

# Compendial Approvals for USP 35–NF 30

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Monograph Title	Monograph Section	Scientific Liaison
<1> INJECTIONS PF 36(6) Pg. 1644	NOMENCLATURE AND DEFINITIONS	<a href="#">Desmond Hunt</a>
<3> TOPICAL AND TRANSDERMAL DRUG PRODUCTS - PRODUCT QUALITY TESTS PF 36(6) Pg. 1647	Introduction, INTRODUCTION, PRODUCT QUALITY TESTS FOR TOPICALLY APPLIED DRUG PRODUCTS	<a href="#">Margareth Marques</a>
<81> ANTIBIOTICS--MICROBIAL ASSAYS PF 36(5) Pg. 1239	Introduction, APPARATUS, MEDIA AND DILUENTS, UNITS AND REFERENCE STANDARDS, PREPARATION OF THE STANDARD, PREPARATION OF THE SAMPLE, ORGANISMS AND INOCULUM, PROCEDURE, CALCULATION, INTRODUCTION AND GENERAL INFORMATION, CYLINDER-PLATE METHOD, TURBIDIMETRIC METHOD, MEDIA AND SOLUTIONS, CALCULATIONS, APPENDIX 1. FORMULAS FOR MANUAL CALCULATIONS OF REGRESSION AND SAMPLE CONCENTRATION, APPENDIX 2. PROCEDURE FOR CHECKING FOR OUTLIERS; REJECTION OF OUTLYING OR ABERRANT MEASUREMENTS	<a href="#">Ahalya Wise</a>
<88> BIOLOGICAL REACTIVITY TESTS, IN VIVO PF 36(6) Pg. 1664	CLASSIFICATION OF PLASTICS—, IMPLANTATION TEST	<a href="#">Radhakrishna Tirumalai</a>
<141> PROTEIN--BIOLOGICAL ADEQUACY TEST PF 36(6) Pg. 1666	Title, DEPLETION DIET—, CONTROL NITROGEN SUPPLEMENT MIXTURE—, DEPLETION AND CONTROL PERIODS—, PROCEDURE—	<a href="#">Maura Kibbey</a>
<401> FATS AND FIXED OILS PF 37(1) Pg. ONLINE	ESTER VALUE, FATTY ACID COMPOSITION, TRACE METALS, STEROL COMPOSITION	<a href="#">Hong Wang</a>
<467> RESIDUAL SOLVENTS PF 37(1) Pg. ONLINE	LIMITS OF RESIDUAL SOLVENTS	<a href="#">Horacio Pappa</a>
<610> ALTERNATIVE MICROBIOLOGICAL SAMPLING METHODS FOR NONSTERILE INHALED AND NASAL PRODUCTS PF 36(6) Pg. 1667	INTRODUCTION, INHALED OR NASAL DOSAGE FORMS, SAMPLE SIZE DETERMINATION, BULK TESTING FOR LOW-CONTENT INDP, SAMPLING METHODS FOR HIGH-CONTENT INDP	<a href="#">Radhakrishna Tirumalai</a>
<659> PACKAGING AND STORAGE REQUIREMENTS PF 36(6) Pg. 1669	Introduction, PACKAGING, GENERAL DEFINITIONS, DEFINITIONS OF SPECIFIC TYPES OF PACKAGING, ASSOCIATED PACKAGING COMPONENTS, POISON PREVENTION PACKAGING ACT (PPPA), STORAGE CONDITIONS	<a href="#">Desmond Hunt</a>
<781> OPTICAL ROTATION PF 37(1) Pg. ONLINE	SPECIFIC ROTATION—	<a href="#">Antonio Hernandez-</a>

<823> RADIOPHARMACEUTICALS  
FOR POSITRON EMISSION  
TOMOGRAPHY--COMPOUNDING PF  
37(1) Pg. ONLINE

Title, Introduction, CONTROL OF COMPONENTS,  
MATERIALS, AND SUPPLIES, COMPOUNDING  
PROCEDURE VERIFICATION, STABILITY  
TESTING AND EXPIRATION DATING, PET  
RADIOPHARMACEUTICAL COMPOUNDING FOR  
HUMAN USE, QUALITY CONTROL,  
STERILIZATION AND STERILITY ASSURANCE,  
INTRODUCTION, DEFINITIONS, PERSONNEL,  
QUALITY ASSURANCE, FACILITIES AND  
EQUIPMENT, PROCESS AND OPERATIONAL  
CONTROLS, CONTROLS AND ACCEPTANCE  
CRITERIA FOR FINISHED PET DRUG PRODUCTS,  
IF A PET DRUG PRODUCT DOES NOT CONFORM  
TO SPECIFICATIONS, REPROCESSING,  
LABELING

[Ravi  
Ravichandran](#)

<1113> MICROBIAL  
IDENTIFICATION PF 36(6) Pg. 1675

INTRODUCTION, ISOLATION OF PURE  
CULTURES, PRIMARY SCREENING and  
CHARACTERIZATION, MICROBIAL  
IDENTIFICATION BY PHENOTYPIC METHODS,  
MICROBIAL IDENTIFICATION BY GENOTYPIC  
METHODS, VERIFICATION OF MICROBIAL  
IDENTIFICATION METHODS, GLOSSARY OF  
TERMS

[Radhakrishna  
Tirumalai](#)

<1116> MICROBIOLOGICAL  
EVALUATION OF CLEAN ROOMS  
AND OTHER CONTROLLED  
ENVIRONMENTS PF 36(6) Pg. 1688

Introduction, ADVANCED ASEPTIC  
TECHNOLOGIES, CLEAN ROOM  
CLASSIFICATION FOR ASEPTIC PROCESSING  
ENVIRONMENTS, IMPORTANCE OF A  
MICROBIOLOGICAL EVALUATION PROGRAM  
FOR CONTROLLED ENVIRONMENTS, PHYSICAL  
EVALUATION OF CONTAMINATION CONTROL  
EFFECTIVENESS, TRAINING OF PERSONNEL,  
CRITICAL FACTORS IN THE DESIGN AND  
IMPLEMENTATION OF A MICROBIOLOGICAL  
ENVIRONMENTAL MONITORING PROGRAM,  
ESTABLISHMENT OF SAMPLING PLAN AND  
SITES, SELECTION OF SAMPLE SITES WITHIN  
CLEAN ROOMS AND ASEPTIC PROCESSING  
AREAS, MICROBIOLOGICAL CONTROL  
PARAMETERS IN ASEPTIC PROCESSING AREAS,  
CLEAN ROOMS, ISOLATORS AND RABS,  
MICROBIAL CONSIDERATIONS AND ACTION  
LEVELS FOR CONTROLLED ENVIRONMENTS,  
SIGNIFICANT EXCURSIONS, FURTHER  
CONSIDERATIONS ABOUT DATA  
INTERPRETATION, SAMPLING AIRBORNE  
MICROORGANISMS, SURFACE SAMPLING,  
CULTURE MEDIA AND DILUENTS,  
IDENTIFICATION OF MICROBIAL ISOLATES,  
CONCLUSION, OPERATIONAL EVALUATION OF  
THE MICROBIOLOGICAL STATUS OF  
ASEPTICALLY FILLED PRODUCTS IN CLEAN

[Radhakrishna  
Tirumalai](#)

ROOMS AND OTHER CONTROLLED ENVIRONMENTS, AN OVERVIEW OF THE EMERGING TECHNOLOGIES FOR ADVANCED ASEPTIC PROCESSING, GLOSSARY, REFERENCES

<1128> NUCLEIC ACID-BASED TECHNIQUES -- MICROARRAY PF 36(6) Pg. 1713

INTRODUCTION, GENERAL PRINCIPLES OF MICROARRAY EXPERIMENTS, MICROARRAY IMAGE ANALYSIS, MICROARRAY DATA ANALYSIS

[Anita Szajek](#)

<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](#)

<1224> TRANSFER OF ANALYTICAL PROCEDURES PF 37(1) Pg. ONLINE

INTRODUCTION, TYPES OF TRANSFERS OF ANALYTICAL PROCEDURES, ELEMENTS RECOMMENDED FOR THE TRANSFER OF ANALYTICAL PROCEDURES, PREAPPROVED PROTOCOL, THE ANALYTICAL PROCEDURE, TRANSFER REPORT

[Horacio Pappa](#)

<1226> VERIFICATION OF COMPENDIAL PROCEDURES PF 36(6) Pg. 1775

VERIFICATION PROCESS, VERIFICATION REQUIREMENTS

[Horacio Pappa](#)

3,5-Dinitrobenzoyl Chloride PF 36(6) Pg. 1777

3,5-Dinitrobenzoyl Chloride,

[Margareth Marques](#)

AGAR PF 33(4) Pg. 702

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

[Hong Wang](#)

ALPRAZOLAM ORALLY-

DEFINITION/Introduction, IDENTIFICATION/Introduction, ASSAY/Procedure, PERFORMANCE TESTS/Disintegration <701>, PERFORMANCE TESTS/Dissolution <711>,

DISINTEGRATING TABLETS PF 36(4) Pg. 890	PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities/Procedure, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Alprazolam RS	<a href="#">Ravi Ravichandran</a>
AMMONIO METHACRYLATE COPOLYMER PF 36(6) Pg. 1631	Chemical Info, DEFINITION/Introduction, IDENTIFICATION/Procedure, ASSAY/Procedure, IMPURITIES/Organic Impurities/Procedure: Limit of Monomers, SPECIFIC TESTS/Viscosity <911>	<a href="#">Hong Wang</a>
AZTREONAM PF 36(6) Pg. 1496	ASSAY/Procedure	<a href="#">Ahalya Wise</a>
BISOPROLOL FUMARATE TABLETS PF 36(6) Pg. 1500	PERFORMANCE TESTS/Dissolution <711>	<a href="#">Sujatha Ramakrishna</a>
RED BLOOD CELLS PF 36(6) Pg. 1501	Title, DEFINITION/Introduction, IDENTIFICATION/A. ABO Blood Group, IDENTIFICATION/B. Rh Type, SPECIFIC TESTS/Visual Inspection, SPECIFIC TESTS/Hemoglobin Content, SPECIFIC TESTS/Leukocyte Count, SPECIFIC TESTS/Adequacy of Deglycerolization (for Red Blood Cells, Deglycerolized), ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Expiration Date, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Hemoglobin RS	<a href="#">Maura Kibbey</a>
PLATELETS PF 36(6) Pg. 1503	Title, DEFINITION/Introduction, IDENTIFICATION/Procedure, SPECIFIC TESTS/Platelet Count, SPECIFIC TESTS/Residual Leukocyte Count, SPECIFIC TESTS/pH <791> (for stored Platelets), ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling	<a href="#">Maura Kibbey</a>
CANDESARTAN CILEXETIL PF 36(6) Pg. 1506	Chemical Info/Chemical Structure, Chemical Info/1H-Benzimidazole-7-carboxylic acid, 2-ethoxy-1-[[2&prime;- (1H-tetrazol-5-yl)[1,1&prime;-biphenyl]-4-y l)methyl]-, 1-[[[(cyclohexyloxy)carbonyl]oxy]ethyl ester, (&plusmn;);, Chemical Info/(&plusmn;)-1-Hydroxyethyl 2-ethoxy-1-[p-(o-1H-tetrazol-5-ylphenyl)benzyl]-7-benzimidazolecarboxylat e, cyclohexyl carbonate (ester)., Chemical Info/610.66, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Inorganic Impurities/Residue on Ignition <281>, IMPURITIES/Organic Impurities/Procedure, SPECIFIC TESTS/Water Determination, Method 1 <921>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Candesartan Cilexetil	<a href="#">Sujatha Ramakrishna</a>

RS

CARMUSTINE FOR INJECTION PF 36(6) Pg. 1508	ASSAY/Procedure	<a href="#">Feiwen Mao</a>
CEFDINIR PF 36(6) Pg. 1509	IMPURITIES/Organic Impurities/Procedure	<a href="#">Ahalya Wise</a>
CEFDINIR CAPSULES PF 36(6) Pg. 1511	IMPURITIES/Organic Impurities/Procedure	<a href="#">Ahalya Wise</a>
CEFDINIR FOR ORAL SUSPENSION PF 36(6) Pg. 1515	IDENTIFICATION/A. Thin-Layer Chromatographic Identification Test <201>, IDENTIFICATION/B., IMPURITIES/Organic Impurities/Procedure, SPECIFIC TESTS/Loss on Drying <731>	<a href="#">Ahalya Wise</a>
CHAMOMILE PF 36(6) Pg. 1584	ADDITIONAL REQUIREMENTS/Labeling	<a href="#">Maged Sharaf</a>
CLINDAMYCIN HYDROCHLORIDE PF 36(6) Pg. 1520	IDENTIFICATION/A. Infrared Absorption <197M>, IDENTIFICATION/B., ASSAY/Procedure	<a href="#">Ahalya Wise</a>
CRANBERRY LIQUID PREPARATION PF 36(6) Pg. 1586	ADDITIONAL REQUIREMENTS/Labeling	<a href="#">Maged Sharaf</a>
DESCRIPTION AND SOLUBILITY PF 36(4) Pg. 1039	Valganciclovir Hydrochloride, Candesartan Cilexetil, Ethylcellulose Dispersion Type B, Polyglyceryl Dioleate, Hydrogenated Starch Hydrolysate, Temozolomide	<a href="#">Leonel Santos</a>
DIETHYLENE GLYCOL MONOETHYL ETHER PF 36(6) Pg. 1633	ASSAY/Procedure, ADDITIONAL REQUIREMENTS/Labeling	<a href="#">Robert Lafaver</a>
DOCETAXEL INJECTION PF 37(1) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Inorganic Impurities, SPECIFIC TESTS/BACTERIAL ENDOTOXINS TEST <85>, SPECIFIC TESTS/STERILITY TESTS <71>, SPECIFIC TESTS/PARTICULATE MATTER <788>, SPECIFIC TESTS/OTHER REQUIREMENTS, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Docetaxel RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Docetaxel Identification RS	<a href="#">Feiwen Mao</a>
DROSPIRENONE PF 36(6) Pg. 1524	ASSAY/Procedure	<a href="#">Domenick Vicchio</a>
ELEUTHERO PF 36(6) Pg. 1588	DEFINITION/Introduction, IDENTIFICATION/A. Thin-Layer Chromatographic Identification Test <201>, IDENTIFICATION/B, COMPOSITION/Content of Eleutherosides B and E, CONTAMINANTS/Microbial Enumeration Tests <2021>, CONTAMINANTS/Microbiological Procedures for Absence of Specified Microorganisms <2022>, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Eleutheroside B RS &beta;-d-	<a href="#">Maged Sharaf</a>

Glucopyranoside, 4-(3-hydroxy-1-propenyl)-2,6-dimethoxyphenyl.C17H24O9372.37, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Eleutheroside E RS &beta;-d-Glucopyranoside, (tetrahydro-1H,3H-furo(3,4-c)furan-1,4-diyl)bis(2,6-dimethoxy-4,1-phenyle ne)bis-.C34H46O18742.70

IDENTIFICATION/Thin-Layer Chromatographic Identification Test <201>, IDENTIFICATION/A. Thin-Layer Chromatographic Identification Test <201>, IDENTIFICATION/B., COMPOSITION/Content of Eleutherosides B and E, CONTAMINANTS/Microbial Enumeration Tests—Nutritional and Dietary Supplements <2021>, CONTAMINANTS/Microbial Enumeration Tests <2021>,

POWDERED ELEUTHERO PF 36(6) Pg. 1590

CONTAMINANTS/Microbiological Procedures for Absence of Specified Microorganisms <2022>, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Eleutheroside B RS &beta;-d-Glucopyranoside, 4-(3-hydroxy-1-propenyl)-2,6-dimethoxyphenyl.C17H24O9372.37, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Eleutheroside E RS &beta;-d-Glucopyranoside, (tetrahydro-1H,3H-furo(3,4-c)furan-1,4-diyl)bis(2,6-dimethoxy-4,1-phenyle ne)bis-.C34H46O18742.70

[Maged Sharaf](#)

DEFINITION/Introduction, IDENTIFICATION/Thin-Layer Chromatographic Identification Test <201>, IDENTIFICATION/A. Thin-Layer Chromatographic Identification Test <201>, IDENTIFICATION/B., COMPOSITION/Content of Eleutherosides B and E, CONTAMINANTS/Microbial Enumeration Tests <2021>, CONTAMINANTS/Microbiological

POWDERED ELEUTHERO EXTRACT PF 36(6) Pg. 1592

Procedures for Absence of Specified Microorganisms <2022>, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Eleutheroside B RS &beta;-d-Glucopyranoside, 4-(3-hydroxy-1-propenyl)-2,6-dimethoxyphenyl.C17H24O9372.37, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Eleutheroside E RS &beta;-d-Glucopyranoside, (tetrahydro-1H,3H-furo(3,4-c)furan-1,4-diyl)bis(2,6-dimethoxy-4,1-phenyle ne)bis-.C34H46O18742.70

[Maged Sharaf](#)

Title, DEFINITION/Introduction, IDENTIFICATION/Melting Range or Temperature, Class I <741>, ASSAY/Procedure, SPECIFIC TESTS/Injections <1>, ADDITIONAL REQUIREMENTS/Packaging and Storage

ESTRONE INJECTION PF 36(6) Pg. 1529

DEFINITION/Introduction, IDENTIFICATION/A. Film Formation, IDENTIFICATION/B. Infrared Absorption, IDENTIFICATION/C., ASSAY/Procedure, OTHER COMPONENTS/Introduction, OTHER COMPONENTS/Content of Medium-Chain Triglycerides, OTHER COMPONENTS/Content of

[Domenick Vicchio](#)

ETHYLCELLULOSE DISPERSION  
TYPE B PF 36(6) Pg. 1635

Oleic Acid, OTHER COMPONENTS/Content of Dibutyl Sebacate and Oleic Acid, IMPURITIES/Inorganic Impurities/Residue on Ignition <281>, IMPURITIES/Organic Impurities/Procedure 1: Limit of Glycerin, IMPURITIES/Organic Impurities/Procedure 2: Limit of 1-Butanol, SPECIFIC TESTS/pH <791>, SPECIFIC TESTS/Total Solids, SPECIFIC TESTS/Viscosity <911>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP 1-Butanol RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Dibutyl Sebacate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ethylcellulose RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Glycerin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Oleic Acid RS

[Hong Wang](#)

FISH OIL CONTAINING OMEGA-3  
ACIDS DELAYED-RELEASE  
CAPSULES PF 36(6) Pg. 1594

DEFINITION/Introduction, IDENTIFICATION/Introduction, STRENGTH/Content of Fish Oil, STRENGTH/Content of EPA and DHA, STRENGTH/Content of Total Omega-3 Acids, PERFORMANCE TESTS/Weight Variation of Dietary Supplements <2091>, PERFORMANCE TESTS/Disintegration and Dissolution of Dietary Supplements <2040>, CONTAMINANTS/Fats and Fixed Oils, Trace Metals <401>, CONTAMINANTS/Limit of Dioxins, Furans, and Polychlorinated Biphenyls, SPECIFIC TESTS/Fats and Fixed Oils, Acid Value <401>, SPECIFIC TESTS/Fats and Fixed Oils, Anisidine Value <401>, SPECIFIC TESTS/Fats and Fixed Oils, Peroxide Value <401>, SPECIFIC TESTS/Fats and Fixed Oils, Total Oxidation Value (TOTOX) <401>, SPECIFIC TESTS/Fats and Fixed Oils, Unsaponifiable Matter <401>, SPECIFIC TESTS/Stearin, SPECIFIC TESTS/Absorbance, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Docosahexaenoic Acid Ethyl Ester RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Eicosapentaenoic Acid Ethyl Ester RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Fish Oil RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methyl Tricosanoate RS

[Natalia Davydova](#)

FLUCONAZOLE INJECTION PF 36(6)  
Pg. 1530

ASSAY/Procedure, IMPURITIES/Organic Impurities/Procedure 2: For Polar Impurities, IMPURITIES/Organic Impurities/Procedure 3, IMPURITIES/Organic Impurities/Procedure 4

[Behnam Davani](#)

[Maged](#)

GINGER PF 36(6) Pg. 1595	ADDITIONAL REQUIREMENTS/Labeling	<a href="#">Sharaf</a>
GINGER CAPSULES PF 36(6) Pg. 1599	ADDITIONAL REQUIREMENTS/Labeling	<a href="#">Maged Sharaf</a>
GINGER TINCTURE PF 36(6) Pg. 1601	ADDITIONAL REQUIREMENTS/Labeling	<a href="#">Maged Sharaf</a>
POWDERED GINGER PF 36(6) Pg. 1597	IDENTIFICATION/A., IDENTIFICATION/B., IDENTIFICATION/C. Thin-Layer Chromatographic Identification Test <201>, SPECIFIC TESTS/Other Requirements, ADDITIONAL REQUIREMENTS/Labeling	<a href="#">Maged Sharaf</a>
GINKGO PF 36(6) Pg. 1602	IDENTIFICATION/Thin-Layer Chromatographic Identification Test <201>, COMPOSITION/ Content of Flavonol Glycosides, CONTAMINANTS/Heavy Metals, Method III <231>, CONTAMINANTS/Microbial Enumeration Tests <2021>, CONTAMINANTS/Microbiological Procedures for Absence of Specified Microorganisms <2022>, SPECIFIC TESTS/Loss on Drying <731>, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Isorhamnetin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Kaempferol RS	<a href="#">Maged Sharaf</a>
GINKGO CAPSULES PF 36(6) Pg. 1609	IDENTIFICATION/A., STRENGTH/Content of Flavonol Glycosides, CONTAMINANTS/Microbial Enumeration Tests <2021>, CONTAMINANTS/Microbiological Procedures for Absence of Specified Microorganisms <2022>, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Isorhamnetin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Kaempferol RS	<a href="#">Maged Sharaf</a>
GINKGO TABLETS PF 36(6) Pg. 1611	IDENTIFICATION/A., STRENGTH/Content of Flavonol Glycosides, CONTAMINANTS/Microbial Enumeration Tests <2021>, CONTAMINANTS/Microbiological Procedures for Absence of Specified Microorganisms <2022>, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Isorhamnetin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Kaempferol RS	<a href="#">Maged Sharaf</a>
POWDERED GINKGO EXTRACT PF 36(6) Pg. 1606	IDENTIFICATION/A. Thin-Layer Chromatographic Identification Test <201>, IDENTIFICATION/B., COMPOSITION/Content of Flavonol Glycosides, CONTAMINANTS/Heavy Metals, Method II <231>, CONTAMINANTS/Microbial Enumeration Tests <2021>, CONTAMINANTS/Microbiological Procedures for Absence of Specified Microorganisms <2022>, SPECIFIC TESTS/Other Requirements,	<a href="#">Maged Sharaf</a>



ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Isorhamnetin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Kaempferol RS

Chemical Info/Pyrrolidinium, 3-[(SR)-(cyclopentylhydroxyphenylacetyl)oxy]-1,1-dimethyl-, [RS-] bromide;, Chemical Info/3-Hydroxy-1,1-dimethylpyrrolidinium bromide &alpha;-cyclopentylmandelate(RS)-[3-(SR)-Hydroxy-1,1-dimethylpyrrolid inium bromide] &alpha;-cyclopentylmandelate, DEFINITION/Introduction, IDENTIFICATION, ASSAY/Procedure, IMPURITIES/Ordinary Impurities <466>, IMPURITIES/Organic Impurities, IMPURITIES/Limit of Erythro Isomer, SPECIFIC TESTS/Melting Range or Temperature, Class I <741>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Glycopyrrolate Related Compound A, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Glycopyrrolate Related Compound B, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Glycopyrrolate Related Compound C, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Glycopyrrolate Erythro Isomer RS

IDENTIFICATION/A., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Glycopyrrolate Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Glycopyrrolate Related Compound C RS

Chemical Info/Chemical Structure, SPECIFIC TESTS/Optical Rotation, Specific Rotation <781S>

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

Hydrochloric Acid, Half-Normal (0.5 N)

L1

L17

L20

GLYCOPYRROLATE PF 37(1) Pg. ONLINE

[Elena Gonikberg](#)

GLYCOPYRROLATE TABLETS PF 37(1) Pg. ONLINE

[Elena Gonikberg](#)

HYDROCORTISONE ACETATE PF 36(6) Pg. 1533

[Domenick Vicchio](#)

HYDROMORPHONE HYDROCHLORIDE PF 35(5) Pg. 1156

[Clydewyn Anthony](#)

Hydrochloric Acid, Half-Normal(0.5 N) PF 37(1) Pg. ONLINE

[Margareth Marques](#)

L1 PF 37(1) Pg. ONLINE

[Margareth Marques](#)

L17 PF 36(6) Pg. 1779

[Margareth Marques](#)

L20 PF 36(6) Pg. 1779

[Margareth Marques](#)

[Margareth](#)

L23 PF 37(1) Pg. ONLINE	L23	<a href="#">Marques</a>
L34 PF 36(6) Pg. 1779	L34	<a href="#">Margareth Marques</a>
L59 PF 36(6) Pg. 1779	L59	<a href="#">Margareth Marques</a>
LACTOBIONIC ACID PF 37(1) Pg. ONLINE	ASSAY/Procedure	<a href="#">Robert Lafaver</a>
LAMOTRIGINE TABLETS PF 36(6) Pg. 1542	PERFORMANCE TESTS/Dissolution <711>	<a href="#">Hariram Ramanathan</a>
LANSOPRAZOLE PF 36(6) Pg. 1547	ASSAY/Procedure, IMPURITIES/Organic Impurities/Procedure, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Lansoprazole Related Compound B	<a href="#">Elena Gonikberg</a>
LEVOFLOXACIN ORAL SOLUTION PF 36(6) Pg. 1548	DEFINITION/Introduction, IDENTIFICATION/Introduction, ASSAY/Procedure, IMPURITIES/Organic Impurities/Procedure, SPECIFIC TESTS/Microbial Enumeration Tests <61> and Tests For Specified Microorganisms <62>, SPECIFIC TESTS/Deliverable volume <698>, SPECIFIC TESTS/pH <791>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Levofloxacin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Levofloxacin Related Compound A RS	<a href="#">Behnam Davani</a>
ALPHA LIPOIC ACID PF 37(1) Pg. ONLINE	IDENTIFICATION/A., IDENTIFICATION/B. Infrared Absorption <197K>, ASSAY/Procedure, IMPURITIES/Chromatographic Purity, Procedure 1/Buffer solution, Mobile phase, Standard solution, Solvent buffer, Sample solution, and Chromatographic system, IMPURITIES/Chromatographic Purity, Procedure 1/Diluted standard solution, IMPURITIES/Chromatographic Purity, Procedure 1/System suitability	<a href="#">Huy Dinh</a>
LORATADINE ORALLY-DISINTEGRATING TABLETS PF 36(6) Pg. 1550	IDENTIFICATION/A. Thin-Layer Chromatographic Identification Test <201>, ASSAY/Introduction, ASSAY/Procedure 1, ASSAY/Procedure 2, PERFORMANCE TESTS/Disintegration <701>, PERFORMANCE TESTS/Dissolution <711>, 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 Loratadine Related Compound A RS 8-Chloro-6,11-dihydro-11-(4-piperidylidene)-5H-benzo[5,6]cyclohepta[1,2-b]pyridine.C19H19CIN2310.83, ADDITIONAL	<a href="#">Mary Waddell</a>

REQUIREMENTS/USP Reference Standards <11>/USP Loratadine Related Compound B RS 8-Chloro-6,11-dihydro-11-(N-methyl-4-piperidylidene)-5H-benzo[5,6]cyclohepta[1,2-b]pyridine.C20H21ClN2324.88, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Loratadine Related Compound C RS 8-Chloro-5,6-dihydro-11H-benzo[5,6]cyclohepta[1,2-b]pyridin-11-one.C14H10ClNO243.69

DEFINITION/Introduction, IDENTIFICATION/A. Thin-Layer Chromatographic Identification Test <201>, IDENTIFICATION/B., COMPOSITION/Content of Vasicine, CONTAMINANTS/Articles of Botanical Origin, General Method for Pesticide Residues Analysis <561>, CONTAMINANTS/Heavy Metals, Method III <231>, CONTAMINANTS/Microbial Enumeration Tests—Nutritional and Dietary Supplements <2021>, CONTAMINANTS/Absence of Specified Microorganisms—Nutritional and Dietary Supplements <2022>, SPECIFIC TESTS/Botanic Characteristics, SPECIFIC TESTS/Loss on Drying <731>, SPECIFIC TESTS/Articles of Botanical Origin, Total Ash <561>, SPECIFIC TESTS/Articles of Botanical Origin, Acid-Insoluble Ash <561>, SPECIFIC TESTS/Articles of Botanical Origin, Foreign Organic Matter <561>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Powdered Malabar-Nut-Tree, Leaf Extract RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Vasicine RS

DEFINITION/Introduction, IDENTIFICATION/A. Thin-Layer Chromatographic Identification Test <201>, IDENTIFICATION/B., COMPOSITION/Content of Vasicine, CONTAMINANTS/Articles of Botanical Origin, General Method for Pesticide Residues Analysis <561>, CONTAMINANTS/Heavy Metals, Method III <231>, CONTAMINANTS/Microbial Enumeration Tests—Nutritional and Dietary Supplements <2021>, CONTAMINANTS/Absence of Specified Microorganisms—Nutritional and Dietary Supplements <2022>, SPECIFIC TESTS/Botanic Characteristics, SPECIFIC TESTS/Loss on Drying <731>, SPECIFIC TESTS/Articles of Botanical Origin, Total Ash <561>, SPECIFIC TESTS/Articles of Botanical Origin, Acid-Insoluble Ash <561>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Powdered Malabar-Nut-Tree, Leaf Extract RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Vasicine RS

MALABAR-NUT-TREE, LEAF PF 36(6)  
Pg. 1614

POWDERED MALABAR-NUT-TREE,  
LEAF PF 36(6) Pg. 1615

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POWDERED MALABAR-NUT-TREE,  
LEAF EXTRACT PF 36(6) Pg. 1616

DEFINITION/Introduction, IDENTIFICATION/A,  
Thin-Layer Chromatographic Identification Test <201>,  
IDENTIFICATION/B., COMPOSITION/Content of  
Vasicine, CONTAMINANTS/Articles of Botanical  
Origin, General Method for Pesticide Residues Analysis  
<561>, CONTAMINANTS/Heavy Metals, Method III  
<231>, CONTAMINANTS/Microbial Enumeration  
Tests—Nutritional and Dietary Supplements <2021>,  
CONTAMINANTS/Absence of Specified  
Microorganisms—Nutritional and Dietary Supplements  
<2022>, SPECIFIC TESTS/Loss on Drying <731>,  
ADDITIONAL REQUIREMENTS/Packaging and  
Storage, ADDITIONAL REQUIREMENTS/Labeling,  
ADDITIONAL REQUIREMENTS/Other Requirements,  
ADDITIONAL REQUIREMENTS/USP Reference  
Standards <11>/USP Powdered Malabar-Nut-Tree, Leaf  
Extract RS, ADDITIONAL REQUIREMENTS/USP  
Reference Standards <11>/USP Vasicine RS

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MERCAPTOPYRINE PF 36(6) Pg. 1552

IDENTIFICATION/A, IDENTIFICATION/B,  
ASSAY/Procedure, IMPURITIES/Inorganic Impurities,  
IMPURITIES/Organic Impurities, ADDITIONAL  
REQUIREMENTS/Packaging and Storage,  
ADDITIONAL REQUIREMENTS/USP Reference  
Standards <11>/USP Didanosine Related Compound A  
RS

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MERCAPTOPYRINE TABLETS PF  
36(6) Pg. 1554

IDENTIFICATION/A., IDENTIFICATION/B,  
ASSAY/Procedure, IMPURITIES/Organic Impurities

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METHACRYLIC ACID COPOLYMER  
DISPERSION PF 36(6) Pg. 1638

IDENTIFICATION/Procedure, ASSAY/Procedure,  
IMPURITIES/Organic Impurities/Limit of Monomers,  
SPECIFIC TESTS/Microbial Enumeration Tests <61>  
and Tests for Specified Microorganisms <62>,  
ADDITIONAL REQUIREMENTS/USP Reference  
Standards <11>/USP Methacrylic Acid and Ethyl  
Acrylate Copolymer (1:1) RS (USP Methacrylic Acid  
Copolymer, Type C RS), DEFINITION/Introduction  
(Line-items for the text included in the new title  
"M49855 Methacrylic Acid and Ethyl Acrylate  
Copolymer Dispersion" begins here),  
IDENTIFICATION/A. Infrared Absorption <197K>,  
IDENTIFICATION/B., IMPURITIES/Inorganic  
Impurities/Residue on Ignition <281>,  
IMPURITIES/Inorganic Impurities/Heavy Metals,  
Method II <231>, SPECIFIC TESTS/Coagulum  
Content, SPECIFIC TESTS/Loss on Drying <731>,  
SPECIFIC TESTS/pH <791>, SPECIFIC  
TESTS/Viscosity <911>, ADDITIONAL  
REQUIREMENTS/Packaging and Storage,  
ADDITIONAL REQUIREMENTS/Labeling

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METHYLDOPA PF 37(1) Pg. ONLINE

IDENTIFICATION/<197M >

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Ramakrishna](#)

MORPHINE SULFATE EXTENDED-  
RELEASE CAPSULES PF 36(2) Pg. 422

PERFORMANCE TESTS/Dissolution <711>

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Anthony](#)

Nitric Acid, Diluted PF 36(6) Pg. 1777

Nitric Acid, Diluted

[Margareth  
Marques](#)

ORLISTAT PF 35(5) Pg. 1166

Chemical Info/Chemical Structure, Chemical  
Info/C<sub>29</sub>H<sub>53</sub>NO<sub>5</sub>, Chemical Info/495.73, Chemical  
Info/l-Leucine, N-formyl-, 1-[(3-hexyl-4-oxo-2-  
oxetanyl)methyl]dodecyl ester, [2S-[2&alpha;(R\*),  
3&beta;]]-, 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>

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Anthony](#)

ORLISTAT CAPSULES PF 35(5) Pg.  
1169

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>

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OctanesulfonicAcidSodiumSalt PF 36(6)  
Pg. 1777

Octanesulfonic Acid Sodium Salt

[Margareth  
Marques](#)

PHENOXYBENZAMINE  
HYDROCHLORIDE CAPSULES PF  
36(6) Pg. 1562

IDENTIFICATION/A. Ultraviolet Absorption

[Sujatha  
Ramakrishna](#)

DEFINITION/Introduction, IDENTIFICATION/A.  
Thin-Layer Chromatographic Identification Test <201>,  
IDENTIFICATION/B., COMPOSITION/Content of  
Lignans, CONTAMINANTS/Articles of Botanical  
Origin, General Method for Pesticide Residues Analysis  
<561>, CONTAMINANTS/Heavy Metals, Method III

PHYLLANTHUS AMARUS PF 36(6) Pg. 1620

<231>, CONTAMINANTS/Microbial Enumeration Tests <2021>, CONTAMINANTS/Absence of Specified Microorganisms <2022>, SPECIFIC TESTS/Botanic Characteristics, SPECIFIC TESTS/Loss on Drying <731>, SPECIFIC TESTS/Articles of Botanical Origin, Total Ash <561>, SPECIFIC TESTS/Articles of Botanical Origin, Acid-Insoluble Ash <561>, SPECIFIC TESTS/Articles of Botanical Origin, Foreign Organic Matter <561>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Phyllanthin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Powdered Phyllanthus amarus Extract RS

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POWDERED PHYLLANTHUS AMARUS PF 36(6) Pg. 1623

DEFINITION/Introduction, IDENTIFICATION/A. Thin-Layer Chromatographic Identification Test <201>, IDENTIFICATION/B., COMPOSITION/Content of Lignans, CONTAMINANTS/Articles of Botanical Origin, General Method for Pesticide Residues Analysis <561>, CONTAMINANTS/Heavy Metals, Method III <231>, CONTAMINANTS/Microbial Enumeration Tests <2021>, CONTAMINANTS/Absence of Specified Microorganisms <2022>, SPECIFIC TESTS/Botanic Characteristics, SPECIFIC TESTS/Loss on Drying <731>, SPECIFIC TESTS/Articles of Botanical Origin, Total Ash <561>, SPECIFIC TESTS/Articles of Botanical Origin, Acid-Insoluble Ash <561>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Phyllanthin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Powdered Phyllanthus amarus Extract RS

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Chemical Info/R-O-(CH<sub>2</sub>-CH(OR)-CH<sub>2</sub>&ndas h;O)<sub>3</sub>-R, Chemical Info/R = H, or CO-C<sub>17</sub>H<sub>33</sub>, Chemical Info/1,2,3-Propanetriol, homopolymer, (9Z)-9-octadecenoate,, Chemical Info/Polyglyceryl 3 Dioleate, Chemical Info/CAS, Chemical Info/R-O-(CH<sub>2</sub>-CH(OR)-CH<sub>2</sub>&ndas h;O)<sub>6</sub>-R, Chemical Info/Polyglyceryl 6 Dioleate,

DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197F>, IDENTIFICATION/B., IDENTIFICATION/C., 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, Method I

POLYGLYCERYL DIOLEATE PF 36(5) Pg. 1234	<921>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, 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 Palmitoleate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methyl Stearate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methyl Oleate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methyl Linoleate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methyl Linolenate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Polyglyceryl 3 Dioleate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Polyglyceryl 6 Dioleate RS	<a href="#">Hong Wang</a>
DIBASIC POTASSIUM PHOSPHATE TRIHYDRATE PF 37(1) Pg. ONLINE	Potassium Phosphate, Dibasic, Trihydrate	<a href="#">Elena Gonikberg</a>
PRIMAQUINE PHOSPHATE PF 37(1) Pg. ONLINE	ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Primaquine Related Compound A RS 8-[(4-Aminopentyl)amino]-6-methoxyquinoline.C15H21N3O259.35	<a href="#">Leonel Santos</a>
PRIMAQUINE PHOSPHATE TABLETS PF 37(1) Pg. ONLINE	IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Primaquine Related Compound A RS 8-[(4-Aminopentyl)amino]-6-methoxyquinoline.C15H21N3O259.35	<a href="#">Leonel Santos</a>
PROTEIN HYDROLYSATE INJECTION PF 36(6) Pg. 1564	Title, DEFINITION/Introduction, OTHER COMPONENTS/Content of &alpha;-amino Nitrogen, OTHER COMPONENTS/Nitrogen Determination, Method II <461>, SPECIFIC TESTS/Non-antigenicity, SPECIFIC TESTS/Bacterial Endotoxins Test <85>, SPECIFIC TESTS/Protein—Biological Adequacy Test <141>, SPECIFIC TESTS/pH <791>, SPECIFIC TESTS/Other Requirements, SPECIFIC TESTS/Potassium Content, SPECIFIC TESTS/Sodium Content, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Endotoxin RS	<a href="#">Leonel Santos</a>
	DEFINITION/Introduction,	

RISPERIDONE ORALLY  
DISINTEGRATING TABLETS PF 36(6)  
Pg. 1565

IDENTIFICATION/Introduction, ASSAY/Procedure, PERFORMANCE TESTS/Disintegration <701>, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities/Procedure, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Risperidone RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Risperidone Related Compounds Mixture RS

[Hariram Ramanathan](#)

ROSIGLITAZONE MALEATE PF 37(1)  
Pg. ONLINE

Chemical Info/Chemical Structure, Chemical Info/C<sub>18</sub>H<sub>19</sub>N<sub>3</sub>O<sub>3</sub>S·C<sub>4</sub>H<sub>4</sub>O<sub>4</sub>, Chemical Info/473.50, Chemical Info/(&plusmn;)-5-[p-[2-(Methyl-2-pyridylamino)ethoxy]benzyl]-2,4-thiazolidinedione maleate (1:1);, Chemical Info/ (RS)-5-{{[4-({2-[Methyl(2-pyridinyl)amino]ethyl)oxy]phenyl)methyl]-1,3-thiazolidine-2,4-dione (Z)-2-butenedioate, Chemical Info/CAS, Chemical Info/Rosiglitazone, Chemical Info/357.43, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197M>, IDENTIFICATION/B., ASSAY/Procedure, OTHER COMPONENTS/Content of Maleic Acid, IMPURITIES/Residue on Ignition, <281>, IMPURITIES/Heavy Metals, Method II <231>, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Water Determination, Method 1A <921>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Fumaric Acid RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Maleic Acid RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Rosiglitazone Maleate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Rosiglitazone Related Compound A RS

[Elena Gonikberg](#)

SODIUM PHOSPHATE, DIBASIC,  
HEPTAHYDRATE PF 36(6) Pg. 1778

Sodium Phosphate, Dibasic, Heptahydrate

[Behnam Davani](#)

Sodium 1-Octanesulfonate PF 36(6) Pg. 1777

Sodium 1-Octanesulfonate

[Margareth Marques](#)

Sodium Perchlorate Monohydrate PF 36(6) Pg. 1777

Sodium Perchlorate,

[Margareth Marques](#)

Sodium Phosphate, Tribasic PF 37(1) Pg. ONLINE

Sodium Phosphate, Tribasic,

[Margareth Marques](#)

Sodium Pyrophosphate PF 36(6) Pg. 1778

Sodium Pyrophosphate,

[Margareth Marques](#)

SPIRONOLACTONE PF 37(1) Pg.

IDENTIFICATION/A. Infrared Absorption <197S><197K>, SPECIFIC TESTS/Optical Rotation,

[Sujatha](#)



ONLINE

Specific Rotation <781S>

[Ramakrishna](#)

HYDROGENATED STARCH  
HYDROLYSATE PF 35(1) Pg. 136

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, IDENTIFICATION/C. Limit of Diethylene Glycol and Ethylene Glycol, SPECIFIC TESTS/Water Determination, Method I <921>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Diethylene Glycol RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ethylene Glycol RS

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Sodium Hydroxide, Normal (1 N) PF  
36(6) Pg. 1778

Sodium Hydroxide, Normal (1 N)

[Margareth  
Marques](#)

TELMISARTAN PF 37(1) Pg. ONLINE

IMPURITIES/Heavy Metals <231>

[Sujatha  
Ramakrishna](#)

TEMAZEPAM PF 36(6) Pg. 1574

ASSAY/Procedure

[Hariram  
Ramanathan](#)

TEMOZOLOMIDE PF 37(1) Pg.  
ONLINE

Chemical Info/Chemical Structure, Chemical Info/C<sub>6</sub>H<sub>6</sub>N<sub>6</sub>O<sub>2</sub>, Chemical Info/194.15, Chemical Info/Imidazo[5,1-d]-1,2,3,5-tetrazine-8-carboxamide, 3,4-dihydro-3-methyl-4-oxo-, Chemical Info/3,4-Dihydro-3-methyl-4-oxoimidazo[5,1-d]-as-tetrazine-8-carboxamide. , Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Heavy Metals, Method II <231>, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Water Determination, Method Ic <921>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Temozolomide RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Dacarbazine Related Compound A RS

[Feiwen Mao](#)

TRAMADOL HYDROCHLORIDE  
TABLETS PF 36(6) Pg. 1577

PERFORMANCE TESTS/Dissolution <711>

[Clydewyn  
Anthony](#)

TRAMADOL HYDROCHLORIDE  
EXTENDED-RELEASE TABLETS PF

DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B. Ultraviolet Absorption <197U>, ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities/Procedure,

[Clydewyn](#)

36(6) Pg. 1578	ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Tramadol Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Tramadol Related Compound A RS	<a href="#">Anthony</a>
TRANDOLAPRIL PF 37(1) Pg. ONLINE	DEFINITION/Introduction, ASSAY/Procedure	<a href="#">Sujatha Ramakrishna</a>
USP AND NF EXCIPIENTS, LISTED BY CATEGORY PF 36(6) Pg. 1625	<p>{Coating Agent} Ethylcellulose Dispersion Type B, {Coating Agent} Methacrylic Acid and Ethyl Acrylate Copolymer Dispersion, {Emulsifying and/or Solubilizing Agent} Polyglyceryl Dioleate, {Film-Forming Agent} Ammonio Methacrylate Copolymer, {Film-Forming Agent} Ethylcellulose Dispersion Type B, {Film-Forming Agent} Methacrylic Acid and Ethyl Acrylate Copolymer Dispersion, {Humectant} Hydrogenated Starch Hydrolysate, {Sweetening Agent} Hydrogenated Starch Hydrolysate, {Tablet Binder} Hydrogenated Starch Hydrolysate, {Tablet and/or Capsule Diluent} Hydrogenated Starch Hydrolysate</p> <p>Chemical Info/C&amp;prime;- Norvincal leukoblastine,3&amp;prime;,4&amp;prime;-didehyd ro-4&amp;prime;-deoxy-,[R-(R*,R*)]-2,3-dihydroxybutanedioate (1:2) (salt);8&amp;prime;- Norvincal leukoblastine,3&amp;prime;,4&amp;prime;-dideh ydro-4&amp;prime;-deoxy-,[R-(R*,R*)]-2,3-dihydroxybutanedioate (1:2) (salt);,</p>	<a href="#">Hong Wang</a>
VINORELBINE TARTRATE PF 37(1) Pg. ONLINE	IDENTIFICATION/B., ASSAY/Procedure	<a href="#">Feiwen Mao</a>
ZEIN PF 36(6) Pg. 1641	IDENTIFICATION/C., IDENTIFICATION/C. SDS-Polyacrylamide Gel Electrophoresis, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Protein Content, ADDITIONAL REQUIREMENTS/Labeling	<a href="#">Hong Wang</a>