

Compendial Cancellations for USP40-NF35

Category	Monograph Title	Monograph Section	Scientific Liaison
Revision	ALBUTEROL SULFATE PF 41(4) Pg. ONLINE	Chemical Info/Chemical Structure, DEFINITION/Introduction, IDENTIFICATION/B. Ultraviolet Absorption <197U>, IDENTIFICATION/C., IDENTIFICATION/D., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Albuterol Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Albuterol Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Albuterol Related Compound C RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Levalbuterol Related Compound C RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Levalbuterol Related Compound E RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Levalbuterol Related Compound H RS	Ravi Ravichandran
New	GAMMA-AMINOBUTYRIC ACID CAPSULES PF 41(4) Pg. ONLINE	Title, DEFINITION/Introduction, IDENTIFICATION/A., STRENGTH/Procedure, PERFORMANCE TESTS/Disintegration and Dissolution <2040>, PERFORMANCE TESTS/Weight Variation <2091>, CONTAMINANTS/Microbial Enumeration Tests <2021>, CONTAMINANTS/Absence of Specified Microorganisms <2022>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Gamma-Aminobutyric Acid RS	Natalia Davydova

New	ATAZANAVIR SULFATE PF 42(1) Pg. ONLINE	<p>Title, Chemical Info/Chemical Structure, Chemical Info/C38H52N6O7· H2SO4, Chemical Info/802.93, Chemical Info/2,5,6,10,13-Pentaazatetradecanedioic acid, 3-12-bis(1,1-dimethylethyl)-8-hydroxy-4,11-dioxo-9-(phenylmethyl)-6-[[4-(2-pyridinyl)phenyl]methyl]-, dimethyl ester, (3S,8S,9S,12S)-, sulfate (1:1) (salt);, Chemical Info/Dimethyl (3S,8S,9S,12S)-9-benzyl-3,12-di-tert-butyl-8-hydroxy-4,11-dioxo-6-(p-2-pyridylbenzyl)-2,5,6,10,13-pentaazatetradecanedioate, sulfate (1:1) (salt), Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197>, IDENTIFICATION/B., IDENTIFICATION/C. Identification Tests-General <191>, Sulfate, ASSAY/Procedure, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Organic Impurities, IMPURITIES/Limit of Atazanavir Related Compound A, IMPURITIES/Limit of N-Methylpyrrolidone (if present), SPECIFIC TESTS/Water Determination <921>, SPECIFIC TESTS/Optical Rotation <781S>, Procedures, Specific Rotation, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Atazanavir Sulfate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Atazanavir Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Atazanavir System Suitability Mixture RS</p>	Shankari Shivaprasad
New	ATAZANAVIR CAPSULES PF 42(1) Pg. ONLINE	<p>Title, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197A>, 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>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Atazanavir Sulfate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Atazanavir System Suitability Mixture RS</p>	Shankari Shivaprasad
Revision	CARBAMAZEPINE EXTENDED-RELEASE TABLETS PF 41(2) Pg. ONLINE	<p>ASSAY/Procedure, IMPURITIES/Organic Impurities: Procedure 1, IMPURITIES/Organic Impurities: Procedure 2, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Carbamazepine Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Carbamazepine Related Compound B RS</p>	Heather Joyce

New CINNAMOMUM CASSIA BARK PF 40(5) Pg. ONLINE

Title, DEFINITION/Introduction, IDENTIFICATION/A. Thin-Layer Chromatography, IDENTIFICATION/B. HPLC, COMPOSITION/Content of Phenylpropanoids and Coumarin, COMPOSITION/Total Phenolic Content, CONTAMINANTS/Elemental Impurities-Procedures <233>, CONTAMINANTS/Articles of Botanical Origin, Pesticide Residues Analysis <561>, CONTAMINANTS/Microbial Enumeration Tests <2021>, CONTAMINANTS/Absence of Specified Microorganisms <2022>, SPECIFIC TESTS/Botanical Characteristics, SPECIFIC TESTS/Articles of Botanical Origin, Foreign Organic Matter <561>, SPECIFIC TESTS/Water Determination, Method II <921>, SPECIFIC TESTS/Articles of Botanical Origin, Total Ash <561>, SPECIFIC TESTS/Articles of Botanical Origin, Acid-Insoluble Ash <561>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Cinnamic Acid RS

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New CINNAMOMUM CASSIA BARK POWDER PF 40(5) Pg. ONLINE

Title, DEFINITION/Introduction, IDENTIFICATION/A. Thin-Layer Chromatography, IDENTIFICATION/B. HPLC, COMPOSITION/Content of Phenylpropanoids and Coumarin, COMPOSITION/Total Phenolic Content, CONTAMINANTS/Elemental Impurities-Procedures <233>, CONTAMINANTS/Articles of Botanical Origin, Pesticide Residues Analysis <561>, CONTAMINANTS/Microbial Enumeration Tests <2021>, CONTAMINANTS/Absence of Specified Microorganisms <2022>, SPECIFIC TESTS/Botanical Characteristics, SPECIFIC TESTS/Articles of Botanical Origin, Foreign Organic Matter <561>, SPECIFIC TESTS/Water Determination, Method II <921>, SPECIFIC TESTS/Articles of Botanical Origin, Total Ash <561>, SPECIFIC TESTS/Articles of Botanical Origin, Acid-Insoluble Ash <561>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Cinnamic Acid RS

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New	CINNAMOMUM VERUM BARK PF 40(5) Pg. ONLINE	Title, DEFINITION/Introduction, IDENTIFICATION/A. Thin-Layer Chromatography, IDENTIFICATION/B. HPLC, IDENTIFICATION/C. GC, COMPOSITION/Content of Phenylpropanoids and Coumarin, COMPOSITION/Total Phenolic Content, COMPOSITION/Content of Eugenol, CONTAMINANTS/Elemental Impurities-Procedures <233>, CONTAMINANTS/Articles of Botanical Origin, Pesticide Residues Analysis <561>, CONTAMINANTS/Microbial Enumeration Tests <2021>, CONTAMINANTS/Absence of Specified Microorganisms <2022>, SPECIFIC TESTS/Botanical Characteristics, SPECIFIC TESTS/Articles of Botanical Origin, Foreign Organic Matter <561>, SPECIFIC TESTS/Water Determination, Method II <921>, SPECIFIC TESTS/Articles of Botanical Origin, Total Ash <561>, SPECIFIC TESTS/Articles of Botanical Origin, Acid-Insoluble Ash <561>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Cinnamic Acid RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Eugenol RS	Anton Bzhelyansky
New	CINNAMOMUM VERUM BARK POWDER PF 40(5) Pg. ONLINE	Title, DEFINITION/Introduction, IDENTIFICATION/A. Thin-Layer Chromatography, IDENTIFICATION/B. HPLC, IDENTIFICATION/C. GC, COMPOSITION/Content of Phenylpropanoids and Coumarin, COMPOSITION/Total Phenolic Content, COMPOSITION/Content of Eugenol, CONTAMINANTS/Elemental Impurities-Procedures <233>, CONTAMINANTS/Articles of Botanical Origin, Pesticide Residues Analysis <561>, CONTAMINANTS/Microbial Enumeration Tests <2021>, CONTAMINANTS/Absence of Specified Microorganisms <2022>, SPECIFIC TESTS/Botanical Characteristics, SPECIFIC TESTS/Articles of Botanical Origin, Foreign Organic Matter <561>, SPECIFIC TESTS/Water Determination, Method II <921>, SPECIFIC TESTS/Articles of Botanical Origin, Total Ash <561>, SPECIFIC TESTS/Articles of Botanical Origin, Acid-Insoluble Ash <561>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Cinnamic Acid RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Eugenol RS	Anton Bzhelyansky
Revision	HYDRALAZINE HYDROCHLORIDE PF 41(2) Pg. ONLINE	ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Water-Insoluble Substances, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP 1-Chlorophthalazine RS C8H5N2Cl164.59, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP 2-Formyl Benzoic Acid RSC8H6O3150.13, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Phthalazine RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP 1-Phthalazinone RS	Sujatha Ramakrishna
Revision	HYDRALAZINE HYDROCHLORIDE TABLETS PF 41(2) Pg. ONLINE	ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Phthalazine RS	Sujatha Ramakrishna

Revision	LIDOCAINE PF 40(4) Pg. ONLINE	IMPURITIES/Organic Impurities, SPECIFIC TESTS/Melting Range or Temperature <741>, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Lidocaine Related Compound H RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ropivacaine Related Compound A RS	Mary Koleck
New	METHYLNALTREXONE BROMIDE PF 41(5) Pg. ONLINE	Title, Chemical Info/Chemical Structure, Chemical Info/C21H26BrNO4, Chemical Info/436.34, Chemical Info/Morphinanum, 17-(cyclopropylmethyl)-4,5-epoxy-3,14-dihydroxy-17-methyl-6-oxo-, bromide, (5α)-, Chemical Info/(17RS)-17-(Cyclopropylmethyl)-4,5α-epoxy-3,14-dihydroxy-17-methyl-6-oxomorphinanum bromide, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., IDENTIFICATION/C. Identification Tests-General <191>, Bromide, ASSAY/Procedure, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Organic Impurities, SPECIFIC TESTS/pH <791>, SPECIFIC TESTS/Water Determination <921>, Method Ic, SPECIFIC TESTS/Optical Rotation <781S>, Specific Rotation, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methylnaltrexone Bromide RS	Elena Gonikberg
Revision	METOPROLOL SUCCINATE PF 41(3) Pg. ONLINE	IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., IMPURITIES/Organic Impurities, Procedure 1, IMPURITIES/Content of Metoprolol Related Compound H and Metoprolol Related Compound I, IMPURITIES/, Procedure 2, SPECIFIC TESTS/Clarity and Color of Solution, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Metoprolol Related Compound H RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Metoprolol Related Compound I RS	Donald Min
Revision	MICONAZOLE PF 41(5) Pg. ONLINE	IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/A. Infrared Absorption <197>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Econazole Nitrate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Miconazole Related Compound F RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Miconazole Related Compound I RS	Clydewyn Anthony

New PALONOSETRON INJECTION PF 41(1) Pg. ONLINE

Title, DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Limit of Specified Impurities, IMPURITIES/Limit of Unspecified Impurities, SPECIFIC TESTS/pH <791>, SPECIFIC TESTS/Particulate Matter in Injections <788>, SPECIFIC TESTS/Bacterial Endotoxins Test <85>, SPECIFIC TESTS/Sterility Tests <71>, SPECIFIC TESTS/Other Requirements, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Endotoxin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Palonosetron Enantiomer RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Palonosetron Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Palonosetron Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Palonosetron Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Palonosetron Related Compound C RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Palonosetron Related Compound D RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Palonosetron Related Compound E RS

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Revision PSEUDOEPHEDRINE SULFATE PF 41(6) Pg. ONLINE

DEFINITION/Introduction, IDENTIFICATION/B. Ultraviolet Absorption <197U>, IDENTIFICATION/B., ASSAY/Procedure, ASSAY/Organic Impurities, SPECIFIC TESTS/Melting Range or Temperature, Class I <741>, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ephedrine Sulfate RS

[Clydewyn Anthony](#)

Revision SALICYLIC ACID GEL PF 40(4) Pg. ONLINE

IDENTIFICATION/A. Procedure, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>

[Ren-Hwa Yeh](#)

New

SOLIFENACIN SUCCINATE PF 41(5) Pg. ONLINE

Title, Chemical Info/Chemical Structure, Chemical Info/C₂₃H₂₆N₂O₂·C₄H₆O₄, Chemical Info/480.55, Chemical Info/Butanedioic acid, compound with (1S)-(3R)-1-azabicyclo[2.2.2]oct-3-yl 3,4-dihydro-1-phenyl-2(1H)-isoquinolinecarboxylate (1:1);, Chemical Info/(R)-Quinuclidin-3-yl (S)-1-phenyl-3,4-dihydroisoquinoline-2(1H)-carboxylate succinate salt (1:1)., Chemical Info/CAS, Chemical Info/Solifenacin, Chemical Info/C₂₃H₂₆N₂O₂, Chemical Info/362.46, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., IDENTIFICATION/C. Identification for Succinate, ASSAY/Procedure, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Organic Impurities, IMPURITIES/Stereoisomer Impurities, SPECIFIC TESTS/Loss on Drying <731>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Solifenacin Succinate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Solifenacin Identification Mixture A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Solifenacin Identification Mixture B RS

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