

Compendial Approvals for USPNF 2024 ISSUE 1

Date: Mon Jul 10 15:39:42 EDT 2023

Category Monograph Title

Monograph Section

Scientific Liaison

Ethyl Butyrate, Acidifying or Alkalinizing Agent, {Acidifying or Alkalinizing Agent} Trolamine, {Emulsifying Agent} Polyethylene Glycol 40 Castor Oil, Adhesive (Pressure Sensitive), {Lubricant} Polyethylene Glycol 40 Castor Oil, {Adhesive (Pressure Sensitive)} Dosage Form, {Solubilizing Agent} Polyethylene Glycol 40 Castor Oil, {Alcohol Denaturant} Ethyl Acetate, {pH Modifier (Acidifying Agent::Alkalinizing Agent::Buffering Agent)} Formic Acid, Antifoaming or Defoaming Agent, {Antimicrobial Preservative} Dosage Form, {Antimicrobial Preservative} Benzyl Benzoate, {Antimicrobial Preservative} Propyl Gallate, {Antimicrobial Preservative} Sorbic Acid, {Antioxidant} Dosage Form, {Antioxidant} Histidine, Antitack Agent, {Antitack Agent} Wax, Yellow, Biodegradable Polymer, {Biodegradable Polymer} Sodium Alginate, Buffering Agent, {Buffering Agent} Sodium Succinate, {Bulking Agent} Polyethylene Glycol, {Bulking Agent} Polyethylene Glycol 3350, {Bulking Agent} Dosage Form, {Capsule Shell} Dosage Form, {Capsule Shell} Carrageenan, {Carrier} Dosage Form, {Carrier} Asparagine, Chelating Agent, {Chelating Agent} Dosage Form, {Chelating Agent} Calcium Acetate, {Chelating Agent} Fumaric Acid, {Chelating Agent} Gamma Cyclodextrin, {Chelating Agent} Polacrilin Potassium, {Chelating Agent} Trehalose, {Coating Agent} Dosage Form, {Coating Agent} Glyceryl Behenate, {Coating Agent} Paraffin, {Coating Agent} Sucrose, {Coating Agent} Sugar, Confectioner's, {Colloid Stabilizing Agent} Dosage Form, {Coloring Agent} Dosage Form, Crystallization Inhibitor, {Diluent} Dosage Form, {Disintegrant} Dosage Form, Drag-Reducing Agent, Dry Binder, {Dry Binder} Xylitol, {Emollient} Dosage Form, {Emulsifying Agent} Dosage Form, {Emulsifying Agent} Ammonium Glycyrrhizate, {Emulsifying Agent} Palm Oil, Hydrogenated, {Emulsifying Agent} Polyoxyl 40 Stearate, {Emulsifying Agent} Sodium Citrate, {Emulsifying Agent} Stearyl Alcohol, Filler, {Filler} Xylitol, {Film-Forming Agent} Dosage Form, {Free Radical Scavenger} Dosage Form, Gelling Agent, {Glidant and::or Anticaking Agent} Dosage Form, Liposome Forming Agent, {Lubricant} Dosage Form, {Lubricant} Canola Oil, {Lubricant} Glycerin, {Lubricant} Glyceryl Behenate, {Lubricant} Leucine, {Lubricant} Octyldodecanol, {Lubricant} Polyoxyl 40 Stearate, {Lubricant} Polyvinyl Alcohol, {Lubricant} Stearic Acid,

SanthiKumar Saladi

Revision EXCIPIENTS (USP and NF), LISTED BY CATEGORY PF 48(5) Pg. ONLINE

Revision <4> MUCOSAL DRUG PRODUCTS-PRODUCT QUALITY TESTS PF 48(5) Pg. ONLINE

Revision

Mingyan Chu

Relative Solubility of USP and NF Articles, E/Ethyl Butyrate, A/Acacia, A/Acetic Acid, A/Glacial Acetic Acid, A/Adipic Acid, A/Agar, A/Alamic Acid, A/Alcohol, A/Alfadex, A/Alginic Acid, A/Aluminum Monostearate, A/Strong Ammonia Solution, A/Ammonium Carbonate, A/Ammonium Chloride, A/Ammonium Glycyrhizate, A/Ammonium Phosphate, A/Ammonium Sulfate, A/Arginine, A/Arginine Hydrochloride, A/Ascorbic Acid, A/Asparagine, A/Activated Attapulgit, A/Colloidal Activated Attapulgit, B/Barium Hydroxide Lime, B/Behenoyl Polyoxylglycerides, B/Benzaldehyde Elixir, Compound, B/Benzalkonium Chloride, B/Benzethonium Chloride, B/Benzyl Benzoate, B/Betadex, B/Betadex Sulfobutyl Ether Sodium, B/Boric Acid, B/Butylene Glycol, B/Butyl Palmitostearate, B/Butyl Stearate, B/Butylated Hydroxyanisole, B/Butylated Hydroxytoluene, C/Calcium Acetate, C/Calcium Carbonate, C/Calcium Hydroxide, C/Calcium Lactate, C/Dibasic Calcium Phosphate, C/Tribasic Calcium Phosphate, C/Calcium Silicate, C/Calcium Sulfate, C/Canola Oil, C/Caprylocaproyl Polyoxylglycerides, C/Carbomer 910, C/Carbomer 934, C/Carbomer 934P, C/Carbomer 940, C/Carbomer 941, C/Carbomer 1342, C/Carbomer Copolymer, C/Carbomer Homopolymer, C/Carbomer Interpolymer, C/Carbon Dioxide, C/Carboxymethylcellulose Calcium, C/Carboxymethylcellulose Sodium, C/Carrageenan, C/Castor Oil, C/Hydrogenated Castor Oil, C/Cellulose Acetate, C/Microcrystalline Cellulose, C/Silicified Microcrystalline Cellulose, C/Powdered Cellulose, C/Cetrimonium Bromide, C/Cetyl Alcohol, C/Cetyl Palmitate, C/Cetylpyridinium Chloride, C/Chitosan, C/Cholesterol, C/Anhydrous Citric Acid, C/Citric Acid Monohydrate, C/Copovidone, C/Corn Syrup Solids, C/Crospovidone, D/Dextran 1, D/Dextrates, D/Dextrose, D/Dibutyl Phthalate, D/Diethanolamine, D/Diethylene Glycol Monoethyl Ether, D/Dimethicone, D/Dimethyl Sulfoxide, D/Docusate Sodium, E/Edetate Calcium Disodium, E/Edetate Disodium, E/Edetic Acid, E/Erythritol, E/Ethyl Acetate, E/Ethylcellulose, F/Ferric Oxide, F/Fumaric Acid, G/Galactose, G/Gamma Cyclodextrin, G/Gelatin, G/Gellan Gum, G/Glaze, Pharmaceutical, G/Liquid Glucose, G/Glycerin, G/Glyceryl Dibehenate, G/Glyceryl Monooleate, G/Glyceryl Monostearate, G/Glycine, H/Histidine, H/Hydrochloric Acid, H/Diluted Hydrochloric Acid, H/Hydroxyethyl Cellulose,

Revision DESCRIPTION AND SOLUBILITY PF 48(6) Pg. ONLINE

Revision

Anni Chang

Revision <232> ELEMENTAL IMPURITIES--LIMITS PF 48(6) Pg. ONLINE
<4//> USER-DETERMINED REPORTING THRESHOLDS PF 48(5) Pg. ONLINE

New

Kakhshan Zaidi

<601> INHALATION AND NASAL DRUG PRODUCTS- AEROSOLS, SPRAYS, AND POWDERS--PERFORMANCE QUALITY TESTS PF 48(4)

Revision

Antonio Hernandez-Cardoso

Pg. ONLINE

Kakhshan Zaidi

Omission	</05> QUALITY ATTRIBUTES OF TABLETS LABELED AS HAVING A FUNCTIONAL SCORE PF 48(5) Pg. ONLINE	Entire document	Mingyan Chu
Revision	</89> SUBVISIBLE PARTICULATE MATTER IN INTRAOCULAR SOLUTIONS PF 48(6) Pg. ONLINE	Revision	Desmond Hunt
Revision	<1059> EXCIPIENT PERFORMANCE PF 48(5) Pg. ONLINE	Revision	Galina Holloway
New	<1079.4> TEMPERATURE MAPPING FOR THE QUALIFICATION OF STORAGE AREAS PF 48(5) Pg. ONLINE	New	Desmond Hunt
New	<1117.1> MICROBIOLOGICAL CHAPTERS – GLOSSARY PF 48(5) Pg. ONLINE	New	Leslie Furr
Revision	<1153> DRUG PRODUCTS CONTAINING NANOMATERIALS PF 48(6) Pg. ONLINE	Revision	Kahkashan Zaidi
New	<1705> QUALITY ATTRIBUTES OF TABLETS LABELED AS HAVING A FUNCTIONAL SCORE PF 48(5) Pg. ONLINE	New	Mingyan Chu
Revision	0.1 N Cupric Nitrate VS PF 48(6) Pg. ONLINE	0.1 N Cupric Nitrate VS	Mingyan Chu
Revision	1 N Sodium Hydroxide VS PF 48(6) Pg. ONLINE	1 N Sodium Hydroxide VS	Margareth Marques
Revision	ACETAZOLAMIDE PF 48(6) Pg. ONLINE	Revision	Christine Hiemer
New	ALOE VERA LEAF DRY JUICE PF 48(3) Pg. ONLINE	New	Nam-Cheol Kim
New	ALOE VERA LEAF JUICE PF 48(3) Pg. ONLINE	New	Nam-Cheol Kim
New	ALOE VERA LEAF JUICE CONCENTRATE PF 48(3) Pg. ONLINE	New	Nam-Cheol Kim
Revision	ALUMINA AND MAGNESIUM TRISILICATE TABLETS PF 47(2) Pg. ONLINE	IDENTIFICATION/A. Identification Tests—General (121), Chemical Identification Tests, Magnesium, IDENTIFICATION/A., IDENTIFICATION/B. Identification Tests—General (191), Chemical Identification Tests, Aluminum, IDENTIFICATION/B., IDENTIFICATION/C. Silicon Dioxide, ASSAY/Procedure 1: Aluminum Hydroxide, ASSAY/Procedure 2: Magnesium Trisilicate, ASSAY/Procedure, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Christine Hiemer
Omission	ASPARTAME ACESULFAME PF 48(5) Pg. ONLINE	Entire document	Galina Holloway
Revision	ASPIRIN SUPPOSITORIES PF 48(2) Pg. ONLINE	Revision	Christine Hiemer
Revision	ASTAXANTHIN ESTERS PF 48(5) Pg. ONLINE	Revision	Binu Koshy
Revision	ASTAXANTHIN ESTERS CAPSULES PF 48(5) Pg. ONLINE	Revision	Binu Koshy
New	Benzoyl Peroxide, 75 percent PF 48(5) Pg. ONLINE	Benzoyl Peroxide, 75 Percent	Margareth Marques
New	BITTER ORANGE YOUNG FRUIT PF 47(5) Pg. ONLINE	New	Cuiying Ma
New	BITTER ORANGE YOUNG FRUIT POWDER PF 47(5) Pg. ONLINE	New	Cuiying Ma
Revision	BORIC ACID PF 48(6) Pg. ONLINE	Revision	Galina Holloway
Revision	BUMETANIDE PF 47(4) Pg. ONLINE	IDENTIFICATION/A. Spectroscopic identification tests (197), Infrared Spectroscopy, IDENTIFICATION/B. Spectroscopic Identification Tests (197), Ultraviolet-Visible Spectroscopy, IDENTIFICATION/C., ASSAY/Procedure, IMPURITIES/Residue on Ignition (281), IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Christine Hiemer

Revision	BUMETANIDE INJECTION PF 47(4) Pg. ONLINE	DEFINITION, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Bacterial Endotoxins Test (85), ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Christine Hiemer
Revision	BUMETANIDE TABLETS PF 47(4) Pg. ONLINE	IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution (711), IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Christine Hiemer
Revision	CARRAGEENAN PF 48(4) Pg. ONLINE	Revision	Devendra Vasant Chavan
Revision	CEFEPIME HYDROCHLORIDE PF 48(3) Pg. ONLINE	Revision	Christine Hiemer
Revision	0.1 N Ceric Sulfate VS PF 48(6) Pg. ONLINE	0.1 N Ceric Sulfate VS	Mingyan Chu
New	CETYLPYRIDINIUM CHLORIDE PF 48(6) Pg. ONLINE	Cetylpyridinium Chloride	Margareth Marques
Revision	CHONDROITIN SULFATE SODIUM, SHARK PF 48(6) Pg. ONLINE	Revision	Fatkhulla Tadjimukhamedov
New	CINNAMOMUM CASSIA BARK PF 48(3) Pg. ONLINE	New	Cuiying Ma
New	CINNAMOMUM CASSIA BARK POWDER PF 48(3) Pg. ONLINE	New	Cuiying Ma
New	COCOYL CAPRYLOCAPRATE PF 47(6) Pg. ONLINE	New	SanthiKumar Saladi
Revision	CRANBERRY FRUIT JUICE PF 48(6) Pg. ONLINE	Revision	Maria Monagas
Revision	CRANBERRY FRUIT JUICE CONCENTRATE PF 48(6) Pg. ONLINE	Revision	Maria Monagas
New	CRANBERRY FRUIT POWDER PF 48(5) Pg. ONLINE	New	Maria Monagas
Omission	DIGITALIS PF 48(5) Pg. ONLINE	Entire document	Nam-Cheol Kim
Omission	POWDERED DIGITALIS PF 48(5) Pg. ONLINE	Entire document	Nam-Cheol Kim
Omission	DIGITALIS CAPSULES PF 48(5) Pg. ONLINE	Entire document	Nam-Cheol Kim
Omission	DIGITALIS TABLETS PF 48(5) Pg. ONLINE	Entire document	Nam-Cheol Kim
New	ETHYL BUTYRATE PF 48(5) Pg. ONLINE	New	SanthiKumar Saladi
Revision	ETODOLAC TABLETS PF 47(5) Pg. ONLINE	Revision	Christine Hiemer
Revision	FENTANYL CITRATE AND ROPIVACAINE HYDROCHLORIDE COMPOUNDED INJECTION PF 48(4) Pg. ONLINE	Revision	Brian Serumaga
Revision	FLUDEOXYGLUCOSE F 18 INJECTION PF 48(6) Pg. ONLINE	Revision	Shankari Shivaprasad
New	FORMIC ACID PF 48(6) Pg. ONLINE	New	SanthiKumar Saladi
Omission	GUAIFENESIN AND PSEUDOEPHEDRINE HYDROCHLORIDE CAPSULES PF 48(5) Pg. ONLINE	Entire document	Christine Hiemer
New	HYDROCORTISONE COMPOUNDED ORAL SUSPENSION PF 47(5) Pg. ONLINE	New	Brian Serumaga
Omission	IOXILAN PF 48(6) Pg. ONLINE	Entire document	Shankari Shivaprasad
Omission	IOXILAN INJECTION PF 48(6) Pg. ONLINE	Entire document	Shankari Shivaprasad
Revision	DILUTED ISOSORBIDE MONONITRATE PF 47(3) Pg. ONLINE	IDENTIFICATION/A. Spectroscopic Identification Tests (197), Infrared Spectroscopy, ASSAY/Procedure, IMPURITIES/Limit of Nitrate, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Christine Hiemer

		IDENTIFICATION/A. Thin-Layer Chromatographic Identification Test (201), ASSAY/Procedure, PERFORMANCE TESTS/Dissolution (711), PERFORMANCE TESTS/Uniformity of Dosage Units (905), IMPURITIES/Limit of Nitrate, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	
Revision	ISOSORBIDE MONONITRATE TABLETS PF 47(4) Pg. ONLINE		Christine Hiemer
New	L129 PF 48(5) Pg. ONLINE	L129	Margareth Marques
New	L130 PF 48(6) Pg. ONLINE	L130	Margareth Marques
Revision	LEVOFLOXACIN ORAL SOLUTION PF 48(6) Pg. ONLINE	Revision	Christine Hiemer
New	LIOTHYRONINE SODIUM INJECTION PF 48(6) Pg. ONLINE	New	Christine Hiemer
Revision	MENAQUINONE-7 PREPARATION PF 48(6) Pg. ONLINE	Revision	Fatkhulla Tadjimukhamedov
Revision	METHYLTESTOSTERONE PF 48(3) Pg. ONLINE	Revision	Shankari Shivaprasad
New	8.7 N ACETIC ACID TS PF 48(5) Pg. ONLINE	8.7 N Acetic Acid TS	Mingyan Chu
Revision	NORTRIPTYLINE HYDROCHLORIDE CAPSULES PF 48(1) Pg. ONLINE	Revision	Shankari Shivaprasad
Revision	ONDANSETRON INJECTION PF 48(5) Pg. ONLINE	Revision	Christine Hiemer
Omission	OXYTETRACYCLINE HYDROCHLORIDE AND POLYMYXIN B SULFATE VAGINAL INSERTS PF 48(5) Pg. ONLINE	Entire document	Rebecca Potts
Omission	PARALDEHYDE PF 48(6) Pg. ONLINE	Entire document	Shankari Shivaprasad
Omission	PAROMOMYCIN ORAL SOLUTION PF 48(5) Pg. ONLINE	Entire document	Rebecca Potts
New	PICRORHIZA SPECIES ROOT AND RHIZOME PF 48(5) Pg. ONLINE	New	Nam-Cheol Kim
New	PICRORHIZA SPECIES ROOT AND RHIZOME DRY EXTRACT PF 48(5) Pg. ONLINE	New	Nam-Cheol Kim
New	PICRORHIZA SPECIES ROOT AND RHIZOME POWDER PF 48(5) Pg. ONLINE	New	Nam-Cheol Kim
New	PIRFENIDONE PF 48(3) Pg. ONLINE	New	Shankari Shivaprasad
New	PIRFENIDONE CAPSULES PF 48(3) Pg. ONLINE	New	Shankari Shivaprasad
New	PIRFENIDONE TABLETS PF 48(3) Pg. ONLINE	New	Shankari Shivaprasad
Revision	PYRIMETHAMINE PF 48(5) Pg. ONLINE	Revision	Christine Hiemer
Omission	QUINIDINE SULFATE EXTENDED-RELEASE TABLETS PF 48(5) Pg. ONLINE	Entire document	Christine Hiemer
Revision	SODIUM BICARBONATE COMPOUNDED INJECTION PF 48(4) Pg. ONLINE	Revision	Brian Serumaga
Revision	Standard Dichlorophenol-Indophenol Solution PF 48(6) Pg. ONLINE	Standard Dichlorophenol-Indophenol Solution	Mingyan Chu
New	TETRABUTYLAMMONIUM HYDROXIDE, 25 PERCENT IN METHANOL PF 48(6) Pg. ONLINE	Tetrabutylammonium Hydroxide, 25 Percent in Methanol	Margareth Marques
Revision	TOLNAFTATE TOPICAL AEROSOL PF 48(4) Pg. ONLINE	Revision	Christine Hiemer
Revision	TOLNAFTATE CREAM PF 48(4) Pg. ONLINE	Revision	Christine Hiemer
Revision	TOLNAFTATE TOPICAL POWDER PF 48(4) Pg. ONLINE	Revision	Christine Hiemer

Revision	TOLNAFTATE TOPICAL SOLUTION PF 48(4) Pg. ONLINE	Revision	Christine Hiemer
Omission	TYROTHRICIN PF 48(3) Pg. ONLINE	Entire document	Ying Han
		DEFINITION, IDENTIFICATION/A, IDENTIFICATION/B, ASSAY/Procedure, PERFORMANCE TESTS/Uniformity of Dosage Units (905), IMPURITIES/Organic Impurities, SPECIFIC TESTS/• pH (791), SPECIFIC TESTS/Water Determination (921), Method I, SPECIFIC TESTS/Microbial Enumeration Tests (61) and Tests for Specified Microorganisms (62), ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	
New	VALGANCICLOVIR FOR ORAL SOLUTION PF 47(3) Pg. ONLINE	Revision	Christine Hiemer
Revision	VITAMIN E PF 48(5) Pg. ONLINE	Revision	Natalia Davydova
Revision	VITAMIN E CAPSULES PF 48(5) Pg. ONLINE	Revision	Natalia Davydova
Revision	VITAMIN E PREPARATION PF 48(5) Pg. ONLINE	Revision	Natalia Davydova
New	OIL-SOLUBLE VITAMINS PREPARATION PF 48(5) Pg. ONLINE	New	Natalia Davydova