Compendial Cancellations for USP38-NF33

Category	Monograph Title <111> DESIGN AND ANALYSIS OF BIOLOGICAL ASSAYS PF	Monograph Section	Scientific Liaison
Revision	39(4) Pg. ONLINE	General Title, INTRODUCTION, POLYETHYLENE CONTAINERS, POLYPROPYLENE CONTAINERS, POLYETHYLENE TEREPHTHALATE BOTTLES AND POLYETHYLENE TEREPHTHALATE G	Maura Kibbey
Revision	<661> CONTAINERS PLASTICS PF 39(5) Pg. ONLINE <661.1> PLASTIC MATERIALS OF CONSTRUCTION PF 39(5)	CONTAINERS, TEST METHODS, SCOPE	<u>Desmond Hunt</u>
New	Pg. ONLINE <661.2> PLASTIC PACKAGING SYSTEMS FOR	Title, INTRODUCTION, SCOPE, TEST METHODS, SPECIFICATIONS	<u>Desmond Hunt</u>
New	PHARMACEUTICAL USE PF 39(5) Pg. ONLINE	Title, INTRODUCTION, SCOPE, TEST METHODS, SPECIFICATIONS	<u>Desmond Hunt</u>
Revision	<851> SPECTROPHOTOMETRY AND LIGHT-SCATTERING PF 39(3) Pg. ONLINE	ULTRAVIOLET, VISIBLE, INFRARED, ATOMIC ABSORPTION, FLUORESCENCE, TURBIDIMETRY, NEPHELOMETRY, AND RAMAN MEASUREMENTLIGHT-SCATTERING, COMPARATIVE UTILITY OF SPECTRAL RANGES, THEORY AND TERMS, APPARATUS, PROCEDURE	Horacio Pappa
Revision	AMANTADINE HYDROCHLORIDE PF 39(3) Pg. ONLINE	ASSAY/Procedure, IMPURITIES/Organic Impurities, IDENTIFICATION/Infrared Absorption <197S>, ASSAY/Procedure	Shankari Shivaprasad
Revision	AMANTADINE HYDROCHLORIDE CAPSULES PF 39(5) Pg. ONLINE	PERFORMANCE TESTS/Dissolution <711>	Shankari Shivaprasad
New	ARTEMETHER AND LUMEFANTRINE TABLETS PF 39(1) Pg. ONLINE	Title, DEFINITION/Introduction, IDENTIFICATION/A., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Procedure for Artemether, IMPURITIES/Procedure for Lumefantrine, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Artemether RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Artemether Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Artemether Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Lumefantrine RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Lumefantrine Related Compound A RS	
		IDENTIFICATION/A. Infrared Absorption <197S>, IDENTIFICATION/A. Infrared Absorption	<u>Shankari Shivupi asau</u>
Revision	CLOFAZIMINE PF 39(6) Pg. ONLINE	<197>, IDENTIFICATION/B., ASSAY/Procedure, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Clofazimine Related Compound B RS	Shankari Shivaprasad
New	COSYNTROPIN PF 39(2) Pg. ONLINE	SPECIFIC TESTS/Optical Rotation, Specific Rotation <781S>	Dale Schmidt
Revision	DESCRIPTION AND SOLUBILITY PF 38(2) Pg. ONLINE	Rabeprazole Sodium, Entecavir	Elena Gonikberg

Title, Chemical Info/Chemical Structure, Chemical Info/C12H15N5O3·H2O, Chemical Info/295.29. Chemical Info/CAS. Chemical Info/6H-Purin-6-one. 2-amino-1.9-dihydro-9-[(1S,3R,4S)-4-hydroxy-3-(hydroxymethyl)-2-methylenecyclopentyl]-, monohydrate; Chemical Info/9-[(1S,3R,4S)-4-Hydroxy-3-(hydroxymethyl)-2-methylenecyclopentyl]guanine monohydrate., Chemical Info/Anhydrous, Chemical Info/277.28 [142217-69-4]., DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B. Infrared Absorption <197>, ASSAY/Procedure, IMPURITIES/Organic Impurities, IMPURITIES/Limit of Entecavir Related Compound A, SPECIFIC TESTS/Water Determination, Method 1c <921>, SPECIFIC TESTS/Optical Rotation, Specific Rotation <781S>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Entecavir Monohydrate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Entecavir Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Entecavir System Suitability Mixture RS

Shankari Shivaprasad

Title, DEFINITION/Introduction, IDENTIFICATION/A., 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>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Entecavir Monohydrate RS Shankari Shivaprasad

IDENTIFICATION/B. Identification of Fixed Oils by Thin-Layer Chromatography <202>

Huy Dinh

{Title} Fluconazole in Dextrose Injection, DEFINITION/Introduction, IDENTIFICATION/B. Test for Dextrose, ASSAY/Procedure, IMPURITIES/Introduction, IMPURITIES/Organic Impurities, IMPURITIES/Procedure 2: For Polar Impurities, IMPURITIES/Organic Impurities: Procedure 3, IMPURITIES/Organic Impurities: Procedure 4, ADDITIONAL REQUIREMENTS/Labeling

Shankari Shivaprasad

IDENTIFICATION/A. Infrared Absorption <197M>, IDENTIFICATION/B.

Sujatha Ramakrishna Sujatha Ramakrishna

PERFORMANCE TESTS/Uniformity of Dosage Units <905>

Huy Dinh

SPECIFIC TESTS/Osmolality and Osmolarity <785>

IMPURITIES/Heavy Metals, Method I <231>

Ahalya Wise

IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, IMPURITIES/Limit of Solvents, SPECIFIC TESTS/Optical Rotation, Specific Rotation <781S>, SPECIFIC TESTS/Loss on Drying (see Thermal Analysis <891>), SPECIFIC TESTS/Water Determination <921>

Ahalya Wise

Revision	GUANADREL SULFATE TABLETS PF 39(6) Pg. ONLINE
Revision	HISTIDINE PF 40(1) Pg. ONLINE IDARUBICIN HYDROCHLORIDE INJECTION PF 39(6) Pg
New	ONLINE

IMIPENEM PF 39(6) Pg. ONLINE

ENTECAVIR PF 39(2) Pg. ONLINE

ENTECAVIR TABLETS PF 39(2) Pg. ONLINE

EVENING PRIMROSE OIL PF 39(4) Pg. ONLINE

FLUCONAZOLE INJECTION PF 39(2) Pg. ONLINE

GUANADREL SULFATE PF 39(6) Pg. ONLINE

New

New New

Revision

Revision

Revision

New		IMIPRAMINE PAMOATE CAPSULES PF 39(6) Pg. ONLINE	Title, DEFINITION/Introduction, IDENTIFICATION/A., 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>/USP Depramine RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Desipramine Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Iminodibenzyl RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Imipramine Pamoate RS IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Melting Range or Temperature <741>, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Loperamide Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP	Heather Joyce
Rev	ision	KETOCONAZOLE PF 39(6) Pg. ONLINE	Reference Standards <11>/USP Terconazole RS	Shankari Shivaprasad
New	v	LAMIVUDINE TABLETS PF 39(1) Pg. ONLINE	Title, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197M>, 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>/USP Lamivudine RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Lamivudine RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Lamivudine Resolution Mixture B RS	Shankari Shivaprasad
Rev	ision	LEVOFLOXACIN PF 39(2) Pg. ONLINE	Chemical Info/(−)-(S)-9-Fluoro-2,3-dihydro-3-methyl-10-(4-methyl-1-piperazinyl)-7-oxo-7H-pyrido[1,2,3-de]-1,4-[1,4]benzoxazine-6-carboxylic acid, hemihydrate, IMPURITIES/Paragraph Text, IMPURITIES/Organic Impurities, Procedure 1, IMPURITIES/Organic Impurities, Procedure 2, IMPURITIES/Organic Impurities (Enantiomeric Purity), Procedure 3, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Levofloxacin Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Levofloxacin Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Levofloxacin Related Compound D RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Reference Standards <11	Shankari Shivaprasad
New	v	LEVOFLOXACIN INJECTION PF 39(5) Pg. ONLINE	Title, DEFINITION/Introduction, IDENTIFICATION/A. Ultraviolet Absorption <197U>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Bacterial Endotoxins <85>, SPECIFIC TESTS/Sterility Tests <71>, SPECIFIC TESTS/PH <791>, SPECIFIC TESTS/Particulate Matter in Injections <788>, SPECIFIC TESTS/Osmolality and Osmolarity <785>, SPECIFIC TESTS/Other Requirements, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Levofloxacin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Levofloxacin Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Levofloxacin Related Compound B RS	Shankari Shivaprasad

Title, Chemical Info/Chemical Structure, Chemical Info/C18H2ON3NaO3S, Chemical Info/381.42, Chemical Info/1H-Benzimidazole, 2-[[[4-(3-methoxypropoxy)-3-methyl-2-pyridinyl]methyl]sulfinyl]-, sodium salt;, Chemical Info/2-[[[4-(3-Methoxypropoxy)-3-methyl-2-pyridinyl]methyl]sulfinyl]benzimidazole sodium salt, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., IDENTIFICATION/C. Identification Tests— General, Sodium <191>, ASSAY/Procedure, IMPURITIES/Heavy Metals, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Loss on Drying <731>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Rabeprazole Sodium RS

Title, DEFINITION/Introduction, IDENTIFICATION/A. Ultraviolet Absorption, IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>

Title, DEFINITION/Introduction, IDENTIFICATION/A. Ultraviolet Absorption, IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Acid Stage, PERFORMANCE TESTS/Buffer Stage, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Rabeprazole Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Rabeprazole Related Compound C RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Rabeprazole Related Compound D RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Rabeprazole Related Compound D RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Rabeprazole Related Compound D RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Rabeprazole Related Compound D RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Rabeprazole Related Compound D RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Rabeprazole Related Compound D RS

Title, Chemical Info/Chemical Structure, Chemical Info/[(C3H7N)m(C3H5ClO)n]·xCH2O3., Chemical Info/ Carbonic acid, compound with (chloromethyl)oxirane polymer with 2-propen-1-amine;, Chemical Info/Prop-2-en-1-amine polymer with (chloromethyl)oxirane carbonate, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197A>, ASSAY/Total Titratable Amines <541>, ASSAY/Carbonate Content, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Heavy Metals, Method II <231>, IMPURITIES/Limit of Chloride, IMPURITIES/Limit of Epichlorohydrin, IMPURITIES/Limit of Soluble Oligomers, IMPURITIES/Limit of Allyl Amine, SPECIFIC TESTS/Loss on Drying, SPECIFIC TESTS/Swell Index, SPECIFIC TESTS/Particle Size Determination, Light Diffraction Measurement of Particle Size <429>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Sevelamer Carbonate RS

Title, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197A>, ASSAY/Total Titratable Amines, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Limit of Soluble Oligomers, IMPURITIES/Limit of Allylamine, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Polyallylamine RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Sevelamer Carbonate RS

Sujatha Ramakrishna

Suiatha Ramakrishna

Elena Gonikberg

RABEPRAZOLE SODIUM DELAYED-RELEASE TABLETS PF 38(2)
Pg. ONLINE

SEVELAMER CARBONATE PF 38(6) Pg. ONLINE

SEVELAMER CARBONATE FOR ORAL SUSPENSION PF 38(6) Pg. ONLINE

New

New

New

SEVELAMED CADRONATE FOD ODAL SLISDENSION D

New	SEVELAMER CARBONATE TABLETS PF 38(6) Pg. ONLINE	Title, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197A>, ASSAY/Total Titratable Amines <541>, PERFORMANCE TESTS/Disintegration <701>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Limit of Soluble Oligomers, IMPURITIES/Limit of Allylamine, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Polyallylamine Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Sevelamer Carbonate RS	Sujatha Ramakrishna
New	SEVELAMER HYDROCHLORIDE PF 38(6) Pg. ONLINE	Title, Chemical Info/Chemical Structure, Chemical Info/(C3H7N)m(C3H5CIO)n·xHCI, Chemical Info/2-Propen-1-amine polymer with (chloromethyl)oxirane, hydrochloride; Chemical Info/Allylamine polymer with 1-chloro-2,3-epoxypropane, hydrochloride, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197A>, ASSAY/Total Titratable Amines, ASSAY/Chloride Content, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Heavy Metals, Method II <231>, IMPURITIES/Limit of Epichlorohydrin, IMPURITIES/Limit of Soluble Oligomers, IMPURITIES/Limit of Allyl Amine, SPECIFIC TESTS/Loss on Drying <731>, SPECIFIC TESTS/Swell Index, SPECIFIC TESTS/Particle Size Determination, Light Diffraction Measurement of Particle Size <429>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Sevelamer Hydrochloride RS	Sujatha Ramakrishna
		Title, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197A>, ASSAY/Total Titratable Amines <541>, PERFORMANCE TESTS/Disintegration <701>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Limit of Soluble Oligomers, IMPURITIES/Limit of Allylamine, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Polyallylamine Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP	
New	SEVELAMER HYDROCHLORIDE TABLETS PF 38(6) Pg. ONLINE	Sevelamer Hydrochloride RS ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Sulbactam Related	Sujatha Ramakrishna
Revision	SULBACTAM SODIUM PF 39(4) Pg. ONLINE	Compound C RS	Ahalya Wise
Revision New	THIORIDAZINE HYDROCHLORIDE PF 39(1) Pg. ONLINE TIGECYCLINE FOR INJECTION PF 39(6) Pg. ONLINE	Chemical Info/Chemical Structure, DEFINITION/Introduction, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Melting Range or Temperature <741>, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Thioridazine Related Compound F RS IDENTIFICATION/A. Infrared Absorption <197K>	Ravi Ravichandran Ahalya Wise
New	TRANDOLAPRIL AND VERAPAMIL HYDROCHLORIDE EXTENDED- RELEASE TABLETS PF 38(6) Pg. ONLINE	Title, DEFINITION/Introduction, IDENTIFICATION/A., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities, Procedure 1, IMPURITIES/Organic Impurities, Procedure 2, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Trandolapril RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Trandolapril Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Verapamil Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP REQUIREMENTS/USP Reference Standards <11>/USP Verapamil Related Compound B RS	Sujatha Ramakrishna