



January 2007

## 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 December 2006; 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that have been discontinued/have a new price and/or have a new package size; items with lots that are (or soon will be) no longer valid; and items with new lots since the last email notice.

### New Reference Standards Now Available

Catalog #	Description	Size	Price (USD)	Lot
1304209	Heptane	3 x 1.2 mL/ amp	168	F0E211
1667905	Tizanidine Hydrochloride	200 mg	281	F0F226
1504933	Pentane	3 x 1.2 mL/ amp	168	F0E196
1672206	Topiramate	200 mg	224	F0F297
1347700	Irbesartan	200 mg	168	F0F293
1224664	Docosyl Ferulate	50 mg	563	F0E143
1102974	Cetrimonium Bromide	1 g	168	F0F316

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

Catalog #	Description	Size	Price (USD)	Lot
1379106	Megestrol Acetate	500 mg	168	I1F281
1186000	Diazoxide	200 mg	168	H0F314
1606503	Rutin	100 mg	168	G1F308
1449518	Nabumetone	200 mg	168	G0F312

### Backorder Availability Estimates, January 2, 2007

Catalog #	Description	Expected Availability*
1667304	Ticarcillin Monosodium Monohydrate (200 mg)	Q1/07
1140509	Clorazepate Dipotassium CIV (125 mg)	Q1/07
1028000	Amitraz (200 mg)	Q1/07
1098231	Cefuroxime Axetil Delta-3-Isomers (15 mg)	Q1/07
1098173	Ceftizoxime (350 mg)	Q1/07
1094004	Carbenicillin Monosodium Monohydrate	Q1/07
1280009	Fluoxymesterone CIII (200 mg)	Q1/07
1498706	Parbendazole (200 mg)	Q1/07
1048620	Benazepril Related Compound A (15 mg)	Q1/07
1107300	Chloramphenicol Palmitate (200 mg)	Q2/07
1041609	Apraclonidine Hydrochloride (100 mg)	Q1/07

\*Dates are targets and may change at any time. Q1/07 = January—March 2007, Q2/07 = April—June 2007, Q3 = July—September 2007, Q4 = October—December 2007

Please contact your Customer Service Representative to place an order at (301)881-0666 or 1-800-227-8772. You can also order online at [www.usp.org](http://www.usp.org) (click on Products).



### RS Lots That Are No Longer Valid

This table lists previous RS lots that are (or will soon be) no longer valid for official use.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 and online at [www.usp.org](http://www.usp.org); click on the USP Products link and look up the RS of interest.

<b>No Longer Valid as of December 31 2006</b>				
<b>Catalog #</b>	<b>Description</b>	<b>Current Lot</b>	<b>Previous Lot/ Valid Use Date</b>	<b>Price</b>
1048007	Bacitracin Zinc (200 mg)	N1E200	N0A024 (12/06)	\$168
1098173	Ceftizoxime (350 mg)	I0E262	H (12/06)	\$168
1119309	Chlorthalidone Related Compound A (15 mg)	I0E270	H0D251 (12/06)	\$526
1176506	Dexamethasone Acetate (200 mg)	H0E339	G (12/06)	\$168
1237509	Epitetracycline Hydrochloride (200 mg) (AS)	G0E261	F (12/06)	\$526
1287609	Gadopentetate Monomeglumine (500 mg)	F1F094	F (12/06)	\$168
1365000	Levothyroxine (500 mg)	L0D226	K (12/06)	\$168
1440003	Methysergide Maleate (350 mg)	H1F038	H (12/06)	\$260
1441265	Metoprolol Related Compound D (50 mg)	G0E188	F0C378 (12/06)	\$563
1471506	Norfloxacin (200 mg)	H1D317	H (12/06)	\$168
1500251	Paroxetine Related Compound D (10 mg) (AS)	G0E096	F0C228 (12/06)	\$526
1500284	Paroxetine Related Compound G (0.4 mg)	G0E121	F0D110 (12/06)	\$526
1564006	Procaine Hydrochloride (200 mg)	I0E089	H (12/06)	\$168
1614308	Sodium Lactate (200 mg)	J0E249	I0C299 (12/06)	\$168
1623502	Succinylcholine Chloride (500 mg)	H1E325	H (12/06)	\$168
1700501	L-Tryptophan (200 mg)	G2E237	G-1 (12/06)	\$168

<b>No Longer Valid as of January 31, 2007</b>				
<b>Catalog #</b>	<b>Description</b>	<b>Current Lot</b>	<b>Previous Lot/ Valid Use Date</b>	<b>Price</b>
1009923	Acetyltriethyl Citrate (500 mg)	G0E085	F-1 (01/07)	\$176
1081501	Butamben (200 mg)	G0F059	F (01/07)	\$176
1177000	Dexamethasone Phosphate (200 mg)	K0E275	J1B070 (01/07)	\$176
1354207	Isradipine (200 mg)	H0E252	G0B054 (01/07)	\$176
1445470	Mometasone Furoate (200 mg)	H0E009	G0B073 (01/07)	\$176
1458009	Neomycin Sulfate (200 mg)	L3E135	L-2 (01/07)	\$176
1492007	Palmitic Acid (500 mg)	K0F048	J0D329(01/07)	\$176
1642212	Sumatriptan Succinate Related Compound A (15 mg)	G0F113	F0C221 (01/07)	\$703
1699005	Tropicamide (200 mg)	H0E307	G-1 (01/07)	\$140



Items with New Lots

Catalog Number	Description	Current Lot	Change Code	Previous Lot/ Valid Use Date	Price
1102974	Cetrimonium Bromide (1 g)	F0F316	1		\$176
1188709	Diclofenac Potassium (200 mg)	F0F269	1		\$176
1224664	Docosyl Ferulate (50 mg)	F0E143	1		\$587
1295724	Glyceryl Distearate (500 mg)	F0F284	1		\$176
1304209	Heptane (1.2 mL/ampule; 3 ampules)	F0E211	1		\$176
1347700	Irbesartan (200 mg)	F0F293	1		\$176
1482014	Oxandrolone Related Compound A <b>CIII</b> (20 mg)	F0F137	1		\$549
1504933	Pentane (1.2 mL/ampule; 3 ampules)	F0E196	1		\$176
1547302	Polyoxyl 10 Oleyl Ether (1 mL)	F0E078	1		\$176
1667905	Tizanidine Hydrochloride (200 mg)	F0F226	1		\$293
1672206	Topiramate (200 mg)	F0F297	1		\$234
1042500	L-Arginine (200 mg)	G2E280	2	G-1 (06/07)	\$176
1081002	Butalbital <b>CIII</b> (200 mg)	I0F204	2	H0C054 (12/07)	\$233
1091006	Capreomycin Sulfate (250 mg)	G1F191	2	G (11/07)	\$176
1091221	Captopril Disulfide (100 mg)	H0F251	2	G1B066 (12/07)	\$549
1095506	Carbidopa (400 mg)	J0F258	2	I (09/07)	\$176
1140430	Clopidogrel Bisulfate (125 mg)	G0F282	2	F0E115 (11/07)	\$785
1185020	Diazepam Related Compound A (25 mg)	I1F077	2	I (12/07)	\$549
1186000	Diazoxide (200 mg)	H0F314	2	G1C017 (11/07)	\$176
1271733	Fluconazole Related Compound C (10 mg)	G0F202	2	F0D082 (12/07)	\$549
1287008	Furosemide (125 mg)	K0F188	2	J1B131 (10/07)	\$140
1288500	Gemfibrozil (200 mg)	H1F285	2	H (11/07)	\$176
1314009	Hydrochlorothiazide (200 mg)	J0F070	2	I (11/07)	\$176
1336205	Ifosfamide (500 mg)	H0F233	2	G1C371 (12/07)	\$176
1342106	Insulin Human (100 mg)	I1F270	2	I0C383 (11/07)	\$176
1379106	Megestrol Acetate (500 mg)	I1F281	2	I (10/07)	\$176
1392705	Mesalamine (200 mg)	I0F121	2	H0C341 (12/07)	\$176
1436006	Methylprednisolone Acetate (200 mg)	I0F082	2	H0D148 (10/07)	\$176
1449518	Nabumetone (200 mg)	G0F312	2	F0C072 (11/07)	\$176
1454008	Nandrolone <b>CIII</b> (50 mg)	G0F291	2	F4D144 (10/07)	\$630
1606503	Rutin (100 mg)	G1F308	2	G0C355 (11/07)	\$176
1609002	Salicylic Acid (125 mg)	K0F112	2	J3C400 (12/07)	\$140
1708795	Valsartan Related Compound C (10 mg)	G0F241	2	F1D025 (10/07)	\$703



## USP Publication Highlights

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

**Publications Scheduled Ship Dates**

Publication	Scheduled Ship Date	On Schedule?
USP 30–NF 25, Supplement One – Print	February 1, 2007	Yes
USP 30–NF 25 – Online	February 1, 2007	Yes
USP 30–NF 25 – CD	February 1, 2007	Yes
PF 33(1) – Print	January 8, 2007	Yes
PF 32(6) – Online	December 29, 2006	Yes

Orders should arrive within two weeks of placement. If you do not receive your publication order when expected, please contact your Account Manager.

### **Stimuli Articles to Be Posted On The USP Website**

Starting in 2007, the *Stimuli* articles that are published in *Pharmacopeial Forum* will be simultaneously published on the USP website. Look for them at [www.usp.org](http://www.usp.org). There are no *Stimuli* articles in this issue of *Pharmacopeial Forum*, but those that will be published in the next issue of *Pharmacopeial Forum* will appear on the website in March 2007. For more information, please contact Stefan Schuber, Ph.D., Director, Scientific Reports (301-816-8551 or [sps@usp.org](mailto:sps@usp.org)).

### **USP Seeks Candidates for Three Expert Committees**

USP is seeking candidates to fill vacancies on the following 2005–2010 Expert Committees:

**Information: Clinical Toxicology**

**Information: Nephrology and Urology**

**Standards: Food Additives**

Expert Committee members directly influence drug quality in the United States and many other countries by establishing quality standards and information in the *United States Pharmacopeia* and the *National Formulary*, the *Food Chemicals Codex*, and the Medicare Model Guidelines. Expert Committee members also help further the best practices in pharmaceutical science nationally and globally.

**The Nominations Process.** Anyone can apply to be a potential candidate for Expert Committees via the candidate application on the USP website ([www.usp.org/nominate](http://www.usp.org/nominate)). Applicants will be asked to identify the Expert Committee(s) position for which they wish to be considered, and indicate their professional experience, education, USP experience, and other relevant experience.

Nominations for Expert Committee member positions close on **February 15, 2007**. Expert Committee member elections will be held in the **Spring 2007**. For further information, contact the Department of Volunteer and Organizational Affairs at [nominate@usp.org](mailto:nominate@usp.org).

### **New USP Pharmaceutical Ingredient Verification Service**

USP now offers pharmaceutical ingredient manufacturers worldwide a service to verify the quality of the products they produce. Drug substances and excipients that pass USP's audit, testing, and review process will receive a Certificate of Standards Compliance and will be awarded use of the USP Verified Pharmaceutical Ingredient Mark. USP also offers verification services for dietary supplements and dietary supplement ingredients. To learn more, visit [www.usp.org/USPVerified](http://www.usp.org/USPVerified)

## Education Highlights

### “USP Seminar on <467> Residual Solvents”

This new, half-day USP Pharmacopeial Education course will provide an overview of the significant changes to General Chapter <467>, which become official requirements on July 1, 2007. The course combines lectures and case studies to provide a practical overview of <467>. See the schedule of offerings below or go to

<http://www.usp.org/pdf/EN/eventsEducation/residualSolvents467Registration.pdf>

### USP to Offer Courses in Middle East, Africa, and Europe Spring 2007

To better serve our EMEA customers, we plan to offer several of our most popular courses in **Istanbul**, Turkey; **Amman**, Jordan; **Port Elisabeth** and **Johannesburg**, South Africa; and **Milan** and **Rome**, Italy this spring. Among the choices will be several dates and locations for **Analytical Method Validation** and **Fundamentals of Dissolution**, with opportunities to attend **Fundamentals of Microbiological Testing** and **Effectively Using the USP-NF** as well. For more details, please contact our European office at +41 (0) 61 361 30 10 or by email at [ap@usp.org](mailto:ap@usp.org).

For more information about our courses, visit us online at <http://www.usp.org/goto/pe>.

### Pharmacopeial Education Course Schedule — January through May 2007

Date	Name of Course	Location
18-19-Jan-07	USP/PDA Joint Conference: Residual Solvents	Bethesda, MD
30-31-Jan-07	Effectively Using the USP-NF -- Sessions I & II	Rockville, MD (USP Headquarters, 2-day)
8-Feb-07	Navigating Chapter <467> Residual Solvents (new)	Rockville, MD (USP Headquarters, half-day seminar)*
13-Feb-07	Navigating Chapter <467> Residual Solvents (new)	Raleigh, NC (half-day seminar)*
20-Feb-07	Navigating Chapter <467> Residual Solvents (new)	Dallas/Fort Worth, TX (half-day seminar)*
23-Feb-07	Essentials of USP Microbiological Testing (new)	Irvine, CA
27-Feb-07	Navigating Chapter <467> Residual Solvents (new)	Chicago, IL (half-day seminar/during Pittcon)*
6-Mar-07	Navigating Chapter <467> Residual Solvents (new)	East Brunswick, New Jersey (half-day seminar)*
15-Mar-07	Essentials of USP Microbiological Testing (new)	Raleigh, NC
15-Mar-07	Analytical Method Validation (in Spanish)	Mexico City, Mexico
20-Mar-07	Navigating Chapter <467> Residual Solvents (new)	San Francisco, CA (half-day seminar)*
22-Mar-07	Navigating Chapter <467> Residual Solvents (new)	Fullerton, CA (half-day seminar)*
27-Mar-07	Navigating Chapter <467> Residual Solvents (new)	Montreal, Canada (half-day seminar) <sup>1</sup>
19-Apr-07	Navigating Chapter <467> Residual Solvents (new)	Rockville, MD (USP Headquarters, half-day seminar)
8-9-May-07	Fundamentals of Dissolution	North Brunswick, NJ (with Distek, 2-day)*
22-May-07	Analytical Method Validation	Raleigh, NC
19-Jun-07	Effectively Using the USP-NF -- Sessions I & II	Raleigh, NC

\* Two identical half-day seminars, morning and afternoon, will be offered. To register, send your contact information by e-mail to [PharmacopeialEducation@usp.org](mailto:PharmacopeialEducation@usp.org) to receive a flyer/registration form by return e-mail. If space permits, registrations accepted later than fourteen days before each seminar date will be \$295.

1. Registration information will be provided closer to the date of the course.



If you are interested in attending a Pharmacopeial Education course in Rockville, MD, or having a custom course at your facility, please contact Kathy Muenchow at 301-816-8589 or email at [kmm@usp.org](mailto:kmm@usp.org).

Also, if you are interested in a Regional Pharmacopeial Education course in your area, please contact Steven Paul at 301-816-8210 or by email at [stp@usp.org](mailto:stp@usp.org).

### Tip of the Month

In the First Interim Revision Announcement in *PF33(1)*, there is a new <711> Dissolution Test 4 for tablets labeled 1.25 mg. There are also revisions to Dissolution Tests 1-3. These changes are official on February 1, 2007.

### Question of the Month

If a material conforms to the USP monograph, may it be labeled “USP”? Or must it be manufactured using USP procedures?

**Answer:** If a material conforms to the USP monograph it may be labeled as USP. Conformance to a USP monograph means that the material will conform to the USP monograph throughout its shelf-life. Conformance also means that the material was manufactured under cGMPs. Please refer to the FDA cGMPs for manufacturing concerns. Any test procedures used, whether in-house or USP, should be performed under cGLPs. Users are encouraged to review USP General Notices in the front of *USP-NF*. Here one will find a wealth of informative and legally binding information.