

Compendial Approvals for USPNF 2024 ISSUE 2

Date: Thu Nov 09 12:01:31 EST 2023

Category	Monograph Title	Monograph Section	Scientific Liaison
Revision	EXCIPIENTS (USP and NF), LISTED BY CATEGORY PF 49(2) Pg. ONLINE	Suspending and/or Viscosity-Increasing Agent	Galina Holloway
Revision	DESCRIPTION AND SOLUBILITY PF 49(2) Pg. ONLINE	C/Carbomer 910, C/Carbomer 934, C/Carbomer 934P, C/Carbomer 940, C/Carbomer 941, C/Carbomer 1342	Galina Holloway
New	<312> MOLECULAR WEIGHT DETERMINATION FOR ALGINATES PF 48(6) Pg. ONLINE	New	Devendra Vasant Chavan
New	<383> CURED SILICONE ELASTOMERS FOR PHARMACEUTICAL PACKAGING AND MANUFACTURING COMPONENTS PF 48(3) Pg. ONLINE	New	Desmond Hunt
Revision	<471> OXYGEN FLASK COMBUSTION PF 49(1) Pg. ONLINE	Revision	Antonio Hernandez-Cardoso
Revision	<541> TITRIMETRY PF 48(5) Pg. ONLINE	Revision	Mingyan Chu
Revision	<661> PLASTIC PACKAGING SYSTEMS AND THEIR MATERIALS OF CONSTRUCTION PF 49(1) Pg. ONLINE	Revision	Desmond Hunt
Revision	<791> pH PF 49(2) Pg. ONLINE	Revision	Antonio Hernandez-Cardoso
New	<1023> EVALUATION STRATEGY FOR TRACE ELEMENTS IN CELL CULTURE MEDIA USED IN THE MANUFACTURE OF RECOMBINANT THERAPEUTIC PROTEINS PF 48(5) Pg. ONLINE	New	Rebecca Potts
New	<1035> POTENCY ASSAYS TO EVALUATE COAGULATION FACTOR VIII AND FACTOR IX PF 49(2) Pg. ONLINE	New	Li Jing
Revision	<1151> PHARMACEUTICAL DOSAGE FORMS PF 49(1) Pg. ONLINE	Revision	Prabhakar Gruddanti
Revision	<1236> SOLUBILITY MEASUREMENTS PF 49(1) Pg. ONLINE	Revision	Margareth Marques
New	L-ALANINE PF 49(2) Pg. ONLINE	l -Alanine	Margareth Marques
New	BETA-ALANINE PF 49(2) Pg. ONLINE	β-Alanine	Margareth Marques
New	ALBUMIN HUMAN PF 49(2) Pg. ONLINE	Albumin Human	Margareth Marques
Revision	0.2 N ALCOHOLIC POTASSIUM HYDROXIDE VS PF 49(2) Pg. ONLINE	0.2 N Alcoholic Potassium Hydroxide VS,	Mingyan Chu
New	AMMONIACAL BUFFER, PH 10 PF 49(2) Pg. ONLINE	Ammoniacal Buffer, pH 10	Mingyan Chu
New	ANTHRANILIC ACID PF 49(2) Pg. ONLINE	Anthranilic Acid	Margareth Marques
New	ARGININE HYDROCHLORIDE PF 49(2) Pg. ONLINE	Arginine Hydrochloride	Margareth Marques
Revision	BETAMETHASONE VALERATE PF 47(4) Pg. ONLINE	CHEMICAL INFORMATION, IDENTIFICATION/A. Spectroscopic Identification Tests 197 , Infrared Spectroscopy, IDENTIFICATION/B. Thin-Layer Chromatographic Identification Test 201 , ASSAY/Procedure, IMPURITIES/Limit of Betamethasone Valerate Related Compound H, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards 11	Shankari Shivaprasad
New	BIOTIN PF 49(2) Pg. ONLINE	Biotin	Margareth Marques
New	CALCIPOTRIENE AND BETAMETHASONE DIPROPIONATE OINTMENT PF 46(6) Pg. ONLINE	ASSAY/Procedure, PERFORMANCE TESTS/Dissolution /11 , IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards 11	Shankari Shivaprasad
Revision	CANDESARTAN CILEXETIL AND HYDROCHLOROTHIAZIDE TABLETS PF 47(4) Pg. ONLINE	ASSAY/Procedure, PERFORMANCE TESTS/Dissolution /11 , IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards 11	Christine Hiemer
Omission	CARBOMER 934 PF 49(2) Pg. ONLINE	Entire document	Galina Holloway
Omission	CARBOMER 934P PF 49(2) Pg. ONLINE	Entire document	Galina Holloway
Omission	CARBOMER 940 PF 49(2) Pg. ONLINE	Entire document	Galina Holloway
Omission	CARBOMER 941 PF 49(2) Pg. ONLINE	Entire document	Galina Holloway
Omission	CARBOMER 1342 PF 49(2) Pg. ONLINE	Entire document	Galina Holloway
Revision	CARBON DIOXIDE PF 49(2) Pg. ONLINE	Carbon Dioxide	Margareth Marques
New	CINNAMOMUM VERUM BARK PF 48(5) Pg. ONLINE	New	Cuiying Ma
New	CINNAMOMUM VERUM BARK POWDER PF 48(5) Pg. ONLINE	New	Cuiying Ma
New	CYANOCOBALAMIN PF 49(2) Pg. ONLINE	Cyanocobalamin	Margareth Marques
New	L-CYSTINE DIHYDROCHLORIDE PF 49(2) Pg. ONLINE	l-Cystine Dihydrochloride	Margareth Marques
New	3-DEOXY-D-GLYCERO-D-GALACTO-2-NONULOSONIC ALIU PF 49(2) Pg. ONLINE	3-Deoxy-D-glycero-D-galacto-2-nonulosonic acid	Margareth Marques
Revision	DEXTROSE PF 48(6) Pg. ONLINE	Revision	Jenny Liu
Revision	0.002 M EDETATE DISODIUM VS PF 49(2) Pg. ONLINE	0.002 M Edetate Disodium VS	Mingyan Chu
Revision	0.01 M EDETATE DISODIUM VS PF 49(2) Pg. ONLINE	0.01 M Edetate Disodium VS	Mingyan Chu
Revision	ERGOCALCIFEROL TABLETS PF 48(6) Pg. ONLINE	Revision	Natalia Davydova
New	ETONOGESTREL PF 48(6) Pg. ONLINE	New	Shankari Shivaprasad
Revision	EZETIMIBE PF 49(2) Pg. ONLINE	Revision	Christine Hiemer

Revision	FLUOROURACIL INJECTION PF 47(3) Pg. ONLINE	IDENTIFICATION/B. Spectroscopic Identification Tests 197 , Infrared Spectroscopy, IDENTIFICATION/C. ASSAY/Procedure, IMPURITIES/Organic Impurities, IMPURITIES/Limit of Urea, SPECIFIC TESTS/Bacterial Endotoxins Test '85 , SPECIFIC TESTS/Particulate Matter in Injections 788 , SPECIFIC TESTS/Sterility test 71 , ADDITIONAL REQUIREMENTS/USP Reference Standards 11	Christine Hiemer
New	FOLIC ACID PF 49(2) Pg. ONLINE	Folic Acid	Margareth Marques
Revision	GANCICLOVIR FOR INJECTION PF 47(5) Pg. ONLINE	Revision	Christine Hiemer
New	GEFITINIB PF 48(4) Pg. ONLINE	New	Christine Hiemer
New	GEFITINIB TABLETS PF 48(4) Pg. ONLINE	New	Christine Hiemer
New	GENTAMICIN SOLUTION PF 49(2) Pg. ONLINE	Gentamicin Solution	Margareth Marques
Revision	LIQUID GLUCOSE PF 49(1) Pg. ONLINE	Revision	SanthiKumar Saladi
New	N-GLYCOSIDASE F PF 49(2) Pg. ONLINE	N-Glycosidase F	Margareth Marques
New	HEPES PF 49(2) Pg. ONLINE	HEPES	Margareth Marques
Revision	0.1 M alcoholic Hydrochloric Acid VS PF 49(2) Pg. ONLINE	0.1 M Alcoholic Hydrochloric Acid VS	Mingyan Chu
New	IODOACETAMIDE PF 49(2) Pg. ONLINE	Iodoacetamide	Margareth Marques
New	L-LEUCINE PF 49(2) Pg. ONLINE	L-Leucine	Margareth Marques
Revision	L-Lysine Hydrochloride PF 49(2) Pg. ONLINE	L -Lysine Hydrochloride	Margareth Marques
Revision	METHADONE HYDROCHLORIDE TABLETS PF 47(4) Pg. ONLINE	IDENTIFICATION/A. Thin-Layer Chromatographic Identification Test 201 , IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution 711 , IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage	Christine Hiemer
New	L-METHIONINE PF 49(2) Pg. ONLINE	L -Methionine	Margareth Marques
Revision	NAPROXEN PF 47(4) Pg. ONLINE	GENERAL INFORMATION, IDENTIFICATION/A. Spectroscopic Identification Tests 197 , Infrared Spectroscopy, IDENTIFICATION/B. Spectroscopic Identification Tests 197 , Ultraviolet-Visible Spectroscopy, ASSAY/Procedure, IMPURITIES/Organic Impurities, IMPURITIES/Enantiomeric Purity Test, SPECIFIC TESTS/Optical Rotation 781S , Procedures, Specific Rotation, ADDITIONAL REQUIREMENTS/USP Reference Standards 11	Christine Hiemer
Revision	NAPROXEN SODIUM PF 47(4) Pg. ONLINE	CHEMICAL INFORMATION, IDENTIFICATION/A. Spectroscopic Identification Tests 197 , Infrared Spectroscopy, IDENTIFICATION/B. Spectroscopic Identification Tests 197 , Ultraviolet-Visible Spectroscopy, ASSAY/Procedure, IMPURITIES/Organic Impurities , Procedure 1, IMPURITIES/Limit of Free Naproxen, IMPURITIES/Enantiomeric Purity Test, SPECIFIC TESTS/Optical Rotation 781S , Procedures, Specific Rotation, ADDITIONAL REQUIREMENTS/USP Reference Standards 11	Christine Hiemer
New	NEURAMINIDASE PF 49(2) Pg. ONLINE	Neuraminidase	Margareth Marques
New	NIACINAMIDE PF 49(2) Pg. ONLINE	Niacinamide	Margareth Marques
Revision	ONDANSETRON PF 48(5) Pg. ONLINE	Revision	Christine Hiemer
Revision	ONDANSETRON HYDROCHLORIDE PF 48(5) Pg. ONLINE	Revision	Christine Hiemer
Omission	OXYTETRACYCLINE HYDROCHLORIDE AND HYDROCORTISONE OINTMENT PF 49(1) Pg. ONLINE	Entire document	Rebecca Potts
Omission	OXYTETRACYCLINE HYDROCHLORIDE AND POLYMYXIN B SULFATE TOPICAL POWDER PF 49(2) Pg. ONLINE	Entire document	Rebecca Potts
New	PENICILLIN G POTASSIUM PF 49(2) Pg. ONLINE	Penicillin G Potassium	Margareth Marques
Revision	PENTOBARBITAL PF 48(6) Pg. ONLINE	Revision	Shankari Shivaprasad
New	PIMECROLIMUS PF 48(6) Pg. ONLINE	New	Christine Hiemer
New	PLERIXAFOR PF 48(6) Pg. ONLINE	New	Christine Hiemer
New	PLERIXAFOR INJECTION PF 48(6) Pg. ONLINE	New	Christine Hiemer
New	POLYBRENE PF 49(2) Pg. ONLINE	Polybrene	Margareth Marques
New	L-PROLINE PF 49(2) Pg. ONLINE	L -Proline	Margareth Marques
New	RIBOFLAVIN PF 49(2) Pg. ONLINE	Riboflavin	Margareth Marques
Revision	ROSUVASTATIN CALCIUM PF 47(4) Pg. ONLINE	GENERAL INFORMATION, IDENTIFICATION/A. Spectroscopic Identification Tests 197 , Infrared Spectroscopy, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, IMPURITIES/Enantiomeric Purity, IMPURITIES/Limit of Chloride, ADDITIONAL REQUIREMENTS/USP Reference Standards 11	Christine Hiemer
Revision	ROSUVASTATIN TABLETS PF 47(4) Pg. ONLINE	DEFINITION, IDENTIFICATION/A., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution 711 , IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards 11	Christine Hiemer
New	L-SERINE PF 49(2) Pg. ONLINE	L-Serine	Margareth Marques
New	SHEEP PLASMA PF 49(2) Pg. ONLINE	Sheep Plasma	Margareth Marques
New	SODIUM CYANOBOROHYDRIDE PF 49(2) Pg. ONLINE	Sodium Cyanoborohydride	Margareth Marques
Revision	0.02 M Sodium Tetraphenylboron VS PF 49(1) Pg. ONLINE	0.02 M Sodium Tetraphenylboron VS	Margareth Marques
New	STREPTOMYCIN SULFATE PF 49(2) Pg. ONLINE	Streptomycin Sulfate	Margareth Marques
Omission	TECHNETIUM Tc 99m DISOFENIN INJECTION PF 49(1) Pg. ONLINE	Entire document	Shankari Shivaprasad
Revision	TECHNETIUM Tc 99m RED BLOOD CELLS INJECTION PF 49(1) Pg. ONLINE	Revision	Shankari Shivaprasad
Revision	TECHNETIUM Tc 99m SESTAMIBI INJECTION PF 49(1) Pg. ONLINE	Revision	Shankari Shivaprasad
New	TF-1 CELLS PF 49(2) Pg. ONLINE	TF-1 Cells	Margareth Marques
New	THIAMINE HYDROCHLORIDE PF 49(2) Pg. ONLINE	Thiamine Hydrochloride	Margareth Marques
New	L-THREONINE PF 49(2) Pg. ONLINE	L-Threonine	Margareth Marques
New	THROMBIN BOVINE PF 49(2) Pg. ONLINE	Thrombin Bovine	Margareth Marques
New	TOPIRAMATE EXTENDED-RELEASE CAPSULES PF 48(2) Pg. ONLINE	New	Shankari Shivaprasad
New	Trisodium 8-aminopyrene-1,3,6-trisulfonate PF 49(2) Pg. ONLINE	Trisodium 8-aminopyrene-1,3,6-trisulfonate	Margareth Marques
Revision	L-Tryptophan PF 49(2) Pg. ONLINE	L -Tryptophan	Margareth Marques
New	L-VALINE PF 49(2) Pg. ONLINE	L -Valine	Margareth Marques