

PHARMACOPEIAL FORUM

33

NUMBER 2

BIMONTHLY: March-April 2007

Featured in This Issue

USP has identified the following content areas in the March-April 2007 issue of *Pharmacoepial Forum* as noteworthy for the pharmaceutical industry worldwide.

- **Policies and Announcements**
 - **USP to Establish Office and Laboratory Facility in China**
 - **USP to Verify the Quality of Pharmaceutical Ingredients Worldwide**
 - **USP Annual Scientific Meeting 2007**
 - **Extractable Volume USP–NF General Chapter <1> Injections: Notice of Harmonized Text**
 - **Harmonized Microbiology General Chapters: Notice of Postponement**

- **Stimuli article**
 - **A New Validated Differential Scanning Calorimetric Procedure for Monitoring the Less Active R,S Isomer of Ethambutol Dihydrochloride in Bulk Drug Samples and Anti-tuberculosis Formulations**

- **Interim Revision Announcement Pertaining to USP 29-NF 24**

A detailed listing of the Table of Contents of the March-April issue of *Pharmacoepial Forum* follows.



U.S. PHARMACOPEIA
The Standard of QualitySM

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STAFF DIRECTORY

This updated directory reflects assignment changes based on 2005–2010 Expert Committees. The general USP telephone number, (301) 881-0666, may still be used for general inquiries or when a particular Expert Committee is not identified. The fax number is (301) 816-8373.

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USP TO ESTABLISH OFFICE AND LABORATORY FACILITY IN CHINA. USP's Board of Trustees has approved the establishment of a USP facility in China. The USP-China facility will be the second international office and laboratory facility established by USP. USP-India Limited opened in February 2006.

The establishment of the USP-China facility supports USP's international public health strategy and mission. The USP office and laboratory facility in China will enable USP to work with Chinese manufacturers, the Chinese Pharmacopoeia, and other constituencies to ensure the quality of medicines.

The facility, located in Zhangjiang Hi-Tech Park in Shanghai, will support collaborative testing, technical assistance, customer service, and training. John Hu, Ph.D., international vice president-China, currently oversees the site and projects hiring approximately 15 people to work in the facility. A February 2007 opening date is planned.

In addition to USP-India Limited (Hyderabad, India), USP has a European sales office (Basel, Switzerland). The USP-China office and laboratory facility in Shanghai will further expand USP's capacity to reach those in the 130 countries around the world that rely upon USP standards.

USP TO VERIFY THE QUALITY OF PHARMACEUTICAL INGREDIENTS WORLDWIDE.

USP has announced a new service to verify the quality of pharmaceutical ingredients. USP will offer this service to manufacturers of drug substances and excipients worldwide. The verification service will identify those pharmaceutical ingredients that meet USP's world class quality standards.

"USP Verified" pharmaceutical ingredients will receive a Certificate of Standards Compliance and will be awarded the distinctive USP Verified Pharmaceutical Ingredients mark to display on the shipping container. USP will award the certificate and mark to drug substances and excipients that pass a rigorous audit, testing, and review process, which includes:

- Evaluation of an ingredient manufacturer's quality systems through an audit for compliance with Good Manufacturing Practices (GMPs)
- Review of manufacturing and quality control documents for ingredients submitted for verification
- Laboratory testing of ingredient samples from USP-selected lots for compliance with USP's FDA-enforceable standards for purity, potency, and quality
- Post-verification surveillance testing of ingredients bearing the USP Verified mark

This service will assure drug product manufacturers and regulatory agencies that the substances with the USP Verified mark have met the highest standards in the world for strength, quality, and purity. USP wants to raise the quality of medicines by calling attention to the best ingredients. Drug product manufacturers and patients worldwide will benefit as a result.

Manufacturers seeking USP Verification for a pharmaceutical ingredient should contact Eric Sheinin, Vice President, Pharmaceutical Ingredient Verification Program (es@usp.org or 301-816-8103) for further information.

USP ANNUAL SCIENTIFIC MEETING 2007. Hold the date! The USP Annual Scientific Meeting will be held in Tampa, Florida, at the Hyatt Regency Tampa on September 25–28, 2007. Information is available on USP's website at www.usp.org.

Contact Ms. Kelly Coates (kct@usp.org or 301-816-8510) for further information.

REVISION BULLETINS. In accordance with Section 9.01 of the Rules and Procedures of the Council of Experts, a Revision Bulletin is an official publication of the United States Pharmacopeia and the National Formulary. Revision Bulletins are posted on USP's website and sent to affected manufacturers via mail and e-mail, and are used to make revisions effective immediately when the need arises.

EXTRACTABLE VOLUME, USP–NF GENERAL CHAPTER <1>, INJECTIONS: NOTICE OF HARMONIZED TEXT.

Effective November 14, 2006, revised text on Extractable Volume has been approved by the Parenteral Products—Industrial Expert Committee, Dr. Steven L. Nail, Chair. The changes to General Chapter <1>, *Injections*, include verbatim harmonized text as proposed in the European and Japanese pharmacopoeias and reflect alignment with the June 2004 signed-off text of the Pharmacopoeial Discussion Group (PDG). Questions should be directed to Dr. Desmond Hunt, Scientific Liaison, PPI Expert Committee (dgh@usp.org or 301-816-8341).

HARMONIZED MICROBIOLOGY GENERAL CHAPTERS: NOTICE OF POSTPONEMENT.

Effective November 14, 2006, the implementation of the following harmonized microbiological quality USP–NF General Chapters has been postponed until May 1, 2009:

- <61> *Microbiological Examination of Nonsterile Products: Microbial Enumeration Tests*
- <62> *Microbiological Examination of Nonsterile Products: Tests for Specified Microorganisms*
- <1111> *Microbiological Examination of Nonsterile Products: Acceptance Criteria for Pharmaceutical Preparations and Substances for Pharmaceutical Use*

These USP–NF General Chapters were originally scheduled to be effective on August 1, 2007. Implementation of the postponed harmonized General Chapters prior to the May 2009 date is at the discretion of the user and may be subject to regulatory consideration.

The currently official *USP–NF* General Chapters <61> *Microbial Limit Tests* and <1111> *Microbiological Attributes of Non-sterile Pharmaceutical Products* will remain effective until May 1, 2009.

Questions should be directed to Dr. Radhakrishna Tirumalai, Senior Scientist (rst@usp.org or 301-816-8339).

USP CATALOG AVAILABLE. While no longer included in the back of this publication, the USP Catalog is still available in online and stand-alone print versions. Online bi-monthly and daily catalogs can be accessed at www.usp.org/referenceStandards/catalog.html. You can also sign up to receive the USP Catalog in print (via postal mail) along with monthly email alerts—which will keep you informed about new Reference Standards, availability, and current lots—by sending an email to marketing@usp.org or calling 301-816-8237.

STIMULI ARTICLES POSTED ON USP’S WEBSITE. Starting in March 2007, the *Stimuli* articles that are published in *Pharmacopeial Forum* will be simultaneously published on USP’s website. Look for them at www.usp.org. For more information about *Stimuli* articles, please contact Stefan Schuber, Ph.D., Director, Scientific Reports (301-816-8551 or sps@usp.org).

PHARMACOPEIAL EDUCATION COURSES. The USP Pharmacopeial Education (PE) courses offer specialized instruction for chemists, other scientists, and professionals in the pharmaceutical and allied industries. USP scientists and USP science experts, who play a key role in establishing official USP standards, teach these courses and provide expert insights into the practical applications of official test procedures and best practices in using the *USP–NF* and other USP resources. The courses also give participants an opportunity to learn how to get involved in USP’s standards-setting processes and the benefits of participating in standards development. Courses offered in 2007 are listed below. For more information and to register, visit www.usp.org/goto/pe. To discuss how USP can bring courses to a location of your choice or design a custom course package for you, call 301-816-8589, or e-mail PharmacopeialEducation@usp.org.

Beginning in the 2007 calendar year, USP’s PE program will be initiating a significant expansion. Both the depth and breadth of course offerings will grow as the Pharmacopeial Education staff works to make the science behind the standards more accessible. As this process begins, the PE program invites you to participate by suggesting titles, developing course objectives, or even joining the teaching staff.

Calendar of Forthcoming Pharmacopeial Education Courses

Date	Name of Course	Location	Price
The Americas			
6-Mar-07	Navigating Chapter <467> Residual Solvents (new)	East Brunswick, NJ (half-day seminar)	\$245*
15-Mar-07	Essentials of USP Microbiological Testing (new)	Raleigh, NC	\$595
20-Mar-07	Navigating Chapter <467> Residual Solvents (new)	San Francisco, CA (half-day seminar)	\$245*
22-Mar-07	Navigating Chapter <467> Residual Solvents (new)	Fullerton, CA (half-day seminar)	\$245*
27-Mar-07	Navigating Chapter <467> Residual Solvents (new)	Montreal, Canada (half-day seminar)	(1)
19-Apr-07	Navigating Chapter <467> Residual Solvents (new)	Rockville, MD (USP Headquarters, half-day seminar)	\$245
8–9 May-07	Fundamentals of Dissolution	North Brunswick, NJ (with Distek, 2-day)	\$1,500
17-May-07	Analytical Method Validation (in Spanish)	Mexico City, Mexico	(2)
22-May-07	Analytical Method Validation	Raleigh, NC	\$595
19-Jun-07	Effectively Using the USP–NF—Sessions I & II	Raleigh, NC	\$595
Europe/Middle East/Africa/India			
23-Apr-07	Navigating Chapter <467> Residual Solvents (new)	Munich, Germany	
24-Apr-07	Navigating Chapter <467> Residual Solvents (new)	Berlin, Germany	
26-Apr-07	Navigating Chapter <467> Residual Solvents (new)	Liverpool, United Kingdom	
27-Apr-07	Navigating Chapter <467> Residual Solvents (new)	Brussels, Belgium	
7–8 May 07	Fundamentals of Dissolution (2-day) (in English with assistance for Italian)	Milan, Italy	
10–11 May 07	Fundamentals of Dissolution (2-day) (in English with assistance for Italian)	Rome, Italy	

Calendar of Forthcoming Pharmacopeial Education Courses (Continued)

Date	Name of Course	Location	Price
30-May-07	Analytical Method Validation	Johannesburg, South Africa	
31-May-07	Fundamentals of Dissolution (Lectures)	Johannesburg, South Africa	
11-Jun-07	Effectively Using the USP–NF—Sessions I and II (in English with assistance for Italian)	Milan, Italy	
12-Jun-07	Analytical Method Validation (in English with assistance for Italian)	Rome, Italy	
<i>To receive further information on all courses in Europe/Middle East/Africa, contact USP, Münchensteinerstrasse 41, CH-4052 Basel, Switzerland, +41 (0)61 316 3010, or AP@usp.org</i>			
* Two identical half-day seminars, morning and afternoon, will be offered. To register, send your contact information by e-mail to PharmacopeialEducation@usp.org to receive a flyer/registration form by return e-mail. If space permits, registrations accepted later than 14 days before each seminar date will be \$295.			
(1) For registration information, contact custserv@acamchem.com (2) For registration information, contact ventas@proquifa.com.mx			

2007 USP DICTIONARY. The new 2007 edition of the USP Dictionary will publish in April. It features more than 3,700 new and revised chemical formulas, over 1,000 new pronunciations, and hundreds of new USAN and INN names. Available in print or online. USP is now accepting orders. Please contact Customer Service at 301-881-0666 or 1-800-227-8772. You may also visit our Online Store at <http://www.usp.org/products/>.

VISIT THE USP WEBSITE AT <http://www.usp.org>. Various resources related to Pharmacopeial standards are presented, including highlights from *PF*.

INTERNATIONAL CORRESPONDENCE. Individuals who wish to correspond with the European and Japanese pharmacopoeias concerning monographs in the Official Inquiry and Consensus stages of international harmonization should address their comments to the coordinating pharmacopoeia, with a copy to USP, for a given article. The addresses for the European and Japanese pharmacopoeias are as follows:

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HOW TO SUBMIT COMMENTS. The USP welcomes and encourages interested parties to submit comments and data regarding potential, proposed, or adopted (official) standards. Submissions concerning a particular item that has appeared in an issue of *PF* should be submitted to the appropriate USP scientific staff liaison identified at the end of the *Briefing* accompanying each item. To submit comments and data to a liaison, use the e-mail address and telephone number listed in the *Staff Directory* included in every *PF*.

Please note that *USP–NF* is being published in an annual edition, with one three-volume primary publication and two *Supplements* a year. In addition, the schedule provided below will repeat every year so that users will know what to expect and will become familiar with the deadlines.

For general inquiries or in cases where a particular liaison is not identified, use the general USP telephone number 301-881-0666 or fax number 301-816-8373.

PHARMACOPEIAL FORUM PUBLIC REVIEW AND COMMENT PERIOD DEADLINES. The full year's listing of comment period deadlines and the targeted official publications appears below. In accordance with the Rules and Procedures of the 2005–2010 Council of Experts, USP has implemented a 90-day comment period by providing a deadline for each issue of *PF* unless otherwise stated in the individual *Briefing*. As previously stated, as a result of the comment deadline extension, the "Intent to Comment" form will no longer be used and will be removed from *PF*. The listing of comment period deadlines and the targeted official publications appears below.

Pharmacopeial Forum	Comment Deadline	Targeted Official Publication	Publication Date	Official Date
<i>PF</i> 32(6)	February 15, 2007	<i>USP 31–NF 26</i>	November 2007	May 2008
<i>PF</i> 33(1)	April 16, 2007			
<i>PF</i> 33(2)	June 15, 2007	<i>USP 31–NF 26</i> <i>1st Supplement</i>	February 2008	August 2008
<i>PF</i> 33(3)	August 15, 2007			

Pharmacopeial Forum	Comment Deadline	Targeted Official Publication	Publication Date	Official Date
PF 33(4)	October 15, 2007	USP 31–NF 26 2nd Supplement	June 2008	December 2008
PF 33(5)	December 15, 2007			
PF 33(6)	February 15, 2008	USP 32–NF 27	November 2008	May 2009
PF 34(1)	April 15, 2008			

All official revisions are published in the annual edition or *Supplements* to *USP–NF* (twice yearly). Between these publications, official revisions are published in *PF* in the *Interim Revision Announcement*; these revisions are also incorporated in the upcoming *Supplement*. The official publication in which an *IRA* is incorporated will depend upon publication deadlines. The *IRAs* appearing in *PF* Numbers 5 and 6 of each volume will not appear until *Supplement 1*. See table below. The

electronic version of *USP–NF* is updated as each *Supplement* becomes available and, therefore, contains all official text up to and including the contents of the latest *Supplement*. The new table below outlines the publications and their release and official dates, and the book or *Supplement* that supersedes them.

Publication Schedules

Publication	Release Date	Official Date	Superseded by
4th <i>IRA</i> [PF 32(4)]	July 1, 2006	Aug. 1, 2006	<i>USP 30–NF 25</i>
5th <i>IRA</i> [PF 32(5)]	Sept. 1, 2006	Oct. 1, 2006	<i>1st Supplement</i>
6th <i>IRA</i> [PF 32(6)]	Nov. 1, 2006	Dec. 1, 2006	<i>1st Supplement</i>
<i>USP 30–NF 25</i>	Nov. 1, 2006*	May 1, 2007*	<i>1st Supplement</i>
<i>IRA</i> [PF 33(1)]	Jan. 1, 2007*	Feb. 1, 2007*	<i>2nd Supplement</i>
<i>1st Supplement</i>	Feb. 1, 2007*	Aug. 1, 2007*	<i>2nd Supplement</i>
<i>IRA</i> [PF 33(2)]	Mar. 1, 2007*	Apr. 1, 2007*	<i>2nd Supplement</i>
<i>IRA</i> [PF 33(3)]	May 1, 2007*	June 1, 2007*	<i>USP 31–NF 26</i>
<i>2nd Supplement</i>	June 1, 2007*	Dec. 1, 2007*	<i>USP 31–NF 26</i>
<i>IRA</i> [PF 33(4)]	July 1, 2007*	Aug. 1, 2007*	<i>USP 31–NF 26</i>
<i>IRA</i> [PF 33(5)]	Sept. 1, 2007*	Oct. 1, 2007*	<i>1st Supplement to USP 31–NF 26</i>
<i>IRA</i> [PF 33(6)]	Nov. 1, 2007*	Dec. 1, 2007*	<i>1st Supplement to USP 31–NF 26</i>
<i>USP 31–NF 26</i>	Nov. 1, 2007*	May 1, 2008*	<i>1st Supplement to USP 31–NF 26</i>

* Tentative.

FOOD CHEMICALS CODEX. PUBLIC NOTICE AND COMMENT. USP acquired the *Food Chemicals Codex (FCC)* in August, 2006 and intends to publish the Sixth Edition in February, 2008. USP plans to create an FCC page on the USP website (www.usp.org/fcc), at which FCC users will have the opportunity to provide public comment on proposed revisions of FCC content prior to publication. The FCC website is expected to be available in June, 2007.

FCC stakeholders and users are encouraged to assist USP in developing a "Priority List" of monographs needing revision that will be posted to the FCC website after review by USP's Food Additives Expert Committee. Submit priority monographs to Catherine Sheehan, Director, Excipients and Food Additives, Standards Division (cxs@usp.org).

PRIORITY NEW MONOGRAPH ITEMS. USP is seeking monographs for the following drug substances and drug products that are or soon will be off patent and thus are of the highest priority. USP also is seeking monographs for the excipients listed below. Monographs are marked received upon receipt of the monograph proposal. Received monographs are removed from this list upon publication in *Pharmacopeial Forum*. (This list has been updated as of December 21, 2006.) For additional information, contact Karen A. Russo, Ph.D., kar@usp.org. Monograph sponsors should consult USP's *Guideline for Submitting Requests for Revision to the USP–NF* (<http://www.usp.org/USPNF/submitMonograph/subGuide.html>).

Small Molecules (Drug Substances)

Acarbose (Received)	Alatrofloxacin Mesylate	Alfuzosin Hydrochloride (Received)
Allopurinol Sodium	Aminopromazine Fumarate	Aminopterin Sodium
Anagrelide Hydrochloride	Arsenic Trioxide	Auranfoin
Azelaic Acid	Balsalazide Disodium	Bentoquatam

Small Molecules (Drug Substances) (Continued)

Benzphetamine Hydrochloride	Bepidil Hydrochloride	Bivalirudin
Cabergoline <i>(Received)</i>	Calcipotriene	Calcium Trisodium Pentetate
Calfactant	Candesartan Cilexetil	Carmustine <i>(Received)</i>
Cefdinir <i>(Received)</i>	Cefditoren Pivoxil	Ceftibuten
Ceftiofur Hydrochloride	Cysteamine Bitartrate	Cetorelix
Cevimeline	Chloroxine	Choline Salicylate
Colfosceril	Cytarabine Liposome	Dalfopristin
Dapirazole Hydrochloride	Desirudin	Desonide <i>(Received)</i>
Dexrazoxane	Dextromethorphan Polistirex	Difenoxin Hydrochloride
Difloxacin Hydrochloride	Diltiazem Malate	Doxacurium Chloride
Entacapone	Epoprostenol Sodium <i>(Received)</i>	Erythromycin Phosphate
Erythromycin Thiocyanate	Esmolol Hydrochloride	Esomeprazole Magnesium <i>(Received)</i>
Estazolam	Estradiol Benzoate <i>(Received)</i>	Estramustine Phosphate Sodium
Ethanolamine Oleate	Etomidate <i>(Received)</i>	Etoposide
Exemestane	Felbamate	Flavoxate Hydrochloride
Fluoromethane F 18	Foscarnet Sodium <i>(Received)</i>	Fosfomycin Tromethamine <i>(Received)</i>
Gadobenate Dimeglumine	Gadopentetic Acid	Galantamine Hydrobromide <i>(Received)</i>
Gallium Nitrate	Ganirelix	Glyceryl Aminobenzoate
Granisetron Hydrochloride <i>(Received)</i>	Guanidine Hydrochloride	Halobetasol Propionate <i>(Received)</i>
Haloperidol Decanoate <i>(Received)</i>	Hydrocodone Polistirex	Ibandronate Sodium
Imipramine Pamoate	Imiquimod	Irinotecan
Isosulfan Blue	Itraconazole <i>(Received)</i>	Lamotrigine <i>(Received)</i>
Latanoprost	Levetriacepam	Levobetaxolol
Levomethadyl Acetate	Lomustine <i>(Received)</i>	Lopinavir
Metipranolol Hydrochloride	Midazolam <i>(Received)</i>	Mifepristone <i>(Received)</i>
Miglitol	Milrinone Lactate	Misoprostol <i>(Received)</i>
Mivacurium Chloride	Moexipril Hydrochloride	Nalbuphine Hydrochloride
Nalmefene Hydrochloride	Nateglinide <i>(Received)</i>	Nedocromil Sodium
Nicardipine Hydrochloride	Nilutamide	Nisoldipine
Olopatadine <i>(Received)</i>	Olsalazine Sodium <i>(Received)</i>	Orbifloxacin <i>(Received)</i>
Orlistat <i>(Received)</i>	Oxcarbazepine <i>(Received)</i>	Oxiconazole Nitrate
Pantoprazole Sodium <i>(Received)</i>	Pemirolast Potassium	Pemoline
Pentamidine Isethionate <i>(Received)</i>	Piperonyl Butoxide	Pirbuterol Acetate
Poractant Alpha	Porfimer Sodium	Pramipexole Dihydrochloride
Proguanil Hydrochloride <i>(Received)</i>	Quetiapine Fumarate <i>(Received)</i>	Ranitidine
Rivastigmine Tartrate	Rose Bengal	Rosiglitazone Maleate
Salmeterol Xinafoate	Sertraline Hydrochloride <i>(Received)</i>	Sirbutramine Hydrochloride <i>(Received)</i>
Sodium Phenylbutyrate	Sodium Phosphates	Spectinomycin Sulfate
Streptozocin	Sulfacytine	Tacrolimus

Small Molecules (Drug Substances) (Continued)

Tenofovir Disoproxil Fumarate	Terbinafine Hydrochloride (Received)	Terconazole (Received)
Tiludronate Disodium	Tiopronin	Trandolapril
Tranexamic Acid (Received)	Tranlylcypromine Sulfate	Trimetrexate Glucuronate
Trovaflaxacin Mesylate	Unoprostone Isopropyl	Venlafaxine Hydrochloride
Voriconazole	Zinc Tridosium Pentetate	Zoledronic Acid

Small Molecules (Drug Products)

Abacavir Sulfate, Lamivudine, and Zidovudine Tablets	Acarbose Tablets	Acetaminophen, Butalbital, Caffeine, and Codeine Phosphate Capsules
Acetaminophen, Clemastine Fumarate, and Pseudoephedrine Hydrochloride Tablets	Acetazolamide Extended-Release Capsules	Albuterol Extended-Release Tablets
Albuterol for Inhalation	Albuterol Inhalation Aerosol	Alendronate Sodium Oral Solution
Alfuzosin Tablets	Allopurinol for Injection	Alprazolam Extended-Release Tablets
Alprostadil Urethral Suppository	Aminopromazine Fumarate and Neomycin Sulfate Tablets	Aminopromazine Fumarate Injection
Aminopromazine Fumarate Tablets	Aminopterin Sodium Tablets	Amlodipine and Benazepril Hydrochloride Capsules
Amphotericin B Injection	Anagrelide Hydrochloride Capsules	Arsenic Trioxide Injection
Atovaquone and Proguanil Hydrochloride Tablets	Atovaquone Tablets	Auranofin Capsules
Azatadine Maleate and Pseudoephedrine Sulfate Extended-Release Tablets	Azelaic Acid Cream	Azithromycin for Injection (Received)
Azithromycin Tablets	Baclofen Injection	Balsalazide Disodium Capsules
Beclomethasone Dipropionate Inhalation Aerosol	Beclomethasone Dipropionate Nasal Suspension	Bentoquatam Topical Suspension
Benzocaine and Cetylpyridinium Chloride Lozenges	Benzocaine and Menthol Lotion	Benzphetamine Hydrochloride Tablets
Bepriidil Tablets	Bicalutamide Tablets	Bivalirudin Injection
Brompheniramine Maleate, Dextromethorphan Hydrobromide, and Pseudoephedrine Hydrochloride Oral Solution	Budesonide Inhalation Aerosol	Bupivacaine and Lidocaine Hydrochlorides Injection
Buprenorphine Hydrochloride Injection	Butalbital and Acetaminophen Capsules	Butalbital and Acetaminophen Tablets
Calcipotriene Cream	Calcipotriene Ointment	Calcipotriene Topical Solution
Cabergoline Tablets	Calcitriol Capsules	Calcitriol Oral Solution
Calcium Acetate Capsules	Calcium Trisodium Pentetate Injection	Calfactant Intratracheal Suspension
Carbidopa and Levodopa Extended-Release Tablets (Received)	Carbidopa and Levodopa Tablets for Oral Suspension (Received)	Carbidopa, Levidopa, and Entacapone Tablets
Carmustine for Injection (Received)	Carmustine Implant	Carvedilol Tablets (Received)
Cefdinir Tablets	Cefditoren Pivoxil Tablets	Ceftibuten Capsules
Ceftibuten for Oral Suspension	Ceftiofur Hydrochloride Oral Suspension	Cetirizine Hydrochloride Oral Solution
Cetirizine Hydrochloride Tablets (Received)	Cetorelix Injection	Cevimeline Hydrochloride Capsules
Chloroxine Cream	Chlorpromazine Hydrochloride Extended-Release Capsules	Choline and Magnesium Salicylates Oral Solution
Choline and Magnesium Salicylates Tablets	Choline Salicylate Oral Solution (Received)	Ciclopirox Shampoo
Ciclopirox Topical Gel	Ciclopirox Topical Solution (Received)	Cilostazol Tablets (Received)
Cimetidine Oral Solution	Ciprofloxacin Hydrochloride and Hydrocortisone Otic Suspension	Ciprofloxacin Otic Solution
Citalopram Hydrobromide Oral Solution	Citric Acid, Gluconolactone, and Magnesium Carbonate Irrigation	Cladribine Injection
Clemastine Fumarate Syrup	Clobetasol Propionate Gel	Clonazepam Orally Disintegrating Tablets
Clorazepate Dipotassium Capsules	Clorazepate Dipotassium Extended-Release Tablets	Clotrimazole and Betamethasone Dipropionate Lotion
Colestipol Hydrochloride Tablets	Colfosceril and Tyloxapol Suspension	Compound Undecylenic Acid Cream
Compound Undecylenic Acid Topical Powder	Conjugated Estrogens and Medroxyprogesterone Acetate Tablets	Cromolyn Sodium Nasal Solution

Small Molecules (Drug Products) (Continued)

Cyclosporine Modified Capsules	Cyclosporine Modified Oral Solution	Cyclosporine Ointment
Cyclosporine Topical Solution	Cysteamine Bitartrate Capsules	Cytarabine Liposome Injection
Dalfopristin and Quinupristin Injection	Dantrolene Sodium Oral Suspension	Dapiprazole for Ophthalmic Solution
Desirudin for Injection	Desonide Cream	Dexrazoxane for Injection
Dextroamphetamine Sulfate Extended-Release Capsules	Dextromethorphan Polistirex Extended-Release Oral Suspension	Diazepam Injectable Emulsion
Diclofenac Sodium Ophthalmic Solution	Diethylpropion Hydrochloride Extended-Release Tablets	Difenoxin and Atropine Tablets
Difloxacin Hydrochloride Tablets	Dihydroergotamine Mesylate Metered Spray	Diltiazem Malate Extended-Release Tablets
Dinoprostone Vaginal Suppositories	Diphenhydramine Hydrochloride and Acetaminophen Tablets	Divalproex Sodium Delayed-Release Capsules
Dorzolamide and Timolol Ophthalmic Solution	Dorzolamide Ophthalmic Solution	Doxacurium Chloride Injection
Doxepin Hydrochloride Cream	Doxycycline Oral Gel	Econazole Nitrate Cream
Edrophonium Chloride and Atropine Sulfate Injection	Enalapril Maleate and Diltiazem Malate Extended-Release Tablets	Enalapril Maleate and Felodipine Extended-Release Tablets
Enalaprilat Injection <i>(Received)</i>	Entacapone Tablets	Ephedrine Sulfate and Guaifenesin Tablets
Epoprostenol for Injection	Epoprostenol Injection	Esmolol Hydrochloride Injection
Esomeprazole Magnesium Capsules	Estazolam Tablets	Estramustine Phosphate Sodium Capsules
Ethanolamine Oleate Injection	Etidronate Disodium Injection Concentrate	Etomidate Injection
Exemestane Tablets	Famotidine Orally Disintegrating Tablets	Felbamate Oral Suspension
Felbamate Tablets	Fentanyl Lozenges	Fentanyl Transdermal System <i>(Received)</i>
Ferrous Fumarate and Docusate Sodium Extended-Release Capsules	Flavoxate Hydrochloride Tablets	Fluconazole Injection <i>(Received)</i>
Fluconazole Tablets	Flunisolide Inhalation Aerosol	Flunisolide Nasal Spray
Fluocinolone Acetonide Shampoo	Fluorescein Sodium Ophthalmic Solution	Fluorometholone Ointment
Fluticasone Propionate Cream <i>(Received)</i>	Fluticasone Propionate Inhalation Powder	Fluticasone Propionate Ointment <i>(Received)</i>
Fluticasone Propionate Pressurized Inhaler	Foscarnet Sodium Injection	Fosfomycin for Oral Solution
Gabapentin Oral Solution	Gadobenate Dimeglumine Injection	Galantamine Tablets <i>(Received)</i>
Gallium Nitrate Injection	Ganciclovir Capsules	Ganirelix Acetate Injection
Gatifloxacin Injection	Gatifloxacin Tablets	Gentamicin Sulfate Oral Solution
Gentamicin Sulfate Soluble Powder	Glimepiride Tablets <i>(Received)</i>	Glipizide Extended-Release Tablets
Granisetron Injection <i>(Received)</i>	Granisetron Tablets <i>(Received)</i>	Guaifenesin and Salts of Dextromethorphan and Pseudoephedrine Oral Solution
Guaifenesin and Pseudoephedrine Hydrochloride Extended-Release Tablets	Guanidine Hydrochloride Tablets	Halobetasol Propionate Cream
Halobetasol Propionate Ointment	Haloperidol Decanoate Injection	Haloperidol Lactate Injection
Haloperidol Lactate Oral Concentrate	Hydralazine Hydrochloride and Hydrochlorothiazide Capsules	Hydrochlorothiazide Capsules
Hydrochlorothiazide Oral Solution Concentrate	Hydrocodone Bitartrate and Acetaminophen Oral Solution	Hydrocodone Bitartrate and Aspirin Tablets
Hydrocodone Bitartrate and Guaifenesin Oral Solution	Hydrocodone Bitartrate and Homatropine Methylbromide Syrup	Hydrocodone Bitartrate and Homatropine Methylbromide Tablets
Hydrocortisone Acetate Dental Paste	Hydrocortisone Acetate Rectal Foam Aerosol	Hydrocortisone Butyrate Lotion
Hydroflumethiazide and Reserpine Tablets	Hydromorphone Hydrochloride Oral Solution <i>(Received)</i>	Hydroquinone Lotion
Ibandronate Sodium Tablets	Ibuprofen Capsules	Idarubicin Hydrochloride Injection
Imipramine Pamoate Capsules	Imiquimod Topical Cream	Ipratropium Bromide Inhalation Aerosol
Ipratropium Bromide Inhalation Solution	Irinotecan Hydrochloride Injection	Isosulfan Blue Injection
Isradipine Extended-Release Tablets	Itraconazole Injection	Itraconazole Oral Solution
Ketoconazole Cream	Ketoconazole Shampoo	Ketoprofen Capsules <i>(Received)</i>
Ketoprofen Extended-Release Capsules	Ketoprofen Tablets	Ketotifen Fumarate Ophthalmic Solution

Small Molecules (Drug Products) (Continued)

Lactic Acid Lotion	Lamivudine Tablets <i>(Received)</i>	Lamotrigine Tablets
Latanoprost Ophthalmic Solution	Leucovorin Calcium for Injection	Levetriacepam Tablets
Levobetaxolol Ophthalmic Suspension	Levocabastine Ophthalmic Suspension	Levofloxacin Solution
Levomethadyl Acetate Hydrochloride Oral Concentrate	Lincomycin Hydrochloride and Spectinomycin Sulfate Soluble Powder	Liothyronine Injection
Lisinopril and Hydrochlorothiazide Tablets <i>(Received)</i>	Lomustine Capsules	Lopinavir and Ritonavir Solution
Lopinavir Capsules	Lopinavir Solution	Loratadine Orally Disintegrating Tablets
Losartan Potassium Tablets	Mefloquine Hydrochloride Tablets	Melphalan for Injection
Mesalamine Suppositories	Mesoridazine Besylate Concentrate	Metaraminol Bitartrate Injection
Methacholine Chloride for Inhalation Solution	Methadone Hydrochloride Oral Concentrate	Methocarbamol and Aspirin Tablets
Methoxsalen Softgels	Methyclothiazide and Deserpidine Tablets	Methylphenidate Hydrochloride Chewable Tablets
Metipranolol Ophthalmic Solution	Metronidazole Capsules	Metronidazole Cream
Metronidazole Extended-Release Tablets	Metronidazole Hydrochloride for Injection	Metronidazole Lotion
Miconazole Nitrate Topical Aerosol	Midazolam Injection <i>(Received)</i>	Mifepristone Tablets
Miglitol Tablets	Milrinone Injection	Misoprostol Tablets <i>(Received)</i>
Mivacurium in Dextrose Injection	Mivacurium Injection	Moexipril Hydrochloride and Hydrochlorothiazide Tablets
Moexipril Hydrochloride Tablets	Molindone Hydrochloride Oral Solution	Morphine Sulfate for Injection Concentrate
Morphine Sulfate Oral Solution	Morphine Sulfate Oral Solution Concentrate	Morphine Sulfate Tablets
Mycophenolate Mofetil Capsules	Mycophenolate Mofetil Oral Solution	Mycophenolate Mofetil Tablets
Nalbuphine Hydrochloride Injection	Nalmefene Hydrochloride Injection	Naphazoline Hydrochloride and Pheniramine Maleate Ophthalmic Solution
Naphazoline Hydrochloride and Pheniramine Maleate Ophthalmic Solution	Naproxen Extended-Release Tablets	Nateglinide Tablets
Nedocromil Sodium Inhalation Aerosol	Neomycin Sulfate Oral Powder	Nicardipine Hydrochloride Capsules
Nilutamide Tablets	Nimodipine Capsules	Nisoldipine Extended-Release Tablets
Nitroglycerin Extended-Release Transdermal Film	Nitroglycerin Transdermal System	Nitroglycerin Solution in Acrylic Adhesive
Nizatidine Tablets	Ofloxacin in Dextrose Injection	Ofloxacin Injection
Olopatadine Ophthalmic Solution <i>(Received)</i>	Olsalazine Sodium Capsules	Ondansetron Tablets
Orbifloxacin Tablets <i>(Received)</i>	Orphenadrine Citrate Extended-Release Tablets <i>(Received)</i>	Orphenadrine Citrate, Aspirin, and Caffeine Tablets
Oxcarbazepine Suspension	Oxcarbazepine Tablets	Oxiconazole Cream
Pantoprazole Sodium for Injection	Pantoprazole Sodium Tablets	Paroxetine Hydrochloride Extended-Release Tablets
Paroxetine Oral Suspension	Pemirolast Potassium Ophthalmic Solution	Pemoline Tablets
Penicillin G Potassium Tablets for Oral Solution	Pentamidine Isethionate for Inhalation	Pentamidine Isethionate Injection <i>(Received)</i>
Pentazocine Hydrochloride and Acetaminophen Tablets	Phendimetrazine Tartrate Extended-Release Capsules	Phenobarbital Capsules
Phentermine Resin Complex Capsules	Phenylephrine Hydrochloride and Chlorpheniramine Maleate Extended-Release Capsules	Phenylephrine Hydrochloride, Chlorpheniramine Maleate, and Acetaminophen Extended-Release Tablets
Pilocarpine Hydrochloride Ophthalmic Gel	Pilocarpine Hydrochloride Ophthalmic Ointment	Pilocarpine Hydrochloride Tablets
Piperonyl Butoxide and Pyrethrins Aerosol Foam	Pirbuterol Acetate Inhalation Aerosol	Poractant Alpha Suspension
Porfimer Sodium for Injection	Povacrylate Solution	Povacrylate-Iodine Topical Solution
Povidone-Iodine Gauze	Povidone-Iodine Swabsticks	Povidone-Iodine Topical Aerosol Foam
Povidone-Iodine Vaginal Suppositories	Pramipexole Dihydrochloride Tablets	Prednisolone Sodium Phosphate Oral Solution
Prochlorperazine Maleate Extended-Release Capsules	Progesterone Capsules	Promethazine and Phenylephrine Hydrochlorides and Codeine Phosphate Syrup
Promethazine and Phenylephrine Hydrochlorides Syrup	Promethazine Hydrochloride and Codeine Phosphate Oral Solution	Promethazine Hydrochloride and Dextromethorphan Hydrobromide Syrup

Small Molecules (Drug Products) (Continued)

Propafenone Hydrochloride Tablets	Pseudoephedrine Hydrochloride and Brompheniramine Maleate Extended-Release Tablets	Pseudoephedrine Hydrochloride and Naproxen Sodium Extended-Release Tablets
Pseudoephedrine Hydrochloride, Chlorpheniramine Maleate, and Codeine Phosphate Oral Solution	Pseudoephedrine Hydrochloride, Guaifenesin, and Codeine Phosphate Oral Solution	Pseudoephedrine Sulfate and Dexbrompheniramine Maleate Extended-Release Tablets
Pseudoephedrine Sulfate and Dexbrompheniramine Maleate Oral Solution	Pseudoephedrine Sulfate, Dexbrompheniramine Maleate, and Acetaminophen Extended-Release Tablets	Pyrimamine Maleate Injection Quinidine Sulfate Injection
Ramipril Capsules	Ranitidine Capsules	Rauwolfia Serpentina and Endroflumethiazide Tablets
Reserpine and Polythiazide Tablets	Rimantadine Hydrochloride Oral Solution	Risperidone Oral Solution
Risperidone Orally Disintegrating Tablets	Rivastigmine Tartrate Capsules	Rivastigmine Tartrate Oral Solution (Received)
Rocuronium Bromide Injection	Ropinirole Hydrochloride Tablets	Rose Bengal Ophthalmic Solution
Rosiglitazone Maleate Tablets	Salicylic Acid and Sulfur Cleansing Lotion	Salicylic Acid and Sulfur Lotion
Salicylic Acid and Sulfur Shampoo	Salicylic Acid Cream	Salicylic Acid Ointment
Salmeterol Inhalation Aerosol	Salmeterol Xinafoate Inhalation Powder	Scopolamine Transdermal System
Selegiline Hydrochloride Capsules	Sertraline Hydrochloride Oral Solution	Sibutramine Hydrochloride Capsules
Sodium Bicarbonate and Sodium Citrate for Oral Solution	Sodium Bicarbonate, Sodium Citrate, and Sodium Tartrate for Oral Suspension	Sodium Iodide Injection
Sodium Phenylbutyrate Oral Powder	Sodium Phenylbutyrate Tablets	Sodium Phosphates for Oral Suspension
Sodium Phosphates Tablets	Sodium Salicylate and Sulfur Shampoo	Sterile Talc Aerosol
Streptozocin for Injection	Sucralfate Oral Suspension	Sulconazole Nitrate Cream
Sulfacetamide Sodium and Fluorometholone Ophthalmic Suspension	Sulfacetamide Sodium and Prednisolone Sodium Phosphate Ophthalmic Solution	Sulfacytine Tablets
Sulfasalazine Oral Suspension	Sulisobenzonzone Lotion	Sumatriptan Injection
Sumatriptan Tablets	Tacrolimus Capsules	Tacrolimus Injection
Tacrolimus Ointment	Tamsulosin Hydrochloride Capsules (Received)	Technetium Tc 99M Teboroxime Injection
Tenofovir Disoproxil Fumarate Tablets	Terbinafine Hydrochloride Cream	Terbinafine Tablets (Received)
Terbinafine Topical Solution	Terconazole Vaginal Cream	Terconazole Vaginal Suppositories
Testosterone Transdermal System	Tetracycline Hydrochloride Periodontal Fiber	Theophylline Extended-Release Tablets
Tioconazole Vaginal Ointment	Tioprozin Tablets	Tolnaftate Topical Aerosol Solution
Topiramate Capsules (Received)	Topiramate Tablets (Received)	Torseamide Injection
Torseamide Tablets (Received)	Trandolapril and Verapamil Hydrochloride Extended-Release Tablets	Trandolapril Tablets
Tranexamic Acid Injection	Tranycypromine Sulfate Tablets	Tretinoin Capsules
Tretinoin Microsphere Gel	Triamcinolone Acetonide Nasal Suspension	Trifluridine Ophthalmic Solution
Trimetrexate for Injection	Trimipramine Maleate Capsules	Triprolidine and Pseudoephedrine Hydrochlorides and Codeine Phosphate Syrup
Trolamine Salicylate Cream	Trolamine Salicylate Gel	Trolamine Salicylate Topical Emulsion
Trovafloxacin Injection	Trovafloxacin Mesylate for Injection	Undecylenic Acid Topical Foam Aerosol
Unoprostone Isopropyl Ophthalmic Solution	Urea Cream	Vecuronium Bromide for Injection
Venlafaxine Extended-Release Capsules (Received)	Venlafaxine Tablets	Verapamil Hydrochloride Capsules
Verapamil Hydrochloride Extended-Release Capsules	Voriconazole Injection	Voriconazole Oral Suspension
Voriconazole Tablets	Yttrium Y-90 Chloride Solution	Yttrium Y-90 Glass Microspheres
Yttrium Y-90 Microspheres Injection	Zidovudine and Lamivudine Tablets (Received)	Zinc Acetate Capsules
Zinc Tridosium Pentetate Injection	Ziprasidone Hydrochloride Capsules	Zoledronic Acid for Injection

Excipients

Acetone Sodium Bisulfite	Acetylated Monoglycerides	Aconitic Acid (Achilleic Acid)
Acrylic Acid-Octyl Acrylate Copolymer	Albumin Colloidal	Aliphatic Polyesters
Allantoin-Sodium Pyrrolidone Carboxylate	Aluminum Ammonium Sulfate	Aluminum Lactate

Excipients (Continued)

Aluminum Oxide	Aluminum Potassium Sulfate	Aluminum Silicate
Aluminum Sodium Sulfate	Aluminum Stearate	Ammonium Bicarbonate
Ammonium Calcium Alginate	Ammonium Phosphate	Batylalcohol Monostearate
Beeswax, Synthetic	Benzododecinium Bromide	Benzyl Chloride
Benzyl Nicotinate	Beta Naphthol	Brominated Vegetable Oil
Butadiene-Styrene Rubber	Butylated Hydromethylphenol	Butylene Glycol
Butylphthalyl Butylglycolate	Calcium Acid Pyrophosphate	Calcium Alginate
Calcium Alginate and Ammonium Alginate	Calcium Bromide	Calcium Chloride Solution
Calcium Glycerophosphate (Received)	Calcium Phosphate Monobasic	Calcium Propionate
Calcium Pyrophosphate	Calcium Sorbate	Calcium Stearoyl Lactylate
Caldiamide Sodium	Calteridol Calcium	Canola Oil
Capric Acid	Caprylic/Capric Diglycerol Succinate	Carbon
Carboxymethyl Starch	Carboxymethylamylopectin Sodium	Carboxymethylcellulose Potassium
Cetostearyl Isononanoate	Chlorodifluoroethane	Cholic Acid
Cinnamaldehyde	Cocamide Diethanolamine	Cocamide Oxide
Cocoyl Caprylocaprate	Crystal Gum	Cutina
Cystine	Dammar Gum	Decanoic Acid
Decyl Oleate	Dehydroacetic Acid (Received)	Desoxycholic Acid
Dextrin Palmitate	Dextrins Modified	Diacetyl Tartaric Acid Esters of Mono- and Diglycerides
Dicetyl Phosphate	Dichlorofluoromethane	Diethyl Sebacate
Difluoroethane	Diglycol Stearate	Diisobutyl Adipate
Diisopropyl Adipate	Diisopropylbenzothiazyl-2-Sulfenamide	Dilauryl Thiodipropionate
Dimethyl Dicarbonate	Dimyristoyl Lecithin	Dimyristoyl Phosphatidylglycerol
Dipropylene Glycol	Disodium Edisylate	Disodium Guanylate
Disodium Inosinate	Disodium Monooleamide Sulfasuccinate	D-Mannose
Docusate Sodium/Sodium Benzoate	Erythorbic Acid	Erythrosine
Ethoxylated Mono- and Diglycerides	Ethoxyquin	Ethyl Hexanediol
Ethyl Linoleate	Ethyl Maltol	Ethylene Dichloride
Ethylurea	Ferric Ammonium Citrate	Ferric Citrate
Ferric Oxide, Brown	Ferric Phosphate	Ferric Pyrophosphate
Ferrous Citrate	Ferrous Glycinate	Ferrous Lactate
Fluorochlorohydrocarbons	Formic Acid	Furcelleran
Gamma Cyclodextrin (Received)	Gentistic Acid	Geraniol
Glutamic Acid Hydrochloride	Gluten	Glycerol Ester of Gum Rosin (Ester Gum)
Glyceryl Laurate	Glyceryl Palmitate	Glyceryl Ricinoleate
Glyceryl Tristearate	Glycine Hydrochloride	Glycofurool
Glycol Stearate	Heptafluoropropane	Heptylparaben
Hexadecyl Isostearate	Hexane	Hexanetriol(-1,2,6-)
Hydrocarbon Gel	Hydrogenated Starch Hydrolysate	Hydroxyethylmethylcellulose
Hydroxylated Lecithin	Hydroxypropyl Beta Cyclodextrin	Indigotine
Inositol (Received)	Iron Carbonyl	Iron Subcarbonate
Isobutylated-Isoprene Copolymer	Isooctylacrylate	Isopropyl Isostearate
Isopropyl Stearate	Isostearic Acid	Isostearyl Alcohol
Lactobionic Acid	Lactose Ferrin, Bovine	Lactylated Fatty Acid Esters of Glycerol and Propylene Glycol
Lactic Esters of Fatty Acids	Lanolin (Wool Fat), Hydrogenated	Lanolin Alcohols, Acetylated
Lanolin Hydrous	L-Ascorbyl Stearate	Lauramine Oxide
Lauric Myristic Diethanolamide	Lauric Acid	Lauric Diethanolamide
Lavender Oil	L-Cysteine Monohydrochloride	Lecithin, Hydroxylated
L-Glutamic Acid	Linoleic Acid	L-Leucine
Macrogol Sorbitan Tristearate	Macrogolglycerol Cocoates	Macrogolglycerol Triisostearate
Magnesium Aluminum Silicate Hydrate	Magnesium Aspartame Dihydrate	Magnesium Aspartate
Magnesium Phosphate, Dibasic, Trihydrate	Magnesium Phosphate Tribasic	Magnesium Tartrate
Malt Syrup	Maltitol Syrup	Maltol Isobutyrate

Excipients (Continued)

Manganese Chloride	Manganese Citrate	Manganese Glycerophosphate
Manganese Hypophosphite	Medical Antifoam Emulsion C	Medronate Disodium
Medronic Acid	Methyl Chloride	Methylchloroisoithiazolinone
Methylisothiazolinone	Microcrystalline Cellulose, Silicified (Received)	Mineral Spirits
Monoisostearyl Glyceryl Ester	Monopotassium Glutamate Monohydrate	Monosodium Citrate
Mullein Leaf	Myristyl Gamma-Picolinium Chloride	Myristyl Lactate
<i>N,N</i> -Bis(2-Hydroxyethyl)Stearamide	<i>N</i> -Acetyl-L-Methionine	Naphtha
<i>N</i> -Methylpyrrolidone (Received)	Non-Pareil Seeds	Nutmeg Oil
Octanoic Acid	Oxystearin	Palm Oil
Pentasodium Triphosphate	Pentetate Calcium Trisodium	Pentetate Pentasodium
Phenprobamate	Phenylmercuric Acetate	Phenylmercuric Nitrate
Pine Oil	Polacrilin	Polydextrose Solution
Polyglycerol Esters of Fatty Acids	Polyglycerol Polyricinoleic Acid	Polyoxyethylene Castor Oil (USP Has 35)
Polyoxyl Stearate (USP Has 40)	Polypropylene Oleate	Polypropylene Stearyl Ether
Polysorbate 65	Polyvinylacetate	Polyvinylacetate Diethylanoacetate
Polyvinylpyrrolidone	Polyvinylpyrrolidone Ethylcellulose	Potassium Acid Tartrate
Potassium Bromate	Potassium Carbonate Solution	Potassium Dichloroisocyanurate
Potassium Gibberellate	Potassium Glycerophosphate	Potassium Iodate
Potassium Nitrite	Potassium Phosphate	Potassium Phosphate Tribasic
Potassium Polymetaphosphate	Potassium Pyrophosphate	Potassium Stearate
Potassium Sulfate	Potassium Sulfite	Potassium Tripolyphosphate
Propyl Propionate	Propylene Glycol Diacetate	Propylene Glycol Mono- and Diesters
Purified Polyoxyl 35 Castor Oil (Received)	Rice Bran Wax	Rosin
Silicone	Sodium Acid Pyrophosphate	Sodium Aluminosilicate
Sodium Aluminum Phosphate Acidic	Sodium Aluminum Phosphate Basic	Sodium Aspartate
Sodium Bisulfate	Sodium Bisulfite	Sodium Carbonate Hydrate
Sodium Carboxymethyl Betaglucon	Sodium Caseinate	Sodium Chlorate
Sodium Citrate, Dibasic	Sodium Citrate, Monobasic	Sodium Dehydroacetate
Sodium Diacetate	Sodium Erythorbate	Sodium Ferric Pyrophosphate
Sodium Ferrocyanide	Sodium Hypophosphite	Sodium Laureth Sulfate
Sodium Lauroyl Sarcosinate	Sodium Lauryl Sulfoacetate	Sodium Magnesium Aluminosilicate
Sodium Magnesium Silicate	Sodium Malate	Sodium Polyphosphates Glassy
Sodium Metasilicate	Sodium Methylate	Sodium Pyrophosphates Glassy
Sodium Potassium Tripolyphosphate	Sodium Pyrophosphate	Sodium Pyrrolidone Carboxylate
Sodium Sesquicarbonate	Sodium Sesquinoate	Sodium Stearoyl Lactylate
Sodium Thiomalate	Sodium Trimetaphosphate	Sodium Trioleate
Sodium Tripolyphosphate	Soy Polysaccharides	Stannous Chloride
Stannous Tartrate	Starch, Pregelatinized Corn	Starch, Pregelatinized Tapioca
Stearalkonium Chloride	Stearyl Citrate	Stearyl Monoglyceridyl Citrate
Succinylated Monoglycerides	Sucrose Acetate Isobutyrate	Sucrose Fatty Acid Esters
Sucrose Stearate	Sugar Fruit Fine	Sulfobutyl Ether Beta Cyclodextran
Tallow	Tallow Glycerides	Tallow Oil
Tetrafluoroethane	Thioglycerol	Thyme Oil
Triphenin	Tricetareth-4 Phosphate	Trichloroethylene
Trimyristin	Trisodium Citrate	Trolamine Lauryl Sulfate
Vegetable Oil	Wheat Flour	Wheat Germ Oil
Wheat Gluten (Received)	Whey	

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Contributions in the form of original research reports, evaluations of new and existing compendial methods, and other commentaries and articles relevant to drug standards or to *USP–NF* revision will be considered for publication in the *Pharmacopeial Forum* under the section *Stimuli to the Revision Process*. Manuscripts are received with the explicit understanding that they have not been published previously and that they are not simultaneously under consideration by any other publication.

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A New Validated Differential Scanning Calorimetric Procedure for Monitoring the Less Active *R,S* Isomer of Ethambutol Dihydrochloride in Bulk Drug Samples and Anti-tuberculosis Formulations*

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ABSTRACT A new and simple validated differential scanning calorimetric (DSC) procedure was developed for quantitation of the less active *R,S* diastereoisomer of ethambutol dihydrochloride in bulk drug samples and marketed anti-tuberculosis formulations. The procedure involves determination of the enthalpy associated with polymorphic transitions, appearing at 42 °C and 77 °C for *R,S* and *S,S* isomers, respectively. Suitable equations were derived and could be successfully used to determine the relative extents of the two isomers in commercial products. The unwanted *R,S* form was found to be present in more than half of the tested drug substances and products and in some products constituted 100% of the active. This suggests that an appropriate test procedure and relevant limits should be included in *USP–NF* and other international compendia to control the inactive isomer in ethambutol dihydrochloride and also in anti-tuberculosis fixed-dose combination products that contain the drug.

INTRODUCTION

Ethambutol dihydrochloride (EB2HCl) can exist in three different diastereoisomeric forms: *S,S*; *R,S*; and *R,R*; designated in this paper as SS-EB2HCl, RS-EB2HCl, and RR-EB2HCl, respectively. SS-EB2HCl is therapeutically active, but RS-EB2HCl is 16 times less active, and RR-EB2HCl is completely inactive (*I*). The synthesis of EB2HCl is carried out using (+)-2-amino-1-butanol as the starting material; hence the process primarily yields a mixture of SS-EB2HCl and RS-EB2HCl without the presence of RR-EB2HCl. RS-

EB2HCl is removed by taking advantage of its low solubility in a number of solvents, but it still can be present in the SS-EB2HCl form of the drug. Incidentally, there is no procedure given in any pharmacopeia to control or determine the extent of RS-EB2HCl in EB2HCl or its products. Only the range of optical rotation values is prescribed to control quality or for assay of the active SS-EB2HCl. The compendial tests (2–5) are listed in *Table 1*, along with their anticipated limitations.

Table 1. Pharmacopoeial evaluations of the isomeric quality of EB2HCl (2–5)

Pharmacopoeia	Test	Postulated drawback of the respective test
<i>United States Pharmacopoeia (USP)</i>	Specific rotation between +6.0° and 6.7° of 10% (w/v) solution at 25 °C and 100 mm	1. The wide range of the specific rotation may allow up to 10% of (<i>R,S</i>) form as an impurity 2. Not applicable in formulations
<i>Indian Pharmacopoeia (IP)</i>	Same as above	Same as above
<i>Japanese Pharmacopoeia (JP)</i>	Specific rotation between +5.5° and 6.1° of 10% (w/v) solution at 20 °C and 200 mm	Same as above
<i>British Pharmacopoeia (BP)</i>	Assay procedure based on optical activity	1. Not applicable in formulations 2. Low sensitivity of the procedure

Fortunately, a few reports exist in the literature for the determination of RS-EB2HCl. These include a study done in early seventies by Ferrari and Graber (6), who used differential thermal analysis (DTA) for the detection and quantitation of the *meso* (or optically inactive) isomer. Several years later Varshney et al. (7) reported the use of more precise differential scanning calorimetry (DSC) for the purpose. The latter procedure was based on quantitation of an endotherm at 178 °C attributed to solid–solid interaction (eutectic formation) between

RS-EB2HCl and SS-EB2HCl. Although the procedure was novel, its use was severely restricted because quantitation of RS-EB2HCl was limited to the range of 0–5%. At higher concentrations of RS-EB2HCl, the endotherm at 178 °C merged with the melting endotherm of EB2HCl at ~200 °C. Following this report, another procedure appeared in the literature and involved chromatographic separation of diastereoisomers of EB2HCl using a chiral column (8). This procedure did not become popular, perhaps due to high costs and restricted commercial availability of the chromatographic column.

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NOMENCLATURE

This section includes supplements to the latest edition of the *USP Dictionary of USAN and International Drug Names* that incorporate new United States Adopted Names (USAN) and revisions to existing Dictionary names. Also listed are Proposed and Recommended International Nonproprietary Names (INN) when they have been announced by the World Health Organization.

Possible names suggested for use as USAN and INN are listed for public review and comment along with information on how nonproprietary names are devised. In addition, readers may find articles relevant to current compendial nomenclature issues that also occasionally report on related matters pertaining to USAN and INN.