



## November 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 October 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that have been discontinued/have a new price and/or have a new package size; items with lots that are (or soon will be) no longer valid; and items with new lots since the last email notice.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)
1249789	Esomeprazole Magnesium	10 mg	F0G260	\$176
1347507	Ipratropium Bromide	100 mg	F0G269	\$176
1478549	Omeprazole Magnesium	10 mg	F0G259	\$176
1478800	Orlistat	200 mg	F0G243	\$389
1554192	Pravastatin 1,1,3,3-Tetramethylbutylamine	200 mg	F0G234	\$189
1554228	Pravastatin Related Compound B	20 mg	F0G230	\$549



## Previously Out-of-Stock Items Now Available

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Catalog #	Description	Size	Lot	Price (USD)
1067001	Betamethasone Acetate	500 mg	K0G274	\$176
1107300	Chloramphenicol Palmitate	200 mg	H0G266	\$176
1166003	Deferoxamine Mesylate	500 mg	J0G233	\$176
1302509	Halcinonide	200 mg	G0G239	\$176
1339000	Indigotindisulfonate Sodium	500 mg	H2G304	\$176
1466007	Nitrofurazone Related Compound A	500 mg	I0G265	\$549
1546900	Polyethylene Terephthalate (PET)	3 strips	G0G240	\$176
1580002	Protriptyline Hydrochloride	200 mg	H0G267	\$176
1676000	Triamcinolone	250 mg	I0G157	\$176

## Backorder Availability Estimates, October 15, 2007

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Catalog #	Description	Expected Availability*
1071304	Bile Salts (10 g)	Q4/07
1254508	Estriol (100 mg)	Q3/08
1282004	Fluphenazine Hydrochloride (125 mg)	Q4/07
1339000	Indigotindisulfonate Sodium (500 mg)	Q4/07
1392002	Mercaptopurine (500 mg)	Q4/07
1642212	Sumatriptan Succinate Rel Cpd A (15 mg)	Q2/08
1670207	Tolcapone (200 mg)	Q1/08

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

## Items with New Package Size

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Catalog #	Description	Old Size	New Size	Lot	Price (USD)
1302509	Halcinonide	300 mg	200 mg	G0G239	\$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 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



**No Longer Valid as of November 30, 2007**

Catalog #	Description	Previous Lot/ Valid Use Date	Current Lot	Price (USD)
1078766	Bupropion Hydrochloride Related Compound C (40 mg)	F0D293 (11/07)	G0G006	\$627
1078799	Bupropion Hydrochloride Related Compound F (30 mg)	F0E076 (11/07)	G0G010	\$627
1091006	Capreomycin Sulfate (250 mg)	G (11/07)	G1F191	\$185
1098173	Ceftizoxime (350 mg)	I0E262 (11/07)	J0F181	\$185
1111103	Chlorhexidine Acetate (500 mg)	G0E008 (11/07)	H0F199	\$185
1140430	Clopidogrel Bisulfate (125 mg)	F0E115 (11/07)	G0F282	\$824
1186000	Diazoxide (200 mg)	G1C017 (11/07)	H0F314	\$185
1205003	Diltiazem Hydrochloride (200 mg)	I (11/07)	J0F005	\$185
1280009	Fluoxymesterone <b>CIII</b> (200 mg)	G-2 (11/07)	G3F292	\$245
1288500	Gemfibrozil (200 mg)	H (11/07)	H1F285	\$185
1314009	Hydrochlorothiazide (200 mg)	I (11/07)	J0F070	\$185
1342106	Insulin Human (100 mg)	I0C383 (11/07)	I1F270	\$185
1449518	Nabumetone (200 mg)	F0C072 (11/07)	G0F312	\$185
1460000	Neostigmine Methylsulfate (200 mg)	I (11/07)	J0F167	\$185
1470004	Norethindrone Acetate (100 mg)	J1E102 (11/07)	K0F227	\$185
1478582	Ondansetron Hydrochloride (300 mg)	G0D154 (11/07)	G1F249	\$246
1606503	Rutin (100 mg)	G0C355 (11/07)	G1F308	\$185
1617000	Sorbitol (125 mg)	H1B139 (11/07)	H2F247	\$147
1724500	Zidovudine (400 mg)	G1D319 (11/07)	H0F263	\$185

**Items with New Lots**

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Catalog #	Description	Previous Lot/ Valid Use Date	Current Lot	Price (USD)
1067001	Betamethasone Acetate (500 mg)	J0B079 (08/08)	K0G274	\$185
1166003	Deferoxamine Mesylate (500 mg)	I (09/08)	J0G233	\$185
1268604	Etidronic Acid Monohydrate (1 g)	G (10/08)	G1G218	\$185
1292347	Glimepiride Related Compound D (20 mg)	F0E235 (09/08)	F1G258	\$576
1327000	Hydroxychloroquine Sulfate (200 mg)	J0B297 (10/08)	K0G211	\$185
1466007	Nitrofurazone Related Compound A (500 mg)	H0B100 (08/08)	I0G265	\$576
1580002	Protriptyline Hydrochloride (200 mg)	G0E034 (09/08)	H0G267	\$185



## 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 Shipping Method—Dry Ice



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In response to customer comments, USP will now offer the ability for products to ship 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

### USP 31–NF 26 Now Available—Order Today!



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The new *USP–NF* just published November 1! Available now in English (print, online, and CD formats), an annual subscription includes a main edition and two *Supplements*. The *USP 31–NF 26 Spanish Edition* (print only) publishes in January 2008. Subscribe now 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).



## New Food Chemicals Codex Publishes February 2008—Reserve Your Copy Now [Return to Top](#)

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. It will be published every two years with a supplement provided in interim years. Print and online subscriptions available in 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).

## Subscriptions [Return to Top](#)

Two year subscriptions will not be offered for 2008 products.

## Publications Scheduled Ship Dates [Return to Top](#)

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

Publication	Scheduled Ship/Post 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! [Return to Top](#)

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, Professional Education, new initiatives, and hot topics.

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

## Professional Education

### Quick Pulse on Upcoming Important Standards Revisions

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Learn about the important standards revisions in no time at all! Each *Pharmacopeial Forum* eSymposium features 60 to 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, as well as an opportunity to discuss key revisions with USP experts. Specific topics will be announced 4–6 weeks prior the date of each eSymposium. For more information, contact Donna Washington, Project Manager, Professional Education, at +1-301-816-8228. See schedule below. Cost: US\$89

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### “Navigating Chapter <467> Residual Solvents—Now Available Online

Professional Education is introducing web based education (WBE) as an alternative to the traditional classroom format. Our first offering is the very popular “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.

WBE is composed of web casts, an instructor- moderated discussion board and practical assignments. All content is available 24-hours-a-day. You may sign in at your convenience and work on the chapter readings and application assignments at your own pace within the 14-day time period. The online course has been created to allow you access to crucial information without the costs of travel, time out of your office, and time away from home. This course is priced at just US\$299. See schedule below.



## New Residual Solvents: Results in Practice-Workshop

### Residual Solvents: Results in Practice-Workshop

Gain an understanding on the implementation issues that have arisen since the creation of the course for General Chapter <467>. You will have direct access to a panel of USP experts associated with the revision to Chapter <467> to discuss suggestions and feedback for potential future direction.

INTENDED FOR: Laboratory scientists, lab managers, and compliance staff in the pharmaceutical and allied industries.

FORMAT(S)/DURATION: Classroom (1 day) at USP Headquarters, Rockville Md.

## Subscribe to New Professional Education Email Alert

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USP Professional Education is developing several new courses for introduction in early 2008. If you would like stay informed of our new curriculum and upcoming schedule, subscribe now to the new Professional Education Email Alert. Simply contact us at [professionaleducation@usp.org](mailto:professionaleducation@usp.org) and type "email alert" in the subject field. Upcoming courses include:

- "Validation of Compendial Procedures"
- "Particulate Matter in Injectables"
- "GMP: A Quality Systems Approach for APIs"

Subscribe now to the new Professional Education Email Alert. Simply contact us at [professionaleducation@usp.org](mailto:professionaleducation@usp.org) and type "email alert" in the subject field.



Professional Education Course Schedule—November 2007 through May 2008

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**Upcoming Online Professional Education Courses  
as of November 1, 2007**

Date	Course Title	Location	Price
14 Nov 2007	USP eSymposium on <i>Pharmacopeial Forum</i> 33(6)	Webinar	\$89
29 Nov 2007	Navigating Chapter <467> Residual Solvents	Web Based Education	\$299
3 Jan 2008	Navigating Chapter <467> Residual Solvents	Web Based Education	\$299
9 Jan 2008	USP eSymposium on <i>Pharmacopeial Forum</i> 34 (1)	Webinar	\$89
23 Jan 08	Particulate Matter In Injectables	Web Based Education	\$299
23 Jan 08	GMP: A Quality Systems Approach to API's	Web Based Education	\$299
24 Jan 08	Validation of Compendial Procedures	Web Based Education	\$299
24 Jan 2008	Navigating Chapter <467> Residual Solvents	Web Based Education	\$299
14 Feb 2008	Navigating Chapter <467> Residual Solvents	Web Based Education	\$299
14 Feb 2008	Validation of Compendial Procedures	Web Based Education	\$299
6 Mar 2008	Navigating Chapter <467> Residual Solvents	Web Based Education	\$299
12 Mar 2008	USP eSymposium on <i>Pharmacopeial Forum</i> 34 (2)	Webinar	\$89
14 May 2008	USP eSymposium on <i>Pharmacopeial Forum</i> 34 (1)	Webinar	\$89



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

Date	Course Title	Location	Price
11 Dec 07	Essentials of USP Microbiological Testing	Somerset, NJ	\$695
13-14 Dec 07	Advanced Dissolution (new course 2-day)	Raleigh, NC (McKimmon Center)	\$1,495
17 Jan 08	Validation of Compendial Procedures	Somerset, NJ	\$695
23-24 Jan 08	Advanced Dissolution	Horsham PA (Sotax)	\$1,495
<b>25 Jan 08</b>	<b>Validation of Compendial Procedures</b>	<b>Irvine, CA (FDA Facility)</b>	<b>\$695</b>
<b>29 Jan 08</b>	<b>Residual Solvents: Results in Practice – Workshop (Full day workshop)</b>	<b>USP Conference Center, Rockville, MD</b>	<b>\$895</b>
January 2008	Validation of Compendial Procedures	Irvine, CA (FDA Facility)	\$695
12-13 Feb 08	Advanced Dissolution	Chicago, IL	\$1,495
20 Feb 08	Particulate Matter in Injectables	New Jersey	\$695
12 Mar 08	Food and Drug HPLC	Chicago, IL	\$695



**Upcoming Professional Classroom Education Courses as of November 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
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	HPLC	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:**

General Chapter <643> Total Organic Carbon Comment Period Extension—10/17/07

USP Statement on Prednisone Tablets: Notice of Change in Performance—10/10/07

**Errata:** Errata to <467> Organic Volatile Impurities Section in USP Monographs revised in *Supplement 1*—10/15/2007

**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**

It has come to USP's attention that there is a discrepancy between the electronic and print versions in the OVI section of several monographs, where the OVI section is omitted from the electronic version. For details and to access PDF's of the corrected monographs, please see <http://www.usp.org/USPNF/notices/errata467.html>

### **Question of the Month**

For a chromatographic test, my peaks are not eluting at the proper relative retention time. How do I address this?

### **Answer:**

Relative retention times may be provided in monographs for informational purposes only, to aid in peak identification. There are no acceptance criteria applied to relative retention times, *PF 32(4)* and *Second Supplement to USP 30–NF 25*.