

## Compendial Cancellations for USP42-NF37 2S

Category	Monograph Title	Monograph Section	Scientific Liaison
New	EXCIPIENTS (USP and NF), LISTED BY CATEGORY PF 42(4) Pg. ONLINE	{Chaotropic Agent}	<a href="#">Galina Holloway</a>
New	DESCRIPTION AND SOLUBILITY PF 44(1) Pg. ONLINE	Guanidine Hydrochloride	<a href="#">Galina Holloway</a>
New	<64> PROBIOTIC TESTS PF 43(2) Pg. ONLINE	Title, INTRODUCTION/Introduction, PROCEDURE/Identification, PROCEDURE/Enumeration, PERFORMANCE TESTS/, CONTAMINANTS/Introduction, CONTAMINANTS/Listeria, ADDITIONAL REQUIREMENTS/Storage, ADDITIONAL REQUIREMENTS/Labeling, ??UNKNOWN?/Introduction	<a href="#">Seong Jae Yoo</a>
Revision	<659> PACKAGING AND STORAGE REQUIREMENTS PF 44(4) Pg. ONLINE	GENERAL DEFINITIONS, MEDICAL GAS PACKAGING, TEMPERATURE AND STORAGE DEFINITIONS	<a href="#">Desmond Hunt</a>
Revision	<1079> GOOD STORAGE AND DISTRIBUTION PRACTICES FOR DRUG PRODUCTS. PF 44(4) Pg. ONLINE	Title, Introduction, INTRODUCTION, SCOPE, BACKGROUND INFORMATION, RESPONSIBILITIES, LABELING CONSIDERATIONS FOR DRUG PRODUCTS, QUALITY MANAGEMENT SYSTEM, CONCLUSION, GLOSSARY, 1. INTRODUCTION, 2. SCOPE, 3. RISK-BASED APPROACH TO THE STORAGE AND TRANSPORTATION OF FINISHED DRUG PRODUCTS, 4. RISK MITIGATION CATEGORIES AS QMS ELEMENTS	<a href="#">Desmond Hunt</a>
Revision	ALCLOMETASONE DIPROPIONATE CREAM PF 43(1) Pg. ONLINE	ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Alclometasone Dipropionate Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Betamethasone Dipropionate RS	<a href="#">Mary Koleck</a>
Revision	ALCLOMETASONE DIPROPIONATE OINTMENT PF 43(1) Pg. ONLINE	ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Alclometasone Dipropionate Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Betamethasone Dipropionate RS	<a href="#">Mary Koleck</a>
New	ANNATTO SEED TOCOTRIENOLS EXTRACT PF 42(3) Pg. ONLINE	Title, DEFINITION/Introduction, IDENTIFICATION/A., ASSAY/Procedure, SPECIFIC TESTS/Fats and Fixed Oils <401>, Peroxide Value, SPECIFIC TESTS/Water Determination <921>, Method Ia, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Annatto Seed Tocotrienols Extract RS	<a href="#">Huy Dinh</a>
Revision	ASPIRIN PF 41(6) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B. Infrared Absorption <197K> or <197A>, ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Readily Carbonizable Substances Test <271>, SPECIFIC TESTS/Substances Insoluble in Sodium Carbonate TS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Salicylic Acid RS	<a href="#">Clydewyn Anthony</a>

New	AZACITIDINE PF 43(5) Pg. ONLINE	<p>Title, Chemical Info/Chemical Structure, Chemical Info/C8H12N4O5, Chemical Info/244.20, Chemical Info/1,3,5-Triazin-2(1H)-one, 4-amino-1-&amp;beta;-d-ribofuranosyl-, Chemical Info/4-Amino-1-&amp;beta;-d-ribofuranosyl-s-triazin-2(1H)-one, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption &lt;197&gt;, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Residue on Ignition &lt;281&gt;, IMPURITIES/Organic Impurities, IMPURITIES/Limit of 1-&amp;beta;-d-Ribofuranosyl-3-guanylurea, SPECIFIC TESTS/Microbial Enumeration Tests &lt;61&gt; and Tests for Specified Microorganisms &lt;62&gt;, SPECIFIC TESTS/Bacterial Endotoxins Test &lt;85&gt;, SPECIFIC TESTS/Water Determination &lt;921&gt;, Method I, Method Ic, SPECIFIC TESTS/Optical Rotation &lt;781S&gt;, Procedures, Specific Rotation, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards &lt;11&gt;/USP Azacitidine RS, ADDITIONAL REQUIREMENTS/USP Reference Standards &lt;11&gt;/USP Azacitidine Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards &lt;11&gt;/USP Azacitidine Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards &lt;11&gt;/USP Azacitidine Related Compound C RS</p>	<a href="#">Feiwen Mao</a>
Revision	BETAMETHASONE DIPROPIONATE CREAM PF 42(6) Pg. ONLINE	<p>IDENTIFICATION/A. Thin-Layer Chromatographic Identification Test &lt;201&gt;, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards &lt;11&gt;/USP Betamethasone RS, ADDITIONAL REQUIREMENTS/USP Reference Standards &lt;11&gt;/USP Betamethasone Dipropionate Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards &lt;11&gt;/USP Betamethasone Dipropionate Related Compound C RS</p>	<a href="#">Mary Koleck</a>
Revision	BETAMETHASONE DIPROPIONATE LOTION PF 42(6) Pg. ONLINE	<p>IDENTIFICATION/A. Thin-Layer Chromatographic Identification Test &lt;201&gt;, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards &lt;11&gt;/USP Betamethasone RS, ADDITIONAL REQUIREMENTS/USP Reference Standards &lt;11&gt;/USP Betamethasone Dipropionate Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards &lt;11&gt;/USP Betamethasone Dipropionate Related Compound C RS</p>	<a href="#">Mary Koleck</a>

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New

BRIMONIDINE TARTRATE OPHTHALMIC SOLUTION PF 44(4) Pg.  
ONLINE

Title, DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/ Sterility Tests <71>, SPECIFIC TESTS/ Antimicrobial Effectiveness Testing <51>, SPECIFIC TESTS/pH <791>, SPECIFIC TESTS/ Particulate Matter in Ophthalmic Solutions <789>, SPECIFIC TESTS/ Osmolality and Osmolarity <785>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/ USP Reference Standards <11>/USP Brimonidine Tartrate RS

[Feiwen Mao](#)

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New

CHOLINE FENOFIBRATE PF 42(6) Pg. ONLINE

Title, Chemical Info/Chemical Structure, Chemical Info/C22H28ClNO5, Chemical Info/421.91, Chemical Info/Ethanaminium, 2-hydroxy-N,N,N-trimethyl-, salt with 2-[4-(4-chlorobenzoyl)phenoxy]-2-methylpropanoic acid (1:1);, Chemical Info/2-Hydroxy-N,N,N-trimethylethanaminium 2-[4-(4-chlorobenzoyl)phenoxy]-2-methylpropanoate, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197A>, IDENTIFICATION/B., IDENTIFICATION/C., ASSAY/Procedure, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Water Determination <921>, Method I, Method Ic, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Choline Chloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Choline Fenofibrate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Fenofibrate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Fenofibric Acid RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Fenofibrate Related Compound C RS

[Sujatha Ramakrishna](#)

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Title, DEFINITION/Introduction, IDENTIFICATION/A. HPTLC for Articles of Botanical Origin <203>, IDENTIFICATION/B. HPLC, COMPOSITION/Content of Caffeoylquinic Acids and Flavone Glycosides, CONTAMINANTS/Articles of Botanical Origin <561>, Limits of Elemental Impurities, CONTAMINANTS/Articles of Botanical Origin <561>, Pesticide Residue Analysis, CONTAMINANTS/Articles of Botanical Origin <561>, Test for Aflatoxins, 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/Botanical Characteristics, SPECIFIC TESTS/Articles of Botanical Origin <561>, Methods of Analysis, Foreign Organic Matter, SPECIFIC TESTS/Articles of Botanical Origin <561>, Methods of Analysis, Alcohol-Soluble Extractives, Method 1, SPECIFIC TESTS/Articles of Botanical Origin <561>, Methods of Analysis, Water-Soluble Extractives, Method 2, SPECIFIC TESTS/Articles of Botanical Origin <561>, Methods of Analysis, Total Ash, SPECIFIC TESTS/Articles of Botanical Origin <561>, Methods of Analysis, Acid-Insoluble Ash, SPECIFIC TESTS/Loss on Drying <731>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Apigenin-7-glucoside RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Chlorogenic Acid RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Chrysanthemum × morifolium Flower Dry Extract RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Isochlorogenic Acid A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Luteolin 7-O-Glucoside RS

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Title, DEFINITION/Introduction, IDENTIFICATION/A. HPTLC for Articles of Botanical Origin <203>, IDENTIFICATION/B. HPLC, COMPOSITION/Content of Caffeoylquinic Acids and Flavone Glycosides, CONTAMINANTS/Botanical Extracts <565>, Preparations, General Pharmacopeial Requirements, Pesticide Residues, CONTAMINANTS/Articles of Botanical Origin <561>, Test for Aflatoxins, 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, SPECIFIC TESTS/Botanical Extracts <565>, Preparations, General Pharmacopeial Requirements, Residual Solvents, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Apigenin-7-glucoside RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Chlorogenic Acid RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Chrysanthemum × morifolium Flower Dry Extract RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Isochlorogenic Acid A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Luteolin 7-O-Glucoside RS

		Title, DEFINITION/Introduction, IDENTIFICATION/A. HPTLC for Articles of Botanical Origin <203>, IDENTIFICATION/B. HPLC, COMPOSITION/Content of Caffeoylquinic Acids and Flavone Glycosides, CONTAMINANTS/Articles of Botanical Origin <561>, Limits of Elemental Impurities, CONTAMINANTS/Articles of Botanical Origin <561>, Pesticide Residue Analysis, CONTAMINANTS/Articles of Botanical Origin <561>, Test for Aflatoxins, 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/Botanical Characteristics, SPECIFIC TESTS/Articles of Botanical Origin <561>, Methods of Analysis, Alcohol-Soluble Extractives, Method 1, SPECIFIC TESTS/Articles of Botanical Origin <561>, Methods of Analysis, Water-Soluble Extractives, Method 2, SPECIFIC TESTS/Articles of Botanical Origin <561>, Methods of Analysis, Total Ash, SPECIFIC TESTS/Articles of Botanical Origin <561>, Methods of Analysis, Acid-Insoluble Ash, SPECIFIC TESTS/Loss on Drying <731>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Apigenin-7-glucoside RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Chlorogenic Acid RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Chrysanthemum × morifolium Flower Dry Extract RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Isochlorogenic Acid A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Luteolin 7-O-Glucoside RS	
New	CHRYSANTHEMUM FLOWER POWDER PF 44(2) Pg. ONLINE		<a href="#">Cuiying Ma</a>
Revision	CLINDAMYCIN INJECTION PF 44(2) Pg. ONLINE	ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Clindamycin Phosphate System Suitability RS	<a href="#">Ramanujam Prasad</a>
Revision	CLINDAMYCIN PHOSPHATE PF 44(3) Pg. ONLINE	ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Sterility Tests <71>, SPECIFIC TESTS/Bacterial Endotoxins Test <85>	<a href="#">Ramanujam Prasad</a>
Revision	CLINDAMYCIN PHOSPHATE VAGINAL CREAM PF 44(4) Pg. ONLINE	ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Clindamycin Phosphate System Suitability RS	<a href="#">Ramanujam Prasad</a>
Revision	CLINDAMYCIN PHOSPHATE GEL PF 44(4) Pg. ONLINE	ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Clindamycin Phosphate System Suitability RS	<a href="#">Ramanujam Prasad</a>
Revision	CLINDAMYCIN PHOSPHATE TOPICAL SOLUTION PF 44(2) Pg. ONLINE	ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Clindamycin Phosphate System Suitability RS	<a href="#">Ramanujam Prasad</a>
Revision	CLINDAMYCIN PHOSPHATE VAGINAL INSERTS PF 44(2) Pg. ONLINE	ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Clindamycin Phosphate System Suitability RS	<a href="#">Ramanujam Prasad</a>

Revision	CLOMIPHENE CITRATE TABLETS PF 43(4) Pg. ONLINE	IDENTIFICATION/Identification-Organic Nitrogenous Bases <181>, IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage	<a href="#">Mary Koleck</a>
Revision	CYPROHEPTADINE HYDROCHLORIDE TABLETS PF 43(1) Pg. ONLINE	IMPURITIES/Organic Impurities	<a href="#">Mary Koleck</a>
New	DIPHENHYDRAMINE HYDROCHLORIDE ORAL POWDER PF 43(5) Pg. ONLINE	Title, DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Benzhydrol RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Benzophenone RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Diphenhydramine Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Diphenhydramine Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Diphenhydramine N-Oxide RS	<a href="#">Clydewyn Anthony</a>
Omission	ERGOTAMINE TARTRATE SUBLINGUAL TABLETS PF 44(2) Pg. ONLINE	Entire document	<a href="#">Heather Joyce</a>

New	EVEROLIMUS PF 42(6) Pg. ONLINE	<p>Title, Chemical Info/Chemical Structure, Chemical Info/C53H83NO14, Chemical Info/958.22, Chemical Info/(1R,9S,12S,15R,16E,18R,19R,21R,23S,24E,26E,28E,30S,32S,35R)-1,18-Dihydroxy-12-[(1R)-2-[(1S,3R,4R)-4-(2-hydroxyethoxy)-3-methoxycyclohexyl]-1-methylethyl]-19,30-dimethoxy-15,17,21,23,29,35-hexamethyl-11,36-dioxo-4-azatricyclo[30.3.1.04,9]hexatriaconta-16,24,26,28-tetraene-2,3,10,14,20-pentaone;, Chemical Info/(3S,6R,7E,9R,10R,12R,14S,15E,17E,19E,21S,23S,26R,27R,34a S)-9,10,12,13,14,21,22,23,24,25,26,27,32,33,34,34a-Hexadecahydro-9,27-dihydroxy-3-[(1R)-2-[(1S,3R,4R)-4-(2-hydroxyethoxy)-3-methoxycyclohexyl]-1-methylethyl]-10,21-dimethoxy-6,8,12,14,20,26-hexamethyl-23,27-epoxy-3H-pyrido[2,1-c][1,4]oxaazacyclohentracontine-1,5,11,28,29(4H,6H,31H)-pentone, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption &lt;197K&gt;, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Residue on Ignition &lt;281&gt;, IMPURITIES/Limit of Alcohol, IMPURITIES/Organic Impurities, IMPURITIES/Limit of Sirolimus, SPECIFIC TESTS/Water Determination &lt;921&gt;, Method I, SPECIFIC TESTS/Optical Rotation &lt;781S&gt;, Procedures, Specific Rotation, SPECIFIC TESTS/Microbial Enumeration Tests &lt;61&gt; and Tests for Specified Organisms &lt;62&gt;, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards &lt;11&gt;/USP Everolimus RS, ADDITIONAL REQUIREMENTS/USP Reference Standards &lt;11&gt;/USP Everolimus System Suitability Mixture RS, ADDITIONAL REQUIREMENTS/USP Reference Standards &lt;11&gt;/USP Sirolimus RS</p>	<a href="#">Morgan Puderbaugh</a>
New	FENOFIBRIC ACID DELAYED-RELEASE CAPSULES PF 42(6) Pg. ONLINE	<p>Title, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption &lt;197A&gt;, IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution &lt;711&gt;, PERFORMANCE TESTS/Uniformity of Dosage Units &lt;905&gt;, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards &lt;11&gt;/USP Fenofibric Acid RS</p>	<a href="#">Sujatha Ramakrishna</a>
Revision	GENTAMICIN SULFATE PF 43(3) Pg. ONLINE	<p>IDENTIFICATION/A. Infrared Absorption &lt;197K&gt;&lt;197&gt;, IDENTIFICATION/B., IMPURITIES/Organic Impurities, SPECIFIC TESTS/Content of Gentamicins</p>	<a href="#">Slavica Shane</a>



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New      GUANIDINE HYDROCHLORIDE PF 43(4) Pg. ONLINE

IDENTIFICATION/C. Identification Tests-General <191>, Chemical Identification Tests, Chloride, Title, Chemical Info/Chemical Structure, Chemical Info/CH5N3·HCl, Chemical Info/95.53, Chemical Info/Guanidine, hydrochloride (1:1);, Chemical Info/Guanidine hydrochloride, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197A> or <197K>, IDENTIFICATION/B. Ultraviolet Absorption <197U>, ASSAY/Procedure, IMPURITIES/Chloride and Sulfate <221>, Sulfate, IMPURITIES/Limit of Nitrate, IMPURITIES/Limit of Cyanide, IMPURITIES/Residue on Ignition <281>, SPECIFIC TESTS/Acidity, SPECIFIC TESTS/Water-Insoluble Substances, SPECIFIC TESTS/Loss on Drying <731>, SPECIFIC TESTS/Melting Range or Temperature <741>, Procedures, Class 1, SPECIFIC TESTS/Bacterial Endotoxins Test <85>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Endotoxin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Guanidine Hydrochloride RS

[Galina Holloway](#)

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New      LACOSAMIDE PF 43(6) Pg. ONLINE

Title, Chemical Info/Chemical Structure, Chemical Info/C13H18N2O3, Chemical Info/250.30, Chemical Info/Propanamide, 2-(acetylamino)-3-methoxy-N-(phenylmethyl)-, (2R)-;-, Chemical Info/(+)-(2R)-2-(Acetylamino)-N-benzyl-3-methoxypropanamide, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Limit of Lacosamide S-Enantiomer, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Water Determination <921>, Method I, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Lacosamide RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Lacosamide S-Enantiomer RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Lacosamide Related Compound B RS

[Ren-Hwa Yeh](#)

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New	LACOSAMIDE INJECTION PF 43(6) Pg. ONLINE	Title, DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/pH <791>, SPECIFIC TESTS/Particulate Matter in Injections <788>, SPECIFIC TESTS/Sterility Tests <71>, SPECIFIC TESTS/Bacterial Endotoxins Test <85>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Lacosamide RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Lacosamide Related Compound D RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Lacosamide Related Compound F RS	<a href="#">Ren-Hwa Yeh</a>
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New	LACOSAMIDE ORAL SOLUTION PF 43(6) Pg. ONLINE	Title, DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Deliverable Volume <698>, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Microbial Enumeration Tests <61> and Tests for Specified Microorganisms <62>, SPECIFIC TESTS/pH <791>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Lacosamide RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Lacosamide Related Compound D RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Lacosamide Related Compound F RS	<a href="#">Ren-Hwa Yeh</a>
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New	LACOSAMIDE TABLETS PF 43(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 Lacosamide RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Lacosamide Related Compound D RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Lacosamide Related Compound F RS	<a href="#">Ren-Hwa Yeh</a>
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Revision	MEGESTROL ACETATE TABLETS PF 42(6) Pg. ONLINE	IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Medroxyprogesterone Acetate RS USP Megestrol Acetate Related Compound D RS 6-Methylene-3,20-dioxopregn-4-ene-17-yl acetate.(C <sub>24</sub> H <sub>32</sub> O <sub>4</sub> 384.51 )USP Megestrol Acetate Related Compound H RS 2 $\alpha$ ,6-Dimethyl-3,20-dioxopregna-4,6-dien-17-yl acetate.(C <sub>25</sub> H <sub>34</sub> O <sub>4</sub> 398.54 )	<a href="#">Gerald Hsu</a>
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New	MESNA INJECTION PF 43(1) Pg. ONLINE	Title, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., ASSAY/Procedure, OTHER COMPONENTS/Content of Benzyl Alcohol (if present), IMPURITIES/Organic Impurities, SPECIFIC TESTS/Sterility Tests <71>, SPECIFIC TESTS/Bacterial Endotoxins Test <85>, SPECIFIC TESTS/Particulate Matter in Injections <788>, SPECIFIC TESTS/pH <791>, SPECIFIC TESTS/Other Requirements, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Benzaldehyde RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Benzyl Alcohol RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Mesna RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Mesna Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Mesna Related Compound B RS	<a href="#">Hillary Cai</a>
Omission	METHYLCELLULOSE OPHTHALMIC SOLUTION PF 44(3) Pg. ONLINE	Entire document	<a href="#">Feiwen Mao</a>
Revision	MICONAZOLE PF 41(5) Pg. ONLINE	ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Miconazole Related Compound C RS	<a href="#">Clydewyn Anthony</a>
Omission	MONOBENZONE PF 44(4) Pg. ONLINE	Entire document	<a href="#">Sujatha Ramakrishna</a>
Revision	NAPROXEN PF 42(4) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/Infrared Absorption <197K>, IDENTIFICATION/B. Ultraviolet Absorption <197U>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, IMPURITIES/Enantiomeric Purity, SPECIFIC TESTS/Optical Rotation, Specific Rotation <781S>, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Naproxen Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Naproxen Related Compound G 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	<a href="#">Richard Nguyen</a>
Revision	NAPROXEN DELAYED-RELEASE TABLETS PF 42(4) Pg. ONLINE	IDENTIFICATION/A. Ultraviolet Absorption <197U>, IDENTIFICATION/A., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, Procedure, Apparatus 1 and Apparatus 2, Delayed-Release Dosage Forms, Method B Procedure, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Naproxen Related Compound A 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	<a href="#">Richard Nguyen</a>

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Revision	NAPROXEN SODIUM PF 42(4) Pg. ONLINE	IDENTIFICATION/Infrared Absorption <197K>, IDENTIFICATION/B. Ultraviolet Absorption <197U>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, Procedure 1, IMPURITIES/Enantiomeric Purity, SPECIFIC TESTS/Optical Rotation, Specific Rotation <781S>, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Naproxen Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Naproxen Related Compound G 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	<a href="#">Richard Nguyen</a>
Omission	NORGESTREL TABLETS PF 44(3) Pg. ONLINE	Entire document	<a href="#">Ren-Hwa Yeh</a>

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New	RANOLAZINE PF 44(3) Pg. ONLINE	Title, Chemical Info/Chemical Structure, Chemical Info/C24H33N3O4, Chemical Info/427.55, Chemical Info/1-Piperazineacetamide, N-(2,6-dimethylphenyl)-4-[2-hydroxy-3-(2-methoxyphenoxy)propyl]-, (±)-; Chemical Info/N-(2,6-Dimethylphenyl)-4-[2-hydroxy-3-(2-methoxyphenoxy)propyl]-piperazin-1-ylacetamide, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K> or <197A>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Organic Impurities, IMPURITIES/Limit of Ranolazine Related Compound A, IMPURITIES/Limit of Epichlorohydrin, SPECIFIC TESTS/Loss on Drying <731>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Guaifenesin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ranolazine RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP p-Ranolazine RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ranolazine Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ranolazine Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ranolazine Related Compound C RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ranolazine Related Compound D RS	<a href="#">Donald Min</a>
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New RANOLAZINE EXTENDED-RELEASE TABLETS PF 44(3) 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 Guaifenesin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ranolazine RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP p-Ranolazine RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ranolazine Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ranolazine Related Compound C RS [Donald Min](#)

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New ROPIVACAINE PF 43(1) Pg. ONLINE Title, Chemical Info/Chemical Structure, Chemical Info/C17H26N2O, Chemical Info/274.40, Chemical Info/(S)-(-)-1-Propylpiperidine-2-carboxylic acid (2,6-dimethylphenyl)-amide;, Chemical Info/(S)-(-)-1-Propyl-2',6'-pipercoloxylidide, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Organic Impurities, IMPURITIES/Limit of Ropivacaine Related Compound A, IMPURITIES/Enantiomeric Purity, SPECIFIC TESTS/Bacterial Endotoxins Test <85>, SPECIFIC TESTS/Color, SPECIFIC TESTS/Water Determination <921>, Method I, Method Ia, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Bupivacaine Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ropivacaine RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ropivacaine Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ropivacaine Related Compound B RS [Ren-Hwa Yeh](#)

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New SITAGLIPTIN AND METFORMIN HYDROCHLORIDE EXTENDED RELEASE TABLETS PF 44(3) Pg. ONLINE Title, DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B., IDENTIFICATION/C., IDENTIFICATION/D., ASSAY/Procedure 1: Sitagliptin, ASSAY/Procedure 2: Metformin Hydrochloride, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities: Sitagliptin, IMPURITIES/Organic Impurities: Metformin Hydrochloride, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Metformin Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Sitagliptin Phosphate RS [Andrea Carney](#)

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New	SITAGLIPTIN AND METFORMIN HYDROCHLORIDE TABLETS PF 44(3) Pg. ONLINE	Title, DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B., IDENTIFICATION/C., IDENTIFICATION/D., ASSAY/Procedure 1: Sitagliptin, ASSAY/Procedure 2: Metformin Hydrochloride, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities: Sitagliptin, IMPURITIES/Organic Impurities: Metformin Hydrochloride, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Metformin Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Sitagliptin Phosphate RS	<a href="#">Andrea Carney</a>
Revision	SPIRONOLACTONE TABLETS PF 44(2) 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>/USP Spironolactone Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Spironolactone Related Compound B RS	<a href="#">Donald Min</a>
Revision	TRANEXAMIC ACID PF 44(5) Pg. ONLINE	DEFINITION/Introduction, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Tranexamic Acid Related Compound C RS	<a href="#">Donald Min</a>
Omission	VANCOMYCIN PF 44(5) Pg. ONLINE	Entire document	<a href="#">Ying Han</a>

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Title, DEFINITION/Introduction, IDENTIFICATION/A. HPTLC for Articles of Botanical Origin <203>, IDENTIFICATION/B. HPLC, COMPOSITION/Content of Caffeoylquinic Acids and Flavone Glycosides, CONTAMINANTS/Articles of Botanical Origin <561>, Limits of Elemental Impurities, CONTAMINANTS/Articles of Botanical Origin <561>, Pesticide Residue Analysis, CONTAMINANTS/Articles of Botanical Origin <561>, Test for Aflatoxins, 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/Botanical Characteristics, SPECIFIC TESTS/Articles of Botanical Origin <561>, Methods of Analysis, Foreign Organic Matter, SPECIFIC TESTS/Articles of Botanical Origin <561>, Methods of Analysis, Alcohol-Soluble Extractives, Method 1, SPECIFIC TESTS/Articles of Botanical Origin <561>, Methods of Analysis, Water-Soluble Extractives, Method 2, SPECIFIC TESTS/Articles of Botanical Origin <561>, Methods of Analysis, Total Ash, SPECIFIC TESTS/Articles of Botanical Origin <561>, Methods of Analysis, Acid-Insoluble Ash, SPECIFIC TESTS/Loss on Drying <731>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Chlorogenic Acid RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Chrysanthemum indicum Flower Dry Extract RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Chrysanthemum × morifolium Flower Dry Extract RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Isochlorogenic Acid A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Linarin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Luteolin 7-O-Glucoside RS

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Title, DEFINITION/Introduction, IDENTIFICATION/A. HPTLC for Articles of Botanical Origin <203>, IDENTIFICATION/B. HPLC, COMPOSITION/Content of Caffeoylquinic Acids and Flavone Glycosides, CONTAMINANTS/Botanical Extracts <565>, Preparations, General Pharmacopeial Requirements, Pesticide Residues, CONTAMINANTS/Articles of Botanical Origin <561>, Test for Aflatoxins, 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, SPECIFIC TESTS/Botanical Extracts <565>, Preparations, General Pharmacopeial Requirements, Residual Solvents, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Chlorogenic Acid RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Chrysanthemum indicum Flower Dry Extract RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Chrysanthemum × morifolium Flower Dry Extract RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Isochlorogenic Acid A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Linarin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Luteolin 7-O-Glucoside RS

New

WILD CHRYSANTHEMUM FLOWER DRY EXTRACT PF 44(2) Pg.  
ONLINE

[Cuiying Ma](#)

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Title, DEFINITION/Introduction, IDENTIFICATION/A. HPTLC for Articles of Botanical Origin <203>, IDENTIFICATION/B. HPLC, COMPOSITION/Content of Caffeoylquinic Acids and Flavone Glycosides, CONTAMINANTS/Articles of Botanical Origin <561>, Limits of Elemental Impurities, CONTAMINANTS/Articles of Botanical Origin <561>, Pesticide Residue Analysis, CONTAMINANTS/Articles of Botanical Origin <561>, Test for Aflatoxins, 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/Botanical Characteristics, SPECIFIC TESTS/Articles of Botanical Origin <561>, Methods of Analysis, Alcohol-Soluble Extractives, Method 1, SPECIFIC TESTS/Articles of Botanical Origin <561>, Methods of Analysis, Water-Soluble Extractives, Method 2, SPECIFIC TESTS/Articles of Botanical Origin <561>, Methods of Analysis, Total Ash, SPECIFIC TESTS/Articles of Botanical Origin <561>, Methods of Analysis, Acid-Insoluble Ash, SPECIFIC TESTS/Loss on Drying <731>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Chlorogenic Acid RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Chrysanthemum indicum Flower Dry Extract RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Chrysanthemum × morifolium Flower Dry Extract RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Isochlorogenic Acid A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Linarin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Luteolin 7-O-Glucoside RS