



## February 2009



### Table of Contents

#### [Reference Standards Highlights](#)

- [New Reference Standards Now Available](#)
- [Previously Out-of-Stock Items Now Available](#)
- [Backorder Availability Estimates, January 26, 2009](#)
- [Items with New Package Size or Description](#)
- [RS Lots That Are No Longer Valid](#)
- [Items with New Lots](#)

#### [USP Publication Highlights](#)

- [First Supplement to USP 32–NF 27 Publishes February 2](#)
- [Subscribe to \*Pharmacoepial Forum \(PF\)\*, Volume 35, for 2009](#)
- [New \*USP Dietary Supplements Compendium\*—Reserve your copy now](#)

#### [Event Highlights](#)

- [USP Customer Days—Coming to a City Near You!](#)

#### [Pharmacoepial Education](#)

- [New USP Pharmacoepial Education Online Catalog](#)
- [Featured Courses](#)
- [Upcoming PE Courses](#)
- [Subscribe to the Pharmacoepial Education Email Bulletin](#)

#### [Compendial Highlights](#)

- [New USP-NF Notices](#)
- [Stimuli Articles](#)

#### [Tip of the month](#)

#### [Question of the Month](#)

Click on links to go to sections.

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

### USP Catalogs

▶ [USP Publications Catalog](#)

▶ [USP Catalog](#)

▶ [USP Pharmacoepial Education Catalog](#)

## 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 January 2009; 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that have been discontinued/have a new price and/or have a new package size; items with lots that are (or soon will be) no longer valid; and items with new lots since the last email notice.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)
1096790	(+)-Catechin	25 mg	F0H389	\$210
1226014	Doxycycline Related Compound A	10 mg	F0H365	\$605
1231626	Ecamsule Related Compound B	50 mg	F0H409	\$605
1231637	Ecamsule Related Compound C	50 mg	F0H408	\$605
1250041	Estradiol Related Compound C	15 mg	F0H282	\$652
1265526	2-Ethylhexan-1-ol	1.5 mL	F0G192	\$185
1302156	Guanine	100 mg	F0H363	\$194
1302203	Purified Guggul Extract	500 mg	F0H359	\$323
1414058	Methotrexate Related Compound E	50 mg	F0H353	\$605
1443759	Mifepristone	200 mg	F0H385	\$252
1481237	Oxaliplatin Related Compound C	20 mg	F0H348	\$605
1643260	Tamulosin Hydrochloride	200 mg	F0H375	\$1874
1643281	Racemic Tamsulosin Hydrochloride	50 mg	F0H379	\$1228
1643485	Terazosin Related Compound C	25 mg	G0H361	\$605

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

Catalog #	Description	Size	Lot	Price (USD)
1047503	Bacitracin (AS)	1 g	H0H096	\$194
1068004	Betamethasone Sodium Phosphate	500 mg	M0H437	\$194
1233508	Edetic Acid	200 mg	F2H030	\$194
1278302	Fluoroquinolonic Acid	150 mg	H1H402	\$605
1285760	Flurbiprofen Related Compound A	100 mg	I0G406	\$605
1601102	Residual Solvents Mixture- Class I	1.2 mL / ampule; 3 ampules	F1H387	\$185
1601281	Residual Solvents Class 2 – Mixture A	3 x 1.2 mL	G0H439	\$194
1643485	Terazosin Related Compound C	25 mg	G0H361	\$605
1647001	Testosterone Cypionate CIII	200 mg	I0G361	\$257

**Backorder Availability Estimates, January 26, 2009**

Catalog #	Description	Expected Availability*
1078766	Bupropion Hydrochloride Related Compound C	Q1/09
1270446	Fexofenadine Related Compound C (15 mg)	Q2/09
1291559	Ginkgo Terpene Lactones (50 mg)	Q2/09
1471007	Norethynodrel (200 mg)	Q4/09
1673828	Trenbolone Acetate CIII (200 mg)	Q1/09
1683504	Trientine Hydrochloride (125 mg)	Q1/09

\*Dates are targets and may change at any time. Q1/09=January–March 2009; Q2/09=April–June 2009  
Q3/09=July–September 2009; Q4/09=October–December 2009

[Table of Contents](#)

**Items with New Package Size or New Description**

Catalog #	Description	Old Size	New Size	Lot	Price (USD)
1235900	Enrofloxacin*		200 mg	G0H417	\$194
1278302	Fluoroquinolonic Acid	50 mg	150 mg	H1H402	\$605

\* This item has changed from AS (Authentic Substance) to an RS (Reference Standard)

**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 January 31, 2009					
Catalog #	Description	Previous Lot/ Valid Use Date		Current Lot	Price (USD)
1046205	Aztreonam (200 mg)	G0C077	(01/09)	H0G293	\$194
1097636	Cefepime Hydrochloride (500 mg)	G0D116	(01/09)	H0G278	\$194
1098231	Cefuroxime Axetil Delta-3-Isomers (15 mg)	H2G014	(01/09)	I0H005	\$605
1138427	Clobetasol Propionate Related Compound A (50 mg)	F2C417	(01/09)	G0G268	\$605
1140597	Clopidogrel Related Compound B (20 mg)	G0F319	(01/09)	G1H047	\$735
1202005	Dihydroergotamine Mesylate (500 mg) <b>(List Chemical)</b>	J0B085	(01/09)	K0H019	\$194
1285862	o-Flutamide (50 mg)	F-1	(01/09)	G0G325	\$605
1354218	Isradipine Related Compound A (10 mg)	F1D243	(01/09)	G0G028	\$605
1375309	Mazindol <b>CIV</b> (350 mg)	H	(01/09)	I0H012	\$257
1468400	Nordazepam <b>CIV</b> (50 mg)	H1B035	(01/09)	I0H001	\$695
1499403	Paricalcitol (10 mg)	F0E303	(01/09)	G0H054	\$1,578
1522301	Pheniramine Maleate (150 mg)	F1C342	(01/09)	G0H038	\$194
1619505	Squalane (500 mg)	G-1	(01/09)	H0G108	\$194





**No Longer Valid as of February 28, 2009**

Catalog #	Description	Previous Lot/ Valid Use Date	Current Lot	Price (USD)
1012633	Albuterol Sulfate (200 mg)	J (02/09)	K0G284	\$194
1054000	Benzocaine (500 mg)	J0C130 (02/09)	J1G214	\$194
1097705	Cefoperazone Dihydrate (200 mg)	H (02/09)	H1G369	\$194
1107401	Chloramphenicol Palmitate Nonpolymorph A (200 mg)	F-1 (02/09)	G0H179	\$605
1140338	Clonazepam Related Compound B (25 mg)	H (02/09)	I0G326	\$605
1046089	N-Demethylazithromycin (15 mg)	F0E068 (02/09)	G0H164	\$605
1173246	Desogestrel Related Compound A (15 mg)	F0B279 (02/09)	G0G004	\$605
1188800	Diclofenac Sodium (200 mg)	H0B150 (02/09)	H1F335	\$194
1229001	Droperidol (250 mg)	I0C029 (02/09)	I1G375	\$194
1278109	Fluorometholone Acetate (200 mg)	F (02/09)	F1G190	\$194
1460725	Nevirapine Related Compound A (15 mg)	F0D035 (02/09)	G0G272	\$605
1478593	Ondansetron Related Compound A (50 mg)	F1F240 (02/09)	G0G305	\$605
1493000	Pamoic Acid (250 mg)	G-4 (02/09)	H0G380	\$194
1528501	Phentermine Hydrochloride <b>CIV</b> (200 mg)	H0B309 (02/09)	H1G389	\$257
1587001	Pyridoxine Hydrochloride (200 mg) (Vitamin B6)	P (02/09)	Q0G409	\$194
1592001	Pyrvinium Pamoate (500 mg)	G (02/09)	G1H093	\$194
1604009	Rifampin (300 mg)	J (02/09)	K0G365	\$194
1709007	Vancomycin Hydrochloride (4 vials, each vial contains 99,300 mcg of vancomycin activity)	L1D039 (02/09)	M0H006	\$194
1719102	Warfarin Related Compound A (50 mg)	H0E268 (02/09)	I0H022	\$194

[Table of Contents](#)



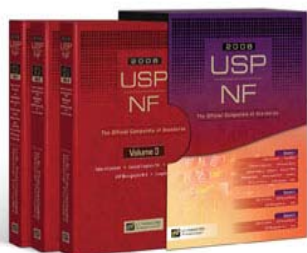
Items with New Lots

Catalog #	Description	Previous Lot/ Valid Use Date	Current Lot	Price (USD)
1033407	Ampicillin Trihydrate (200 mg)	G1D147 (01/10)	H0H346	\$194
1047503	Bacitracin (1 g) (AS) (Susceptibility disk standard)	G1C254 (03/09)	H0H096	\$194
1130505	Chlorzoxazone (350 mg)	I (12/09)	J0H074	\$194
1154558	Alpha Cyclodextrin (50 mg)	F-1 (12/09)	G0H079	\$194
1162330	Dacarbazine Related Compound B (50 mg)	G0C325 (01/10)	H0H274	\$746
1233508	Edetic Acid (200 mg)	F-1 (12/09)	F2H030	\$194
1265504	Ethylcellulose (1 g)	H-1 (11/09)	I0H084	\$194
1278302	Fluoroquinolonic Acid (150 mg)	H0C140 (11/09)	H1H402	\$605
1285760	Flurbiprofen Related Compound A (100 mg)	H (12/09)	I0G406	\$605
1292325	Glimepiride Related Compound B (20 mg)	F0E233 (01/10)	F1H420	\$605
1295888	Glycyrrhizic Acid (25 mg)	F0C006 (01/10)	G0H394	\$605
1339000	Indigotindisulfonate Sodium (500 mg)	H2G304 (01/10)	I0H368	\$194
1356632	Ketoprofen (200 mg)	H0B216 (01/10)	H1H247	\$194
1488000	Oxymorphone CII (500 mg)	H0B214 (11/09)	I0H349	\$257
1494501	Panthenol, Racemic (200 mg)	G (01/10)	H0H102	\$194
1546547	Polyethylene Glycol 3350 (1 g)	F0F012 (01/10)	G0H367	\$194
1588004	Pyrilamine Maleate (200 mg)	I0B276 (12/09)	I1H177	\$194
1598507	Ranitidine Related Compound A (50 mg)	H1B137 (01/10)	H2G343	\$605
1601102	Residual Solvents Mixture - Class 1 (1.2 mL/ampule; 3 ampules)	F0C407 (10/09)	F1H387	\$194
1601281	Residual Solvents Class 2 - Mixture A (1.2 mL/ampule; 3 ampules)	F0D051 (12/09)	G0H439	\$194
1601441	Residual Solvent Class 2 - Methylene Chloride (1.2 mL/ampule; 3 ampules)	F0D046 (12/09)	G0H319	\$194
1612608	Silver Sulfadiazine (200 mg)	I (01/10)	J0H366	\$194
1626500	Sulfadoxine (200 mg)	F3C336 (12/09)	F4H227	\$194
1643485	Terazosin Related Compound C (25 mg)	F0C257 (01/10)	G0H361	\$605
1652500	Thalidomide (200 mg)	F0C107 (12/09)	G0H225	\$227
1711202	Verapamil Hydrochloride (200 mg)	G1E095 (01/10)	H0H100	\$194
1711461	Verteporfin (200 mg)	F0C166 (01/10)	G0H316	\$194

[Table of Contents](#)



## USP Publication Highlights



### **First Supplement to USP 32–NF 27 Publishes February 2\***

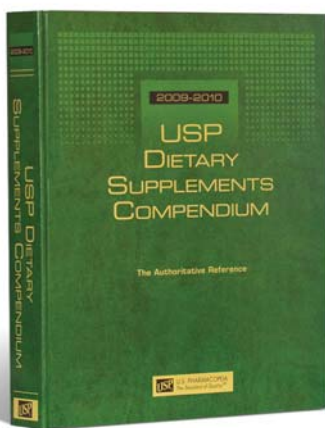
Make sure you have important standards updates found only in *USP 32–NF 27* and its *Supplements*. The 2009 edition through the *First Supplement* contains significant new information: more than 200 new and revised monographs and 16 new and revised General Chapters. To order, visit [www.usp.org/products/USPNF](http://www.usp.org/products/USPNF) or call USP Customer Service at 1-800-227-8772 (U.S. and Canada), +1-301-881-0666, or 00-800-4875-5555 (Europe).

\*English edition. *First Supplement* to *USP 32–NF 27* in Spanish publishes in April 2009.



### **Subscribe to *Pharmacopeial Forum (PF)*, Volume 35, for 2009**

Review, comment on, and track proposals for standards revisions in 2009 with *PF 35*. Published six times a year, *PF* gives you 2 to 12 months advance notice of changes, allowing you to prepare early for revisions. Order *PF 35* today—print and online formats, English only. Visit [www.usp.org/products/PF](http://www.usp.org/products/PF) 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 *USP Dietary Supplements Compendium*—Reserve your copy now**

Publishing in March, the new *USP Dietary Supplements Compendium (DSC)* combines *USP–NF* standards with information from the *Food Chemicals Codex, Sixth Edition*; regulatory and industry documents; and helpful tools and resources. The *DSC* will be published every two years in hardcover print, English only. The 2009–2010 edition is scheduled to ship March 31. Learn more and order at

[www.usp.org/products/dietarySupplementsCompendium/](http://www.usp.org/products/dietarySupplementsCompendium/), or call USP Customer Service at 1-800-227-8772 (U.S. and Canada), +1-301-881-0666, or 00-800-4875-5555 (Europe).

[Table of Contents](#)



## Event Highlights

### 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, Pharmacopeial Education, new initiatives, and scientific hot topics.

**Meetings are scheduled for Toronto, Canada (March 3, 2009);** and Rockville, MD (May 11, 2009). Registration and more information are available at [www.usp.org/products/USPCustomerDays/](http://www.usp.org/products/USPCustomerDays/) or contact: [uspcustomerday@usp.org](mailto:uspcustomerday@usp.org)



Visit the USP booth #4513 at Pittcon on March 9-12, 2009 in Chicago

## Pharmacopeial Education

### New USP Pharmacopeial Education Online Catalog—[www.uspeducation.com](http://www.uspeducation.com)

Get the details on current and upcoming education offerings, including new on-demand online courses, classroom lectures, and lab training. Updated throughout the year, this convenient online catalog provides click-through links for registration, instructor information, and related products.

### Featured Courses

#### Residual Solvents: Practical Applications <467>

USP experts are presenting this new one-day lecture on <467> implementation, misconceptions, and alternative validation methods at various locations in February 2009. Topics include

- Guidelines contained in Chapter <467>
- Common mistakes and misconceptions in the implementation of the new standards
- Options 1 and 2, as well as procedures A, B, and C
- Introduction of risk-based strategy concept when dealing with compliance issues
- How to develop and validate alternative methods
- Q&A session with USP expert

**Classroom Cost:** US \$695

**Dates and Locations:** [Click here](#) to find the latest location and date information for this course.



## Aseptic Processing and Compliance Tools for *USP* <797> **SAVE \$575, for a limited time only!**

Conducted in association with the Star Center, this course is designed to provide practical experience to successfully implemented *USP* <797> requirements in healthcare settings. Participants will earn 21 hours of CE credit, including 1 hour of law credit. Topics include

- How primary and secondary engineering controls contribute to airflow velocity, direction and ultimately ISO classification
- Best and worst practices of aseptic technique
- Proper hand washing and gowning requirements
- Aseptic technique in LAFWs and isolators in a clean room environment
- Performing a media fill challenge
- Determining the key issues to manage a clean room contractor successfully
- Proper people and product movement and workflow in anteroom and clean room areas
- History of sterile compounding in pharmacy practice and the role of training in pharmacy compliance and practice excellence

**Classroom Cost:** US \$2,075 **Now \$1,500! Offer available through March 31, 2009.**

### Upcoming Dates and Locations:

March 18 – 20, 2009; Denver, CO

(For additional course dates, [click here](#).)

[Click here](#) to register.

## On-demand Module 1 for “Developing Compendial HPLC Practices” is now available! (\$149)

This course provides an introduction to the basic concepts, calculations, and underpinnings of high performance liquid chromatography (HPLC) as applied in everyday practice for quality control and assurance in the pharmaceutical industry.

[Click here](#) to register.

## On-demand Online Courses on Food Ingredient Standards

Learn about food ingredient standards in the *Food Chemicals Codex (FCC)* and how you can help shape them with this special webinar series. (Click course title for more information, or click “Register” to take the course.)

[Introduction to the New FCC](#) (\$99)

[“Register”](#)

[Navigating the FCC](#) (\$99)

[“Register”](#)

[How to Use the FCC Forum—Making the FCC Your Own](#) (\$99)

[“Register”](#)

[How to Develop an FCC Monograph](#) (\$99)

[“Register”](#)

[Table of Contents](#)





## Compounding Sterile Preparations—<797> Webinar Series Save \$30 through March 31, 2009 (regularly priced at \$150 per course)!

On-demand courses available at a fraction of the cost of the live classroom sessions. (Click course title for more information, or click “Register” to take the course.)

<a href="#">Microbial Contamination and Sterilization</a> (\$150, \$120)	<a href="#">“Register”</a>
<a href="#">Disinfectant Cleansing and Garbing</a> (\$150, \$120)	<a href="#">“Register”</a>
<a href="#">Microbial Contamination, Media Fill Testing, and Hazardous Drugs</a> (\$150, \$120)	<a href="#">“Register”</a>
<a href="#">Environmental Monitoring Controls and Facility Design</a> (\$150, \$120)	<a href="#">“Register”</a>
<a href="#">Radiopharmaceuticals, Sterilization Methods, and Specialty CSPs</a> (\$150, \$120)	<a href="#">“Register”</a>

### Upcoming PE Courses Worldwide

- [Dissolution: Theory and Best Practices](#)
- [Effectively Using USP–NF](#)
- [Aseptic Processing and Compliance Tools for USP <797>](#)
- [Validation of Compendial Procedures](#)

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

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

## **Compendial Highlights**

**Monograph Redesign**—USP is seeking comments for proposed design changes to all monographs contained in the *USP–NF*. In November and December, USP posted monographs on its Web site, on a staggered basis, in alphabetically ordered sets, for comment. The comment period is 90 days for each set. This is your chance to become familiar with the new formats and identify any errors that may have been introduced through the conversion of the monographs to this new style. The new format will be incorporated in *USP 33–NF 28*. Click [here](#) for more details.

[Table of Contents](#)



## 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:** Nothing New

## Stimuli Articles

Featured in *PF 35(1)*, January–February 2009

There are no stimuli articles at this time.

## Tip of the Month

Did you know USP is developing a new standard to be included in the *Food Chemicals Codex* for Rebaudioside A, a stevia-based sweetener used in foods and beverages around the world? The proposed *Food Chemicals Codex* standard is available for review and comment to all interested parties via the *Food Chemicals Codex Forum* ([www.usp.org/fcc/forum](http://www.usp.org/fcc/forum)). It was posted on December 31, 2008 and will be available for 90 days. The USP Food Ingredients Expert Committee will approve the final monograph to be included in the 2009 *Food Chemicals Codex Supplement*.

## Question of the Month

Can a vacuum oven be used (e.g. with vacuum of <20mm Hg) for drying a USP Reference Standard if a monograph states only to dry at a specific temperature without specifying to dry under vacuum?

Your different approach (i.e., using a vacuum where one is not specified) would be deemed an alternative method. This is specifically addressed in USP General Notices:

"Compliance may be determined also by the use of alternative methods, chosen for advantages in accuracy, sensitivity, precision, selectivity, or adaptability to automation or computerized data reduction or in other special circumstances. Such alternative or automated procedures or methods shall be validated. However, Pharmacopeial standards and procedures are interrelated; therefore, where a difference appears or in the event of dispute, only the result obtained by the procedure given in this Pharmacopeia is conclusive."

[Table of Contents](#)