



October 2008



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Click on links to go to sections.

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 2008; 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that have been discontinued/have a new price and/or have a new package size; items with lots that are (or soon will be) no longer valid; and items with new lots since the last email notice.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 USP 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

Catalog #	Description	Size	Lot	Price (USD)
1224620	Docosahexaenoic Acid Ethyl Ester	500 mg	F0H167	\$500
1250020	Estradiol Related Compound B	10 mg	F0H263	\$621
1286107	Formoterol Fumarate	100 mg	F0H187	\$432
1286118	Formoterol Fumarate System Suitability Mixture	20 mg	F0H166	\$673
1362103	Levofloxacin*	350 mg	F0H194	\$185
1494895	Pantoprazole Sodium	200 mg	F0H266	\$185
1494909	Pantoprazole Related Compound A	25 mg	F0H267	\$576
1494910	Pantoprazole Related Compound B	20 mg	F0H268	\$576
1494920	Pantoprazole Related Compound C	20 mg	F0H259	\$576

\*This product requires documentation of intended use before purchase. Please contact customer service to avoid delays in processing

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

Catalog #	Description	Size	Lot	Price (USD)
1224008	Disulfiram	200 mg	G0H277	\$185
1224802	Docusate Sodium	500 mg	L0H276	\$185
1254508	Estriol	100 mg	K0H209	\$185
1358503	Leuprolide Acetate	200 mg	G0H255	\$1805
1381006	Menadione	200 mg	I0H273	\$185
1392002	Mercaptopurine	500 mg	J0G300	\$185
1598700	Ranitidine Related Compound C	50 mg	I2G232	\$576
1708707	Valproic Acid	500 mg	M0G249	\$185

**Backorder Availability Estimates, September 22, 2008**

Catalog #	Description	Expected Availability*
1032007	Amphotericin B (125 mg)	Q4/08
1044800	Atracurium Besylate (100 mg)	Q4/08
1045009	Atropine Sulfate (500 mg)	Q4/08
1047503	Bacitracin (1 g) (Susceptibility disk standard)	Q4/08
1068004	Betamethasone Sodium Phosphate (500 mg)	Q4/08
1410002	Methicillin Sodium (500 mg) (AS)	Q4/08
1471007	Norethynodrel (200 mg)	Q4/08
1499414	Paricalcitol Solution (3 mL)	Q4/08
1547007	Polymyxin B Sulfate (200 mg)	Q4/08
1601623	Residual Solvent Class 2 - Methanol (1.2 mL/ampule; 3 ampules)	Q4/08
1651621	Delta-9-Tetrahydrocannabinol (1 mL)	Q4/08
1673828	Trenbolone Acetate CIII (200 mg)	Q4/08

\*Dates are targets and may change at any time. Q4/08=October–December 2008



**RS Lots That are No Longer Valid**

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 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, 2008				
Catalog #	Description	Previous Lot/ Valid Use Date	Current Lot	Price (USD)
1043003	Ascorbic Acid (1 g) (Vitamin C)	Q0B012 (09/08)	Q1G135	\$185
1166003	Deferoxamine Mesylate (500 mg)	I (09/08)	J0G233	\$185
1194009	Diethylpropion Hydrochloride <b>CIV</b> (200 mg)	H (09/08)	I0G127	\$245
1213001	Dinoprost Tromethamine (50 mg)	F (09/08)	G0G082	\$1,805
1282004	Fluphenazine Hydrochloride (125 mg)	H (09/08)	I0G294	\$147
1292347	Glimepiride Related Compound D (20 mg)	F0E235 (09/08)	F1G258	\$576
1349502	L-Isoleucine (200 mg)	F-2 (09/08)	G0G167	\$185
1370462	Losartan Potassium (250 mg)	F0D287 (09/08)	G0G169	\$185
1441287	Metoprolol Fumarate (200 mg)	F (09/08)	G0G148	\$185
1445211	Mitoxantrone System Suitability Mixture (0.3 mg)	F0D010 (09/08)	G0F107	\$592
1511203	Perphenazine Sulfoxide (100 mg)	G-1 (09/08)	H0G202	\$576
1578000	Propylthiouracil (200 mg)	G (09/08)	H0G031	\$185
1580002	Protriptyline Hydrochloride (200 mg)	G0E034 (09/08)	H0G267	\$185
1602706	Ribavirin (200 mg)	H1C335 (09/08)	I0G153	\$342
1643500	Terbutaline Sulfate (125 mg)	H (09/08)	I0G250	\$147

No Longer Valid as of October 31, 2008				
Catalog #	Description	Previous Lot/ Valid Use Date	Current Lot	Price (USD)
1027302	Amiodarone Hydrochloride (200 mg)	F0D257 (10/08)	G0G340	\$185
1145003	Codeine Sulfate <b>CII</b> (250 mg)	H-2 (10/08)	I0G213	\$245
1154569	Beta Cyclodextrin (250 mg)	G (10/08)	G1G216	\$185
1170000	Demeclocycline Hydrochloride (200 mg)	H1C036 (10/08)	H2G314	\$185
1268604	Etidronic Acid Monohydrate (1 g)	G (10/08)	G1G218	\$185
1285807	Flurbiprofen Sodium (200 mg)	F (10/08)	G0G056	\$185
1305008	Hexachlorophene (500 mg)	I (10/08)	J0G217	\$185
1327000	Hydroxychloroquine Sulfate (200 mg)	J0B297 (10/08)	K0G211	\$185
1341001	Indomethacin (200 mg)	J0B165 (10/08)	J1G345	\$185
1375058	Mandelic Acid (500 mg) (AS)	F (10/08)	G0H130	\$185
1392002	Mercaptopurine (500 mg)	I2C263 (10/08)	J0G300	\$185
1485191	Oxycodone <b>CII</b> (200 mg)	J0F026 (10/08)	K0G276	\$245
1586009	Pyridostigmine Bromide (200 mg)	I0C324 (10/08)	J0G251	\$185
1674004	Tretinoin (30 mg/vial; 5 vials)	J0D145 (10/08)	J1F266	\$185
1708795	Valsartan Related Compound C (10 mg)	G0F241 (10/08)	G2H042	\$738



## Items with New Lots

Catalog #	Description	Previous Lot/ Valid Use Date	Current Lot	Price (USD)
1056504	1,4-Benzoquinone (200 mg)	H0G261 (09/09)	H1G332	\$185
1078008	Brompheniramine Maleate (125 mg)	I1A036 (09/09)	J0H148	\$147
1126009	Chlorpropamide (200 mg)	H (09/09)	I0H184	\$185
1197007	Diethyltoluamide (3 g)	H1D076 (09/09)	I0H013	\$147
1224008	Disulfiram (200 mg)	F-3 (08/09)	G0H277	\$185
1254508	Estriol (100 mg)	J (05/08)	K0H209	\$185
1271700	Fluconazole (200 mg)	G0F102 (08/09)	H0H087	\$185
1285931	Fluvastatin Sodium (350 mg)	F0F015 (08/09)	G0G313	\$246
1358503	Leuprolide Acetate (200 mg)	F0C430 (03/09)	G0H255	\$1,805
1381006	Menadione (200 mg) (Vitamin K3)	H-3 (08/09)	I0H273	\$185
1392002	Mercaptopurine (500 mg)	I2C263 (10/08)	J0G300	\$185
1470004	Norethindrone Acetate (100 mg)	K0F227 (09/09)	L0G410	\$185
1500400	Parthenolide (25 mg)	F (09/09)	G0F255	\$185
1500808	Penbutolol Sulfate (200 mg)	F (06/09)	G0H272	\$185
1544508	Piroxicam (200 mg)	H1D038 (08/09)	H2H258	\$185
1576005	Propranolol Hydrochloride (200 mg)	I0C170 (09/09)	I1G348	\$185
1598700	Ranitidine Related Compound C (50 mg)	I1B136 (08/09)	I2G232	\$576
1620220	Stavudine System Suitability Mixture (10 mg)	F0E051 (07/09)	F1G128	\$576
1676000	Triamcinolone (250 mg)	I0G157 (07/09)	J0H208	\$185
1687006	Trihexyphenidyl Hydrochloride (200 mg)	J (09/09)	J1G359	\$185
1708707	Valproic Acid (500 mg)	L0E030 (08/09)	M0G249	\$185
1708762	Valsartan (350 mg)	H0G139 (09/09)	I0H060	\$185
1708795	Valsartan Related Compound C (10 mg)	G1G244 (08/09)	G2H042	\$738

**USP Residual Solvents Reference Standards for <467> Compliance**

USP encourages all global manufacturers of drug substances, excipients, and drug products to conform to the standards delineated in the *USP–NF* General Notices and General Chapter <467> Residual Solvents (official July 1, 2008). To assist manufacturers, USP has developed 36 new residual solvents Reference Standards designed to support <467> procedures. These standards were manufactured in a GMP facility and contain the class 1 or class 2 solvent mixed in pure DMSO. View list of and purchase current USP residual solvents Reference Standards [here](#).

Coming soon a Residual Solvents Hot Topics page with <467> resources at [www.usp.org/hottopics/residualsolvents.html](http://www.usp.org/hottopics/residualsolvents.html).

[Register now](#) for a one-day lecture focusing on Chapter <467> implementation, misconceptions, and developing alternative validation methods.

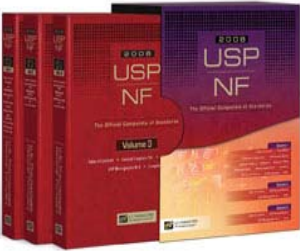



## USP Introduces Certified Reference Materials (CRMs)

USP CRMs represent the next generation of exceptional quality Reference Standards from USP. They have undergone additional metrologically based tests and statistical analysis that meet both USP's stringent criteria and ISO guidelines. USP CRMs are accompanied by a special Certificate of Analysis (COA) compliant with ISO Guide 31. COA features metrological data: certified property value with associated uncertainty and expiration date/period of validity. The USP CRM program meets the requirements of ISO 17025 and ISO Guide 34 for Reference Material Producers. Learn more at <http://www.usp.org/referenceStandards/>

Just released USP CRM: Dextromethorphan Hydrobromide (500 mg). [Order now.](#)

## USP Publication Highlights

	<p><b>Be Prepared for 2009—Order <i>USP 32–NF 27</i> Today!</b> Available November 1 in English in print, online, and CD formats. An annual subscription includes a main edition and two <i>Supplements</i>. The <i>USP 32–NF 27 Spanish Edition</i> will be published in print only in January. Subscribe today at <a href="http://www.usp.org/products/USPNF">www.usp.org/products/USPNF</a> or call USP Customer Service at 1-800-227-8772 (U.S. and Canada), +1-301-881-0666, or 00-800-4875-5555 (Europe).</p>
	<p><b>Comment on and Propose Standards Revisions with <i>Pharmacopeial Forum (PF)</i>, Volume 35—Subscribe for 2009</b> Published six times a year, <i>PF</i> lets you review and submit both comments and proposals for standards revisions. Plus, <i>PF</i> gives you 2 to 12 months advance notice of changes, allowing you to prepare early for revisions. Order <i>PF 35</i> today—print and online formats, English only. Visit <a href="http://www.usp.org/products/PF">www.usp.org/products/PF</a> or call USP Customer Service at 1-800-227-8772 (U.S. and Canada), +1-301-881-0666, or 00-800-4875-5555 (Europe).</p>

## Publications Scheduled Ship Dates

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

Publication	Scheduled Ship/Post Date
Pharmacists' Pharmacopeia Second Edition Supplement 2 Online	October 1, 2008
<i>PF 34(6)</i> Highlights	October 24, 2008
<i>PF 34(6)</i> Online	October 31, 2008
<i>USP32–NF27</i> Print	November 3, 2008
<i>USP32–NF27</i> Online	November 3, 2008
<i>USP32–NF27</i> CD	November 3, 2008
<i>PF 34(6)</i> Print	November 7, 2008

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)

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## Event Highlights

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### USP Customer Days—Coming to a City Near You!

The USP Account Management Team will be traveling across the U.S. and Canada holding free seminars to discuss USP publications, Reference Standards, USP Verified Services, Professional Education, new initiatives, and hot topics. **Meetings are scheduled for Columbus, OH (December 2, 2008)**; Northern CA (February 2009); Toronto, Canada (March 2009); and Rockville, MD (May 11, 2009). Registration and more information are available at <http://www.usp.org/products/USPCustomerDays/> or contact: [uspcustomerday@usp.org](mailto:uspcustomerday@usp.org).

### International Food Ingredient Workshop

On **Wednesday, October 15, 2008**, USP will hold its first International Food Ingredient Issues Workshop at USP headquarters in Rockville, MD. This workshop will bring together diverse experts from around the world to discuss real issues that food ingredients professionals face every day. It will feature speakers representing the US, Canada, Europe, China, Japan, Brazil, Australia, and the Middle East. For more information, please visit <http://www.usp.org/pdf/EN/meetings/agendas/2008-10-15-ifiwAgenda.pdf>. To register, please visit <http://ems.intellor.com/index.cgi?p=201983&t=12&do=register&s=&rID=289&edID=>

## Pharmacopeial Education

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### Featured Courses

#### Practical Applications of Chapter <467> Residual Solvents

Dr. Horacio Pappa, Senior Scientist, Department of Standards Development at USP presents this custom one-day lecture focusing on implementation, misconceptions, and developing alternative validation methods.

- Review guidelines contained in Chapter <467>
- Discuss common mistakes and misconceptions in the implementation of the new standards
- Illustrate Option 1 and 2, as well as procedures A, B, and C
- Introduce risk-based strategy concept when dealing with compliance issues
- Explain how to develop and validate alternative methods
- Q&A session with Dr. Horacio Pappa to address your specific concerns

**Classroom Cost:** US \$695 for the first person, 25% off for each additional person from the same company

**Date and Location:** October 28, 2008; Toronto, Canada. Click [here](#) to register.

**Date and Location:** October 30, 2008, Montreal, Canada. Click [here](#) to register.



## Validation of Compendial Procedures

Gain insight into USP's perspective on validation methods required by General Chapter <1225>. Learn requirements of specific validation performance parameters and their relationships to other relevant General Chapters.

**Classroom Cost:** US \$695.00

**Date and Location:** October 16, 2008; Chicago, IL. Click [here](#) to register.

**Date and Location:** November 7, 2008, Rockville, MD. Click [here](#) to register.

## TLC for Dietary Supplements: Botanicals

This course offers guidance in translating the information of Chapter <621> into a practical methodology and interpreting results obtained with compendial thin layer chromatography (TLC) methods within the realm of botanicals. We are offering a one-day lecture/demonstration course and a two-day lecture/lab course.

**1-day offering – Date, Location, and Cost:** October 30, 2008; Salt Lake City, UT (Lecture and Demonstration), \$495.00 for the first person, \$295 per each additional person from the same company. Click [here](#) for registration information.

**2-day offering – Date, Location, and Cost:** November 5–6, 2008; Irvine, CA (Lecture and Lab), \$995.00 per person. Click [here](#) to register.

## Essentials of Microbiological Testing

Course establishes a practical understanding of microbiological practices in the pharmaceutical industry and provides an overview of the USP General Chapters which address microbiological testing.

**1-day offering – Cost, Date and Location:** \$695, November 3, 2008 – Raleigh, NC, click [here](#) to register.

**2-day offering – Cost, Date and Location:** \$995, November 3–4, 2008 – Raleigh, NC (Lecture and Lab), click [here](#) to register.

## Free On-Demand Courses!

USP's on-demand online courses are 60- to 90-minute Web casts designed with your scheduling and budget needs in mind. These modules are available 24 hours a day, 7 days a week via a computer with broadband connection, and cover a wide range of standards-based courses critical to performing your job. You have the flexibility to subscribe to a series or a single Web cast, allowing you to control the breadth and the topics you would like to learn about. USP experts are also available to answer your questions via email.

On demand courses available now for free include: (click course title for more information or click view to take the course):

[Introduction to the New FCC](#)

[Navigating the FCC](#)

[How to Use the FCC Forum—Making the FCC Your Own](#)

[How to Develop an FCC Monograph](#)

[View](#)

[View](#)

[View](#)

[View](#)

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## Upcoming PE Courses Worldwide

- [USP/ISMP Workshop: Using Data Effectively to Manage the Risks to Medication Safety](#)
- [Dissolution: Theory and Best Practices](#)
- [Advanced Dissolution](#)
- [Validation of Compendial Procedures](#)
- [Essentials of Microbiological Testing](#)
- [Effectively Using USP-NF](#)

## **Subscribe to the Pharmacopeial Education Email Bulletin**

USP Pharmacopeial Education is developing several new courses for introduction in 2008 and 2009. If you would like to stay informed of our new curriculum and upcoming schedule, [subscribe now](#) to the Pharmacopeial Education Bulletin.

For the complete USP Education course list, please go to <http://www.usp.org/education/pe/courses.html>

## **Compendial Highlights**

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### [USP-NF Notices](#)

Sign up to receive Notices electronically at

<http://www.usp.org/support/products/uspNewslettersRequest.html?promo=compendial>

**Revision Bulletins:** Nothing New

**Explanatory Notes/Announcements:** Nothing New

**Intent to Revise:** Nothing New

**Errata:** Nothing New

**Postponements:** Nothing New

**General:** *USP 31-NF 26 Online* and CD subscribers, please note: Page numbers were erroneously omitted in the Auxiliary Information from eight new or revised Chapters. Click [here](#) for full information. (09/10/08)

### Stimuli Articles

Featured in *PF 34(5)*, September–October 2008

[General Chapter on Inorganic Impurities: Heavy Metals](#)  (336KB)

[The Cadaver Skin Absorption Model and the Drug Development Process](#)  (331KB)

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## Tip of the Month

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View the New Electronic USP Publications Catalog at [www.usppublications.com](http://www.usppublications.com)

You'll find complete details on current and upcoming USP publications and links to sample pages, Flash previews, and more! Plus to expedite ordering, it features easy "click through" links to the USP Online Store. Published online twice a year –it's FREE!

## Question of the Month

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*Where can I find the IRA Commentary that used to be in Pharmacopeial Forum?*

The IRA commentary can be found at <http://www.usp.org/USPNF/revisions/>

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