



**October 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 September 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that have been discontinued/have a new price and/or have a new package size; items with lots that are (or soon will be) no longer valid; and items with new lots since the last email notice.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)
1050905	Benzaldehyde	1 mL	F0F093	\$176
1071224	Bicalutamide Related Compound B	10 mg	F0G219	\$549
1347529	Ipratropium Bromide Related Compound B	10 mg	F0G242	\$549
1358853	Levalbuterol Related Compound G	20 mg	F0G184	\$549
1442100	Metronidazole Benzoate	100 mg	F0G254	\$176
1604665	Risperidone System Suitability Mixture	10 mg	F0G225	\$549



## Previously Out-of-Stock Items Now Available

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Catalog #	Description	Size	Lot	Price (USD)
1045337	Avobenzone	500 mg	H0G220	\$176
1068004	Betamethasone Sodium Phosphate	500 mg	LOG223	\$176
1171900	Desflurane	0.5 mL	G0G018	\$176
1183002	Diacetylmorphine Hydrochloride <b>Cl</b> (AS)	25 mg	J1G200	\$233
1317302	Hydrocortisone Butyrate	200 mg	I0G158	\$176
1643500	Terbutaline Sulfate	125 mg	I0G250	\$140
1711155	Vecuronium Bromide	50 mg	G0G252	\$176

## Backorder Availability Estimates, September 24, 2007

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Catalog #	Description	Expected Availability*
1067001	Betamethasone Acetate (500 mg)	Q4/07
1071304	Bile Salts (10 g)	Q3/07
1107300	Chloramphenicol Palmitate (200 mg)	Q4/07
1254508	Estriol (100 mg)	Q3/08
1282004	Fluphenazine Hydrochloride (125 mg)	Q4/07
1302509	Halcinonide (300 mg)	Q3/07
1339000	Indigotindisulfonate Sodium (500 mg)	Q4/07
1546900	Polyethylene Terephthalate (PET) (3 Strips)	Q4/07
1642212	Sumatriptan Succinate Rel Cpd A (15 mg)	Q2/08
1670207	Tolcapone (200 mg)	Q1/08
1676000	Triamcinolone (250 mg)	Q4/07

\*Dates are targets and may change at any time. Q3/07 = July—September 2007, Q4/07 = October—December 2007, Q1/08 = January—March 2008, Q2/08 = April—June 2008, Q3/08 = July—September 2008



## 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 September 30, 2007				
Catalog #	Description	Previous Lot/ Valid Use Date	Current Lot	Price (USD)
1012757	Alclometasone Dipropionate (300 mg)	H (09/07)	I0C302	\$176
1022808	2-Amino-5-chlorobenzophenone (25 mg)	I (09/07)	J0F197	\$549
1045756	Azaperone (200 mg)	F (09/07)	F1F183	\$176
1065709	Betaine Hydrochloride (200 mg)	F-1 (09/07)	G0F176	\$176
1086301	Calcitriol (10 mg)	F0E062 (09/07)	G0F104	\$1,410
1094004	Carbenicillin Monosodium Monohydrate (200 mg)	G-2 (09/07)	G3G012	\$176
1095506	Carbidopa (400 mg)	I (09/07)	J0F258	\$176
1095517	Carbidopa Related Compound A (25 mg)	H0B121 (09/07)	H1F245	\$549
1200600	Dihydrocapsaicin (25 mg)	G0C071 (09/07)	H0F210	\$293
1271008	Floxuridine (250 mg)	F-2 (09/07)	G0F207	\$176
1271722	Fluconazole Related Compound B (10 mg)	F0D081 (09/07)	G0F218	\$549
1285851	Flutamide (200 mg)	H0B278 (09/07)	H1E297	\$176
1296009	Glycopyrrolate (200 mg)	H0B304 (09/07)	I0F193	\$176
1310008	Homatropine Hydrobromide (200 mg)	H2C049 (09/07)	I0E341	\$176
1336806	Imidurea (200 mg)	H (09/07)	I0F180	\$176
1344600	Iohexol (200 mg)	F-1 (09/07)	G0F254	\$184
1491343	Paclitaxel Related Compound A (20 mg)	F0C179 (09/07)	G0F248	\$850
1546707	Polyethylene, High Density (3 strips)	G1D115 (09/07)	H0F046	\$176
1554658	Praziquantel Related Compound A (50 mg)	F-1 (09/07)	G0F142	\$549
1711009	Vanillin Melting Point Standard (1 g) (Approximately 82 degrees)	J1C303 (09/07)	K0F097	\$105
1724521	Zidovudine Related Compound B (25 mg)	G0B116 (09/07)	H0F230	\$549



**No Longer Valid as of October 31, 2007**

Catalog #	Description	Previous Lot/ Valid Use Date	Current Lot	Price (USD)
1173235	Desogestrel (50 mg)	G0C390 (10/07)	G1F145	\$176
1227006	Doxylamine Succinate (300 mg)	I0B266 (10/07)	I1F141	\$176
1287008	Furosemide (125 mg)	J1B131 (10/07)	K0F188	\$140
1379106	Megestrol Acetate (500 mg)	I (10/07)	I1F281	\$176
1396604	Methacrylic Acid Copolymer Type C (200 mg)	G1B088 (10/07)	G2E288	\$176
1436006	Methylprednisolone Acetate (200 mg)	H0D148 (10/07)	I0F082	\$176
1454008	Nandrolone <b>CIII</b> (50 mg)	F4D144 (10/07)	G0F291	\$630
1463701	Nifedipine Nitrosophenylpyridine Analog (25 mg)	K (10/07)	K1F147	\$549
1478593	Ondansetron Related Compound A (50 mg)	F0C191 (10/07)	F1F240	\$549
1491503	Padimate O (300 mg)	H0B154 (10/07)	H1E172	\$176
1501108	Penicillamine Disulfide (200 mg)	H (10/07)	I0F234	\$549
1705800	Uracil Arabinoside (50 mg)	G (10/07)	H0F084	\$176
1708795	Valsartan Related Compound C (10 mg)	F1D025 (10/07)	G0F241	\$703

**Items with New Lots**

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Catalog #	Description	Previous Lot/ Valid Use Date	Current Lot	Price (USD)
1015008	Alprazolam <b>CIV</b> (200 mg)	H1C133 (09/08)	I0G195	\$233
1043003	Ascorbic Acid (1 g) (Vitamin C)	Q0B012 (09/08)	Q1G135	\$176
1045337	Avobenzone (500 mg)	G1E109 (08/08)	H0G220	\$176
1068004	Betamethasone Sodium Phosphate (500 mg)	K0C358 (07/08)	L0G223	\$176
1317302	Hydrocortisone Butyrate (200 mg)	H (08/08)	I0G158	\$176
1349502	L-Isoleucine (200 mg)	F-2 (09/08)	G0G167	\$176
1441287	Metoprolol Fumarate (200 mg)	F (09/08)	G0G148	\$176
1445211	Mitoxantrone System Suitability Mixture (0.3 mg)	F0D010 (09/08)	G0F107	\$564
1511203	Perphenazine Sulfoxide (100 mg)	G-1 (09/08)	H0G202	\$549
1578000	Propylthiouracil (200 mg)	G (09/08)	H0G031	\$176
1711155	Vecuronium Bromide (50 mg)	F0C367 (08/08)	G0G252	\$176

**New Reference Standards Notification Service Available Online**

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If you are awaiting the release of a particular new USP Reference Standard, the Reference Standards Notification Program can be used to notify you when a never-before-released Reference Standard becomes available. To sign up, please fill out the form at <http://www.usp.org/referenceStandards/notificationProgram.html>

The Notification Program does not communicate the release of back-ordered items. To find out when back-ordered items will become available again, please refer to the table in this Notice or contact customer service at [custsvc@usp.org](mailto:custsvc@usp.org) or call +1-301-881-0666 or 1-800-227-8772.



## New USP Near-Infrared (NIR) System Suitability Reference Standard



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Intended for the qualification of NIR wavelength uncertainty where measurements are taken in diffuse reflectance mode, the new NIR Reference Standard comprises a mixture of talc and three rare earth oxides of dysprosium, holmium, and erbium. Suitable for Dispersive, FT, and CCD Array, it offers extended range applicability and the flexibility to choose user-specified bands. The new USP NIR Reference Standard does not require recertification in its lifecycle! Catalog number: 1457844. Price: \$1849 (US dollars).

## New Shipping Method – Dry Ice



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In response to customer comments, USP will now offer the ability for customers to ship product on dry ice.

Customers can request special shipping on dry ice for an additional charge of US\$8 *per unit* for orders to the United States or an additional charge of US\$16 *per unit* for orders outside of the United States. Furthermore, the following items must be shipped on dry ice and the additional shipping charge will apply.

- 1342106 Insulin Human
- 1342321 Insulin Lispro
- 1342300 Insulin (Pork)
- 1342208 Insulin (Beef)
- 1342004 Insulin

Please note that USP does not accept responsibility for any potential adverse effects of products shipped on dry ice upon request.

## USP Publication Highlights

Publication	Release Date	Official Date	Official Until
<i>USP 30–NF 25</i>	Nov. 1, 2006	May 1, 2007	May 1, 2008 (except as superseded by Supplements, IRAs, and Revision Bulletins)
<i>First Supplement</i>	Feb. 1, 2007	Aug. 1, 2007	May 1, 2008 (except as superseded by Second Supplement, IRAs, and Revision Bulletins)
<i>Second Supplement</i>	June 1, 2007	Dec. 1, 2007	May 1, 2008 (except as superseded by IRAs and Revision Bulletins)
<i>USP 31–NF 26</i>	Nov. 1, 2007	May 1, 2008	May 1, 2009 (except as superseded by Supplements, IRAs, and Revision Bulletins)



## Be Prepared for 2008—Order *USP 31–NF 26* Today!



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Available November 1 in English in print, online, and CD formats. An annual subscription includes a main edition and two *Supplements*. The *USP 31–NF 26 Spanish Edition* will be published in print only in January. Subscribe today at [www.usp.org](http://www.usp.org) or call USP Customer Service at 1-800-227-8772 (U.S. and Canada), +1-301-881-0666, or 00-800-4875-5555 (Europe).

## Comment on and Propose Standards Revisions with *Pharmacopeial Forum (PF)*, Volume 34—Subscribe for 2008



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Published six times a year, *PF* lets you review and submit both comments and proposals for standards revisions. Plus, *PF* gives you 2 to 12 months advance notice of changes, allowing you to prepare early for revisions. Order *PF* 34 today to ensure that you receive the first 2008 issue in January! Print and online formats, English only. Visit [www.usp.org](http://www.usp.org) or call USP Customer Service at 1-800-227-8772 (U.S. and Canada), +1-301-881-0666, or 00-800-4875-5555 (Europe).

## New *Food Chemicals Codex* publishes February 2008—Reserve your copy now



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USP will be publishing the *Food Chemicals Codex (FCC)* 6<sup>th</sup> edition in February 2008. The *FCC* provides internationally recognized standards of purity and quality for food ingredients. Used by manufacturers and regulatory agencies to ensure that products are prepared according to GMPs and do not contain harmful levels of contaminants, it will be published every two years with a supplement provided in interim years. Print and online subscriptions, English only. Reserve your copy today! Visit [www.usp.org](http://www.usp.org) or call USP Customer Service at 1-800-227-8772 (U.S. and Canada), +1-301-881-0666, or 00-800-4875-5555 (Europe).

## New *Chromatographic Reagents*—Available



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Make sure you have the new 2007-2008 edition of *Chromatographic Reagents*! This valuable, time-saving companion reference to *USP–NF* and *PF* provides a cumulative listing of column reagents referenced in liquid- and gas-chromatographic methods since 1980. Includes brand names, manufacturers, and more. Soft cover print, spiral format with storage pocket, in English only. Order today! Visit [www.usp.org](http://www.usp.org) or contact USP Customer Service at 1-800-227-8772 (U.S. and Canada), +1-301-881-0666, or 00-800-4875-5555 (Europe).

## Subscriptions



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Two year subscriptions will not be offered for 2008 products.



## Publications Scheduled Ship Dates

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

Publication	Scheduled Ship Date
<i>PF33(6)Highlights</i>	October 25, 2007
<i>PF33(6) Online</i>	November 1, 2007
<i>PF33(6) Print</i>	November 8, 2007
<i>USP31–NF26 Print</i>	November 1, 2007
<i>USP31–NF26 Online</i>	November 1, 2007
<i>USP31–NF26 CD</i>	November 1, 2007

Orders should arrive within two weeks of placement. If you do not receive your publication order when expected, please contact USP Customer Service at +1-301-881-0666 or email: [custsvc@usp.org](mailto:custsvc@usp.org).

## Education And Events Highlights

### USP Customer Days—Coming to a city near you!

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The USP Account Management Team will be traveling across the U.S. and Canada and select locations outside the U.S. holding free seminars to discuss USP publications, Reference Standards, USP Verified Services, Pharmacopeial Education, new initiatives, and hot topics.

Meetings are scheduled for East Brunswick, NJ (October 30, 2007, Hilton East Brunswick); Raleigh, NC (November 29, 2007); Irvine, CA (February 28, 2008); St. Louis, MO (May 15, 2008); and Montreal, Canada (June 4, 2008). Registration and more information are available at: <http://www.usp.org/goto/USPCustomerDays> or contact: [marketing@usp.org](mailto:marketing@usp.org).

### Exhibitions— Come Visit Us!

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Booth #1617 at AAPS in San Diego, CA November 12-14

Booth #100 and #101 at EAS in Somerset, NJ November 12-14

USP will have a booth at the **PABME** Pharmaceutical Manufacturing and Biotechnology Middle East: 27 – 29 April 2008 Dubai, International Exhibition Center, UAE



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## Learning about the most important standards revisions is as easy as sitting at your desk!

Each *Pharmacopeial Forum* eSymposium features 60-90 minutes of expert presentations on the **most important** standards updates and proposed revisions. Scheduled to follow the release of each issue of *Pharmacopeial Forum*, USP eSymposia provide participants with a cost-effective and convenient way to learn about upcoming revisions, and offers a unique opportunity to discuss changes with USP experts on topics included in that PF. Specific topics will be announced 4-6 weeks prior the date of each eSymposium. For more information, contact Donna Washington, Project Manager, Pharmacopeial Education, at +1-301-816-8228. See schedule below. Cost: \$89 (US)

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## The NEW online course “Navigating Chapter <467> Residual Solvents is now available!

USP has created a new online course from the popular classroom offering “Navigating Chapter <467> Residual Solvents.” This course will provide a broad understanding of the requirements in USP General Chapter <467> allowing the student to structure protocol for the tests and procedures necessary to demonstrate compliance.

Composed of web casts, discussion boards, online evaluation and practical assignments, the new online version of Chapter <467> has been created to allow you to take this crucial course on your own schedule, at your own pace and in the comfort of your office, lab or home. This course is priced at a fraction of our classroom offering and you also save money by not having to travel. See schedule below.

## New online course “How to Build a Monograph” is available on-demand

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Discover how you can influence official USP-NF standards by learning how to build new monographs and how to participate in the revision of existing ones. Developed by USP experts, this course takes you step-by-step through the processes. To register, call 1-800-227-8772 or [custsvc@usp.org](mailto:custsvc@usp.org).

## Subscribe to new Professional Education Email Alert

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USP Professional Education is developing new courses at a faster pace than ever. If you would like to be informed of our new curriculum and upcoming schedule, you should subscribe to the new Professional Education Email Alert. Simply email us at [professionaleducation@usp.org](mailto:professionaleducation@usp.org) and type “email alert” in the subject field.



## Pharmacopeial Education Course Schedule — October 2007 through May 2008

### Upcoming Online Professional Education Courses as of October 1, 2007

Date	Course Title	Location	Price
11-Oct-07	Navigating Chapter <467> Residual Solvents	On-Line	Web Based Education
1-Nov-07	Navigating Chapter <467> Residual Solvents	On-Line	Web Based Education
14-Nov-07	USP eSymposium on Pharmacopeial Forum 33(6)	Webinar	Webinar
29-Nov-07	Navigating Chapter <467> Residual Solvents	On-Line	Web Based Education
3-Jan-08	Navigating Chapter <467> Residual Solvents	On-Line	Web Based Education
9-Jan-08	USP eSymposium on Pharmacopeial Forum 34 (1)	Webinar	Webinar
12-Mar-08	USP eSymposium on Pharmacopeial Forum 34 (2)	Webinar	Webinar
14-May-08	USP eSymposium on Pharmacopeial Forum 34 (3)	Webinar	Webinar



### Upcoming Professional Classroom Education Courses as of October 1, 2007 The Americas

Date	Course Title	Location	Price
16-Oct-07	Validation of Compendial Procedures	Somerset, NJ	\$695
7-8 Nov 07	Advanced Dissolution (new course - 2 day)	Horsham PA	\$1,495
27-Nov-07	Food and Drug HPLC	Kansas City, MO	\$695
November TBD	Dissolution Testing: Theory and Best Practices	Cincinnati, OH (Barr Labs)	\$750
11-Dec-07	Essentials of USP Microbiological Testing	Somerset, NJ	\$695
12-13 Dec 07	Advanced Dissolution (new course 2-day)	Raleigh, NC (McKimmon Center)	\$1,495
17-Jan-08	Validation of Compendial Procedures	San Francisco, CA	\$695
23-24 Jan 08	Advanced Dissolution	Horsham PA (Sotax)	\$1,495
29-Jan-08	Basic Statistics and their Application to the USP-NF	Kansas City, MO	\$595
January TBD	Residual Solvents: Results in Practice -- Workshop (Full day workshop)	Rockville, MD	\$895
January TBD	Validation of Compendial Procedures	Irvine, CA (FDA Facility)	\$695
January TBD	Dissolution Testing: Theory and Best Practices	Promona, NY (Barr Labs)	\$750
12-13 Feb 08	Advanced Dissolution	Chicago, IL	\$1,495
Feb TBD	Particulate Matter in Injectables	New Jersey	\$695
March TBD	Food and Drug HPLC	Chicago, IL	\$695
March TBD	Effectively Using the USP-NF	New Jersey	\$695



**Upcoming Professional Classroom Education Courses as of October 1, 2007  
Europe/Middle East/Africa/India**

Date	Course Title	Location	Price
13-14 Nov-07	Fundamentals of Dissolution (New Title–Dissolution Testing; Theory and Best Practices), (1 day of lecture theory and 1 day of practical hands-on laboratory). <b>Course language English</b> <b>(Course literature German/English)</b>	*SOTAX, Allschwil, Switzerland	EUR 1,500
15-16 Nov-07	Fundamentals of Dissolution (New Title–Dissolution Testing; Theory and Best Practices), (1 day of lecture theory and 1 day of practical hands-on laboratory). <b>Course language English</b> <b>(Course literature French/English)</b>	*SOTAX, Allschwil, Switzerland	EUR 1,500
Nov 07	HPLC	Classroom / India	US \$400
Nov 07	Validation of Compendial Procedures	Classroom / India	US \$400
3-Dec-07	Validation of Compendial Procedures	^ Istanbul, Turkey	^ Call for Information
4-Dec-07	Dissolution Testing; Theory and Best Practices (formerly Fundamentals of Dissolution)	^ Istanbul, Turkey	^ Call for Information
Feb TBD	HPCL	India	US \$400
Feb TBD	Validation of Compendial Procedures	India	US \$400
Feb TBD	Essentials of USP Microbiological Testing	India	US \$450

**Notes:**

\*To register, contact Sotax AG; Tel (+41) 61 487 54 54; Fax: (+41) 61 482 13 31; email: [sales@sotax.ch](mailto:sales@sotax.ch)  
Link: <http://www.sotax.com/sotax/events.html>

^ To register, contact: Ekin Kimya Ticaret Limited Sirketi, Bulgurlu Mahallesi, Sarigazi Cad. No. 29, Camlica-Usküdar 34696 Istanbul, Turkey, Phone: +216 524 12 24, Fax: +216 524 12 80-81;  
[pinar@ekinkimya.com](mailto:pinar@ekinkimya.com) Link: <http://www.ekinkimya.com>



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

**Revision Bulletin:** Nothing New

**Explanatory Notes/Announcements:** Nothing New

**Errata:** Nothing New

**Postponements:** Nothing New

## **Stimuli Articles**

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Featured in PF 33 (5), September—October 2007

Toward a Uniform System for Naming Vaccines and Polyclonal Immune Globulins

<http://www.usp.org/pdf/EN/USPNF/Vol33No5Stimuli.pdf>

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### **Tip of the Month**

Find out how you can participate in USP's public standards-setting process, visit <http://www.usp.org/USPNF/submitMonograph/> for details.

### **Question of the Month**

**Does my drug substance need to comply with the statements in the *Description and Solubility* section?**

### **Answer:**

**No.** The specifications in the *Description and Solubility* section are not considered official requirements by the USP. The “description” and “solubility” statements pertaining to an article (formerly included in the individual monograph) are general in nature. The information is provided for those who use, prepare, and dispense drugs, solely to indicate descriptive and solubility properties of an article complying with monograph standards. The properties are not in themselves standards or tests for purity even though they may indirectly assist in the preliminary evaluation of the integrity of an article.