



**April 2007**

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For all the latest information visit [www.usp.org](http://www.usp.org)



## Reference Standards Highlights

Below are several tables with the latest Reference Standard information including out-of-stock items now available; new Reference Standards released in March 2007; backordered items with estimated availability dates; items that have been discontinued/have a new price and/or have a new package size; items with lots that are (or soon will be) no longer valid; and items with new lots since the last email notice.

Please contact your Customer Service Representative to place an order at +1 (301) 881-0666 or 1-800-227-8772. European customers can call 00-800-4875-5555. You can also order online at [www.usp.org/products](http://www.usp.org/products).

### New Reference Standards Now Available

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Catalog #	Description	Size	Lot	Price (USD)
1090706	Capecitabine	200 mg	F0G037	\$176
1134175	Cilostazol Related Compound B	50 mg	F0G073	\$549
1134186	Cilostazol Related Compound C	50 mg	F0G074	\$549
1134266	Citalopram Related Compound C	25 mg	F0G048	\$549
1165408	Decoquinatone	200 mg	F0G036	\$192
1229409	Drospirenone	200 mg	F0G064	\$176
1265457	Ethylbenzene	0.5 mL/ ampule; 3 ampules	F0F060	\$176
1283460	Fosinopril Related Compound F	15 mg	F0F344	\$549
1292610	Glipizide Related Compound B	15 mg	F0G049	\$549
1292631	Glipizide Related Compound C	15 mg	F0G050	\$549
1448912	Mupirocin Calcium	200 mg	F0G070	\$176
1554217	Pravastatin Related Compound A	15 mg	F0G024	\$549
1554920	Prednicarbate Related Compound B	20 mg	F0G017	\$549
1593401	Quinapril Hydrochloride	400 mg	F0C112	\$367
1692516	Trimethoprim Related Compound A (AS)	25 mg	F0G008	\$549
1711439	Verapamil Related Compound E	50 mg	F0G029	\$549

### Previously Out-of-Stock Items Now Available

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Catalog #	Description	Size	Lot	Price (USD)
1094004	Carbenicillin Monosodium Monohydrate	200 mg	G3G012	\$176
1098027	Cefpodoxime Proxetil	350 mg	G0G067	\$176
1131009	Cholecalciferol	30 mg/ ampule; 5 ampules	N0G038	\$180
1140509	Clorazepate Dipotassium CIV	125 mg	G1F159	\$233
1181007	Dextromethorphan Hydrobromide	500 mg	K0F118	\$176
1242010	Erythromycin B	100 mg	G2F259	\$176
1280009	Fluoxymesterone CIII	200 mg	G3F292	\$233
1478618	Ondansetron Related Compound C	30 mg	G0F283	\$549
1616008	1,4-Sorbitan	300 mg	J0F351	\$176
1389008	Meprobamate	200mg	G2G065	\$176



## Backorder Availability Estimates, March 19, 2007

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Catalog #	Description	Expected Availability*
1028000	Amitraz (200 mg)	Q1/07
1078766	Bupropion Hydrochloride Rel Cpd C	Q2/07
1078799	Bupropion Hydrochloride Rel Cpd F	Q2/07
1107300	Chloramphenicol Palmitate (200 mg)	Q2/07
1134040	Ciclopirox Related Compound B (25 mg)	Q1/07
1134051	Cilastatin Ammonium Salt (100 mg)	Q2/07
1138507	Clocortolone Pivalate (200 mg)	Q1/07
1140393	Clonidine (200 mg)	Q2/07
1169001	Demecarium Bromide (250 mg)	Q4/07
1478618	Ondansetron Related Compound C (50 mg)	Q1/07
1660000	Thioguanine (200 mg)	Q3/07
1719000	Warfarin (200 mg)	Q2/07
1720203	Xanthone (100 mg)	Q2/07

\*Dates are targets and may change at any time. Q1/07 = January—March 2007, Q2/07 = April—June 2007, Q3/07 = July—September 2007, Q4/07 = October—December 2007

## Items with New Package Size

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Catalog #	Description	Old Size	New Size	Lot	Price (USD)
1242010	Erythromycin B	150 mg	100 mg	G2F259	\$176
1478618	Ondansetron Related Compound C	50 mg	30 mg	G0F283	\$549
1616008	1,4-Sorbitan	200mg	300 mg	J0F351	\$176



## RS Lots That Are No Longer Valid

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This table lists previous RS lots that are (or will soon be) no longer valid for official use. If you still have any of these materials on hand, do not use them for compendial testing purposes after the last day of the month for the valid use dates listed. To test products, always be sure you use a current, valid lot of USP RS. Current lot numbers and valid use dates for previous lots are available in the USP Catalog and online at [www.usp.org](http://www.usp.org); click on the USP Products link and look up the RS of interest.

No Longer Valid as of March 31, 2007				
Catalog #	Description	Previous Lot/ Valid Use Date	Current Lot	Price (USD)
1008501	Acetylcholine Chloride (200 mg)	G (03/07)	H0F091	\$176
1031401	Amoxapine (200 mg)	G (03/07)	G1D375	\$176
1078325	Bumetanide Related Compound A (10 mg)	F-2 (03/07)	G0F031	\$549
1083008	2-tert-Butyl-4-hydroxyanisole (200 mg)	L0C028 (03/07)	L1E348	\$176
1138904	Clofazimine (200 mg)	F (03/07)	F1C392	\$176
1171003	Denatonium Benzoate (200 mg)	I0B129 (03/07)	I1F025	\$176
1173257	Desogestrel Related Compound B (15 mg)	F0B284 (03/07)	G0F144	\$549
1250008	Estradiol (500 mg)	L0C337 (03/07)	M0E309	\$176
1286708	Fumaric Acid (200 mg)	G-1 (03/07)	H0E328	\$176
1295607	Glycerin (2 mL)	H0C073 (03/07)	H1E032	\$176
1299007	Griseofulvin (200 mg)	I (03/07)	I1D406	\$176
1333003	Hydroxyzine Hydrochloride (500 mg)	I0C385 (03/07)	J0F024	\$176
1372005	L-Lysine Hydrochloride (200 mg)	H (03/07)	I0E230	\$176
1377508	Meclocycline Sulfosalicylate (300 mg)	G (03/07)	H0F087	\$176
1388005	Meprednisone (200 mg)	G (03/07)	H0F217	\$176
1441243	Metoprolol Related Compound B (50 mg)	F0C377 (03/07)	G0E189	\$587
1485191	Oxycodone <b>CII</b> (200 mg)	I1D206 (03/07)	J0F026	\$233
1559006	Prednisone (250 mg)	M0D211 (03/07)	N0E330	\$176
1708762	Valsartan (350 mg)	F0C147 (03/07)	G0F065	\$176



**No Longer Valid as of April 30, 2007**

Catalog #	Description	Previous Lot/ Valid Use Date	Current Lot	Price (USD)
1044403	Atenolol (200 mg)	H1C320 (04/07)	I0F032	\$176
1061901	Benzyl Alcohol (500 mg/ampule)	G0B306 (04/07)	G1E155	\$176
1134380	Clarithromycin Related Compound A (50 mg)	G (04/07)	G1E310	\$549
1181302	Dextrose (500 mg)	J-1 (04/07)	J2E294	\$140
1260012	Ethinyl Estradiol Related Compound A (20 mg)	F0B252 (04/07)	G0E301	\$549
1272204	Fludarabine Phosphate (300 mg)	F0C374 (04/07)	G0E247	\$176
1286504	Fructose (125 mg)	I-2 (04/07)	I3E340	\$140
1354003	Isoxsuprine Hydrochloride (200 mg)	F-3 (04/07)	G0E146	\$176
1356665	Ketorolac Tromethamine (200 mg)	G (04/07)	G1E331	\$176
1358004	Leucovorin Calcium (500 mg)	J2B219 (04/07)	K0F033	\$181
1368008	Liothyronine (250 mg)	M0D338 (04/07)	N0F098	\$176
1443908	Milrinone (500 mg)	G0D340 (04/07)	H0F083	\$293
1511000	Perphenazine (200 mg)	J0B249 (04/07)	K0F018	\$176
1575206	Propoxyphene Related Compound A (50 mg)	G6D124 (04/07)	H0F117	\$549
1581504	Pseudoephedrine Sulfate (200 mg) (List Chemical)	G1C135 (04/07)	H0E285	\$176
1673500	Trazodone Hydrochloride (200 mg)	F-2 (04/07)	G0F069	\$176
1708707	Valproic Acid (500 mg)	K0D224 (04/07)	L0E030	\$176



Items with New Lots

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Catalog #	Description	Change Code	Previous Lot/ Valid Use Date	Current Lot	Price (USD)
1023403	Diazepam Related Compound B (25 mg)	2	I1C102 (02/08)	J0F235	\$549
1041609	Apraclonidine Hydrochloride (100 mg)	2	H0B112 (12/07)	I0G001	\$540
1048620	Benazepril Related Compound A (15 mg)	2	F0C252 (02/08)	G0F352	\$549
1066009	Betamethasone (200 mg)	2	K2C204 (03/08)	L0G059	\$176
1094004	Carbenicillin Monosodium Monohydrate (200 mg)	2	G-2 (09/07)	G3G012	\$176
1096699	Carprofen (200 mg)	2	F0D335 (02/08)	F1G039	\$176
1098027	Cefpodoxime Proxetil (350 mg)	2	F0C192 (03/08)	G0G067	\$176
1131009	Cholecalciferol (30 mg/ampule; 5 ampules) (Vitamin D3)	2	M0B157 (01/08)	N0G038	\$180
1140509	Clorazepate Dipotassium <b>CIV</b> (125 mg)	2	G0B027 (12/07)	G1F159	\$233
1140586	Clopidogrel Related Compound A (20 mg)	2	F0E117 (03/08)	F1F332	\$667
1150353	Creatinine (100 mg)	2	F (01/08)	F1F318	\$176
1158504	Cyclosporine (50 mg)	2	H-1 (12/07)	I0F343	\$540
1180503	Dextromethorphan (2 g)	2	H (03/08)	I0F274	\$549
1181007	Dextromethorphan Hydrobromide (500 mg)	2	J0B167 (03/08)	K0F118	\$176
1242010	Erythromycin B (100 mg)	2	G1C080 (03/08)	G2F259	\$176
1280009	Fluoxymesterone <b>CIII</b> (200 mg)	2	G-2 (11/07)	G3F292	\$233
1316004	Hydrocortisone (200 mg)	2	M1C110 (02/08)	N0F289	\$176
1370611	Lovastatin Related Compound A (10 mg)	2	H0D274 (1/08)	I0F257	\$549
1445200	Mitoxantrone Hydrochloride (400 mg)	2	I0D174 (03/08)	J0F278	\$562
1469005	Norethindrone (200 mg)	2	K0C307 (02/08)	L0F237	\$176
1478505	Omeprazole (200 mg)	2	H1B211 (03/08)	I0F081	\$176
1478618	Ondansetron Related Compound C (30 mg)	2	F0C251 (03/08)	G0F283	\$549
1500218	Paroxetine Hydrochloride (350 mg)	2	G0D003 (02/08)	G1F261	\$176
1500240	Paroxetine Related Compound C (15 mg)	2	G0D053 (03/08)	G1F101	\$549
1500262	Paroxetine Related Compound E Mixture (25 mg)	2	F1F028 (01/08)	F2G002	\$549
1533002	Phenylephrine Hydrochloride (125 mg)	2	K1C290 (03/08)	L0F273	\$140
1548190	Potassium Chloride (1 g) (AS)	2	F0D127 (03/08)	G0F268	\$176
1576708	Propylene Glycol (1 mL)	2	I0C022 (12/07)	J0F211	\$176
1616008	1,4-Sorbitan (300 mg)	2	I0A003 (02/08)	J0F351	\$176
1692505	Trimethoprim (300 mg)	2	J0B228 (03/08)	K0F080	\$176
1098231	Cefuroxime Axetil Delta-3-Isomers (10 mg)	2,3	H1E186 (12/07)	H2G014	\$549
1667304	Ticarcillin Monosodium Monohydrate (350 mg)	2,3	H (08/07)	I0G021	\$176



## USP Publication Highlights

### Reminder of Delayed Implementation for *USP30-NF25*

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Please be aware that USP has delayed the implementation of *USP30-NF25* by several months. This change was adopted to give users more time to bring their methods and procedures into compliance with new and revised *USP-NF* requirements. Below is a schedule for when new issues will be official. Until May 1, 2007, please continue to use *USP29-NF24* and the appropriate Supplement and Interim Revision Announcements. For more details, please visit our website at:

<http://www.usp.org/USPNF/notices/implementationPeriodExtension.html>

Publication	Release Date	Official Date	Official Until
USP30-NF25	Nov. 1, 2006	May 1, 2007	May 1, 2008 (except as superceded by Supplements, IRAs, and Revision Bulletins)
First Supplement	Feb. 1, 2007	Aug. 1, 2007	May 1, 2008 (except as superceded by Second Supplement, IRAs, and Revision Bulletins)
Second Supplement	June 1, 2007	Dec. 1, 2007	May 1, 2008 (except as superceded by IRAs and Revision Bulletins)
USP31-NF26	Nov. 1, 2007	May 1, 2008	May 1, 2009 (except as superceded by Supplements, IRAs, and Revision Bulletins)

### 2007 USP Dictionary Available April 1

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The new USP Dictionary of USAN and International Drug Names will be available in April, in print and online formats, \$299 each. The 2007 edition features more than 9,000 updates, including over 3,700 new and revised graphic formulas and over 1,000 additional pronunciations! Order now at

<http://www.usp.org/products/dictionary/>.



## Publications Scheduled Ship Dates

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The following table lists the scheduled ship dates for USP publications.

Publication	Scheduled Ship Date	On Schedule?
<i>USP30-NF25 First Supplement—Spanish</i>	March 30, 2007	Yes
<i>USAN Online 2007</i>	March 31, 2007	Yes
<i>USAN 2007</i>	April 1, 2007	Yes

Orders should arrive within two weeks of placement. If you do not receive your publication order when expected, please contact your Account Manager.

## USP International Standards

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The United States Pharmacopeia (USP) approach for International Standards allows the creation of documentary standards (monographs) for drug substances and drug products that have been approved in and are legally marketed in countries other than the United States and are intended to treat neglected diseases. The purpose of these monographs is to support testing by first (e.g., manufacturer), second (e.g., payors), and third (e.g., government control laboratories) parties. Manufacturers wishing to signal conformance to these monographs may use the following block letters—USP-I. USP Reference Standards to allow testing in accordance with an International Standards monograph may be available in USP's catalogue at a future date.

The initial two drugs included in the program are used in the treatment of HIV-AIDS: Abacavir Sulfate and Efavirenz. These monographs are posted in draft form, with a 90-day period for public comment that ends on April 30, 2007. The draft monographs, instructions for submitting comments and more information on the program are at <http://www.usp.org/internationalStandards/>.



## Education Highlights



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### **USP Annual Scientific Meeting 2007**

September 25–27, 2007

**Hyatt Regency Tampa**  
**211 North Tampa Street**  
**Tampa, Florida 33602**

#### ***USP invites you to get involved ...***

- The USP Annual Scientific Meeting 2007 is your opportunity to interact with USP's scientific staff, Council of Experts and your Scientific Colleagues.
- Learn about USP's approach to Quality of Manufactures medicines and Quality of Care, and the standards that are being implemented and how they will impact you and your organization.
- Engage in discussions that will help establish standards setting priorities for USP and shape USP/quality requirement.

Preliminary Topics for this year's Annual Scientific Meeting are:

**TRACK I Quality of Manufactured Medicines – *Monographs and Reference Standards***

**TRACK II Quality of Manufactured Medicines – *General Chapters and Performance Testing***

**TRACK III Quality of Manufactured Medicines – *Biologics and Biotechnology***

**TRACK IV Quality of Care**

**TRACK V International Health**

For more information please visit our website at [www.usp.org](http://www.usp.org) or contact:

- [conferences@usp.org](mailto:conferences@usp.org)
- 301-816-8134

### **“Detecting Counterfeit Drugs Workshop”**



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A [Three-day Workshop, June 5-7, 2007](#) to be held at FDA's Northeast Regional Laboratory

The Commissioner of Food and Drugs, Dr. Andrew von Eschenbach, recently declared the elimination of counterfeits one of the top priorities of the agency. Regulatory agencies in every country and international organizations such as the World Health Organization are also seeking ways to address the problem. The US Pharmacopeia, York College, and the FDA's Northeast Regional Laboratory are co-sponsoring a three-day workshop on this important issue. This workshop will cover the practical aspects of a variety of laboratory techniques focused on the detection of counterfeits. This unique perspective will add depth and value to the information that has been presented at many other meetings on the interdiction of counterfeits, and is highly recommended for any individual with interest in the detection and elimination of counterfeit drugs. More information and registration procedures for the workshop can be found on [York College's website](#).



## “Navigating Chapter <467> Residual Solvents”

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This half-day USP Pharmacopeial Education seminar provides an overview of the significant changes to General Chapter <467>, which become official requirements on July 1, 2007. The three-hour seminar combines lectures, case studies, and question and answer time to provide a practical overview. See the schedule of offerings below or go to <http://www.usp.org/pdf/EN/eventsEducation/residualSolvents467Registration.pdf>

## USP to Offer Courses in Africa and Europe Spring 2007

To better serve our European, Middle Eastern and African customers, we are offering several of our most popular courses in **Johannesburg**, South Africa; and **Milan** and **Rome**, Italy this spring. Among the choices will be several dates and locations for **Analytical Method Validation** and **Fundamentals of Dissolution**, with opportunities to attend **Effectively Using the USP-NF** as well.

## Pharmacopeial Education Course Schedule — April through June 2007

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The Americas		
Date	Name of Course	Location
10 Apr 07	Navigating Chapter <467> Residual Solvents	Toronto, Canada <sup>1</sup>
17-Apr-07	Navigating Chapter <467> Residual Solvents	East Brunswick, NJ (Morning seminar)
17-Apr-07	Navigating Chapter <467> Residual Solvents	East Brunswick, NJ (Afternoon seminar)
19-Apr-07	Navigating Chapter <467> Residual Solvents	Rockville, MD (USP Headquarters, Morning)
8-May-07	Fundamentals of Dissolution – Lecture only	North Brunswick, NJ (1-day)
8-9-May-07	Fundamentals of Dissolution – Lecture & Lab	North Brunswick, NJ (with Distek, 2-day)
17-May-07	Analytical Method Validation (in Spanish)	Mexico City, Mexico <sup>2</sup>
22-May-07	Analytical Method Validation	Raleigh, NC
19-Jun-07	Effectively Using the USP-NF	Raleigh, NC

For all courses offered in the Americas, except where noted by footnote, **more information and registration** can be obtained by phone or fax, through USP’s Customer Service group. **Phone: 1-800-227-8772**, choose option 3, then option 4, **Fax: 1-301-816-8148**. Customer Service Representatives may also be reached at [custsvc@usp.org](mailto:custsvc@usp.org)

If you have questions on specific course content, please contact Kathy Muenchow at 301-816-8589 or [PharmacopeialEducation@usp.org](mailto:PharmacopeialEducation@usp.org).

1. For registration, see Pharmaceutical Sciences Group website: <http://psg.ca/>; or phone (905) 513-7743.
2. For registration information, contact [ventas@proquifa.com.mx](mailto:ventas@proquifa.com.mx)



Europe/ Middle East/ Africa/ India		
Date	Name of Course	Location
11 Apr 07	Effectively Using the USP-NF	Hyderabad, India†
11 Apr 07	Navigating Chapter <467> Residual Solvents	Hyderabad, India†
23-Apr-07	Navigating Chapter <467> Residual Solvents	Munich, Germany*
24-Apr-07	Navigating Chapter <467> Residual Solvents	Berlin, Germany*
26-Apr-07	Navigating Chapter <467> Residual Solvents	Liverpool, UK*
27-Apr-07	Navigating Chapter <467> Residual Solvents	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**
30-May-07	Analytical Method Validation	Johannesburg, SA***
31-May-07	Fundamentals of Dissolution (Lectures)	Johannesburg, SA***
12-Jun-07	Effectively Using the USP-NF (In English with assistance for Italian)	Milan, Italy ****
14-Jun-07	Analytical Method Validation (In English with assistance for Italian)	Rome, Italy****

†Contact USP—India Private Ltd. +91-40-2348-0088.

\*Register with: USP Customer Service, Rockville, Maryland: Phone: 00-800-4875-5555 (from Europe); Fax: +1-301-816-8586;  
E-mail: [custsvc@usp.org](mailto:custsvc@usp.org)

\*\* Register with SOTAX AG: <http://www.sotax.com/sotax/events.html> (lecture in English language with course presentation slides in Italian)

\*\*\* Register with: Industrial Analytical Ltd., Ms. Berdine du Plessis, Phone: +27 (0)11 466 4321; E-mail: [berdine@industrialanalytical.co.za](mailto:berdine@industrialanalytical.co.za)

\*\*\*\* Register with: Nova Chimica, Via Galileo Galilei 47, 20092 Cinisello Balsamo (MI) Italy, Phone: +39 (02) 660 45392; Fax: +39 (02) 660 45394; E-mail: [info@novachimica.com](mailto:info@novachimica.com) (lecture in English language with course presentation slides in Italian)

For more details on offerings outside the Americas, please contact our European office at +41 (0) 61 316 30 10 or by email at: [ap@usp.org](mailto:ap@usp.org) Additional information about our courses is available online at <http://www.usp.org/qoto/pe>



**New Notices Pertaining to USP-NF** (<http://www.usp.org/USPNF/notices/?h>)  [Return to Top](#)

**Correction:** Notice of Correction to Ranitidine Injection—03/16/07

**Postponement:** New monographs for which Reference Standards are not yet available—03/07/07

**Intent to Revise:** Sodium Fluoride and Acidulated Phosphate Topical Solution—03/07/07

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**Tip of the Month**

Interim Revision Announcement to *USP 29* and to *NF 24* published in *Pharmacopeial Forum* Vol. 33(2)[Mar.— Apr. 2007] Official April 1, 2007 includes the following USP Monographs: Acetaminophen Extended-Release Tablets, Bisoprolol Fumarate Tablets, Bupropion Hydrochloride Extended-Release Tablets, Diltiazem Hydrochloride Extended-Release Capsules, Metformin Hydrochloride Tablets

and General Chapters: <1> Injections, <61> Microbiological Examination of Nonsterile Products: Microbial Enumeration Tests, <62> Microbiological Examination of Nonsterile Products: Tests for Specified Microorganisms, <788> Particulate Matter in Injections, <1111> Microbiological Examination of Nonsterile Products: Acceptance Criteria for Pharmaceutical Preparations and Substances for Pharmaceutical Use

**Question of the Month**

When using the *USP-NF* electronic product, I am getting a “too many users” error message even though I am the only user. Why?

**Answer:**

The most frequent cause of this error for a single user is closing out of the product by closing the window (clicking on the X at the top right of the screen) rather than logging out with the logout button. It takes about 30 minutes with no activity for the server to close out the session unless the logout button is used. If you try and log back in before the server has closed out the session, the “too many users” error will appear.