



September 2010

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For all the latest information, visit 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 August 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that have been discontinued/have a new price and/or have a new package size; items with lots that are (or soon will be) no longer valid; and items with new lots since the last email notice.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.

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New Reference Standards Now Available

Catalog #	Description	Size	Lot	Price (USD)
1118328	Chloroquine Related Compound A	25 mg	F0J200	\$620
1288408	Gatifloxacin	300 mg	F0J187	\$199
1342150	High Molecular Weight Insulin Human	8.4 mg	F0J216	\$620
1570439	2-Propanol System Suitability	3 X1 mL	F0J171	\$199
1579310	Protocatechuic Acid	25 mg	F0J180	\$199

Previously Out-of-Stock Items Now Available

Catalog #	Description	Size	Lot	Price (USD)
1075203	Bis(2-ethylhexyl) maleate	2 mL	H0J224	\$620
1704003	Tyloxapol	600 mg	J0J220	\$199

Backorder Availability Estimates, August 30, 2010

Catalog #	Description	Expected Availability*
1028000	Amitraz (200 mg)	Q4/10
1044538	Atorvastatin Related Compound B (20 mg)	Q3/10
1044571	Atorvastatin Related Compound E (10 mg)	Q1/11
1098118	Cefpiramide (300 mg)	Q4/10
1487007	Oxymetholone CIII 9200 mg)	Q4/10

*Dates are targets and may change at any time. Q3/10=July-September 2010; Q4/10=October-December 2010; Q1/11=January-March 2011

Items with New Package Size or New Description

Catalog #	Description	Old Size	Size	Lot	Price (USD)
1370291	Loratadine Related Compound B*	15 mg	15 mg	G0I358	\$620
1370611	Lovastatin Related Compound A	10 mg	20 mg	J0J060	\$660
1046409	Open Ring Aztreonam	25 mg	15 mg	H0J067	\$620

* The chemical name has changed from (8-Chloro-6,11-dihydro-11-(N-methyl-4-piperidinylidene)-5H-benzo[5,6]cyclohepta[1,2-b]pyridine) to (8-Chloro-6,11-dihydro-11-(N-methyl-4-piperidinylidene)-5H-benzo[5,6]cyclohepta[1,2-b]pyridine)

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RS Lots That are No Longer Valid

These Tables lists previous RS lots that are (or will soon be) no longer valid for official use.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 August 31, 2010					
Catalog #	Description	Previous Lot/ Valid Use Date	Current Lot	Price (USD)	
1029501	Amlodipine Besylate (350 mg)	G0F133 (08/10)	H0I102	\$199	
1042500	L-Arginine (200 mg)	G2E280 (08/10)	H0I181	\$199	
1093012	Carbamazepine Related Compound A (50 mg)	F0G095 (08/10)	G0I124	\$620	
1103105	Cetyl Palmitate (50 mg)	F0B241 (08/10)	G0H314	\$199	
1134277	Citalopram Related Compound D (15 mg)	F0F170 (08/10)	G0I121	\$620	
1135000	Clidinium Bromide (500 mg)	H0B115 (08/10)	H1I271	\$199	
1185020	Diazepam Related Compound A (25 mg)	I1F077 (08/10)	J0H438	\$620	
1188811	Diclofenac Related Compound A (25 mg)	J0F294 (08/10)	K0I100	\$620	
1269390	Felodipine Related Compound A (15 mg)	F1F260 (08/10)	G0I105	\$620	
1315001	Hydrocodone Bitartrate CII (100 mg)	M0G061 (08/10)	N0I034	\$263	
1350603	Isopropyl Palmitate (500 mg)	I1G013 (08/10)	J0H390	\$199	
1443952	Mineral Oil (1.5 mL)	F0G096 (08/10)	G0I016	\$199	
1457006	Naphazoline Hydrochloride (200 mg)	L0E207 (08/10)	L1H386	\$199	
1462006	Niacinamide (500 mg) (Vitamin B3)	N0E024 (08/10)	N1H378	\$199	
1478629	Ondansetron Related Compound D (30 mg)	G0F153 (08/10)	H0I048	\$620	
1496008	Papaverine Hydrochloride (200 mg)	H (08/10)	H1I070	\$199	
1499414	Paricalcitol Solution (3 mL) (COLD SHIPMENT REQUIRED)	G1I063 (08/10)	H0I227	\$372	
1510007	Pepsin (5 g) DISCONTINUED	F-2 (08/10)		\$199	
1572503	Propofol (200 mg)	F0D379 (08/10)	G0H334	\$199	
1573007	Propoxycaine Hydrochloride (200 mg)	F (08/10)	F1I011	\$199	
1584003	Pyrantel Pamoate (500 mg)	I (08/10)	J0I208	\$199	
1595509	Quinidine Sulfate (500 mg)	H-1 (08/10)	I0H393	\$199	
1612652	Simethicone (50 g)	I0F165 (08/10)	K0I213	\$199	

No Longer Valid as of September 30, 2010					
Catalog #	Description	Previous Lot/ Valid Use Date	Current Lot	Price (USD)	
1133580	Oversulfated Chondroitin Sulfate (10 mg) (COLD SHIPMENT REQUIRED)	F0I113 (09/10)	F1I165	\$666	
1275009	Fluocinolone Acetonide (100 mg)	J1E014 (09/10)	J2I027	\$199	
1286800	Furazolidone (200 mg)	G-2 (09/10)	H0I140	\$199	
1349003	Isoflurane (1 mL)	H1C199 (09/10)	I0I115	\$199	
1356982	Letrozole Related Compound A (25 mg)	G0D298 (09/10)	H0I119	\$620	
1379423	Meloxicam Related Compound B (25 mg)	F0E168 (09/10)	G0I108	\$620	
1453005	Naloxone (125 mg)	M0D085 (09/10)	M1I123	\$158	
1457469	Naratriptan Hydrochloride (125 mg)	F0C360 (09/10)	G0I229	\$264	
1667520	Tinidazole (200 mg)	F0C093 (09/10)	G0I057	\$199	
1696109	Tripolidine Hydrochloride Z-Isomer (50 mg)	G (09/10)	H0I096	\$620	

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No Longer Valid as of October 31, 2010				
Catalog #	Description	Previous Lot/ Valid Use Date	Current Lot	Price (USD)
1065618	Betahistine Hydrochloride (200 mg)	FOC105 (10/10)	G0H384	\$199
1098195	Ceftriaxone Sodium E-Isomer (25 mg)	I0C190 (10/10)	I1I212	\$620
1110009	Chlordiazepoxide Hydrochloride CIV (200 mg)	G-4 (10/10)	G5I352	\$263
1164700	Daunorubicin Hydrochloride (200 mg)	L0B307 (10/10)	M0I190	\$610
1174001	Desoxycorticosterone Acetate (200 mg)	J0C014 (10/10)	J1I297	\$199
1023403	Diazepam Related Compound B (25 mg)	J0F235 (10/10)	K0H414	\$620
1266008	Ethyl Maltol (1 g)	H (10/10)	I0I142	\$199
1348000	Isocarboxazid (200 mg)	F-1 (10/10)	G0I328	\$199
1349025	Isoflurane Related Compound B (0.1 mL)	F0C233 (10/10)	G0I118	\$620
1356803	Lactulose (750 mg)	H (10/10)	I0I186	\$199
1356858	Lamivudine Resolution Mixture B (10 mg)	G0H055 (10/10)	H0I145	\$620
1451000	Nalidixic Acid (200 mg)	G (10/10)	H0I155	\$199
1463304	Nicotine Bitartrate Dihydrate (500 mg)	G1C070 (10/10)	G2H304	\$199
1546300	Polydimethylsiloxane (500 mg)	I0G306 (10/10)	I1H318	\$199
1601146	Residual Solvent Class 1 - Benzene (1.2 mL/ampule; 3 ampules)	F0C408 (10/10)	G0H452	\$199
1604202	Rifampin Quinone (25 mg)	H (10/10)	I0I128	\$620
1671006	Tolnaftate (200 mg)	J0C405 (10/10)	K0H308	\$199
1672337	Torsemide Related Compound C (30 mg)	F0B078 (10/10)	G0I087	\$620
1705006	L-Tyrosine (500 mg)	K0C141 (10/10)	K1I093	\$199

Items with New Lots

Catalog #	Description	Previous Lot/ Valid Use Date	Current Lot	Price (USD)
1009923	Acetyltriethyl Citrate (500 mg)	G0E085 (08/11)	H0I339	\$199
1075203	Bis(2-ethylhexyl)maleate (2 mL)	G0E308 (08/11)	H0J224	\$620
1135021	Clidinium Bromide Related Compound A (250 mg)	I (08/11)	J0J154	\$620
1226014	Doxycycline Related Compound A (10 mg)	F0H365 (08/11)	G0J058	\$620
1287303	Gabapentin (250 mg)	G0E005 (08/11)	H0J020	\$199
1370291	Loratadine Related Compound B (15 mg)	F0D230 (08/11)	G0I358	\$620
1375706	Mebrofenin (100 mg)	F (08/11)	F1I392	\$199
1379401	Meloxicam (400 mg)	G0I026 (07/11)	H0J100	\$331
1446804	Monostearyl Maleate (100 mg)	G1I191 (07/11)	H0J012	\$620
1463508	Nifedipine (125 mg)	K0D401 (08/11)	L0J059	\$158
1547346	Polyoxyl 2 Stearyl Ether (1 g)	F0D353 (06/11)	F1J086	\$199
1623670	Sulbactam (250 mg) (COLD SHIPMENT REQUIRED)	I0G133 (08/11)	J0J117	\$199
1704003	Tyloxapol (600 mg)	I0E111 (06/10)	J0J220	\$199

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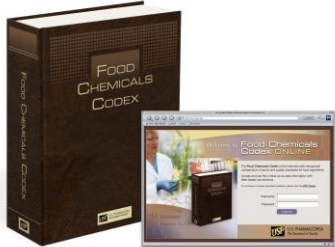
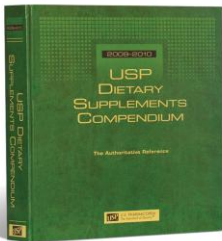


USP Publication Highlights

ATTENTION: *USP–NF* Subscribers--Important Renewal Information

It's time to renew your *USP–NF* (print and CD) for 2011! Customers with USP Online Store accounts can log in to their accounts and view subscription information by clicking "Yes" under the "Renewal Alert"; customers without USP Online Store accounts will receive their renewal information by email, mail, or fax in September. Should you have any questions or would like to renew at anytime by phone, please contact USP Customer Service at 1-800-227-8772 (U.S. and Canada), +1-301-881-0666, or 00-800-4875-5555 (Select Europe).

Important Notice: *Pharmacopeial Forum (PF)* Will Transition to Free Online Service Beginning January 2011. To better serve the pharmaceutical community and further encourage participation in the *USP–NF* standards-setting process, USP is redesigning *PF*—its bimonthly journal of standards revision and commentary. Beginning in January 2011, USP will be offering *PF* exclusively as a complimentary online service. To learn more about this transition, visit <http://www.usp.org/USPNF/pf/pfRedesign.html>.

	<p>USP 34–NF 29: Preorder Now and Be Prepared!</p> <p>The new edition of <i>USP–NF</i> features more than 4,500 monographs and more than 230 General Chapters, including important new and revised standards. Available in print, online, and CD formats, <i>USP 34–NF 29</i> will publish on November 1, 2010, and its standards are official beginning May 1, 2011. (Please note: the print format will publish as a 3-volume set with two separate <i>Supplements</i>.) Preorder your copy today 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>Supplement to Food Chemicals Codex (FCC) Just Released</p> <p>The <i>First Supplement</i> to the <i>FCC, Seventh Edition</i>, published August 31, 2010. Order the complete edition now for important standards updates and helpful information for your work with colorings, flavorings, nutrients, and other food ingredients. Two-year print and online subscriptions are available and include a main book and all <i>Supplements</i> that publish during the subscription period. Visit www.usp.org/products/FCC 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>Order the <i>USP Dietary Supplements Compendium</i> Today</p> <p>Only the <i>USP Dietary Supplements Compendium</i> combines <i>USP–NF</i> standards with information from the <i>FCC</i>; regulatory and industry documents; and helpful tools and resources—all under one cover! Published every two years in hardcover print. Order now at 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>



Event Highlights

USP User Forums (formerly Customer Days)—Coming to a City Near You!

The USP Account Management Team will be traveling across the U.S. and Canada holding free seminars to discuss timely USP initiatives and how to use available USP resources to your advantage.

Meetings are scheduled for November 3, 2010 in Raleigh, NC and January 11, 2011 in Arlington, TX. Registration and more information is available at <http://www.usp.org/products/USPCustomerDays/> or contact: uspcustomerday@usp.org

Please consider attending a **USP Workshop** in the coming months. Visit www.usp.org/meetings/workshops/ for details.

[5th Annual Global Conference on Pharmaceutical Microbiology](#) *Advances in Microbial Control and Product Quality*, co-sponsored by PDA and USP, will be held October 25–27, 2010, at the Capital Hilton, Washington, DC.

[Impurities, Adulteration, and the Changing Role of the USP in Global Drug Quality](#) will be held November 13–14, 2010, in New Orleans, LA.

[Particle Size Analysis Workshop](#) will be held December 8–10, 2010, at USP Headquarters in Rockville, MD.

Pharmacopeial Education

Featured Courses

Analysis of Elemental Impurities

This half-day program will cover method selection and validation for analysis of elemental impurities in pharmaceutical materials currently being tested using USP General Chapter Heavy Metals <231>. The course addresses the elements and limits proposed in the current draft general chapter <232> Elemental Impurities, with an emphasis on ICP and ICP-MS analyses consistent with USP general chapter Plasma Spectrochemistry <730> and the default methodology proposed in draft general chapter <233> Elemental Impurities - Procedures.

Classroom Lecture: \$250 (Register by September 16 and save \$25; Register 3 or more from the same company and save \$50)

October 7, 2010; Rockville, MD

[Click here](#) to register.

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Dissolution: Theory and Best Practices

This newly revised two-day course provides focused, relevant instruction on the fundamentals of pharmaceutical dissolution testing as described in USP General Chapter <711>. Gain an overview of the theory, practice, and history of dissolution. Learn the practical aspects of conducting dissolution tests, best practices, and performance verification testing. The newly revised course covers recent changes to the PVT test and the acceptance criteria and General Chapter <711>.

Lecture and Lab: \$950 (Register by September 21 and save \$100; Register 3 or more from the same company and save \$100!)

October 19-20, 2010; Somerset, NJ (Please note that an additional lab day has been reserved for October 21 in anticipation of registrations exceeding lab space capacity. Enrollment in the October 20 lab day will be reserved first for all out-of-town attendees in order to best accommodate their travel schedules while the October 21 lab day will be reserved for all local attendees. Please see [Pharmacopeial Education Website](#) for complete information.)

[Click here](#) to register.

Determining Particulate Matter in Parenterals

This course will provide a solid foundation of knowledge on the subject as well as equip the student with the ability to extend their learning beyond formulaic application of concepts covered in the course. Two specific methods for determination of particulate matter in solution will be discussed in great detail: Light Obscuration and Membrane Microscopy. These methodologies are most widely associated with Chapter <788> Particulate Matter in Injections, but they also apply to Chapter <789> Particulate Matter in Ophthalmic Solutions. Additionally, this course will address recent changes to Chapter <788> Particulate Matter in Injections that came about due to harmonization efforts.

This course precedes the USP Particle Size Analysis Workshop.

Classroom Lecture: \$700 (Register by October 31 and save \$100!)

December 7, 2010; Rockville, MD

Special Offer! Register for Determining Particulate Matter in Parenterals (December 7, 2010) AND the Particle Size Analysis Workshop (December 8–10, 2010) for a special discounted price of \$1,295.

[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.

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Compendial Highlights

New Official Text

Revision Bulletins:

[Acetaminophen and Tramadol Hydrochloride Tablets](#) (posted 27-Aug-2010; official 01-Oct-2010)

[Levothyroxine Sodium](#) (posted 27-Aug-2010; official 01-Oct-2010)

[Nateglinide](#) (posted 27-Aug-2010; official 01-Oct-2010)

[Oxaliplatin for Injection](#) (posted 27-Aug-2010; official 01-Oct-2010)

[Tamsulosin Hydrochloride Capsules](#) (posted 27-Aug-2010; official 01-Oct-2010)

[Tetracycline Hydrochloride Capsules](#) (posted 27-Aug-2010; official 01-Oct-2010)

[Topiramate Tablets](#) (posted 27-Aug-2010; official 01-Oct-2010)

IRAs

[Pharmacopeial Forum 36\(5\) September–October 2010](#) (211KB) (09/01/10)

Errata

[Vol. 36, No. 5](#) (43KB) [September-October 2010] (09/01/10)

Compendial Notices

New:

<81> [Antibiotics – Microbial Assays: USP Proposes Revisions in PF 36\(5\)](#) (posted 27-Aug-2010)

General Announcements: see New above

Intent to Revise: Nothing New

Sign up to receive updates electronically at

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

Stimuli Articles

Featured in *PF 36(5)*, September–October 2010

[Determination of Organic Carbon Contamination in Packaged Pharmaceutical Water—Contributions by the Container](#) (68KB)

[Updating Sterile Packaged Water Attributes: Conductivity and Total Organic Carbon](#) (37KB)

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Tip of the Month

USP launches "Advancing Public Health through Quality Standards" public awareness campaign —visit <http://www.usp.org/goto/QualityStandards>.

Question of the Month

The %CV requirement in the new acceptance criteria for performance verification testing with prednisone tablets seems incredibly tight. We have data that pass the current Lot P0E203 ranges and yet would fail the new criteria based on the %CV requirement. Has USP made the test more difficult to pass?

There was no intent to make the test more difficult to pass. However, it is different, so some data that would pass the previous test could fail the new one and vice versa. The %CV requirement is based on the estimate of within-laboratory variability from the participants in the collaborative study for Lot P11300.

Updated frequently asked questions and answers for performance verification testing using Prednisone Tablets are posted at <http://www.usp.org/referenceStandards/useAndStorage/calibrators.html>

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