



June 2009



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For all the latest information, visit www.usp.org

USP Catalogs ▶ [USP Publications Catalog](#) ▶ [USP Catalog](#) ▶ [USP Pharmacopeial Education Catalog](#)

USP Print Catalog Schedule is Changing: USP will publish the print version of the catalog three times a year in January, May, and September. Please note that the electronic version of the USP Catalog will still be published six times a year in January, March, May, July, September, and November. The electronic catalog features the same information as the print version and can be downloaded and printed from your computer. The electronic catalog can be accessed 24/7 at www.uspcatalog.com.

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 2009; 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that have been discontinued/have a new price and/or have a new package size; items with lots that are (or soon will be) no longer valid; and items with new lots since the last email notice.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)
1012112	S-Adenosyl-L-Homocysteine	50 mg	F0G241	\$216
1235853	Enoxaparin Sodium Molecular Weight Calibrant A	6.2 mg	F0H193	\$400
1457618	Nateglinide Related Compound A	10 mg	F0I015	\$605
1457630	Nateglinide Related Compound C	5 mg	F0I014	\$605
1600121	Rebaudioside A	300 mg	F0I077	\$330
1617474	Defatted Powdered Soy	2.5 g	F0I076	\$194
1622408	Stevioside	30 mg	F0I080	\$210
1667144	Ticlopidine Hydrochloride	150 mg	F0I089	\$194
1667155	Ticlopidine Related Compound A	20 mg	F0I090	\$605
1667166	Ticlopidine Related Compound B	20 mg	F0I091	\$605
1707855	Valacyclovir Related Compound C	10 mg	F0I078	\$605
1707861	Valacyclovir Related Compound D	15 mg	F0I083	\$605
1707894	Valacyclovir Related Compound G	50 mg	F0I075	\$605
1711100	Vasopressin	1.78 mg	F0G346	\$194
1724907	Zolpidem Tartrate	200 mg	F0I086	\$257

Previously Out-of-Stock Items Now Available

Catalog #	Description	Size	Lot	Price (USD)
1078799	Bupropion Hydrochloride Related Compound F	30 mg	H0H224	\$658
1119309	Chlorthalidone Related Compound A	10 mg	J0I095	\$605
1354218	Isradipine Related Compound A	15 mg	H0H457	\$605
1598303	Ramipril	125 mg	G11058	\$197

Backorder Availability Estimates, June 8, 2009

Catalog #	Description	Expected Availability*
1471007	Norethynodrel (200 mg)	N/A-Discontinued**
1500262	Paroxetine Related Compound E Mixture (25 mg)	Q2/09

*Dates are targets and may change at any time. Q2/09=April–June 2009

**PF 35(1) - page 92 monograph and RS are going to be canceled because the drug is no longer used and there is no source of material.

Items with New Package Size or New Description

Catalog #	Description	Old Size	New Size	Lot	Price (USD)
1119309	Chlorthalidone Related Compound A	15 mg	10 mg	J0I095	\$605
1354218	Isradipine Related Compound A	10 mg	15 mg	H0H457	\$605
1598303	Ramipril	200 mg	125 mg	G11058	\$197



RS Lots That are No Longer Valid

These Tables 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, 2009				
Catalog #	Description	Previous Lot/ Valid Use Date	Current Lot	Price (USD)
1020008	Aminobutanol (500 mg)	G-1 (05/09)	H0G256	\$484
1032007	Amphotericin B (125 mg)	J3C246 (05/09)	K0H185	\$154
1086301	Calcitriol (10 mg)	G0F104 (05/09)	H0H053	\$1,555
1091006	Capreomycin Sulfate (250 mg)	G1F191 (05/09)	H0H181	\$194
1134379	Clarithromycin (75 mg)	G0D356 (05/09)	G1G324	\$194
1154503	Cyclobenzaprine Hydrochloride (200 mg)	G0A013 (05/09)	H0G399	\$194
1235274	Enalaprilat (300 mg)	J0C268 (05/09)	J1G349	\$154
1392454	Meropenem (300 mg)	G0F100 (05/09)	H0G402	\$227
1448005	Morphine Sulfate CII (500 mg)	O0F186 (05/09)	P0H037	\$413
1460736	Nevirapine Related Compound B (15 mg)	F0D033 (05/09)	G0G271	\$605
1467804	Nizatidine (200 mg)	G (05/09)	H0G401	\$194
1472000	Norgestrel (125 mg)	J0C269 (05/09)	J1G387	\$154
1514008	Phenacetin Melting Point Standard (500 mg) (Approximately 135 degrees)	H3A009 (05/09)	I0H080	\$116
1546300	Polydimethylsiloxane (500 mg)	H0C020 (05/09)	I0G306	\$194
1559006	Prednisone (250 mg)	N0E330 (05/09)	O0G356	\$194
1592409	Quercetin (500 mg)	G0D407 (05/09)	H0G321	\$194
1667472	Tioconazole Related Compound C (25 mg)	G (05/09)	H0F262	\$605



No Longer Valid as of June 30, 2009				
Catalog #	Description	Previous Lot/ Valid Use Date	Current Lot	Price (USD)
1002505	Acesulfame Potassium (200 mg)	F0C136 (06/09)	G0H082	\$323
1005706	Glacial Acetic Acid (1.5 mL/ampule; 3 ampules)	F0D002 (06/09)	G0E279	\$194
1029909	Ammonio Methacrylate Copolymer Type A (500 mg)	F-1 (06/09)	G0G291	\$194
1061005	Benztropine Mesylate (200 mg)	I0C038 (06/09)	I1H117	\$194
1288510	Gemfibrozil Related Compound A (20 mg)	G0D369 (06/09)	H0H180	\$605
1292303	Glimepiride (200 mg)	F0E228 (06/09)	F1H150	\$299
1300004	Guaiacol (1 g)	K (06/09)	L0G102	\$194
1330005	Hypromellose (250 mg) (Hydroxypropyl Methylcellulose)	H0C387 (06/09)	H1H066	\$194
1357001	L-Leucine (200 mg)	H0B237 (06/09)	H1H198	\$194
1361009	Levodopa (200 mg)	I (06/09)	J0H244	\$194
1448923	Mupirocin Lithium (100 mg)	H0C176 (06/09)	I0H095	\$194
1500808	Penbutolol Sulfate (200 mg)	F (06/09)	G0H272	\$194
1601000	Reserpine (200 mg)	O0C106 (06/09)	P0H197	\$194
1611900	Selegiline Hydrochloride (200 mg)	G (06/09)	H0G394	\$194
1612550	Sevoflurane Related Compound A (0.2 mL)	G0F348 (06/09)	H0H072	\$605
1623648	Sufentanil Citrate CII (25 mg)	H1E105 (06/09)	I0G358	\$273
1665003	Thiothixene (250 mg)	G (06/09)	H0B317	\$194
1667461	Tioconazole Related Compound B (25 mg)	G (06/09)	H0F264	\$605
1681000	Trichlormethiazide (200 mg)	H (06/09)	I0H202	\$194

No Longer Valid as of July 31, 2009				
Catalog #	Description	Previous Lot/ Valid Use Date	Current Lot	Price (USD)
1044800	Atracurium Besylate (100 mg)	F0B143 (07/09)	F1H342	\$194
1140586	Clopidogrel Related Compound A (20 mg)	F1F332 (07/09)	G0H250	\$735
1140600	Clopidogrel Related Compound C (20 mg)	F1F333 (07/09)	F2H215	\$735
1224802	Docusate Sodium (500 mg)	K0D134 (07/09)	L0H276	\$194
1329800	Hydroxypropyl Cellulose (500 mg)	G0F066 (07/09)	H0H051	\$194
1335541	Ibuprofen Related Compound C (0.2 mL/ampule; 3 ampules)	F0F011 (07/09)	F1H048	\$605
1347700	Irbesartan (200 mg)	F0F293 (07/09)	G0H216	\$194
1432005	Methylparaben (125 mg)	K0C382 (07/09)	K1H071	\$154
1457403	Naproxen Sodium (200 mg)	J0C379 (07/09)	J1H092	\$194
1499414	Paricalcitol Solution (3 mL)	F0F182 (07/09)	G1I063	\$310
1500502	Particle Count Set (2 blanks and 2 suspensions)	J0D067 (07/09)	K0H089	\$605
1539508	Pimozide (200 mg)	G (07/09)	G1H103	\$194
1546809	Low-Density Polyethylene (3 strips)	H0E114 (07/09)	I0G312	\$194
1553000	Pralidoxime Chloride (200 mg)	G-2 (07/09)	H0H050	\$194
1601623	Residual Solvent Class 2 - Methanol (1.2 mL/ampule; 3 ampules)	F0D045 (07/09)	G0H294	\$194
1604701	Ritodrine Hydrochloride (200 mg)	G-1 (07/09)	H0G333	\$194
1612630	Silybin (50 mg)	G0D392 (07/09)	G1H175	\$194
1613509	Sodium Ascorbate (200 mg)	G2C067 (07/09)	H0G289	\$194
1620220	Stavudine System Suitability Mixture (10 mg)	F0E051 (07/09)	F1G128	\$605
1676000	Triamcinolone (250 mg)	I0G157 (07/09)	J0H208	\$194
1708784	Valsartan Related Compound B (10 mg)	F0G129 (07/09)	G0H058	\$775



Items with New Lots

Catalog #	Description	Previous Lot/ Valid Use Date	Current Lot	Price (USD)
1078799	Bupropion Hydrochloride Related Compound F (30 mg)	G0G010 (05/10)	H0H224	\$658
1087009	Calcium Pantothenate (200 mg) (Vitamin B5)	O0C331 (05/10)	O1H081	\$194
1119309	Chlorthalidone Related Compound A (10 mg)	I0E270 (05/10)	J0I095	\$605
1197302	Diflorasone Diacetate (200 mg)	G (06/10)	H0G388	\$194
1353500	Isotretinoin (200 mg)	I1E066 (05/10)	J0I094	\$194
1354218	Isradipine Related Compound A (15 mg)	G0G028 (05/10)	H0H457	\$605
1379401	Meloxicam (400 mg)	F0E158 (05/10)	G0I026	\$323
1441232	Metoprolol Related Compound A (20 mg)	F0C343 (05/10)	G0I042	\$647
1598303	Ramipril (125 mg)	G0D345 (05/10)	G1I058	\$194
1601340	Residual Solvent Class 2 - Acetonitrile (1.2 mL/ampule; 3 ampules)	F0D049 (05/10)	G0H335	\$194
1651009	Tetracycline Hydrochloride (200 mg)	L0C216 (05/10)	L1H374	\$194
1708795	Valsartan Related Compound C (10 mg)	G2H042 (06/10)	H0I005	\$775

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USP Publication Highlights

Please note: Prices for *USP–NF Online* will increase July 1. New price will be \$1005 per user for *USP–NF Online*.

	<p>Second Supplement to USP 32–NF 27 Published June 1. Make Sure You Have the Latest Standards.</p> <p>The <i>Second Supplement</i> to <i>USP 32–NF 27</i> published June 1, and standards in the main edition became official May 1. Subscribe today to ensure that you have access to the latest FDA-enforceable drug standards. <i>USP 32–NF 27</i> contains significant new information: more than 300 new and revised monographs and 26 new and revised General Chapters! Available in print, CD, and online formats. 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 (Select Europe).</p>
	<p>New 2009 USP Dictionary—More than 4,500 Updates!</p> <p>The new <i>USP Dictionary of USAN and International Drug Names</i> published April 1. Features include significant updates for generic and brand drug names, pronunciations, chemical structures, UNII codes, and more. Available in print and online formats. To order, visit 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 (Select Europe).</p>
	<p>New USP Dietary Supplements Compendium—Save \$50 through July 31!</p> <p>The new <i>USP Dietary Supplements Compendium (DSC)</i>, scheduled to publish this year, 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. Reserve your copy through July 31, 2009, for only \$375 (regular price is \$425)! Visit 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 (Select Europe).</p>
	<p>The Chinese Pharmacopoeia 2005 English Edition Now Available from USP</p> <p>Prepared in accordance with the principles and design plan decided by the Eighth Chinese Pharmacopoeia Commission and its Secretariat over more than two years, <i>The Chinese Pharmacopoeia 2005</i> features more than 3,200 drug monographs, with 525 new admissions, and other new revisions. Translated into English. To learn more or order, contact USP Customer Service at +1-301-881-0666, 1-800-227-8772 (U.S. and Canada), or 00-800-4875-5555 (Europe).</p>



Event Highlights

Hot Topic Meetings and Workshops

Enzymes (July 8–9, 2009): [Register](#)

Excipients (July 20–21, 2009) [Learn More](#)

Bioassays (August 12–13, 2009) [Learn More](#)

Topical Dermal Dosage Forms Workshop (September 14–15, 2009)

USP Annual Scientific Meeting 2009—North America, September 22–25, 2009, Toronto, Canada

USP's Annual Scientific Meeting is open to the public and serves as an interactive forum where USP and its stakeholders can discuss new direction and standards that affect the pharmaceutical, and food ingredients industries. The meeting provides attendees an opportunity to better understand the scope of USP's scientific work and provide input on key standards-setting issues. [Learn More](#)

Pharmacopeial Education

View the Latest USP Pharmacopeial Education Online Catalog—www.uspeducation.com

Get details on current and upcoming education offerings, including 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

Fundamentals of Bioassay Practices

Gain insight into the fundamentals of bioassay practices and principles necessary to implement the guidance outlined in *USP* chapters. Course provides discussion on statistical and assay design, analysis, and validation to help scientists develop and perform bioassays. Visit www.usp.org/education/pe/courses.html?course_id=175 to obtain details on special offers and group discounts.

Classroom Lecture: US \$595 (Special offers and group discounts available)

August 11, 2009; Rockville, MD

[Click here](#) to register.



Good Weighing Practices in the Pharmaceutical Industry: A Risk-Based Guideline

Driven by sound scientific and risk assessment principles, this course provides guidance to correct common misconceptions held by many companies regarding balance selection and use as well as incorrect testing programs utilized for maintenance e purposes.

Classroom Lecture: US \$795 (Special offers and group discounts available)

Coming in August, Raleigh, N.C.

Contact PharmEd@usp.org for additional information.

On-demand Modules 1 and 2 for “Developing Compendial HPLC Practices” Are now Available! (\$149 each)

Module 1 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. Module 2 covers equipment components, practical considerations, troubleshooting and issues related to USP and HPLC such as definitions, types of tests and calculation of results for monographs.

[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)

[“Register”](#)

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

[“Register”](#)

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

[“Register”](#)

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

[“Register”](#)

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

Call for Candidates—USP Council of Experts and Expert Committees

SCIENCE • INNOVATION • PASSION • COMMITMENT—YOU set the Standard

Volunteers on the Council of Experts, Expert Committees, and Expert Panels are an integral part of the USP standards-setting process. Participation as a USP volunteer expert affords you the unique opportunity to

- Influence Drug Quality
- Utilize Your Expertise
- Advance Your Profession
- Improve Public Health

USP invites qualified candidates—pharmaceutical scientists, academicians, regulatory professionals, healthcare professionals, and others—to apply to serve as scientific decision makers on the Council of Expert Committees. The 2010–2015 Council of Experts includes 20 Expert Committees in the areas of Nomenclature, Small Molecules, Biologics and Biotechnology, Excipients, General Chapters, Reference Standards, Compounding, Food Ingredients, and Dietary Supplements, with each member of the Council of Experts chairing an Expert Committee. USP is also seeking qualified candidates for its Expert Panels, which play an important advisory role to the Council of Experts. [Learn More](#)

Monograph Redesign—USP has received more than 2400 comments and is continuing the comment review process. Although the deadline has passed for comments to be included in *USP 33–NF 28*, you can still comment on the proposed design changes for *USP–NF* monographs. The comments received will be considered for Errata. 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.



New Official Text

Revision Bulletins:

[<1053> Biotechnology-Derived Articles--Capillary Electrophoresis](#) (HARMONIZATION)

(posted 29-May-2009; official 01-Jul-2009)

[<1054> Biotechnology-Derived Articles--Isoelectric Focusing](#) (HARMONIZATION)

(posted 29-May-2009; official 01-Jul-2009)

[<1055> Biotechnology-Derived Articles--Peptide Mapping](#) (HARMONIZATION)

(posted 29-May-2009; official 01-Jul-2009)

[Ethinyl Estradiol Tablets](#) (posted 29-May-2009; official 01-Jul-2009)

[Fenofibrate Capsules](#) (posted 29-May-2009; official 01-Jul-2009)

[Fluvoxamine Maleate Tablets](#) (posted 29-May-2009; official 01-Jul-2009)

[Triamcinolone Hexacetonide](#) (posted 29-May-2009; official 01-Jul-2009)

[Verapamil Hydrochloride Extended-Release Tablets](#) (posted 29-May-2009; official 01-Jul-2009)

IRAs (*Pharmacopeial Forum* 35(3) May–June 2009)

[Amantadine Hydrochloride Capsules and Bupropion Hydrochloride Extended-Release Tablets](#) (77KB)

(04/30/09)

Errata

[Vol. 35, No. 3 \[May–June 2009\]](#) (44KB) (04/30/09)

Compendial Notices

New:

[Metal Impurities Advisory Panel Recommendations to the General Chapters Expert Committee](#)

(28KB) (posted 02-June-2009)

[<3> and <725> Topical and Transdermal Products - USP Forwards Proposed General Chapters on](#)

[Topical and Transdermal Drug Products](#) (posted 29-May-2009)

General Announcements: Nothing new

Intent to Revise: [Levalbuterol Hydrochloride](#) (posted 29-May-2009)

General Chapter Status

The [General Chapters status page](#) provides users with the status of General Chapter revisions. The status is revised every other month to coincide with the Pharmacopeial Forum publication schedule.

Sign up to receive updates electronically at

www.usp.org/support/products/uspNewslettersRequest.html?promo=compendial



Stimuli Articles

Featured in *PF 35(3)*, May–June 2009

[Drug Product Performance and Interchangeability of Multisource Drug Substances and Drug Products](#) (2.4MB)

[Topical and Transdermal Drug Products](#) (2.4MB)

[Performance-based Monographs](#) (2.4MB)

[Acceptable, Equivalent, or Better: Approaches for Alternatives to Official Compendial Procedures](#) (2.4MB)

Tip of the Month

USP recently upgraded its Web site to offer visitors a more user-friendly and updated visual interface with enhanced navigation tools, including a new [A to Z index](#), a [Featured Events page](#), an updated [References Standards section](#), an expanded [log-in menu](#), and an improved "Information For" section that organizes links to specific content for key audiences. In addition, the [Healthcare Quality and Safety section](#) is now accessible from the [About USP page](#). A tutorial on how to use the site is available at www.usp.org/tutorial/.

Your comments and suggestions on the USP Web site upgrades are highly valued; we encourage all visitors to fill out the [Web site feedback survey](#). Thank you.

Question of the Month

In a **Related compounds** test, the *Chromatographic system* says to proceed as directed in the *Assay*. Do we pass system suitability as described in the *Assay* using the *Standard preparation* (if specified under the *Assay*) or do we use the *Standard solution* from the **Related compounds** test with some other specification?

You follow the requirements listed for the **Assay**.

