

Compendial Deferrals for USP 34-NF 29

Monograph Title	Monograph Section	Scientific Liaison
<3> TOPICAL AND TRANSDERMAL PRODUCTS-PRODUCT QUALITY TESTS PF 35(3) Pg. 602	Title, I. INTRODUCTION, II. GLOSSARY OF TERMS, III. PRODUCT QUALITY TESTS FOR ALL TOPICALLY APPLIED DRUG PRODUCTS, III. A. PRODUCT QUALITY TESTS FOR TOPICAL DRUG PRODUCTS INTENDED FOR LOCAL ACTION, III. B. PRODUCT QUALITY TESTS FOR TRANSDERMAL DRUG PRODUCTS, IV. PRODUCT PERFORMANCE TEST FOR TOPICAL DRUG PRODUCTS, V. IN VITRO DRUG RELEASE FROM SEMISOLID DOSAGE FORMS, V. A. THEORY, V. B. APPLICATION OF DRUG RELEASE	Margareth Marques
<11> USP REFERENCE STANDARDS PF 34(4) Pg. 1021	USP Ceftiofur Hydrochloride RS, USP Ceftiofur Sodium RS, USP Ceftiofur System Suitability Mixture RS, USP Alpha-Lactalbumin RS, USP Sertraline Related Compound A RS	Elena Gonikberg
<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
<729> GLOBULE SIZE DISTRIBUTION IN LIPID INJECTABLE EMULSIONS PF 36(1) Pg. 223	INTRODUCTION	Desmond Hunt
<795> PHARMACEUTICAL COMPOUNDING--NONSTERILE PREPARATIONS PF 35(4) Pg. 926	Introduction, RESPONSIBILITY OF THE COMPOUNDER, COMPOUNDING ENVIRONMENT	Rick Schnatz
<911> NEWTONIAN VISCOSITY PF 34(6) Pg. 1536	Title, MEASUREMENT OF VISCOSITY, PROCEDURE FOR CELLULOSE DERIVATIVES, CALIBRATION OF CAPILLARY-TYPE VISCOSIMETERS, CALCULATIONS, INTRODUCTION, METHOD I-MEASUREMENT OF VISCOSITY USING A CAPILLARY VISCOMETER, METHOD II-MEASUREMENT OF VISCOSITY USING A ROTATIONAL VISCOMETER	Hong Wang
<912> ROTATIONAL VISCOMETER METHOD	Title, INTRODUCTION, METHOD I. MEASUREMENT OF VISCOSITY USING A ROTATIONAL RHEOMETER, METHOD II. MEASUREMENT OF	Hong Wang

PF 34(6) Pg. 1541

VISCOSITY USING A NONROTATIONAL RHEOMETER

<1033> VALIDATION OF
BIOLOGICAL ASSAYS
PF 35(2) Pg. 349

Title, INTRODUCTION, FUNDAMENTALS OF A VALIDATION STUDY FOR RELATIVE POTENCY ASSAYS, BIOLOGICAL ASSAY VALIDATION STUDY PROTOCOL, DESIGN OF A BIOLOGICAL ASSAY STUDY VALIDATION PROTOCOL, VALIDATION STRATEGIES FOR ASSAY PERFORMANCE CHARACTERISTICS, VALIDATION TARGET ACCEPTANCE CRITERIA, BIOASSAY MAINTENANCE, STATISTICAL CONSIDERATIONS, A BIOASSAY STUDY VALIDATION EXAMPLE, APPENDIX I, APPENDIX II

[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, 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

[Desmond Hunt](#)

<1097> BULK POWDER
SAMPLING
PROCEDURES PF 35(2)
Pg. 367

Title, INTRODUCTION, SAMPLING THEORY AND TERMINOLOGY, GENERAL SAMPLE COLLECTION: CONSIDERATIONS AND TOOLS, PRIMARY SAMPLE COLLECTION, PRIMARY SAMPLE SIZE REDUCTION, APPENDIX 1: SUBSAMPLING EXAMPLES, APPENDIX 2: MATERIAL CHARACTERIZATION AND SAMPLING, APPENDIX 3: RANDOM NUMBER TABLES, APPENDIX 4. ADDITIONAL SOURCES OF INFORMATION

[Horacio Pappa](#)

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

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](#)

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

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](#)

<1180> HUMAN
PLASMA PF 35(2) Pg. 388

Title, SCOPE, OVERVIEW, PLASMA COLLECTION AND PROCESSING, PLASMA SAFETY CONSIDERATIONS, QUALITY SYSTEMS, GLOSSARY,

[Anita Szajek](#)

APPENDICES

<2232> ELEMENTAL CONTAMINANTS IN DIETARY SUPPLEMENTS PF 36(1) Pg. 258	Title, INTRODUCTION, LIMITS OF ELEMENTAL CONTAMINANTS, OPTIONS FOR COMPLIANCE WITH THE LIMITS OF ELEMENTAL CONTAMINANTS, ANALYTICAL PROCEDURES FOR TOTAL ELEMENTAL CONTAMINANTS, ANALYTICAL PROCEDURE FOR INORGANIC ARSENIC, ANALYTICAL PROCEDURE FOR METHYLMERCURY	Yoshiyuki Tokiwa
93.0 PERCENT OXYGEN CERTIFIED STANDARD PF 35(4) Pg. 991	93.0% Oxygen Certified Standard	Kahkashan Zaidi
AGAR PF 33(4) Pg. 702	Chemical Info, Definition, Botanic characteristics, Packaging and storage, USP Reference standards <11>, Identification, Microbial limits <61>, Limit of foreign insoluble matter	Hong Wang
MEDICAL AIR PF 35(4) Pg. 828	IDENTIFICATION/Introduction, ASSAY/Procedure, IMPURITIES/Inorganic Impurities/Carbon Dioxide, IMPURITIES/Inorganic Impurities/Sample, 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
ATROPINE SULFATE PF 35(4) Pg. 829	IDENTIFICATION/C., IMPURITIES/Organic Impurities/Procedure, SPECIFIC TESTS/ Melting Range or Temperature, Class Ia <741>, SPECIFIC TESTS/Optical Rotation, Angular Rotation <781A>, SPECIFIC TESTS/Optical Rotation, Specific Rotation <781S>, SPECIFIC TESTS/Acidity, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>	Ravi Ravichandran
BUTYL STEARATE PF 35(6) Pg. 1502	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	Robert Lafaver
CARBIDOPA AND LEVODOPA EXTENDED-RELEASE TABLETS PF 34(6) Pg. 1433	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	Ravi Ravichandran
CEFEPIME HYDROCHLORIDE PF 36(1) Pg. 76	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	Ahalya Wise
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	Ahalya Wise

<11>/USP Cefepime Hydrochloride System Suitability RS

CEFTIOFUR HYDROCHLORIDE PF 34(4) Pg. 908	Title, Chemical Info, Definition, Packaging and storage, Labeling, USP Reference standards <11>, Identification, Specific rotation <781S>, Bacterial endotoxins <85>, Water, Method I <921>, Chromatographic purity, Assay	Elena Gonikberg
CEFTIOFUR SODIUM PF 34(4) Pg. 912	Title, Chemical Info, Definition, Packaging and storage, Labeling, USP Reference standards <11>, Identification, Bacterial endotoxins <85>, pH <791>, Water, Method I <921>, Limit of acetone and tetrahydrofuran, Chromatographic purity, Assay	Elena Gonikberg
CHITOSAN PF 35(1) Pg. 115	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, 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	Hong Wang
CRYPTHECODINIUM COHNII OIL PF 35(4) Pg. 892	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>	Gabriel Giancaspro
CRYPTHECODINIUM COHNII OIL CAPSULES PF 35(5) Pg. 1187	Title, DEFINITION/Introduction, IDENTIFICATION/Fatty Acid Profile, OTHER COMPONENTS/Content of Crypthecodinium cohnii 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>	Natalia Davydova
DALTEPARIN SODIUM PF 30(5) Pg. 1598	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), Bacterial endotoxins	Anita Szajek
DIETHYL SEBACATE PF 35(5) Pg. 1203	Title, Chemical Info/Chemical Structure, Chemical Info/CH ₃ CH ₂ OOC(CH ₂) ₈ COOCH ₂ CH ₃ , Chemical Info/C ₁₄ H ₂₆ O ₄ , 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	Robert Lafaver

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>

ESTRADIOL
TRANSDERMAL
SYSTEM PF 35(5) Pg.
1136

PERFORMANCE TESTS/Drug Release <724>

[Margareth Marques](#)

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, 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>

[Thomas Sigambris](#)

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>

[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, Bacterial endotoxins

[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

[Kahkashan Zaidi](#)

HYDROMORPHONE
HYDROCHLORIDE PF
35(5) Pg. 1156

IMPURITIES/Organic Impurities/Procedure, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>

[Clydewyn Anthony](#)

L##_Emtricitabine,
Chirobiotic V PF 35(5) Pg.
1340

L## (Emtricitabine, Chirobiotic V)

[Margareth Marques](#)

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](#)

METOLAZONE
TABLETS PF 35(6) Pg.
1464

PERFORMANCE TESTS/Dissolution

[Margareth Marques](#)

MONTELUKAST

Title, Chemical Info/Chemical Structure, Chemical Info/C35H35CINNaO3S,

[Mary](#)

SODIUM PF 36(1) Pg. 121	<p>Chemical Info/ 608.17, Chemical Info/Cyclopropaneacetic acid, 1-[[[1-[3-[2-(7-chloro-2-quinolinyl)ethenyl]phenyl]-3-[2-(1-hydroxy-1-methylethyl)phenyl]propyl]thio]methyl]-, sodium salt, [R-,(E)-];, Chemical Info/Sodium 1-[[[(R)-m-(E)-2-(7-chloro-2-quinolyl)vinyl]-&alpha;-[o-(1-hydroxy-1-methylethyl)phenethyl]benzyl]thio]-methyl]cyclopropaneacetate, Chemical Info/CAS, Chemical Info/C35H36ClNO3S, Chemical Info/ 586.18, Chemical Info/Montelukast, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197>, IDENTIFICATION/B. Identification Tests&#151;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>/C35H36ClNO3S&#151;C12H23N767.50), ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Montelukast Racemate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Montelukast for Peak Identification RS</p>	Waddell
MORPHINE SULFATE EXTENDED-RELEASE TABLETS PF 35(5) Pg. 1164	<p>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></p>	Clydewyn Anthony
OXYGEN IN NITROGEN CERTIFIED STANDARD PF 35(4) Pg. 991	<p>Oxygen in Nitrogen Certified Standard</p>	Kahkashan Zaidi
OXYGEN CERTIFIED STANDARD PF 35(5) Pg. 1339	<p>Oxygen Certified Standard</p>	Kahkashan Zaidi
NITROGEN PF 35(4) Pg. 910	<p>IDENTIFICATION/Introduction, ASSAY/Procedure, IMPURITIES/Inorganic Impurities/Carbon Monoxide, SPECIFIC TESTS/Odor, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling</p>	Kahkashan Zaidi
NITROGEN 97 PERCENT PF 35(4) Pg. 911	<p>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</p>	Kahkashan Zaidi
NITROGEN CERTIFIED STANDARD PF 35(4) Pg. 990	<p>Nitrogen Certified Standard</p>	Kahkashan Zaidi
NITROUS OXIDE PF 35(4) Pg. 859	<p>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</p>	Kahkashan Zaidi

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/l-Leucine, N-formyl-, 1-[(3-hexyl-4-oxo-2-oxetanyl)methyl]dodecyl ester, [2S-[2α(R*), 3β]]-, Chemical Info/N-Formyl-l-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, 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>	Clydewyn Anthony
ORLISTAT CAPSULES PF 32(6) Pg. 1739	Dissolution <711>, 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>	Margareth Marques
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
PROMETHAZINE HYDROCHLORIDE AND CODEINE PHOSPHATE ORAL SOLUTION PF 35(2) Pg. 292	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>	Clydewyn Anthony
PROMETHAZINE HYDROCHLORIDE AND DXTROMETHORPHAN HYDROBROMIDE ORAL SOLUTION PF 35(2) Pg. 295	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>	Clydewyn Anthony
PROMETHAZINE AND PHENYLEPHRINE HYDROCHLORIDE ORAL SOLUTION PF 35(2) Pg. 298	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>	Clydewyn Anthony
PROMETHAZINE AND PHENYLEPHRINE HYDROCHLORIDE AND CODEINE PHOSPHATE ORAL SOLUTION PF 35(2) Pg. 301	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>	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>	Behnam Davani
RIZATRIPTAN BENZOATE PF 36(1) Pg. 132	Title, Chemical Info/Chemical Structure, Chemical Info/C22H25N5O2, Chemical Info/391.47, Chemical Info/1H-Indole-3-ethanamine, N,N-dimethyl-5-(1H-1,2,4-triazol-1-ylmethyl)-, monobenzoate;, Chemical Info/3-[2-(Dimethylamino)ethyl]-5-(1H-1,2,4-triazol-1-ylmethyl)indole monobenzoate, 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 <231>, IMPURITIES/Inorganic Impurities/Sample solution, IMPURITIES/Inorganic Impurities/Reference solution, IMPURITIES/Inorganic Impurities/Blank solution, IMPURITIES/Inorganic Impurities/Analysis, IMPURITIES/Organic Impurities/Procedure, SPECIFIC TESTS/Water Determination, Method Ia <921>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Rizatriptan Benzoate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Rizatriptan Benzoate System Suitability Mixture RS. Mixture of rizatriptan benzoate and at least 0.1% of rizatriptan impurity C. Rizatriptan impurity C is 2-{5-[(1H-1,2,4-triazol-1-yl)methyl]-1H-indol-2-yl}-N,N-dimethylethanamine. (C15H19N5 269.34)	Ravi Ravichandran

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 Sennosides A and B, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>	Maged Sharaf
SERTRALINE HYDROCHLORIDE PF 34(5) Pg. 1189	Related compounds	Ravi Ravichandran
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
TACROLIMUS PF 35(2) Pg. 310	Title, Chemical Info/Chemical Structure, Chemical Info/C44H69NO12·H2O, Chemical Info/822.03, Chemical Info/15,19-Epoxy-3H-pyrido[2,1-c][1,4]oxaazacyclotricosine-1,7,20,21(4H,23H)-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-methoxycyclohexyl)-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*,26aR*]]-; 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-dihydroxy-3-[(E)-2-[(1R,3R,4R)-4-hydroxy-3-methoxycyclohexyl]-1-	Ahalya Wise

methylvinyl]-14,16-dimethoxy-4,10,12,18-tetramethyl-15,19-epoxy-3H-pyrido[2,1-c][1,4]oxaazacyclotricosine-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
CAPSULES PF 35(2) Pg.
312

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>

[Ahalya Wise](#)

TERAZOSIN CAPSULES
PF 35(4) Pg. 872

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

[Sujatha Ramakrishna](#)

TERAZOSIN TABLETS
PF 35(4) Pg. 874

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

[Sujatha Ramakrishna](#)

TETRAFLUOROETHANE
PF 31(6) Pg. 1672

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

[Kahkashan Zaidi](#)

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

{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

[Robert Lafaver](#)

VALACYCLOVIR
TABLETS PF 35(4) Pg.
878

Title, DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B. Identification Tests-General, Chloride <191>, 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>

[Behnam Davani](#)

DESCRIPTION AND
SOLUBILITY PF 35(6)
Pg. 1571

Butyl Stearate, Donepezil Hydrochloride, Montelukast Sodium, Rizatriptan Benzoate, Diethyl Sebacate, Chitosan, Hydrogenated Starch Hydrolysate, Albumin Human

[Robert Lafaver](#)