

Compendial Approvals for USP35-NF30ž: JfghSi dd`Ya Ybh

| Monograph Title | Monograph Section | Scientific Liaison |
|-------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------|
| <181> IDENTIFICATION-- ORGANIC NITROGENOUS BASES PF 37(2) Pg. ONLINE | INTRODUCTION/Introduction, ASSAY/Procedure | Antonio Hernandez-Cardoso |
| <660> CONTAINERS -- GLASS PF 37(2) Pg. ONLINE | DESCRIPTION, SPECIFIC TESTS, IMPURITIES, FUNCTIONALITY | Desmond Hunt |
| <698> DELIVERABLE VOLUME PF 37(3) Pg. ONLINE | DENSITY DETERMINATION, PROCEDURE | William Brown |
| <731> LOSS ON DRYING PF 37(3) Pg. ONLINE | Introduction | Horacio Pappa |
| <1032> DEVELOPMENT AND DESIGN OF BIOASSAYS PF 36(4) Pg. 956 | 1. INTRODUCTION, 2. BIOASSAY FITNESS FOR USE, 3. BIOASSAY FUNDAMENTALS, 4. STATISTICAL ASPECTS OF BIOASSAY FUNDAMENTALS, 5. STAGES IN THE BIOASSAY PROCESS | Tina Morris |
| <1033> VALIDATION OF BIOLOGICAL ASSAYS PF 36(4) Pg. 986 | 1. INTRODUCTION, 2. FUNDAMENTALS OF BIOASSAY VALIDATION, 3. A BIOASSAY VALIDATION EXAMPLE, 4. LITERATURE | Tina Morris |
| <1034> ANALYSIS OF BIOLOGICAL ASSAYS PF 36(4) Pg. 1005 | 1. INTRODUCTION, 2. OVERVIEW OF ANALYSIS OF BIOASSAY DATA, 3. ANALYSIS MODELS, 4. CONFIDENCE INTERVALS, 5. LITERATURE, APPENDIX–GLOSSARY, GLOSSARY REFERENCES | Tina Morris |
| <1105> IMMUNOLOGICAL TEST METHODS- SURFACE PLASMON RESONANCE PF 37(3) Pg. ONLINE | Title, Introduction, Overview, Use of SPR in a Regulated Environment | Maura Kibbey |
| <1119> NEAR- INFRARED SPECTROSCOPY PF 37(2) Pg. ONLINE | INSTRUMENTATION | Horacio Pappa |
| <1231> WATER FOR PHARMACEUTICAL PURPOSES PF 37(3) Pg. ONLINE | TYPES OF WATER, CHEMICAL CONSIDERATIONS | Antonio Hernandez-Cardoso |
| <1644> THEORY AND PRACTICE OF ELECTRICAL CONDUCTIVITY MEASUREMENTS OF | Introduction, INTRODUCTION, THEORY OF OPERATION, OPERATIONAL CONSIDERATIONS, CALIBRATION | Antonio Hernandez-Cardoso |

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| SOLUTIONS PF 37(3) Pg. ONLINE | | |
| 1- Hydroxybenzotriazole Hydrate PF 37(3) Pg. ONLINE | 1-Hydroxybenzotriazole Hydrate, | Margareth Marques |
| 2- Dimethylaminoethyl methacrylate PF 37(2) Pg. ONLINE | 2-Dimethylaminoethyl Methacrylate, | Margareth Marques |
| ALLANTOIN PF 37(2) Pg. ONLINE | IDENTIFICATION/C. | Feiwen Mao |
| AMILOXATE PF 37(2) Pg. ONLINE | Chemical Info/2-propenoic acid, 3-(4-methoxyphenyl)-3-methylbutyl ester 3-Methylbutyl 3-(4-methoxyphenyl)-(E)-2-propenoate, DEFINITION/Introduction, ASSAY/Procedure, IMPURITIES/Organic Impurities | Feiwen Mao |
| ANAGRELIDE HYDROCHLORIDE PF 36(5) Pg. 1160 | Chemical Info/Chemical Structure, Chemical Info/C10H7Cl2N3O·HCl·H2O, Chemical Info/310.56, Chemical Info/Anhydrous, Chemical Info/292.55, Chemical Info/CAS, Chemical Info/Imidazo[2,1-b]quinazolin-2(3H)-one, 6,7-dichloro-1,5-dihydro-, monohydrochloride, monohydrate;, Chemical Info/6,7-Dichloro-1,5-dihydroimidazo[2,1-b]-quinazolin-2(3H)-one monohydrochloride, monohydrate, DEFINITION/Introduction, 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/Water Determination, Method I <921>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Anagrelide Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Anagrelide Related Compound A RS [ethyl 2-(6-amino-2,3-dichlorobenzylamino)acetate] (C11H14Cl2N2O2277.15), ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Anagrelide Related Compound B RS [(2-amino-5,6-dichloroquinazolin-3(4H)-yl)acetic acid] (C10H9Cl2N3O2274.10) | Sujatha Ramakrishna |
| ANAGRELIDE CAPSULES PF 36(5) Pg. 1162 | 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 Anagrelide Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Anagrelide Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Anagrelide Related Compound C RS | Sujatha Ramakrishna |
| Ammonium Sulfide TS PF 37(2) Pg. ONLINE | Ammonium Sulfide TS— | Margareth Marques |
| BETADEX | IMPURITIES/Limit of Sodium Chloride, IMPURITIES/Limit of 4-Hydroxybutane-1-Sulfonic Acid, IMPURITIES/Limit of Bis(4-Sulfobutyl) Ether Disodium, IMPURITIES/Limit of Sodium Chloride, 4-Hydroxybutane-1-Sulfonic Acid, and Bis(4-Sulfobutyl) Ether Disodium, SPECIFIC TESTS/Average Degree of Substitution, Chemical Info/Chemical Structure, Chemical Info/C42H70-nO35·(C4H8SO3Na)n, Chemical Info/2163 when n = 6.5, Chemical Info/Beta Cyclodextrin Sulfobutyl Ethers, Sodium Salts;, Chemical Info/Beta Cyclodextrin Sulfobutyl Ether Sodium, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., IDENTIFICATION/C., IDENTIFICATION/D. Identification Tests—General, Sodium <191>, ASSAY/Procedure, IMPURITIES/Inorganic Impurities/Heavy Metals, Method II <231>, IMPURITIES/Inorganic Impurities/Limit | |

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| SULFOBUTYL ETHER SODIUM PF 37(2) Pg. ONLINE | of Sodium Chloride, IMPURITIES/Organic Impurities/Procedure 1: Limit of Beta Cyclodextrin (Betadex), IMPURITIES/Organic Impurities/Procedure 2: Limit of 4-Hydroxybutane-1-Sulfonic Acid, IMPURITIES/Organic Impurities/Procedure 3: Limit of Bis(4-Sulfobutyl) Ether Disodium, IMPURITIES/Organic Impurities/Procedure 4: Limit of 1,4-Butane Sultone, SPECIFIC TESTS/Bacterial Endotoxins Test <85>, SPECIFIC TESTS/Microbial Enumeration Tests <61> and Tests for Specified Microorganisms <62>, SPECIFIC TESTS/Clarity of Solution, SPECIFIC TESTS/pH <791>, SPECIFIC TESTS/Water Determination, Method I <921>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Beta Cyclodextrin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Betadex Sulfobutyl Ether Sodium RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Endotoxin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Sodium Chloride RS | Hong Wang |
| BISACODYL PF 37(3) Pg. ONLINE | Chemical Info, IDENTIFICATION, ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Melting Range or Temperature <741>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Bisacodyl Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Bisacodyl Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Bisacodyl Related Compound C RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Bisacodyl Related Compound E RS | Elena Gonikberg |
| CEFAMANDOLE NAFATE PF 37(3) Pg. ONLINE | IDENTIFICATION/Thin-Layer Chromatography, IDENTIFICATION/A., ASSAY/Procedure | Ahalya Wise |
| CEFAMANDOLE NAFATE FOR INJECTION PF 37(3) Pg. ONLINE | IDENTIFICATION/A. Thin-Layer Chromatography, ASSAY/Procedure | Ahalya Wise |
| CEFPIRAMIDE PF 37(3) Pg. ONLINE | ASSAY/Procedure, IMPURITIES/Organic Impurities | Ahalya Wise |
| CEFPIRAMIDE FOR INJECTION PF 37(3) Pg. ONLINE | ASSAY/Procedure | Ahalya Wise |
| CELECOXIB PF 36(6) Pg. 1519 | Chemical Info/C17H14F3N3O2S, Chemical Info/381.4, Chemical Info/4-[5-(4-Methylphenyl)-3-(trifluoromethyl)-1H-pyrazol-1-yl]benzenesulfonamide; , Chemical Info/p-[5-p-Tolyl-3-(trifluoromethyl)pyrazol-1-yl]benzenesulfonamide, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Inorganic Impurities/Heavy Metals, IMPURITIES/Inorganic Impurities/Residue on Ignition <281>, IMPURITIES/Organic Impurities/Procedure, SPECIFIC TESTS/Water Determination, Method I <921>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Celecoxib RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Celecoxib Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Celecoxib Related Compound B RS | Clydewyn Anthony |
| CETIRIZINE HYDROCHLORIDE TABLETS PF 36(2) Pg. 389 | DEFINITION/Introduction, IDENTIFICATION/Introduction, ASSAY/Procedure, PERFORMANCE TESTS, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities/Procedure, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Cetirizine Hydrochloride RS | Domenick Vicchio |
| DESCRIPTION AND SOLUBILITY PF 37(3) Pg. ONLINE | Felbamate, Betadex Sulfobutyl Ether Sodium, Montelukast Sodium, Celecoxib, Estazolam, Anagrelide Hydrochloride | Ravi Ravichandran |
| DIPHENHYDRAMINE | IDENTIFICATION/Identification—Organic Nitrogenous Bases <181>, | Domenick |

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| HYDROCHLORIDE PF 37(3) Pg. ONLINE | SPECIFIC TESTS/Melting Range or Temperature <741>, SPECIFIC TESTS/Acidity or Alkalinity | Vicchio |
| EPINEPHRINE PF 37(2) Pg. ONLINE | SPECIFIC TESTS/Optical Rotation, Specific Rotation <781S> | Domenick Vicchio |
| ESOMEPRAZOLE MAGNESIUM DELAYED-RELEASE CAPSULES PF 37(3) Pg. ONLINE | DEFINITION/Introduction, IDENTIFICATION/A., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Omeprazole RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Omeprazole Related Compound A RS | Elena Gonikberg |
| ESTAZOLAM PF 36(6) Pg. 1527 | Chemical Info/Chemical Structure, Chemical Info/C16H11CIN4, Chemical Info/294.74, Chemical Info/4H-[1,2,4]Triazolo[4,3-a][1,4]benzodiazepine, 8-chloro-6-phenyl-, Chemical Info/8-Chloro-6-phenyl-4H-s-triazolo[4,3-a][1,4]benzodiazepine, 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>, SPECIFIC TESTS/Loss on Drying <731>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Estazolam RS | Ravi Ravichandran |
| ESTAZOLAM TABLETS PF 36(6) Pg. 1528 | 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 Estazolam RS | Ravi Ravichandran |
| ESTRADIOL VAGINAL INSERTS PF 37(2) Pg. ONLINE | DEFINITION/Introduction, ASSAY/Procedure | Domenick Vicchio |
| ESTRADIOL TRANSDERMAL SYSTEM PF 35(5) Pg. 1136 | PERFORMANCE TESTS/Drug Release <724> | Domenick Vicchio |
| CONJUGATED ESTROGENS PF 37(3) Pg. ONLINE | IMPURITIES/Limit of Estrone, Equilin, and 17α-Dihydroequilin (free steroids), ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP 17α-Dihydroequilin RS | Domenick Vicchio |
| ESTERIFIED ESTROGENS PF 37(3) Pg. ONLINE | IDENTIFICATION/A., ASSAY/Procedure, IMPURITIES/Free Steroids | Domenick Vicchio |
| ESTERIFIED ESTROGENS TABLETS PF 37(3) Pg. ONLINE | IDENTIFICATION/A., ASSAY/Procedure, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Estradiol RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Testosterone RS | Domenick Vicchio |
| ETHINYL ESTRADIOL PF 37(3) Pg. ONLINE | SPECIFIC TESTS/Optical Rotation, Specific Rotation <781S> | Domenick Vicchio |
| EUCALYPTOL PF 37(2) Pg. ONLINE | IDENTIFICATION/A. Infrared Absorption <197F>, IDENTIFICATION/B., ADDITIONAL REQUIREMENTS/USP Reference Standards <11> | Clydewyn Anthony |
| EUGENOL PF 37(2) Pg. ONLINE | IDENTIFICATION/A. Infrared Absorption <197F>, ADDITIONAL REQUIREMENTS/USP Reference Standards <11> | Clydewyn Anthony |
| FAMOTIDINE PF 37(3) Pg. ONLINE | Chemical Info, IDENTIFICATION, IMPURITIES/Chromatographic Purity, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Famotidine Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Famotidine Related Compound C RS, ADDITIONAL | Elena Gonikberg |

REQUIREMENTS/USP Reference Standards <11>/USP Famotidine Related Compound D RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Famotidine Related Compound E RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Famotidine Related Compound F RS

FAMOTIDINE
INJECTION PF 37(3)
Pg. ONLINE

IMPURITIES/Organic Impurities, OTHER COMPONENTS/Content of Benzyl Alcohol (if present)

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FAMOTIDINE FOR
ORAL SUSPENSION
PF 37(3) Pg. ONLINE

IMPURITIES/Organic Impurities

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FAMOTIDINE
TABLETS PF 37(3)
Pg. ONLINE

ASSAY/Procedure, IMPURITIES/Organic Impurities

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Gonikberg](#)

FELBAMATE PF 37(3)
Pg. ONLINE

Chemical Info/Chemical Structure, Chemical Info/C11H14N2O4, Chemical Info/238.24, Chemical Info/1,3-Propanediol, 2-phenyl-, dicarbamate;, Chemical Info/2-Phenyl-1,3-propanediol dicarbamate, 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, Early Eluting, IMPURITIES/Organic Impurities, Late Eluting, IMPURITIES/Limit of Methylcarbamate, SPECIFIC TESTS/Loss on Drying <731>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Felbamate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Felbamate Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Felbamate Related Compound B RS

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FELBAMATE ORAL
SUSPENSION PF
37(3) Pg. ONLINE

DEFINITION/Introduction, IDENTIFICATION/A., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, IMPURITIES/Organic Impurities, SPECIFIC TESTS/pH <791>, SPECIFIC TESTS/Microbial Enumeration Tests <61> and Tests for Specified Microorganisms <62>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Felbamate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Felbamate Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methylparaben RS

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FELBAMATE TABLETS
PF 37(3) Pg. ONLINE

DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197>, IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Felbamate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Felbamate Related Compound A RS

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HALOPERIDOL
INJECTION PF 37(2)
Pg. ONLINE

IDENTIFICATION/Introduction, IDENTIFICATION/A., ASSAY/Procedure, ADDITIONAL REQUIREMENTS/Packaging and Storage

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Ravichandran](#)

HALOPERIDOL ORAL
SOLUTION PF 37(2)
Pg. ONLINE

IDENTIFICATION/Ultraviolet Absorption <197U>, IDENTIFICATION/A., ASSAY/Procedure, ADDITIONAL REQUIREMENTS/Packaging and Storage

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HOMOSALATE PF
37(2) Pg. ONLINE

ASSAY/Procedure

[Feiwen Mao](#)

ITRACONAZOLE PF
37(3) Pg. ONLINE

IMPURITIES/Organic Impurities, SPECIFIC TESTS/Melting Range <741>, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Miconazole RSUSP Itraconazole System Suitability Mixture RS USP Itraconazole System Suitability Mixture RS contains itraconazole and 6 other minor components (4-triazolyl isomer, propyl analog, isopropyl analog, epimer, n-butyl isomer, and didioxolanyl analog).

[Behnam
Davani](#)

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| L7 PF 37(3) Pg. ONLINE | L7 | Margareth Marques |
| LACTULOSE SOLUTION PF 37(3) Pg. ONLINE | IDENTIFICATION/A., IDENTIFICATION/B., PERFORMANCE TESTS/Uniformity of Dosage Units <905>, SPECIFIC TESTS/Other Requirements | Elena Gonikberg |
| LAMOTRIGINE TABLETS FOR ORAL SUSPENSION PF 36(6) Pg. 1544 | DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities /Procedure 1, IMPURITIES/Organic Impurities /Analysis, IMPURITIES/Organic Impurities /Procedure 2, 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, ADDITIONAL REQUIREMENTS/ USP Reference Standards <11>/USP Lamotrigine Related Compound C RS | Hariram Ramanathan |
| LEFLUNOMIDE TABLETS PF 37(3) Pg. ONLINE | PERFORMANCE TESTS/Dissolution <711> | Clydewyn Anthony |
| MIRTAZAPINE ORALLY DISINTEGRATING TABLETS PF 37(2) Pg. ONLINE | ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Mirtazapine Related Compound A RS 1,2,3,4,10,14b-Hexahydropyrazino[2,1-a]pyrido[2,3-c][2]benzazepine.C16H17N3251.33, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Mirtazapine Related Compound B RS 1,2,3,4,10,14b-Hexahydro-2-methylpyrazino[2,1-a]pyrido[2,3-c][2]benzazepine 2-oxide monohydrate.C17H19N3O & middot; H2O299.36, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Mirtazapine Related Compound C RS 2-Methyl-3,4,10,14b-tetrahydrobenzo[c]pyrazino[1,2-a]pyrido[3,2-f]azepin-1(2H)-one.C17H17N3O 279.34, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Mirtazapine Related Compound D RS 2-Methyl-1,2,3,4-tetrahydrobenzo[c]pyrazino[1,2-a]pyrido[3,2-f]azepin-10(14bH)-one.C17H17N3O 279.34 | Hariram Ramanathan |
| MONTELUKAST SODIUM PF 37(2) Pg. ONLINE | DEFINITION/Introduction, IDENTIFICATION/B. Identification Tests—General, Sodium <191>, ASSAY/Introduction, ASSAY/Procedure, IMPURITIES/Heavy Metals, IMPURITIES/Organic Impurities, IMPURITIES/Enantiomeric Purity, SPECIFIC TESTS/Water Determination, Method Ia <921>, Chemical Info/Chemical Structure, Chemical Info/C35H35CINNaO3S, 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]-α-[o-(1-hydroxy-1-methylethyl)phenethyl]benzyl]thio]-methyl]cyclopropaneacetate, Chemical Info/CAS, Chemical Info/C35H36CINO3S, Chemical Info/ 586.18, Chemical Info/Montelukast, IDENTIFICATION/A. Infrared Absorption <197>, IDENTIFICATION/B. Identification Tests—General, Sodium <191>, IDENTIFICATION/C., ASSAY/Note, IMPURITIES/Inorganic Impurities/Heavy Metals, IMPURITIES/Organic Impurities/Procedure, SPECIFIC TESTS/Enantiomeric Purity, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Montelukast Sodium RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Montelukast Dicyclohexylamine (DCHA) RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/(C35H36CINO3S·C12H23N767.50), ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Montelukast Racemate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Montelukast for Peak Identification RS | Mary Waddell |
| OMEGA-3 ACIDS | DEFINITION/Introduction, IDENTIFICATION/A., ASSAY/Content of EPAee and DHAee, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, PERFORMANCE TESTS/Disintegration <701>, IMPURITIES/Oligomers, 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>, | |

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| ETHYL ESTERS CAPSULES PF 37(3) Pg. ONLINE | SPECIFIC TESTS/Absorbance, SPECIFIC TESTS/ Microbial Enumeration Tests <61> and Tests for Specified Microorganisms <62>, 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 Methyl Tricosanoate RS | Natalia Davydova |
| OXCARBAZEPINE ORAL SUSPENSION PF 37(3) Pg. ONLINE | DEFINITION/Introduction, IDENTIFICATION/A., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Deliverable Volume <698>, IMPURITIES/Procedure, SPECIFIC TESTS/pH <791>, SPECIFIC TESTS/Microbial Enumeration Tests <61> and Test for Specified Microorganisms <62>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Carbamazepine RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Oxcarbazepine RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Oxcarbazepine Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Oxcarbazepine Related Compound C RS | Hariram Ramanathan |
| Pancreatic Digest of Casein PF 37(3) Pg. ONLINE | Pancreatic Digest of Casein | Margareth Marques |
| PIPERACILLIN FOR INJECTION PF 37(3) Pg. ONLINE | IDENTIFICATION/A. Infrared Absorption <197K>, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Other Requirements | Ahalya Wise |
| Platinic Chloride PF 37(3) Pg. ONLINE | Platinic Chloride | Margareth Marques |
| QUININE SULFATE PF 37(3) Pg. ONLINE | IMPURITIES/Dihydroquinine Sulfate | Leonel Santos |
| SINCALIDE FOR INJECTION PF 37(3) Pg. ONLINE | DEFINITION/Introduction, ASSAY/Procedure, SPECIFIC TESTS/pH <791>, SPECIFIC TESTS/Particulate Matter in Injections <788>, SPECIFIC TESTS/Constituted Solution, SPECIFIC TESTS/Bacterial Endotoxins Test <85>, SPECIFIC TESTS/Other Requirements, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Endotoxin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Sincalide RS | Ravi Ravichandran |
| Sodium Bitartrate PF 37(2) Pg. ONLINE | Sodium Bitartrate, | Margareth Marques |
| Sodium Borate decahydrate PF 37(2) Pg. ONLINE | Sodium Borate | Margareth Marques |
| | 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-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, | |

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| TACROLIMUS PF 35(2) Pg. 310 | <p>Specific Rotation <781S>, SPECIFIC TESTS/Water Determination, Method I <921>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>, IMPURITIES/Organic Impurities/Procedure 1, IMPURITIES/Organic Impurities/Procedure 2, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Tacrolimus Related Compound A RS (E)-8-Ethyl-5,6,8,11,12,13,14,15,16,17,18,19,24,25,26,26a-Hexadecahydro-5,19-dihydroxy-3-[(E)-2-(4-hydroxy-3-methoxycyclohexyl)-1-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.C43H69NO12792.01, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Tacrolimus System Suitability Mixture RS&mdash;This is a mixture of tacrolimus, ascomycin ((3S,4R,5S,8R,9E,12S,14S,15R,16S,18R,19R,26aS)-8-Ethyl-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-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; C43H69NO12; 792.01), and tacrolimus 8-propyl analog ((3S,4R,5S,8S,9E,12S,14S,15R,16S,18R,19R,26aS)-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-methylvinyl]-14,16-dimethoxy-4,10,12,18-tetramethyl-15,19-epoxy-8-propyl-3H-pyrido[2,1-c][1,4]oxaazacyclotricosine-1,7,20,21(4H,23H)-tetrone; C44H71NO12; 806.03)</p> | Ahalya Wise |
| TACROLIMUS CAPSULES PF 35(2) Pg. 312 | <p>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>, PERFORMANCE TESTS/Dissolution <711>, IMPURITIES/Organic Impurities/Procedure 1, IMPURITIES/Organic Impurities/Procedure 2, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Tacrolimus RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Tacrolimus Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Tacrolimus System Suitability RS</p> | Ahalya Wise |
| TERBINAFINE TABLETS PF 37(3) Pg. ONLINE | ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711> | Leonel Santos |
| TRIAZOLAM PF 37(2) Pg. ONLINE | <p>IDENTIFICATION/Ultraviolet Absorption <197U>, ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Alprazolam Related Compound A RS 2-(2-Acetylhydrazino)-7-chloro-5-phenyl-3H-1,4-benzodiazepine.C17H15CIN4O 326.78</p> | Hariram Ramanathan |
| Uridine PF 37(2) Pg. ONLINE | Uridine, | Margareth Marques |
| USP AND NF EXCIPIENTS, LISTED BY CATEGORY PF 36(2) Pg. 440 | {Complexing Agent} Betadex Sulfobutyl Ether Sodium, {Sequestering Agent} Betadex Sulfobutyl Ether Sodium, {Wetting and/or Solubilizing Agent} Betadex Sulfobutyl Ether Sodium | Hong Wang |
| VALSARTAN TABLETS PF 37(3) Pg. ONLINE | <p>DEFINITION/Introduction, IDENTIFICATION/A., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Valsartan RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Valsartan Related Compound B RS</p> | Sujatha Ramakrishna |
| VERAPAMIL HYDROCHLORIDE EXTENDED-RELEASE | <p>DEFINITION/Introduction, IDENTIFICATION/A., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP</p> | Sujatha Ramakrishna |

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Pg. ONLINE

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