

Compendial Cancellations for USPNF 2023 ISSUE 2

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Category	Monograph Title	Monograph Section	Scientific Liaison
Revision	EXCIPIENTS (USP and NF), LISTED BY CATEGORY PF 46(6) Pg. ONLINE	{Emulsifying Agent} Soybean Phosphatidylcholine, {Suspending and:::or Viscosity-Increasing Agent} Soybean Phosphatidylcholine, {Wetting and:::or Solubilizing Agent} Soybean Phosphatidylcholine	Peng Zhang
Revision	<2> ORAL DRUG PRODUCTS-PRODUCT QUALITY TESTS PF 48(2) Pg. ONLINE	Revision	Antonio Hernandez-Cardoso
Revision	DESCRIPTION AND SOLUBILITY PF 46(6) Pg. ONLINE	S/Soybean Phosphatidylcholine, U/Ulipristal Acetate	Peng Zhang
New	<621> CHROMATOGRAPHY PF 43(5) Pg. ONLINE	DEFINITIONS, SYSTEM SUITABILITY, ADJUSTMENT OF CHROMATOGRAPHIC CONDITIONS, QUANTIFICATION	Horacio Pappa
New	<1095> BATCH RELEASE TESTING FOR ENSURING COMPLIANCE WITH UNIFORMITY OF DOSAGE UNITS PF 47(4) Pg. ONLINE	New	Steven Walfish
Revision	<1099> LIMIT ON NUMBER OF LARGE DEVIATIONS WHEN ASSESSING CONTENT UNIFORMITY IN LARGE SAMPLES PF 47(4) Pg. ONLINE	Revision	Steven Walfish
Revision	<1604> PRESENTATION OF AERODYNAMIC PARTICLE SIZE DISTRIBUTION MEASUREMENT DATA PF 46(5) Pg. ONLINE	Revision	Kakhshan Zaidi
Revision	<1912> MEASUREMENT OF HARDNESS OF SEMISOLIDS PF 47(2) Pg. ONLINE	Revision	Antonio Hernandez-Cardoso
Revision	ABACAVIR, LAMIVUDINE AND ZIDOVUDINE TABLETS PF 47(3) Pg. ONLINE	IDENTIFICATION/A., IDENTIFICATION/B., PERFORMANCE TESTS/Dissolution (711), IMPURITIES/Organic Impurities IDENTIFICATION/A. Spectroscopic Identification Tests (177), Infrared Spectroscopy, IDENTIFICATION/B. Thin-Layer Chromatographic Identification Test (201), ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Christine Hiemer
Revision	BETAMETHASONE DIPROPIONATE PF 46(3) Pg. ONLINE	DEFINITION, IDENTIFICATION/A. HPTLC for Articles of Botanical Origin (203), IDENTIFICATION/B. HPLC, COMPOSITION/Content of Glucoraphanin, COMPOSITION, CONTAMINANTS/Botanicals Extracts (565), General Pharmacopeial Requirements, Preparations, Pesticide Residues, 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, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Shankari Shivaprasad
New	BROCCOLI SEED DRY EXTRACT PF 46(3) Pg. ONLINE		Maria Monagas

New	CARBIDOPA TABLETS PF 46(4) Pg. ONLINE	DEFINITION, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution (711), PERFORMANCE TESTS/Uniformity of Dosage Units (905), IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Shankari Shivaprasad
Revision	CLOBETASOL PROPIONATE CREAM PF 47(2) Pg. ONLINE	IDENTIFICATION/A. 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), SPECIFIC TESTS/pH (791), ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Shankari Shivaprasad
New	CLOBETASOL PROPIONATE LOTION PF 47(2) Pg. ONLINE	DEFINITION, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, IMPURITIES/Analysis, PERFORMANCE TESTS/Minimum Fill (755), SPECIFIC TESTS/pH (791), SPECIFIC TESTS/Microbial Enumeration Tests (61) and Tests for Specified Microorganisms (62), ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Shankari Shivaprasad
Revision	DANAZOL PF 46(4) Pg. ONLINE	CHEMICAL INFORMATION, IDENTIFICATION/B. Spectroscopic Identification Tests (197), Ultraviolet-Visible Spectroscopy: 197U, ASSAY/Procedure, IMPURITIES/Organic Impurities, IMPURITIES, SPECIFIC TESTS/Optical Rotation (781S), Specific Rotation, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Shankari Shivaprasad
Revision	DANAZOL CAPSULES PF 46(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)	Shankari Shivaprasad
New	DESOXIMETASONE TOPICAL SPRAY PF 46(4) Pg. ONLINE	DEFINITION, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, OTHER COMPONENTS/Content of Isopropyl Alcohol (2-Propanol), PERFORMANCE TESTS/Minimum Fill (755), IMPURITIES/Organic Impurities, SPECIFIC TESTS/Microbial Enumeration Tests (61) and Tests for Specified Microorganisms (62), ADDITIONAL REQUIREMENTS/Packaging and storage, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Shankari Shivaprasad
New	FULVESTRANT INJECTION PF 46(4) Pg. ONLINE	DEFINITION, IDENTIFICATION/A. Spectroscopic Identification Tests (197), Infrared Spectroscopy, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Bacterial Endotoxins Test (85), SPECIFIC TESTS/Sterility Tests (71), SPECIFIC TESTS/Particulate Matter in Injections (788), SPECIFIC TESTS/Other Requirements, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Shankari Shivaprasad
Revision	HARD GELATIN CAPSULE SHELLS PF 48(1) Pg. ONLINE	Revision	Margareth Marques

New	GEMCITABINE 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/pH (791), SPECIFIC TESTS/Sterility tests (71), SPECIFIC TESTS/Other Requirements, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Christine Hiemer
Revision	GLYCOPYRROLATE INJECTION PF 46(4) Pg. ONLINE	IDENTIFICATION/Chromatography (621), General Procedures, Thin-Layer Chromatography, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, OTHER COMPONENTS/Content of Benzyl Alcohol (if present), IMPURITIES/Organic Impurities, SPECIFIC TESTS/Bacterial Endotoxins Test (85), SPECIFIC TESTS/Sterility Tests (71), SPECIFIC TESTS/Particulate Matter in Injections (788), ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Christine Hiemer
Revision	HARD HYPROMELLOSE CAPSULE SHELLS PF 48(1) Pg. ONLINE	Revision	Margareth Marques
New	IBANDRONATE SODIUM INJECTION PF 46(4) Pg. ONLINE	DEFINITION, IDENTIFICATION/A. Spectroscopic Identification Tests (197), Ultraviolet-Visible Spectroscopy, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/pH (791), SPECIFIC TESTS/Particulate Matter in Injections (788), SPECIFIC TESTS/Bacterial Endotoxins Test (85), SPECIFIC TESTS/Osmolality and Osmolarity (785), Osmolality, SPECIFIC TESTS/Sterility Tests (71), ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards (11), FOOTNOTES	Christine Hiemer
New	IBANDRONATE SODIUM TABLETS PF 46(4) Pg. ONLINE	DEFINITION, IDENTIFICATION/A. Spectroscopic Identification Tests (197), Ultraviolet-Visible 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 REQUIREMENTS/USP Reference Standards (11), FOOTNOTES	Christine Hiemer
Revision	ANHYDROUS LACTOSE PF 46(5) Pg. ONLINE	IDENTIFICATION/B. Thin-Layer Chromatographic Identification Test (201), OTHER COMPONENTS/♦ Content of Alpha and Beta Anomers, SPECIFIC TESTS/Microbial Enumeration Tests (61) , Tests for Specified Microorganisms (62), and ♦Microbiological Examination of Nonsterile Products—Tests for Burkholderia Cepacia Complex (60)♦, SPECIFIC TESTS/♦ Bacterial Endotoxins Test (85), ADDITIONAL REQUIREMENTS/♦Labeling	Jenny Liu

Revision	LACTOSE MONOHYDRATE PF 46(5) Pg. ONLINE	DEFINITION, IDENTIFICATION/B., Thin-Layer Chromatographic Identification Test (201), SPECIFIC TESTS/Microbial Enumeration Tests (61) , Tests for Specified Microorganisms (62),♦ and ♦Microbiological Examination of Nonsterile Products—Tests for Burkholderia Cepacia Complex (60)♦, SPECIFIC TESTS/♦ Bacterial Endotoxins Test (85), SPECIFIC TESTS/Loss on Drying (731), ADDITIONAL REQUIREMENTS/♦Labeling	Jenny Liu
Revision	LIDOCAINE HYDROCHLORIDE INJECTION PF 46(3) Pg. ONLINE	IDENTIFICATION/Spectroscopic Identification Tests (197), Infrared Spectroscopy, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Sterility Tests (71), SPECIFIC TESTS/Bacterial Endotoxins Test (85), ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Shankari Shivaprasad
Revision	METHYLPHENIDATE HYDROCHLORIDE TABLETS PF 46(4) Pg. ONLINE	IDENTIFICATION/A. Spectroscopic Identification Tests (197), Infrared Spectroscopy, IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution (711) Procedure, Apparatus 1 and Apparatus 2, Immediate-release dosage forms, Procedure for a pooled sample for immediate release dosage forms, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Shankari Shivaprasad
Revision	NORTRIPTYLINE HYDROCHLORIDE ORAL SOLUTION PF 46(4) Pg. ONLINE	DEFINITION, IDENTIFICATION/A., IDENTIFICATION/C., ASSAY/Procedure, OTHER COMPONENTS/Alcohol Determination (611), Procedures, Method II (if present), IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Shankari Shivaprasad
New	OLMESARTAN MEDOXOMIL AND HYDROCHLOROTHIAZIDE TABLETS PF 46(3) Pg. ONLINE	DEFINITION, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution (711), PERFORMANCE TESTS/Uniformity of Dosage Units (905), IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Christine Hiemer
Revision	OXYBUTYNIN CHLORIDE TABLETS PF 47(1) 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, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Christine Hiemer
Revision	PROCARBAZINE HYDROCHLORIDE PF 46(4) Pg. ONLINE	CHEMICAL INFORMATION, DEFINITION, ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Christine Hiemer
New	HARD PULLULAN CAPSULE SHELLS PF 48(1) Pg. ONLINE	New	Margareth Marques
Revision	0.1 N Silver Nitrate VS PF 48(1) Pg. ONLINE	Revision	Mingyan Chu

New	SOYBEAN PHOSPHATIDYLCHOLINE PF 46(6) Pg. ONLINE	Identification of Phospholipids by Thin-Layer Chromatography, IDENTIFICATION/B. Identity by Fatty Acid Composition, ASSAY/Procedure, IMPURITIES/Organic Impurities, IMPURITIES/Free fatty acids and Triglycerides by Thin-layer Chromatography, SPECIFIC TESTS/Peroxide Value, SPECIFIC TESTS/Total Phosphorus Content, SPECIFIC TESTS/Microbial Enumeration Tests (61) and Tests for Specified Microorganisms (62), SPECIFIC TESTS/Bacterial Endotoxins Test (85), SPECIFIC TESTS/Water Determination (921), Method I, Method Ia, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards (11), FOOTNOTES	Peng Zhang
New	SUNITINIB MALATE PF 46(4) Pg. ONLINE	CHEMICAL INFORMATION, DEFINITION, 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), ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Christine Hiemer
Revision	TOLMETIN SODIUM PF 46(5) Pg. ONLINE	CHEMICAL INFORMATION, IDENTIFICATION/A. Spectroscopic Identification Tests (197), Infrared Spectroscopy, IDENTIFICATION/B. Spectroscopic Identification Tests (197), Ultraviolet-Visible Spectroscopy: 197U, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities	Christine Hiemer
New	TRIMIPRAMINE CAPSULES PF 46(3) Pg. ONLINE	DEFINITION, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution (711), PERFORMANCE TESTS/Uniformity of Dosage Units (905), IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Shankari Shivaprasad
New	ULIPRISTAL ACETATE TABLETS PF 46(5) Pg. ONLINE	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, Method Ic, SPECIFIC TESTS/Bacterial Endotoxins Test (85), SPECIFIC TESTS/Sterility Tests (71), SPECIFIC TESTS/Constituted Solution, SPECIFIC TESTS/Particulate Matter in Injections (788), SPECIFIC TESTS/Other Requirements, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards (11)	Shankari Shivaprasad
New	VECURONIUM BROMIDE FOR INJECTION PF 46(3) Pg. ONLINE	REQUIREMENTS/USP Reference Standards (11)	Shankari Shivaprasad