USP 35 Admissions xxvii

# **Admissions**

## Articles Admitted to USP 35 by Supplement

## First Supplement (August 1, 2011)

#### **GENERAL CHAPTERS**

(1084) Glycoprotein and Glycan Analysis—General

Considerations

(1097) Bulk Powder Sampling Procedures

(1180) Human Plasma

(1601) Products For Nebulization—Characterization Tests

#### **DIETARY SUPPLEMENTS**

Forskohlii

Powdered Forskohlii

Powdered Forskohlii Extract

#### **USP MONOGRAPHS**

Abacavir Sulfate

Abacavir Oral Solution

**Abacavir Tablets** 

Alprazolam Extended-Release Tablets

Citalopram Oral Solution

Divalproex Sodium Delayed-Release Capsules Divalproex Sodium Extended-Release Tablets

Donepezil Hydrochloride Tablets

Donepezil Hydrochloride Orally Disintegrating Tablets

Efavirenz

**Efavirenz Capsules** 

Entacapone

**Entacapone Tablets** 

Escitalopram Oxalate

Flecainide Acetate Oral Suspension Hydrochlorothiazide Capsules Lopinavir

Mefloquine Hydrochloride Tablets

Midodrine Hydrochloride

Midodrine Hydrochloride Tablets

Olanzapine and Fluoxetine Capsules

Pramipexole Dihydrochloride

Rizatriptan Benzoate Ropinirole Tablets

Scaffold Human Dermis

Telmisartan and Hydrochlorothiazide Tablets

Terazosin Capsules

Terazosin Tablets

Theophylline Oral Suspension

Valacyclovir Tablets Zonisamide Capsules

## Second Supplement (December 1, 2011)

#### **GENERAL CHAPTERS**

(413) Impurities Testing in Medical Gases

(415) Medical Gases Assay

(1027) Flow Cytometry

(1047) Gene Therapy Products

xxviii Admissions USP 35

#### **DIETARY SUPPLEMENTS**

Bacopa Garcinia cambogia

Powdered Bacopa Powdered Garcinia cambogia

Powdered Bacopa Extract Powdered Garcinia Hydroxycitrate Extract

Centella asiatica Garcinia indica

Powdered Centella asiatica Powdered Garcinia indica

Powdered Centella asiatica Extract Glutathione
Centella asiatica Triterpenes Schizochytrium Oil

Crypthecodinium cohnii Oil Schizochytrium Oil Capsules

Crypthecodinium cohnii Oil Capsules

#### **USP MONOGRAPHS**

Escitalopram Tablets Trospium Chloride Etomidate Vitamin A Tablets

Etomidate Injection Zaleplon

Trandolapril Tablets Zaleplon Capsules

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

[NOTE—The articles included in this list are noted in the book with the following symbols A AUSP35. This applies to new articles as well as sections of existing items that have been revised.]

#### **GENERAL CHAPTERS**

(3) Topical and Transdermal Drug Products—Product Quality Tests

(267) Porosimetry By Mercury Intrusion

(610) Alternative Microbiological Sampling Methods for Nonsterile Inhaled and Nasal Products

(659) Packaging and Storage Requirements

(1113) Microbial Characterization, Identification, and Strain Typing

(1128) Nucleic Acid-Based Techniques—Microarray

(1224) Transfer Of Analytical Procedures

#### **DIETARY SUPPLEMENTS**

Fish Oil Containing Omega-3 Acids Delayed-Release Capsules

Malabar-Nut-Tree, Leaf

Powdered Malabar-Nut-Tree, Leaf

Powdered Malabar-Nut-Tree, Leaf Extract

Phyllanthus amarus

Powdered Phyllanthus amarus

#### USP MONOGRAPHS

Alprazolam Orally Disintegrating Tablets Orlistat Capsules

Candesartan Cilexetil Risperidone Orally Disintegrating Tablets

Docetaxel Injection Rosiglitazone Maleate

Levofloxacin Oral Solution Temozolomide

Loratadine Orally Disintegrating Tablets

Tramadol Hydrochloride Extended-Release Tablets

Orlistat

#### Articles Included in USP 34 But Not Included in USP 35

**GENERAL CHAPTERS** 

(521) Sulfonamides (1101) Medicine Dropper

(727) Capillary Electrophoresis (1221) Teaspoon

USP 35 Admissions xxix

#### Articles Included in USP 34 But Not Included in USP 35

(1070) Emergency Medical Services Vehicles and Ambulances—Storage of Preparations

**USP MONOGRAPHS** 

Anti-A Blood Grouping Serum Anti-B Blood Grouping Serum Anti-Human Globulin Serum Antihemophilic Factor

Antivenin (Crotalidae) Polyvalent Antivenin (Latrodectus mactans) Antivenin (Micrurus fulvius) Blood Grouping Serums

Blood Grouping Serums Anti-D, Anti-C, Anti-E, Anti-c, Anti-e

Botulism Antitoxin Coccidioidin

Cryoprecipitated Antihemophilic Factor Diphtheria and Tetanus Toxoids Adsorbed

Heparin Calcium

Heparin Calcium Injection

Histoplasmin

Influenza Virus Vaccine

Measles and Rubella Virus Vaccine Live

Measles Virus Vaccine Live

Measles, Mumps, and Rubella Virus Vaccine Live

Mumps Skin Test Antigen Mumps Virus Vaccine Live Paramethasone Acetate Paramethasone Acetate Tablets Pentobarbital Oral Solution Pentobarbital Sodium Capsules

Platelet Concentrate

Poliovirus Vaccine Inactivated

Rabies Vaccine

Rubella Virus Vaccine Live Secobarbital Oral Solution

**Smallpox Vaccine** 

Tetanus and Diphtheria Toxoids Adsorbed for Adult Use

**Tetanus Toxoid** 

**Tetanus Toxoid Adsorbed** 

Thrombin Tuberculin Whole Blood Yellow Fever Vaccine

**USP 35** xxx Annotated List

#### ANNOTATED LIST

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

Page citations refer to the pages of USP 35. 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 Chapters**

## General Tests and Assays

#### **General Requirements for Tests and Assays**

(1) Injections, 33

Nomenclature and Definitions

(3) Topical and Transdermal Drug Products— Product Quality Tests (new), 37

Biological Tests and Assays (81) Antibiotics—Microbial Assays, 74

(85) Bacterial Endotoxins Test, 88 Determination of Maximum Valid Dilution (MVD)

Gel-Clot Technique (88) Biological Reactivity Tests, In Vivo, 94 Classification of Plastics

Implantatation Test

leted), 126

**Limit Tests** 

(267) Porosimetry by Mercury Intrusion (new), 149

Other Tests and Assays (401) Fats and Fixed Oils, 163 Éster Value Fatty Acid Composition Trace Metals Sterol Composition (467) Residual Solvents, 185 Limits of Residual Solvents

**Physical Tests and Determinations** 

(610) Alternative Microbiological Sampling Methods for Nonsterile Inhaled and Nasal Products (new), 253

(659) Packaging and Storage Requirements (new), 270

(781) Optical Rotation, 334

Specific Rotation (811) Powder Fineness, 390

(823) Positron Emission Tomography Drugs for Compounding, Investigational, and Research Uses, 398

#### General Information

(1113) Microbial Characterization, Identification, and Strain Typing (new), 694 (1116) Microbiological Control and Monitoring of Aseptic Processing Environments, 697 (1128) Nucleic Acid-Based Techniques— Microarray (new), 747 (1151) Pharmacéutical Dosage Forms, 765 (1224) Transfer of Analytical Procedures (new),

(1226) Verification of Compendial Procedures,

Verification Process Verification Requirements

## Dietary Supplements

 $\langle 2040 \rangle$  Disintegration and Dissolution of Dietary Supplements, 972 Dissolution

## Reagents, Indicators, and Solutions

Reagent Specifications 3,5-Dinitrobenzoyl Chloride, 1022 Nitric Acid, Diluted, 1036 Octanesulfonic Acid Sodium Salt, 1037 Potassium Phosphate, Dibasic, Trihydrate (new), Sodium 1-Octanesulfonate, 1053 Sodium Perchlorate, 1053 Sodium Phosphate, Dibasic, Heptahydrate (new),

Sodium Phosphate, Tribasic, 1054

Sodium Pyrophosphate, 1054

**Volumetric Solutions** 

Hydrochloric Acid, Half-Normal (0.5 N), 1079 Sódium Hydroxide, Normal (1 N), 1083

#### **Chromatographic Columns**

L1, 1085 L17, 1086 L20, 1086

L23, 1086 L34, 1086 L59, 1087

### Reference Tables

#### **Container Specifications for Capsules and Tablets**

Alprazolam Tablets, Orally Disintegrating, 1089
Fish Oil Containing Omega-3 Acids Capsules, Delayed-Release, 1092 Loratadine Tablets, Orally Disintegrating, 1093 Orlistat Capsules, 1094 Risperidone Tablets, Orally Disintegrating, 1096 Tramadolol Hydrochloride Tablets, Extended-Release, 1097

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

Candesartan Cilexetil, 1106 Ethylcellulose Dispersion Type B, 1118 Polýglyceryl Dioleate, 1138 Hydrogenated Starch Hydrolysate, 1146 Temozolomide, 1149 Valganciclovir Hydrochloride, 1152