

**May 2009****Email Notice**

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

USP Catalogs

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have been discontinued/have a new price and/or have a new package size; items with lots that are (or soon will be) no longer valid; and items with new lots since the last email notice.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

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New Reference Standards Now Available

Catalog #	Description	Size	Lot	Price (USD)
1010106	N-Acetyl-L-Tyrosine	100 mg	F0I085	\$194
1048550	Behenoyl Polyoxylglycerides	500 mg	F0I006	\$194
1096688	Carvedilol System Suitability Mixture	25 mg	F0I001	\$605
1161586	Cystine	200 mg	F0I088	\$194
1171455	Dermatan Sulfate	25 mg	F0I068	\$605
1180015	Dextroamphetamine Related Compound A	25 mg	F0H131	\$605
1368201	Alpha Lipoic Acid	500 mg	F0I018	\$194
1448016	Morphine Sulfate Related Compound A	20 mg	F0H436	\$605
1479304	Oseltamivir Phosphate	200 mg	F0H431	\$250
1491296	Oxytocin Identification	15 mg	F0I056	\$250
1604621	Risedronate Related Compound A	20 mg	F0I072	\$605
1604632	Risedronate Related Compound B	20 mg	F0I073	\$605
1604643	Risedronate Related Compound C	20 mg	F0I082	\$605
1604916	Rocuronium Peak ID Mixture	25 mg	F0I053	\$905
1707872	Valacyclovir Related Compound E	25 mg	F0I079	\$605
1711133	Lypressin	2.2. mg	F0G404	\$194
1724893	Zolpidem CIV	10 mg	F0I064	\$257
1724918	Zolpidem Related Compound A CIV	15 mg	F0I065	\$605

Previously Out-of-Stock Items Now Available

Catalog #	Description	Size	Lot	Price (USD)
1048200	Baclofen	350 mg	J0H297	\$194
1430349	Methyl Linolenate	5 X 50 mg	H0I008	\$194

Backorder Availability Estimates, May 4, 2009

Catalog #	Description	Expected Availability*
1471007	Norethynodrel (200 mg)	Q3/09
1500262	Paroxetine Related Compound E Mixture (25 mg)	Q3/09

*Dates are targets and may change at any time. Q3/09=July–September 2009

Items with New Package Size or New Description

Catalog #	Description	Old Size	New Size	Lot	Price (USD)
1048200	Baclofen	500 mg	350 mg	J0H297	\$194



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 April 30, 2009				
Catalog #	Description	Previous Lot/ Valid Use Date	Current Lot	Price (USD)
1009005	Acetylcysteine (200 mg)	H1B169 (04/09)	I0G320	\$194
1030001	Amobarbital CII (200 mg)	F-2 (04/09)	F3G273	\$257
1040708	Apigenin-7-glucoside (30 mg)	F (04/09)	G0H057	\$605
1074007	Bisacodyl (125 mg)	I1B162 (04/09)	J0G408	\$154
1078325	Bumetanide Related Compound A (10 mg)	G0F031 (04/09)	H0G264	\$605
1082708	Butylated Hydroxytoluene (500 mg)	F0D122 (04/09)	F1G286	\$194
1097104	Cefadroxil (200 mg)	I1B319 (04/09)	J0H018	\$194
1098129	Ceftazidime, Delta-3-Isomer (10 mg)	H0E106 (04/09)	I0G189	\$605
1134233	Citalopram Hydrobromide (125 mg)	F0F157 (04/09)	F1G292	\$349
1242000	Erythromycin (250 mg)	M1E251 (04/09)	N0G117	\$194
1242032	Erythromycin Related Compound N (50 mg)	F2A023 (04/09)	G0H032	\$605
1270005	Fentanyl Citrate CII (100 mg)	K0C264 (04/09)	L0G319	\$299
1302305	Halazepam CIV (200 mg) (AS)	F1C224 (04/09)	G0H075	\$257
1303002	Haloperidol (200 mg)	I (04/09)	I1G285	\$194
1319002	Hydrocortisone Hemisuccinate (200 mg)	I0D343 (04/09)	J0H091	\$194
1370350	Lorazepam Related Compound D (25 mg)	G0A014 (04/09)	H0H002	\$605
1396502	Methacrylic Acid Copolymer Type B (200 mg)	G0B141 (04/09)	H0G385	\$194
1399001	Methamphetamine Hydrochloride CII (125 mg)	I (04/09)	I1G299	\$257
1415006	Methotrimeprazine (200 mg)	F-2 (04/09)	F3G335	\$194
1430305	Methyl Laurate (500 mg)	G0C356 (04/09)	H0H035	\$194
1443307	Mezlocillin Sodium (350 mg)	G (04/09)	H0H213	\$194
1444004	Minocycline Hydrochloride (200 mg)	I0C178 (04/09)	I1G208	\$194
1457301	Naproxen (200 mg)	I-1 (04/09)	J0H044	\$194
1463600	Nifedipine Nitrophenylpyridine Analog (25 mg)	K (04/09)	K1G378	\$605
1477900	Octinoxate (500 mg) (Octyl Methoxycinnamate)	H0D213 (04/09)	I0G246	\$194
1495005	Papain (1 g)	I1F174 (04/09)	J0H138	\$194
1645006	Testolactone CIII (125 mg)	F-1 (04/09)	F2E319	\$206
1653004	Theophylline (200 mg)	J0B180 (04/09)	J1H052	\$194
1667406	Timolol Maleate (200 mg)	G-1 (04/09)	H0H046	\$194

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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



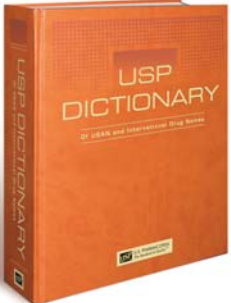
Items with New Lots

Catalog #	Description	Previous Lot/ Valid Use Date	Current Lot	Price (USD)
1031503	Amoxicillin (200 mg)	J0C043 (04/10)	K0H332	\$194
1048200	Baclofen (350 mg)	I (04/10)	J0H297	\$194
1152009	Cyanocobalamin (1.5 g of mixture with mannitol; 10.4 mcg/mg of mixture) (Vitamin B12)	N (03/10)	O0H288	\$194
1292507	Glipizide (125 mg)	G1C174 (04/10)	H0H396	\$154
1379300	Melphalan Hydrochloride (100 mg) (FOR U.S. SALE ONLY)	H0B296 (02/10)	I0H174	\$194
1430349	Methyl Linolenate (5 x 50 mg)	G0D320 (04/10)	H0I008	\$194
1449530	Nabumetone Related Compound A (15 mg)	F0D165 (03/10)	G0I062	\$605
1464001	Nitrofurantoin (500 mg)	J (04/10)	K0I060	\$194
1501108	Penicillamine Disulfide (200 mg)	I0F234 (04/10)	J0I007	\$605
1538006	Phytonadione (500 mg) (Vitamin K1)	N0B303 (04/10)	O0H310	\$194
1598314	Ramipril Related Compound A (30 mg)	F0C100 (02/10)	G0H441	\$615
1633007	Sulfanilamide Melting Point Standard (500 mg) (Approximately 165 degrees)	K0B133 (05/10)	L0H043	\$93
1642212	Sumatriptan Succinate Related Compound A (15 mg)	H0H253 (04/10)	H1H418	\$775
1683606	Triethyl Citrate (500 mg)	G0C393 (04/10)	G1G390	\$194
1708773	Valsartan Related Compound A (10 mg)	H1H329 (04/10)	H2I040	\$775

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USP Publication Highlights

	<p>USP 32–NF 27 Is Now Official! Make Sure You're Prepared to Meet Current Standards. <i>USP 32–NF 27</i> became official May 1, 2009. Subscribe today to ensure that you have access to up-to-date and FDA-enforceable drug standards. Through the <i>Second Supplement</i>, this latest edition contains significant new information: more than 300 new and revised monographs and 26 new and revised General Chapters! 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! The new <i>USP Dictionary of USAN and International Drug Names</i> published April 1. Features includes 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 June 30! 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 June 30, 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 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

Adulteration of Food Protein—The Need for New Prevention Strategies (June 16–17, 2009) [Learn More](#)

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)

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

Analysis of Metal Impurities by ICP–OES and ICP–MS

This highly-anticipated course covers instrumentation, method development, and method validation for the analysis of metal impurities in pharmaceutical materials currently being tested using *USP* General Chapter <231> Heavy Metals. The course will be taught with an emphasis on Inductively Coupled Plasma–Optical Emission Spectroscopy (ICP–OES) and Inductively Coupled Plasma–Mass Spectroscopy (ICP–MS) analysis consistent with *USP* General Chapter <730> Plasma Spectrochemistry.

Classroom Lecture: CAD \$495 (group discounts available)

June 11, 2009; Saint-Laurent, Quebec, Canada

[Click here](#) to register.

Dissolution: Theory and Best Practices

This two-day course provides focused, relevant instruction on the fundamentals of pharmaceutical dissolution testing as described in *USP* General Chapter <711> along with an overview of the theory, practice, and history of dissolution. In the lab session, you will also learn the practical aspects of conducting dissolution tests, best practices, and performance verification testing.

June 1–2, 2009; Distek Headquarters, Somerset, NJ

[Click here](#) to register.



Drug Product Performance, In Vivo and In Vitro (also know as Advanced Dissolution)

This two-day course provides in-depth instruction on USP in vivo and in vitro performance testing. Covers drug characteristics, data, and instrument qualification to establish the quality and safety of many different dosage forms.

June 3–4, 2009; Distek Headquarters, Somerset, NJ

[Click here](#) to register.

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.

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

This unique course, developed in conjunction with Mettler-Toledo, provides an in-depth look at the factors that contribute to weighing uncertainty as well as practical advice on how to avoid common mistakes in the lab. You will learn about balance selection, apparatus use, and maintenance testing programs.

Classroom Lecture: US \$795

May 19, 2009; Basel, Switzerland

June 4, 2009; Somerset, NJ

[Click here](#) to register.

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, trouble-shooting and issues related to USP and HPLC such as definitions, types of tests and calculation of results for monographs.

[Click here](#) to register.





General Notices: Cornerstone of *USP–NF* (Free Webinar)

The General Notices and Requirements section (the General Notices) presents the basic assumptions, definitions, and default conditions for interpretation and application of the *United States Pharmacopeia (USP)* and the *National Formulary (NF)*. For many scientific professionals, the *USP–NF* serves as a routine reference, but many individuals do not review and fully appreciate the information which resides in the General Notices section of the compendia. If used to its fullest, many come to appreciate the General Notices as a basis of understanding and return to it often for reference

[Click here](#) to register.

Upcoming PE Courses Worldwide—Click on Link for Dates and Details

- [Drug Product Performance, In Vivo and In Vitro \(also know as Advanced Dissolution\)](#)
- [Aseptic Processing and Compliance Tools for USP <797>](#)
- [Dissolution: Theory and Best Practices](#)

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—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 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:

[<2040> Disintegration and Dissolution of Dietary Supplements \(POSTPONEMENT\)](#) (posted 04/30/09; official 05/01/10)

[Enoxaparin Sodium and Enoxaparin Sodium Injection \(POSTPONEMENT\)](#) (posted 04/29/2009; official 12/01/2009)

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](#)

General Announcements:

[<1> Injections—USP Announcement on Labeling on Ferrules and Cap Overseals Section](#) (05/08/09)

[Update on the USP Green Tea Extract Monograph](#) (04/10/09)

[USP Revises Admission Criteria and Safety Classification for Dietary Supplements](#) (04/10/09)

Intent to Revise: [Tamsulosin Hydrochloride Capsules](#) (04/08/09)

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


<http://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

STAGE 4 AND STAGE 6 HARMONIZED STANDARDS ARE NOW FEATURED IN TWO SEPARATE PF SECTIONS. USP publishes monographs and general chapters that are undergoing international harmonization by the Pharmacopeial Discussion Group (PDG) at Stage 4 and Stage 6. The Stage 4 documents are published for public comment. The Stage 6 documents have received PDG approval. These documents are being published to inform readers of their PDG sign-off status.

To make clear the distinction between Stages 4 and 6, USP has revised the Harmonization section of *Pharmacopeial Forum* (*PF*) by separating the two types of documents. To help users further distinguish the documents, the Stage 6 documents in the print version of *PF* will bear a watermark indicating that they are not for comment. Stage 4 documents are published in *PF* in draft form and are available for public comment. The Japanese and the European Pharmacopoeias and the USP analyze comments and revise the general chapters and monographs accordingly. The documents are revised based on the comments received and then forwarded to the next stage. The Stage 6 documents are provided in *PF* as an informational resource, and these documents will be published in the next available official publication. The Stage 6 documents published in *PF* 35(3) will be official in *USP 33–NF 28*.

Question of the Month

An official monograph says “**Microbial enumeration tests <61> and Absence of specified microorganisms <62>**—It meets the requirements of the test for absence of *Salmonella* species”
Are all the tests in <61> required?

It does not mean that tests under <61> are required, when the monograph calls for only absence of specified microorganisms (<62>) and vice-versa. Both chapters are referenced because

- 1) Media for use in <61> are contained in <62>
- 2) Sample Prep, Neutralization for <62> are contained in <61>

Thus, only the test for absence of *Salmonella* species is required.

