

Compendial Approvals for USP 34-NF 29

Monograph Title	Monograph Section	Scientific Liaison
<1> INJECTIONS PF 36(1) Pg. 194	PACKAGING	Shawn Becker
<11> USP REFERENCE STANDARDS PF 35(5) Pg. 1217	USP Fetal Bovine Serum RS, USP Partially-Neutralized Methacrylic Acid and Ethyl Acrylate Copolymer (1:1) RS, Introduction, AUTHORITY FOR ESTABLISHMENT AND RELEASE, HISTORY, NOMENCLATURE, DIVERSITY AND IMPLICATIONS, USES OF USP REFERENCE STANDARDS, STEPS IN ESTABLISHING A USP REFERENCE STANDARD, COLLABORATIVE STUDY FOR THE EVALUATION OF A USP RS CANDIDATE MATERIAL, BIOLOGICAL REFERENCE STANDARDS, SUITABILITY FOR USE AND PURITY ASSIGNMENT, LABEL TEXT, USP REFERENCE STANDARDS EXPERT COMMITTEE, PACKAGING, IMPURITY REFERENCE STANDARDS, CONTINUED SUITABILITY FOR USE PROGRAM, PROPER USE, STORAGE, RELATIONSHIPS WITH OTHER STANDARDS-SETTING ORGANIZATIONS, USP REFERENCE STANDARDS SPECIFIED IN USP AND NF MONOGRAPHS AND GENERAL CHAPTERS, TYPES OF REFERENCE STANDARDS, APPLICATIONS OF USP REFERENCE STANDARDS, LABELING	Barbara Jones
<90> FETAL BOVINE SERUM QUALITY ATTRIBUTES AND FUNCTIONALITY TESTS PF 35(5) Pg. 1219	Title, PROCESSING, FETAL BOVINE SERUM QUALITY ATTRIBUTES, FBS FUNCTIONALITY TESTS	Fouad Atouf
<521> SULFONAMIDES PF 35(6) Pg. 1515	Title, IDENTIFICATION OF INDIVIDUAL SULFONAMIDES IN MIXED SULFONAMIDES, DETERMINATION OF INDIVIDUAL SULFONAMIDES IN MIXED SULFONAMIDES	Behnam Davani
<561> ARTICLES OF BOTANICAL ORIGIN PF 36(1) Pg. 207	SAMPLING, TEST FOR AFLATOXINS, GENERAL METHOD FOR PESTICIDE RESIDUES ANALYSIS, TEST FOR PESTICIDES	Yoshiyuki Tokiwa
<621> CHROMATOGRAPHY PF 35(6) Pg. 1516	INTRODUCTION, PAPER CHROMATOGRAPHY, THIN-LAYER CHROMATOGRAPHY, COLUMN CHROMATOGRAPHY, GAS CHROMATOGRAPHY, HIGH-PRESSURE LIQUID CHROMATOGRAPHY, SIZE-EXCLUSION CHROMATOGRAPHY, INTERPRETATION OF CHROMATOGRAMS,	Horacio Pappa

SYSTEM SUITABILITY, GLOSSARY OF SYMBOLS, CHROMATOGRAPHIC REAGENTS, GENERAL PROCEDURES, CHROMATOGRAPHIC COLUMNS, DEFINITIONS AND INTERPRETATION OF CHROMATOGRAMS, QUANTITATION

<727> CAPILLARY ELECTROPHORESIS PF 36(1) Pg. 218

Title, PRINCIPLES OF CAPILLARY ZONE ELECTROPHORESIS, PRINCIPLES OF MICELLAR ELECTROKINETIC CHROMATOGRAPHY, INSTRUMENTAL CONSIDERATIONS, ANALYTICAL CONSIDERATIONS, OPERATIONAL PARAMETERS

[Kabkashan Zaidi](#)

<795> PHARMACEUTICAL COMPOUNDING--NONSTERILE PREPARATIONS PF 35(4) Pg. 926

INTRODUCTION, DEFINITIONS, CATEGORIES OF COMPOUNDING, RESPONSIBILITIES OF THE COMPOUNDER, COMPOUNDING PROCESS, COMPOUNDING FACILITIES, COMPOUNDING EQUIPMENT, COMPONENT SELECTION, HANDLING, AND STORAGE, STABILITY CRITERIA AND BEYOND-USE DATING, PACKAGING AND DRUG PREPARATION CONTAINERS, COMPOUNDING DOCUMENTATION, QUALITY CONTROL, PATIENT COUNSELING, TRAINING, COMPOUNDING FOR ANIMAL PATIENTS

[Rick Schnatz](#)

<1053> BIOTECHNOLOGY-DERIVED ARTICLES -- CAPILLARY ELECTROPHORESIS PF 36(1) Pg. 225

Title

[Tina Morris](#)

<1070> EMERGENCY MEDICAL SERVICES VEHICLES AND AMBULANCES -- STORAGE OF PREPARATIONS PF 36(1) Pg. 225

Title, Introduction, PHARMACEUTICAL STORAGE CABINET MONITORING; LOCATION OF PARKED VEHICLES, STOCK ROTATION, PORTABLE CARRYING CASE STORAGE AND MONITORING, ADDITIONAL REQUIREMENTS FOR SOME ARTICLES, STORAGE AND HANDLING OF SENSITIVE PREPARATIONS, USE OF TIME–TEMPERATURE INDICATORS

[Desmond Hunt](#)

<1163> QUALITY ASSURANCE IN PHARMACEUTICAL COMPOUNDING PF 36(1) Pg. 247

INTRODUCTION, TRAINING, STANDARD OPERATING PROCEDURES, DOCUMENTATION, VERIFICATION, TESTING, PHYSICAL TESTING OF DOSAGE UNITS, WEIGHT AND VOLUME ASSESSMENT, MICROBIOLOGICAL TESTING, CLEANING AND DISINFECTING, CONTAINERS, PACKAGING, REPACKAGING, AND STORAGE, OUTSOURCING, SUMMARY

[Rick Schnatz](#)

<1230> WATER FOR HEALTH APPLICATIONS PF 35(6) Pg. 1531

Title, WATER FOR HEMODIALYSIS, MICROBIAL CONSIDERATIONS

[Antonio Hernandez-Cardoso](#)

<1788> PARTICULATE MATTER

Title, INTRODUCTION, LIGHT OBSCURATION

[Desmond](#)

DETERMINATION IN PARENTERAL AND OPHTHALMIC PRODUCTS PF 35(6) Pg. 1533	PARTICLE COUNT TEST, MEMBRANE MICROSCOPE PARTICLE COUNT TEST	Hunt
<2030> SUPPLEMENTAL INFORMATION FOR ARTICLES OF BOTANICAL ORIGIN PF 35(6) Pg. 1551	PROTOCOL CONTENTS, SUPPLEMENTAL INFORMATION AND GENERAL GUIDANCE PROTOCOLS, ELM	Yoshiyuki Tokiwa
<2040> DISINTEGRATION AND DISSOLUTION OF DIETARY SUPPLEMENTS PF 35(6) Pg. 1561	DISSOLUTION	Natalia Davydova
ACETYLTRIBUTYL CITRATE PF 35(6) Pg. 1495	ASSAY/Procedure, SPECIFIC TESTS/Acidity	Robert Lafaver
ALPHA-CHYMOTRYPSIN PF 35(6) Pg. 1567	Alpha-Chymotrypsin	Margareth Marques
ALUMINUM OXIDE PF 36(1) Pg. 190	Title, Chemical Info/Al ₂ O ₃ , Chemical Info/101.96, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/Identification Tests—General, Aluminum <191>, ASSAY/Procedure, IMPURITIES/Inorganic Impurities/Arsenic, Method I <211>, IMPURITIES/Inorganic Impurities/Heavy Metals, IMPURITIES/Inorganic Impurities/Chloride and Sulfate, Chloride <221>, IMPURITIES/Inorganic Impurities/Chloride and Sulfate, Sulfate <221>, SPECIFIC TESTS, SPECIFIC TESTS/Microbial Enumeration Tests <61> and Tests for Specified Microorganisms <62>, SPECIFIC TESTS/Appearance of Solution, SPECIFIC TESTS/Clarity of Solution, SPECIFIC TESTS/Alkaline Impurities, SPECIFIC TESTS/Neutralizing Capacity, ADDITIONAL REQUIREMENTS/Packaging and Storage	Robert Lafaver
AMIFOSTINE PF 36(1) Pg. 62	ASSAY/Procedure, IMPURITIES/Organic Impurities/Procedure, IMPURITIES/Organic Impurities/Acceptance criteria	Sujatha Ramakrishna
AMIFOSTINE FOR INJECTION PF 36(1) Pg. 63	ASSAY/Procedure, IMPURITIES/Organic Impurities/Procedure 1, IMPURITIES/Organic Impurities/Procedure 2	Sujatha Ramakrishna
AMMONIUM BICARBONATE PF 35(6) Pg. 1567	Ammonium Bicarbonate (Ammonium Hydrogen Carbonate),	Margareth Marques
AMOXICILLIN PF 36(1) Pg. 66	ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Sterility Tests <71>, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Amoxicillin Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Amoxicillin Related Compound D RS	Ahalya Wise

AMPHETAMINE SULFATE PF 36(1) Pg. 68	DEFINITION/Introduction, ASSAY/Procedure, IMPURITIES/Organic Impurities/Procedure	Ravi Ravichandran
ARGININE CAPSULES PF 36(1) Pg. 147	PERFORMANCE TESTS/Disintegration and Dissolution of Dietary Supplements <2040>	Natalia Davydova
ARGININE TABLETS PF 36(1) Pg. 147	PERFORMANCE TESTS/Disintegration and Dissolution of Dietary Supplements <2040>	Natalia Davydova
AZITHROMYCIN PF 36(1) Pg. 70	ASSAY/Procedure, IMPURITIES/Organic Impurities/Procedure 1, IMPURITIES/Organic Impurities/Procedure 2, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Azaerythromycin A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Azithromycin-N-Oxide RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Desosaminylazithromycin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Azithromycin Related Compound F RS	Ahalya Wise
BALSALAZIDE DISODIUM CAPSULES PF 35(4) Pg. 832	Title, DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B. Ultraviolet Absorption, ASSAY/Procedure, IMPURITIES/Organic Impurities/Procedure, PERFORMANCE TESTS, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>	Elena Gonikberg
BENZALKONIUM CHLORIDE PF 35(6) Pg. 1496	IDENTIFICATION/D., ASSAY/Procedure 1: Ratio of Alkyl Components, ASSAY/Procedure 2: Total Alkylbenzyltrimethylammonium Chlorides, IMPURITIES/Organic Impurities/Procedure 1: Limit of Amines and Amine Salts, IMPURITIES/Organic Impurities/Procedure 2: Limit of Benzyl Alcohol, Benzaldehyde, and (Chloromethyl)benzene, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Benzalkonium Chloride RS	Hong Wang
BENZALKONIUM CHLORIDE SOLUTION PF 35(6) Pg. 1499	DEFINITION/Introduction, IDENTIFICATION/A. Procedure, IDENTIFICATION/D., ASSAY/Procedure 1: Ratio of Alkyl Components, ASSAY/Procedure 2: Total Alkylbenzyltrimethylammonium Chlorides, OTHER COMPONENTS/Alcohol Content (if added), IMPURITIES/Organic Impurities/Procedure 1: Limit of Amines and Amine Salts, IMPURITIES/Organic Impurities/Procedure 2: Limit of Benzyl Alcohol, Benzaldehyde, and (Chloromethyl)benzene, SPECIFIC TESTS/Acidity or Alkalinity, SPECIFIC TESTS/Alcohol Determination, Method I <611> (if present), SPECIFIC TESTS/Limit of Foreign Amines, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL	Hong Wang

REQUIREMENTS/USP Reference Standards <11>

BUSPIRONE HYDROCHLORIDE PF 36(1) Pg. 74	IDENTIFICATION/C. Identification Tests–General, Chloride <191>, ASSAY/Procedure, OTHER COMPONENTS/Content of Chloride	Ravi Ravichandran
BUTYLATED HYDROXYANISOLE PF 35(6) Pg. 1503	IDENTIFICATION/A. Procedure, IDENTIFICATION/B., ASSAY/Procedure	Robert Lafaver
CABERGOLINE PF 36(1) Pg. 75	IMPURITIES/Inorganic Impurities	Ravi Ravichandran
CALCIUM WITH VITAMIN D TABLETS PF 35(6) Pg. 1486	PERFORMANCE TESTS/Disintegration and Dissolution of Dietary Supplements <2040>	Natalia Davydova
CAPREOMYCIN SULFATE PF 35(6) Pg. 1448	IDENTIFICATION/B., SPECIFIC TESTS/Capreomycin 1 Content	Ahalya Wise
CAPREOMYCIN FOR INJECTION PF 35(6) Pg. 1449	IDENTIFICATION/A. Identification Tests—General, Sulfate <191>, IDENTIFICATION/B., SPECIFIC TESTS/Capreomycin 1 Content, SPECIFIC TESTS/Other Requirements	Ahalya Wise
CAT'S CLAW CAPSULES PF 36(1) Pg. 148	PERFORMANCE TESTS/Disintegration and Dissolution of Dietary Supplements <2040>	Maged Sharaf
CAT'S CLAW TABLETS PF 36(1) Pg. 149	PERFORMANCE TESTS/Disintegration and Dissolution of Dietary Supplements <2040>	Maged Sharaf
CETIRIZINE HYDROCHLORIDE AND PSEUDOEPHEDRINE HYDROCHLORIDE EXTENDED- RELEASE TABLETS PF 36(1) Pg. 82	Title, DEFINITION/Introduction, IDENTIFICATION/Introduction, ASSAY/Cetirizine Hydrochloride, ASSAY/ Pseudoephedrine Hydrochloride, PERFORMANCE TESTS, PERFORMANCE TESTS/Dissolution <711>, IMPURITIES/Organic Impurities/Procedure 1: Cetirizine Hydrochloride Related Compounds, IMPURITIES/Organic impurities/Procedure 2: Pseudoephedrine Hydrochloride Related Compounds, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Cetirizine Hydrochloride RS [[2-[4-[(4-Chlorophenyl)phenylmethyl]-1- piperazinyl]ethoxy], dihydrochloride (+/and#150;) acetic acid](C ₂₁ H ₂₅ ClN ₂ O ₃ ·2HCl461.81), ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ephedrine Sulfate RS [[R-(R*,S*)], α-[1-(Methylamino)ethyl]-benzenemethanol sulfate (2:1 salt)] ((C ₁₀ H ₁₅ NO) ₂ ·H ₂ SO ₄ 428.54), ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/ USP Pseudoephedrine Hydrochloride RS [[S- (R*,R*)], α-[1-(Methylamino)ethyl] benzenemethanol hydrochloride](C ₁₀ H ₁₅ NO·HCl201.69)	Domenick Vicchio

CHLORHEXIDINE ACETATE PF 36(1) Pg. 85	IDENTIFICATION/A., IDENTIFICATION/B. Procedure, IDENTIFICATION/C. Melting Range or Temperature <741>, ASSAY/Procedure, IMPURITIES/Organic Impurities/Procedure	Elena Gonikberg
CHLORHEXIDINE ACETATE TOPICAL SOLUTION PF 36(1) Pg. 87	Title, DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B. Identification Tests—General, Acetate <191>, ASSAY/Procedure, IMPURITIES/Organic Impurities/Procedure: Limit of p-Chloroaniline, SPECIFIC TESTS/pH <791>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Chlorhexidine Acetate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP p-Chloroaniline RS	Elena Gonikberg
CHLORHEXIDINE GLUCONATE SOLUTION PF 36(1) Pg. 88	IDENTIFICATION/B., IDENTIFICATION/C. Procedure, IDENTIFICATION/D., ASSAY/Procedure, IMPURITIES/Organic Impurities/Procedure 2: Limit of p-Chloroaniline	Elena Gonikberg
CHLORHEXIDINE GLUCONATE TOPICAL SOLUTION PF 36(1) Pg. 90	Title, DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B. Thin-Layer Chromatographic Identification Test <201>, ASSAY/Procedure, IMPURITIES/Organic Impurities/Procedure: Limit of p-Chloroaniline, SPECIFIC TESTS/pH <791>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Chlorhexidine Acetate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP p-Chloroaniline RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Potassium Gluconate RS	Elena Gonikberg
CHLORHEXIDINE HYDROCHLORIDE PF 36(1) Pg. 91	IDENTIFICATION/A. Procedure, IDENTIFICATION/B. Melting Range or Temperature <741>, IDENTIFICATION/C., IDENTIFICATION/D., ASSAY/Procedure, IMPURITIES/Organic Impurities/Procedure	Elena Gonikberg
2-CHLOROETHANOL PF 35(6) Pg. 1567	2-Chloroethanol	Margareth Marques
CLOTRIMAZOLE PF 35(6) Pg. 1449	IDENTIFICATION/Thin-Layer Chromatographic Identification Test <201>, ASSAY/Procedure, IMPURITIES/Organic Impurities/Procedure 2: Limit of Clotrimazole Related Compound A	Behnam Davani
CLOTRIMAZOLE CREAM PF 35(6) Pg. 1451	IDENTIFICATION/Thin-Layer Chromatographic Identification Test <201>, ASSAY/Procedure	Behnam Davani
BLACK COHOSH TABLETS PF	PERFORMANCE TESTS/Disintegration and Dissolution	Maged

36(1) Pg. 150	of Dietary Supplements <2040>	Sharaf
DACTINOMYCIN FOR INJECTION PF 35(6) Pg. 1452	DEFINITION/Introduction, IDENTIFICATION/B.	Ahalya Wise
DEFEROXAMINE MESYLATE PF 35(4) Pg. 847	DEFINITION/Introduction, IDENTIFICATION/Procedure, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage	Elena Gonikberg
DESFLURANE PF 36(1) Pg. 93	DEFINITION/Introduction, IDENTIFICATION/Introduction, ASSAY/Procedure, IMPURITIES/Inorganic Impurities/Limit of Nonvolatile Residue, IMPURITIES/Inorganic Impurities/Limit of Fluoride, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Acidity or Alkalinity, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Halothane RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Isoflurane RS	Domenick Vicchio
DILTIAZEM HYDROCHLORIDE TABLETS PF 35(6) Pg. 1453	PERFORMANCE TESTS/Dissolution <711>	Margareth Marques
DONEPEZIL HYDROCHLORIDE PF 36(1) Pg. 97	Title, Chemical Info/Chemical Structure, Chemical Info/C ₂₄ H ₂₉ NO ₃ ·HCl, Chemical Info/415.95, Chemical Info/(±)-2-[(1-Benzyl-4- piperidyl)methyl]-5,6-dimethoxy-1-indanone hydrochloride, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., IDENTIFICATION/C. Identification Tests—General, Chloride <191>, ASSAY/Procedure, IMPURITIES/Inorganic Impurities/Heavy Metals, Method II <231>, IMPURITIES/Inorganic Impurities/Residue on Ignition <281>, IMPURITIES/Organic Impurities/Procedure, SPECIFIC TESTS/Water Determination, Method Ia <921>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Donepezil Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Donepezil Related Compound A [(E)-2-[(1-benzylpiperidin-4-yl)methylene]-5,6- dimethoxy-2,3-dihydro-1H-indan-1-one](C ₂₄ H ₂₇ NO ₃ 377.48)	Ravi Ravichandran
ETHAMBUTOL HYDROCHLORIDE PF 36(1) Pg. 98	SPECIFIC TESTS/ Limit of Total Stereoisomers, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ethambutol Hydrochloride RS	Behnam Davani

FISH OIL CONTAINING OMEGA-3 ACIDS CAPSULES PF 36(1) Pg. 152	PERFORMANCE TESTS/Disintegration and Dissolution of Dietary Supplements <2040>	Natalia Davydova
FLAVOXATE HYDROCHLORIDE PF 35(6) Pg. 1454	IMPURITIES/Organic Impurities/Procedure, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Flavoxate Related Compound A RS	Ravi Ravichandran
GADODIAMIDE INJECTION PF 36(1) Pg. 99	ADDITIONAL REQUIREMENTS/Packaging and Storage	Ravi Ravichandran
GALANTAMINE HYDROBROMIDE PF 36(1) Pg. 100	IMPURITIES/Organic Impurities/Procedure, SPECIFIC TESTS/Enantiomeric Purity, SPECIFIC TESTS/Optical Rotation, Specific Rotation <781>,, ADDITIONAL REQUIREMENTS/Labeling	Ravi Ravichandran
GINGER CAPSULES PF 36(1) Pg. 155	PERFORMANCE TESTS/Disintegration and Dissolution of Dietary Supplements <2040>	Maged Sharaf
AMERICAN GINSENG CAPSULES PF 36(1) Pg. 157	PERFORMANCE TESTS/Disintegration and Dissolution of Dietary Supplements <2040>	Maged Sharaf
AMERICAN GINSENG TABLETS PF 36(1) Pg. 159	PERFORMANCE TESTS/Disintegration and Dissolution of Dietary Supplements <2040>	Maged Sharaf
ASIAN GINSENG TABLETS PF 36(1) Pg. 160	PERFORMANCE TESTS/Disintegration and Dissolution of Dietary Supplements <2040>	Maged Sharaf
L-GLUTAMIC ACID, HYDROCHLORIDE PF 35(5) Pg. 1203	Title, Chemical Info/Chemical Structure, Chemical Info/C5H9NO4&middledot;HCl, Chemical Info/183.59, Chemical Info/1-2-Aminoglutaric acid, hydrochloride;, Chemical Info/2-Aminopentanedioic acid, hydrochloride, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/Infrared Absorption <197K>, ASSAY/Procedure, IMPURITIES/Inorganic Impurities/Residue on Ignition <281>, IMPURITIES/Inorganic Impurities/Heavy Metals, Method I <231>, SPECIFIC TESTS/Optical Rotation, Specific Rotation <781S>, SPECIFIC TESTS/Loss on Drying <731>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>	Robert Lafaver
GLYBURIDE AND METFORMIN HYDROCHLORIDE TABLETS PF 35(6) Pg. 1456	PERFORMANCE TESTS/Dissolution <711>	Margareth Marques
Glycolic Acid PF 35(6) Pg. 1567	Glycolic Acid,	Margareth Marques
HALOBETASOL PROPIONATE PF 35(6) Pg. 1458	Title, Chemical Info/Chemical Structure, Chemical Info/C25H31ClF2O5, Chemical Info/484.96, Chemical Info/Pregna-1,4-diene-3,20-dione, 21-chloro-6,9-difluoro-11-hydroxy-16-methyl-17-(1-oxopropoxy)-,	Clydewyn Anthony

(6 α ,11 β ,16 β)-, Chemical Info/21-Chloro-6 α ,9-difluoro-11 β ,17-dihydroxy-16 β -methylpregna-1,4-diene-3,20-dione 17-propionate, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Inorganic Impurities/Residue On Ignition <281>, IMPURITIES/Inorganic Impurities/Heavy Metals, Method II <231>, IMPURITIES/Organic Impurities/Procedure, SPECIFIC TESTS/Loss on Drying <731>, SPECIFIC TESTS/Optical Rotation, Specific Rotation <781>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Halobetasol Propionate RS

HYDROBROMIC ACID PF 36(1) Pg. 267

Hydrobromic Acid,

[Elena Gonikberg](#)

HYDROMORPHONE HYDROCHLORIDE ORAL SOLUTION PF 35(4) Pg. 851

Title, DEFINITION/Introduction, IDENTIFICATION/A. Ultraviolet Absorption <197U>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities/Procedure, SPECIFIC TESTS, SPECIFIC TESTS/Microbial Enumeration Tests <61> and Tests for Specified Microorganisms <62>, SPECIFIC TESTS/ pH <791>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/ USP Reference Standards <11>

[Clydewyn Anthony](#)

IODIXANOL INJECTION PF 36(1) Pg. 103

IDENTIFICATION/A. Procedure, IDENTIFICATION/B., IMPURITIES/Inorganic Impurities, IMPURITIES/Organic Impurities/Procedure, SPECIFIC TESTS/Limit of Free Iodide, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Iodixanol RS

[Ravi Ravichandran](#)

IOHEXOL INJECTION PF 36(1) Pg. 106

IDENTIFICATION/A. Procedure, IDENTIFICATION/B. Thin-Layer Chromatographic Identification Test <201>, IDENTIFICATION/Introduction, IMPURITIES/Inorganic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage

[Ravi Ravichandran](#)

IRBESARTAN AND HYDROCHLOROTHIAZIDE TABLETS PF 36(1) Pg. 108

IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Irbesartan RS

[Sujatha Ramakrishna](#)

LAMOTRIGINE TABLETS PF 36(1) Pg. 110

Title, DEFINITION/Introduction, IDENTIFICATION/A. Ultraviolet Absorption <197U>, IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS,

[Ravi Ravichandran](#)

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 Lamotrigine RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Lamotrigine Related Compound B RS

LEAD ACETATE COTTON PF 35(6)
Pg. 1568

Lead Acetate Cotton

[Robert Lafaver](#)

LETROZOLE PF 36(1) Pg. 111

ASSAY/Procedure, IMPURITIES/Organic Impurities/Procedure, IMPURITIES/Organic Impurities/Acceptance criteria

[Feiwen Mao](#)

LETROZOLE TABLETS PF 36(1)
Pg. 113

ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities/Procedure

[Feiwen Mao](#)

LEVETIRACETAM TABLETS PF
36(1) Pg. 115

Title, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, 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>/USP Levetiracetam RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Levetiracetam Related Compound B RS

[Ravi Ravichandran](#)

LEVOCABASTINE
HYDROCHLORIDE PF 36(1) Pg. 116

IMPURITIES/Organic Impurities/Procedure

[Mary Waddell](#)

LEVOFLOXACIN PF 35(6) Pg. 1459

Title, Chemical Info/Chemical Structure, Chemical Info/C18H20FN3O4·½H2O, Chemical Info/370.38, Chemical Info/7H-Pyrido[1,2,3-de]-1,4-benzoxazine-6-carboxylic acid, 9-fluoro-2,3-dihydro-3-methyl-10-(4-methyl-1-piperazinyl)-7-oxo-hydrate (2:1), (S)-;-, Chemical Info/(−)-(S)-9-Fluoro-2,3-dihydro-3-methyl-10-(4-methyl-1-piperazinyl)-7-oxo-7H-pyrido[1,2,3-de]-1,4-benzoxazine-6-carboxylic acid, hemihydrate, Chemical Info/CAS, Chemical Info/Anhydrous, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Inorganic Impurities/Residue on Ignition <281>, IMPURITIES/Inorganic Impurities/Heavy Metals, Method II <231>, IMPURITIES/Organic Impurities/Procedure, SPECIFIC TESTS/Optical rotation,

[Behnam Davani](#)

	Specific Rotation <781S>, SPECIFIC TESTS/Water Determination, Method Ia <921>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Levofloxacin RS	
LEVONORGESTREL AND ETHINYL ESTRADIOL TABLETS PF 36(1) Pg. 117	IDENTIFICATION/A., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Levonorgestrel RS	Mary Waddell
ALPHA LIPOIC ACID CAPSULES PF 36(1) Pg. 145	PERFORMANCE TESTS/Disintegration and Dissolution of Dietary Supplements <2040>	Natalia Davydova
ALPHA LIPOIC ACID TABLETS PF 36(1) Pg. 146	PERFORMANCE TESTS/Disintegration and Dissolution of Dietary Supplements <2040>	Natalia Davydova
LITHIUM CARBONATE TABLETS PF 35(6) Pg. 1461	PERFORMANCE TESTS/Dissolution <711>	Margareth Marques
METANIL YELLOW PF 36(1) Pg. 267	Metanil Yellow (Acid Yellow 36; 3-(4-Anilinophenylazo)benzenesulfonic Acid Sodium Salt),	Robert Lafaver
PARTIALLY-NEUTRALIZED METHACRYLIC ACID AND ETHYL ACRYLATE COPOLYMER PF 35(5) Pg. 1204	Title, Chemical Info/Chemical Structure, Chemical Info/Partially-Neutralized Poly(methacrylic acid, ethyl acrylate);, Chemical Info/Partially-Neutralized Methacrylic acid-ethyl acrylate copolymer, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Inorganic Impurities/Residue on Ignition <281>, IMPURITIES/Inorganic Impurities/Heavy Metals, Method II <231>, IMPURITIES/Organic Impurities/Procedure: Limit of Methacrylic Acid and Ethyl Acrylate, SPECIFIC TESTS/Loss on Drying <731>, SPECIFIC TESTS/Viscosity <911>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>	Hong Wang
METHYLPHENIDATE HYDROCHLORIDE PF 36(1) Pg. 119	DEFINITION/Introduction, IDENTIFICATION/B. Identification Tests—General, Chloride <191>, ASSAY/Procedure, IMPURITIES/Organic Impurities	Ravi Ravichandran
METHYLPHENIDATE HYDROCHLORIDE EXTENDED-RELEASE TABLETS PF 35(6) Pg. 1461	PERFORMANCE TESTS/Dissolution <711>	Margareth Marques
MYCOPHENOLATE MOFETIL FOR INJECTION PF 35(6) Pg. 1464	Title, DEFINITION/Introduction, IDENTIFICATION/Introduction, ASSAY/Procedure, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities/Procedure,	Feiwen Mao

SPECIFIC TESTS, SPECIFIC TESTS/Bacterial Endotoxins <85>, SPECIFIC TESTS/Sterility <71>, SPECIFIC TESTS/Water Determination, Method Ia <921>, SPECIFIC TESTS/pH <791>, SPECIFIC TESTS/Particulate Matter <788>, SPECIFIC TESTS/Constituted Solution, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Endotoxin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Mycophenolate Mofetil RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Mycophenolate Mofetil Related Compound A RS [2-morpholinoethyl (E)-6-(1,3-dihydro-4,6-dihydroxy-7-methyl-3-oxo-5-isobenzofuranyl)-4-methyl-4-hexenoate], ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Mycophenolate Mofetil Related Compound B RS [(RS)-7-hydroxy-5-methoxy-4-methyl-6-[2-(5-methyl-2-oxo-tetrahydrofuran-5-yl)ethyl]-3H-isobenzofuranyl-1-one]

MYCOPHENOLATE MOFETIL
FOR ORAL SUSPENSION PF 35(6)
Pg. 1466

Title, DEFINITION/Introduction, IDENTIFICATION/Introduction, ASSAY/Procedure, PERFORMANCE TESTS, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, PERFORMANCE TESTS/Deliverable Volume <698>, IMPURITIES/Organic Impurities/Procedure, SPECIFIC TESTS/pH <791>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Mycophenolate Mofetil RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Mycophenolate Mofetil Related Compound A RS [2-morpholinoethyl (E)-6-(1,3-dihydro-4,6-dihydroxy-7-methyl-3-oxo-5-isobenzofuranyl)-4-methyl-4-hexenoate], ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Mycophenolate Mofetil Related Compound B RS [(RS)-7-hydroxy-5-methoxy-4-methyl-6-[2-(5-methyl-2-oxo-tetrahydrofuran-5-yl)ethyl]-3H-isobenzofuranyl-1-one]

[Feiwen Mao](#)

Mercuric Bromide Test Paper PF
35(6) Pg. 1568

Mercuric Bromide Test Paper

[Margareth Marques](#)

DILUTED NITROGLYCERIN PF
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IMPURITIES/Organic Impurities/Procedure

[Sujatha Ramakrishna](#)

NONOXYNOL-9 PF 36(1) Pg. 267

Nonoxynol-9

[Margareth Marques](#)

OSELTAMIVIR PHOSPHATE PF
36(1) Pg. 124

IMPURITIES/Organic Impurities/Procedure 1

[Behnam Davani](#)

OXALIPLATIN PF 35(6) Pg. 1467	IMPURITIES/Organic Impurities/Procedure 1: Limit of Oxalic Acid, SPECIFIC TESTS/Content of Platinum	Feiwen Mao
PARAMETHASONE ACETATE PF 35(6) Pg. 1471	Title, Chemical Info/Chemical Structure, Chemical Info/C24H31FO6, Chemical Info/434.50, Chemical Info/Pregna-1,4-diene-3,20-dione, 21-(acetyloxy)-6-fluoro-11,17-dihydroxy-16-methyl-, (6α,11β,16α)-, Chemical Info/6α-Fluoro-11β,17,21-trihydroxy-16α-methylpregna-1,4-diene-3,20-dione 21-acetate, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B. Ultraviolet Absorption <197U>, IDENTIFICATION/C. Thin-Layer Chromatography, ASSAY/Procedure, SPECIFIC TESTS/X-Ray Diffraction <941>, SPECIFIC TESTS/Optical Rotation, Specific Rotation <781S>, SPECIFIC TESTS/Loss on Drying <731>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Paramethasone Acetate RS	Mary Waddell
PARAMETHASONE ACETATE TABLETS PF 35(6) Pg. 1472	Title, DEFINITION/Introduction, IDENTIFICATION/Introduction, ASSAY/Procedure, PERFORMANCE TESTS/Disintegration <701>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Paramethasone Acetate RS	Mary Waddell
PILOCARPINE HYDROCHLORIDE PF 35(6) Pg. 1473	DEFINITION/Introduction, ASSAY/Procedure, SPECIFIC TESTS/Melting Range or Temperature <741>, ADDITIONAL REQUIREMENTS/Packaging and Storage	Feiwen Mao
PIOGLITAZONE HYDROCHLORIDE PF 36(1) Pg. 126	Title, Chemical Info/Chemical Structure, Chemical Info/C19H20N2O3SċHCl, Chemical Info/392.90, Chemical Info/2,4-Thiazolidinedione, 5-[[4-[2-(5-ethyl-2-pyridinyl)ethoxy]phenyl]methyl]-, monohydrochloride, (±)-, Chemical Info/(±)-5-[p-[2-(5-Ethyl-2-pyridinyl)ethoxy]benzyl]-2,4-thiazolidinedione monohydrochloride, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B. Identification Tests--General, Chloride <191>, IDENTIFICATION/C., ASSAY/Procedure, IMPURITIES/Inorganic Impurities/Residue on Ignition <281>, IMPURITIES/Inorganic Impurities/Heavy Metals, IMPURITIES/Organic Impurities/Procedure, SPECIFIC TESTS/Water Determination, Method Ic <921>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP	Elena Gonikberg

Reference Standards <11>/USP Pioglitazone Hydrochloride RS

PIOGLITAZONE TABLETS PF 36(1) Pg. 128

Title, DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B. Ultraviolet Absorption, 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>/USP Pioglitazone Hydrochloride RS

[Elena Gonikberg](#)

POLYETHYLENE OXIDE PF 36(1) Pg. 191

Chemical Info, DEFINITION/Introduction, IDENTIFICATION/B., ADDITIONAL REQUIREMENTS/Labeling

[Hong Wang](#)

POLYOXYL STEARYL ETHER PF 35(6) Pg. 1504

Chemical Info/CH₃(CH₂)₁₇(OCH₂CH₂)_nOH, n = 2-20, IDENTIFICATION/C., IMPURITIES/Organic Impurities/PROCEDURE: LIMIT OF FREE ETHYLENE OXIDE AND DIOXANE, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>

[Hong Wang](#)

POTASSIUM ARSENATE MONOBASIC PF 35(6) Pg. 1568

Potassium Arsenate Monobasic,

[Margareth Marques](#)

PROPAFENONE HYDROCHLORIDE PF 36(1) Pg. 129

IMPURITIES/Organic Impurities/Procedure 1: Limit of Methanol and Acetone

[Sujatha Ramakrishna](#)

PYGEUM CAPSULES PF 36(1) Pg. 162

PERFORMANCE TESTS/Disintegration and Dissolution of Dietary Supplements <2040>

[Maged Sharaf](#)

QUINIDINE SULFATE ORAL SUSPENSION PF 35(6) Pg. 1475

ASSAY/Procedure

[Rick Schnatz](#)

(R)-(+)-alpha-METHYLBENZYL ISOCYANATE PF 36(1) Pg. 267

(R)-(+)-alpha-Methylbenzyl Isocyanate

[Margareth Marques](#)

RIVASTIGMINE TARTRATE PF 35(6) Pg. 1476

Title, Chemical Info/Chemical Structure, Chemical Info/C₁₄H₂₂N₂O₂·C₄H₆O₆, Chemical Info/400.42, Chemical Info/Ethylmethylcarbamic acid, 3-[(S)-1-(dimethylamino)ethyl]phenyl ester, (2R,3R)-2,3-dihydroxybutanedioate;, Chemical Info/(S)-3-[1-(Dimethylamino)ethyl]phenyl ethylmethylcarbamate, hydrogen tartrate, Chemical Info/CAS, Chemical Info/Rivastigmine, Chemical Info/250.34, 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, IMPURITIES/Organic

[Elena Gonikberg](#)

Impurities/Procedure 2: Enantiomeric Purity, IMPURITIES/Organic Impurities/Acceptance criteria, SPECIFIC TESTS/Water Determination, Method IA <921>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Rivastigmine Tartrate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Rivastigmine Related Compound A RS [Di-p-toluoyl-d-(+)-tartaric acid monohydrate]C20H20O9404.37, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Rivastigmine Related Compound B RS [N,N-Dimethylcarbamic acid-3-[1-(dimethyl-amino)ethyl]phenyl ester]C13H20N2O2236.32, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Rivastigmine Tartrate R-Isomer RS [(R)-3-[1-(Dimethylamino)ethyl]phenyl ethyl(methyl)carbamate, hydrogen tartrate]C14H22N2O2&middledot;C4H6O6400.42

RIVASTIGMINE TARTRATE
CAPSULES PF 36(1) Pg. 131

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>/USP Rivastigmine Tartrate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Rivastigmine Related Compound A RS (DPTTA impurity) Di-p-toluoyl-d-(+)-tartaric acid monohydrate(C20H20O9 404.37), ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Rivastigmine Related Compound B RS (Nor impurity) N,N-Dimethylcarbamic acid-3-[1-(dimethyl-amino)ethyl]phenyl ester(C13H20N2O2 236.32)

[Elena
Gonikberg](#)

ROPINIROLE HYDROCHLORIDE
PF 36(1) Pg. 133

Title, Chemical Info/Chemical Structure, Chemical Info/C16H24N2O&middledot;HCl, Chemical Info/296.84, Chemical Info/2H-Indol-2-one, 4-[2-(dipropylamino)ethyl]-1,3-dihydro-, monohydrochloride;, Chemical Info/4-[2-(Dipropylamino)ethyl]-2-indolinone monohydrochloride, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., IDENTIFICATION/C. Identification Test—General, Chloride <191>, ASSAY/Procedure, IMPURITIES/Inorganic Impurities/Residue on Ignition <281>, IMPURITIES/Inorganic Impurities/Heavy Metals, Method II <231>, SPECIFIC TESTS/Water Determination, Method Ic <921>, SPECIFIC TESTS/Limit of Pd, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference

[Ravi
Ravichandran](#)

Standards <11>/USP Ropinirole Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ropinirole Related Compound A RS 4-(2-Hydroxyethyl)indolin-2-one(C10H11NO2177.20), ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ropinirole Related Compound B RS 4-[2-(Dipropylamino)ethyl]indoline-2,3-dione(C16H22N2O2274.36)

ROPIVACAINE HYDROCHLORIDE PF 36(1) Pg. 135

IMPURITIES/Organic Impurities/Procedure 3: Enantiomeric Purity, SPECIFIC TESTS/Optical Rotation, Specific Rotation <781S>

[Mary Waddell](#)

SAW PALMETTO CAPSULES PF 36(1) Pg. 163

PERFORMANCE TESTS/Disintegration and Dissolution of Dietary Supplements <2040>, PERFORMANCE TESTS/Rupture

[Maged Sharaf](#)

SERTRALINE TABLETS PF 36(1) Pg. 138

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 Sertraline Hydrochloride RS [(1-Naphthalenamine, 4-(3,4-dichlorophenyl)-1,2,3,4-tetrahydro-N-methyl-, hydrochloride, (1S-cis)-](C17H17Cl2NċHCl342.69), ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Sertraline Hydrochloride Racemic Mixture RS [(1:1 mixture of (1S,4S) and (1R,4R)-4-(3,4-dichlorophenyl)-N-methyl-1,2,3,4-tetrahydro-1-naphthylamine hydrochloride](C17H17Cl2NċHCl342.69)

[Ravi Ravichandran](#)

SEVOFLURANE PF 36(1) Pg. 139

IMPURITIES/Inorganic Impurities/Limit of Peroxide, IMPURITIES/Organic Impurities/Procedure 2

[Mary Waddell](#)

SIMETHICONE EMULSION PF 35(6) Pg. 1477

IDENTIFICATION/Infrared Absorption <197S>, IDENTIFICATION/Infrared Absorption <197A>

[Elena Gonikberg](#)

SODIUM 1-PENTANESULFONATE, ANHYDROUS PF 36(1) Pg. 268

Sodium 1-Pentanesulfonate, Anhydrous (1-Pentanesulfonic Acid Sodium Salt, Anhydrous),

[Margareth Marques](#)

SODIUM FLUORIDE GEL PF 35(5) Pg. 1175

Title, DEFINITION/Introduction, IDENTIFICATION/Procedure, ASSAY/Procedure, SPECIFIC TESTS/pH <791>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>

[Elena Gonikberg](#)

Sodium 1-Pentanesulfonate PF 36(1) Pg. 268	Sodium 1-Pentanesulfonate	Margareth Marques
SOY ISOFLAVONES CAPSULES PF 36(1) Pg. 165	PERFORMANCE TESTS/Disintegration and Dissolution of Dietary Supplements <2040>	Maged Sharaf
SOY ISOFLAVONES TABLETS PF 36(1) Pg. 167	PERFORMANCE TESTS/Disintegration and Dissolution of Dietary Supplements <2040>	Maged Sharaf
SPIRONOLACTONE PF 36(1) Pg. 141	SPECIFIC TESTS/Melting Range or Temperature <741>	Sujatha Ramakrishna
SULFASALAZINE PF 35(6) Pg. 1478	IDENTIFICATION/B. Procedure	Behnam Davani
SULFASALAZINE TABLETS PF 35(6) Pg. 1479	IDENTIFICATION/Procedure	Behnam Davani
TERBINAFINE HYDROCHLORIDE PF 35(6) Pg. 1480	DEFINITION/Introduction, ASSAY/Procedure, IMPURITIES/Organic Impurities/Procedure, IMPURITIES/Organic Impurities/Acceptance criteria	Behnam Davani
TERBINAFINE TABLETS PF 36(1) Pg. 142	Title, DEFINITION/Introduction, IDENTIFICATION/Introduction, ASSAY/Procedure, PERFORMANCE TESTS, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities/Procedure 1, IMPURITIES/Organic Impurities/Procedure 2: Limit of Terbinafine Dimer, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/ USP Reference Standards <11>/USP Terbinafine Hydrochloride RS	Behnam Davani
USP AND NF EXCIPIENTS, LISTED BY CATEGORY	{ Buffering Agent } Alpha-Lactalbumin, { Bulking Agent for Freeze-Drying } Alpha-Lactalbumin, { Coating Agent } Alpha-Lactalbumin, { Complexing Agent } Alpha-Lactalbumin, { Emulsifying and/or Solubilizing Agent } Alpha-Lactalbumin, { Coating Agent } Partially-Neutralized Methacrylic Acid and Ethyl Acrylate Copolymer, { Film-Forming Agent } Partially-Neutralized Methacrylic Acid and Ethyl Acrylate Copolymer, { Coloring Agent }	Hong Wang
VALERIAN TABLETS PF 36(1) Pg. 169	PERFORMANCE TESTS/Disintegration and Dissolution of Dietary Supplements <2040>	Maged Sharaf
VENLAFAXINE HYDROCHLORIDE PF 35(6) Pg. 1482	Title, Chemical Info/Chemical Structure, Chemical Info/C17H27NO2·HCl, Chemical Info/313.86, Chemical Info/Cyclohexanol, 1-[2-(dimethylamino)-1-(4-methoxyphenyl)ethyl]-, hydrochloride;, Chemical Info/(±)-1-[α-[(Dimethylamino)methyl]-p-methoxybenzyl]cyclohexanol hydrochloride, Chemical Info/CAS, DEFINITION/Introduction,	Ravi Ravichandran

IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., IDENTIFICATION/C. Identification Tests—General, Chloride <191>, ASSAY/Procedure, IMPURITIES/Inorganic Impurities/Residue on Ignition <281>, IMPURITIES/Inorganic Impurities/Heavy Metals, Method II <231>, IMPURITIES/Organic Impurities/Procedure, SPECIFIC TESTS/Loss on Drying <731>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Venlafaxine Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Venlafaxine Related Compound A RS [1-(1-(4-methoxyphenyl)-2-(methylamino)ethyl)cyclohexanol]C16H25NO2263.38

VENLAFAXINE TABLETS PF 35(6)
Pg. 1483

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>/USP Venlafaxine Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Venlafaxine Related Compound A RS [1-(1-(4-methoxyphenyl)-2-(methylamino)ethyl)cyclohexanol]C16H25NO2263.38

[Ravi Ravichandran](#)

OIL-SOLUBLE VITAMINS
CAPSULES PF 36(1) Pg. 169

PERFORMANCE TESTS/Disintegration and Dissolution of Dietary Supplements <2040>

[Natalia Davydova](#)

OIL-SOLUBLE VITAMINS
TABLETS PF 36(1) Pg. 176

PERFORMANCE TESTS/Disintegration and Dissolution of Dietary Supplements <2040>

[Natalia Davydova](#)

WATER FOR INJECTION PF 35(2)
Pg. 316

DEFINITION/Introduction, SPECIFIC TESTS/Bacterial Endotoxins Test <85>, SPECIFIC TESTS/Water Conductivity, Bulk Water <645>, SPECIFIC TESTS/Sterility Tests <71>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, SPECIFIC TESTS/Introduction, SPECIFIC TESTS/ Sterility Tests <71>, ADDITIONAL REQUIREMENTS/Introduction

[Antonio Hernandez-Cardoso](#)

WATER FOR HEMODIALYSIS PF
35(6) Pg. 1485

SPECIFIC TESTS/, SPECIFIC TESTS/Paragraph Text, SPECIFIC TESTS/Oxidizable Substances, SPECIFIC TESTS/Microbial Enumeration Tests <61> and Tests for Specified Microorganisms <62>, SPECIFIC TESTS/Bacterial Endotoxins Test <85>

[Antonio Hernandez-Cardoso](#)

GENERAL NOTICES TO USP-NF

2. OFFICIAL STATUS AND LEGAL RECOGNITION,

[Todd Cecil](#)

PF 36(1) Pg. 56

3. CONFORMANCE TO STANDARDS, 4.
MONOGRAPHS AND GENERAL CHAPTERS, 5.
MONOGRAPH COMPONENTS, 7. TEST RESULTS

ZINC, ACTIVATED PF 35(6) Pg.
1568

Zinc, Activated

[Margareth
Marques](#)

DESCRIPTION AND SOLUBILITY
PF 36(1) Pg. 271

Aluminum Oxide, Cefoperazone Sodium, Doxycycline,
Pioglitazone Hydrochloride, Ferric Sulfate, Partially-
Neutralized Methacrylic Acid and Ethyl Acrylate
Copolymer, Halobetasol Propionate, Ropinirole
Hydrochloride, Levofloxacin, Paramethasone Acetate,
Pravastatin Sodium, Rivastigmine Tartrate, Venlafaxine
Hydrochloride

[Robert
Lafaver](#)