Compendial Approvals for USPNF 2022 ISSUE 1

Date: Fri Jul 09 14:21:59 EDT 2021

Category	Monograph Title	Monograph Section D/Donepezil Hydrochloride, D/Doxylamine Succinate, C/Carbamazepine, C/Cisatracurium Besylate, D/Doxepin	Scientific Liaison
Revision	DESCRIPTION AND SOLUBILITY PF 46(6) Pg. ONLINE <162> DIPHTHERIA ANTITOXIN POTENCY TESTING FOR HUMAN	Hydrochloride	Devendra Pratap Singh
Revision	IMMUNE GLOBULINS PF 46(6) Pg. ONLINE	Revision	Li Jing
Revision	<401> FATS AND FIXED OILS PF 46(6) Pg. ONLINE	Revision	Peng Zhang
New	<426> HISTAMINE TEST METHOD PF 46(4) Pg. ONLINE	New	Ying Han
Revision	<591> ZINC DETERMINATION PF 46(6) Pg. ONLINE <000> PLASTIC COMPONENTS AND SYSTEMS USED TO MANUFACTURE PHARMACEUTICAL DRUG PRODUCTS AND BIOPHARMACEUTICAL DRUG SUBSTANCES AND PRODUCTS PF	Revision	Kahkashan Zaidi
Revision	46(5) Pg. ONLINE	Revision	Desmond Hunt
Revision	<711> DISSOLUTION PF 46(6) Pg. ONLINE	Revision	Margareth Marques
Revision	<921> WATER DETERMINATION PF 46(6) Pg. ONLINE <1001> IN VITRO RELEASE TEST METHODS FOR PARENTERAL	Revision	Lucy Botros
New	DRUG PREPARATIONS PF 46(3) Pg. ONLINE <1220> ANALYTICAL PROCEDURE LIFE CYCLE PF 46(5) Pg.	New	Desmond Hunt
New	ONLINE <1005> CHAKACTEKIZATION AND QUALIFICATION OF PLASTIC COMPONENTS AND SYSTEMS USED TO MANUFACTURE PHARMACEUTICAL DRUG PRODUCTS AND BIOPHARMACEUTICAL	New	Horacio Pappa
Revision	DRUG SUBSTANCES AND PRODUCTS PF 46(5) Pg. ONLINE	Revision	Desmond Hunt
Revision	<1790> VISUAL INSPECTION OF INJECTIONS PF 46(6) Pg. ONLINE <2740> MANUFACTURING PRACTICES FOR DIETARY INGREDIENTS		Desmond Hunt
New	PF 46(6) Pg. ONLINE	New	Binu Koshy
Revision	ACETAZOLAMIDE PF 46(5) Pg. ONLINE ACETYLCYSTEINE AND ISOPROTERENOL HYDROCHLORIDE	IMPURITIES/Selenium (291)	Devarshi Narendra Thaker
Omission	INHALATION SOLUTION PF 46(5) Pg. ONLINE	Entire document IDENTIFICATION/A. Spectroscopic Identification Tests (197), Infrared Spectroscopy, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Procedure 1: Limit of Guanine, IMPURITIES/Ordinary Impurities (466), IMPURITIES/Organic Impurities, ADDITIONAL	Hillary Cai
Revision	ACYCLOVIR PF 45(4) Pg. ONLINE	REQUIREMENTS/USP Reference Standards (11)	Shankari Shivaprasad

New	ACYCLOVIR INJECTION PF 46(4) Pg. ONLINE	DEFINITION, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Bacterial Endotoxins Test (85), SPECIFIC TESTS/Particulate Matter in Injections (788), SPECIFIC TESTS/Sterility Tests (71), SPECIFIC TESTS/pH (791), SPECIFIC TESTS/Other Requirements, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/PS Reference Standards (11)	Shankari Shivaprasad
Revision	ALPHA-CHYMOTRYPSIN PF 46(6) Pg. ONLINE	Alpha-Chymotrypsin,	Margareth Marques
Revision	Alpha-(2-(methylamino)ethyl)benzyl alcohol PF 46(5) Pg. ONLINE	Alpha-(2-(methylamino)ethyl)benzyl Alcohol, IDENTIFICATION/A.Spectroscopic Identification Tests (197), Infrared Spectroscopy, IMPURITIES/Limit of Chromium, IMPURITIES/Limit of Rhodium, IMPURITIES/Limit of Foreign Prostaglandins, Test 1, IMPURITIES/Limit of Foreign Prostaglandins,	Heather Joyce
Revision	ALPROSTADIL PF 46(5) Pg. ONLINE	Test 2	Mary Koleck
Revision	AMERICAN GINSENG ROOT AND RHIZOME PF 45(4) Pg. ONLINE	Origin (203), IDENTIFICATION/B. HPLC, COMPOSITION/Content of Ginsenosides, CONTAMINANTS/Absence of Specified Microorganisms (2022), 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/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Cuiying Ma
Revision	AMERICAN GINSENG ROOT AND RHIZOME DRY EXTRACT PF 45(4) Pg. ONLINE	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 (2022), Test Procedures, Test for Absence of Salmonella Species, and Test for Absence of Escherichia coli, SPECIFIC TESTS/Botanical Extracts (565), Preparations, General Pharmacopeial Requirements, Residual Solvents, SPECIFIC TESTS/Alcohol Determination, Method II(611), ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Cuiying Ma

Origin (203), IDENTIFICATION/B. HPLC, COMPOSITION/Content of Ginsenosides, CONTAMINANTS/Absence of Specified Microorganisms (2022), Test Procedures, Test for Absence of Salmonella Species, and Test for Absence of Escherichia coli, SPECIFIC TESTS/Botanical Characteristics, SPECIFIC TESTS/Articles of Botanical Origin, Foreign Organic Matter(561), 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

DEFINITION, IDENTIFICATION/A. HPTLC for Articles of Botanical Origin (203), IDENTIFICATION/B. LC, STRENGTH/Content of Ginsenosides, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL

REQUIREMENTS/USP Reference Standards (11)

Reference Standards (11)

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

Revision ONLINE

Revision AMERICAN GINSENG CAPSULES PF 46(6) Pg. ONLINE

AMERICAN GINSENG TABLETS PF 46(6) Pg. ONLINE Revision

Omission APROTININ PF 46(5) Pg. ONLINE

Omission APROTININ INJECTION PF 46(5) Pg. ONLINE

New

ARSENAZO III DISODIUM SALT PF 46(6) Pg. ONLINE

Revision ASIAN GINSENG TABLETS PF 46(6) Pg. ONLINE Cuiying Ma

Natalia Davydova

Natalia Davydova

DEFINITION, IDENTIFICATION/A. HPTLC for Articles of Botanical Origin (203), IDENTIFICATION/B. LC, STRENGTH/Content of Ginsenosides, CONTAMINANTS/Microbial Enumeration Tests (2021), CONTAMINANTS/Absence of Specified Microorganisms (2022), Test Procedures, Test for Absence of Salmonella Species and Test for Absence of Escherichia coli, ADDITIONAL REQUIREMENTS/Labeling,

ADDITIONAL REQUIREMENTS/USP Reference Standards (11)

Entire document Li Jing

Entire document Li Jing

Arsenazo III Disodium Salt Margareth Margues

DEFINITION, IDENTIFICATION/A. HPTLC for Articles of Botanical Origin (203), IDENTIFICATION/B. LC, STRENGTH/Content of Ginsenosides, CONTAMINANTS/Microbial Enumeration Tests (2021), CONTAMINANTS/Absence of Specified Microorganisms (2022), Test Procedures, Test for Absence of Salmonella Species and Test for Absence of Escherichia coli, ADDITIONAL REOUIREMENTS/Labeling,

ADDITIONAL REQUIREMENTS/USP Reference Standards (11)

Natalia Davydova

IDENTIFICATION/B. HPLC, STRENGTH/Content of Total	
Astaxanthin, PERFORMANCE TESTS/Weight Variation (2091),	
PERFORMANCE TESTS/Disintegration and Dissolution (2040),	
Rupture Test for Soft-Shell Capsules, CONTAMINANTS/Microbial	
Enumeration Tests (2021), CONTAMINANTS/Absence of Specified	
Microorganisms (2022), Test Procedures, Test for Absence of	
Salmonella Species and Test for Absence of Escherichia coli,	
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REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP	_
Reference Standards (11), FOOTNOTES	Binu Koshy
CHEMICAL INFORMATION, IDENTIFICATION D. UILIAVIOIEL	BITIU KOSTIY
Absorption (197U), ASSAY/Procedure, IMPURITIES/Chloride and	
Sulfate (221), Chloride, IMPURITIES/Organic Impurities, SPECIFIC	
TESTS/Melting Range or Temperature, Class I(741), ADDITIONAL	
REQUIREMENTS/Packaging and Storage, ADDITIONAL	
REQUIREMENTS/USP Reference Standards (11)	Vanyin Vang
IDENTIFICATION/A. Spectroscopic Identification Tests (197),	Yanyin Yang
Infrared Spectroscopy: 197K, IDENTIFICATION/B.,	
ASSAY/Procedure, PERFORMANCE TESTS/Dissolution (711),	
IMPURITIES/Organic Impurities, ADDITIONAL	
REQUIREMENTS/Packaging and Storage, ADDITIONAL	
REQUIREMENTS/USP Reference Standards (11)	Vanyin Vang
DELIMITATION, IDENTIFICATION A. PROSCOPIC INCHINICATION,	Yanyin Yang
IDENTIFICATION/B. Nucleic Acid-Based Identification,	
ASSAY/Enumeration, SPECIFIC TESTS/Loss on Drying (731),	
CONTAMINANTS/Probiotic Tests (64), Contaminants, Contaminant	
Microorganisms, CONTAMINANTS/Probiotic Tests (64),	
Contaminants, Specified Microorganisms, ADDITIONAL	
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REQUIREMENTS/Labeling, FOOTNOTES	Binu Koshy
IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/PROCEdure,	BITIU KOSTIY
IMPURITIES/Organic Impurities, IMPURITIES/Limit of Nitrites,	
SPECIFIC TESTS/Oxidizing Substances, ADDITIONAL	
REQUIREMENTS/USP Reference Standards (11)	Suiatha Damakrichna
REQUIREMENTS/OSF Reference Standards (11)	Sujatha Ramakrishna
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Infrared Spectroscopy, IDENTIFICATION/B., ASSAY/Procedure,	
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Wei Yang

Michael Chang

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New

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ONLINE

ASTAXANTHIN ESTERS CAPSULES PF 46(6) Pg. ONLINE

ATENOLOL PF 45(6) Pg. ONLINE

ATENOLOL TABLETS PF 45(6) Pg. ONLINE

BACILLUS CLAUSII PF 46(5) Pg. ONLINE

BUTORPHANOL TARTRATE PF 46(2) Pg. ONLINE

CALCIUM ACETATE CAPSULES PF 46(5) Pg. ONLINE

BENZETHONIUM CHLORIDE TOPICAL SOLUTION PF 46(5) Pg.

Revision	CARBOMER 934 PF 45(5) Pg. ONLINE	(197), Infrared Spectroscopy: 197K or 197A., IDENTIFICATION/B., IDENTIFICATION/C., ASSAY/Carboxylic Acid Content, IMPURITIES/Limit of Benzene, IMPURITIES/Limit of Acrylic Acid, SPECIFIC TESTS/Viscosity—Rotational Methods (912), ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards (11) DETINITION, IDENTIFICATION/A. SPECIFIC TESTS/VISCOSITY. 197A or 197K., IDENTIFICATION/B., IDENTIFICATION/C., ASSAY/Carboxylic Acid Content, IMPURITIES/Limit of Benzene, IMPURITIES/Limit of Acrylic Acid, SPECIFIC TESTS/Viscosity—Rotationage, ADDITIONAL	Galina Holloway
Revision	CARBOMER 934P PF 45(5) Pg. ONLINE	REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards (11) DETERMINED TO THE LEAST ONLY AS SPECIOSCOPIC IDENTIFICATION/B., IDENTIFICATION/C., ASSAY/Carboxylic Acid Content, IMPURITIES/Limit of Benzene, IMPURITIES/Limit of Acrylic Acid, SPECIFIC TESTS/Viscosity—Rotational Methods (912), ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL	Galina Holloway
Revision	CARBOMER 940 PF 45(5) Pg. ONLINE	REQUIREMENTS/USP Reference Standards (11) DETINITION, IDENTIFICATION, A. SPECIOSCOPIC IDENTIFICATION/B., IDENTIFICATION/C., ASSAY/Carboxylic Acid Content, IMPURITIES/Limit of Benzene, IMPURITIES/Limit of Acrylic Acid, SPECIFIC TESTS/Viscosity—Rotational Methods (912), ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL	Galina Holloway
Revision	CARBOMER 941 PF 45(5) Pg. ONLINE	REQUIREMENTS/USP Reference Standards (11) DETINITION, IDENTIFICATION, A. Spectroscopic Identification rests (197), Infrared Spectroscopy: 197K or 197A., IDENTIFICATION/B., IDENTIFICATION/C., ASSAY/Carboxylic Acid Content, IMPURITIES/Limit of Benzene, IMPURITIES/Limit of Acrylic Acid, SPECIFIC TESTS/Viscosity—Rotational Methods (912), ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL	Galina Holloway
Revision	CARBOMER 1342 PF 45(5) Pg. ONLINE	REQUIREMENTS/USP Reference Standards (11) IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic	Galina Holloway
Revision	CEFAZOLIN IN DEXTROSE INJECTION PF 46(5) Pg. ONLINE	Impurities, SPECIFIC TESTS/Bacterial Endotoxins Test (85) CHEMICAL INFORMATION, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Limit of p-Chloroaniline, ADDITIONAL	Slavica Shane
Revision	CHLORHEXIDINE ACETATE PF 46(6) Pg. ONLINE	REQUIREMENTS/USP Reference Standards (11) IDENTIFICATION/C., ASSAY/Procedure, IMPURITIES/LIMIT OF p- Chloroaniline, SPECIFIC TESTS/Microbial Enumeration Tests (61)	Jane Li
Revision	CHLORHEXIDINE ACETATE TOPICAL SOLUTION PF 46(6) Pg. ONLINE	and Tests for Specified Microorganisms (62), ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Jane Li

		IDENTIFICATION/B. Procedure, IDENTIFICATION/B., IDENTIFICATION/C. Thin-Layer Chromatographic Identification Test (201), ASSAY/Procedure, OTHER COMPONENTS/Content of Alcohol,	
Revision	CHLORHEXIDINE GLUCONATE ORAL RINSE PF 46(6) Pg. ONLINE	IMPURITIES/Limit of p-Chloroaniline, ADDITIONAL REQUIREMENTS/USP Reference Standards (11) CHEMICAL INFORMATION, IDENTIFICATION/C., ASSAY/Procedure,	Jane Li
Revision	CHLORHEXIDINE GLUCONATE SOLUTION PF 46(6) Pg. ONLINE	IMPURITIES/Limit of p-Chloroaniline, ADDITIONAL REQUIREMENTS/USP Reference Standards (11) IDENTIFICATION/C., ASSAY/Procedure, IMPURITIES/LIMIT OF p-	Jane Li
Revision	CHLORHEXIDINE GLUCONATE TOPICAL SOLUTION PF 46(6) Pg. ONLINE	Chloroaniline, SPECIFIC TESTS/Microbial Enumeration Tests (61) and Tests for Specified Microorganisms (62), ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Jane Li
Revision	CHLORHEXIDINE HYDROCHLORIDE PF 46(6) Pg. ONLINE	CHEMICAL INFORMATION, IDENTIFICATION/C., ASSAY/Procedure, IMPURITIES/Limit of p-Chloroaniline, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Jane Li
Revision	CHLOROPHYLLIN COPPER COMPLEX SODIUM PF 46(6) Pg. ONLINE	IMPURITIES/Arsenic (211), Method II, IMPURITIES/Lead (251) Articles of Botanical Origin (203), IDENTIFICATION/B. HPLC, COMPOSITION/Content of Caffeoylquinic Acids and Flavone Glycosides, CONTAMINANTS/Articles of Botanical Origin (561), Limits of Elemental Impurities:, CONTAMINANTS/Articles of Botanical Origin (561), Pesticide Residue Analysis:, CONTAMINANTS/Articles of Botanical Origin (561), Test for Aflatoxins:, CONTAMINANTS/Microbial Enumeration Tests (2021):, CONTAMINANTS/Absence of Specified Microorganisms (2022), Test Procedures, Test for Absence of Salmonella Species and Test for Absence of Escherichia coli:, SPECIFIC TESTS/Botanical Characteristics, SPECIFIC TESTS/Articles of Botanical Origin (561), Methods of Analysis, Foreign Organic Matter:, SPECIFIC TESTS/Articles of Botanical Origin (561), Methods of Analysis, Alcohol-Soluble Extractives, Method 1:, SPECIFIC TESTS/Articles of Botanical Origin (561), Methods of Analysis, Water-Soluble Extractives, Method 2:, 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:, SPECIFIC TESTS/Loss on Drying (731), ADDITIONAL REQUIREMENTS/Packaging and Storage:, ADDITIONAL	Jane Li
Revision	CHRYSANTHEMUM FLOWER PF 45(1) Pg. ONLINE	REQUIREMENTS/Labeling:, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Cuiying Ma

DEFINITION/Untitled Section, IDENTIFICATION/A. HPTLC for Articles of Botanical Origin (203), IDENTIFICATION/B. HPLC, COMPOSITION/Content of Caffeovlquinic Acids and Flavone Glycosides, CONTAMINANTS/Botanical Extracts (565), Preparations, General Pharmacopeial Requirements, Pesticide Residues:, CONTAMINANTS/Articles of Botanical Origin (561), Test for Aflatoxins:, CONTAMINANTS/Microbial Enumeration Tests (2021):, CONTAMINANTS/Absence of Specified Microorganisms (2022), Test Procedures, Test for Absence of Salmonella Species and Test for Absence of Escherichia coli:, SPECIFIC TESTS/Loss on Drying (731), 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)

DEFINITION/Untitled Section, IDENTIFICATION/A, HPTLC for Articles of Botanical Origin (203), IDENTIFICATION/B. HPLC, COMPOSITION/Content of Caffeoylquinic Acids and Flavone Glycosides, CONTAMINANTS/Articles of Botanical Origin (561), Limits of Elemental Impurities:, CONTAMINANTS/Articles of Botanical Origin (561), Pesticide Residue Analysis:, CONTAMINANTS/Articles of Botanical Origin (561), Test for

Aflatoxins:, CONTAMINANTS/Microbial Enumeration Tests (2021):, CONTAMINANTS/Absence of Specified Microorganisms (2022), Test Procedures, Test for Absence of Salmonella Species and Test for Absence of Escherichia coli:, SPECIFIC TESTS/Botanical

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TESTS/Articles of Botanical Origin (561), Methods of Analysis, Total Ash:, SPECIFIC TESTS/Articles of Botanical Origin (561), Methods of Analysis, Acid-Insoluble Ash:, SPECIFIC TESTS/Loss on Drying (731), ADDITIONAL REQUIREMENTS/Packaging and Storage:,

ADDITIONAL REQUIREMENTS/Labeling:, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)

ASSAY/Procedure, IMPURITIES/Related Compounds, ADDITIONAL

REQUIREMENTS/USP Reference Standards (11)

Copper-EDTA Complex Solution

IDENTIFICATION/A., IMPURITIES/Limit of Antimony,

IMPURITIES/Organic Impurities

CHEMICAL INFORMATION, IMPURITIES/Organic Impurities,

2,5-Dimethylphenol,

Cuiying Ma

IMPURITIES/Selenium (291)

Cuiving Ma

Binu Koshy

Margareth Marques

Mary Koleck

Devarshi Narendra Thaker

Margareth Marques

Revision CHRYSANTHEMUM FLOWER POWDER PF 45(1) Pg. ONLINE Revision CITRULLINE PF 46(4) Pg. ONLINE COPPER-EDTA COMPLEX SOLUTION PF 45(2) Pg. ONLINE New Revision DESFLURANE PF 46(6) Pg. ONLINE DICHLORPHENAMIDE PF 46(5) Pg. ONLINE Revision

2,5-Dimethylphenol PF 46(6) Pg. ONLINE

CHRYSANTHEMUM FLOWER DRY EXTRACT PF 45(1) Pg. ONLINE

Revision

Revision

Revision Revision Omission	DOXYCYCLINE HYCLATE PF 46(3) Pg. ONLINE DUTASTERIDE PF 46(5) Pg. ONLINE ENFLURANE PF 46(5) Pg. ONLINE	Identification Tests (197), Infrared Spectroscopy, IDENTIFICATION/B., IDENTIFICATION/C. Identification Tests—General (191), Chemical Identification Tests, Chloride, ASSAY/Procedure, IMPURITIES/Organic Impurities, IMPURITIES/Content of Ethanol, SPECIFIC TESTS/Sterility Tests (71), ADDITIONAL REQUIREMENTS/USP Reference Standards (11) ASSAY/Procedure, IMPURITIES/Limit of Platinum, IMPURITIES/Organic Impurities, Procedure 2 Entire document	Praveen Pabba Mary Koleck Gerald Hsu
		CHEMICAL INFORMATION, DEFINITION, IDENTIFICATION/A. Spectroscopic Identification Tests (197), Infrared Spectroscopy,	
		IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Residue on Ignition (281), IMPURITIES/Limit of Alcohol, IMPURITIES/Organic Impurities, IMPURITIES/Limit of Sirolimus, SPECIFIC TESTS/Water Determination (921), Method I, SPECIFIC TESTS/Optical Rotation (781S), Procedures, Specific Rotation, SPECIFIC TESTS/Microbial Enumeration Tests (61) and Tests for Specified Organisms (62), ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP	
New	EVEROLIMUS PF 46(6) Pg. ONLINE	Reference Standards (11) DEFINITION, IDENTIFICATION/B., ASSAT/PROCEdure, OTHER COMPONENTS/Fluorouracil, IMPURITIES/Organic Impurities, IMPURITIES/Residue on Ignition (281), IMPURITIES/Limit of Fluoride Ion, ADDITIONAL REQUIREMENTS/USP Reference	Praveen Pabba
Revision	FLUCYTOSINE PF 46(5) Pg. ONLINE	Standards (11) IDENTIFICATION/A. Spectroscopic Identification Tests (197), Ultraviolet Absorption, IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution (711), IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage,	Shankari Shivaprasad
Revision	FLUCYTOSINE CAPSULES PF 46(5) Pg. ONLINE	ADDITIONAL REQUIREMENTS/USP Reference Standards (11) IMPURITIES/LIMIT OF FORMOTEROI RElated Compound I, ADDITIONAL REQUIREMENTS/USP Reference Standards (11),	Shankari Shivaprasad
Revision	FORMOTEROL FUMARATE PF 46(4) Pg. ONLINE	IMPURITIES/Organic Impurities	Gerald Hsu
Revision	FRUCTOSE PF 46(5) Pg. ONLINE	IMPURITIES/Arsenic (211), Method II	Gerald Hsu
		Ultraviolet-Visible Spectroscopy: 197U, IDENTIFICATION/A. Spectroscopic Identification Tests (197), Ultraviolet-Visible Spectroscopy: 197U, IDENTIFICATION/A., ASSAY/Procedure, PERFORMANCE TESTS/Minimum fill (755), IMPURITIES/Limit of Furosemide Related Compound B, SPECIFIC TESTS/Microbial Enumeration Tests (61) and Tests for Specified Microorganisms (62), ADDITIONAL REQUIREMENTS/Packaging and Storage,	
Revision	FUROSEMIDE ORAL SOLUTION PF 46(4) Pg. ONLINE	ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Tamara Bourne
Revision	GALANTAMINE HYDROBROMIDE PF 46(5) Pg. ONLINE	IMPURITIES/Limit of Palladium, IMPURITIES/Limit of the 4R,6S,8R Isomer	Heather Joyce

New	GADOLINIUM CHLORIDE HEXAHYDRATE PF 46(6) Pg. ONLINE	Gadolinium Chloride Hexahydrate DELINITION, IDENTIFICATION/A: Spectroscopic Identification Tests (197), Infrared Spectroscopy, IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution (711), PERFORMANCE TESTS/Uniformity of dosage units (905), IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL	Margareth Marques
New	GEMIFLOXACIN TABLETS PF 46(6) Pg. ONLINE	REQUIREMENTS/USP Reference standards (11)	Shankari Shivaprasad
New	GLYCINE ANHYDRIDE PF 46(6) Pg. ONLINE	Glycine Anhydride IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, SPECIFIC TESTS/pH (791), ADDITIONAL REQUIREMENTS/Packaging	Margareth Marques
Revision	GUAIFENESIN ORAL SOLUTION PF 46(5) Pg. ONLINE	and Storage	Edith Chang
Revision	HEXYLRESORCINOL PF 46(5) Pg. ONLINE	IMPURITIES/Mercury IDENTIFICATION/B. Spectroscopic Identification Tests (197), Ultraviolet-Visible Spectroscopy, IDENTIFICATION/B. Spectroscopic Identification Tests (197), Ultraviolet-Visible Spectroscopy, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Selenium	Sujatha Ramakrishna
Revision	HYDROCHLOROTHIAZIDE PF 46(4) Pg. ONLINE	(291), IMPURITIES/Organic Impurities IDENTIFICATION/C., IMPURITIES/Organic Impurities, SPECIFIC	Tamara Bourne
Revision	HYDROXYZINE HYDROCHLORIDE PF 46(6) Pg. ONLINE	TESTS/Water Determination (921), Method I	Heather Joyce
New	0.005 N IODINE VS PF 46(6) Pg. ONLINE	0.005 N Iodine VS	Margareth Marques
Revision	ISOFLURANE PF 46(6) Pg. ONLINE	IMPURITIES/Limit of Fluoride, IMPURITIES/Organic Impurities	Gerald Hsu
Omission	ISOSORBIDE DINITRATE CHEWABLE TABLETS PF 46(5) Pg. ONLINE ISOSORBIDE DINITRATE SUBLINGUAL TABLETS PF 46(5) Pg.	Entire document	Tamara Bourne
Omission	ONLINE	Entire document	Tamara Bourne
New	L124 PF 46(5) Pg. ONLINE	L124	Margareth Marques
Revision	LAMIVUDINE AND ZIDOVUDINE TABLETS PF 46(5) Pg. ONLINE	IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution (711)	Shankari Shivaprasad
Revision	LAMOTRIGINE EXTENDED-RELEASE TABLETS PF 46(6) Pg. ONLINE	PERFORMANCE TESTS/Dissolution (711) DETINITION, IDENTIFICATION/N. Spectroscopic Identification Tests (197), Infrared Spectroscopy, IDENTIFICATION/B., IDENTIFICATION/C., ASSAY/Procedure, PERFORMANCE TESTS/Topical Aerosols (603), IMPURITIES/Organic Impurities, SPECIFIC TESTS/Microbial Enumeration Tests (61) and Tests for Specified Microorganisms (62), ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL	Ren-Hwa Yeh
Revision	LIDOCAINE TOPICAL AEROSOL PF 46(2) Pg. ONLINE	REQUIREMENTS/USP Reference Standards (11) DEFINITION/ORIGINED Section, IDENTIFICATION/A. IDENTIFICATION/A. IDENTIFICATION/A. IDENTIFICATION/A. IDENTIFICATION/A. IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Iron (241), ADDITIONAL REQUIREMENTS/Packaging and Storage:,	Richard Nguyen
Revision	MAGNESIUM SULFATE PF 45(2) Pg. ONLINE	ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Michael Chang

Revision	MALATHION PF 46(5) Pg. ONLINE	CHEMICAL INFORMATION, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Limit of Isomalathion, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards $\langle 11 \rangle$	Shankari Shivaprasad
Revision	MALTOL PF 46(2) Pg. ONLINE	CHEMICAL INFORMATION, DEFINITION, IDENTIFICATION/B. Chromatographic Identity, ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Peng Zhang
Revision	MECLOFENAMATE SODIUM CAPSULES PF 46(4) Pg. ONLINE	IDENTIFICATION/Thin-Layer Chromatographic Identification Test (201), IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution (711), IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage	Hillary Cai
Omission	METHENAMINE TABLETS PF 46(5) Pg. ONLINE	Entire document	Shankari Shivaprasad
Revision	METHIMAZOLE PF 46(5) Pg. ONLINE	IMPURITIES/Selenium (291), IMPURITIES/Organic Impurities	Behnaz Almasi
Omission	METHOXYFLURANE PF 46(4) Pg. ONLINE METHYLENE BLUE COMPOUNDED INJECTION, VETERINARY PF	Entire document	Gerald Hsu
Revision	46(6) Pg. ONLINE	DEFINITION, ASSAY/Procedure	Brian Serumaga
New	MORPHOLINOETHANESULFONIC ACID PF 46(6) Pg. ONLINE NAPROXEN COMPOUNDED ORAL SUSPENSION PF 46(4) Pg.	Morpholinoethanesulfonic Acid	Margareth Marques
Revision	ONLINE	ASSAY/Procedure	Brian Serumaga
New	NDBA-D18 PF 46(6) Pg. ONLINE	NDBA-d18	Margareth Marques
New	NDEA-D10 PF 46(6) Pg. ONLINE	NDEA-d10	Margareth Marques
New	NDMA C13-D6 PF 46(6) Pg. ONLINE	NDMA c13-d6	Margareth Marques
Omission	NITROFURAZONE TOPICAL SOLUTION PF 46(5) Pg. ONLINE	Entire document	Shankari Shivaprasad
New	NMBA-D3 PF 46(6) Pg. ONLINE	NMBA-d3 ASSAY/Content of EPAee, DHAee, and Total Omega-3-Acid Ethyl	Margareth Marques
Revision	OMEGA-3-ACIDS ETHYL ESTERS PF 46(6) Pg. ONLINE	Esters	Fatkhulla Tadjimukhamedov
Revision	0.1 N Oxalic Acid VS PF 46(6) Pg. ONLINE	0.1 N Oxalic Acid VS CHEMICAL INFORMATION, IMPURITIES/Arsenic (211), Procedures,	Margareth Marques
Revision	OXAPROZIN PF 46(5) Pg. ONLINE	Method II IDENTIFICATION/A. Spectroscopic Identification Tests (197), Infrared Spectroscopy:, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Residue on Ignition (281):, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Loss on Drying (731), SPECIFIC TESTS/pH (791), ADDITIONAL REQUIREMENTS/Packaging and Storage:, ADDITIONAL REQUIREMENTS/USP Reference Standards	Hillary Cai
New	OXICONAZOLE NITRATE PF 45(2) Pg. ONLINE	(11)	Shankari Shivaprasad
Omission	PAPAVERINE HYDROCHLORIDE TABLETS PF 46(5) Pg. ONLINE	Entire document	Donald Min
Omission	PENICILLIN G PROCAINE, DIHYDROSTREPTOMYCIN SULFATE, AND PREDNISOLONE INJECTABLE SUSPENSION PF 46(4) Pg. ONLINE	Entire document	Julie Zhang

Omission	PHENDIMETRAZINE TARTRATE CAPSULES PF 46(5) Pg. ONLINE	Entire document DELIMITION/OFFICIENT SECTION, IDENTIFICATION/A. Spectroscopic Identification Tests (197), Infrared Spectroscopy:, IDENTIFICATION/B. Ultraviolet Absorption (197U), ASSAY/Procedure, IMPURITIES/Ordinary Impurities (466), IMPURITIES/Organic Impurities, SPECIFIC TESTS/Melting Range or Temperature (741), Class I:, ADDITIONAL REQUIREMENTS/USP	Hillary Cai
Revision	PHENOXYBENZAMINE HYDROCHLORIDE PF 45(2) Pg. ONLINE	Reference Standards (11) ASSAY/PROCEGURE, PERFURMANCE TESTS/DISSOLUTION (/11), IMPURITIES/Organic Impurities, ADDITIONAL	Donald Min
Revision	PHENOXYBENZAMINE HYDROCHLORIDE CAPSULES PF 45(2) Pg. ONLINE	REQUIREMENTS/Packaging and Storage:, ADDITIONAL REQUIREMENTS/USP Reference Standards (11) DELITIVITY OF INTERIOR SPECTION, ASSECTION OF SPECTION OF STANDARD SPECTION OF STANDARD SPECTION OF STANDARD STANDARD SPECTION OF STANDARD SPECTION OF STANDARD STANDARD SPECTION OF STANDARD ST	Donald Min
Revision	PHENTERMINE HYDROCHLORIDE PF 45(3) Pg. ONLINE	ADDITIONAL REQUIREMENTS/TUSP Reference Standards (11) CHEMICAL INFORMATION, IDENTIFICATION/A. Spectroscopic Identification Tests (197), Infrared Spectroscopy: 197Mor 197A, IDENTIFICATION/C., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards	Hillary Cai
Revision	PHENTOLAMINE MESYLATE PF 45(6) Pg. ONLINE	(11) ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Bacterial Endotoxins Test (85), SPECIFIC TESTS/pH (791), SPECIFIC TESTS/Particulate Matter in Injections (788), Method 1, SPECIFIC TESTS/Sterility Tests (71), SPECIFIC TESTS/Other Requirements, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards	Donald Min
New	PHENTOLAMINE MESYLATE INJECTION PF 45(6) Pg. ONLINE	(11)	Donald Min
Omission	PIPERAZINE ADIPATE PF 46(5) Pg. ONLINE	Entire document DEFINITION, SPECIFIC TESTS/Botanical Characteristics, SPECIFIC	Morgan Puderbaugh
Revision	PLANTAGO SEED PF 46(6) Pg. ONLINE	TESTS/Water Absorption IMPURITIES/Limit of Ethylene Glycol and Diethylene Glycol,	Nam-Cheol Kim
Revision	POLYOXYL 40 HYDROGENATED CASTOR OIL PF 46(6) Pg. ONLINE	ADDITIONAL REQUIREMENTS/USP Reference Standards $\langle 11 \rangle$	Peng Zhang
Revision	Potassium-Bismuth Iodide TS PF 46(6) Pg. ONLINE POTASSIUM GLUCONATE AND POTASSIUM CHLORIDE ORAL	Potassium-Bismuth Iodide TS	Margareth Marques
Omission	SOLUTION PF 46(5) Pg. ONLINE POTASSIUM GLUCONATE AND POTASSIUM CHLORIDE FOR ORAL	Entire document	Ren-Hwa Yeh
Omission	SOLUTION PF 46(5) Pg. ONLINE POTASSIUM GLUCONATE AND POTASSIUM CITRATE ORAL	Entire document	Ren-Hwa Yeh
Omission	SOLUTION PF 46(5) Pg. ONLINE POTASSIUM GLUCONATE, POTASSIUM CITRATE, AND AMMONIUM	Entire document	Ren-Hwa Yeh
Omission	CHLORIDE ORAL SOLUTION PF 46(5) Pg. ONLINE	Entire document	Ren-Hwa Yeh

Revision	POTASSIUM GUAIACOLSULFONATE PF 46(6) Pg. ONLINE	IMPURITIES/Selenium (291)	Sujatha Ramakrishna
Omission	PREDNISOLONE HEMISUCCINATE PF 46(4) Pg. ONLINE	Entire document	Ren-Hwa Yeh
	PREDNISOLONE SODIUM PHOSPHATE COMPOUNDED ORAL	DEFINITION, ASSAY/Procedure, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL	
Revision	SOLUTION PF 46(4) Pg. ONLINE	REQUIREMENTS/Beyond-Use Date	Brian Serumaga
	PREDNISOLONE SODIUM SUCCINATE FOR INJECTION PF 46(4) Pg.		_
Omission	ONLINE	Entire document	Morgan Puderbaugh
Omission	PROGESTERONE INJECTABLE SUSPENSION PF 46(5) Pg. ONLINE	Entire document	Ren-Hwa Yeh
		IDENTIFICATION/B. Spectroscopic Identification Tests (197), Ultraviolet-Visible Spectroscopy, ASSAY/Procedure,	
Revision	PROMAZINE HYDROCHLORIDE PF 46(6) Pg. ONLINE	IMPURITIES/Selenium (291)	Ren-Hwa Yeh
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		of Propofol Related Compound B, Procedure 1, ADDITIONAL	
		REQUIREMENTS/Packaging and Storage, ADDITIONAL	
Revision	PROPOFOL PF 46(6) Pg. ONLINE	REQUIREMENTS/USP Reference Standards (11)	Ren-Hwa Yeh
Revision	PROPYLTHIOURACIL PF 46(5) Pg. ONLINE	IDENTIFICATION/A. Spectroscopic Identification Tests (197), Infrared Spectroscopy, IMPURITIES/Selenium (291)	Andrea Carney
Omission	ROXARSONE PF 46(5) Pg. ONLINE	Entire document	•
Omission	SACCHARIN SODIUM ORAL SOLUTION PF 46(6) Pg. ONLINE	Entire document	Morgan Puderbaugh
OHIISSIOH	SACCHARIN SODIUM ORAL SOLUTION PF 40(6) Pg. ONLINE	IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic	Devarshi Narendra Thaker
Revision	SELEGILINE HYDROCHLORIDE CAPSULES PF 45(2) Pg. ONLINE	Impurities	Claire Chisolm
		IMPURITIES/Chloride and Sulfate (221), Chloride,	
Revision	SODIUM GLUCONATE PF 46(5) Pg. ONLINE	IMPURITIES/Chloride and Sulfate (221), Sulfate, IMPURITIES/Lead (251)	Andrea Carney
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Revision	ONLINE	Phosphate	Brian Serumaga
Omission	SODIUM SULFATE INJECTION PF 46(5) Pg. ONLINE	Entire document	Andrea Carney
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Revision	STEAROYL POLYOXYLGLYCERIDES PF 46(6) Pg. ONLINE	Composition	Peng Zhang
Omission	STREPTOMYCIN INJECTION PF 46(5) Pg. ONLINE	Entire document	Slavica Shane
Revision	SULFAMETHIZOLE PF 46(6) Pg. ONLINE	IMPURITIES/Selenium (291)	Praveen Pabba
Omission	SULFAPYRIDINE TABLETS PF 46(6) Pg. ONLINE TECHNETIUM TC 99M (PYRO- AND TRIMETA-) PHOSPHATES	Entire document	Praveen Pabba
Omission	•	Entire document	Gerald Hsu
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New	TESTOSTERONE COMPOUNDED CREAM PF 46(3) Pg. ONLINE	Reference Standards (11)	Brian Serumaga
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Revision	TETRAHYDROZOLINE HYDROCHLORIDE OPHTHALMIC SOLUTION PF 45(3) Pg. ONLINE	IDENTIFICATION/A. Ultraviolet Absorption (1970), ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Sujatha Ramakrishna
Omission	THEOPHYLLINE TABLETS PF 46(6) Pg. ONLINE	Entire document	Ren-Hwa Yeh
Omission	THIABENDAZOLE CHEWABLE TABLETS PF 46(5) Pg. ONLINE	Entire document IDENTIFICATION/A. Spectroscopic Identification Tests (197), Infrared Spectroscopy: 197M, 197K, or 197A, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Limit of Non-Sulfonyl Urea, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Melting Range or Temperature (741), ADDITIONAL REQUIREMENTS/USP Reference	Praveen Pabba
Revision	TOLBUTAMIDE PF 45(6) Pg. ONLINE TRIHEXYPHENIDYL HYDROCHLORIDE EXTENDED-RELEASE	standards (11)	Andrea Carney
Omission	CAPSULES PF 46(3) Pg. ONLINE	Entire document	Nicholas Garito Jr.
Omission	TRIKATES ORAL SOLUTION PF 46(5) Pg. ONLINE	Entire document	Andrea Carney
Omission	TRIMEPRAZINE ORAL SOLUTION PF 46(5) Pg. ONLINE	Entire document	Devarshi Narendra Thaker
New	TRIMETHYL CITRATE PF 46(6) Pg. ONLINE	Trimethyl Citrate Articles of Botanical Origin (203), IDENTIFICATION/B. HPLC, COMPOSITION/Content of Caffeoylquinic Acids and Flavone Glycosides, CONTAMINANTS/Articles of Botanical Origin (561), Limits of Elemental Impurities:, CONTAMINANTS/Articles of Botanical Origin (561), Pesticide Residue Analysis:, CONTAMINANTS/Articles of Botanical Origin (561), Test for Aflatoxins:, CONTAMINANTS/Microbial Enumeration Tests (2021):, CONTAMINANTS/Absence of Specified Microorganisms (2022), Test Procedures, Test for Absence of Salmonella Species and Test for Absence of Escherichia coli:, SPECIFIC TESTS/Botanical Characteristics, SPECIFIC TESTS/Articles of Botanical Origin (561), Methods of Analysis, Foreign Organic Matter:, SPECIFIC TESTS/Articles of Botanical Origin (561), Methods of Analysis, Alcohol-Soluble Extractives, Method 1:, SPECIFIC TESTS/Articles of Botanical Origin (561), Methods of Analysis, Water-Soluble Extractives, Method 2:, SPECIFIC TESTS/Articles of Botanical Origin (561), Methods of Analysis, Acid-Insoluble Ash:, SPECIFIC TESTS/Loss on Drying (731), ADDITIONAL REQUIREMENTS/Packaging and Storage:, ADDITIONAL REQUIREMENTS/Labeling:, ADDITIONAL REQUIREMENTS/USP	Margareth Marques
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