

# USP Annotated List

## General Notices, Monographs, General Chapters, Reagents, and Tables Affected by Changes Appearing in USP 2021, Issue 1

Note—This list only contains In-Process Revision file types. In the lists 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

1. Title and Revision, 2. Official Status and Legal Recognition, and 3. Conformance to Standards

### General Chapters

#### General Tests and Assays

##### Chemical Tests and Assays

- <191> Identification Tests—General

##### CHEMICAL IDENTIFICATION TESTS

###### Chloride

- <210> Monosaccharide Analysis

##### SIALIC ACID QUANTIFICATION

##### PROCEDURES

*Procedure 1: Enzymatic Release and Analysis by HPAEC-PAD of Unlabeled Sialic Acids and Procedure 3: Enzymatic Hydrolysis and Analysis by RP-HPLC of DMB-Labeled Sialic Acids*

##### USP REFERENCE STANDARDS

- <476> Control of Organic Impurities in Drug Substances and Drug Products (new)

##### Physical Tests and Determinations

- <601> Inhalation and Nasal Drug Products: Aerosols, Sprays, and Powders—Performance Quality Tests

- <631> Color and Achromicity

- <643> Total Organic Carbon

##### INTRODUCTION

##### PROCEDURES

- <915> Measurement of Structural Strength of Semisolids by Penetrometry (new)

- <922> Water Activity (new)

#### General Information

- <1051> Cleaning Glass Apparatus

- <1086> Impurities in Drug Substances and Drug Products

- <1088> In Vitro and In Vivo Evaluation of Dosage Forms

- <1102> Immunological Test Methods—General

##### Considerations

##### INTRODUCTION

##### KEY CONSIDERATIONS IN ITM DEVELOPMENT

##### VALIDATION

- <1151> Pharmaceutical Dosage Forms

- <1153> Drug Products Containing Nanomaterials (new)

- <1195> Significant Change Guide for Bulk Pharmaceutical Excipients

- <1235> Vaccines for Human Use—General Considerations

##### INTRODUCTION

##### OVERALL MANUFACTURING PLAN

##### SEED LOT SYSTEMS (deleted)

##### RAW MATERIALS, FERMENTATION, AND CELL CULTURE MEDIA

##### MATERIALS OF ANIMAL ORIGIN (added)

##### SEED LOT SYSTEMS AND CELL BANKING (added)

##### PROPAGATION AND HARVEST

##### VACCINES PRODUCED BY RECOMBINANT TECHNOLOGY (added)

##### PURIFICATION

##### INTERMEDIATES

##### FILTERED BULK OR DRUG SUBSTANCE (added)

##### FINAL BULK (FORMULATED BULK)

##### FINAL CONTAINER

##### EVALUATING THE STABILITY OF VACCINES

##### CONTAINER (added)

##### LABELING

##### LOT RELEASE TESTING

##### RETENTION SAMPLES AND OTHER REQUIREMENTS (added)

##### GLOSSARY

##### APPENDIX

- <1238> Vaccines for Human Use—Bacterial Vaccines

- <1239> Vaccines for Human Use—Viral Vaccines (new)

- <1711> Oral Dosage Forms—Performance Tests (new)

- <1788> Methods for the Determination of Subvisible Particulate Matter

- <1788.1> Light Obscuration Method for the Determination of Subvisible Particulate Matter (new)

- <1788.2> Membrane Microscope Method for the Determination of Subvisible Particulate Matter (new)

- <1788.3> Flow Imaging Method for the Determination Of Subvisible Particulate Matter (new)

- <1912> Measurement of Hardness of Semisolids (new)

### Reagents, Indicators, and Solutions

#### Reagent Specifications

Benzoyl Hydrazide (new)

Biuret (new)

Chlorophenylacetylbenzoic Acid (new)

*p*-Dimethylaminocinnamaldehyde

2-Dimethylaminoethanol (new)

Hydrochloric Acid, Ultratrace (new)

Methyl Acrylate (new)

#### Test Solutions

Phosphoric Acid TS, 50 Percent (new)

#### Volumetric Solutions

0.05 M Edetate Disodium VS

0.1 M Edetate Disodium VS

0.1 N Ferric Ammonium Sulfate VS

0.07 N Ferrous Ammonium Sulfate VS

0.1 N Ferrous Ammonium Sulfate VS

0.02 N Hydrochloric Acid VS

- 0.1 N Hydrochloric Acid VS
- 0.5 N Hydrochloric Acid VS
- 1 N Hydrochloric Acid VS
- 0.1 N Potassium Dichromate VS

**CHROMATOGRAPHIC COLUMNS**

- L119 (new)
- L120 (new)
- L121 (new)

**Reference Tables**

**Containers For Dispensing Capsules And Tablets**

- Abacavir, Lamivudine, and Zidovudine Tablets (new)
- Clonidine Hydrochloride Tablets, Extended-Release (new)
- Doxycycline Capsules, Extended-Release (deleted)
- Ethinodiol Diacetate and Mestranol Tablets (deleted)
- Exemestane Tablets (new)
- Guanethidine Monosulfate Tablets (deleted)
- Hyoscyamine Tablets (deleted)
- Lacosamide Tablets (new)
- Lamotrigine Tablets, Orally Disintegrating (new)
- Nadolol and Bendroflumethiazide Tablets
- Penbutolol Sulfate Tablets (deleted)
- Penicillin V Tablets (deleted)
- Sodium Phenylbutyrate Tablets (added)
- Sorafenib Tablets (added)
- Trioxsalen Tablets (deleted)
- Zalcitabine Tablets (deleted)

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

- Clotrimazole
- Gemifloxacin Mesylate (added)
- Regorafenib (new)
- Sorafenib Tosylate (new)

**Monographs (USP 2021, Issue 1)**

- Abacavir, Lamivudine, and Zidovudine Tablets (new)
- Acebutolol Hydrochloride
  - IDENTIFICATION
  - Identification Tests—General, Chloride, Test C*
  - ASSAY
  - IMPURITIES
  - Organic Impurities*
- Albuterol Inhalation Solution (new)
- Amlodipine Besylate Tablets
  - DEFINITION
  - IDENTIFICATION
  - Test A*
  - ASSAY
  - PERFORMANCE TESTS
  - Dissolution*
  - IMPURITIES
  - ADDITIONAL REQUIREMENTS
  - Labeling (added) and USP Reference Standards*
- Atomoxetine Hydrochloride
  - CHEMICAL INFORMATION
  - IDENTIFICATION
  - Identification Tests—General, Chloride, Test C*
  - ASSAY
  - IMPURITIES
  - Organic Impurities, Procedure 1 and Organic Impurities, Procedure 2*
  - ADDITIONAL REQUIREMENTS
  - USP Reference Standards*

- Azithromycin for Oral Suspension
  - IDENTIFICATION
  - Spectroscopic Identification Tests, Infrared Spectroscopy, Test B (added)*
  - PERFORMANCE TESTS
  - Dissolution*
- Baclofen Injection (new)
- Benazepril Hydrochloride and Hydrochlorothiazide Tablets (new)
- Benzotropine Mesylate
  - CHEMICAL INFORMATION
  - DEFINITION
  - IDENTIFICATION
  - ASSAY
  - IMPURITIES
  - Organic Impurities (added)*
  - SPECIFIC TESTS
  - ADDITIONAL REQUIREMENTS
  - USP Reference Standards*
- Betaxolol Hydrochloride
  - IDENTIFICATION
  - Identification Tests—General, Chloride, Test C*
- Bethanechol Chloride Injection (deleted)
- Calcipotriene
  - CHEMICAL INFORMATION
  - DEFINITION
  - ASSAY
  - IMPURITIES
  - SPECIFIC TESTS
  - ADDITIONAL REQUIREMENTS
- Carbachol
  - IDENTIFICATION
  - Identification Tests—General, Chloride, Test B*
  - ASSAY
  - IMPURITIES
  - Ordinary Impurities*
- Carbachol Ophthalmic Solution (deleted)
- Carbidopa and Levodopa Tablets
  - IMPURITIES
- Urea C 13
  - IDENTIFICATION
  - ASSAY
  - IMPURITIES
  - Isotopic Purity*
  - ADDITIONAL REQUIREMENTS
  - USP Reference Standards*
- Cefepime for Injection
  - IDENTIFICATION
  - Test C (added)*
  - ASSAY
  - IMPURITIES
  - SPECIFIC TESTS
  - Bacterial Endotoxins Test, Sterility Tests, and Water Determination (deleted)*
  - ADDITIONAL REQUIREMENTS
  - Packaging and Storage*
- Cefonicid for Injection (deleted)
- Cefonicid Sodium (deleted)
- Cetirizine Hydrochloride
  - CHEMICAL INFORMATION

IDENTIFICATION	ADDITIONAL REQUIREMENTS
<i>Spectroscopic Identification Tests, Infrared Spectroscopy, Test A and Test C (added)</i>	<i>USP Reference Standards</i>
ASSAY	Clozapine Tablets
IMPURITIES	IDENTIFICATION
<i>Organic Impurities, Procedure 1 and Organic Impurities, Procedure 2</i>	<i>Test A</i>
ADDITIONAL REQUIREMENTS	ASSAY
<i>USP Reference Standards</i>	PERFORMANCE TESTS
Cetylpyridinium Chloride	<i>Dissolution</i>
IMPURITIES	IMPURITIES
<i>Organic Impurities</i>	ADDITIONAL REQUIREMENTS
ADDITIONAL REQUIREMENTS	Codeine Phosphate
<i>USP Reference Standards</i>	DEFINITION
Cilostazol Tablets	IDENTIFICATION
IDENTIFICATION	ASSAY
<i>Test A (added)</i>	IMPURITIES
ASSAY	ADDITIONAL REQUIREMENTS
PERFORMANCE TESTS	<i>USP Reference Standards</i>
<i>Dissolution</i>	Cyclopropane (deleted)
IMPURITIES (added)	Dacarbazine
ADDITIONAL REQUIREMENTS	CHEMICAL INFORMATION
<i>USP Reference Standards</i>	IDENTIFICATION
Ciprofloxacin Ophthalmic Ointment	ASSAY
IDENTIFICATION	IMPURITIES
<i>Test B (added)</i>	<i>Organic Impurities and Limit of Dimethylamine (added)</i>
ASSAY	ADDITIONAL REQUIREMENTS
IMPURITIES (added)	<i>USP Reference Standards</i>
Clarithromycin Extended-Release Tablets	Dacarbazine for Injection
PERFORMANCE TESTS	IDENTIFICATION
<i>Dissolution</i>	ASSAY
IMPURITIES (added)	<i>Procedure</i>
ADDITIONAL REQUIREMENTS	IMPURITIES
<i>USP Reference Standards</i>	SPECIFIC TESTS
Clobetasol Propionate Ointment	<i>Particulate Matter in Injections (added)</i>
IDENTIFICATION	ADDITIONAL REQUIREMENTS
ASSAY	<i>USP Reference Standards</i>
IMPURITIES (added)	Diazoxide
ADDITIONAL REQUIREMENTS	IDENTIFICATION
<i>USP Reference Standards</i>	ASSAY
Clonazepam Tablets	IMPURITIES
IDENTIFICATION	<i>Organic Impurities (added)</i>
<i>Test A</i>	Dibucaine Hydrochloride
ASSAY	IDENTIFICATION
PERFORMANCE TESTS	<i>Identification Tests—General, Chloride, Test C</i>
<i>Dissolution</i>	ASSAY
IMPURITIES	IMPURITIES
ADDITIONAL REQUIREMENTS	<i>Organic Impurities</i>
<i>Packaging and Storage</i>	Dimenhydrinate
Clonidine Hydrochloride Extended-Release Tablets (new)	IDENTIFICATION
Clozapine	ASSAY
IDENTIFICATION	IMPURITIES
<i>Spectroscopic Identification Tests, Infrared Spectroscopy, Test A</i>	<i>Organic Impurities</i>
ASSAY	ADDITIONAL REQUIREMENTS
IMPURITIES	<i>USP Reference Standards</i>
<i>Organic Impurities</i>	Dimenhydrinate Tablets
SPECIFIC TESTS	IDENTIFICATION
	ASSAY
	OTHER COMPONENTS
	PERFORMANCE TESTS
	IMPURITIES

ADDITIONAL REQUIREMENTS  
Doxepin Hydrochloride  
IDENTIFICATION  
ASSAY  
IMPURITIES  
*Organic Impurities*  
ADDITIONAL REQUIREMENTS  
*USP Reference Standards*  
Doxepin Hydrochloride Capsules  
DEFINITION  
IDENTIFICATION  
*Test B (added)*  
ASSAY  
PERFORMANCE TESTS  
IMPURITIES (added)  
ADDITIONAL REQUIREMENTS  
Doxycycline Extended-Release Capsules (deleted)  
Edetate Disodium Compounded Ophthalmic Solution (new)  
Epinephrine Bitartrate  
DEFINITION  
IDENTIFICATION  
ASSAY  
IMPURITIES  
SPECIFIC TESTS  
ADDITIONAL REQUIREMENTS  
*USP Reference Standards*  
Epinephryl Borate Ophthalmic Solution (deleted)  
Ergotamine Tartrate Injection (deleted)  
Escitalopram Oral Solution  
IDENTIFICATION  
*Test B (added)*  
ASSAY  
IMPURITIES  
ADDITIONAL REQUIREMENTS  
*USP Reference Standards*  
Esomeprazole Magnesium  
IDENTIFICATION  
*Test C (added)*  
ASSAY  
IMPURITIES  
Ethinodiol Diacetate and Mestranol Tablets (deleted)  
Exemestane Tablets (new)  
Felodipine  
CHEMICAL INFORMATION  
ASSAY  
IMPURITIES  
*Limit of Ethyl 3-Aminocrotonate (added) and Organic Impurities*  
SPECIFIC TESTS  
*Color of Solution*  
ADDITIONAL REQUIREMENTS  
*USP Reference Standards*  
Fentanyl Citrate  
CHEMICAL INFORMATION  
IDENTIFICATION  
ASSAY  
IMPURITIES  
*Ordinary Impurities (deleted) and Organic Impurities (added)*

ADDITIONAL REQUIREMENTS  
*USP Reference Standards*  
Ferumoxides Injection (deleted)  
Flavoxate Hydrochloride  
CHEMICAL INFORMATION  
DEFINITION  
IDENTIFICATION  
*Identification Tests—General, Chloride, Test C*  
ASSAY  
IMPURITIES  
*Organic Impurities*  
SPECIFIC TESTS  
*Loss on Drying*  
ADDITIONAL REQUIREMENTS  
*USP Reference Standards*  
Fluconazole Tablets  
IDENTIFICATION  
ASSAY  
IMPURITIES (added)  
ADDITIONAL REQUIREMENTS  
*USP Reference Standards*  
Flumethasone Pivalate (deleted)  
Flumethasone Pivalate Cream (deleted)  
Gadoterate Meglumine Injection (new)  
Galantamine Tablets  
IDENTIFICATION  
*Test A*  
ASSAY  
PERFORMANCE TESTS  
IMPURITIES  
ADDITIONAL REQUIREMENTS  
*Labeling and USP Reference Standards*  
Gallamine Triethiodide (deleted)  
Gallamine Triethiodide Injection (deleted)  
Gemifloxacin Mesylate (new)  
Granisetron Hydrochloride Injection  
IDENTIFICATION  
*Test A*  
ASSAY  
IMPURITIES  
SPECIFIC TESTS  
*Bacterial Endotoxins Test*  
ADDITIONAL REQUIREMENTS  
*USP Reference Standards*  
Granisetron Hydrochloride Tablets  
IDENTIFICATION  
*Test A*  
ASSAY  
PERFORMANCE TESTS  
*Dissolution*  
IMPURITIES  
ADDITIONAL REQUIREMENTS  
*USP Reference Standards*  
Guanethidine Monosulfate Tablets (deleted)  
Haloperidol  
CHEMICAL INFORMATION  
IDENTIFICATION  
*Spectroscopic Identification Tests, Infrared Spectroscopy, Test A*  
ASSAY

IMPURITIES  
*Organic Impurities*  
ADDITIONAL REQUIREMENTS  
*USP Reference Standards*  
Haloperidol Tablets  
IDENTIFICATION  
*Test B (added)*  
ASSAY  
PERFORMANCE TESTS  
IMPURITIES (added)  
ADDITIONAL REQUIREMENTS  
Haloperidol Decanoate  
CHEMICAL INFORMATION  
DEFINITION  
IDENTIFICATION  
ASSAY  
IMPURITIES  
*Organic Impurities*  
SPECIFIC TESTS  
ADDITIONAL REQUIREMENTS  
*USP Reference Standards*  
Hydroxychloroquine Sulfate Tablets  
ASSAY  
PERFORMANCE TESTS  
*Organic Impurities (added)*  
Hyoscyamine Tablets (deleted)  
Insulin Human  
OTHER COMPONENTS  
SPECIFIC TESTS  
*Bacterial Endotoxins Test and Microbial Enumeration Tests and Tests for Specified Microorganisms*  
ADDITIONAL REQUIREMENTS  
*Labeling*  
Ipratropium Bromide  
CHEMICAL INFORMATION  
ASSAY  
IMPURITIES  
*Limit of Ipratropium Related Compound A and Organic Impurities*  
ADDITIONAL REQUIREMENTS  
*USP Reference Standards*  
Ipratropium Bromide Inhalation Solution (new)  
Ipratropium Bromide and Albuterol Sulfate Inhalation Solution  
ASSAY  
IMPURITIES  
ADDITIONAL REQUIREMENTS  
*USP Reference Standards*  
Isoetharine Hydrochloride (deleted)  
Isoetharine Inhalation Solution (deleted)  
Isoetharine Mesylate (deleted)  
Isoxsuprine Hydrochloride Injection (deleted)  
Lacosamide (new)  
Lacosamide Injection (new)  
Lacosamide Oral Solution (new)  
Lacosamide Tablets (new)  
Lamotrigine Orally Disintegrating Tablets (new)

Levofloxacin Tablets  
IDENTIFICATION  
*Test B (added)*  
ASSAY  
IMPURITIES  
Liothyronine Sodium  
DEFINITION  
IDENTIFICATION  
*Test A, Test B, and Test D (deleted)*  
ASSAY  
IMPURITIES  
SPECIFIC TESTS  
*Sodium Content (deleted)*  
ADDITIONAL REQUIREMENTS  
*USP Reference Standards*  
Loratadine Capsules (new)  
Maprotiline Hydrochloride  
IDENTIFICATION  
*Identification Tests—General, Chloride, Test C*  
IMPURITIES  
*Organic Impurities, Procedure 1*  
Methylphenidate Hydrochloride  
IDENTIFICATION  
*Identification Tests—General, Chloride, Test B*  
ASSAY  
IMPURITIES  
*Organic Impurities, Procedure 1 and Organic Impurities, Procedure 2*  
Minoxidil Tablets  
IDENTIFICATION  
ASSAY  
PERFORMANCE TESTS  
*Dissolution*  
IMPURITIES  
ADDITIONAL REQUIREMENTS  
*Packaging and Storage*  
Modafinil  
IDENTIFICATION  
ASSAY  
IMPURITIES  
*Organic Impurities*  
Modafinil Tablets  
IDENTIFICATION  
ASSAY  
PERFORMANCE TESTS  
*Dissolution*  
IMPURITIES  
Nadolol and Bendroflumethiazide Tablets  
IDENTIFICATION  
ASSAY  
PERFORMANCE TESTS  
*Dissolution, Procedure for a pooled sample for immediate-release dosage forms*  
IMPURITIES (added)  
ADDITIONAL REQUIREMENTS  
*Packaging and Storage*  
Naratriptan Hydrochloride  
DEFINITION  
IDENTIFICATION  
*Test C*

ASSAY  
 IMPURITIES  
 Nefazodone Hydrochloride  
 DEFINITION  
 IDENTIFICATION  
*Test C (added)*  
 ASSAY  
 IMPURITIES  
*Organic Impurities*  
 ADDITIONAL REQUIREMENTS  
*USP Reference Standards*  
 Nortriptyline Hydrochloride  
 IDENTIFICATION  
*Identification Tests—General, Chloride, Test C*  
 ASSAY  
 IMPURITIES  
*Organic Impurities*  
 SPECIFIC TESTS  
 Nortriptyline Hydrochloride Capsules  
 IDENTIFICATION  
 ASSAY  
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*Dissolution*  
 ADDITIONAL REQUIREMENTS  
*Packaging and Storage*  
 Nortriptyline Hydrochloride Oral Solution  
 IDENTIFICATION  
 ASSAY  
 ADDITIONAL REQUIREMENTS  
*Packaging and Storage*  
 Omeprazole Magnesium  
 IDENTIFICATION  
*Test C (added)*  
 ASSAY  
 IMPURITIES  
*Organic Impurities*  
 Oxcarbazepine Oral Suspension  
 IDENTIFICATION  
*Test B (added)*  
 ASSAY  
 PERFORMANCE TESTS  
*Dissolution*  
 ADDITIONAL REQUIREMENTS  
*Packaging and Storage*  
 Oxcarbazepine Tablets  
 IDENTIFICATION  
*Test A*  
 ASSAY  
 IMPURITIES  
 Oxycodone Hydrochloride Oral Solution  
 IDENTIFICATION  
 ASSAY  
 IMPURITIES (added)  
 ADDITIONAL REQUIREMENTS  
 Oxymetholone  
 IDENTIFICATION  
 ASSAY  
 IMPURITIES (added)

SPECIFIC TESTS  
*Melting Range or Temperature (deleted) and Completeness of Solution (deleted)*  
 ADDITIONAL REQUIREMENTS  
*USP Reference Standards*  
 Oxymetholone Tablets  
 IDENTIFICATION  
 ASSAY  
 PERFORMANCE TESTS  
 IMPURITIES (added)  
 ADDITIONAL REQUIREMENTS  
 Paclitaxel Injection  
 IDENTIFICATION  
*Test A*  
 ASSAY  
 IMPURITIES  
 SPECIFIC TESTS  
*Bacterial Endotoxins Test*  
 ADDITIONAL REQUIREMENTS  
*Packaging and Storage and USP Reference Standards*  
 Penbutolol Sulfate (deleted)  
 Penbutolol Sulfate Tablets (deleted)  
 Penicillin V Benzathine (deleted)  
 Penicillin V Benzathine Oral Suspension (deleted)  
 Penicillin V for Oral Suspension (deleted)  
 Penicillin V Tablets (deleted)  
 Pilocarpine Ocular System (deleted)  
 Pindolol  
 IDENTIFICATION  
*Test A*  
 ASSAY  
 IMPURITIES  
*Organic Impurities*  
 ADDITIONAL REQUIREMENTS  
*USP Reference Standards*  
 Potassium Chloride in Lactated Ringer's and Dextrose Injection  
 IDENTIFICATION  
*Identification Tests—General, Chloride and Calcium, Test B*  
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*Lactate*  
 IMPURITIES  
 Prazosin Hydrochloride  
 DEFINITION  
 IDENTIFICATION  
*Spectroscopic Identification Tests, Infrared Spectroscopy, Test A, Test B, and Test C*  
 ASSAY  
 IMPURITIES  
*Organic Impurities*  
 ADDITIONAL REQUIREMENTS  
*USP Reference Standards*  
 Proparacaine Hydrochloride  
 IDENTIFICATION  
*Identification Tests—General, Chloride, Test C*  
 Pyrazinamide  
 DEFINITION  
 IDENTIFICATION  
*Test B and Test C (deleted)*

ASSAY  
 IMPURITIES  
     *Organic Impurities (added)*  
 SPECIFIC TESTS  
     *Melting Range or Temperature (deleted)*  
 ADDITIONAL REQUIREMENTS  
     *USP Reference Standards*  
 Quinapril Hydrochloride  
 CHEMICAL INFORMATION  
 DEFINITION  
 IDENTIFICATION  
     *Spectroscopic Identification Tests, Infrared Spectroscopy, Test A*  
 ASSAY  
 IMPURITIES  
     *Limit of Residual Solvents (deleted) and Organic Impurities*  
 SPECIFIC TESTS  
     *Content of Acetone (added)*  
 ADDITIONAL REQUIREMENTS  
 Quinapril Tablets  
 IDENTIFICATION  
     *Test A*  
 ASSAY  
 PERFORMANCE TESTS  
 IMPURITIES  
 ADDITIONAL REQUIREMENTS  
     *USP Reference Standards*  
 Quinine Sulfate Capsules  
 IDENTIFICATION  
     *Test B and Test C*  
 ASSAY  
 PERFORMANCE TESTS  
 IMPURITIES  
 ADDITIONAL REQUIREMENTS  
     *Packaging and Storage and USP Reference Standards*  
 Regorafenib (new)  
 Rifabutin  
 ASSAY  
 IMPURITIES  
     *Chromatographic Purity (deleted) and Organic Impurities, Procedure 2 (added)*  
 Rifabutin Capsules  
 ASSAY  
 PERFORMANCE TESTS  
 IMPURITIES  
 ADDITIONAL REQUIREMENTS  
     *Packaging and Storage*  
 Lactated Ringer's Injection  
 IDENTIFICATION  
     *Identification Tests—General, Test A*  
 ASSAY  
     *Chloride*  
 SPECIFIC TESTS  
     *Sterility Tests (added)*  
 Lactated Ringer's and Dextrose Injection  
 IDENTIFICATION  
     *Identification Tests—General, Chloride, Test B*

ASSAY  
     *Chloride and Dextrose*  
 IMPURITIES  
 SPECIFIC TESTS  
     *Sterility Tests (added)*  
 Half-Strength Lactated Ringer's and Dextrose Injection  
 IDENTIFICATION  
     *Identification Tests—General, Chloride and Calcium, Test B*  
 ASSAY  
     *Chloride and Dextrose*  
 SPECIFIC TESTS  
     *Sterility Tests (added)*  
 Modified Lactated Ringer's and Dextrose Injection  
 IDENTIFICATION  
     *Identification Tests—General, Chloride and Calcium, Test B*  
 ASSAY  
     *Calcium, Chloride and Dextrose*  
 IMPURITIES  
 SPECIFIC TESTS  
     *Sterility Tests (added)*  
 Risperidone Oral Solution  
 IDENTIFICATION  
     *Test B (added)*  
 ASSAY  
 IMPURITIES  
 ADDITIONAL REQUIREMENTS  
     *USP Reference Standards*  
 Ropinirole Extended-Release Tablets  
 PERFORMANCE TESTS  
     *Dissolution*  
 IMPURITIES  
 Ropinirole Hydrochloride  
 IDENTIFICATION  
     *Identification Tests—General, Chloride, Test C*  
 ASSAY  
 IMPURITIES  
     *Limit of Palladium and Organic Impurities, Procedure 3*  
 Rufinamide Tablets  
 IDENTIFICATION  
     *Test B (added)*  
 ASSAY  
 PERFORMANCE TESTS  
     *Dissolution*  
 IMPURITIES  
 Sertraline Hydrochloride  
 IDENTIFICATION  
     *Identification Tests—General, Chloride, Test C*  
 ASSAY  
 IMPURITIES  
     *Limit of (R,R) Sertraline Hydrochloride, Organic Impurities, Procedure 1, Organic Impurities, Procedure 2 and Limit of Mandelic Acid*  
 Sodium Chloride Tablets  
 IDENTIFICATION  
 ASSAY  
 ADDITIONAL REQUIREMENTS  
     *USP Reference Standards (added)*

Sodium Chloride Tablets for Solution  
 IDENTIFICATION  
 ASSAY  
 ADDITIONAL REQUIREMENTS  
*USP Reference Standards (added)*

Sodium Phenylbutyrate Oral Powder (new)  
 Sodium Phenylbutyrate Tablets (new)  
 Sorafenib Tablets (new)  
 Sorafenib Tosylate (new)  
 Sorbitol Solution  
 IMPURITIES  
*Limit of Nickel*  
 SPECIFIC TESTS  
*pH (deleted) and Conductivity (added)*

Spirolactone Compounded Oral Suspension  
 DEFINITION  
 ASSAY  
 SPECIFIC TESTS  
 ADDITIONAL REQUIREMENTS  
*Packaging and Storage and Beyond-Use-Date*

Telmisartan  
 DEFINITION  
 IDENTIFICATION  
 ASSAY  
 IMPURITIES  
*Organic Impurities*  
 ADDITIONAL REQUIREMENTS  
*Packaging and Storage*

Tetracycline Hydrochloride Compounded Oral Suspension (deleted)  
 Tetraxetan (new)  
 Thioridazine Hydrochloride  
 IDENTIFICATION  
*Identification Tests—General, Chloride, Test B*  
 ASSAY  
 IMPURITIES  
*Organic Impurities*

Ticarcillin and Clavulanic Acid Injection (deleted)  
 Tizanidine Hydrochloride  
 IDENTIFICATION  
*Identification Tests—General, Chloride, Test C*  
 ASSAY  
 IMPURITIES  
*Organic Impurities*  
 ADDITIONAL REQUIREMENTS  
*USP Reference Standards*

Tranexamic Acid  
 DEFINITION  
 IDENTIFICATION  
*Test B (added)*  
 ASSAY  
 IMPURITIES  
*Organic Impurities*  
 ADDITIONAL REQUIREMENTS  
*USP Reference Standards*

Triflupromazine Oral Suspension (deleted)  
 Trioxsalen (deleted)  
 Trioxsalen Tablets (deleted)  
 Vecuronium Bromide  
 CHEMICAL INFORMATION

ASSAY  
 IMPURITIES  
 SPECIFIC TESTS  
*Optical Rotation, Specific Rotation and Bacterial Endotoxins Test*

ADDITIONAL REQUIREMENTS  
*Labeling (added) and USP Reference Standards*

Sterile Water for Inhalation  
 SPECIFIC TESTS  
*Oxidizable Substances (deleted) and Total Organic Carbon, Sterile Water*

Sterile Water for Injection  
 SPECIFIC TESTS  
*Oxidizable Substances (deleted) and Total Organic Carbon, Sterile Water*

Sterile Water for Irrigation  
 SPECIFIC TESTS  
*Oxidizable Substances (deleted) and Total Organic Carbon, Sterile Water*

Sterile Purified Water  
 SPECIFIC TESTS  
*Oxidizable Substances (deleted) and Total Organic Carbon, Sterile Water*

Zalcitabine (deleted)  
 Zalcitabine Tablets (deleted)  
 Zinc Carbonate  
 IDENTIFICATION  
*Test B (added)*  
 ASSAY

### Monographs (Dietary Supplements)

*Bifidobacterium bifidum (new)*  
*Bifidobacterium longum subsp. longum (new)*  
 Calcium Magnesium Citrate (new)  
 Citicoline (new)  
 L-alpha-Glycerolphosphorylcholine  
 IDENTIFICATION  
*Spectroscopic Identification Tests, Infrared Spectroscopy, Test A*  
 IMPURITIES  
*Organic Impurities*  
 ADDITIONAL REQUIREMENTS  
*USP Reference Standards*

*Lactobacillus reuteri (new)*  
*Lactobacillus rhamnosus*  
 TITLE  
 DEFINITION  
 IDENTIFICATION  
 ASSAY  
 CONTAMINANTS  
*Microbial Enumeration Tests (deleted), Non-Lactic Acid Bacteria (deleted), Absence of Specified Microorganisms, Test for Absence of Escherichia coli and Test for Absence of Salmonella Species (deleted), Probiotic Tests, Contaminant Microorganisms (added), and Probiotic Tests, Specified Microorganisms (added)*  
 ADDITIONAL REQUIREMENTS  
*Labeling*

Tomato Extract Containing Lycopene  
 DEFINITION



COMPOSITION

SPECIFIC TESTS

*Viscosity—Rotational Methods and Particle Size Distribution*

Oil- and Water-Soluble Vitamins with Minerals

Chewable Gels (new)

Water-Soluble Vitamins Preparation (new)

To Be Official