

**June 2008**

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have been discontinued/have a new price and/or have a new package size; items with lots that are (or soon will be) no longer valid; and items with new lots since the last email notice.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

Announcing the New USP Online Catalog

Please go to www.uspcatalog.com to check out the new interactive catalog. There are many new features and a tutorial is included on how to use the catalog. You may use your USP Store Login ID and Password to place orders from the new catalog.

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New Reference Standards Now Available

Catalog #	Description	Size	Lot	Price (USD)
1042780	Artemether	100 mg	F0H107	\$185
1075305	Bisdemethoxycurcumin	30 mg	F0H152	\$185
1096655	Carvedilol Related Compound C	20 mg	F0H151	\$576
1096666	Carvedilol Related Compound D	15 mg	F0H149	\$576
1151855	Curcumin	30 mg	F0H127	\$185
1173100	Desmethoxycurcumin	30 mg	F0H153	\$185
1193265	Diethylene Glycol	0.5 mL	F0G400	\$185
1265515	Ethylene Glycol	0.5 mL	F0G403	\$185
1265559	Ethylhexyl Triazone Related Compound B	20 mg	F0H137	\$576
1265560	Ethylhexyl Triazone Related Compound C	20 mg	F0H139	\$576
1273841	Flumazenil Related Compound C	500 mg	F0F300	\$738
1286650	Fulvestrant	150 mg	F0H065	\$460
1370746	Lumefantrine	100 mg	F0H108	\$185
1478312	Olanzapine Related Compound A	25 mg	F0H156	\$576
1478323	Olanzapine Related Compound B	25 mg	F0H160	\$576
1479020	Orphenadrine Related Compound B	20 mg	F0H110	\$576
1479031	Orphenadrine Related Compound C	20 mg	F0H111	\$576
1541601	Piperazine	200 mg	F0H155	\$185
1568040	Proguanil Hydrochloride	200 mg	F0H119	\$185
1568051	Proguanil Related Compound C	25 mg	F0H125	\$576
1568062	Proguanil Related Compound D	25 mg	F0H128	\$576
1585505	Pyrethrum Extract	100 mg	F0C369	\$185
1613597	Sodium Bromide	1 g	F0H116	\$185
1642802	Tacrolimus	150 mg	F0H135	\$616
1708004	Valganciclovir Hydrochloride	500 mg	F0H008	\$285

Previously Out-of-Stock Items Now Available

Catalog #	Description	Size	Lot	Price (USD)
1082708	Butylated Hydroxytoluene*	500 mg	F1G286	\$185
1134233	Citalopram Hydrobromide	125 mg	F1G292	\$332
1242000	Erythromycin	250 mg	N0G117	\$185
1392454	Meropenem	300 mg	H0G402	\$216
1472000	Norgestrel	125 mg	J1G387	\$147
1499403	Paricalcitol	10 mg	G0H054	\$1503
1604508	Rimantadine Hydrochloride	300 mg	G0H143	\$185

*This was an Authentic Substance and is now a Reference Standard

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Backorder Availability Estimates, May 27, 2008

Catalog #	Description	Expected Availability*
1046078	Desosaminylazithromycin (15 mg)	Q2/08
1046089	N-Demethylazithromycin (15 mg)	Q2/08
1047503	Bacitracin (1 g) (Susceptibility disk standard)	Q2/08
1086301	Calcitriol (10 mg)	Q3/08
1091006	Capreomycin Sulfate (250 mg)	Q2/08
1107401	Chloramphenicol Palmitate Nonpolymorph A	Q2/08
1254508	Estriol (100 mg)	Q2/08
1320001	Hydrocortisone Phosphate Triethylamine	Q2/08
1358503	Leuprolide Acetate (200 mg)	Q4/08
1375058	Mandelic Acid (500 mg)	Q2/08
1379254	Melengestrol Acetate (125 mg)	Q2/08
1392002	Mercaptopurine (500 mg)	Q2/08
1410002	Methicillin Sodium (500 mg) (AS)	Q4/08
1443307	Mezlocillin Sodium (350 mg)	Q3/08
1471007	Norethynodrel (200 mg)	Q4/08
1495005	Papain (1 g)	Q2/08
1546300	Polydimethylsiloxane (500 mg)	Q2/08
1612415	Sesame Oil Related Compound A (6	Q3/08
1642212	Sumatriptan Succinate Rel Cpd A	Q2/08
1651621	Delta-9-Tetrahydrocannabinol (1 mL)	Q3/08
1673828	Trenbolone Acetate CIII (200 mg)	Q4/08

*Dates are targets and may change at any time. Q2/08=April–June 2008, Q3/08=July–September 2008, Q4/08=October–December 2008

Items with New Package Size

Catalog #	Description	Old Size	New Size	Lot	Price (USD)
1134233	Citalopram Hydrobromide	200 mg	125 mg	F1G292	\$332

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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 May 31, 2008				
Catalog #	Description	Previous Lot/ Valid Use Date	Current Lot	Price (USD)
1017105	Altretamine (500 mg)	F (05/08)	G0D184	\$185
1046056	Azithromycin (100 mg)	H0C212 (05/08)	I0F079	\$185
1071304	Bile Salts (10 g)	I0C003 (05/08)	J0G309	\$147
1089004	Cannabidiol CI (25 mg) (AS) DISCONTINUED	F-2 (05/08)		
1127001	Chlorprothixene (200 mg) DISCONTINUED	F-1 (05/08)		
1134426	Clavulanate Lithium (200 mg)	I1C270 (05/08)	J0G109	\$185
1144000	Codeine Phosphate CII (100 mg)	J0C200 (05/08)	K0G040	\$245
1152508	Cyclacillin (200 mg) DISCONTINUED	G (05/08)		
1159008	Cyclothiazide (200 mg) (AS)	F-1 (05/08)	F2F329	\$185
1180004	Dextroamphetamine Sulfate CII (500 mg)	I0C311 (05/08)	I1F106	\$256
1236506	4-Epianhydrotetracycline Hydrochloride (50 mg)	J0C041 (05/08)	K0F299	\$576
1241007	Ergosterol (50 mg)	H (05/08)	I0G053	\$185
1254508	Estriol (100 mg)	J (05/08)		\$185
1260012	Ethinyl Estradiol Related Compound A (20 mg)	G0E301 (05/08)	H0G051	\$576
1264002	Ethosuximide (500 mg)	H (05/08)	I0F301	\$185
1302000	Guanethidine Sulfate (500 mg) DISCONTINUED	G-1 (05/08)		
1303308	Haloproglin (200 mg) DISCONTINUED	F (05/08)		
1308505	L-Histidine (200 mg)	G0A018 (05/08)	H0F158	\$185
1322007	Hydroflumethiazide (200 mg)	F-2 (05/08)	G0G093	\$185
1346005	Ipodate Calcium (200 mg) DISCONTINUED	F-1 (05/08)		
1407008	Methdilazine (200 mg) DISCONTINUED	F-1 (05/08)		
1453526	Naltrexone Related Compound A CII (30 mg)	F (05/08)	F1G035	\$576
1510801	Perflubron (0.5 mL)	G0C103 (05/08)	H0F213	\$185
1512002	Phenacemide (250 mg) DISCONTINUED	F (05/08)		
1629000	Sulfamethazine (1 g)	G-3 (05/08)	H0F324	\$185
1676000	Triamcinolone (250 mg)	H-1 (05/08)	I0G157	\$185
1708762	Valsartan (350 mg)	G0F065 (05/08)	H0G139	\$185
1708773	Valsartan Related Compound A (10 mg)	F1E272 (05/08)	H0G357	\$738



No Longer Valid as of June 30, 2008				
Catalog #	Description	Previous Lot/ Valid Use Date	Current Lot	Price (USD)
1046103	Azlocillin Sodium (200 mg) DISCONTINUED	F (06/08)		
1060002	Benzthiazide (200 mg) DISCONTINUED	F (06/08)		
1096000	Carbinoxamine Maleate (200 mg)	H (06/08)	H1G030	\$185
1133547	Choline Chloride (200 mg)	F0C058 (06/08)	G0G022	\$185
1140702	Clorsulon (200 mg)	F1B084 (06/08)	G0F275	\$185
1171900	Desflurane (0.5 mL)	F0C187 (06/08)	G0G018	\$185
1188811	Diclofenac Related Compound A (25 mg)	I0D337 (06/08)	J0F294	\$576
1225703	Doxorubicin Hydrochloride (50 mg)	K (06/08)	K1G106	\$567
1231003	Dydrogesterone (200 mg)	I0B114 (06/08)	I1G011	\$185
1288463	Gemcitabine Hydrochloride (200 mg)	F0D037 (06/08)	G0G083	\$185
1304005	Heparin Sodium (10 x 1 mL)	K-5 (06/08)	L0G091	\$185
1315001	Hydrocodone Bitartrate CII (100 mg)	L0E176 (06/08)	M0G061	\$245
1342503	Iocetamic Acid (200 mg) DISCONTINUED	F (06/08)		
1377009	Meclizine Hydrochloride (500 mg)	I-1 (06/08)	J0G107	\$185
1396310	Metformin Related Compound A (50 mg)	F0C210 (06/08)	G0G104	\$576
1474005	Nortriptyline Hydrochloride (200 mg)	I1D054 (06/08)	J0G063	\$185
1548000	Polythiazide (200 mg) DISCONTINUED	F-1 (06/08)		
1567004	Procyclidine Hydrochloride (200 mg)	G (06/08)	H0G084	\$185
1610001	Scopolamine Hydrobromide (250 mg)	J0B051 (06/08)	K0G033	\$185
1642212	Sumatriptan Succinate Related Compound A (15 mg)	G0F113 (06/08)		\$738
1680007	Triamterene (200 mg)	I (06/08)	J0F277	\$185

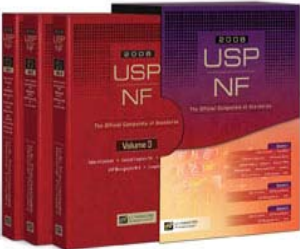
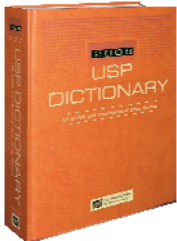
Items with New Lots

Catalog #	Description	Previous Lot/ Valid Use Date	Current Lot	Price (USD)
1020008	Aminobutanol (500 mg)	G-1 (05/09)	H0G256	\$461
1040708	Apigenin-7-glucoside (30 mg)	F (04/09)	G0H057	\$576
1134379	Clarithromycin (75 mg)	G0D356 (05/09)	G1G324	\$185
1154503	Cyclobenzaprine Hydrochloride (200 mg)	G0A013 (05/09)	H0G399	\$185
1235274	Enalaprilat (300 mg)	J0C268 (05/09)	J1G349	\$147
1392454	Meropenem (300 mg)	G0F100 (05/09)	H0G402	\$216
1448005	Morphine Sulfate CII (500 mg)	O0F186 (05/09)	P0H037	\$393
1460736	Nevirapine Related Compound B (15 mg)	F0D033 (05/09)	G0G271	\$576
1467804	Nizatidine (200 mg)	G (05/09)	H0G401	\$185
1472000	Norgestrel (125 mg)	J0C269 (05/09)	J1G387	\$147
1499403	Paricalcitol (10 mg)	F0E303 (01/09)	G0H054	\$1,503
1559006	Prednisone (250 mg)	N0E330 (05/09)	O0G356	\$185
1592409	Quercetin (500 mg)	G0D407 (05/09)	H0G321	\$185
1604508	Rimantadine Hydrochloride (300 mg)	F0C266 (03/09)	G0H143	\$185
1667472	Tioconazole Related Compound C (25 mg)	G (05/09)	H0F262	\$576

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USP Publication Highlights

	<p>USP 31–NF 26 is Official! Don't be without the latest FDA-enforceable drug standards—make sure you're using <i>USP 31–NF 26</i> standards in your work! Official as of May 1, 2008, <i>USP 31–NF 26</i> is available in English (print, online, and CD) and Spanish (print).</p> <p>Subscription includes main edition and two <i>Supplements</i>. Order now at 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>New USP Dictionary is Available The 2008 edition of the <i>USP Dictionary of USAN and International Drug Names</i> provides comprehensive, up-to-date drug name information—generic and brand name drugs, pronunciations, formulas, CAS numbers, UNII codes (new for 2008), and more! Order today at www.usp.org/products/dictionary 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
<i>USP 31–NF 26 Second Supplement</i> Print	June 1, 2008
<i>USP 31–NF 26 Second Supplement</i> Online	June 1, 2008
<i>USP 31–NF 26 Second Supplement</i> CD	June 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



Event Highlights

IFT08 Annual Meeting and Food Expo, June 28–July 1, 2008 Morial Convention Center in New Orleans, LA. Visit USP at Booth 2264!

USP Bioassay Workshop, August 13–14, 2008, USP Headquarters in Rockville, MD

Bioassays continue to play an essential role in drug development and in many phases of the pharmaceutical product lifecycle. This workshop will address USP General Chapters on the Design, Development, Analysis and Validation of Bioassays. The development, analysis, and validation of bioassays typically require teams of scientists, technicians and statisticians to move a bioassay from development to practice. The new USP chapters and this workshop will provide best-practice guidelines to facilitate this process. The workshop will also explore the role of bioassays in monographs, the transition from animal assays to cell based assays, and bioassays for potency and immunogenicity testing. This interactive event will not only provide guidance and information on bioassays, but will also provide an opportunity for vigorous discussion of the compendial proposals.

For more information or to register for this event please click on the following link:

<http://ems.intellor.com/?p=201821&do=register&t=12>

Pharmacopeial Education

Featured Courses

Navigating Chapter <467> Residual Solvents

SAVE \$100 when taking this online course beginning June 19!

Gain a broad understanding of the new requirements, addressing identification, control and quantification of residual solvents. Instruction will provide information on the ingredients and products affected by the new standard, the testing and validation practices that will be accepted as well as the procedures to document compliance.

Intended For: Lab managers, bench chemists, QA/QC personnel, those involved with method validation in the pharmaceutical and allied industries.

Format: Web based education, 10 hours of self paced learning over 10 days.

Cost: June 19 —US \$299; July 17—US \$399; click [here](#) to register.

Dates and Location: June 19, 2008; available online! View on your PC at home or at the office.
July 17, 2008; available online! View on your PC at home or at the office.



Laboratory Practicum for Chapter <467> Residual Solvents

USP, in partnership with Phenomenex, a worldwide manufacturer of separation science consumables, will present a comprehensive course including lectures and complementary laboratory sessions on the use of analytical procedure in General Chapter <467> Residual Solvents and using alternative testing protocols.

Intended For: Lab managers, bench chemists, QA/QC personnel, and those involved with method validation in the pharmaceutical and allied industries.

Format: Traditional Classroom, Full Day, Lecture and Lab

Classroom Cost: US \$1,495, click [here](#) to register.

Dates and Locations: June 26, 2008; Somerset, NJ
June 27, 2008; Somerset, NJ
July 23, 2008; Torrance, CA

Effectively Using USP–NF

Learn about the most efficient and effective way to use the trusted standards of the *USP–NF*, *USP–NF Supplements*, and *Pharmacopeial Forum* to your organization's best advantage.

Intended For: Laboratory scientists, lab managers, and compliance staff in the pharmaceutical and allied industries.

Format: Traditional Classroom, Full Day, Lecture

Classroom Cost: US \$695, click [here](#) to register.

Date and Location: August 6, 2008; Rockville, MD

Upcoming PE Courses

- [Navigating Chapter <467> Residual Solvents](#)
- [Laboratory Practicum for Chapter <467> Residual Solvents](#)
- [USP/ISMP Workshop](#)
- [Essentials of Microbiological Testing](#)
- [Practical Applications of Chapter <467> Residual Solvents](#)
- [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>

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Compendial Highlights

[USP–NF Notices](#)

Revision Bulletins: [USP Postpones the Official Date of the Glycerin Monograph: Revisions and Clarifications to be Made](#) (05/09/08)

General Chapter <2040> Disintegration and Dissolution of Dietary Supplements—Official Date Delayed for Dissolution Requirements for Soft Gelatin Capsules to May 1, 2009 (05/09/08)

Explanatory Notes/Announcements: Nothing New

Intent to Revise: Nothing New

Errata: Nothing New

Postponements: USP Postpones the Official Date of the Glycerin Monograph: Revisions and Clarifications to be Made (05/09/08)

Inorganic Impurities (Heavy Metals) Stimuli Article—04/23/08. To read the article before it is published in *PF3(5)* click [here](#)

Stimuli Articles

Featured in *PF 34(3)*, May–June 2008

[Making Sense of Trueness, Precision, Accuracy, and Uncertainty Product Performance Test for Medicated Chewing Gums](#)

Tip of the Month

Coming soon: USP Hot Topics Page on Glycerin

At the request of the Food and Drug Administration, USP revised its Glycerin monograph in March, with a projected official date of June 15. Based on feedback from industry and extensive discussion among USP, industry, and FDA, the monograph may need further revision, and the official date has been postponed.

Come visit the [Glycerin Hot Topics](#) page to view all available information related to the changes in the glycerin monograph, timetables, and impact on users. It centralizes access to the relevant information throughout the USP Web site and includes links to other related documents.



Question of the Month

How was the [Pending Monographs Guideline](#) modified?

In response to questions and comments received by USP, the Pending Monographs Guideline was modified in several ways. The revised Guideline:

- Clarifies what constitutes intent to file an application with FDA;
- Indicates that sponsors must promptly inform USP of any changes resulting from the regulatory review and approval process so the Pending Monograph can be updated accordingly;
- Indicates that USP will use its Revision Bulletin process to move a Pending Monograph to official status upon product approval rather than using an Interim Revision Announcement; and
- Indicates that USP must receive the bulk material necessary to develop any accompanying USP Reference Standards before posting a proposed Pending Monograph on its public Web site.