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Sujatha Ramakrishna

Radhakrishna Tirumalai

Krishna Menon
Revision Alcohol, 70 Percent, 80 Percent, and 90 Percent PF 45(5) Pg. ONLINE

- ASSAY/Procedure, PERFORMANCE TESTS/Dissolution (711), Procedure, Apparatus 1 and Apparatus 2, Immediate-release dosage forms, Procedure for a pooled sample for immediate-release dosage forms, PERFORMANCE TESTS/Uniformity of Dosage Units (905), IMPURITIES/Organic Impurities

Margareth Marques

Revision ALPRAZOLAM TABLETS PF 45(5) Pg. ONLINE

- ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)

Heather Joyce

Revision AMICINONIDE PF 46(2) Pg. ONLINE

- IDENTIFICATION/B.

Mary Koleck

Revision AMICINONIDE CREAM PF 46(2) Pg. ONLINE

- IDENTIFICATION/B.

Mary Koleck

Revision AMERICAN GINSENG ROOT AND RHIZOME PF 45(4) Pg. ONLINE

- DEFINITION, IDENTIFICATION/A. HPTLC for Articles of Botanical Origin (203), IDENTIFICATION/B. HPLC, COMPOSITION/Content of Ginsenosides, CONTAMINANTS/Absence of Specified Microorganisms (202), Test Procedures, Test for Absence of Salmonella Species, and Test for Absence of Escherichia coli, SPECIFIC TESTS/Articles of Botanical Origin (561), Methods of Analysis, Alcohol-Soluble Extractives, Method 2, SPECIFIC TESTS/Articles of Botanical Origin (561), Methods of Analysis, Water-Soluble Extractives, Method 2, SPECIFIC TESTS/Loss on Drying (731), SPECIFIC TESTS/Articles of Botanical Origin (561), Methods of Analysis, Total Ash, SPECIFIC TESTS/Articles of Botanical Origin (561), Methods of Analysis, Acid-Insoluble Ash, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)

Cuiying Ma

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- DEFINITION, IDENTIFICATION/A. HPTLC for Articles of Botanical Origin (203), IDENTIFICATION/B. HPLC, COMPOSITION/Content of Ginsenosides, CONTAMINANTS/Botanical Extracts (565), Preparations, General Pharmacopeial Requirements, Pesticide Residues, CONTAMINANTS/Absence of Specified Microorganisms (202), Test Procedures, Test for Absence of Salmonella Species, and Test for Absence of Escherichia coli, SPECIFIC TESTS/Articles of Botanical Origin (561), Methods of Analysis, Alcohol-Soluble Extractives, Method 2, SPECIFIC TESTS/Articles of Botanical Origin (561), Methods of Analysis, Water-Soluble Extractives, Method 2, SPECIFIC TESTS/Loss on Drying (731), SPECIFIC TESTS/Articles of Botanical Origin (561), Methods of Analysis, Total Ash, SPECIFIC TESTS/Articles of Botanical Origin (561), Methods of Analysis, Acid-Insoluble Ash, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)

Cuiying Ma

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- DEFINITION, IDENTIFICATION/A. IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Reflectance (791), SPECIFIC TESTS/Particulate Matter in Injections (788), SPECIFIC TESTS/Osmolarity and Osmolality (785), Osmolality, SPECIFIC TESTS/Endotoxins Test (71), SPECIFIC TESTS/Bacterial Endotoxins Test (85), SPECIFIC TESTS/Other Requirements, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)

Cuiying Ma

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New CRANBERRY FRUIT JUICE CONCENTRATE PF 45(6) Pg. ONLINE

Maria Monagas

DEFINITION, IDENTIFICATION/A. HPLC Profile of Organic Acids, IDENTIFICATION/B. HPLC Profile of Flavonoids, COMPOSITION/Content of Proanthocyanidins, ADULTERANTS/HPLC Profile of Phenolic Compounds, ADULTERANTS/CONTAMINANTS, ADULTERANTS/Botanical Extracts (565), Preparations, General Pharmacopeial Requirements, Pesticide Residues, ADULTERANTS/Microbial Enumeration Tests (2021), ADULTERANTS/Absence of Specified Microorganisms (2022), Test Procedures, Test for Absence of Salmonella Species and Test for Absence of Escherichia coli, SPECIFIC TESTS/Water Determination (921), Method I, Method Ia, SPECIFIC TESTS/Articles of Botanical Origin (561), Methods of Analysis, Total Ash, SPECIFIC TESTS/Botanical Extracts (565), Preparations, General Pharmacopeial Requirements, Residual Solvents, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)

New CRANBERRY FRUIT JUICE DRY EXTRACT PF 45(6) Pg. ONLINE

Maria Monagas

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New CROMOLYN SODIUM ORAL SOLUTION PF 45(4) Pg. ONLINE

Mary Koleck

New CYCLOPHOSHAMIDE CAPSULES PF 44(6) Pg. ONLINE

Jane Li

CHEMICAL INFORMATION, DEFINITION, IDENTIFICATION/A. Spectroscopic Identification Tests (197), Infrared Spectroscopy, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Residue on Ignition (281), IMPURITIES/Organic Impurities, Procedure 1, IMPURITIES/Organic Impurities, Procedure 2, SPECIFIC TESTS/Specific Rotation (781S), Procedures, Specific Rotation, SPECIFIC TESTS/Microbial Enumeration Tests (61) and Tests for Specified Microorganisms (62), SPECIFIC TESTS/Bacteriological Endotoxin Test (85), SPECIFIC TESTS/Water Determination (921), Method I, Method Ic, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)

New DECITABINE PF 45(4) Pg. ONLINE

Jane Li
**New**
DEXAMETHASONE COMPOUNDED ORAL SUSPENSION PF 46(2) Pg. ONLINE

**Definition, Assay/Procedure, Specific Tests/Ph (791), Additional Requirements/Packaging and Storage, Additional Requirements/Beyond-Use Date, Additional Requirements/Labeling, Additional Requirements/USP Reference Standards (11)

**Identification/A.** Thin-Layer Chromatography, **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)

Brian Serumaga

**Revision**
DEXAMETHASONE TABLETS PF 45(6) Pg. ONLINE

**Identification/A.** Spectroscopic Identification Tests (197), Infrared Spectroscopy:, **Identification/B.** Thin-Layer Chromatographic Identification Test (201), **Identification/B.** Assay/Procedure, Impurities/Organic Impurities, Specific Tests/Melting Range or Temperature, Class I (741); Additional Requirements/USP Reference Standards (11)

Mary Koleck

**Reversion**
DIAZEPAM PF 45(2) Pg. ONLINE

**Identification/A.** Spectroscopic Identification Tests (197), Infrared Spectroscopy:, **Identification/B.** Infrared Absorption, **Identification/B.** Assay/Procedure, Impurities/Organic Impurities, Specific Tests/Bacterial Endotoxins Test (85); Additional Requirements/Packaging and Storage;, Additional Requirements/USP Reference Standards (11)

Heather Joyce

**Reversion**
DIAZEPAM INJECTION PF 45(2) Pg. ONLINE

**Identification/A.** Spectroscopic Identification Tests (197), Infrared Spectroscopy:, **Identification/B.** Infrared Absorption, **Identification/B.** Assay/Procedure, Impurities/Organic Impurities, Specific Tests/Melting Range or Temperature, Class I (741); Additional Requirements/USP Reference Standards (11)

Heather Joyce

**Reversion**
DIAZEPAM TABLETS PF 45(2) Pg. ONLINE

**Identification/A.** Spectroscopic Identification Tests (197), Infrared Spectroscopy:, **Identification/B.** Thin-Layer Chromatographic Identification Test (201), **Identification/B.** Assay/Procedure, Impurities/Organic Impurities, Specific Tests/Bacterial Endotoxins Test (85); Additional Requirements/Packaging and Storage;, Additional Requirements/USP Reference Standards (11)

Heather Joyce

**Omission**
DIGITALIS PF 44(3) Pg. ONLINE

Entire Document

Nam-Cheol Kim

**Omission**
DIGITALIS CAPSULES PF 44(3) Pg. ONLINE

Entire Document

Nam-Cheol Kim

**Omission**
DIGITALIS TABLETS PF 44(3) Pg. ONLINE

Entire Document

Nam-Cheol Kim

**Revision**
DIMENHYDRINATE INJECTION PF 45(5) Pg. ONLINE

**Identification/A.** Spectroscopic Identification Tests (197), Infrared Spectroscopy:, **Identification/B.** Thin-Layer Chromatographic Identification Test (201), **Identification/B.** Assay/Procedure, Impurities/Organic Impurities, Specific Tests/Readily Carbonizable Substances Test (271), Specific Tests/Clarity and Color of Solution, Additional Requirements/Packaging and Storage, Additional Requirements/USP Reference Standards (11)

Heather Joyce

**Revision**
DOPAMINE HYDROCHLORIDE PF 46(2) Pg. ONLINE

**Identification/A.** Spectroscopic Identification Tests (197), Infrared Spectroscopy:, **Identification/B.** Spectroscopic Identification Tests (197), Ultraviolet-Visible Spectroscopy: 197U, **Identification/B.** Assay/Procedure, Impurities/Organic Impurities, Specific Tests/Radioactivity (621), Specific Tests/Clarity and Color of Solution, Additional Requirements/Packaging and Storage, Additional Requirements/USP Reference Standards (11)

Tsion Bililign

**Revision**
DOXEPIN HYDROCHLORIDE ORAL SOLUTION PF 45(5) Pg. ONLINE

**Chemical Information, Definition, Identification/A.** Spectroscopic Identification Tests (197), Infrared Spectroscopy:, **Identification/B.** Assay/Procedure, Impurities/Limit of Platinum, Impurities/Organic Impurities, Impurities/Limit of Heptamethyl Trisiloxane, Additional Requirements/Packaging and Storage;, Additional Requirements/USP Reference Standards (11)

Heather Joyce

**New**
DROMETRIZOLE TRISILOXANE PF 45(2) Pg. ONLINE

**Identification/A.** Spectroscopic Identification Tests (197), Infrared Spectroscopy:, **Identification/B.** Assay/Procedure, Impurities/Limit of Platinum, Impurities/Organic Impurities, Impurities/Limit of Heptamethyl Trisiloxane, Additional Requirements/Packaging and Storage;, Additional Requirements/USP Reference Standards (11)

Sujatha Ramakrishna

**Revision**
ENALAPRIL MALEATE AND HYDROCHLOROTHIAZIDE TABLETS PF 46(2) Pg. ONLINE

**Chemical Information, Definition, Identification/A.** Spectroscopic Identification Tests (197), Infrared Spectroscopy:, **Identification/B.** Assay/Procedure, Impurities/Limit of Platinum, Impurities/Organic Impurities, Impurities/Limit of Heptamethyl Trisiloxane, Additional Requirements/Packaging and Storage;, Additional Requirements/USP Reference Standards (11)

Tsion Bililign
**Revision EPINEPHRINE INJECTION PF 44(6) Pg. ONLINE**

- **Gerald Hsu**

**New EPTIFIBATIDE PF 46(2) Pg. ONLINE**

- **Elena Curti**
- **Chemical Information, Definition, Identification/A. HPLC, Identification/B. Mass Spectrometry (736), Assay/Procedure, Impurities/Eptifibatide-Related Impurities, Impurities/Trifluoroacetic Acid (TFA) in Peptides (503.1), Other Components/Acetic Acid in Peptides (503), Method 2, Specific Tests/Bacterial Endotoxins Test (85), Specific Tests/Microbial Enumeration Tests (61) and Tests for Specified Microorganisms (62), Specific Tests/Water Determination (921), Method I, Method Ic, Additional Requirements/Packaging and Storage, Additional Requirements/Labeling, Additional Requirements/USP Reference Standards (11)**

**New ERLOTINIB TABLETS PF 46(2) Pg. ONLINE**

- **Jane Li**

**New ERLOTINIB HYDROCHLORIDE PF 46(2) Pg. ONLINE**

- **Jane Li**

**Revision ESTRADIOL VAGINAL INSERTS PF 45(3) Pg. ONLINE**

- **Gerald Hsu**
- **Identification/A. Thin-Layer Chromatographic Identification Test (201); Assay/Procedure, Performance Tests/Dissolution (711), Impurities/Organic Impurities, Additional Requirements/USP Reference Standards (11)**

**Revision ETHACRYNATE SODIUM FOR INJECTION PF 45(4) Pg. ONLINE**

- **Tsion Bililign**

**Revision ETHACRYNIC ACID PF 45(4) Pg. ONLINE**

- **Tsion Bililign**
New ETOPOSIDE PHOSPHATE PF 45(2) Pg. ONLINE

CHEMICAL INFORMATION, DEFINITION, IDENTIFICATION/A. Spectroscopic Identification Tests (197), Infrared Spectroscopy.; IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Optical Rotation (781S), Procedures, Specific Rotation, SPECIFIC TESTS/Water Determination (921), Method I.; SPECIFIC TESTS/Bacterial Endotoxins Test (85); ADDITIONAL REQUIREMENTS/Packaging and Storage.; ADDITIONAL REQUIREMENTS/Labeling.; ADDITIONAL REQUIREMENTS/USP Reference Standards (11)

Jane Li

New ETOPOSIDE PHOSPHATE FOR INJECTION PF 45(2) Pg. ONLINE

Reference Standards (11)

Jane Li

Revision EXENATIDE PF 45(3) Pg. ONLINE

Requirements/Labeling:

Manoj Metta

Revision FENOPROFEN CALCIUM PF 45(4) Pg. ONLINE

ASSAY/Procedure, OTHER COMPONENTS/Content of Calcium, IMPURITIES/Organic Impurities

Wei Yang

Revision FENOPROFEN CALCIUM CAPSULES PF 45(4) Pg. ONLINE

ASSAY/Procedure, PERFORMANCE TESTS/Dissolution (711), IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage

Wei Yang

Revision FENOPROFEN CALCIUM TABLETS PF 45(4) Pg. ONLINE

ASSAY/Procedure, PERFORMANCE TESTS/Dissolution (711), IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage

Wei Yang

New FEXOFENADINE HYDROCHLORIDE ORALLY DISINTEGRATING TABLETS PF 44(6) Pg. ONLINE

ASSAY/Procedure, SPECIFIC TESTS/pH (791), ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Beyond-Use Date, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)/USP Fexofenadine Related Compound C RS

Richard Nguyen

New FLUDROCORTISONE ACETATE COMPOUNDED ORAL SUSPENSION PF 46(2) Pg. ONLINE

ASSAY/Procedure, SPECIFIC TESTS/pH (791), ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Beyond-Use Date, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)

Brian Serumaga

New FLUDROCORTISONE ACETATE COMPOUNDED ORAL SUSPENSION, VETERINARY PF 46(2) Pg. ONLINE

ASSAY/Procedure, SPECIFIC TESTS/pH (791), ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Beyond-Use Date, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)

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Tsion Billign

Revised

Omission ISOSORBIDE ORAL SOLUTION PF 45(4) Pg. ONLINE

Chemical Information, Definition, Identification/A. Infrared Absorption (197K) or (197A), Identification/B. Ultraviolet Absorption (197B), Assay/Procedure, Impurities/Ordinary Impurities (466), Impurities/Organic Impurities

Hillary Cai

Revised

Revision LEVORPHANOL TARTRATE PF 45(5) Pg. ONLINE


Richard Nguyen

Revised

Revision LIDOCAINE TOPICAL AEROSOL PF 46(2) Pg. ONLINE

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Richard Nguyen

Revision LIDOCAINE AND PRILOCAINE CREAM PF 45(3) Pg. ONLINE

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Richard Nguyen

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Shankari Shivaprasad

Revision LINDANE SHAMPOO PF 45(5) Pg. ONLINE


Shankari Shivaprasad

Revision MAGNESIUM SULFATE PF 45(2) Pg. ONLINE


Michael Chang

Revision MALTOL PF 46(2) Pg. ONLINE


Peng Zhang

Revised

New MEMANTINE HYDROCHLORIDE EXTENDED RELEASE CAPSULES PF 44(6) Pg. ONLINE


Mary Koleck

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Donald Min

Revision MOLINDONE HYDROCHLORIDE PF 45(6) Pg. ONLINE


Mary Koleck
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Nam-Cheol Kim

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Christine Hiemer

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Sujatha Ramakrishna

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Sujatha Ramakrishna

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Andrea Carney

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Andrea Carney

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Andrea Carney

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Michael Chang

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Andrea Carney