

---

# Admissions

## Articles Admitted to *USP 40* by Supplement

### First Supplement (August 1, 2016)

#### GENERAL CHAPTERS

---

- |   |  |
|---|--|
| ⟨507⟩ Protein Determination Procedures  | ⟨1228⟩ Depyrogenation  |
| ⟨800⟩ Hazardous Drugs—Handling in Healthcare Settings   | ⟨1228.1⟩ Dry Heat Depyrogenation   |
| ⟨1050.1⟩ Design, Evaluation, and Characterization of Viral Clearance Procedures                   | ⟨1229.5⟩ Biological Indicators for Sterilization                         |
| ⟨1207.1⟩ Package Integrity Testing in the Product Life Cycle—Test Method Selection and Validation | ⟨1229.9⟩ Physicochemical Integrators and Indicators for Sterilization    |
| ⟨1207.2⟩ Package Integrity Leak Test Technologies   | ⟨1229.12⟩ New Sterilization Methods                                      |
| ⟨1207.3⟩ Package Seal Quality Test Technologies   | ⟨2251⟩ Adulteration of Dietary Supplements with Drugs and Drug Analogues |

#### USP MONOGRAPHS

---

- |  |                                     |
|--|-------------------------------------|
| Abacavir and Lamivudine Tablets                      | Palonosetron Hydrochloride          |
| Adapalene Gel  | Perindopril Erbumine                |
| Amiodarone Hydrochloride Injection                   | Perindopril Erbumine Tablets        |
| Argatroban   | Rabeprazole Sodium                  |
| Calcium Succinate                                    | Sildenafil Tablets                  |
| Candesartan Cilexetil Tablets                        | Teniposide                          |
| Diphenhydramine Hydrochloride and Ibuprofen Capsules | Teniposide Injection                |
| Dronedarone Hydrochloride                            | Triamcinolone Acetonide Nasal Spray |
| Dronedarone Tablets                                  | Vardenafil Hydrochloride            |
| Exemestane   | Zolmitriptan                        |
| Lufenuron  | Zolmitriptan Tablets                |

#### DIETARY SUPPLEMENTS

---

- |                                |                    |
|--------------------------------|--------------------|
| <i>Rhodiola rosea</i> Capsules | Ubiquinol          |
| <i>Rhodiola rosea</i> Tablets  | Ubiquinol Capsules |
| Ribose                         |                    |

---

# Admissions

## New Articles Appearing in *NF 35* That Were Not Included in *NF 34* Including Supplements

[NOTE—The articles included in this list are noted in the book with the following symbols ▲▲<sub>NF35</sub>. This applies to new articles as well as sections of existing items that have been revised.]

### New Articles Appearing in *NF 35*

---

Eucalyptus Oil  
Sodium Succinate

## Second Supplement (December 1, 2016)

### GENERAL CHAPTERS

---

⟨782⟩ Vibrational Circular Dichroism Spectroscopy	⟨1228.3⟩ Depyrogenation by Filtration
⟨1004⟩ Mucosal Drug Products—Performance Tests	⟨1228.5⟩ Endotoxin Indicators for Depyrogenation
⟨1029⟩ Good Documentation Guidelines	⟨1229.13⟩ Sterilization-in-Place
⟨1063⟩ Shear Cell Methodology for Powder Flow Testing	⟨1782⟩ Vibrational Circular Dichroism Spectroscopy—Theory and Practice

### USP MONOGRAPHS

---

Cetirizine Hydrochloride Orally Disintegrating Tablets	Octreotide Acetate
Desloratadine	Oxymorphone Hydrochloride Tablets
Desloratadine Tablets	Oxymorphone Hydrochloride Extended-Release Tablets
Desloratadine Orally Disintegrating Tablets	Polyethylene Glycol 3350
Imipramine Pamoate Capsules	Ropinirole Extended-Release Tablets
Metronidazole Extended-Release Tablets	Zolmitriptan Orally Disintegrating Tablets

### DIETARY SUPPLEMENTS

---

Methylcobalamin Tablets	Northern Schisandra Fruit Dry Extract
-------------------------	---------------------------------------

## New Articles Appearing in *USP 40* That Were Not Included in *USP 39* Including Supplements

[NOTE—The articles included in this list are noted in the book with the following symbols ▲▲*USP40*. This applies to new articles as well as sections of existing items that have been revised.]

### GENERAL CHAPTERS

---

⟨89.1⟩ Collagenase I	⟨1602⟩ Spacers and Valved Holding Chambers Used with Inhalation Aerosols—Characterization Tests
⟨89.2⟩ Collagenase II	⟨1821⟩ Radioactivity—Theory and Practice
⟨127⟩ Flow Cytometric Enumeration of CD34+ Cells	⟨1823⟩ Positron Emission Tomography Drugs—Information
⟨1039⟩ Chemometrics	

### USP MONOGRAPHS

---

Cidofovir	Pemetrexed Disodium
Cidofovir Injection	Pemetrexed for Injection
Doxercalciferol	Quetiapine Extended-Release Tablets
Ixabepilone	Selamectin
	Tissue Human Amnion Chorion Membrane Dehydrated

### GLOBAL HEALTH MONOGRAPHS

---

Chlorhexidine Gluconate Topical Gel
-------------------------------------

**DIETARY SUPPLEMENTS**

Citrulline	St. John's Wort Flowering Top Dry Extract Tablets
Hesperidin	Sodium Ferrous Citrate
Japanese Honeysuckle Flower	Tienchi Ginseng Root and Rhizome Dry Extract Capsules
Japanese Honeysuckle Flower Dry Extract	Tienchi Ginseng Root and Rhizome Dry Extract Tablets
Japanese Honeysuckle Flower Powder	Tienchi Ginseng Root and Rhizome Powder Capsules
St. John's Wort Flowering Top Dry Extract Capsules	Tienchi Ginseng Root and Rhizome Powder Tablets

**Articles Included in *USP 39* But Not Included in *USP 40***

## GENERAL CHAPTERS

<21> Thermometers	<1035> Biological Indicators for Sterilization
<751> Metal Particles in Ophthalmic Ointments	<1045> Biotechnology-Derived Articles
<851> Spectrophotometry and Light-Scattering	<1209> Sterilization—Chemical and Physicochemical Indicators and Integrators

## USP MONOGRAPHS

Biological Indicator for Dry-Heat Sterilization, Paper Carrier	lophendylate
Biological Indicator for Ethylene Oxide Sterilization, Paper Carrier	lophendylate Injection
Biological Indicators for Moist Heat, Dry Heat, and Gaseous Modes of Sterilization, Liquid Spore Suspensions	Mangafodipir Trisodium
Biological Indicators for Moist Heat, Dry Heat, and Gaseous Modes of Sterilization, Nonpaper Carriers	Mangafodipir Trisodium Injection
Biological Indicator for Steam Sterilization, Paper Carrier	Oxtriphylline Delayed-Release Tablets
Biological Indicator for Steam Sterilization, Self-Contained	Oxymorphone Hydrochloride Suppositories
Chlordiazepoxide Hydrochloride for Injection	Propoxyphene Hydrochloride
Dolasetron Mesylate Injection	Propoxyphene Hydrochloride Capsules
Dolasetron Mesylate Tablets	Propoxyphene Hydrochloride and Acetaminophen Tablets
Multiple Electrolytes and Dextrose Injection Type 4	Propoxyphene Hydrochloride, Aspirin, and Caffeine Capsules
Multiple Electrolytes and Invert Sugar Injection Type 1	Propoxyphene Napsylate
Multiple Electrolytes and Invert Sugar Injection Type 2	Propoxyphene Napsylate Oral Suspension
Multiple Electrolytes and Invert Sugar Injection Type 3	Propoxyphene Napsylate Tablets
Iopanoic Acid	Propoxyphene Napsylate and Acetaminophen Tablets
Iopanoic Acid Tablets	Propoxyphene Napsylate and Aspirin Tablets
Ipodate Sodium	Sodium Chloride and Dextrose Tablets
Ipodate Sodium Capsules	Succinylcholine Chloride for Injection

## ANNOTATED LIST

## General Notices, Monographs, General Chapters, Reagents, and Tables Affected by Changes Appearing in USP 40

Page citations refer to the pages of USP 40. Note—In the table below, if a section is new or if a subsection is added to or deleted from an existing section, it is labeled as such in parentheses after the section or subsection name. Items on this list that appear without the designation “new”, “added”, or “deleted” are items in which changes have been made to existing official text.

### General Notices

- General Notices, 3  
 3. Conformance to Standards; 5. Monograph Components; 6. Testing Practices and Procedures; and 8. Terms and Definitions

### General Chapters

#### General Tests and Assays

##### General Requirements for Tests and Assays

- ⟨1⟩ Injections and Implanted Drug Products (Parenterals)—Product Quality Tests, 67

##### Biological Tests and Assays

- ⟨89.1⟩ Collagenase I (new), 180  
 ⟨89.2⟩ Collagenase II (new), 185  
 ⟨127⟩ Flow Cytometric Enumeration of CD34+ Cells (new), 216  
 ⟨151⟩ Pyrogen Test, 234  
*Introduction*  
 ⟨165⟩ Prekallikrein Activator (new), 241

##### Chemical Tests and Assays

- ⟨481⟩ Riboflavin Assay, 386  
*ASSAY*  
 ⟨531⟩ Thiamine Assay, 407  
*ASSAY*

##### Physical Tests and Determinations

- ⟨659⟩ Packaging and Storage Requirements, 529  
 ⟨670⟩ Auxiliary Packaging Components, 558  
 ⟨821⟩ Radioactivity, 751

### General Information

- ⟨1015⟩ Automated Radiochemical Synthesis Apparatus (deleted), 851  
 ⟨1039⟩ Chemometrics (new), 963  
 ⟨1602⟩ Spacers and Valved Holding Chambers Used with Inhalation Aerosols—Characterization Tests (new), 1988  
 ⟨1821⟩ Radioactivity—Theory and Practice (new), 2177  
 ⟨1823⟩ Positron Emission Tomography Drugs—Information (new), 2190

### Dietary Supplements

- ⟨2251⟩ Screening for Undeclared Drugs and Drug Analogues, 2285

### Reagents, Indicators, and Solutions

#### Reagent Specifications

Reagents Introduction, 2323

##### 4. Definitions

- Butylated Hydroxytoluene (new), 2341  
 Copper Sulfate Pentahydrate (new), 2348  
 Cupric Nitrate, 2348  
 1,1-Cyclobutanedicarboxylic Acid (new), 2349  
 Hydroxypropyl Cellulose (new), 2364  
 Isonicotinic Acid, 2366  
 (R)-(+)-Limonene (new), 2367  
 Lithium (new), 2368  
 Malonic Acid (new), 2368  
 D-Mannitol (new), 2369  
 Nickel Nitrate Hexahydrate (new), 2373  
 (R)-(-)- $\alpha$ -Phellandrene (new), 2378  
 (+)- $\alpha$ -Pinene (new), 2380  
 $\beta$ -Pinene (new), 2380  
 Polysorbate 80 (new), 2381  
 Propionic Acid (new), 2383  
 Sabinene (new), 2386  
 Sodium 1-Dodecanesulfonate (new), 2391  
 Tetrabutylammonium Hydroxide 30-Hydrate, 2397  
 Tetrahydrofuran, 2398  
 Water (new), 2405  
 Water, Carbon Dioxide-Free, 2405  
 Water, Deaerated, 2405  
 Water, Organic-Free (new), 2405  
 Water, Particle-Free (new), 2405

#### Test Solutions

- 1 M Acetic Acid TS (new), 2411  
 2 M Acetic Acid TS (new), 2412  
 1 M Ammonium Hydroxide TS (new), 2413  
 2 M Ammonium Hydroxide TS (new), 2413  
 0.01 M Edetate Disodium TS (new), 2415  
 0.01 N Hydrochloric Acid TS (new), 2416  
 0.025 N Hydrochloric Acid TS (new), 2416  
 0.05 N Hydrochloric Acid TS (new), 2416  
 0.05 M Phosphoric Acid TS (new), 2419  
 0.06 M Phosphoric Acid TS (new), 2419  
 1 N Phosphoric Acid TS (new), 2419  
 20% Phosphoric Acid TS (new), 2419  
 1.8 N Potassium Hydroxide TS (new), 2420  
 45% Potassium Hydroxide TS (new), 2420  
 0.02 M Monobasic Potassium Phosphate TS (new), 2420  
 0.2 M Dibasic Potassium Phosphate TS (new), 2420  
 0.0025 N Sodium Hydroxide TS (new), 2421  
 0.02 N Sodium Hydroxide TS (new), 2421  
 2 N Sodium Hydroxide TS (new), 2421  
 2.5 N Sodium Hydroxide TS (new), 2421  
 10 N Sodium Hydroxide TS (new), 2421  
 1 M Sulfuric Acid TS (new), 2422  
 0.2 N Sulfuric Acid TS (new), 2422

## ANNOTATED LIST

## General Notices, Monographs, General Chapters, Reagents, and Tables Affected by Changes Appearing in NF 35

Page citations refer to the pages of NF 35. Note—In the list below, if a section is new or if a subsection is added to or deleted from an existing section, it is labeled as such in parentheses after the section or subsection name. Items on this list that appear without the designation “new”, “added”, or “deleted” are items in which changes have been made to existing official text.

### Excipients

#### Flavors and Fragrance

Eucalyptus Oil, 7489

Sodium Succinate, 7489

#### pH Modifier (Acidifying Agent/Alkalizing Agent/Buffering Agent)

Sodium Succinate, 7490

### Monographs (NF 35)

Tribasic Calcium Phosphate, 7552

IDENTIFICATION

Croscarmellose Sodium, 7625

INTRODUCTION (added)

IDENTIFICATION

Test C

IMPURITIES

Sodium Chloride and Sodium Glycolate

#### SPECIFIC TESTS

Content of Water-Soluble Material and Microbial Enumeration Tests and Tests for Specified Microorganisms

Eucalyptus Oil (new), 7663

Glyceryl Tristearate, 7691

#### IDENTIFICATION

Monosodium Glutamate, 7771

CHEMICAL INFORMATION (added)

#### IDENTIFICATION

ADDITIONAL REQUIREMENTS

USP Reference Standards (added)

Potassium Hydroxide, 7844

#### DEFINITION

#### IDENTIFICATION

pH, Test B (added)

#### ASSAY

#### IMPURITIES

Sodium Succinate (new), 7890

0.5 N Sulfuric Acid TS (new), 2422  
 2 N Sulfuric Acid TS (new), 2422  
 0.02 M Tetrabutylammonium Hydrogen Sulfate TS (new), 2422

**Volumetric Solutions**

2 N Acetic Acid VS, 2424  
 0.1 N Ammonium Thiocyanate VS, 2424  
 0.01 M Bismuth Nitrate VS, 2424  
 0.1 N Bromine VS, 2424  
 0.05 N Ceric Ammonium Nitrate VS, 2424  
 0.1 N Ceric Sulfate VS, 2424  
 0.1 N Cupric Nitrate VS, 2425  
 Cupric Tartrate, Alkaline, Solution (Fehling's Solution), 2425  
 0.05 M Edetate Disodium VS, 2425  
 0.1 M Edetate Disodium VS, 2426  
 0.1 N Ferric Ammonium Sulfate VS, 2426  
 0.1 N Ferrous Ammonium Sulfate VS, 2426  
 0.02 N Hydrochloric Acid VS (new), 2426  
 0.1 N Hydrochloric Acid VS (new), 2426  
 0.5 N Hydrochloric Acid VS, 2427  
 1 N Hydrochloric Acid VS, 2427  
 0.1 M Alcoholic Hydrochloric Acid VS, 2427  
 0.5 N Hydrochloric Acid in Methanol VS, 2427  
 0.01 N Iodine VS, 2427  
 0.05 N Iodine VS, 2427  
 0.1 N Iodine VS, 2427  
 0.01 M Lead Nitrate VS, 2428  
 0.01 M Lead Perchlorate VS, 2428  
 0.1 M Lead Perchlorate VS, 2428  
 0.1 N Lithium Methoxide in Chlorobenzene VS, 2428  
 0.02 N Lithium Methoxide in Methanol VS, 2428  
 0.1 N Lithium Methoxide in Methanol VS, 2429  
 0.1 N Lithium Methoxide in Toluene VS, 2429  
 0.01 M Magnesium Chloride VS, 2429  
 0.1 M Mercuric Nitrate VS, 2429  
 0.1 N Oxalic Acid VS, 2429  
 0.1 N Perchloric Acid in Dioxane VS, 2429  
 0.1 N Perchloric Acid in Glacial Acetic Acid VS, 2430  
 0.1 N Potassium Arsenite VS, 2430  
 0.1 N Potassium Bromate VS, 2430  
 0.1 N Potassium Bromide–Bromate VS, 2430  
 0.1 N Potassium Dichromate VS, 2430  
 0.05 M Potassium Ferricyanide VS, 2431  
 0.1 M Alcoholic Potassium Hydroxide VS, 2431  
 0.5 N Alcoholic Potassium Hydroxide VS, 2431  
 0.1 N Methanolic Potassium Hydroxide VS, 2431  
 1 N Potassium Hydroxide VS, 2431  
 0.05 M Potassium Iodate VS, 2431  
 0.1 N Potassium Permanganate VS, 2432  
 0.1 N Potassium Thiocyanate VS, 2432  
 0.002 N Silver Nitrate in Isopropyl Alcohol VS (new), 2432  
 0.1 N Silver Nitrate VS, 2432  
 0.05 N Silver Nitrate VS (new), 2432  
 0.05 M Sodium Arsenite VS, 2432  
 1 N Sodium Hydroxide VS, 2432  
 0.1 N Alcoholic Sodium Hydroxide VS, 2433  
 0.1 N Sodium Hydroxide VS (new), 2433  
 0.5 N Sodium Methoxide in Methanol VS, 2433  
 0.1 N Sodium Methoxide in Toluene VS, 2433  
 0.1 M Sodium Nitrite VS, 2433  
 0.02 M Sodium Tetraphenylboron VS, 2434  
 0.1 N Sodium Thiosulfate VS, 2434  
 Standard Dichlorophenol–Indophenol Solution, 2434  
 1 N Sulfuric Acid VS, 2434  
 0.5 N Sulfuric Acid in Alcohol VS, 2434  
 0.1 N Tetrabutylammonium Hydroxide VS, 2434  
 0.1 N Tetrabutylammonium Hydroxide in Methanol/Isopropyl Alcohol VS, 2435

0.1 M Tetramethylammonium Bromide VS, 2435  
 0.1 M Tetramethylammonium Chloride VS, 2435  
 0.1 N Titanium Trichloride VS, 2435  
 0.05 M Zinc Sulfate VS, 2436  
 0.1 M Zinc Sulfate VS (new), 2436

**Chromatographic Columns**

L19, 2437  
 L22, 2437  
 L40, 2437  
 L45, 2437  
 L51, 2438  
 L54, 2438  
 L56, 2438  
 L80, 2439  
 L90 (new), 2439  
 L91 (new), 2439

**Reference Tables****Container Specifications for Capsules and Tablets**

Biperiden Hydrochloride Tablets (deleted), 2444  
 Quetiapine Extended-Release Tablets (new), 2450  
 St. John's Wort Flowering Top Dry Extract Capsules (new), 2451  
 St. John's Wort Flowering Top Dry Extract Tablets (new), 2451  
 Tienchi Ginseng Root and Rhizome Powder Capsules (new), 2451  
 Tienchi Ginseng Root and Rhizome Powder Tablets (new), 2451  
 Tienchi Ginseng Root and Rhizome Dry Extract Capsules (new), 2451  
 Tienchi Ginseng Root and Rhizome Dry Extract Tablets (new), 2451

**Description and Relative Solubility of USP and NF Articles**

Doxercalciferol (new), 2471  
 Eucalyptus Oil (new), 2474  
 Ixabepilone (new), 2482  
 Methacrylic Acid and Ethyl Acrylate Copolymer Dispersion, 2485  
 Methylene Blue, 2486  
 Pemetrexed Disodium (new), 2492  
 Perindopril Erbumine (new), 2493  
 Sodium Succinate (new), 2503

**Monographs (USP 40)**

Acebutolol Hydrochloride Capsules, 2538  
 IDENTIFICATION  
 ASSAY  
 PERFORMANCE TESTS  
*Dissolution*  
 IMPURITIES  
 Acetaminophen, Chlorpheniramine Maleate, and Dextromethorphan Hydrobromide Tablets, 2561  
 ASSAY  
*Acetaminophen, Chlorpheniramine Maleate, and Dextromethorphan Hydrobromide*  
 IMPURITIES  
*4-Aminophenol in Acetaminophen-Containing Drug Products* (added)  
 ADDITIONAL REQUIREMENTS  
*USP Reference Standards*  
 Acetaminophen and Codeine Phosphate Oral Solution, 2564  
 ASSAY  
*Acetaminophen and Codeine Phosphate*  
 IMPURITIES  
*4-Aminophenol in Acetaminophen-Containing Drug Products* (added)

Acetaminophen and Codeine Phosphate Oral Suspension, 2565

ASSAY

*Acetaminophen and Codeine Phosphate*

IMPURITIES

*4-Aminophenol in Acetaminophen-Containing Drug Products* (added)

Acetaminophen, Dextromethorphan Hydrobromide, Doxylamine Succinate, and Pseudoephedrine Hydrochloride Oral Solution, 2567

ASSAY

*Acetaminophen and Dextromethorphan Hydrobromide*

IMPURITIES

*4-Aminophenol in Acetaminophen-Containing Drug Products* (added)

Acetaminophen and Diphenhydramine Citrate Tablets, 2569

ASSAY

*Acetaminophen and Diphenhydramine Citrate*

IMPURITIES

*4-Aminophenol in Acetaminophen-Containing Drug Products* (added)

Acetaminophen, Diphenhydramine Hydrochloride, and Pseudoephedrine Hydrochloride Tablets, 2570

ASSAY

*Acetaminophen and Diphenhydramine Hydrochloride*

IMPURITIES

*4-Aminophenol in Acetaminophen-Containing Drug Products* (added)

Acetaminophen and Pseudoephedrine Hydrochloride Tablets, 2571

ASSAY

IMPURITIES

*4-Aminophenol in Acetaminophen-Containing Drug Products* (added)

Acetaminophen and Tramadol Hydrochloride Tablets, 2572

TITLE

ASSAY

OTHER COMPONENTS

*Limit of p-Aminophenol* (deleted)

IMPURITIES

ADDITIONAL REQUIREMENTS

*USP Reference Standards*

Tramadol Hydrochloride Extended-Release Tablets, 2575

PERFORMANCE TESTS

*Dissolution*

IMPURITIES

Alfuzosin Hydrochloride Extended-Release Tablets, 2626

PERFORMANCE TESTS

*Dissolution*

IMPURITIES

Alprazolam Extended-Release Tablets, 2644

IDENTIFICATION

*Test B* (added)

ASSAY

PERFORMANCE TESTS

*Dissolution*

ADDITIONAL REQUIREMENTS

*USP Reference Standards*

Alprazolam Orally Disintegrating Tablets, 2648

IDENTIFICATION

*Test A and Test B* (added)

ASSAY

PERFORMANCE TESTS

*Dissolution*

Amiloxate, 2719

IDENTIFICATION

*Ultraviolet Absorption, Test B and Test C* (added)

ASSAY

SPECIFIC TESTS

*Acidity*

Aminobenzoate Potassium, 2720

CHEMICAL INFORMATION

DEFINITION

IDENTIFICATION

*Test A and Test B*

ASSAY

IMPURITIES

*Chloride and Sulfate, Chloride; Chloride and Sulfate, Sulfate; Volatile Diazotizable Substances; Limit of Aniline and p-Toluidine; and Organic Impurities*

ADDITIONAL REQUIREMENTS

*USP Reference Standards*

Aminobenzoate Potassium Capsules, 2722

IDENTIFICATION

*Test B* (added)

ASSAY

IMPURITIES

ADDITIONAL REQUIREMENTS

*USP Reference Standards*

Aminophylline, 2735

IDENTIFICATION

*Infrared Absorption, Test A and Test B*

ASSAY

OTHER COMPONENTS

IMPURITIES

ADDITIONAL REQUIREMENTS

*Packaging and Storage and USP Reference Standards*

Aminophylline Injection, 2737

IDENTIFICATION

*Infrared Absorption, Test B and Test C*

ASSAY

IMPURITIES

ADDITIONAL REQUIREMENTS

*Packaging and Storage and USP Reference Standards*

Aminophylline Oral Solution, 2739

IDENTIFICATION

*Infrared Absorption, Test A*

ASSAY

IMPURITIES

ADDITIONAL REQUIREMENTS

*USP Reference Standards*

Aminophylline Tablets, 2742

IDENTIFICATION

*Infrared Absorption, Test A and Test B*

ASSAY

IMPURITIES

ADDITIONAL REQUIREMENTS

*Packaging and Storage and USP Reference Standards*

Amlodipine and Valsartan Tablets, 2763

DEFINITION

ASSAY

PERFORMANCE TESTS

*Dissolution*

IMPURITIES

ADDITIONAL REQUIREMENTS

*Labeling* (added)

Amlodipine, Valsartan, and Hydrochlorothiazide Tablets, 2767

DEFINITION

ASSAY

PERFORMANCE TESTS

*Dissolution*

IMPURITIES

ADDITIONAL REQUIREMENTS

*Labeling* (added)

Aripiprazole Tablets, 2858

ASSAY

- PERFORMANCE TESTS  
*Dissolution*  
 IMPURITIES  
 Ascorbic Acid Injection, 2866  
 IDENTIFICATION  
*Test C*  
 Azathioprine Sodium for Injection, 2917  
 IDENTIFICATION  
*Test B* (added)  
 ASSAY  
 SPECIFIC TESTS  
*Completeness of Solution* (deleted)  
 ADDITIONAL REQUIREMENTS  
*Packaging and Storage*  
 Betamethasone Valerate Cream, 3012  
 IDENTIFICATION  
*Test A and Test B*  
 ASSAY  
 IMPURITIES  
 ADDITIONAL REQUIREMENTS  
*USP Reference Standards*  
 Betamethasone Valerate Ointment, 3014  
 IDENTIFICATION  
*Test A and Test B*  
 ASSAY  
 IMPURITIES  
 ADDITIONAL REQUIREMENTS  
*USP Reference Standards*  
 Biperiden (deleted), 3028  
 Biperiden Hydrochloride (deleted), 3028  
 Biperiden Hydrochloride Tablets (deleted), 3029  
 Biperiden Lactate Injection (deleted), 3030  
 Carboplatin, 3202  
 DEFINITION  
 IDENTIFICATION  
*Infrared Absorption, Test A and Test B*  
 (added)  
 ASSAY  
 OTHER COMPONENTS  
 IMPURITIES  
*Limit of 1,1-Cyclobutanedicarboxylic Acid and Organic Impurities*  
 SPECIFIC TESTS  
*Water Determination, Method I* (deleted)  
 and *Loss on Drying* (added)  
 ADDITIONAL REQUIREMENTS  
*Packaging and Storage*  
 Carboplatin for Injection, 3203  
 IDENTIFICATION  
*Test B* (added)  
 ASSAY  
 IMPURITIES  
 ADDITIONAL REQUIREMENTS  
*Packaging and Storage*  
 Ceftriaxone for Injection, 3305  
 ASSAY  
 IMPURITIES  
 ADDITIONAL REQUIREMENTS  
*Packaging and Storage*  
 Ceftriaxone Sodium, 3307  
 ASSAY  
 IMPURITIES  
 ADDITIONAL REQUIREMENTS  
*Packaging and Storage*  
 Cidofovir (new), 3414  
 Cidofovir Injection (new), 3415  
 Cisatracurium Besylate, 3440  
 IMPURITIES  
*Organic Impurities*  
 SPECIFIC TESTS  
*pH* (deleted) and *Water Determination*  
 ADDITIONAL REQUIREMENTS  
*USP Reference Standards*
- Cisplatin, 3444  
 IDENTIFICATION  
*Infrared Absorption, Test B and Thin-Layer Chromatography, Test C* (deleted)  
 ASSAY  
 IMPURITIES  
*Limit of Trichloroamineplatin and Limit of Transplatin*  
 SPECIFIC TESTS  
*Platinum Content*  
 ADDITIONAL REQUIREMENTS  
*Packaging and Storage*  
 Cisplatin for Injection, 3446  
 IDENTIFICATION  
*Test B* (added)  
 ASSAY  
 IMPURITIES  
*Limit of Trichloroamineplatin and Limit of Transplatin*  
 Corticotropin Injection, 3577  
 ASSAY  
 Corticotropin for Injection, 3578  
 ASSAY  
 Repository Corticotropin Injection, 3580  
 ASSAY  
 Cyanocobalamin, 3596  
 ASSAY  
 Cysteine Hydrochloride, 3621  
 SPECIFIC TESTS  
*Loss on Drying*  
 Demeclocycline Hydrochloride Tablets, 3647  
 IDENTIFICATION  
 ASSAY  
 PERFORMANCE TESTS  
*Dissolution*  
 SPECIFIC TESTS  
*Loss on Drying* (deleted)  
 Desipramine Hydrochloride Tablets, 3651  
 IDENTIFICATION  
*Test A and Test B* (added)  
 ASSAY  
 IMPURITIES  
 Dextromethorphan, 3704  
 IDENTIFICATION  
*Test B*  
 SPECIFIC TESTS  
*Melting Range or Temperature* (deleted) and  
*Optical Rotation* (deleted)  
 ADDITIONAL REQUIREMENTS  
*USP Reference Standards*  
 Dextromethorphan Hydrobromide, 3705  
 IDENTIFICATION  
*Test A, Test B, and Test C* (deleted)  
 SPECIFIC TESTS  
*Optical Rotation* (deleted)  
 ADDITIONAL REQUIREMENTS  
*USP Reference Standards*  
 Diphenhydramine Hydrochloride Capsules, 3803  
 IMPURITIES  
 Diphenhydramine Hydrochloride Oral Solution, 3806  
 IMPURITIES  
 ADDITIONAL REQUIREMENTS  
*USP Reference Standards*  
 Diphenhydramine and Phenylephrine Hydrochlorides Tablets, 3810  
 IMPURITIES  
 ADDITIONAL REQUIREMENTS  
*USP Reference Standards*  
 Doxercalciferol (new), 3880  
 Doxycycline Hyclate Capsules, 3897  
 IDENTIFICATION  
 ASSAY  
 PERFORMANCE TESTS  
*Dissolution*

- IMPURITIES  
*Organic Impurities* (added)  
 SPECIFIC TESTS  
*Water Determination, Method I* (deleted)  
 ADDITIONAL REQUIREMENTS  
*Packaging and Storage* and *USP Reference Standards*  
 Doxycycline Hyclate Tablets, 3900  
 IDENTIFICATION  
*Procedure* (deleted) and *Test A* (added)  
 ASSAY  
 PERFORMANCE TESTS  
*Dissolution*  
 IMPURITIES  
*Organic Impurities* (added)  
 SPECIFIC TESTS  
*Water Determination, Method I* (deleted)  
 ADDITIONAL REQUIREMENTS  
*Packaging and Storage* and *USP Reference Standards*  
 Dutasteride, 3924  
 IMPURITIES  
*Organic Impurities, Procedure 2*  
 Esomeprazole Magnesium, 4057  
 SPECIFIC TESTS  
*Water Determination* and *Crystallinity* (added)  
 ADDITIONAL REQUIREMENTS  
*Packaging and Storage* and *Labeling*  
 Fenbendazole, 4151  
 IDENTIFICATION  
 IMPURITIES  
*Organic Impurities*  
 ADDITIONAL REQUIREMENTS  
*Packaging and Storage*  
 Fexofenadine Hydrochloride and Pseudoephedrine Hydrochloride Extended-Release Tablets, 4189  
 PERFORMANCE TESTS  
*Dissolution*  
 Galantamine Extended-Release Capsules, 4367  
 ASSAY  
 PERFORMANCE TESTS  
*Dissolution*  
 IMPURITIES  
 Heparin Sodium, 4475  
 IDENTIFICATION  
*Molecular Weight Determinations, Test D* and *Test E*  
 IMPURITIES  
*Nucleotidic Impurities*  
 Hydrocortisone Sodium Succinate, 4519  
 IDENTIFICATION  
*Test C*  
 Hydroxyzine Hydrochloride, 4539  
 IDENTIFICATION  
*Infrared Absorption, Test A*  
 ASSAY  
 IMPURITIES  
*Organic Impurities*  
 ADDITIONAL REQUIREMENTS  
*USP Reference Standards*  
 Hydroxyzine Hydrochloride Tablets, 4542  
 IDENTIFICATION  
*Test A* and *Test B* (added)  
 ASSAY  
 IMPURITIES  
*Organic Impurities* (added)  
 ADDITIONAL REQUIREMENTS  
*Packaging and Storage* and *USP Reference Standards*  
 Ibuprofen Oral Suspension, 4556  
 IDENTIFICATION  
*Test A* and *Test B*  
 ASSAY  
 IMPURITIES  
*Limit of Ibuprofen Related Compound C* (deleted) and *Organic Impurities* (added)  
 ADDITIONAL REQUIREMENTS  
*USP Reference Standards*  
 Iodine Topical Solution, 4630  
 IDENTIFICATION  
*Identification Tests—General, Iodide, Test B* and *Sodium, Test C* (added)  
 Iodine Tincture, 4631  
 IDENTIFICATION  
*Identification Tests—General, Iodide, Test B* and *Sodium, Test C* (added)  
 Strong Iodine Tincture, 4632  
 IDENTIFICATION  
*Identification Tests—General, Iodide, Test B* and *Potassium, Test C* (added)  
 Iothalamate Sodium Injection (deleted), 4659  
 Isoflurane, 4688  
 IMPURITIES  
*Chloride*  
 SPECIFIC TESTS  
*Acidity or Alkalinity* (added)  
 Ixabepilone (new), 4739  
 Ketorolac Tromethamine, 4753  
 IDENTIFICATION  
*Test B*  
 IMPURITIES  
*Organic Impurities*  
 Levetiracetam Extended-Release Tablets, 4812  
 PERFORMANCE TESTS  
*Dissolution*  
 Levocetirizine Dihydrochloride, 4825  
 IMPURITIES  
*Residue on Ignition, Organic Impurities, and Enantiomeric Purity*  
 SPECIFIC TESTS  
*Loss on Drying*  
 Losartan Potassium and Hydrochlorothiazide Tablets, 4913  
 PERFORMANCE TESTS  
*Dissolution*  
 ADDITIONAL REQUIREMENTS  
*Labeling* (added)  
 Memantine Hydrochloride Tablets, 5000  
 IMPURITIES  
*Limit of Memantine–Lactose Adduct*  
 Methocarbamol Tablets, 5079  
 IMPURITIES  
 Methylene Blue, 5105  
 Metoprolol Fumarate, 5135  
 DEFINITION  
 IDENTIFICATION  
*Test B*  
 ASSAY  
 IMPURITIES  
*Organic Impurities*  
 SPECIFIC TESTS  
*Melting Range or Temperature* (deleted)  
 ADDITIONAL REQUIREMENTS  
*Packaging and Storage* and *USP Reference Standards*  
 Moexipril Hydrochloride, 5201  
 IMPURITIES  
*Organic Impurities*  
 Moexipril Hydrochloride Tablets, 5203  
 IMPURITIES  
*Organic Impurities*  
 Moxifloxacin Hydrochloride, 5240  
 ASSAY  
 IMPURITIES  
*Organic Impurities* and *Enantiomeric Purity* (added)  
 SPECIFIC TESTS  
*Optical Rotation* (deleted)

- ADDITIONAL REQUIREMENTS  
*USP Reference Standards*
- Nicotine Polacrilex, 5347  
DEFINITION  
IDENTIFICATION  
*Infrared Absorption for Nicotine, Test A and Infrared Absorption for Polacrilex, Test B*  
ASSAY  
SPECIFIC TESTS  
*Water Determination (deleted), Loss on Drying (added), and Nicotine Release*  
ADDITIONAL REQUIREMENTS  
*Packaging and Storage*
- Olopatadine Hydrochloride, 5425  
IDENTIFICATION  
*Infrared Absorption, Test A*  
ASSAY  
IMPURITIES  
*Organic Impurities*
- Olopatadine Hydrochloride Ophthalmic Solution, 5426  
IDENTIFICATION  
*Test B (added)*  
ASSAY  
IMPURITIES  
*Limit of Early Eluting Impurities and Limit of Late Eluting Impurities*
- Pemetrexed Disodium (new), 5588  
Pemetrexed for Injection (new), 5590
- Penicillin G Procaine, 5607  
CHEMICAL INFORMATION  
ASSAY  
SPECIFIC TESTS  
*Content of Penicillin G and Procaine, Sterility Tests, and pH*  
ADDITIONAL REQUIREMENTS  
*Packaging and Storage and USP Reference Standards*
- Pentazocine and Acetaminophen Tablets, 5625  
ASSAY  
*Pentazocin and Acetaminophen*  
IMPURITIES  
*4-Aminophenol in Acetaminophen-Containing Drug Products (added)*
- Phenoxybenzamine Hydrochloride Capsules, 5669  
IDENTIFICATION  
*Test A and Test B (added)*  
ASSAY  
PERFORMANCE TESTS  
*Dissolution and Uniformity of Dosage Units*
- Phenylephrine Hydrochloride Tablets, 5685  
IMPURITIES  
ADDITIONAL REQUIREMENTS  
*USP Reference Standards*
- Prompt Phenytoin Sodium Capsules (deleted), 5696
- Pioglitazone and Metformin Hydrochloride Tablets, 5720  
IDENTIFICATION  
*Ultraviolet Absorption, Test A*  
ASSAY
- Polymyxin B Sulfate, 5750  
IMPURITIES  
*Organic Impurities*  
SPECIFIC TESTS  
*Composition of Polymyxins*
- Potassium Gluconate, 5777  
IDENTIFICATION  
*Test B*
- Potassium Gluconate Oral Solution, 5778  
IDENTIFICATION  
*Test A*
- Potassium Gluconate Tablets, 5779  
IDENTIFICATION  
*Test B*
- Prochlorperazine Maleate, 5849  
DEFINITION  
IDENTIFICATION  
*Test A and Test B (added)*  
ASSAY  
IMPURITIES  
*Organic Impurities*
- Propafenone Hydrochloride Extended-Release Capsules, 5876  
PERFORMANCE TESTS  
*Dissolution*  
IMPURITIES  
*Organic Impurities and Content of Propafenone Related Compound A*  
ADDITIONAL REQUIREMENTS  
*Labeling (added)*
- Protamine Sulfate, 5902  
ASSAY  
IMPURITIES  
*Elemental Impurities (deleted)*  
ADDITIONAL REQUIREMENTS  
*USP Reference Standards*
- Protamine Sulfate Injection, 5903  
ASSAY
- Quetiapine Extended-Release Tablets (new), 5937
- Ribavirin Capsules, 5996  
PERFORMANCE TESTS  
*Dissolution*
- Riboflavin Tablets, 6002  
ASSAY
- Ringer's Injection, 6019  
IDENTIFICATION  
*Identification Tests—General, Test A; Sodium, Test B (added); and Potassium, Test C (added)*
- Secobarbital Sodium Injection (deleted), 6132  
Secobarbital Sodium for Injection (deleted), 6132  
Secobarbital Sodium and Amobarbital Sodium Capsules (deleted), 6133  
Selamectin (new), 6133
- Sodium Citrate and Citric Acid Oral Solution, 6186  
IDENTIFICATION  
*Test A and Identification Tests—General, Test D*  
ASSAY  
*Sodium, Sodium Citrate, and Citric Acid*
- Sodium Hypochlorite Solution, 6192  
IDENTIFICATION  
*Test B and Test C (deleted)*  
ASSAY
- Sulfadoxine and Pyrimethamine Tablets, 6263  
IDENTIFICATION  
*Test A*  
ASSAY
- Tamsulosin Hydrochloride Capsules, 6320  
ASSAY  
*Procedure 8 and Procedure 10 (added)*  
PERFORMANCE TESTS  
*Dissolution*
- Tetrahydrozoline Hydrochloride, 6410  
DEFINITION  
IDENTIFICATION  
*Infrared Absorption, Test A and Test B*  
ASSAY  
IMPURITIES  
*Ordinary Impurities (deleted) and Organic Impurities (added)*  
ADDITIONAL REQUIREMENTS  
*Packaging and Storage*
- Thiamine Hydrochloride Tablets, 6432  
ASSAY
- Tinidazole, 6483  
DEFINITION

IDENTIFICATION  
*Test B and Test C (deleted)*  
 ASSAY  
 IMPURITIES  
*Organic Impurities*  
 SPECIFIC TESTS  
*Melting Range or Temperature (deleted)*  
 Tissue Human Amnion Chorion Membrane Dehydrated (new), 6486  
 Valine, 6642  
 IMPURITIES  
*Related Compounds*  
 ADDITIONAL REQUIREMENTS  
*USP Reference Standards*

## Monographs (Global Health)

Chlorhexidine Gluconate Topical Gel (new), 6779

## Monographs (Dietary Supplements)

Ashwagandha Root, 6800  
 IDENTIFICATION  
*HPTLC for Articles of Botanical Origin, Test A and HPLC, Test B*  
 COMPOSITION  
 ADDITIONAL REQUIREMENTS  
*USP Reference Standards*  
 Powdered Ashwagandha Root, 6802  
 IDENTIFICATION  
*HPTLC for Articles of Botanical Origin, Test A and HPLC, Test B*  
 COMPOSITION  
 ADDITIONAL REQUIREMENTS  
*USP Reference Standards*  
 Powdered Ashwagandha Root Extract, 6804  
 DEFINITION  
 IDENTIFICATION  
*HPTLC for Articles of Botanical Origin, Test A and HPLC, Test B*  
 COMPOSITION  
 ADDITIONAL REQUIREMENTS  
*USP Reference Standards*  
 Citrulline (new), 6907  
*Crypthocodium cohnii* Oil, 6912  
 IDENTIFICATION  
 Curcuminoids, 6917  
 IDENTIFICATION  
*HPTLC for Articles of Botanical Origin, Test A and HPLC, Test B*  
 COMPOSITION  
 CONTAMINANTS  
*Botanical Extracts (added)*  
 Hesperidin (new), 7048  
 Japanese Honeysuckle Flower (new), 7055  
 Japanese Honeysuckle Flower Dry Extract (new), 7058  
 Japanese Honeysuckle Flower Powder (new), 7060

Rutin, 7164  
 IMPURITIES  
*Quercetin and Other Related Compounds*  
 St. John's Wort Flowering Top, 7166  
 TITLE  
 DEFINITION  
 IDENTIFICATION  
*HPTLC for Articles of Botanical Origin, Test B*  
 COMPOSITION  
*Content of Hypericin and Pseudohypericin and Content of Hyperforin*  
 SPECIFIC TESTS  
*Loss on Drying*  
 St. John's Wort Flowering Top Powder, 7168  
 TITLE  
 DEFINITION  
 IDENTIFICATION  
*HPTLC for Articles of Botanical Origin, Test B*  
 COMPOSITION  
*Content of Hypericin and Pseudohypericin and Content of Hyperforin*  
 SPECIFIC TESTS  
*Loss on Drying*  
 St. John's Wort Flowering Top Dry Extract, 7169  
 TITLE  
 DEFINITION  
 IDENTIFICATION  
*HPTLC for Articles of Botanical Origin, Test A and Thin-Layer Chromatography, Test B*  
 COMPOSITION  
*Content of Hypericin and Pseudohypericin and Content of Hyperforin*  
 St. John's Wort Flowering Top Dry Extract Capsules (new), 7172  
 St. John's Wort Flowering Top Dry Extract Tablets (new), 7173  
 Sodium Ferrous Citrate (new), 7195  
 Tienchi Ginseng Root and Rhizome Powder Capsules (new), 7218  
 Tienchi Ginseng Root and Rhizome Powder Tablets (new), 7219  
 Tienchi Ginseng Root and Rhizome Dry Extract Capsules (new), 7223  
 Tienchi Ginseng Root and Rhizome Dry Extract Tablets (new), 7225  
 Turmeric, 7228  
 DEFINITION  
 IDENTIFICATION  
*Test A and Test B*  
 COMPOSITION  
 Powdered Turmeric, 7230  
 DEFINITION  
 IDENTIFICATION  
*Test A and Test B*  
 COMPOSITION  
 SPECIFIC TESTS  
*Articles of Botanical Origin, Foreign Organic Matter (deleted)*  
 Powdered Turmeric Extract, 7232  
 IDENTIFICATION  
*Test A and Test B*  
 COMPOSITION