



March 2007

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For all the latest information visit www.usp.org



Reference Standards Highlights

New Milestone: USP has 2000 Reference Standard Catalog items

Below are several tables with the latest Reference Standard information including out-of-stock items now available; new Reference Standards released in February 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that have been discontinued/have a new price and/or have a new package size; items with lots that are (or soon will be) no longer valid; and items with new lots since the last email notice.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

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Catalog #	Description	Size	Lot	Price (USD)
1090717	Capecitabine Related Compound A	20 mg	F0G027	\$549
1090728	Capecitabine Related Compound B	20 mg	F0G026	\$549
1090739	Capecitabine Related Compound C	20 mg	F0G023	\$549
1134459	Ciprofloxacin Formamide	125 mg	F0G009	\$549
1154605	Cyclohexylmethanol	1 mL/ ampule; 2 ampules	F0F072	\$176
1161010	Cyproheptadine Related Compound A (AS)	40 mg	F0F350	\$549
1225511	Doxepin Related Compound A	50 mg	F0G020	\$549
1283415	Fosinopril Related Compound A	25 mg	F0G019	\$549
1283426	Fosinopril Related Compound B	15 mg	F0F337	\$549
1283437	Fosinopril Related Compound C	15 mg	F0F339	\$549
1283448	Fosinopril Related Compound D	15 mg	F0F340	\$549
1283459	Fosinopril Related Compound E	15 mg	F0F341	\$549
1283481	Fosinopril Related Compound H	25 mg	F0F346	\$549
1291683	Powdered American Ginseng Extract	1.5 g	F0F323	\$587
1379183	Melamine	250 mg	F0G025	\$176
1430203	Methyl Isobutyl Ketone	1.2 mL/ampule; 3 ampules	F0E195	\$176
1437600	Methylsulfonylmethane	200 mg	F0F298	\$176
1554206	Pravastatin Sodium	50 mg	F0G003	\$189
1554931	Prednicarbate Related Compound C	20 mg	F0G016	\$549
1623615	Sucrose Octaacetate	500 mg	F0G032	\$176
1692527	Trimethoprim Related Compound B (AS)	25 mg	F0G010	\$549
1711440	Verapamil Related Compound F	150 mg	F0F185	\$549



Previously Out-of-Stock Items Now Available

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Catalog #	Description	Size	Lot	Price (USD)
1041609	Apraclonidine Hydrochloride	100 mg	I0G001	\$540
1048620	Benazepril Related Compound A	15 mg	G0F352	\$549
1098231	Cefuroxime Axetil Delta-3 Isomers	10 mg	H2G014	\$549
1158504	Cyclosporine	50 mg	I0F343	\$540
1316004	Hydrocortisone	200 mg	N0F289	\$176
1500262	Paroxetine Related Compound E Mixture	25 mg	F2G002	\$549
1576708	Propylene Glycol	1 mL	J0F211	\$176
1667304	Ticarcillin Monosodium Monohydrate	350 mg	I0G021	\$176

Backorder Availability Estimates, February 19, 2007

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Catalog #	Description	Expected Availability*
1028000	Amitraz (200 mg)	Q1/07
1078766	Bupropion Hydrochloride Rel Cpd C	Q2/07
1078799	Bupropion Hydrochloride Rel Cpd F	Q2/07
1094004	Carbenicillin Monosodium Monohydrate	Q1/07
1098027	Cefpodoxime Proxetil (350 mg)	Q1/07
1107300	Chloramphenicol Palmitate (200 mg)	Q2/07
1131009	Cholecalciferol (30 mg/ampule; 5	Q1/07
1138507	Clocortolone Pivalate (200 mg)	Q1/07
1140509	Clorazepate Dipotassium CIV (125 mg)	Q1/07
1280009	Fluoxymesterone CIII (200 mg)	Q1/07
1719000	Warfarin (200 mg)	Q2/07

*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

Items with New Package Size

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Catalog #	Description	Old Size	New Size	Lot	Price (USD)
1098231	Cefuroxime Axetil Delta-3 Isomers	15 mg	10 mg	H2G014	\$549
1667304	Ticarcillin Monosodium Monohydrate	200 mg	350 mg	I0G021	\$176



RS Lots That Are No Longer Valid

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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 February 28, 2007				
Catalog #	Description	Previous Lot/ Valid Use Date	Current Lot	Price (USD)
1042000	Aprobarbital CIII (200 mg) (AS) DISCONTINUED	F-1 (02/07)		
1048630	Benazepril Related Compound B (15 mg)	F0C256 (02/07)	F1E156	\$549
1055002	Benzoic Acid (300 mg)	F6B173 (02/07)	G0D223	\$176
1057507	Benzothiadiazine Related Compound A (100 mg)	H0B069 (02/07)	I0F027	\$549
1083100	3-tert-Butyl-4-hydroxyanisole (200 mg)	K0C239 (02/07)	L0E259	\$176
1134313	Ciprofloxacin (200 mg)	G-1 (02/07)	H0E306	\$140
1242000	Erythromycin (250 mg)	M (02/07)	M1E251	\$176
1270377	Fexofenadine Hydrochloride (200 mg)	F0D244 (02/07)	F1E289	\$176
1356654	Labetalol Hydrochloride (200 mg)	G (02/07)	G1F090	\$176
1431603	Methyl Palmitate (300 mg)	F (02/07)	G0E329	\$176
1438001	Methyltestosterone CIII (200 mg)	J (02/07)	J1E324	\$233
1457006	Naphazoline Hydrochloride (200 mg)	K (02/07)	L0E207	\$176
1461003	Niacin (200 mg)	H2C121 (02/07)	I0E295	\$176
1535507	Phenytoin Sodium (200 mg)	H (02/07)	H1E335	\$176
1623626	Sucralose (400 mg)	G0B028 (02/07)	G1E317	\$176
1636005	Sulfasalazine (125 mg)	G-2 (02/07)	G3F035	\$140
1640002	Sulfisoxazole Diolamine (500 mg) DISCONTINUED	F (02/07)		
1667450	Tioconazole Related Compound A (25 mg)	G (02/07)	H0F095	\$549
1694001	Tripelennamine Citrate (200 mg) DISCONTINUED	G (02/07)		
1719102	Warfarin Related Compound A (50 mg)	G1B111 (02/07)	H0E268	\$176



No Longer Valid as of March 31, 2007

Catalog #	Description	Previous Lot/ Valid Use Date	Current Lot	Price (USD)
1008501	Acetylcholine Chloride (200 mg)	G (03/07)	H0F091	\$176
1031401	Amoxapine (200 mg)	G (03/07)	G1D375	\$176
1078325	Bumetanide Related Compound A (10 mg)	F-2 (03/07)	G0F031	\$549
1083008	2-tert-Butyl-4-hydroxyanisole (200 mg)	L0C028 (03/07)	L1E348	\$176
1138904	Clofazimine (200 mg)	F (03/07)	F1C392	\$176
1171003	Denatonium Benzoate (200 mg)	I0B129 (03/07)	I1F025	\$176
1173257	Desogestrel Related Compound B (15 mg)	F0B284 (03/07)	G0F144	\$549
1250008	Estradiol (500 mg)	L0C337 (03/07)	M0E309	\$176
1286708	Fumaric Acid (200 mg)	G-1 (03/07)	H0E328	\$176
1295607	Glycerin (2 mL)	H0C073 (03/07)	H1E032	\$176
1299007	Griseofulvin (200 mg)	I (03/07)	I1D406	\$176
1333003	Hydroxyzine Hydrochloride (500 mg)	I0C385 (03/07)	J0F024	\$176
1372005	L-Lysine Hydrochloride (200 mg)	H (03/07)	I0E230	\$176
1377508	Meclocycline Sulfosalicylate (300 mg)	G (03/07)	H0F087	\$176
1388005	Meprednisone (200 mg)	G (03/07)	H0F217	\$176
1441243	Metoprolol Related Compound B (50 mg)	F0C377 (03/07)	G0E189	\$587
1485191	Oxycodone CII (200 mg)	I1D206 (03/07)	J0F026	\$233
1559006	Prednisone (250 mg)	M0D211 (03/07)	N0E330	\$176
1708762	Valsartan (350 mg)	F0C147 (03/07)	G0F065	\$176

Items with New Lots

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Catalog #	Description	Change Code	Previous Lot/ Valid Use Date	Current Lot	Price (USD)
1023403	Diazepam Related Compound B (25 mg)	2	I1C102 (02/08)	J0F235	\$549
1041609	Apraclonidine Hydrochloride (100 mg)	2	H0B112 (12/07)	I0G001	\$540
1048620	Benazepril Related Compound A (15 mg)	2	F0C252 (02/08)	G0F352	\$549
1098231	Cefuroxime Axetil Delta-3-Isomers (10 mg)	2,3	H1E186 (12/07)	H2G014	\$549
1150353	Creatinine (100 mg)	2	F (01/08)	F1F318	\$176
1158504	Cyclosporine (50 mg)	2	H-1 (12/07)	I0F343	\$540
1316004	Hydrocortisone (200 mg)	2	M1C110 (02/08)	N0F289	\$176
1370611	Lovastatin Related Compound A (10 mg)	2	H0D274 (1/08)	I0F257	\$549
1469005	Norethindrone (200 mg)	2	K0C307 (02/08)	L0F237	\$176
1500218	Paroxetine Hydrochloride (350 mg)	2	G0D003 (02/08)	G1F261	\$176
1500262	Paroxetine Related Compound E Mixture (25 mg)	2	F1F028 (01/08)	F2G002	\$549
1576708	Propylene Glycol (1 mL)	2	I0C022 (12/07)	J0F211	\$176
1667304	Ticarillin Monosodium Monohydrate (350 mg)	2,3	H (08/07)	I0G021	\$176



USP Publication Highlights

Reminder of Delayed Implementation for *USP30-NF25*

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Please be aware that USP has delayed the implementation of *USP30-NF25* by several months. This change was adopted to give users more time to bring their methods and procedures into compliance with new and revised *USP-NF* requirements. Below is a schedule for when new issues will be official. Until May 1, 2007, please continue to use *USP29-NF24* and the appropriate Supplement and Interim Revision Announcements. For more details, please visit our website at:

<http://www.usp.org/USPNF/notices/implementationPeriodExtension.html>

Publication	Release Date	Official Date	Official Until
USP30-NF25	Nov. 1, 2006	May 1, 2007	May 1, 2008 (except as superceded by Supplements, IRAs, and Revision Bulletins)
First Supplement	Feb. 1, 2007	Aug. 1, 2007	May 1, 2008 (except as superceded by Second Supplement, IRAs, and Revision Bulletins)
Second Supplement	June 1, 2007	Dec. 1, 2007	May 1, 2008 (except as superceded by IRAs and Revision Bulletins)
USP31-NF26	Nov. 1, 2007	May 1, 2008	May 1, 2009 (except as superceded by Supplements, IRAs, and Revision Bulletins)

2007 USP Dictionary Available April 1

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The new USP Dictionary of USAN and International Drug Names will be available in April, in print and online formats, \$299 each. The 2007 edition features more than 9,000 updates, including over 3,700 new and revised graphic formulas and over 1,000 additional pronunciations! Order now at <http://www.usp.org/products/dictionary/>.



Publications Scheduled Ship Dates

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

Publication	Scheduled Ship Date	On Schedule?
PF 33(2)—Online	March 1, 2007	Yes
PF 33(2)—Print	March 8, 2007	Yes
USP30-NF25 First Supplement—Spanish	March 30, 2007	Yes
USAN Online 2007	March 31, 2007	Yes
USAN 2007	April 1, 2007	Yes

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

USP International Standards

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The United States Pharmacopeia (USP) approach for International Standards allows the creation of documentary standards (monographs) for drug substances and drug products that have been approved in and are legally marketed in countries other than the United States and are intended to treat neglected diseases. The purpose of these monographs is to support testing by first (e.g., manufacturer), second (e.g., payors), and third (e.g., government control laboratories) parties. Manufacturers wishing to signal conformance to these monographs may use the following block letters—USP-I. USP Reference Standards to allow testing in accordance with an International Standards monograph may be available in USP's catalogue at a future date.

The initial two drugs included in the program are used in the treatment of HIV-AIDS: Abacavir Sulfate and Efavirenz. These monographs are posted in draft form, with a 90-day period for public comment that ends on April 30, 2007. The draft monographs, Instructions for submitting comments and more information on the program are at <http://www.usp.org/internationalStandards/>.

Education Highlights

“Essentials of USP Microbiological Testing”

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Our microbiology course has been thoroughly revised to reflect revisions to the Microbiological Tests General Chapters. The revised course now includes <1227> Validation of Microbial Recovery, and <1223> Validation of Alternative Microbiological Methods. Also covered are newly harmonized <61> and <62> Microbiological Examination of Nonsterile Products. Also, the following additional topics will be covered: Metabolism and Environmental Requirements, Taxonomy, Basic Lab Practices, Variability of Microbial Data. This course will be offered in Raleigh, NC, on March 15, 2007.



“Navigating Chapter <467> Residual Solvents”

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This 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 Africa and Europe Spring 2007

To better serve our EMEA customers, we plan to offer several of our most popular courses in **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 **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.

Pharmacopeial Education Course Schedule — March through June 2007

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The Americas		
Date	Name of Course	Location
6-Mar-07	Navigating Chapter <467> Residual Solvents*	East Brunswick, New Jersey (half-day seminar)
7-Mar-07	Navigating Chapter <467> Residual Solvents	East Brunswick, New Jersey (morning only)
15-Mar-07	Essentials of USP Microbiological Testing	Raleigh, NC
20-Mar-07	Navigating Chapter <467> Residual Solvents*	San Francisco, CA (half-day seminar)
22-Mar-07	Navigating Chapter <467> Residual Solvents*	Fullerton, CA (half-day seminar)
27-Mar-07	Navigating Chapter <467> Residual Solvents*	Montreal, Canada (half-day seminar) ¹
10-Apr-07	Navigating Chapter <467> Residual Solvents (new)	Toronto, Canada (half-day seminar) ³
19-Apr-07	Navigating Chapter <467> Residual Solvents	Rockville, MD (USP Headquarters, half-day seminar)
8-9-May-07	Fundamentals of Dissolution	North Brunswick, NJ (with Distek, 2-day)
17-May-07	Analytical Method Validation (in Spanish)	Mexico City, Mexico ²
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 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. For registration information, contact custserv@acamchem.com
2. For registration information, contact ventas@proquifa.com.mx
3. For registration information, contact Pharmaceutical Sciences Group, Wendy Drake 905-513-7743 ext. 223 or Email: wdrake@psg.ca



Europe/ Middle East/ Africa/ India		
Date	Name of Course	Location
23-Apr-07	Navigating Chapter <467> Residual Solvents	Munich, Germany*
24-Apr-07	Navigating Chapter <467> Residual Solvents	Berlin, Germany*
26-Apr-07	Navigating Chapter <467> Residual Solvents	Liverpool, UK*
27-Apr-07	Navigating Chapter <467> Residual Solvents	Brussels, Belgium*
7, 8-May-07	Fundamentals of Dissolution (2-day) (In English with assistance for Italian)	Milano, Italy**
10, 11-May-07	Fundamentals of Dissolution (2-day) (In English with assistance for Italian)	Rome, Italy**
30-May-07	Analytical Method Validation	Johannesburg, SA***
31-May-07	Fundamentals of Dissolution (Lectures)	Johannesburg, SA***
12-Jun-07	Effectively Using the USP-NF -- Sessions I & II (In English with assistance for Italian)	Milano, Italy ****
14-Jun-07	Analytical Method Validation (In English with assistance for Italian)	Rome, Italy****

* Register with: USP Basel, Alfonsa Paschaloudis, Phone: +41 (0)61 316 30 10; Fax: +41 (0)61 316 30 11; E-mail: ap@usp.org

** Register with SOTAX AG: <http://www.sotax.com/sotax/events.html> (lecture in English language with course handbook and presentation slides in Italian)

*** Register with: Industrial Analytical Ltd., Ms. Berdine du Plessis, Phone: +27 (0)11 466 4321; E-mail: berdine@industrialanalytical.co.za

**** Register with: Nova Chimica, Via Galileo Galilei 47, 20092 Cinisello Balsamo (MI) Italy, Phone: +39 (02) 660 45392; Fax: +39 (02) 660 45394; E-mail: info@novachimica.com (lecture in English language with course handbook and presentation slides in Italian)

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.

Also, if you are interested in a Regional Pharmacopeial Education course in your area, please contact Kathy Meunchow at 301-816-8589 or by email at kmm@usp.org. For a course at your facility, please contact Steven Paul at 301-816-8210 or by email at stp@usp.org.

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



Tip of the Month

Visit the USP web site at <http://www.usp.org/USPNF/notices/> for Revision Bulletins and Announcements. From Rules and Procedures of the 2005-2010 Council of Experts 9.02(d)- If the circumstances require immediate publication of official text, a proposal or postponement may be published as final through a Revision Bulletin. Revision Bulletins shall be published on the USP website, and shall be immediately official unless otherwise specified in the Revision Bulletin. Notice of a Revision Bulletin shall also be provided directly to affected parties, including the Food and Drug Administration (FDA).

Question of the Month

When performing a USP dissolution test and an out of specification result is obtained for one vessel, after investigation, is it OK to just repeat the dissolution with one dosage unit and use the other results from the initial run?

Answer:

No. Some tests, such as those for Dissolution and Uniformity of dosage units, require multiple dosage units in conjunction with a decision scheme. These tests, albeit using a number of dosage units, are in fact the singlet determination of those particular attributes of the specimen. (General Notices section Test Results, Statistics, and Standards *USP 29-NF 24* p. 8 -9)