



December 2008

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have been discontinued/have a new price and/or have a new package size; items with lots that are (or soon will be) no longer valid; and items with new lots since the last email notice.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





New Reference Standards Now Available

Catalog #	Description	Size	Lot	Price (USD)
1012644	Albuterol Related Compound A	25 mg	F0H223	\$576
1084306	Cabergoline	125 mg	F0H240	\$1785
1111908	P-Chloroaniline	200 mg	F0H281	\$185
1283313	Foscarnet Related Compound B	10 mg	F0H254	\$576
1294284	N-Glycolylneuraminic Acid	200 mg	F0H145	\$450
1295753	Glyceryl Monooleate 40%	500 mg	F0H033	\$185
1356756	Lamotrigine	100 mg	F0H256	\$540
1359404	Levetiracetam	200 mg	F0H295	\$250
1438205	Methyl Tricosanoate	200 mg	F0H169	\$196
1443599	Midazolam CIV	300 mg	F0H195	\$393
1481204	Oxaliplatin	125 mg	F0H306	\$950
1481306	Oxaliplatin System Suitability	25 mg	F0H330	\$576
1544406	Piroctone Olamine	200 mg	F0H085	\$185
1642813	Tacrolimus Related Compound A	15 mg	F0H098	\$673
1672687	Trandolapril	125 mg	F0H140	\$185
1672745	Tranexamic Acid	200 mg	F0H312	\$185
1680685	Tributyl Phosphine Oxide	25 mg	F0H196	\$185

Previously Out-of-Stock Items Now Available

Catalog #	Description	Size	Lot	Price (USD)
1032007	Amphotericin B	125 mg	K0H185	\$147
1044800	Atracurium Besylate	100 mg	F1H342	\$185
1078507	Bupivacaine Hydrochloride	500 mg	H2H088	\$185
1410002	Methicillin Sodium (AS)	500 mg	K0H338	\$185
1491015	Oxytetracycline Hydrochloride*	200 mg	F1H290	\$185
1623003	Streptomycin Sulfate	200 mg	J1H337	\$185
1651621	Delta-9-tetrahydrocannabinol	1 mL	G0H324	\$215
1708773	Valsartan Related Compound A	10 mg	H1H329	\$738

*This item has changed from an Authentic Substance to a Reference Standard

Backorder Availability Estimates, November 24, 2008

Catalog #	Description	Expected Availability*
1047503	Bacitracin (1 g) (Susceptibility disk standard)	Q1/09
1068004	Betamethasone Sodium Phosphate (500 mg)	Q1/09
1162400	Dactinomycin (50 mg)	Q1/09
1270446	Fexofenadine Related Compound C (15 mg)	Q2/09
1471007	Norethynodrel (200 mg)	Q4/08
1601102	Residual Solvents Mixture - Class 1 (1.2 mL/ampule; 3 ampules)	Q1/09
1673828	Trenbolone Acetate CIII (200 mg)	Q4/08

*Dates are targets and may change at any time. Q4/08=October–December 2008; Q1/09=January–March 2009; Q2/09=April–June 2009

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Items with New Package Size

Catalog #	Description	Old Size	New Size	Lot	Price (USD)
1078507	Bupivacaine Hydrochloride	1 g	500 mg	H2H088	\$185

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

No Longer Valid as of November 30, 2008				
Catalog #	Description	Previous Lot/ Valid Use Date	Current Lot	Price (USD)
1019701	Amiloride Hydrochloride (500 mg)	H (11/08)	H1G197	\$194
1056504	1,4-Benzoquinone (200 mg)	G1B145 (11/08)	H1G332	\$194
1078700	Buprenorphine Hydrochloride CIII (50 mg)	G0E026 (11/08)	H0G362	\$257
1078711	Buprenorphine Related Compound A CII (25 mg)	F1C076 (11/08)	G0G353	\$605
1083100	3-tert-Butyl-4-hydroxyanisole (200 mg)	L0E259 (11/08)	M0G066	\$194
1130527	Chlorzoxazone Related Compound A (50 mg)	G-1 (11/08)	H0G336	\$605
1134029	Ciclopirox Related Compound A (25 mg)	F0E087 (11/08)	G0G212	\$605
1477003	Nystatin (200 mg)	O0D177 (11/08)	O1G308	\$194
1491332	Paclitaxel (200 mg)	G0E018 (11/08)	H0G193	\$1,874
1494079	Pancreatin Lipase (2 g)	I1E327 (11/08)	J0G363	\$194
1530503	L-Phenylalanine (200 mg)	H (11/08)	I0G255	\$194
1570304	Propafenone Hydrochloride (200 mg)	G1C184 (11/08)	H0F302	\$194
1625009	Sulfadiazine (200 mg)	J (11/08)	J1G290	\$194



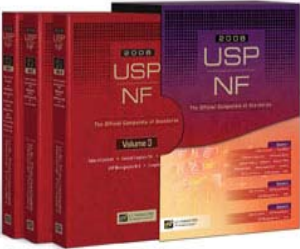
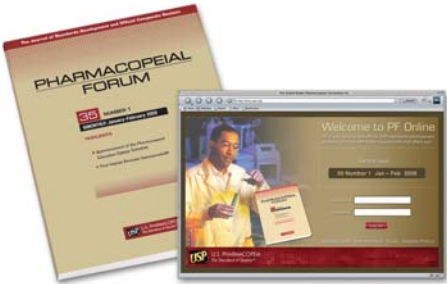
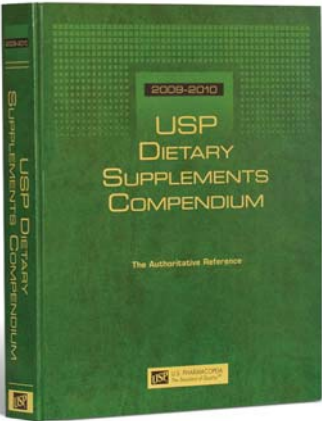
No Longer Valid as of December 31, 2008				
Catalog #	Description	Previous Lot/ Valid Use Date	Current Lot	Price (USD)
1078802	Buspirone Hydrochloride (200 mg)	H0B301 (12/08)	I0G171	\$194
1107004	Chloramphenicol (200 mg)	N1C074 (12/08)	O0H011	\$194
1140429	Clonidine Related Compound B (25 mg)	F0C403 (12/08)	G0G323	\$605
1179504	Dexpanthenol (500 mg)	J0C293 (12/08)	J1F296	\$200
1197506	Diflunisal (200 mg)	G (12/08)	G1F320	\$194
1221000	Disodium Guanylate (350 mg) (FCC)	F-1 (12/08)	G0H049	\$194
1225292	Dorzolamide Hydrochloride Related Compound A (20 mg)	G0E029 (12/08)	H0G052	\$605
1303013	Haloperidol Related Compound A (10 mg)	K0C362 (12/08)	L0G226	\$605
1320001	Hydrocortisone Phosphate Triethylamine (200 mg)	F-1 (12/08)	G0H109	\$194
1356858	Lamivudine Resolution Mixture B (10 mg)	F0E152 (12/08)	G0H055	\$605
1433008	Methylphenidate Hydrochloride CII (125 mg)	I1C241 (12/08)	J0G307	\$206
1485103	Oxybutynin Chloride (200 mg)	H0E080 (12/08)	I0G281	\$194
1491354	Paclitaxel Related Compound B (20 mg)	G0E019 (12/08)	H0G196	\$938
1535700	Phosphated Riboflavin (100 mg)	G1B286 (12/08)	H0G253	\$154
1570508	Propantheline Bromide (200 mg)	I0A019 (12/08)	J0G354	\$194
1571001	Proparacaine Hydrochloride (200 mg)	G (12/08)	H0G228	\$194
1623637	Sucrose (100 mg)	H1C223 (12/08)	H2G263	\$194
1646009	Testosterone CIII (125 mg)	I1B253 (12/08)	J0G360	\$206
1677002	Triamcinolone Acetonide (500 mg)	K (12/08)	L0G322	\$194

Items with New Lots

Catalog #	Description	Previous Lot/ Valid Use Date	Current Lot	Price (USD)
1032007	Amphotericin B (125 mg)	J3C246 (05/09)	K0H185	\$154
1044800	Atracurium Besylate (100 mg)	F0B143 (07/09)	F1H342	\$194
1078507	Bupivacaine Hydrochloride (500 mg)	H1E255 (11/09)	H2H088	\$194
1223005	2,4-Disulfamyl-5-trifluoromethylaniline (30 mg)	G (10/09)	H0H040	\$605
1241903	Erythritol (200 mg)	F0E313 (11/09)	F1F295	\$194
1279000	Fluorouracil (250 mg)	H2D190 (10/09)	I0G371	\$194
1337809	Imipenem Monohydrate (100 mg)	H0E040 (10/09)	I0H217	\$194
1398009	Methadone Hydrochloride CII (200 mg)	I0B163 (11/09)	I1H270	\$257
1410002	Methicillin Sodium (500 mg) (AS)	J0C333 (03/09)	K0H338	\$194
1491015	Oxytetracycline Hydrochloride (200 mg)	F0E258 (11/09)	F1H290	\$194
1589007	Pyrimethamine (200 mg)	H (10/09)	I0H212	\$194
1623003	Streptomycin Sulfate (200 mg)	J0B195 (09/09)	J1H337	\$194
1651621	Delta-9-Tetrahydrocannabinol (1 mL)	F0G081 (03/09)	G0H324	\$226
1708773	Valsartan Related Compound A (10 mg)	H0G357 (11/09)	H1H329	\$775
1713004	Vinblastine Sulfate (50 mg)	M0B308 (10/09)	N0H327	\$440



USP Publication Highlights

	<p>USP 32–NF 27 is Available—Be Prepared for 2009 Standards</p> <p>The new 2009 edition of the <i>USP–NF</i> is available now in English (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> (print only) publishes in January 2009. Subscribe today and be prepared for standards that become official May 1, 2009. Visit 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).</p>
	<p>Comment on Standards Revisions with <i>Pharmacopeial Forum</i> (PF), Volume 35—Subscribe for 2009</p> <p>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</i> 35 today—print and online formats, English only. Visit 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).</p>
	<p>New <i>USP Dietary Supplements Compendium</i>—Reserve your copy now</p> <p>Publishing in early 2009, the new <i>USP Dietary Supplements Compendium</i> (<i>DSC</i>) combines <i>USP–NF</i> standards with information from the <i>Food Chemicals Codex, Sixth Edition</i>; regulatory and industry documents; and helpful tools and resources. The <i>DSC</i> will be published every two years in hardcover print, English only. Learn more and order at 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).</p>

Standards in *USP 31–NF 26* Second Supplement are official December 1, 2008.

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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 San Francisco, CA (February 3, 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.

Pharmacopeial Education

New USP Pharmacopeial Education Online Catalog—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>

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

Upcoming Dates and Locations:

January 28 – 30, 2009; Denver, CO

February 11 – 13, 2009; Denver, CO

February 18 – 20, 2009; Denver, CO

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)

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

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

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

[“Register”](#)

[“Register”](#)

[“Register”](#)

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Compounding Sterile Preparations—<797> Webinar Series (\$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.)

Microbial Contamination and Sterilization (\$150)	“Register”
Disinfectant Cleansing and Garbing (\$150)	“Register”
Microbial Contamination, Media Fill Testing, and Hazardous Drugs (\$150)	“Register”
Environmental Monitoring Controls and Facility Design (\$150)	“Register”
Radiopharmaceuticals, Sterilization Methods, and Specialty CSPs (\$150)	“Register”

Upcoming PE Courses Worldwide

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

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*. Beginning, November 3, USP has been posting 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.

[USP–NF Notices](#)

Sign up to receive Notices electronically at

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

Revision Bulletins: [Enoxaparin Sodium Monograph](#) (10/31/08)

Explanatory Notes/Announcements: Nothing New

Intent to Revise: Nothing New

Errata: Nothing New

Postponements: Nothing New

General: Nothing New

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Stimuli Articles

Featured in *PF 34(6)*, November–December 2008

[USP Responses to Comments on Stimuli Article: The Application of Uncertainty to USP's Compendial Reference Standards Program: Certified Reference Materials](#)  (527KB)

[The Use of Inductively Coupled Plasma–Optical Emission Spectroscopy in the Determination of Heavy Metals in Crospovidone and Povidone as a Replacement for the Concomitant Visual Comparison Test](#)  (527KB)

[Compendial Calculations: Recommendations for Improving USP–NF Calculations](#)  (527KB)

[General Chapter Containers–Packaging Auxiliary Components <670>](#)  (527KB)

[Description of the Upcoming Change in Data Analysis for USP Dissolution Performance Verification Tests](#)  (527KB)

[USP Responses to Comments on Stimuli Article Uncertainty Statements Regarding USP Reference Standards](#)  (527KB)

[Redesign of the United States Pharmacopeia and National Formulary](#)  (527KB)

Tip of the Month

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](#).

Visit the Residual Solvents Hot Topics page with <467> resources at www.usp.org/hottopics/residualsolvents.html.

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

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Question of the Month

If a monograph for an API states that the assay results are reported on the anhydrous basis, in addition to a water determination for the sample, should a water determination be done on the Reference Standard used for the assay?

Reference Standards should be handled as per their label instructions, not the instructions in the monograph for the article under test. In some cases, a Reference Standard label will indicate that for quantitative uses a water determination is to be performed at the time of use.

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