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities/Procedure, SPECIFIC TESTS/Water Determination, Method I <921>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Milbemycin Oxime RS

MILBEMYCIN OXIME PF
36(2) Pg. 417

[Morgan Puderbaugh](#)

Title, Chemical Info/Chemical Structure, Chemical Info/C35H35CINNaO3S, Chemical Info/ 608.17, Chemical Info/Cyclopropaneacetic acid, 1-[[[1-[3-[2-(7-chloro-2-quinoliny)ethenyl]phenyl]-3-[2-(1-hydroxy-1-methyl-ethyl)phenyl]propyl]thio]methyl]-, sodium salt, [R-, (E)]-, Chemical Info/Sodium 1-[[[(R)-m-(E)-2-(7-chloro-2-quinolyl)vinyl]- α ;-[o-(1-hydroxy-1-methylethyl)phenethyl]benzyl]thio]-methyl]cyclopropaneacetate, Chemical Info/CAS, Chemical Info/C35H36CINO3S, Chemical Info/ 586.18, Chemical Info/Montelukast, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197>, IDENTIFICATION/B. Identification Tests—General, Sodium <191>, IDENTIFICATION/C., ASSAY/Note, ASSAY/Procedure, IMPURITIES/Inorganic Impurities/Heavy Metals, IMPURITIES/Organic Impurities/Procedure, SPECIFIC TESTS/Water Determination, Method Ia <921>, SPECIFIC TESTS/Enantiomeric Purity, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Montelukast Sodium RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Montelukast Dicyclohexylamine (DCHA) RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/(C35H36CINO3S—C12H23N767.50), ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Montelukast Racemate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Montelukast for Peak Identification RS

MONTELUKAST SODIUM
PF 36(1) Pg. 121

[Mary Waddell](#)

MORPHINE SULFATE

EXTENDED-RELEASE CAPSULES PF 36(2) Pg. 422	PERFORMANCE TESTS/Dissolution <711>	Clydewyn Anthony
MORPHINE SULFATE EXTENDED-RELEASE TABLETS PF 35(5) Pg. 1164	Title, DEFINITION/Introduction, IDENTIFICATION/A. Identification Tests-General, Sulfate <191>, IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS, PERFORMANCE TESTS/Drug Release <724>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities/Procedure, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>	Clydewyn Anthony
OXYGEN IN NITROGEN CERTIFIED STANDARD PF 35(4) Pg. 991	Oxygen in Nitrogen Certified Standard	Kahkashan Zaidi
OXYGEN CERTIFIED STANDARD PF 35(5) Pg. 1339	Oxygen Certified Standard	Kahkashan Zaidi
NITROGEN PF 35(4) Pg. 910	IDENTIFICATION/Introduction, ASSAY/Procedure, IMPURITIES/Inorganic Impurities/Carbon Monoxide, SPECIFIC TESTS/Odor, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling	Kahkashan Zaidi
NITROGEN 97 PERCENT PF 35(4) Pg. 911	DEFINITION/Introduction, IDENTIFICATION/Introduction, ASSAY/Procedure, IMPURITIES/Inorganic Impurities/Carbon Dioxide, IMPURITIES/Inorganic Impurities/Carbon Monoxide, IMPURITIES/Inorganic Impurities/Sulfur Dioxide, IMPURITIES/Inorganic Impurities/Limit of Nitric Oxide and Nitrogen Dioxide, ADDITIONAL REQUIREMENTS/Packaging and Storage	Kahkashan Zaidi
NITROGEN CERTIFIED STANDARD PF 35(4) Pg. 990	Nitrogen Certified Standard	Kahkashan Zaidi
NITROUS OXIDE PF 35(4) Pg. 859	DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B., IDENTIFICATION/C., ASSAY/Procedure, IMPURITIES/Inorganic Impurities/Ammonia, IMPURITIES/Inorganic Impurities/Nitric Oxide, IMPURITIES/Inorganic Impurities/Nitrogen Dioxide, IMPURITIES/Inorganic Impurities/Halogens, IMPURITIES/Inorganic Impurities/Carbon Monoxide, IMPURITIES/Inorganic Impurities/Carbon Dioxide, SPECIFIC TESTS/Water, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling	Kahkashan Zaidi
NONYL PARABEN PF 36(2) Pg. 575	Nonylparaben (4-Hydroxybenzoic acid nonyl ester, nonyl 4-hydroxybenzoate),	Morgan Puderbaugh
OMEGA-3 ACIDS ETHYL ESTERS PF 35(5) Pg. 1190	IMPURITIES/Organic Impurities/Procedure 4: Limit of DDT, Hexachlorobenzene (HCB), and Lindane	Gabriel Giancaspro
ORLISTAT PF 35(5) Pg. 1166	Title, Chemical Info/Chemical Structure, Chemical Info/C29H53NO5, Chemical Info/495.73, Chemical Info/1-Leucine, N-formyl-, 1-[(3-hexyl-4-oxo-2-oxetanyl)methyl]dodecyl ester, [2S-[2α(R*), 3β]]-, Chemical Info/N-Formyl-1-leucine, ester with (3S,4S)-3-hexyl-4-[(2S)-2-hydroxytridecyl]-2-oxetanone, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197M>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Inorganic Impurities/Residue on Ignition <281>, IMPURITIES/Inorganic Impurities/Heavy Metals, Method II <231>, IMPURITIES/Organic Impurities/Procedure 1: Limit of Orlistat Related Compound A, IMPURITIES/Organic Impurities/Procedure 2: Limit of Orlistat Related Compound B, IMPURITIES/Organic Impurities/Procedure 3,	Clydewyn Anthony

IMPURITIES/Organic Impurities/Procedure 4: Limit of Orlistat Related Compound D, IMPURITIES/Organic Impurities/Procedure 5: Limit of Orlistat Related Compound E, SPECIFIC TESTS/Optical Rotation, Specific Rotation <781>, SPECIFIC TESTS/Water Determination, Method Ic <921>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>

Title, DEFINITION/Introduction, IDENTIFICATION/Introduction, ASSAY/Procedure, PERFORMANCE TESTS, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities/Procedure, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>

ORLISTAT CAPSULES PF
35(5) Pg. 1169

[Clydewyn
Anthony](#)

OXCARBAZEPINE PF 34(5)
Pg. 1177

Related compounds

[Ravi
Ravichandran](#)

OXCARBAZEPINE
TABLETS PF 34(6) Pg. 1478

Title, Definition, Packaging and storage, USP Reference standards <11>, Identification, Uniformity of dosage units <905>, Related compounds, Assay

[Ravi
Ravichandran](#)

OXYGEN PF 35(4) Pg. 861

IDENTIFICATION/Procedure, IDENTIFICATION/B. Procedure, ASSAY/Procedure, IMPURITIES/Inorganic Impurities/Carbon Dioxide, IMPURITIES/Inorganic Impurities/Carbon Monoxide, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling

[Kahkashan
Zaidi](#)

OXYGEN 93 PERCENT PF
35(4) Pg. 862

IDENTIFICATION/A. Procedure, IDENTIFICATION/B. Procedure, ASSAY/Procedure, IMPURITIES/Inorganic Impurities/Carbon Dioxide, IMPURITIES/Inorganic Impurities/Carbon Monoxide, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling

[Kahkashan
Zaidi](#)

21.0 PERCENT OXYGEN IN
NITROGEN CERTIFIED
STANDARD PF 35(4) Pg.
991

21.0% Oxygen in Nitrogen Certified Standard

[Kahkashan
Zaidi](#)

3.0 PERCENT OXYGEN IN
NITROGEN CERTIFIED
STANDARD PF 35(4) Pg.
991

3.0% Oxygen in Nitrogen Certified Standard

[Kahkashan
Zaidi](#)

OXYGEN-HELIUM
CERTIFIED STANDARD PF
35(4) Pg. 991

Oxygen-Helium Certified Standard

[Kahkashan
Zaidi](#)

PANCURONIUM BROMIDE
INJECTION PF 32(4) Pg.
1097

Title, Definition, Packaging and storage, USP Reference standards <11>, Identification, Bacterial endotoxins <85>, pH <791>, Particulate matter <788>, Related compounds, Other requirements, Assay

[Mary
Waddell](#)

POLYGLYCERYL 3
DIISOSTEARATE PF 36(2)
Pg. 451

Title, Chemical
Info/R–O–(CH2–CH(OR)–CH2–O)³–R, Chemical Info/R H, or CO–C17H35-iso,
Chemical Info/1,2,3-Propanetriol, homopolymer, diisooctadecanoate,;
Chemical Info/Triglyceryl diisostearate, Chemical Info/CAS,
DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197F>, IDENTIFICATION/B., ASSAY/Content of Fatty Acids, IMPURITIES/Inorganic Impurities/Residue on Ignition, IMPURITIES/Inorganic Impurities/Heavy Metals, Method II <231>, SPECIFIC TESTS/Acid Value, SPECIFIC TESTS/Fats and Fixed Oils, Hydroxyl Value <401>, SPECIFIC TESTS/Iodine Value, SPECIFIC TESTS/Fats and Fixed Oils, Peroxide Value <401>, SPECIFIC TESTS/Fats and Fixed Oils, Saponification Value <401>, SPECIFIC TESTS/Water Determination, Method

[Hong Wang](#)

I <921>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methyl Myristate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methyl Palmitate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methyl Stearate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Polyglyceryl 3 Diisostearate RS

Title, DEFINITION/Introduction, IDENTIFICATION/A. Thin-Layer Chromatographic Identification Test <201>, IDENTIFICATION/B., COMPOSITION/Content of (–)-Hydroxycitric Acid and (–)-Hydroxycitric Acid Lactone, IMPURITIES/Inorganic Impurities/Articles of Botanical Origin, Acid-Insoluble Ash <561>, IMPURITIES/Inorganic Impurities/Heavy Metals, Method III <231>, IMPURITIES/Organic Impurities/Procedure: Articles of Botanical Origin, General Method for Pesticide Residues Analysis <561>, SPECIFIC TESTS/Botanic Characteristics, SPECIFIC TESTS/Limit of Citric Acid, SPECIFIC TESTS/Loss on Drying <731>, SPECIFIC TESTS/Articles of Botanical Origin, Total Ash <561>, SPECIFIC TESTS/Microbial Enumeration Tests—Nutritional and Dietary Supplements <2021>, SPECIFIC TESTS/Absence of Specified Microorganisms—Nutritional and Dietary Supplements <2022>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Calcium (–)-Hydroxycitrate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Citric Acid RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Powdered Garcinia Hydroxycitrate Extract RS

POWDERED GARCINIA
INDICA PF 36(3) Pg. 704

[Maged Sharaf](#)

Title, 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>

PROMETHAZINE AND
PHENYLEPHRINE
HYDROCHLORIDE ORAL
SOLUTION PF 35(2) Pg. 298

[Clydewyn Anthony](#)

Title, 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, Method II <611> (if present), SPECIFIC TESTS/Deliverable Volume <698>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>

PROMETHAZINE AND
PHENYLEPHRINE
HYDROCHLORIDE AND
CODEINE PHOSPHATE
ORAL SOLUTION PF 35(2)
Pg. 301

[Clydewyn Anthony](#)

Title, 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>

PROMETHAZINE
HYDROCHLORIDE AND
CODEINE PHOSPHATE
ORAL SOLUTION PF 35(2)
Pg. 292

[Clydewyn Anthony](#)

Title, 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>

PROMETHAZINE
HYDROCHLORIDE AND
DXTROMETHORPHAN
HYDROBROMIDE ORAL
SOLUTION PF 35(2) Pg. 295

[Clydewyn Anthony](#)

RIBAVIRIN CAPSULES PF 35(3) Pg. 576	Title, DEFINITION/Introduction, IDENTIFICATION/Introduction, ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities/Procedure, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>	Leonel Santos
ROPINIROLE HYDROCHLORIDE PF 36(1) Pg. 133	IMPURITIES/Organic Impurities /Procedure 1, IMPURITIES/Organic Impurities /Procedure 2, ADDITIONAL REQUIREMENTS/Labeling	Ravi Ravichandran
SCHIZOCHYTRIUM OIL PF 35(4) Pg. 894	Title, DEFINITION/Introduction, IDENTIFICATION/Long Chain Unsaturated Fatty Acid Profile, COMPOSITION/Content of DHA, IMPURITIES/Inorganic Impurities/Limit of Arsenic, IMPURITIES/Inorganic Impurities/Limit of Lead, IMPURITIES/Inorganic Impurities/Limit of Cadmium, IMPURITIES/Inorganic Impurities/Limit of Mercury, SPECIFIC TESTS/Fats and Fixed Oils, Anisidine Value <401>, SPECIFIC TESTS/Fats and Fixed Oils, Free Fatty Acids <401>, SPECIFIC TESTS/Fats and Fixed Oils, Peroxide Value <401>, SPECIFIC TESTS/Fats and Fixed Oils, Total Oxidation Value (TOTOX) <401>, SPECIFIC TESTS/Fats and Fixed Oils, Unsaponifiable Matter <401>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>	Gabriel Giancaspro
SCHIZOCHYTRIUM OIL CAPSULES PF 35(5) Pg. 1192	Title, DEFINITION/Introduction, IDENTIFICATION/Fatty Acid Profile, OTHER COMPONENTS/Content of Schizochytrium Oil, OTHER COMPONENTS/Content of DHA, PERFORMANCE TESTS, PERFORMANCE TESTS/Disintegration and Dissolution of Dietary Supplements <2040>, PERFORMANCE TESTS/Weight Variation <2091>, IMPURITIES/Inorganic Impurities/Limit of Arsenic, IMPURITIES/Inorganic Impurities/Limit of Lead, IMPURITIES/Inorganic Impurities/Limit of Cadmium, IMPURITIES/Inorganic Impurities/Limit of Mercury, SPECIFIC TESTS/Fats and Fixed Oils, Anisidine Value <401>, SPECIFIC TESTS/Fats and Fixed Oils, Free Fatty Acids <401>, SPECIFIC TESTS/Fats and Fixed Oils, Peroxide Value <401>, SPECIFIC TESTS/Fats and Fixed Oils, Total Oxidation Value (TOTOX) <401>, SPECIFIC TESTS/Fats and Fixed Oils, Unsaponifiable Matter <401>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>	Natalia Davydova
SENNOSIDES PF 35(2) Pg. 309	SPECIFIC TESTS/Content of Senosides A and B, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>	Maged Sharaf
SERTRALINE HYDROCHLORIDE PF 34(5) Pg. 1189	Related compounds	Ravi Ravichandran
SODIUM HYDROXIDE TS3 PF 36(3) Pg. 783	Sodium Hydroxide TS 3	Antonio Hernandez-Cardoso
HYDROGENATED STARCH HYDROLYSATE PF 35(1) Pg. 136	Title, Chemical Info, Definition, Packaging and storage, Labeling, USP Reference standards <11>, Identification, Microbial limits <61>, pH <791>, Water, Method I <921>, Residue on ignition <281>, Reducing sugars, Limit of chloride, Limit of sulfate <221>, Limit of nickel, Content of maltitol and sorbitol, Hydrogenated polysaccharides	Hong Wang
SUMATRIPTAN TABLETS PF 35(4) Pg. 871	IMPURITIES/Organic Impurities/Procedure	Ravi Ravichandran
	Title, Chemical Info/Chemical Structure, Chemical	

Info/C44H69NO12&middledot;H2O, Chemical Info/822.03, Chemical Info/15,19-Epoxy-3H-pyrido[2,1-c][1,4]oxaazacyclotricosine-1,7,20,21(4H,2= 3H)-tetrone-5,6,8,11,12,13,14,15, 16,17,18,19,24,25,26,26a-hexadecahydro-5,19-dihydroxy-3-[2-(4-hydroxy-3-m= ethoxycyclohexyl)-1-methylethenyl]-14,16-dimethoxy-4,10,12,18-tetramethyl= -8-(2-propenyl)-, monohydrate, [3S-[3R*,E(1S*,3S*,4S*)],4S*,5R*,8S*,9E,12R*,14R*,15S*,16R*,18S*,19S*,26a=R*]]-; Chemical Info/(−)- (3S,4R,5S,8R,9E,12S,14S,15R,16S,18R,19R,26aS)-8-Allyl= 5,6,8,11,12,13,14,15,16,17,18,19,24,25,26,26a-hexadecahydro-5,19-dihydrox= y-3-[(E)-2-[(1R,3R,4R)-4-hydroxy-3-methoxycyclohexyl]-1-methylvinyl]-14,1= 6-dimethoxy-4,10,12,18-tetramethyl-15,19-epoxy-3H-pyrido[2,1-c][1,4]oxaaz= acyclotricosine-1,7,20,21(4H,23H)-tetrone, monohydrate, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197M>, IDENTIFICATION/B., IDENTIFICATION/C., ASSAY/Procedure, IMPURITIES/Inorganic Impurities/Residue on Ignition <281>, IMPURITIES/Inorganic Impurities/Heavy Metals, Method II <231>, IMPURITIES/Organic Impurities/Procedure, SPECIFIC TESTS/Optical Rotation, Specific Rotation <781S>, SPECIFIC TESTS/Water Determination, Method I <921>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>

TACROLIMUS PF 35(2) Pg. 310

[Ahalya Wise](#)

Title, DEFINITION/Introduction, IDENTIFICATION/A. Procedure, IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities/Procedure, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>

TACROLIMUS CAPSULES PF 35(2) Pg. 312

[Ahalya Wise](#)

Title, DEFINITION/Introduction, IDENTIFICATION/A. Ultraviolet Absorption <197U>, IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities/Procedure, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>

TERAZOSIN CAPSULES PF 35(4) Pg. 872

[Sujatha Ramakrishna](#)

Title, DEFINITION/Introduction, IDENTIFICATION/A. Ultraviolet Absorption <197U>, IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities/Procedure, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>

TERAZOSIN TABLETS PF 35(4) Pg. 874

[Sujatha Ramakrishna](#)

Title, Chemical structure, Chemical formula, Molecular weight, Chemical names, Cas number, Definition, Packaging and storage, USP Reference standards, Identification, Water, High boiling residues, Ionic contaminants, Chromatographic purity, Assay

TETRAFLUOROETHANE PF 31(6) Pg. 1672

[Kahkashan Zaidi](#)

{Emollient} Butyl Stearate, {Flavors and Perfumes} Diethyl Sebacate, {Coating Agent} Chitosan, {Film-Forming Agent} Chitosan, {Humectant} Hydrogenated Starch Hydrolysate, {Suspending and/or Viscosity-Increasing Agent} Chitosan, {Sweetening Agent} Hydrogenated Starch Hydrolysate, {Tablet Binder} Hydrogenated Starch Hydrolysate, {Tablet and/or Capsule Diluent} Hydrogenated Starch Hydrolysate, {Vehicle} {solid carrier}Chitosan, {Complexing Agent} Betadex Sulfobutyl Ether Sodium, {Emulsifying and/or Solubilizing Agent} Polyglyceryl 3 Diisostearate, {Ointment Base} Polyglyceryl 3 Diisostearate, {Sequestering Agent} Betadex Sulfobutyl Ether Sodium, {Wetting and/or Solubilizing Agent} Betadex Sulfobutyl Ether Sodium

USP AND NF EXCIPIENTS, LISTED BY CATEGORY PF 35(6) Pg. 1488

[Robert Lafaver](#)

L## Dalteparin Sodium, anion-exchange Dowex 1X8--[to come.], L## (Dalteparin Sodium, anion-exchange Dowex 1X8), L## (Dalteparin Sodium,

CHROMATOGRAPHIC
REAGENTS

cation-exchange Dowex 50WX2), L## Dalteparin Sodium, cation-exchange Dowex 50WX2--[to come], Chromatographic reagents Packings: L## Dalteparin Sodium, anion-exchange Dowex 1X8--[to come.] L## Dalteparin Sodium, cation-exchange Dowex 50WX2--[to come], S## Tetrafluoroethane

[Anita Szajek](#)

DESCRIPTION AND
SOLUBILITY PF 36(2) Pg.
578

Artemether, Butyl Stearate, Betadex Sulfobutyl Ether Sodium, Montelukast Sodium, Fosfomycin Tromethamine, Diethyl Sebacate, Lumefantrine, Milbemycin Oxime, Polyglyceryl 3 Diisostearate, Chitosan, Hydrogenated Starch Hydrolysate, Albumin Human

[Behnam Davani](#)