



February 2008

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, January 21, 2008**
- **RS Lots That Are No Longer Valid**
- **Items with New Lots**

USP Publication Highlights

- ***Pharmacopeial Forum (PF)*, Volume 34—Subscribe for 2008**
- ***USP 31–NF 26* Now Available—Order Today!**
- ***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—General Chapter <905> Ensuring Confidence in Dosage Unit Uniformity**
 - **New—Determining Particulate Matter in Parenterals**
 - **New—Chapter <797> Pharmaceutical Compounding-Webinars**
 - **Subscribe to New Professional Education Email Bulletin**
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- **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 January 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that have been discontinued/have a new price and/or have a new package size; items with lots that are (or soon will be) no longer valid; and items with new lots since the last email notice.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 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)
1097589	Cefdinir Related Compound B	10 mg	F0G374	\$576
1224201	Divalproex Sodium	200 mg	F0G392	\$185
1234103	Efavirenz*	200 mg	F0G376	\$450
1234114	Efavirenz Racemic*	20 mg	F0G381	\$450
1241823	Erythorbic Acid	50 mg	F0G391	\$185
1283200	Formic Acid	1.2 mL/ ampule; 3 ampules	F0E217	\$176
1287777	Galantamine Hydrobromide Related Compounds Mixture	25 mg	F0G350	\$549
1298106	Granisetron Hydrochloride	150 mg	F0G393	\$408
1298117	Granisetron Related Compound A	15 mg	F0G382	\$587
1298128	Granisetron Related Compound B	15 mg	F0G383	\$587
1448956	Mycophenolate Mofetil	200 mg	F0G372	\$185
1448967	Mycophenolate Mofetil Related Compound A	15 mg	F0G370	\$576
1448978	Mycophenolate Mofetil Related Compound B	15 mg	F0G384	\$576
1457458	Narasin	125 mg	F0G303	\$245
1598201	Raloxifene Hydrochloride	200 mg	F0G364	\$176

*These products require documentation of intended use before purchase. Please contact customer service to avoid delays in processing.



Previously Out-of-Stock Items Now Available

[Return to Top](#)

Catalog #	Description	Size	Lot	Price (USD)
1078700	Buprenorphine Hydrochloride CIII	50 mg	H0G362	\$233
1341001	Indomethacin	200 mg	J1G345	\$185
1494079	Pancreatin Lipase	2 g	J0G363	\$185
1570508	Proprantheline Bromide	200 mg	J0G354	\$185
1670207	Tolcapone	200 mg	F1G397	\$185

Backorder Availability Estimates, January 21, 2008

[Return to Top](#)

Catalog #	Description	Expected Availability*
1140597	Clopidogrel Related Compound B (20 mg)	Q2/08
1254508	Estriol (100 mg)	Q3/08
1320001	Hydrocortisone Phosphate Triethylamine (200 mg)	Q2/08
1356858	Lamivudine Resolution Mixture B (10 mg)	Q2/08
1375058	Mandelic Acid (500 mg)	Q2/08
1392002	Mercaptopurine (500 mg)	Q1/08
1477003	Nystatin (200 mg)	Q1/08
1642212	Sumatriptan Succinate Related Compound A (15 mg)	Q2/08
1646009	Testosterone CIII (125 mg)	Q2/08

*Dates are targets and may change at any time. 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 January 31, 2008				
Catalog #	Description	Previous Lot/ Valid Use Date	Current Lot	Price (USD)
1131009	Cholecalciferol (30 mg/ampule; 5 ampules) (Vitamin D3)	M0B157 (01/08)	N0G038	\$189
1138008	Clindamycin Phosphate (125 mg)	I0C165 (01/08)	I1F315	\$253
1140600	Clopidogrel Related Compound C (20 mg)	F0E118 (01/08)	F1F333	\$700
1150353	Creatinine (100 mg)	F (01/08)	F1F318	\$185
1236801	Epilactose (200 mg)	H0E049 (01/08)	I0F194	\$576
1241506	Ergotamine Tartrate (150 mg) (List Chemical)	I0B174 (01/08)	J0F349	\$185
1269390	Felodipine Related Compound A (25 mg)	F0B207 (01/08)	F1F260	\$576
1287700	Galactose (200 mg)	F-4 (01/08)	G0F252	\$576
1343007	Iodipamide (200 mg)	G (01/08)	H0F334	\$185
1366002	Lidocaine (250 mg)	L (01/08)	M0F220	\$185
1448005	Morphine Sulfate CII (500 mg)	N0E161 (01/08)	O0F186	\$393
1500262	Paroxetine Related Compound E Mixture (25 mg)	F1F028 (01/08)	F2G002	\$576
1525707	Phenothiazine (500 mg)	F0D231 (01/08)	F1F267	\$185
1578500	Prostaglandin A1 (25 mg)	H0B108 (01/08)	I0F103	\$1,481
1643452	Terazosin Hydrochloride (200 mg)	F0C244 (01/08)	G0F290	\$185
1650006	Tetracaine Hydrochloride (200 mg)	J (01/08)	K0F307	\$185
1719000	Warfarin (200 mg)	I0B305 (01/08)	I1G072	\$185

No Longer Valid as of February 29, 2008				
Catalog #	Description	Previous Lot/ Valid Use Date	Current Lot	Price (USD)
1048620	Benazepril Related Compound A (15 mg)	F0C252 (02/08)	G0F352	\$576
1096699	Carprofen (200 mg)	F0D335 (02/08)	F1G039	\$185
1134040	Ciclopirox Related Compound B (25 mg)	F0E088 (02/08)	G0G105	\$576
1134051	Cilastatin Ammonium Salt (100 mg)	G0C334 (02/08)	H0G121	\$185
1023403	Diazepam Related Compound B (25 mg)	I1C102 (02/08)	J0F235	\$576
1287609	Gadopentetate Monomeglumine (500 mg)	F1F094 (02/08)	G0G222	\$185
1316004	Hydrocortisone (200 mg)	M1C110 (02/08)	N0F289	\$185
1469005	Norethindrone (200 mg)	K0C307 (02/08)	L0F237	\$185
1500218	Paroxetine Hydrochloride (350 mg)	G0D003 (02/08)	G1F261	\$185
1616008	1,4-Sorbitan (300 mg)	I0A003 (02/08)	J0F351	\$185
1656002	Thiamine Hydrochloride (500 mg) (Vitamin B1 Hydrochloride)	O (02/08)	O1F236	\$185
1660000	Thioguanine (200 mg)	F-1 (02/08)	G0G215	\$185
1720203	Xanthone (100 mg)	F-1 (02/08)	G0G076	\$576



Items with New Lots

[Return to Top](#)

Catalog #	Description	Previous Lot/ Valid Use Date	Current Lot	Price (USD)
1078700	Buprenorphine Hydrochloride CIII (50 mg)	G0E026 (11/08)	H0G362	\$245
1078802	Bupirone Hydrochloride (200 mg)	H0B301 (12/08)	I0G171	\$185
1130527	Chlorzoxazone Related Compound A (50 mg)	G-1 (11/08)	H0G336	\$576
1197506	Diflunisal (200 mg)	G (12/08)	G1F320	\$185
1494079	Pancreatin Lipase (2 g)	I1E327 (11/08)	J0G363	\$185
1570508	Propantheline Bromide (200 mg)	I0A019 (01/09)	J0G354	\$185
1670207	Tolcapone (200 mg)	F0D280 (07/08)	F1G397	\$185
1674004	Tretinoin (30 mg/vial; 5 vials)	J0D145 (10/08)	J1F266	\$185

USP Publication Highlights

[Return to Top](#)

Pharmacopeial Forum (PF), Volume 34—Order Today!

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. 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).

[Return to Top](#)

USP 31—NF 26 Now Available. Subscribe Now for the Latest Standards.

The new *USP—NF* is available now in English (print, online, and CD) and Spanish (print). An annual subscription includes a main edition and two *Supplements*. 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).

[Return to Top](#)

New Food Chemicals Codex Coming Soon—Reserve Your Copy Now.

USP will be publishing the *Food Chemicals Codex (FCC), Sixth 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>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
<i>Food Chemicals Codex</i>	February 29, 2008
<i>PF 34(2) Highlights</i>	February 22, 2008
<i>PF 34(2) Online</i>	February 29, 2008
<i>PF 34(2) Print</i>	March 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.

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); San Juan, Puerto Rico (April 1, 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: uspcustomerday@usp.org.

Exhibitions—Come Visit Us!

[Return to Top](#)

Booth #6833 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 will take place on February 27, 2008. This will be a unique interactive opportunity to gain and share insight with colleagues in the industry on implementation issues stemming from revision to General Chapter <467>. You will draw upon lessons learned by industry experts, 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: Traditional Classroom, 1 day consisting of presentations and working sessions for open discussion and approaches to problem solving in the afternoon. USP Headquarters, Rockville, MD

Cost: US \$995.00 *Register Now!* Click [here](#) to register.

For additional information on full course offerings for <467>, visit www.usp.org/education/pe/courses.html.

NEW Courses

General Chapter <905> Ensuring Confidence in Dosage Unit Uniformity

[Return to Top](#)

The ICH Steering Committee considers international harmonization of about 10 specific compendial test chapters as critical to attaining full utility of the ICH Q6A guideline. ICH Q6A recommended the harmonization of certain tests for dosage forms, including General Chapter <905> Uniformity of Dosage Units.

Through the harmonization process, General Chapter <905> is now based on a more statistically sound approach for the analysis of test data, specifically arising from the Content Uniformity and Weight Variation tests. This change in methodology represents a shift from the use of testing by attributes to testing by variables.

This new course will provide the necessary theory and practical application of statistics-based methodology of Content Uniformity and Weight Variation tests associated with the revised Chapter <905>.

Intended For: Laboratory supervisors, bench chemists, as well as compliance staff in the pharmaceutical and allied industries.

Format: Traditional Classroom, One-Half Day, Lecture

Classroom Cost: US \$295.00, click [here](#) to register.



Determining Particulate Matter in Parenterals

[Return to Top](#)

Determination of particulate matter in solutions (for injections, infusions, and ophthalmic treatments) is an important and complex subject that requires an in-depth understanding of scientific principals and applications, especially when dealing with compendial compliance. This course is being created to provide a solid foundation of knowledge on the subject as well as to equip the students with the ability to extend their learning beyond formulaic application of concepts covered in the course.

Two specific methods for determination of particulate matter in solution will be discussed in great detail – Light Obscuration and Membrane Microscopy. These methodologies are most widely associated with Chapter <788> Particulate Matter in Injections, but they also apply to Chapter <789> Particulate Matter in Ophthalmic Solutions.

Intended for: Laboratory supervisors, bench chemists and compliance staff in parenteral drug manufacturers, ophthalmic solution manufacturers with less than 5 years of experience

Format: Traditional Classroom, One Full Day, Lecture

Classroom Cost: US \$695.00, click [here](#) to register.

Chapter <797> Pharmaceutical Compounding Webinars

[Return to Top](#)

General Chapter <797> has been revised and will become official on June 1, 2008. Make sure you're prepared to incorporate upcoming changes into your work environment – [Register Now](#) for special <797> Webinars and hands-on workshops. There will be 7 web-based educational seminars, addressing all the key topics covered in Chapter <797>. Webinars include live expert presenters, accompanying online slides, and an interactive Q&A session. Participants will also receive a copy of the new Guidebook on USP General Chapter <797> (a \$99 value)

Format: Web based education formats

Cost: US \$225.00 each. Special offer through February 18th - US \$1,200 for package of 6. Click [here](#) to register.

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:

- "cGMP: A Quality Systems Approach for APIs"
- "TLC for Dietary Supplements: Botanicals"
- "General Chapter <797> Pharmaceutical Compounding Sterile Preparations"

For the complete 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: Nothing New

Explanatory Notes/Announcements: Nothing New

Intent to Revise: Nothing New

Errata: Nothing New

Postponements: Nothing New

Stimuli Articles



Return to Top

Featured in *PF* 34 (1), January–February 2008

No articles published



Return to Top

Tip of the Month

The Dissolution Toolkit (last month's tip) is one of the Compendial Tools. Are there more? **Check it out at** <http://www.usp.org/USPNF/compendialTools.html>

Compendial Tools are documents, spreadsheets, databases, photographs, and other items that are intended to aid the user in the application of USP standards. These tools are not official, and do not affect the interpretation of the USP, NF, FCC, or any other USP-developed compendium. These tools are not intended to be used to determine that an article does or does not comply with compendial requirements, are not sufficient for that purpose, and should not be used in that manner. These tools are used at the user's own discretion and risk.

Question of the Month

The USP Reference Standard I have does not have a purity value on the label; can I use it for the Assay? Do I assume 100%?

Answer:

The current lot of a USP Reference Standard (or previous lot within its valid use date) is suitable for its official uses and yes, if there is no purity value on the label you would assume it is 100.0% pure.