Compendial Cancellations for USP40-NF35 2S

Category	Monograph Title	Monograph Section	Scientific Liaison
Revision	DESCRIPTION AND SOLUBILITY PF 42(4) Pg. ONLINE	Guanidine Hydrochloride	Galina Holloway
New	<797> PHARMACEUTICAL COMPOUNDING--STERILE PREPARATIONS PF 41(6) Pg. ONLINE	INTRODUCTION, ORGANIZATION OF THIS CHAPTER, RESPONSIBILITY OF COMPOUNDING PERSONNEL, CSP MICROBIAL CONTAMINATION RISK LEVELS, PERSONNEL TRAINING AND EVALUATION IN ASEPTIC MANIPULATION SKILLS, IMMEDIATE-USE CSPS, SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS, HAZARDOUS DRUGS AS CSPS, RADIOPHARMACEUTICALS AS CSPS, ALLERGEN EXTRACTS AS CSPS, VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY, ENVIRONMENTAL QUALITY AND CONTROL, SUGGESTED STANDARD OPERATING PROCEDURES (SOPS), ELEMENTS OF QUALITY CONTROL, VERIFICATION OF AUTOMATED COMPOUNDING DEVICES (ACDS) FOR PARENTERAL NUTRITION COMPOUNDING, FINISHED PREPARATION RELEASE CHECKS AND TESTS, STORAGE AND BEYOND-USE DATING, MAINTAINING STERILITY, PURITY, AND STABILITY OF DISPENSED AND DISTRIBUTED CSPS, PATIENT OR CAREGIVER TRAINING, PATIENT MONITORING AND ADVERSE EVENTS REPORTING, QUALITY ASSURANCE (QA) PROGRAM, ABBREVIATIONS AND ACRONYMS, GLOSSARY, *No Head*, 1. INTRODUCTION AND SCOPE, 2. PERSONNEL QUALIFICATIONS-TRAINING, EVALUATION, AND REQUALIFICATION, 3. PERSONAL HYGIENE AND PERSONAL PROTECTIVE EQUIPMENT, 4. BUILDINGS AND FACILITIES, 5. ENVIRONMENTAL MONITORING, 6. CLEANING AND DISINFECTING COMPOUNDING AREAS, 7. EQUIPMENT AND COMPONENTS, 8. STERILIZATION AND DEPYROGENATION, 9. SOPS AND MASTER FORMULATION AND COMPOUNDING RECORDS, 10. RELEASE TESTING, 11. LABELING, 12. ESTABLISHING BEYOND-USE DATES AND IN-USE TIMES, 13. QUALITY ASSURANCE AND QUALITY CONTROL, 14. CSP STORAGE, HANDLING, PACKAGING, AND TRANSPORT, 15. COMPLAINT HANDLING AND ADVERSE EVENT REPORTING, 16. DOCUMENTATION, 17. RADIOPHARMACEUTICALS AS CSPS, APPENDICES	Jeanne Sun
New	<1168> COMPOUNDING FOR PHASE I INVESTIGATIONAL STUDIES PF 39(5) Pg. ONLINE	I. INTRODUCTION, II. REGULATORY ENVIRONMENT AND GUIDANCE, III. FACILITIES, IV. EQUIPMENT, V. PERSONNEL, VI. MATERIALS MANAGEMENT-PREPARATION, VII. MATERIALS MANAGEMENT-FINISHED PREPARATION, VIII. COMPOUNDING, IX. PACKAGING, LABELING, AND LABELS, X. QUALITY ASSURANCE PROGRAM MANAGEMENT, XI. STABILITY, STORAGE, AND DISTRIBUTION, XII. PROCEDURES AND DOSAGE FORMS, XIII. MISCELLANEOUS, XIV. CONCLUSIONS	Rick Schnatz
New	<1210> STATISTICAL TOOLS FOR PROCEDURE VALIDATION PF 40(5) Pg. ONLINE	Title, 1. INTRODUCTION, 2. WORK DONE BEFORE VALIDATION, 3. ACCURACY AND PRECISION, 4. RANGE DEFINITIONS, 5. LIMITS OF DETECTION AND QUANTITATION, 6. MODELLING THE CALIBRATION RELATIONSHIP (LINEARITY), 7. APPENDIX, 8. REFERENCES	Steven Walfish
Revision	CYPROHEPTADINE HYDROCHLORIDE TABLETS PF 42(3) Pg. ONLINE	IDENTIFICATION/A. Identification-Organic Nitrogenous Bases <181>, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Amitriptyline Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Cyproheptadine Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Cyproheptadine Related Compound C RS	Mary Koleck

Category	Monograph Title	Monograph Section	Scientific Liaison
Revision	DEXAMETHASONE TABLETS PF 39(5) Pg. ONLINE	IDENTIFICATION/A. Thin-Layer Chromatography, IDENTIFICATION/A. Infrared Absorption <197>, IDENTIFICATION/B., IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methylprednisolone RS	Domenick Vicchio
Revision	DOXYCYCLINE HYCLATE DELAYED-RELEASE TABLETS PF 42(4) Pg. ONLINE	IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Doxycycline Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Oxytetracycline Hydrochloride RS	Praveen Pabba
Revision	ETIDRONATE DISODIUM PF 42(3) Pg. ONLINE	IMPURITIES/Limit of Phosphite, IMPURITIES/Limit of Phosphite and Phosphate	Elena Gonikberg
New	FAMCICLOVIR TABLETS PF 42(4) Pg. ONLINE	Title, DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS, 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>/USP Famciclovir RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Famciclovir Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Famciclovir Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Famciclovir System Suitability Mixture RS	Shankari Shivaprasad
New	FENTANYL CITRATE COMPOUNDED INJECTION PF 42(5) Pg. ONLINE	Title, DEFINITION/Introduction, ASSAY/Procedure, SPECIFIC TESTS/pH <791>, SPECIFIC TESTS/Sterility Tests <71>, Test for Sterility of the Product to be Examined, Membrane Filtration, SPECIFIC TESTS/Bacterial Endotoxins Test <85>, SPECIFIC TESTS/Particulate Matter in Injections <788>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Beyond-Use Date, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Fentanyl Citrate RS	Jeanne Sun
New	FENTANYL CITRATE AND BUPIVACAINE HYDROCHLORIDE COMPOUNDED INJECTION PF 42(5) Pg. ONLINE	Title, DEFINITION/Introduction, ASSAY/Procedure, SPECIFIC TESTS/pH <791>, SPECIFIC TESTS/Sterility Tests <71>, Test for Sterility of the Product to be Examined, Membrane Filtration, SPECIFIC TESTS/Bacterial Endotoxins Test <85>, SPECIFIC TESTS/Particulate Matter in Injections <788>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Beyond-Use Date, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Bupivacaine Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Fentanyl Citrate RS	Jeanne Sun
New	FENTANYL CITRATE AND ROPIVACAINE HYDROCHLORIDE COMPOUNDED INJECTION PF 42(5) Pg. ONLINE	Title, DEFINITION/Introduction, ASSAY/Procedure, ASSAY/Enantiomeric Purity, SPECIFIC TESTS/pH <791>, SPECIFIC TESTS/Sterility Tests <71>, Test for Sterility of the Product to be Examined, Membrane Filtration, SPECIFIC TESTS/Bacterial Endotoxins Test <85>, SPECIFIC TESTS/Particulate Matter in Injections <788>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Beyond-Use Date, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Fentanyl Citrate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ropivacaine Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ropivacaine Related Compound B RS	Jeanne Sun

Category	Monograph Title	Monograph Section	Scientific Liaison
Revision	FLUORESCEIN PF 40(5) Pg. ONLINE	IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Fluorescein Related Compound C RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Phthalic Acid RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Resorcinol RS	Feiwen Mao
Revision	GONADORELIN ACETATE PF 40(3) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, OTHER COMPONENTS/Acetic Acid in Peptides <503>, IMPURITIES/Gonadorelin Related Impurities, IMPURITIES/Acetic Acid and, IMPURITIES/Limit of Fluoride, SPECIFIC TESTS/Optical Rotation, Specific Rotation <781S>, SPECIFIC TESTS/Bacterial Endotoxins <85>, SPECIFIC TESTS/Microbial Enumeration Tests <61> and Tests for Specified Microorganisms <62>, SPECIFIC TESTS/Amino Acid Analysis, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Endotoxin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Glacial Acetic Acid RS	Trish Li
Revision	HYPROMELLOSE PF 42(5) Pg. ONLINE	ASSAY/Procedure	Kevin Moore
Revision	METHYLCELLULOSE PF 42(5) Pg. ONLINE	ASSAY/Procedure	Kevin Moore
New	NAPROXEN SODIUM AND PSEUDOEPHEDRINE HYDROCHLORIDE EXTENDED-RELEASE TABLETS PF 40(5) Pg. ONLINE	Title, DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Naproxen Sodium Related Impurities, IMPURITIES/Pseudoephedrine Hydrochloride Related Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ephedrine Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Naproxen Related Compound K RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Naproxen Related Compound L RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Naproxen Sodium RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Pseudoephedrine Hydrochloride RS	Hillary Cai