

Compendial Approvals for USP43-NF38

Category	Monograph Title	Monograph Section	Scientific Liaison
Revision	EXCIPIENTS (USP and NF), LISTED BY CATEGORY PF 44(4) Pg. ONLINE	{Emollient} Polypropylene Glycol 11 Stearyl Ether, {Solvent} Polypropylene Glycol 11 Stearyl Ether, {Vehicle} Polypropylene Glycol 11 Stearyl Ether, {Flavors and Fragrance} Neohesperidin Dihydrochalcone NF, {Sweetening Agent} Neohesperidin Dihydrochalcone NF, {Flavors and Fragrance} Anise Oil, {Emulsifying Agent} Glyceryl Mono and Dicaprylate, {Emulsifying Agent} Glyceryl Mono and Dicaprylocaprate, {Lubricant} Glyceryl Mono and Dicaprylate, {Lubricant} Glyceryl Mono and Dicaprylocaprate	Peng Zhang
Revision	DESCRIPTION AND SOLUBILITY PF 44(4) Pg. ONLINE	Polypropylene Glycol 11 Stearyl Ether, Neohesperidin Dihydrochalcone, Medium-Chain Triglycerides, Anise Oil, Glyceryl Mono and Dicaprylate, Glyceryl Mono and Dicaprylocaprate	Peng Zhang
Revision	<203> HIGH PERFORMANCE THIN-LAYER CHROMATOGRAPHY PROCEDURE FOR IDENTIFICATION OF ARTICLES OF BOTANICAL ORIGIN PF 44(4) Pg. ONLINE	INTRODUCTION, REQUIRED EQUIPMENT, PROCEDURE	Maria Monagas
Revision	<701> DISINTEGRATION Stage 6 Harmonization	Entire Document	William Brown
New	<856> NEAR-INFRARED SPECTROSCOPY PF 44(5) Pg. ONLINE	1. INTRODUCTION, 2. QUALIFICATION OF NIR SPECTROMETERS, 3. PROCEDURE, 4. VALIDATION AND VERIFICATION	Kahkashan Zaidi
Revision	<1010> ANALYTICAL DATA -- INTERPRETATION AND TREATMENT PF 44(5) Pg. ONLINE	INTRODUCTION, PREREQUISITE LABORATORY PRACTICES AND PRINCIPLES, MEASUREMENT PRINCIPLES AND VARIATION, OUTLYING RESULTS, COMPARISON OF ANALYTICAL PROCEDURES, APPENDICES, INTRODUCTION, BASIC STATISTICAL PRINCIPLES AND UNCERTAINTY, STUDY CONSIDERATIONS, REFERENCES	Steven Walfish
Revision	<1043> ANCILLARY MATERIALS FOR CELL, GENE AND TISSUE ENGINEERED PRODUCTS PF 44(6) Pg. ONLINE	INTRODUCTION, REGULATORY CONSIDERATIONS, IMPACT OF ANCILLARY MATERIAL QUALITY ON PRODUCT QUALITY, QUALIFICATION OF ANCILLARY MATERIALS, RISK CLASSIFICATION/MANAGEMENT, PERFORMANCE TESTING, ANCILLARY MATERIALS RESIDUAL LEVEL/RESIDUAL ASSESSMENT AND REMOVAL, CONCLUSION, APPENDIX	Rebecca Potts
Revision	<1046> CELLULAR AND TISSUE-BASED PRODUCTS PF 44(6) Pg. ONLINE	INTRODUCTION, COMPONENTS USED IN CELL-BASED ADVANCED THERAPIES/AND TISSUE-BASED PRODUCT MANUFACTURING, MANUFACTURING OF CELL-BASED ADVANCED THERAPIES OR TISSUE-BASED PRODUCTS, ANALYTICAL METHODS, QUALITY SYSTEMS, FACILITY DESIGN AND OPERATION CONSIDERATIONS, CONSIDERATIONS FOR VALIDATION AND QUALIFICATION, CLINICAL SITE PREPARATION AND ADMINISTRATION, STABILITY, STORAGE AND SHIPPING, LABELING, CONSIDERATIONS FOR TECHNOLOGY TRANSFER, REGULATIONS AND STANDARDS, GLOSSARY, APPENDIX	Rebecca Potts
Revision	<1047> GENE THERAPY PRODUCTS PF 44(6) Pg. ONLINE	MANUFACTURING OF GENE THERAPY PRODUCTS, ON-SITE PREPARATION AND ADMINISTRATION, ANALYTICAL METHODS, GLOSSARY, APPENDIX	Rebecca Potts
Revision	<1119> NEAR-INFRARED SPECTROSCOPY PF 44(5) Pg. ONLINE	1. THEORY, 2. TRANSMISSION, REFLECTION, AND TRANSFLECTION MODES, 3. FACTORS THAT AFFECT NIR SPECTRA, 5. INSTRUMENTATION, 6. APPLICATIONS	Kahkashan Zaidi
New	<1850> EVALUATION OF SCREENING TECHNOLOGIES FOR ASSESSING MEDICINE QUALITY PF 44(3) Pg. ONLINE	Introduction, 1. INTRODUCTION, 2. APPLICATION OF THE TECHNOLOGY, 3. GENERAL INFORMATION ABOUT THE TECHNOLOGY, 4. PERFORMANCE EVALUATION, 5. FIELD EVALUATION, GLOSSARY, REFERENCES	Daniel Bempong
Revision	ALGINIC ACID PF 44(6) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/A. Spectroscopic Identification Tests <197>, Infrared Spectroscopy, IDENTIFICATION/B., ADDITIONAL REQUIREMENTS/USP Reference Standards <11>	Sean Delaney

Revision	ALLOPURINOL COMPOUNDED ORAL SUSPENSION PF 44(2) Pg. ONLINE	DEFINITION/Introduction, ASSAY/Oral Suspension in Syrspend SF PH4, SPECIFIC TESTS/pH <791>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Beyond-Use Date, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>	Brian Serumaga
Revision	AMITRIPTYLINE HYDROCHLORIDE PF 44(4) Pg. ONLINE	IMPURITIES/Organic Impurities	Heather Joyce
Omission	APOMORPHINE HYDROCHLORIDE TABLETS PF 44(6) Pg. ONLINE	Entire document	Behnaz Almasi
Revision	ARGININE HYDROCHLORIDE COMPOUNDED ORAL SOLUTION PF 44(5) Pg. ONLINE	DEFINITION/Introduction, 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 Arginine Hydrochloride RS	Brian Serumaga
Omission	AUROTHIOGLUCOSE INJECTABLE SUSPENSION PF 44(6) Pg. ONLINE	Entire document	Wei Yang
Omission	AZATADINE MALEATE PF 44(5) Pg. ONLINE	Entire document	Mary Koleck
Omission	AZATADINE MALEATE TABLETS PF 44(6) Pg. ONLINE	Entire document	Mary Koleck
Revision	AZATHIOPRINE TABLETS PF 43(3) Pg. ONLINE	IDENTIFICATION/Thin-Layer Chromatographic Identification Test <201>, IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Azathioprine Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Mercaptopurine RS	Feiwen Mao
Revision	BETAXOLOL HYDROCHLORIDE PF 43(6) Pg. ONLINE	IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Betaxolol Related Compound A RS	Feiwen Mao
Revision	BETAXOLOL TABLETS PF 43(6) Pg. ONLINE	IDENTIFICATION/B, ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Betaxolol Related Compound A RS	Feiwen Mao
Revision	CALCIUM WITH VITAMIN D TABLETS PF 44(6) Pg. ONLINE	IDENTIFICATION/A., IDENTIFICATION/B., STRENGTH/Introduction, STRENGTH/Vitamin D (Cholecalciferol or Ergocalciferol), Method 1, STRENGTH/Vitamin D (Cholecalciferol or Ergocalciferol), Method 2	Natalia Davydova
Revision	CALCIUM AND VITAMIN D WITH MINERALS TABLETS PF 44(6) Pg. ONLINE	IDENTIFICATION/A., IDENTIFICATION/B., STRENGTH/Introduction, STRENGTH/Vitamin D (Cholecalciferol or Ergocalciferol), Method 1, STRENGTH/Vitamin D (Cholecalciferol or Ergocalciferol), Method 2, ADDITIONAL REQUIREMENTS/Labeling	Natalia Davydova
Revision	LOW-SUBSTITUTED CARBOXYMETHYLCELLULOSE SODIUM PF 43(6) Pg. ONLINE	IDENTIFICATION/A. Infrared Absorption <197K> or <197A>, IDENTIFICATION/A., IDENTIFICATION/B., IDENTIFICATION/C., ADDITIONAL REQUIREMENTS/USP Reference Standards <11>	Tong Liu
New	CARBOXYMETHYLCELLULOSE SODIUM COMPOUNDED INTRAPERITONEAL SOLUTION, VETERINARY PF 44(6) Pg. ONLINE	DEFINITION/Introduction, ASSAY/Procedure, SPECIFIC TESTS/pH <791>, SPECIFIC TESTS/Sterility Tests <71>, Test for Sterility of the Product to be Examined, Direct Inoculation of the Culture Medium, SPECIFIC TESTS/Bacterial Endotoxins Test <85>, SPECIFIC TESTS/Viscosity-Rotational Methods <912>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/Beyond-Use Date, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Sodium Chloride RS	Brian Serumaga
Revision	CHLORAMBUCIL COMPOUNDED ORAL SUSPENSION PF 44(5) Pg. ONLINE	DEFINITION/Introduction, 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 Chlorambucil RS	Brian Serumaga

Revision	CHLORAMPHENICOL COMPOUNDED ORAL SUSPENSION, VETERINARY PF 44(5) Pg. ONLINE	DEFINITION/Introduction, 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 Chloramphenicol RS	Brian Serumaga
Revision	CHOLECALCIFEROL PF 44(6) Pg. ONLINE	IDENTIFICATION/Infrared Absorption <197K>, IDENTIFICATION/Ultraviolet Absorption <197U>, IDENTIFICATION/C., IDENTIFICATION/D. Thin-Layer Chromatography, ASSAY/Procedure	Huy Dinh
Revision	CLONIDINE HYDROCHLORIDE PF 44(4) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K><197>, IDENTIFICATION/Ultraviolet Absorption <197U>, ASSAY/Procedure, IMPURITIES/Organic Impurities	Edith Chang
New	CLONIDINE HYDROCHLORIDE COMPOUNDED ORAL SUSPENSION PF 44(5) Pg. ONLINE	DEFINITION/Introduction, 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 Clonidine Hydrochloride RS	Brian Serumaga
New	CREATINE PF 44(3) Pg. ONLINE	Title, Chemical Info/Chemical Structure, Chemical Info/C4H9N3O2.H2O, Chemical Info/149.15, Chemical Info/Glycine, N-(aminoiminomethyl)-N-methyl-, monohydrate;, Chemical Info/N-Carbamimidoyl-N-methylglycine monohydrate, Chemical Info/CAS, Chemical Info/C4H9N3O2, Chemical Info/131.14, Chemical Info/Anhydrous, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Chloride and Sulfate <221>, Sulfate, ??UNKNOWN??/Note, ??UNKNOWN??/Procedure 1, ??UNKNOWN??/Procedure 2, SPECIFIC TESTS/Loss on Drying <731>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Creatine RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Creatinine RS	Huy Dinh
Revision	DEMECLOCYCLINE HYDROCHLORIDE PF 44(6) Pg. ONLINE	Chemical Info/Chemical Structure, IDENTIFICATION/A.Spectroscopic Identification Tests <197>, Infrared Spectroscopy, IDENTIFICATION/B., ASSAY/Procedure	Praveen Pabba
Revision	DEMECLOCYCLINE HYDROCHLORIDE TABLETS PF 44(6) Pg. ONLINE	IDENTIFICATION/B., ASSAY/Procedure, ADDITIONAL REQUIREMENTS/Packaging and Storage	Praveen Pabba
Omission	DESLANOSIDE PF 44(5) Pg. ONLINE	Entire document	Edith Chang
Omission	DESLANOSIDE INJECTION PF 44(6) Pg. ONLINE	Entire document	Edith Chang
Omission	DIAZOXIDE CAPSULES PF 44(6) Pg. ONLINE	Entire document	Edith Chang
Omission	DIAZOXIDE INJECTION PF 44(6) Pg. ONLINE	Entire document	Edith Chang
New	DICLOFENAC POTASSIUM FOR ORAL SOLUTION PF 44(3) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Microbial Enumeration Tests <61> and Tests for Specified Microorganisms <62>, SPECIFIC TESTS/pH <791>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Diclofenac Potassium RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Diclofenac Related Compound A RS	Wei Yang
Revision	DIFLUNISAL TABLETS PF 44(6) Pg. ONLINE	IDENTIFICATION/B. 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	Wei Yang
New	DIPHENHYDRAMINE HYDROCHLORIDE ORAL POWDER PF 44(5) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/A.	Clydewyn Anthony

Revision	DOBUTAMINE HYDROCHLORIDE PF 43(6) Pg. ONLINE	IDENTIFICATION/A. Infrared Absorption <197K><197>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Color of Solution, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Dobutamine Related Compound C RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Dopamine Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Raspberry Ketone RS	Edith Chang
Revision	DOXYCYCLINE COMPOUNDED ORAL SUSPENSION, VETERINARY PF 44(4) Pg. ONLINE	DEFINITION/Introduction, ASSAY/Procedure1: Oral Suspension in Paraben Solution, ASSAY/Procedure 2: Oral Suspension in Fixed Oil, SPECIFIC TESTS/pH <791>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Beyond-Use Date	Brian Serumaga
Revision	ERGOCALCIFEROL PF 44(6) Pg. ONLINE	IDENTIFICATION/Infrared Absorption <197K>, IDENTIFICATION/Ultraviolet Absorption <197U>, IDENTIFICATION/C., IDENTIFICATION/D. Thin-Layer Chromatography, ASSAY/Procedure, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ergosterol RSC28H44O396.66	Huy Dinh
Revision	FENTANYL PF 44(1) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K><197>, ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/ USP Fentanyl Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/ USP Fentanyl Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/ USP Fentanyl Related Compound D RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Fentanyl Related Compound E RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Fentanyl Related Compound G RS	Wei Yang
Revision	GELATIN Stage 6 Harmonization	Entire Document	Tong Liu
New	GLYCERYL MONO AND DICAPRYLATE PF 44(5) Pg. ONLINE	Chemical Info/Chemical Structure, Chemical Info/Octanoic acid, monoester and diester with 1,2,3-propanetriol;, Chemical Info/Caprylic acid, monoglyceride and diglyceride;, Chemical Info/ Glyceryl mono and dioctanoate;, Chemical Info/Mono and dicapryl glycerides, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Fatty Acid Composition, IDENTIFICATION/B. Glyceride Content, IDENTIFICATION/C. Fats and Fixed Oils <401>, Procedures, Saponification Value, ASSAY/Content of Monoglycerides, Diglycerides, and Triglycerides, IMPURITIES/Total Ash, IMPURITIES/Limit of Free Glycerol, SPECIFIC TESTS/Fats and Fixed Oils <401>, Procedures, Acid Value, SPECIFIC TESTS/Fats and Fixed Oils <401>, Procedures, Peroxide Value, SPECIFIC TESTS/Water Determination <921>, Method I, Method Ia, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Glyceryl Monocaprylate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methyl Caprate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methyl Caproate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methyl Caprylate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methyl Laurate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methyl Myristate RS	Peng Zhang

		Chemical Info/Chemical Structure, Chemical Info/Octanoic acid, monoester and diester with 1,2,3-propanetriol and decanoic acid, monoester and diester with 1,2,3-propanetriol; , Chemical Info/Caprylic acid monoglyceride and diglyceride and capric acid monoglyceride and diglyceride; , Chemical Info/Glyceryl mono and dioctanoate and glyceryl mono and didecanoate; , Chemical Info/Glycerides, C8-10 monoglycerides and diglycerides; , Chemical Info/C8-10 mono- and diglycerides, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Fatty Acid Composition, IDENTIFICATION/B. Glyceride Content, IDENTIFICATION/C. Fats and Fixed Oils <401>, Procedures, Saponification Value, ASSAY/Content of Monoglycerides, Diglycerides, and Triglycerides, IMPURITIES/Total Ash, IMPURITIES/Limit of Free Glycerol, SPECIFIC TESTS/Fats and Fixed Oils <401>, Procedures, Acid Value, SPECIFIC TESTS/Fats and Fixed Oils <401>, Procedures, Peroxide Value, SPECIFIC TESTS/Water Determination <921>, Method I, Method Ia, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Glyceryl Mono and Dicaprylocaprate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methyl Caprate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methyl Caproate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methyl Caprylate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methyl Laurate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methyl Myristate RS	
New	GLYCERYL MONO AND DICAPRYLOCAPRATE PF 44(5) Pg. ONLINE		Peng Zhang
New	GLYCERYL MONOSTEARATE PF 44(6) Pg. ONLINE	Glyceryl Monostearate	Margareth Marques
Revision	GLYCERYL MONOCAPRYLATE PF 44(5) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/C. Fats and Fixed Oils <401>, Procedures, Saponification Value, ASSAY/Content of Monoglycerides, Diglycerides, and Triglycerides, ADDITIONAL REQUIREMENTS/Labeling	Peng Zhang
Revision	GLYCERYL MONOCAPRYLOCAPRATE PF 44(5) Pg. ONLINE	Chemical Info/Chemical Name Monoglycerides, C8-10 C8-10 monoglycerides91052-46-9Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/C. Fats and Fixed Oils <401>, Procedures, Saponification Value, ASSAY/Content of Monoglycerides, Diglycerides, and Triglycerides, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Glyceryl Monocaprylocaprate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Glyceryl Mono and Dicaprylocaprate RS	Peng Zhang
Revision	HEXYLENE GLYCOL PF 44(4) Pg. ONLINE	Chemical Info/118.17118.18, 2-Methylpentane-2,4-diol, DEFINITION/Introduction, IDENTIFICATION/B. Chromatographic Identity, ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Acetone RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP 2-Propanol RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Propylene Glycol RS	Peng Zhang
Revision	HYDROCHLOROTHIAZIDE COMPOUNDED ORAL SUSPENSION PF 44(5) Pg. ONLINE	DEFINITION/Introduction, ASSAY/Procedure, SPECIFIC TESTS/pH <791>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Beyond-Use Date, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standard <11>/USP Hydrochlorothiazide RS	Jeanne Sun
Revision	HYDROCORTISONE GEL PF 44(6) Pg. ONLINE	IDENTIFICATION/Thin-Layer Chromatographic Identification Test <201>, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Microbial Enumeration Tests <61> and Tests for Specified Microorganisms <62>, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Prednisolone RS	Gerald Hsu

		IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., IDENTIFICATION/C., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Limit of 4-Chlorobenzoic Acid, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Indomethacin Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Indomethacin Related Compound B RS	
Revision	INDOMETHACIN EXTENDED-RELEASE CAPSULES PF 44(4) Pg. ONLINE		Wei Yang
New	LECITHIN PF 44(6) Pg. ONLINE	Lecithin	Margareth Marques
		ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Loperamide System Suitability Mixture RS	
Revision	LOPERAMIDE HYDROCHLORIDE PF 43(4) Pg. ONLINE		Andrea Carney
New	LYSOLECITHIN PF 44(6) Pg. ONLINE	Lysolecithin	Margareth Marques
New	MANGANESE CHLORIDE TETRAHYDRATE PF 44(6) Pg. ONLINE	Manganese Chloride Tetrahydrate	Margareth Marques
New	MANGANESE SULFATE PF 44(6) Pg. ONLINE	Manganese Sulfate	Margareth Marques
Omission	MANGANESE CHLORIDE FOR ORAL SOLUTION PF 44(2) Pg. ONLINE	Entire document	Gerald Hsu
Omission	MAZINDOL PF 44(4) Pg. ONLINE	Entire document	Hillary Cai
		DEFINITION/Introduction, IDENTIFICATION/Infrared Absorption <197K>, IDENTIFICATION/C., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Melamine RS	
Revision	METFORMIN HYDROCHLORIDE PF 44(6) Pg. ONLINE		Andrea Carney
		DEFINITION/Introduction, IDENTIFICATION/Infrared Absorption <197M>, ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Loss on Drying <731>, SPECIFIC TESTS/Water Determination <921>, Method I, Method Ia, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Beta-Methylcholine Chloride RS	
Revision	METHACHOLINE CHLORIDE PF 44(5) Pg. ONLINE		Mary Koleck
Revision	Methyl Red PF 44(6) Pg. ONLINE	Methyl Red	Margareth Marques
Revision	Methyl Red PF 44(6) Pg. ONLINE	Methyl Red	Margareth Marques
Omission	MINOCYCLINE HYDROCHLORIDE ORAL SUSPENSION PF 44(3) Pg. ONLINE	Entire document	Praveen Pabba
		IDENTIFICATION/A. Infrared Absorption <197M><197>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities	
Revision	MINOXIDIL PF 44(2) Pg. ONLINE		Donald Min
		DEFINITION/Introduction, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Limit of N-Benzyl-N-methyl-ethanolamine, IMPURITIES/Organic Impurities, OTHER COMPONENTS/Content of Sorbitol, SPECIFIC TESTS/Bacterial Endotoxins Test <85>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Sorbitol RS, ORGANIC IMPURITIES	
Revision	NICARDIPINE HYDROCHLORIDE INJECTION PF 44(4) Pg. ONLINE		Donald Min
Omission	OPRENOLOL HYDROCHLORIDE EXTENDED-RELEASE TABLETS PF 44(6) Pg. ONLINE	Entire document	Donald Min
Omission	OXYCODONE AND ACETAMINOPHEN CAPSULES PF 44(6) Pg. ONLINE	Entire document	Hillary Cai
Omission	PARACHLOROPHENOL PF 44(6) Pg. ONLINE	Entire document	Praveen Pabba
		DEFINITION/Introduction, ASSAY/Procedure, SPECIFIC TESTS/pH <791>, SPECIFIC TESTS/Viscosity-Rotational Methods <912>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Beyond-Use Date, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Phenytoin RS	
New	PHENYTOIN COMPOUNDED TOPICAL GEL PF 44(5) Pg. ONLINE		Jeanne Sun
New	18 N PHOSPHORIC ACID TS PF 44(6) Pg. ONLINE	18 N Phosphoric Acid TS-	Margareth Marques
Omission	PHYSOSTIGMINE SALICYLATE OPHTHALMIC SOLUTION PF 44(5) Pg. ONLINE	Entire document	Claire Chisolm

Omission	PIPERAZINE CITRATE TABLETS PF 44(6) Pg. ONLINE	Entire document	Jane Li
New	POLYPEPTONE PF 44(6) Pg. ONLINE	Polypeptone	Margareth Marques
		Chemical Info/Chemical Structure, Chemical Info/C18H38O(C3H6O) _n , where the average value of n is 11., Chemical Info/Poly[oxy(methyl-1,2-ethanedyl)], α-octadecyl-ω-hydroxy-; , Chemical Info/Polypropylene glycol monooctadecyl ether; , Chemical Info/Polyoxypropylene 11 stearyl ether, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197A>, IDENTIFICATION/B., IDENTIFICATION/C., IDENTIFICATION/D. Viscosity, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Limit of Free Propylene Oxide, SPECIFIC TESTS/Fats and Fixed Oils <401>, Procedures, Acid Value, SPECIFIC TESTS/Fats and Fixed Oils <401>, Procedures, Hydroxyl Value, SPECIFIC TESTS/Fats and Fixed Oils <401>, Procedures, Iodine Value, Method I, SPECIFIC TESTS/Fats and Fixed Oils <401>, Procedures, Peroxide Value, SPECIFIC TESTS/Fats and Fixed Oils <401>, Procedures, Saponification Value, SPECIFIC TESTS/Water Determination <921>, Method I, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Polypropylene Glycol 11 Stearyl Ether RS	
New	POLYPROPYLENE GLYCOL 11 STEARYL ETHER PF 44(4) Pg. ONLINE		Peng Zhang
New	POLYSORBATE 20 PF 44(6) Pg. ONLINE	Polysorbate 20	Margareth Marques
		DEFINITION/Introduction, IDENTIFICATION/A. Spectroscopic Identification Tests <197>, Infrared Spectroscopy, IDENTIFICATION/B., IDENTIFICATION/D. Identification Tests-General <191>, Chemical Identification Tests, Potassium, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>	
Revision	POTASSIUM ALGINATE PF 44(6) Pg. ONLINE		Sean Delaney
		2,4-Hexadienoic acid, potassium salt; , Chemical Info/Chemical Name Potassium (2E,4E)-hexa-2,4-dienoate; , Chemical Info/Chemical Name, DEFINITION/Introduction, IDENTIFICATION/B.Infrared Absorption <197A> or <197K>, ASSAY/Procedure, ASSAY/Procedure 1: Content of Potassium Sorbate, ASSAY/Procedure 2: Content of Potassium, IMPURITIES/Limit of Aldehyde, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>	
Revision	POTASSIUM SORBATE PF 44(2) Pg. ONLINE		Peng Zhang
Omission	PREDNISOLONE CREAM PF 44(6) Pg. ONLINE	Entire document	Ren-Hwa Yeh
Omission	PRIMIDONE ORAL SUSPENSION PF 44(6) Pg. ONLINE	Entire document	Claire Chisolm
Omission	PROCAINE AND TETRACAINE HYDROCHLORIDES AND LEVONORDEFRIN INJECTION PF 44(6) Pg. ONLINE	Entire document	Ren-Hwa Yeh
Omission	PROMAZINE HYDROCHLORIDE SYRUP PF 44(6) Pg. ONLINE	Entire document	Ren-Hwa Yeh
Omission	PROPOXYCAINE HYDROCHLORIDE PF 44(5) Pg. ONLINE	Entire document	Ren-Hwa Yeh
Omission	PROPOXYCAINE AND PROCAINE HYDROCHLORIDES AND LEVONORDEFRIN INJECTION PF 44(6) Pg. ONLINE	Entire document	Ren-Hwa Yeh
Omission	PROPOXYCAINE AND PROCAINE HYDROCHLORIDES AND NOREPINEPHRINE BITARTRATE INJECTION PF 44(6) Pg. ONLINE	Entire document	Ren-Hwa Yeh
		DEFINITION/Introduction, ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Melting Range or Temperature, Class Ia <741>, SPECIFIC TESTS/Optical Rotation <781S>, Specific Rotation, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/ USP Propranolol Related Compound A RS	
Revision	PROPRANOLOL HYDROCHLORIDE PF 43(6) Pg. ONLINE		Donald Min
Omission	PROPYLIODONE PF 44(6) Pg. ONLINE	Entire document	Claire Chisolm
Omission	PYRVINIUM PAMOATE PF 44(6) Pg. ONLINE	Entire document	Praveen Pabba
Omission	PYRVINIUM PAMOATE ORAL SUSPENSION PF 44(6) Pg. ONLINE	Entire document	Praveen Pabba
Omission	PYRVINIUM PAMOATE TABLETS PF 44(6) Pg. ONLINE	Entire document	Praveen Pabba

		IDENTIFICATION/Infrared Absorption <197>, IDENTIFICATION/C., ASSAY/Procedure, IMPURITIES/Organic Impurities, Procedure 1, IMPURITIES/Organic Impurities, Procedure 2, SPECIFIC TESTS/Water Determination <921> , Method Ic, SPECIFIC TESTS/Loss on Drying, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Risedronate Related Compound A RS	
Revision	RISEDRONATE SODIUM PF 44(6) Pg. ONLINE		Andrea Carney
Omission	RITODRINE HYDROCHLORIDE PF 44(6) Pg. ONLINE	Entire document	Ren-Hwa Yeh
Omission	RITODRINE HYDROCHLORIDE INJECTION PF 44(6) Pg. ONLINE	Entire document	Ren-Hwa Yeh
Omission	RITODRINE HYDROCHLORIDE TABLETS PF 44(6) Pg. ONLINE	Entire document	Ren-Hwa Yeh
		DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Drug Release <724>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Rotigotine Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Rotigotine Related Compound C RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Rotigotine Related Compound K RS	
New	ROTIGOTINE TRANSDERMAL SYSTEM PF 43(5) Pg. ONLINE		Ravi Ravichandran
		DEFINITION/Introduction, ASSAY/Procedure, SPECIFIC TESTS/Ready Carbonizable Substances Test <271>, SPECIFIC TESTS/Color of Solution, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP o-Toluenesulfonamide RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP p-Toluenesulfonamide RS	
Revision	SACCHARIN CALCIUM PF 44(2) Pg. ONLINE		Tong Liu
Omission	SCOPOLAMINE HYDROBROMIDE INJECTION PF 44(6) Pg. ONLINE	Entire document	Feiwen Mao
Omission	SCOPOLAMINE HYDROBROMIDE OPHTHALMIC SOLUTION PF 44(6) Pg. ONLINE	Entire document	Feiwen Mao
Omission	SCOPOLAMINE HYDROBROMIDE TABLETS PF 44(6) Pg. ONLINE	Entire document	Feiwen Mao
Omission	SECOBARBITAL PF 44(6) Pg. ONLINE	Entire document	Claire Chisolm
		DEFINITION/Introduction, IDENTIFICATION/A. Spectroscopic Identification Tests <197>, Infrared Spectroscopy, IDENTIFICATION/B., IDENTIFICATION/C. Identification Tests-General <191>, Chemical Identification Tests, Sodium, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>	
Revision	SODIUM ALGINATE PF 44(6) Pg. ONLINE		Sean Delaney
New	SODIUM BUTYRATE PF 44(6) Pg. ONLINE	Sodium Butyrate	Margareth Marques
New	50 PERCENT SODIUM HYDROXIDE TS PF 44(6) Pg. ONLINE	50% Sodium Hydroxide TS	Margareth Marques
New	SODIUM OLEATE PF 44(6) Pg. ONLINE	Sodium Oleate	Margareth Marques
New	SODIUM PROPIONATE PF 44(6) Pg. ONLINE	Sodium Propionate	Margareth Marques
New	SODIUM TAUROCHOLATE PF 44(6) Pg. ONLINE	Sodium Taurocholate	Margareth Marques
New	SODIUM TAURODEOXYCHOLATE PF 44(6) Pg. ONLINE	Sodium Taurodeoxycholate	Margareth Marques
		Title, DEFINITION/Introduction, 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 Sodium Benzoate RS	
New	SODIUM BENZOATE COMPOUNDED ORAL SOLUTION PF 44(6) Pg. ONLINE		Brian Serumaga
		IDENTIFICATION/Procedure, IDENTIFICATION/B., ASSAY/Procedure, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Sodium Acetate RS	
Revision	SODIUM FLUORIDE GEL PF 44(4) Pg. ONLINE		Michael Chang
		IDENTIFICATION/B., ASSAY/Procedure, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Sodium Acetate RS	
Revision	SODIUM FLUORIDE TABLETS PF 44(5) Pg. ONLINE		Michael Chang

Revision	TETRACYCLINE HYDROCHLORIDE PF 43(3) Pg. ONLINE	IDENTIFICATION/C. Identification Tests-General <191>, Chemical Identification Tests, Chloride, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Loss on Drying <731>	Praveen Pabba
Omission	THIORIDAZINE HYDROCHLORIDE ORAL SOLUTION PF 44(6) Pg. ONLINE	Entire document	Sridevi Ramachandran
Revision	TORSEMIDE COMPOUNDED ORAL SUSPENSION PF 44(5) Pg. ONLINE	DEFINITION/Introduction, 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 Torsemide RS	Brian Serumaga
Revision	MEDIUM-CHAIN TRIGLYCERIDES PF 44(6) Pg. ONLINE	IDENTIFICATION/A., IDENTIFICATION/B., IMPURITIES/Alkaline Impurities, SPECIFIC TESTS/Fats and Fixed Oils, Unsaponifiable Matter <401>, SPECIFIC TESTS/Fats and Fixed Oils, Saponification Value <401>, SPECIFIC TESTS/Refractive Index <831>, SPECIFIC TESTS/Bacterial Endotoxins Test <85>, ADDITIONAL REQUIREMENTS/Labeling	Galina Holloway
New	VANCOMYCIN HYDROCHLORIDE COMPOUNDED ORAL SOLUTION PF 44(2) Pg. ONLINE	DEFINITION/Introduction, 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 Vancomycin B RS	Jeanne Sun
Revision	VITAMIN A TABLETS PF 44(6) Pg. ONLINE	ASSAY/Introduction, ASSAY/Procedure 1, ASSAY/Procedure 2, PERFORMANCE TESTS/Dissolution <711>, ADDITIONAL REQUIREMENTS/Labeling	Natalia Davydova
Revision	OIL-SOLUBLE VITAMINS TABLETS PF 44(6) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/A., STRENGTH/Vitamin A, Method 1, STRENGTH/Vitamin A, Method 2, STRENGTH/Vitamin A, Method 3, STRENGTH/Vitamin D (Cholecalciferol or Ergocalciferol), Method 1, STRENGTH/Vitamin D (Cholecalciferol or Ergocalciferol), Method 2, STRENGTH/Vitamin D (Cholecalciferol or Ergocalciferol), Method 3, STRENGTH/Vitamin E, Method 1, STRENGTH/Vitamin E, Method 2, STRENGTH/Vitamin E, Method 3, STRENGTH/Vitamin A, Vitamin D, and Vitamin E, Method 4; Phytonadione, Method 3, ADDITIONAL REQUIREMENTS/Labeling:1  USP Units of activity for vitamins, where such exist or formerly existed, are equivalent to the corresponding international units, where such formerly existed. The USP Unit for Vitamin E has been discontinued. International units (IU) for vitamins also have been discontinued; however, the use of IU on the labels of vitamin products continues. Where articles are labeled in terms of Units in addition to the required labeling, the relationship of the USP Units or IU to mass is as follows. One USP Vitamin A Unit = 0.3 µg of all-trans-retinol (vitamin A alcohol) or 0.344 µg of all-trans-retinyl acetate (vitamin A acetate) or 0.55 µg of all-trans-retinyl palmitate (vitamin A palmitate), and 1 µg of retinol (3.3 USP Vitamin A Units) = 1 retinol equivalent (RE); 1 IU of beta carotene = 0.6 µg of all-trans-beta carotene; 1 USP Vitamin D Unit = 0.025 µg of ergocalciferol or cholecalciferol; and 1 mg of dlall-rac-alpha-tocopherol = 1., ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Retinyl Acetate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Retinyl Palmitate RS	Natalia Davydova

DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B.,
STRENGTH/Introduction, STRENGTH/Vitamin A, Method 1, STRENGTH/Vitamin D
(Cholecalciferol or Ergocalciferol), Method 1, STRENGTH/Vitamin E, Method 1,
STRENGTH/Phytonadione, Method 1, STRENGTH/Vitamin A, Vitamin D, Vitamin E, and
Phytonadione, Method 2, STRENGTH/Beta Carotene, ADDITIONAL
REQUIREMENTS/Labeling:1 1  USP Units of activity for vitamins, where such
exist or formerly existed, are equivalent to the corresponding international units, where
such formerly existed. The USP Unit for Vitamin E has been discontinued. International
units (IU) for vitamins also have been discontinued; however, the use of IU on the
labels of vitamin products continues. Where articles are labeled in terms of Units in
addition to the required labeling, the relationship of the USP Units or IU to mass is as
follows. One USP Vitamin A Unit = 0.3 µg of all-trans-retinol (vitamin A alcohol) or
0.344 µg of all-trans-retinyl acetate (vitamin A acetate) or 0.55 µg of all-trans-retinyl
palmitate (vitamin A palmitate), and 1 µg of retinol (3.3 USP Vitamin A Units) = 1
retinol equivalent (RE); 1 IU of beta carotene = 0.6 µg of all-trans-beta carotene; 1
USP Vitamin D Unit = 0.025 µg of ergocalciferol or cholecalciferol; and 1 mg of dlall-rac
alpha tocopherol = 1., ADDITIONAL REQUIREMENTS/USP Reference Standards
<11>/USP Beta Carotene RS, ADDITIONAL REQUIREMENTS/USP Reference Standards
<11>/USP Beta Carotene System Suitability RS

DEFINITION/Introduction, IDENTIFICATION/A., STRENGTH/Vitamin A, Method 1, STRENGTH/Vitamin A, Method 2, STRENGTH/Vitamin A, Method 3, STRENGTH/Vitamin D (Cholecalciferol or Ergocalciferol), Method 1, STRENGTH/Vitamin D (Cholecalciferol or Ergocalciferol), Method 2, STRENGTH/Vitamin D (Cholecalciferol or Ergocalciferol), Method 3, STRENGTH/Vitamin E, Method 1, STRENGTH/Vitamin E, Method 2, STRENGTH/Vitamin E, Method 3, STRENGTH/Vitamin A, Vitamin D (Cholecalciferol or Ergocalciferol), Vitamin E, Method 4; Phytonadione, Method 3, STRENGTH/Ascorbic Acid, Calcium Ascorbate, and Sodium Ascorbate, STRENGTH/Biotin, Method 2, STRENGTH/Cyanocobalamin, Method 2, STRENGTH/Folic Acid, Method 1, STRENGTH/Folic Acid, Method 2, STRENGTH/Calcium Pantothenate, Method 2, STRENGTH/Niacin or Niacinamide, Pyridoxine Hydrochloride, Riboflavin, and Thiamine, Method 1, STRENGTH/Niacin, Method 2, STRENGTH/Niacinamide, Method 2, STRENGTH/Riboflavin, Method 2, STRENGTH/Thiamine, Method 2, STRENGTH/Niacin or Niacinamide, Pyridoxine Hydrochloride, Riboflavin, and Thiamine, Method 3, STRENGTH/Folic Acid, Method 3; Ascorbic Acid, Niacin or Niacinamide, Pyridoxine Hydrochloride, Calcium Pantothenate, Riboflavin, and Thiamine, Method 4, ADDITIONAL REQUIREMENTS/Labeling:4 4  USP Units of activity for vitamins, where such exist or formerly existed, are equivalent to the corresponding international units, where such formerly existed. The USP Unit for Vitamin E has been discontinued. International units (IU) for vitamins also have been discontinued; however, the use of IU on the labels of vitamin products continues. Where articles are labeled in terms of Units in addition to the required labeling, the relationship of the USP Units or IU to mass is as follows. One USP Vitamin A Unit = 0.3 µg of all-trans-retinol (vitamin A alcohol) or 0.344 µg of all-trans-retinyl acetate (vitamin A acetate) or 0.55 µg of all-trans-retinyl palmitate (vitamin A palmitate), and 1 µg of retinol (3.3 USP Vitamin A Units) = 1 retinol equivalent (RE); 1 IU of beta carotene = 0.6 µg of all-trans-beta carotene; 1 USP Vitamin D Unit = 0.025 µg of ergocalciferol or cholecalciferol; and 1 mg of dlα-tocopherol = 1.1, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Retinyl Acetate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Retinyl Palmitate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Vitamin A RS 3,7-Dimethyl-9-(2,6,6-trimethyl-1-cyclohexen-1-yl) 2,4,6,8-nonatetraen-1-ol acetate (vitamin A acetate).

DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B., STRENGTH/Vitamin A, Method 1, STRENGTH/Vitamin A, Method 2, STRENGTH/Vitamin A, Method 3, STRENGTH/Vitamin D (Cholecalciferol or Ergocalciferol), Method 1, STRENGTH/Vitamin D (Cholecalciferol or Ergocalciferol), Method 2, STRENGTH/Vitamin D (Cholecalciferol or Ergocalciferol), Method 3, STRENGTH/Vitamin E, Method 1, STRENGTH/Vitamin E, Method 2, STRENGTH/Vitamin E, Method 3, STRENGTH/Vitamin A, Vitamin D (Cholecalciferol or Ergocalciferol), and Vitamin E, Method 4; Phytonadione, Method 3, STRENGTH/Ascorbic Acid, Calcium Ascorbate, and Sodium Ascorbate, STRENGTH/Biotin, Method 2, STRENGTH/Cyanocobalamin, Method 2, STRENGTH/Folic Acid, Method 1, STRENGTH/Folic Acid, Method 2, STRENGTH/Calcium Pantothenate, Method 2, STRENGTH/Niacin or Niacinamide, Pyridoxine Hydrochloride, Riboflavin, and Thiamine, Method 1, STRENGTH/Niacin, Method 2, STRENGTH/Niacinamide, Method 2, STRENGTH/Riboflavin, Method 2, STRENGTH/Thiamine, Method 2, STRENGTH/Niacin or Niacinamide, Pyridoxine Hydrochloride, Riboflavin, and Thiamine, Method 3, STRENGTH/Folic Acid Method 3; Ascorbic Acid, Niacin or Niacinamide, Pyridoxine Hydrochloride, Calcium Pantothenate, Riboflavin, and Thiamine, Method 4, ADDITIONAL REQUIREMENTS/Labeling:4 4  USP Units of activity for vitamins, where such exist or formerly existed, are equivalent to the corresponding international units, where such formerly existed. The USP Unit for Vitamin E has been discontinued. International units (IU) for vitamins also have been discontinued; however, the use of IU on the labels of vitamin products continues. Where articles are labeled in terms of Units in addition to the required labeling, the relationship of the USP Units or IU to mass is as follows. One USP Vitamin A Unit = 0.3 µg of all-trans-retinol (vitamin A alcohol) or 0.344 µg of all-trans-retinyl acetate (vitamin A acetate) or 0.55 µg of all-trans-retinyl palmitate (vitamin A palmitate), and 1 µg of retinol (3.3 USP Vitamin A Units) = 1 retinol equivalent (RE); 1 IU of beta carotene = 0.6 µg of all-trans-beta carotene; 1 USP Vitamin D Unit = 0.025 µg of ergocalciferol or cholecalciferol; and 1 mg of dlall-rac-alpha-tocopherol = 1.1, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Retinyl Acetate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Retinyl Palmitate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Vitamin A RS 3,7-Dimethyl-9-(2,6,6-trimethyl-1-cyclohexen-1-yl) 2,4,6,8-nonatetraen-1-ol acetate (vitamin A acetate).

Revision OIL- AND WATER-SOLUBLE VITAMINS WITH MINERALS TABLETS PF 44(6) Pg. ONLINE

Natalia Davydova

DEFINITION/Introduction, IDENTIFICATION/A., STRENGTH/Ascorbic Acid, Calcium Ascorbate, and Sodium Ascorbate, STRENGTH/Cyanocobalamin, Method 2, STRENGTH/Folic Acid, Method 1, STRENGTH/Folic Acid, Method 2, STRENGTH/Niacin or Niacinamide, Pyridoxine Hydrochloride, Riboflavin, and Thiamine, Method 1, STRENGTH/Niacin, Method 2, STRENGTH/Niacinamide, Method 2, STRENGTH/Riboflavin, Method 2, STRENGTH/Thiamine, Method 2, STRENGTH/Niacin or Niacinamide, Pyridoxine Hydrochloride, Riboflavin, and Thiamine, Method 3, STRENGTH/Folic Acid, Method 3; Ascorbic Acid, Niacin or Niacinamide, Pyridoxine Hydrochloride, Calcium Pantothenate, Riboflavin, and Thiamine, Method 4

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DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B.,
STRENGTH/Ascorbic Acid, Calcium Ascorbate, and Sodium Ascorbate, STRENGTH/Folic
Acid, Method 1, STRENGTH/Folic Acid, Method 2, STRENGTH/Niacin or Niacinamide,
Pyridoxine Hydrochloride, Riboflavin, and Thiamine, Method 1, STRENGTH/Niacin,
Method 2, STRENGTH/Niacinamide, Method 2, STRENGTH/Riboflavin, Method 2,
STRENGTH/Thiamine, Method 2, STRENGTH/Niacin or Niacinamide, Pyridoxine
Hydrochloride, Riboflavin, and Thiamine, Method 3, STRENGTH/Folic Acid, Method 3;
Ascorbic Acid, Niacin or Niacinamide, Pyridoxine Hydrochloride, Calcium Pantothenate,
Riboflavin, and Thiamine, Method 4, ADDITIONAL REQUIREMENTS/USP Reference
Standards <11>/USP Ascorbic Acid RS

Revision WATER-SOLUBLE VITAMINS WITH MINERALS TABLETS PF 44(6) Pg. ONLINE

Natalia Davydova

Revision Xylenol Orange PF 44(6) Pg. ONLINE

Xylenol Orange

Margareth Marques

Revision Xylenol Orange TS PF 44(6) Pg. ONLINE

Xylenol Orange TS

Margareth Marques
