



December 2007

Table of Contents (includes links to sections)

Reference Standards Highlights

- **New Reference Standards Now Available**
- **Previously Out-of-Stock Items Now Available**
- **Backorder Availability Estimates, November 26, 2007**
- **RS Lots That Are No Longer Valid**
- **Items with New Lots**

USP Publication Highlights

- **USP 31–NF 26 Now Available—Order Today!**
- **USP 30–NF 25 Second Supplement is now official**
- **Pharmacopeial Forum (PF), Volume 34—Subscribe for 2008**
- **New Food Chemicals Codex Coming Soon**
- **Publications Scheduled Ship Dates**

Events Highlights



- **USP Customer Days—Coming to a City Near You!**
- **Exhibitions**

Professional Education

- **Open Forum Workshop: Residual Solvents: Results in Practice Seminar**
- **New—Advanced Dissolution**
- **New—Validation of Compendial Procedures**
- **Subscribe to New Professional Education Email Bulletin**



Table of Contents Continued (includes links to sections)

-  **New Notices to *USP-NF***
-  **Stimuli Articles**
-  **Tip of the Month**
-  **Question of the Month**

For all the latest information visit 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 November 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that have been discontinued/have a new price and/or have a new package size; items with lots that are (or soon will be) no longer valid; and items with new lots since the last email notice.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.

New Reference Standards Now Available

 [Return to Top](#)

Catalog #	Description	Size	Lot	Price (USD)
1035300	1,6-Anhydro-D-Glucose	50 mg	F0G227	\$178
1048572	Bemotrizinol	200 mg	F0G275	\$176
1142108	Clozapine Resolution Mixture	30 mg	F0G277	\$549
1291548	Ginkgolic Acids	10 mg	F0G279	\$198
1340960	Inositol	500 mg	F0G327	\$176
1359856	Levocabastine Hydrochloride	50 mg	F0G317	\$206
1359867	Levocabastine Related Compound A	50 mg	F0G318	\$549
1445346	Modafinil Related Compound A	20 mg	F0G295	\$549
1445357	Modafinil Related Compound B	20 mg	F0G296	\$549
1445368	Modafinil Related Compound C	20 mg	F0G302	\$549
1445379	Modafinil Related Compound D	20 mg	F0G297	\$549
1445380	Modafinil Related Compound E	20 mg	F0G298	\$549
1496904	Paraffin	1 g	F0G311	\$176
1604654	Risperidone	200 mg	F0G288	\$176
1607506	Powdered St. John's Wort Extract	600 mg	F0G245	\$176
1643496	Terbinafine Hydrochloride	200 mg	F0G310	\$176



Previously Out-of-Stock Items Now Available

[Return to Top](#)

Catalog #	Description	Size	Lot	Price (USD)
1154569	Beta Cyclodextrin	250 mg	G1G216	\$176
1071304	Bile Salts	10 g	J0G309	\$140

Backorder Availability Estimates, November 26, 2007

[Return to Top](#)

[Return to Top](#)

Catalog #	Description	Expected Availability*
1027302	Amiodarone Hydrochloride (200 mg)	Q4/07
1078700	Buprenorphine Hydrochloride CIII (50 mg)	Q4/07
1078711	Buprenorphine Related Compound A CII (50 mg)	Q4/07
1254508	Estriol (100 mg)	Q3/08
1282004	Fluphenazine Hydrochloride (125 mg)	Q4/07
1341001	Indomethacin (200 mg)	Q4/07
1375058	Mandelic Acid (500 mg)	Q1/08
1392002	Mercaptopurine (500 mg)	Q4/07
1477003	Nystatin (200 mg)	Q1/08
1494079	Pancreatin Lipase (2 g)	Q1/08
1642212	Sumatriptan Succinate Related Compound 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



RS Lots That Are No Longer Valid

[Return to Top](#)

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; click on the USP Products link and look up the RS of interest.

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 CIII (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	



No Longer Valid as of December 31, 2007

Catalog #	Description	Previous Lot/ Valid Use Date	Current Lot	Price (USD)
1041609	Apraclonidine Hydrochloride (100 mg)	H0B112 (12/07)	I0G001	\$567
1081002	Butalbital CIII (200 mg)	H0C054 (12/07)	I0F204	\$245
1091221	Captopril Disulfide (100 mg)	G1B066 (12/07)	H0F251	\$576
1096757	Carteolol Hydrochloride (200 mg)	F-1 (12/07)	G0F326	\$185
1096917	Cefaclor, Delta-3 Isomer (30 mg)	G (12/07)	H0G136	\$576
1098231	Cefuroxime Axetil Delta-3-Isomers (10 mg)	H1E186 (12/07)	H2G014	\$576
1107300	Chloramphenicol Palmitate (200 mg)	G-1 (12/07)	H0G266	\$185
1138507	Clocortolone Pivalate (200 mg)	G (12/07)	H0G097	\$185
1140597	Clopidogrel Related Compound B (20 mg)	F0E119 (12/07)	G0F319	\$700
1140509	Clorazepate Dipotassium CIV (125 mg)	G0B027 (12/07)	G1F159	\$245
1158504	Cyclosporine (50 mg)	H-1 (12/07)	I0F343	\$567
1185020	Diazepam Related Compound A (25 mg)	I (12/07)	I1F077	\$576
1271733	Fluconazole Related Compound C (10 mg)	F0D082 (12/07)	G0F202	\$576
1336205	Ifosfamide (500 mg)	G1C371 (12/07)	H0F233	\$185
1392705	Mesalamine (200 mg)	H0C341 (12/07)	I0F121	\$185
1498706	Parbendazole (200 mg)	F (12/07)	G0F331	\$185
1576708	Propylene Glycol (1 mL)	I0C022 (12/07)	J0F211	\$185
1609002	Salicylic Acid (125 mg)	J3C400 (12/07)	K0F112	\$147

Items with New Lots

[Return to Top](#)

Catalog #	Description	Previous Lot/ Valid Use Date	Current Lot	Price (USD)
1056504	1,4-Benzoquinone (200 mg)	G1B145 (11/08)	H0G261	\$185
1071304	Bile Salts (10 g)	I0C003 (05/08)	J0G309	\$147
1083100	3-tert-Butyl-4-hydroxyanisole (200 mg)	L0E259 (11/08)	M0G066	\$185
1145003	Codeine Sulfate CII (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
1194009	Diethylpropion Hydrochloride CIV (200 mg)	H (09/08)	I0G127	\$245
1285807	Flurbiprofen Sodium (200 mg)	F (10/08)	G0G056	\$185
1305008	Hexachlorophene (500 mg)	I (10/08)	J0G217	\$185
1339000	Indigotindisulfonate Sodium (500 mg)	H1B153 (08/08)	H2G304	\$185
1343007	Iodipamide (200 mg)	G (01/08)	H0F334	\$185
1485191	Oxycodone CII (200 mg)	J0F026 (10/08)	K0G276	\$245
1491332	Paclitaxel (200 mg)	G0E018 (11/08)	H0G193	\$1,785
1530503	L-Phenylalanine (200 mg)	H (11/08)	I0G255	\$185
1586009	Pyridostigmine Bromide (200 mg)	I0C324 (10/08)	J0G251	\$185
1625009	Sulfadiazine (200 mg)	J (11/08)	J1G290	\$185
1708795	Valsartan Related Compound C (10 mg)	G0F241 (10/08)	G1G244	\$738



USP Publication Highlights

USP 31–NF 26 Now Available—Order Today!



[Return to Top](#)

The new *USP–NF* is 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 or call USP Customer Service at 1-800-227-8772 (U.S. and Canada), +1-301-881-0666, or 00-800-4875-5555 (Europe).

***USP 30–NF 25 Second Supplement* is now official. Be sure to incorporate these new and revised standards into your work.**

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



[Return to Top](#)

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 receive the first 2008 issue in January! Print and online formats, English only. Visit 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* Coming Soon—Reserve Your Copy Now



[Return to Top](#)

USP will be publishing the *Food Chemicals Codex* (FCC), 6th edition, in spring 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 are available in English only. Reserve your copy today! Visit 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).



Publications Scheduled Ship Dates

[Return to Top](#)

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

Publication	Scheduled Ship/Post Date
<i>PF34(1)Highlights</i>	December 28, 2007
<i>PF34(1) Online</i>	January 1, 2008
<i>PF34(1) Print</i>	January 8, 2008
<i>First Supplement to USP31–NF26 Print</i>	February 1, 2008
<i>First Supplement to USP31–NF26 Online</i>	February 1, 2008
<i>First Supplement to USP31–NF26 CD</i>	February 1, 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.

Events

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 Irvine, CA (February 28, 2008); St. Louis, MO (May 15, 2008); San Juan, Puerto Rico (April 1, 2008) and Montreal, Canada (June 4, 2008). Registration and more information are available at: <http://www.usp.org/goto/USPCustomerDays> or contact: uspcustomerday@usp.org.

Exhibitions—Come Visit Us!

[Return to Top](#)

USP will have a Booth at Pittcon 2008 in New Orleans, LA March 3-6, 2008.

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



Professional Education

New Open Forum Workshop

Residual Solvents: Results in Practice Seminar

[Return to Top](#)

The Residual Solvents: Results in Practice Seminar is an additional, informal opportunity to gain and share insight on implementation issues stemming from revision to General Chapter <467>. You will draw upon lessons learned in labs, USP's educational programs, and experience at the FDA.

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

FORMAT(S)/DURATION: Traditional Classroom, 1 day of presentations with breakout sessions for open discussion in the afternoon. USP Headquarters, Rockville, MD, Cost US \$895.00

NEW Courses

Advanced Dissolution

[Return to Top](#)

In-depth instruction on USP's dissolution and drug release tests. These tests include in-vitro performance tests that are applicable to many dosage forms such as tablets, capsules, suspensions, transdermal patches and, suppositories. They are important components of the specifications that establish the quality and safety of the drug product for the end user.

INTENDED FOR: Scientists, chemists, and laboratory technicians who perform dissolution testing in the lab; quality control staff; and product development professionals who review dissolution data.

FORMAT(S)/DURATION: Traditional Classroom, 2 days. Cost US \$1,495.00

Validation of Compendial Procedures

[Return to Top](#)

Validation of Compendial Procedures will comprehensively address USP's validation requirements. Focusing on the types and characteristics of the analytical procedures utilized to demonstrate compliance, the student will have an opportunity to define the characteristics of validation procedures, design experiments to consider those characteristics and interpret the results using a statistically-based methodology.

INTENDED FOR: Laboratory scientists and managers as well as compliance staff working for Pharmaceutical Manufacturers, API Manufacturers, Excipient Manufacturers, Contract Labs, and Regulators.

FORMAT(S)/DURATION: Traditional Classroom; 1 day, Cost US \$695.00 and Online; 10 hours over two week period. Cost US \$299.00



Subscribe to New Professional Education Email Bulletin

[Return to Top](#)

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 Bulletin. Simply contact us at professionaleducation@usp.org and type “email bulletin” in the subject field. Upcoming courses include:

- “Validation of Compendial Procedures”
- “Particulate Matter in Injections”
- “GMP: A Quality Systems Approach for APIs”

For the USP Education Course List please go to <http://www.usp.org/education>

USP–NF Notices (<http://www.usp.org/USPNF/notices/?h>)

[Return to Top](#)

Revision Bulletin: General Chapter <671> Containers – Performance Testing—12/01/07

Explanatory Notes/Announcements: Nothing New

Errata: Nothing New

Postponements: Nothing New

Stimuli Articles

[Return to Top](#)

Featured in PF 33 (6), November–December 2007

The Application of Uncertainty to USP's Compendial Reference Standards Program: Certified Reference Materials <http://www.usp.org/pdf/EN/USPNF/Vol33No6Stimuli.pdf>

Proposed New USP General Information Chapter, Excipient Performance <1059>

<http://www.usp.org/pdf/EN/USPNF/Vol33No7Stimuli.pdf>



Tip of the Month

The USP–Notices tab on the USP home page (www.usp.org) has been renamed to **Compendial Notices** to more accurately reflect the contents listed. This tab now includes links to the *USP–NF* Notices, *FCC* Notices, and Pending and Non-U.S. Standards sections.

Question of the Month

Does USP develop the tests in the monographs?

Answer:

Usually no, they are supplied along with appropriate validation data to USP by sponsor companies.