



## June 2010

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For all the latest information, visit [www.usp.org](http://www.usp.org)

[USP Online Catalog](#)

## 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 2010; 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that have been discontinued/have a new price and/or have a new package size; items with lots that are (or soon will be) no longer valid; and items with new lots since the last email notice.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](http://www.usp.org/products).

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**New Reference Standards Now Available**

Catalog #	Description	Size	Lot	Price (USD)
1031514	Amoxicillin Related Compound A	15 mg	F0J120	\$620
1031536	Amoxicillin Related Compound C	15 mg	F0J128	\$620
1031591	Amoxicillin Related Compound I	15 mg	F0J147	\$620
1042805	Artemether Related Compound B	15 mg	F0I295	\$620
1134619	Clarithromycin Impurity D	10 mg	F0J140	\$620
1134620	Clarithromycin Impurity H	10 mg	F0J141	\$620
1134631	Clarithromycin Impurity Q	10 mg	F0J142	\$620
1257018	Ethambutol Related Compound A	15 mg	F0J050	\$620
1269163	Famciclovir System Suitability Mixture	20 mg	F0J076	\$620
1269174	Famciclovir Related Compound A	20 mg	F0J126	\$620
1269185	Famciclovir Related Compound B	20 mg	F0J077	\$620
1304050	Heparin Sodium with Oversulfated Chondroitin Sulfate	8.8 mg	F0J038	\$620
1437202	Methylpyrrolidone	2 g	F0I296	\$199
1443806	Milbemycin Oxime	200 mg	F0J089	\$199
1463960	Nitazoxanide	200 mg	F0J149	\$199
1463971	Nitazoxanide Related Compound A	25 mg	F0J133	\$620
1553859	Pramipexole Dihydrochloride Monohydrate	200 mg	F0J116	\$199
1576945	Propylene Oxide	5 X 0.1 mL	F0J087	\$199
1604676	Risperidone Related Compounds Mixture	25 mg	F0J004	\$620
1643554	Temozolomide Related Compound A	15 mg	F0I321	\$620
1643576	Temozolomide Related Compound C	15 mg	F0I323	\$620
1643656	Tenofovir Disoproxil Fumarate	200 mg	F0J134	\$199
1653117	Theophylline Melting Point Standard	500 mg	F0J123	\$119
1711268	Venlafaxine Hydrochloride	100 mg	F0I324	\$250
1724420	Ziprasidone Related Compound B	10 mg	F0I399	\$620

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

Catalog #	Description	Size	Lot	Price (USD)
1222002	Disodium Inosinate	500 mg	G0J162	\$199
1249789	Esomeprazole Magnesium	10 mg	G0I290	\$199
1294848	Gamma-Glutamyl-(S)-allyl-L-cysteine	25 mg	G0J002	\$860

**Backorder Availability Estimates, June 8, 2010**

No Backordered Items

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## Items with New Package Size or New Description

Catalog #	Description	Old Size	Size	Lot	Price (USD)
1059003	Benzphetamine Hydrochloride CIII*	200 mg	200 mg	G0I243	\$263
1150706	Crospovidone	200 mg	100 mg	H0I211	\$199
1294848	Gamma-Glutamyl-(S)-allyl-L-cysteine**	25 mg	25 mg	G0J002	\$860
1572536	Propofol Related Compound A	15 mg	10 mg	H0J107	\$620

\*This item has changed from an Authentic Substance to a Reference Standard

\*\*The chemical name has changed from Gamma-Glutamyl-S-allyl-L-cysteine to Gamma-Glutamyl-(S)-allyl-L-cysteine

## 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 Store online [here](#) using the Reference Standards: Alphabetical Listings to look up the item of interest.

No Longer Valid as of May 31, 2010				
Catalog #	Description	Previous Lot/ Valid Use Date	Current Lot	Price (USD)
1078799	Bupropion Hydrochloride Related Compound F (30 mg) (COLD SHIPMENT REQUIRED)	G0G010 (05/10)	H0H224	\$674
1087009	Calcium Pantothenate (200 mg) (Vitamin B5)	O0C331 (05/10)	O1H081	\$199
1119309	Chlorthalidone Related Compound A (10 mg)	I0E270 (05/10)	J0I095	\$620
1295006	Glutethimide CII (500 mg) <b>DISCONTINUED</b>	F (05/10)		\$263
1353500	Isotretinoin (200 mg)	I1E066 (05/10)	J0I094	\$199
1354218	Isradipine Related Compound A (15 mg)	G0G028 (05/10)	H0H457	\$620
1379401	Meloxicam (400 mg)	F0E158 (05/10)	G0I026	\$331
1441232	Metoprolol Related Compound A (20 mg)	F0C343 (05/10)	G0I042	\$663
1517607	L-Phenethicillin Potassium (200 mg) <b>DISCONTINUED</b>	F (05/10)		\$199
1598303	Ramipril (125 mg)	G0D345 (05/10)	G1I058	\$199
1601340	Residual Solvent Class 2 - Acetonitrile (1.2 mL/ampule; 3 ampules)	F0D049 (05/10)	G0H335	\$199
1633007	Sulfanilamide Melting Point Standard (500 mg) (Approximately 165 degrees)	K0B133 (05/10)	L0H043	\$95
1643000	Talbutal CIII (250 mg) <b>DISCONTINUED</b>	F (05/10)		\$263
1651009	Tetracycline Hydrochloride (200 mg)	L0C216 (05/10)	L1H374	\$199
1656308	Thiamylal CIII (200 mg) <b>DISCONTINUED</b>	F (05/10)		\$263

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No Longer Valid as of June 30, 2010					
Catalog #	Description	Previous Lot/ Valid Use Date	Current Lot	Price (USD)	
1134040	Ciclopirox Related Compound B (25 mg)	G0G105 (06/10)	G1H440	\$620	
1197302	Diflorasone Diacetate (200 mg)	G (06/10)	H0G388	\$199	
1286027	Folic Acid Related Compound A (50 mg)	I0B176 (06/10)	I1I097	\$199	
1287008	Furosemide (200 mg)	K0F188 (06/10)	L0H311	\$199	
1295800	Glycine (200 mg)	G0E099 (06/10)	G1H369	\$199	
1304038	Heparin Sodium Identification (50 mg)	F0H210 (06/10)	G0I116	\$199	
1370270	Loratadine (200 mg)	G0D344 (06/10)	H0H450	\$331	
1376006	Mecamylamine Hydrochloride (200 mg)	F-2 (06/10)	G0H154	\$199	
1441254	Metoprolol Related Compound C (20 mg)	F0C344 (06/10)	G0I043	\$663	
1478582	Ondansetron Hydrochloride (300 mg)	G1F249 (06/10)	G2I029	\$264	
1500251	Paroxetine Related Compound D (10 mg) (AS)	G0E096 (06/10)	H0H383	\$620	
1570428	2-Propanol (1.2 mL/ampule; 3 ampules)	F0E245 (06/10)	G0H068	\$199	
1622000	Stearyl Alcohol (125 mg)	H2B217 (06/10)	I0I061	\$158	
1672206	Topiramate (150 mg)	F0F297 (06/10)	G0I135	\$264	
1708795	Valsartan Related Compound C (10 mg)	G2H042 (06/10)	H0I005	\$794	

No Longer Valid as of July 31, 2010					
Catalog #	Description	Previous Lot/ Valid Use Date	Current Lot	Price (USD)	
1017502	Dried Aluminum Hydroxide Gel (200 mg)	F2B120 (07/10)	G0I104	\$199	
1019508	Amikacin (300 mg)	J0E226 (07/10)	K0I162	\$199	
1076352	Bretylum Tosylate (200 mg)	F-1 (07/10)	G0I231	\$199	
1097658	Cefixime (500 mg)	F (07/10)	G0I139	\$199	
1134335	Ciprofloxacin Hydrochloride (400 mg)	I0C265 (07/10)	J0H307	\$199	
1161509	L-Cysteine Hydrochloride (200 mg)	H (07/10)	I0I177	\$199	
1239005	Ergocalciferol (30 mg/ampule; 5 ampules) (Vitamin D2)	P0B275 (07/10)	Q0I099	\$215	
1301007	Guaifenesin (200 mg)	I1C098 (07/10)	J0G257	\$199	
1446804	Monostearyl Maleate (100 mg)	G (07/10)	G1I191	\$620	
1478108	Ofloxacin (200 mg)	G0E180 (07/10)	G1I182	\$199	
1483505	Oxprenolol Hydrochloride (200 mg)	I0C344 (07/10)	I1I183	\$199	
1526200	Phenoxyethanol (500 mg) (2-Phenoxyethanol)	F0D069 (07/10)	G0H449	\$199	
1561507	Primaquine Phosphate (200 mg)	F-1 (07/10)	G0J115	\$199	
1572536	Propofol Related Compound A (10 mg)	F0E060 (07/10)	H0J107	\$620	
1601292	Residual Solvents Class 2 - Mixture B (1.2 mL/ampule; 3 ampules)	F0D248 (07/10)	G0I069	\$199	
1628007	Sulfamerazine (500 mg)	H1C171 (07/10)	I0I081	\$199	
1667600	Alpha Tocopherol (250 mg) (Vitamin E Alcohol)	M (07/10)	N0F068	\$199	
1708762	Valsartan (350 mg)	I0H060 (07/10)	K0I386	\$199	

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**Items with New Lots**

Catalog #	Description	Previous Lot/ Valid Use Date	Current Lot	Price (USD)
1012101	Adenine (200 mg)	G2D279 (05/11)	H0I348	\$199
1059003	Benzphetamine Hydrochloride <b>CIII</b> (200 mg)	F2C272 (05/10)	G0I243	\$263
1119309	Chlorthalidone Related Compound A (10 mg)	J0I095 (04/11)	K0J098	\$620
1150706	Crospovidone (100 mg)	G2E126 (06/11)	H0I211	\$199
1222002	Disodium Inosinate (500 mg)	F (03/11)	G0J162	\$199
1288306	Ganciclovir (200 mg)	F0C287 (05/11)	G0J026	\$465
1294848	gamma-Glutamyl-S-allyl-L-cysteine (25 mg)	F (05/11)	G0J002	\$860
1359903	Levocarnitine (400 mg)	G0B197 (06/11)	G1J095	\$199
1478505	Omeprazole (200 mg)	I0F081 (05/11)	J0H412	\$199
1572536	Propofol Related Compound A (10 mg)	G0I092 (05/11)	H0J107	\$620
1601383	Residual Solvent Class 2 - Chloroform (1.2 mL/ampule; 3 ampules)	F0D186 (06/11)	G0I192	\$199
1605523	Ropivacaine Related Compound B (50 mg)	F0E318 (05/11)	F1J075	\$620
1708762	Valsartan (350 mg)	J0I020 (05/11)	K0I386	\$199
1708784	Valsartan Related Compound B (10 mg)	G0H058 (05/11)	G1I283	\$794
1724656	Zileuton (150 mg)	F0C062 (05/11)	G0J062	\$199

**USP Donor Recognition Program is Expanding**

The goal of USP’s Donor Recognition Program is to acknowledge industry for its vital participation in and support of standards-setting activities. To honor those vital contributions, USP has expanded its Donor Recognition Program to include the following:


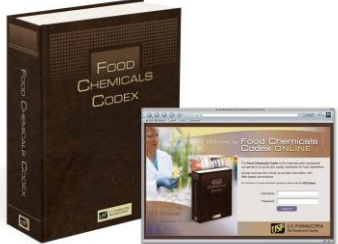
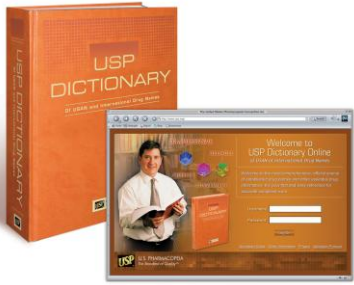
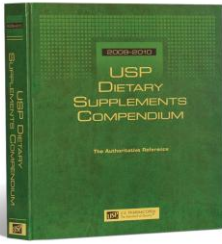
- Recognition in USP Publications
- Complimentary or discounted registrations to USP meetings
- Complimentary print subscription to either *USP–NF*, *Food Chemicals Codex*, or *USP Dietary Supplements Compendium*
- Complimentary USP Reference Standards
- Complimentary Pharmacopeial Education courses

More details coming soon on our web site. For questions or comments, contact the Standards Acquisition Group at [STACQ@USP.ORG](mailto:STACQ@USP.ORG)

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## USP Publication Highlights

	<p><b>Order <i>USP 33–NF 28 Reissue</i> Today!</b> <i>USP 33–NF 28 Reissue</i>, the replacement publication for <i>USP 33–NF 28</i> that was recalled on January 8, 2010—is available now. Standards in <i>USP 33–NF 28 Reissue</i> will become official on October 1, 2010. Please note that subscription components have changed: print subscribers will not receive a 3-volume print set. <a href="#">Click here</a> for additional details. To order, visit <a href="http://www.usp.org/products/USPNF">www.usp.org/products/USPNF</a> 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><b>Subscribe to the New <i>Food Chemicals Codex (FCC), Seventh Edition</i></b> The <i>FCC, Seventh Edition</i>, includes important standards updates and helpful information for manufacturers, suppliers, and users of food ingredients. Offered in print and online formats, a two-year subscription includes a main edition and all <i>Supplements</i> that publish during the subscription period. To order, visit <a href="http://www.usp.org/products/FCC">www.usp.org/products/FCC</a> 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><b>2010 <i>USP Dictionary</i> Features Up-to-date Drug Name Information</b> The 2010 <i>USP Dictionary of USAN and International Drug Names</i> features new and updated generic and brand drug names, pronunciations, chemical structures, UNII codes, and more. Available in print and online formats. To order, visit <a href="http://www.usp.org/products/dictionary">www.usp.org/products/dictionary</a> 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><b>Order the Comprehensive <i>USP Dietary Supplements Compendium</i></b> Only the <i>USP Dietary Supplements Compendium</i> 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. Published every two years in hardcover print, English only. Visit <a href="http://www.usp.org/products/dietarySupplementsCompendium/">www.usp.org/products/dietarySupplementsCompendium/</a> 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>

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## Event Highlights

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Please consider attending a **USP Webinar or Workshop** in the coming months. Visit [www.usp.org/meetings/workshops/](http://www.usp.org/meetings/workshops/) for details.

The [Nomenclature Workshop](#) will be held July 27–28, 2010, at USP Headquarters in Rockville, MD.

The Compendial Nomenclature, Overview and Challenges Workshop is USP's first ever forum for discussion of current policy issues regarding U.S. and international compendial nomenclature.

[Third Annual Bioassay Workshop](#) will be held August 11–12, 2010, at USP Headquarters in Rockville, MD.

[The 10th International Symposium on Pharmaceutical Reference Standards](#) will be held September 13–14, 2010, at USP Headquarters in Rockville, MD.

## Pharmacopeial Education

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### Featured Courses

#### **Determining Particulate Matter in Parenterals**

In this 60-minute webinar, the audience will benefit from instruction on two specific methods for determination of particulate matter in solution.

**Live Webinar: \$150**

July 27, 2010 (60 minutes)

[Click here](#) to register.

#### **Fundamentals of Bioassay Practices**

What started as one USP General Chapter, <111>, The Design and Analysis of Biological Assays, has grown to a suite of several interrelated chapters that much more comprehensively address bioassay design, analysis, and validation. In addition to providing broadly elaborated ideas on bioassay design, the chapters employ complex statistical perspectives in pursuit of optimal bioassay analysis and validation. This course provides the attendee with the fundamentals of bioassay practices and principles in order to implement the guidance outlined in USP chapters. Tools for statistical and assay design, analysis, and validation will be discussed to assist scientists in developing and performing bioassays.

**Classroom Lecture: \$600 (Register by June 15 and save \$50 or save \$100 when you register 3 or more attendees from the same company)**

August 9–10, 2010; Rockville, MD.

[Click here](#) to register.

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## **Practical Applications of Residual Solvents <467>**

This one-day lecture moves beyond an overview of the new requirements and focuses on implementation issues in the lab. Analytical procedures contained in Chapter <467> and alternative testing protocols will be covered, as well as common points of confusion and concerns encountered by the industry. A question and answer period is included to address the specific inquires of attendees.

**Classroom Lecture: \$700 (Register by August 31 and save \$200 or save \$200 when you register 3 or more attendees from the same company)**

September 14, 2010; Dallas, TX

[Click here](#) to register.

## **Analysis of Elemental Impurities**

Participants will learn about the methodologies and testing strategies proposed in draft chapter <233>, and strategies for method development and method validation when analyzing these impurities in materials that are currently tested using the USP Chapter Heavy Metals <231>. The course concludes with descriptions, advantages, and disadvantages of three instrumental techniques: Atomic Absorption (AA), ICP-OS and ICP-MS.

**Classroom Lecture: \$695 (Register by September 16 and save \$200)**

October 7, 2010; Rockville, MD

[Click here](#) to register.

## **Subscribe to the Pharmacopeial Education Email Bulletin**

USP Pharmacopeial Education is developing several new courses for introduction in 2010. If you would like to stay informed of our new curriculum and upcoming schedule, [subscribe now](#) to the Pharmacopeial Education Bulletin.

## **Compendial Highlights**

### **New Official Text**

#### **Revision Bulletins:**

[<1066> Physical Environments that Promote Safe Medication Use](#) (posted 28-May-2010; official 01-Oct-2010)

[Estradiol Vaginal Inserts](#) (posted 28-May-2010; official 01-Jul-2010)

[Oxaliplatin](#) (posted 28-May-2010; official 01-Jul-2010)

**IRAs** (*Pharmacopeial Forum* 36(3) May–June 2010)

None

#### **Errata**

[Vol. 36, No. 3](#) (45KB) [May–June 2010] (04/29/10)

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## Compendial Notices

**New:** [USP Seeks Submission of Proposals for Monograph Modernization](#) (posted 28-May-2010)

**General Announcements:** See New above

**Intent to Revise:** Nothing New

## **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](http://www.usp.org/support/products/uspNewslettersRequest.html?promo=compendial)

## Stimuli Articles

Featured in *PF* 36(3), May–June 2010

[A Light-obscuration Method Specific for Quantifying Subvisible Particles in Protein Therapeutics](#) (1.5MB)

[Generalized Simplified Approaches for Mass Median Aerodynamic Determination](#) (7.1MB)

## **Tip of the Month**

USP is seeking submission of proposals to support the modernization of USP–NF small molecule and excipient monographs that utilize outdated technology (e.g., use of packed gas chromatography columns), have safety/environmental concerns (e.g., chlorinated solvents, etc) or are missing procedures for key aspects such as impurities. Learn more [here](#).

## **Question of the Month**

In the preparation of the Assay sample the monograph says to use a glass centrifuge tube, can we use plastic instead?

The use of plastic would have to be demonstrated via validation to have no detrimental impact upon the analysis. For guidance on method validation, see USP General Chapter <1225>.

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