

## Compendial Cancellations for USP40-NF35 1S

Category	Monograph Title	Monograph Section	Scientific Liaison
New	<661.3> PLASTIC COMPONENTS AND SYSTEMS USED IN PHARMACEUTICAL MANUFACTURING PF 42(3) Pg. ONLINE	Title, Introduction, 1. INTRODUCTION, 2. SCOPE, 3. INITIAL ASSESSMENT, 4. RISK ASSESSMENT, 5. TEST METHODS, 6. SPECIFICATIONS	Desmond Hunt
Revision	<1225> VALIDATION OF COMPENDIAL METHODS PF 42(2) Pg. ONLINE	LIFE CYCLE MANAGEMENT OF ANALYTICAL PROCEDURES	Horacio Pappa
Revision	<1661> EVALUATION OF PLASTIC PACKAGING SYSTEMS AND THEIR MATERIALS OF CONSTRUCTION WITH RESPECT TO THEIR USER SAFETY IMPACT PF 42(3) Pg. ONLINE	Title, Introduction, 1. PLASTIC PACKAGING SYSTEMS AND THEIR MATERIALS OF CONSTRUCTION, 2. PLASTIC COMPONENTS AND SYSTEMS USED TO MANUFACTURE PHARMACEUTICAL DRUG PRODUCTS, GLOSSARY	Desmond Hunt
New	ACAMPROSATE CALCIUM PF 41(5) Pg. ONLINE	Title, Chemical Info/Chemical Structure, Chemical Info/C10H20CaN2O8S2, Chemical Info/400.48, Chemical Info/1-Propanesulfonic acid, 3-(acetylamino)-, calcium salt (2:1);, Chemical Info/Calcium 3-(acetylamino)propane-1-sulfonate, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., IDENTIFICATION/C. Identification Tests-General <191>, Calcium, ASSAY/Procedure, IMPURITIES/Limit of Acamprosate Related Compound A, IMPURITIES/Organic Impurities, SPECIFIC TESTS/pH <791>, SPECIFIC TESTS/Loss on Drying <731>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Acamprosate Calcium RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Acamprosate Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Acamprosate Related Compound B RS	Heather Joyce
Revision	ACETAZOLAMIDE PF 41(3) Pg. ONLINE	IMPURITIES/Silver-Reducing Substances, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Acetazolamide Related Compound D RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Acetazolamide Related Compound E RS	Ramanujam Prasad

		Title, DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities Related to Amlodipine, IMPURITIES/Organic Impurities Related to Atorvastatin, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Amlodipine Besylate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Amlodipine Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Amlodipine Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Amlodipine Related Compound E RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Amlodipine Related Compound F RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Atorvastatin Calcium RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Atorvastatin Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Atorvastatin Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Atorvastatin Related Compound C RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Atorvastatin Related Compound H RS	
New	AMLODIPINE AND ATORVASTATIN TABLETS PF 42(1) Pg. ONLINE	DEFINITION/Introduction	Sujatha Ramakrishna
Revision	AMOXICILLIN PF 42(3) Pg. ONLINE	IMPURITIES/Organic Impurities	Morgan Puderbaugh
Revision	CEFUROXIME AXETIL PF 41(2) Pg. ONLINE	DEFINITION/Introduction	Morgan Puderbaugh
New	1-CHLORO-4-NITROBENZENE PF 42(3) Pg. ONLINE	1-Chloro-4-nitrobenzene, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., IDENTIFICATION/C. Identification Tests-General <191>, Sodium, ASSAY/Procedure, IMPURITIES/Organic Impurities, IMPURITIES/Limit of Oxalate, SPECIFIC TESTS/Acidity or Alkalinity, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Cromolyn Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Cromolyn Related Compound B RS	Shankari Shivaprasad
Revision	CROMOLYN SODIUM PF 42(1) Pg. ONLINE	Febantel	Ravi Ravichandran
Revision	DESCRIPTION AND SOLUBILITY PF 41(4) Pg. ONLINE	IDENTIFICATION/A., IDENTIFICATION/A. Infrared Absorption <197A>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Doxycycline Related Compound A RS	Morgan Puderbaugh
Revision	DOXYCYCLINE PF 42(2) Pg. ONLINE	IDENTIFICATION/A. Infrared Absorption <197K><197>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Sterility Tests <71>, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Doxycycline Related Compound A RS	Morgan Puderbaugh
Revision	DOXYCYCLINE HYCLATE PF 42(2) Pg. ONLINE	SPECIFIC TESTS/Loss on Drying <731>	Morgan Puderbaugh
Revision	DOXYCYCLINE FOR INJECTION PF 42(3) Pg. ONLINE		Morgan Puderbaugh

Title, Chemical Info/Chemical Structure, Chemical Info/C20H22N4O6S, Chemical Info/446.48, Chemical Info/Carbamic acid, [[2-[(methoxyacetyl)amino]-4-(phenylthio)phenyl]carbonimidoyl]bis-, dimethyl ester;, Chemical Info/Dimethyl { [2-(2-methoxyacetamido)-4-(phenylthio)phenyl]imidocarbonyl}dicarbamate, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, 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/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Febantel RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Febantel Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Febantel Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Fenbendazole RS

New FEBANTEL PF 41(4) Pg. ONLINE

Morgan Puderbaugh

ASSAY/Procedure, OTHER COMPONENTS/Content of Benzalkonium Chloride, PERFORMANCE TESTS/Delivered Dose Uniformity (within container), PERFORMANCE TESTS/Delivered Dose Uniformity (within batch), IMPURITIES/Organic Impurities, SPECIFIC TESTS/Foreign Particulates, SPECIFIC TESTS/Droplet Size Distribution, SPECIFIC TESTS/Spray Pattern, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Benzalkonium Bromide RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Docusate Sodium RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Fluticasone Propionate Related Compound D RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Fluticasone Propionate Related Compounds Mixture RS This Reference Standard is a mixture of fluticasone propionate and fluticasone propionate related compounds D and F, and the chemical names for all are given below: Fluticasone propionate: S-Fluoromethyl 6 $\alpha$ ; , 9 $\alpha$ ; -difluoro-11 $\beta$ ; -hydroxy-16 $\alpha$ ; -methyl-3-oxo-17 $\alpha$ ; -propionyloxyandrosta-1,4-diene-17 $\beta$ ; -carbothioate. Fluticasone propionate related compound D: S-Methyl6 $\alpha$ ; , 9 $\alpha$ ; -difluoro-11 $\beta$ ; -hydroxy-16 $\alpha$ ; -methyl-3-oxo-17 $\alpha$ ; -propionyloxyandrosta-1,4-diene-17 $\beta$ ; -carbothioate. Fluticasone propionate related compound F: 6 $\alpha$ ; , 9 $\alpha$ ; -Difluoro-11 $\beta$ ; , 17 $\alpha$ ; -dihydroxy-16 $\alpha$ ; -methyl-3-oxoandrosta-1,4-diene-17 $\beta$ ; -carboxylic acid.

Revision FLUTICASONE PROPIONATE NASAL SPRAY PF 41(6) Pg. ONLINE

Ravi Ravichandran

Revision	HISTIDINE PF 41(6) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Heavy Metals <231>, Method I, IMPURITIES/Related Compounds, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP I-Alanine RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP I-Arginine RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Biotin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP I-Lysine Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Thiamine Hydrochloride RS	Huy Dinh
Revision	LEVAMISOLE HYDROCHLORIDE PF 41(3) Pg. ONLINE	IDENTIFICATION/A., IDENTIFICATION/A. Infrared Absorption <197>, IDENTIFICATION/B., IMPURITIES/Organic Impurities, SPECIFIC TESTS/Melting Range or Temperature <741>, SPECIFIC TESTS/Light Absorption, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Levamisole System Suitability Mixture RS	Morgan Puderbaugh
Revision	LINDANE PF 42(3) Pg. ONLINE	IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Lindane Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Lindane Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Lindane Related Compound C RS	Shankari Shivaprasad
Revision	LINDANE LOTION PF 42(3) Pg. ONLINE	IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Lindane Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Lindane Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Lindane Related Compound C RS	Shankari Shivaprasad
Revision	LINDANE SHAMPOO PF 42(3) Pg. ONLINE	IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Lindane Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Lindane Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Lindane Related Compound C RS	Shankari Shivaprasad
Revision	METHYLENE BLUE INJECTION PF 42(1) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B. Thin-Layer Chromatographic Identification Test <201>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, IMPURITIES/Limit of Azure B, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Azure B RS, DEFINITION/Introduction	Donald Min
Revision	MICONAZOLE NITRATE TOPICAL POWDER PF 41(2) Pg. ONLINE	IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Miconazole Related Compound F RS	Alan Potts

Revision	NORETHINDRONE PF 42(1) Pg. ONLINE	IDENTIFICATION/<197K>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Chromatographic Purity, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Melting Range or Temperature <741>, SPECIFIC TESTS/Completeness of Solution, SPECIFIC TESTS/Limit of Ethynyl Group, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Norethindrone Related Compound B RS	Ren-Hwa Yeh
Revision	NORETHINDRONE ACETATE PF 42(1) Pg. ONLINE	IDENTIFICATION/Infrared Absorption <197K>, IDENTIFICATION/B., IDENTIFICATION/C., ASSAY/Procedure, IMPURITIES/Chromatographic Purity, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Limit of Ethynyl Group, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Norethindrone RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Norethindrone Related Compound B RS	Ren-Hwa Yeh
Revision	POTASSIUM CHLORIDE EXTENDED-RELEASE TABLETS PF 42(3) Pg. ONLINE	IDENTIFICATION/ <191>	Ren-Hwa Yeh
New	ROSUVASTATIN TABLETS PF 40(6) Pg. ONLINE	Title, DEFINITION/Introduction, 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>/USP Rosuvastatin Calcium RS	Sujatha Ramakrishna
New	ROSUVASTATIN CALCIUM PF 40(2) Pg. ONLINE	Title, Chemical Info/Chemical Structure, Chemical Info/(C22H27FN3O6S)2 · Ca, Chemical Info/1001.14, Chemical Info/6-Heptenoic acid, 7-[4-(4-fluorophenyl)-6-(1-methylethyl)-2-[methyl(methylsulfonyl)amino]-5-pyrimidinyl]-3,5-dihydroxy-, calcium salt (2:1), (3R, 5S, 6E);, Chemical Info/[S-[R*, S*-(E)]]-7-[4-(4-Fluorophenyl)-6-(1-methylethyl)-2-[methyl(methylsulfonyl)amino]-5-pyrimidinyl]-3,5-dihydroxy-6-heptenoic acid, calcium salt (2:1);, Chemical Info/Calcium (3R,5S,E)-7-(4-(4-fluorophenyl)-6-isopropyl-2-(N-methylmethylsulfonamido)pyrimidin-5-yl)-3,5-dihydroxyhept-6-enoate salt (2:1), Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., IDENTIFICATION/C. Identification Tests-General, Calcium <191>, ASSAY/Procedure, IMPURITIES/Organic Impurities, IMPURITIES/Enantiomeric Purity, IMPURITIES/Limit of Chloride, SPECIFIC TESTS/Water Determination, Method Ic <921>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Rosuvastatin Calcium RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Rosuvastatin Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Rosuvastatin Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Rosuvastatin Related Compound C RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Rosuvastatin Related Compound D RS	Sujatha Ramakrishna

Revision TRETINOIN PF 41(4) Pg. ONLINE

DEFINITION/Introduction, IDENTIFICATION/B. Ultraviolet  
Absorption <197U>, IDENTIFICATION/B., ASSAY/Procedure,  
IMPURITIES/Limit of Isotretinoin, IMPURITIES/Organic  
Impurities

Feiwen Mao