



June 2011

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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 2011; 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that have been discontinued/have a new price and/or have a new package size; items with lots that are (or soon will be) no longer valid; and items with new lots since the last email notice.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.

Call for Candidates: Dissolution Apparatus 4 PVT Collaborative Testing

USP anticipates developing and releasing a USP Performance Verification Tablet (PVT) to assist in demonstrating correct performance of the USP Apparatus 4. In anticipation of that project, we are developing a list of candidates for a collaborative test. Results from collaborative testing protocols will be used to guide the development of the Apparatus 4 PVT, and to ultimately set acceptance ranges.

To register as a candidate for the collaborative test, simply complete and submit the form [here](#). We will contact you when we are preparing the collaborative testing logistics.

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New Reference Standards Now Available

Catalog #	Description	Size	Lot	Price (USD)
1012214	Agar	500 mg	F0K137	\$199
1013534	Almotriptan System Suitability	20 mg	F0K134	\$620
1034738	Anagrelide Hydrochloride	100 mg	F0K113	\$872
1034749	Anagrelide Related Compound A	25 mg	F0K164	\$620
1034750	Anagrelide Related Compound B	25 mg	F0K172	\$620
1034771	Anagrelide Related Compound C	25 mg	F0K162	\$620
1048288	Beta Glucan	1 g	F0K129	\$350
1086200	Calcitonin Salmon	20 mg	F0K101	\$1945
1086210	Calcitonin Salmon Related Compound A	20 mg	F0K102	\$961
1115705	Chloromethyl Isopropyl Carbonate	100 mg	F0K031	\$620
1134084	Ciclopirox Related Compound C	10 mg	F0K084	\$620
1218016	Diphenhydramine Related Compound A	15 mg	F0K144	\$620
1229872	Duloxetine Related Compound F	10 mg	F0J325	\$620
1229883	Duloxetine Related Compound H	10 mg	F0J326	\$620
1249701	Esmolol Hydrochloride	100 mg	F0K112	\$280
1269232	Famotidine Related Compound C	25 mg	F0K160	\$620
1269298	Famotidine Sulfoxide	25 mg	F0K116	\$620
1269312	Felbamate	250 mg	F0K169	\$697
1269323	Felbamate Related Compound A	25 mg	F0K170	\$620
1269334	Felbamate Related Compound B	25 mg	F0K171	\$620
1296010	Glycopyrrolate Erythro Isomer	25 mg	F0K076	\$620
1354262	Itraconazole System Suitability Mixture	25 mg	F0K086	\$620
1356337	Ketorolac Related Compound C	20 mg	F0K167	\$620
1356348	Ketorolac Related Compound D	20 mg	F0K168	\$620
1483163	Oxcarbazepine Related Compound A	10 mg	F0K165	\$620
1483185	Oxcarbazepine Related Compound C	10 mg	F0K166	\$620
1536509	Phyllanthin	15 mg	F0K152	\$199
1536510	Powdered Phyllanthus Amarus Extract	1 g	F0K140	\$199
1604836	Rivastigmine	0.1 mL	F0J302	\$199
1605817	Rosiglitazone Maleate	200 mg	F0J407	\$199
1623659	Sucromalt	200 mg	F0J409	\$199
1683559	Triethylamine	2 mL/ampule; 4 ampules	F0J160	\$199
1718063	Voriconazole Related Compound F	50 mg	F0K127	\$620
1727009	Zolmitriptan	150 mg	F0K147	\$199
1727018	Zolmitriptan R-Isomer	20 mg	F0K148	\$620
1727020	Zolmitriptan Related Compound A	20 mg	F0K149	\$1250
1727053	Zolmitriptan Related Compound D	20 mg	F0K151	\$620

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Previously Out-of-Stock Items Now Available

Catalog #	Description	Size	Lot	Price (USD)
1028000	Amitraz	200 mg	H0K161	\$199

Backorder Availability Estimates, June 6, 2011

Catalog #	Description	Expected Availability*
1265402	Ethyl Acetate (1.2 mL/ampule; 3 ampules)	Q3/11
1441265	Metoprolol Related Compound D (50 mg)	Q2/11
1481226	Oxaliplatin Related Compound B (15 mg)	Q2/11
1491300	Oxytocin (5 vials, 46 USP units per vial)	Q3/11
1604905	Rocuronium Bromide (250 mg)	Q2/11

*Dates are targets and may change at any time. Q2/11=April-June 2011; Q3/11=July-September 2011

Items with New Package Size or New Description

Catalog #	Description	Old Size	Size	Lot	Price (USD)
1133503	Cholic Acid*	2 g	2 g	G0J404	\$199
1287369	Gabapentin Related Compound E	25 mg	10 mg	F1J405	\$620
1417001	Methoxsalen	500 mg	200 mg	I0K139	\$199
1474504	Noscapine	500 mg	100 mg	H0K132	\$199
1613804	Sodium Chloride*	1 g	1 g	H0K004	\$199

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

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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 May 31, 2011					
Catalog #	Description	Previous Lot/ Valid Use Date	Current Lot	Price (USD)	
1012101	Adenine (200 mg)	G2D279 (05/11)	H0I348	\$199	
1013013	Allopurinol Related Compound B (25 mg)	F0G092 (05/11)	G0J139	\$620	
1026401	Aminosalicylic Acid (125 mg)	F-1 (05/11)	G0J177	\$158	
1059003	Benzphetamine Hydrochloride CIII (200 mg)	F2C272 (05/11)	G0I243	\$263	
1143008	Cocaine Hydrochloride CII (250 mg)	I0B074 (05/11)	I1I294	\$263	
1288306	Ganciclovir (200 mg)	F0C287 (05/11)	G0J026	\$465	
1294848	Gamma-Glutamyl-(S)-allyl-L-cysteine (25 mg)	F (05/11)	G0J002	\$860	
1313006	Hydralazine Hydrochloride (200 mg)	LOG068 (05/11)	M0I216	\$199	
1478505	Omeprazole (200 mg)	I0F081 (05/11)	J0H412	\$199	
1494217	Pancuronium Bromide (200 mg)	F0D377 (05/11)	G0J003	\$358	
1572536	Propofol Related Compound A (10 mg)	G0I092 (05/11)	I0K007	\$620	
1605523	Ropivacaine Related Compound B (50 mg)	F0E318 (05/11)	F1J075	\$620	
1642212	Sumatriptan Succinate Related Compound A (15 mg)	H1H418 (05/11)	I0I220	\$794	
1708762	Valsartan (350 mg)	J0I020 (05/11)	K0I386	\$199	
1708784	Valsartan Related Compound B (10 mg)	G0H058 (05/11)		\$794	
1724656	Zileuton (150 mg)	F0C062 (05/11)	G0J062	\$199	

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No Longer Valid as of June 30, 2011				
Catalog #	Description	Previous Lot/ Valid Use Date	Current Lot	Price (USD)
1044538	Atorvastatin Related Compound B (20 mg)	F01172 (06/11)	G0J256	\$620
1044571	Atorvastatin Related Compound E (10 mg)	F01175 (06/11)	G0J426	\$620
1048007	Bacitracin Zinc (200 mg)	N1E200 (06/11)	P0J327	\$199
1150706	Crospovidone (100 mg)	G2E126 (06/11)	H0I211	\$199
1231706	Powdered Echinacea Angustifolia Extract (1 g)	F0D019 (06/11)	G0I377	\$663
1257007	Ethambutol Hydrochloride (200 mg)	H (06/11)	H1J063	\$199
1277252	Fluoride Dentifrice: Sodium Fluoride/Silica (4.6 oz)	K0F055 (06/11)	L0J093	\$583
1285862	o-Flutamide (50 mg)	G0G325 (06/11)	H0I306	\$620
1289003	Gentamicin Sulfate (200 mg)	M0D314 (06/11)	M1J001	\$199
1311000	Homatropine Methylbromide (250 mg)	J (06/11)	K0I368	\$199
1335508	Ibuprofen (750 mg)	J1E043 (06/11)	K0J008	\$199
1359903	Levocarnitine (400 mg)	G0B197 (06/11)	G1J095	\$199
1370611	Lovastatin Related Compound A (20 mg)	I0F257 (06/11)	J0J060	\$660
1379106	Megestrol Acetate (500 mg)	I1F281 (06/11)	J0J101	\$199
1424109	Methyl Alcohol (3 x 1.5 mL)	F0D015 (06/11)	G0I318	\$199
1453504	Naltrexone (200 mg)	H0C150 (06/11)	H1I265	\$199
1021703	Nitrofurantoin Related Compound A (20 mg)	F2E037 (06/11)	G0J181	\$620
1547346	Polyoxyl 2 Stearyl Ether (1 g)	F0D353 (06/11)	F1J086	\$199
1601383	Residual Solvent Class 2 - Chloroform (1.2 mL/ampule; 3 ampules)	F0D186 (06/11)	G0I192	\$199
1649007	Testosterone Propionate CIII (200 mg)	L1C005 (06/11)	M0J023	\$263
1673001	Travoprost (3 mL) (COLD SHIPMENT REQUIRED)	F1I374 (06/11)	G0J306	\$199
1724306	Zalcitabine (200 mg)	F (06/11)	F1I038	\$199

No Longer Valid as of July 31, 2011				
Catalog #	Description	Previous Lot/ Valid Use Date	Current Lot	Price (USD)
1003009	Acetaminophen (400 mg)	J2C423 (07/11)	K0I244	\$199
1046409	Open Ring Aztreonam (15 mg)	G0D071 (07/11)	H0J067	\$620
1162308	Dacarbazine (125 mg)	H (07/11)	I0J135	\$158
1356836	Lamivudine (200 mg)	G0F114 (07/11)	H0I378	\$199
1379401	Meloxicam (400 mg)	G0I026 (07/11)	H0J100	\$331
1440003	Methysergide Maleate (350 mg)	H1F038 (07/11)	I0J203	\$306
1446804	Monostearyl Maleate (100 mg)	G1I191 (07/11)	H0J012	\$620
1457083	Naphthalene (200 mg)	F0H077 (07/11)	G0I219	\$199
1487007	Oxymetholone CIII (200 mg)	G1B247 (07/11)	H0J381	\$263
1491332	Paclitaxel (200 mg)	H0G193 (07/11)	I0I393	\$1,921
1547368	Polyoxyl 20 Stearyl Ether (1 g)	F0D355 (07/11)	G0J118	\$199
1604905	Rocuronium Bromide (250 mg)	F0H078 (07/11)		\$199

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Items with New Lots

Catalog #	Description	Previous Lot/ Valid Use Date	Current Lot	Price (USD)
1028000	Amitraz (200 mg) (COLD SHIPMENT REQUIRED)	G0F313 (06/10)	H0K161	\$199
1095517	Carbidopa Related Compound A (25 mg)	H1F245 (05/12)	I0J400	\$620
1097705	Cefoperazone Dihydrate (200 mg)	H1G369 (05/12)	I0K056	\$199
1133503	Cholic Acid (2 g)	F3B159 (05/12)	G0J404	\$199
1136002	Clindamycin Hydrochloride (200 mg)	H0E044 (05/12)	H1K043	\$545
1171455	Dermatan Sulfate (25 mg) (COLD SHIPMENT REQUIRED)	F0I068 (06/12)	F1J362	\$620
1179741	Dextran 70 (50 mg)	F0C260 (06/12)	F1J372	\$199
1193301	Diethylene Glycol Monoethyl Ether (0.5 mL/ampule)	G0C159 (05/12)	G1I320	\$199
1285873	Fluticasone Propionate (100 mg)	F0F036 (05/12)	G0K029	\$980
1287369	Gabapentin Related Compound E (10 mg)	F0E190 (05/12)	F1J405	\$620
1288317	Ganciclovir Related Compound A (15 mg)	F0C288 (04/12)	G0J294	\$794
1359925	Levocarnitine Related Compound A (100 mg)	F2I202 (04/12)	G0K130	\$620
1378001	Medroxyprogesterone Acetate (200 mg)	I0D013 (04/12)	I1K073	\$199
1417001	Methoxsalen (200 mg)	H (05/12)	I0K139	\$199
1448956	Mycophenolate Mofetil (200 mg)	F0G372 (05/12)	G0J078	\$199
1474504	Noscapine (100 mg)	G (05/12)	H0K132	\$199
1516502	Phendimetrazine Tartrate CIII (350 mg)	G (05/12)	H0J146	\$263
1568007	Progesterone (200 mg)	I0D373 (05/12)	I1J239	\$158
1601601	Residual Solvent Class 2 - Hexane (1.2 mL/ampule; 3 ampules)	F0D268 (05/12)	G0K012	\$199
1613804	Sodium Chloride (1 g)	G0H275 (05/12)	H0K004	\$199
1672206	Topiramate (150 mg)	G0I135 (05/12)	H0K055	\$264

The Reference Standards Notification Program can be used to notify you when a new never-before-released Reference Standard becomes available. The Notification Program does not communicate the release of back-ordered items or lot changeovers. To participate in the New Reference Standards Release Notification Program, please fill out the form online at www.usp.org/referenceStandards/notificationProgram.html.

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USP Publication Highlights

ATTENTION: *USP–NF* Subscribers—Renew Your Subscription Today

Don't be without new *USP 34–NF 29* standards that became official May 1! Customers with USP Online Store accounts can renew by logging in to their accounts and viewing subscription information by clicking "Yes" under "Renewal Alert;" customers without USP Online Store accounts should have received renewal information by email, mail, or fax. **If 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).**

	<p><i>USP 34–NF 29</i> Standards Are Official and FDA-enforceable—Order Now!</p> <p>The 2011 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> became official May 1, 2011. (Please note: the print format is a 3-volume set with two separate <i>Supplements</i>. <i>Second Supplement</i> recently published June 1, 2011.) Subscribe 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>New 2011 <i>USP Dictionary</i>—Order Today for Important Drug Name Updates</p> <p>The 2011 <i>USP Dictionary of USAN and International Drug Names</i> features more than 4,200 new and revised entries and includes 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 (Europe).</p>
	<p><i>FCC, Seventh Edition, through Second Supplement</i> Available now!</p> <p>Rely on the latest <i>FCC</i> 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. Subscription includes a main book and all <i>Supplements</i> that publish during the subscription period; <i>Second Supplement</i> published February 2011. 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><i>USP Dietary Supplements Compendium</i>—Comprehensive Information Under One Cover!</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 resources into one convenient reference! 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

Science & Standards Symposium on Biologics & Biotechnology: Advancing Quality Standards through Analytics and Assays

Westin Seattle, Seattle, WA

Oct. 3-6, 2011

The event will bring together an international panel of experts to speak on regulatory challenges across the globe associated with the development of regulation and characterization of pancrelipase/therapeutic enzymes, monoclonal antibodies, tissue and cell therapy products, and much more.

Click [here](#) for more information.

Workshops

Save the Date—Although still in the planning stages, the following workshops are scheduled.

Call +1-301-816-8130 for additional information.

Workshop	Date
<7> Labeling	postponed
OTC	September 8–9, 2011
Bioassay Workshop as part of the USP Science & Standards Symposium	October 3–6, 2011
Intentional and Unintentional Adulteration of Foods and Dietary Supplements	November 16–17, 2011
Aerosols–Inhalation and Nasal Drug Products	December 12–13, 2011
Dissolution Methods for Liquid Filled Capsules	Early 2012
Probiotics Workshop	May 9–12, 2012
Extractables and Leachables Workshop	TBD 2012

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Pharmacopeial Education

Featured Courses

Note: Early registration and group discounts may apply see course listings www.usp.org/education/pe/courses.html for details.

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

July 12–13, 2011; Hopkinton, MA (SOTAX Corporation)

[Click here](#) to learn more.

Understanding the USP Compendial Process: Monographs, General Chapters and General Notices

This course is designed to give a better understanding on how monographs and general chapters are developed. Furthermore, the process for proposal of compendial improvements, public review & comment and approval & adoption are also discussed.

Classroom Lecture: \$495 (Special discount for combined registration with OTC Drug Substances and Drug Products Workshop)

September 7, 2011; Rockville, MD

[Click here](#) to learn more.

Overview of Pharmacopeial Harmonization from the USP Perspective

Webinar: \$150

July 14, 2011; 1:00 - 2:00 (ET)

[Click here](#) to learn more.

New Updates on Good Storage & Shipping Practices <1079>

Webinar: \$150

August 18, 2011; 1:00 – 2:00 (ET)

[Click here](#) to learn more.

[Subscribe](#) to the Pharmacopeial Education Email Bulletin

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Compendial Highlights

New Official Text

Revision Bulletins:

[Budesonide](#) (posted 27-May-2011; official 01-Jun-2011)

[Sertraline Tablets](#) (posted 27-May-2011; official 01-Jun-2011)

Updated Revision Bulletin:

[<2040> Disintegration and Dissolution of Dietary Supplements, Dissolution Section \(POSTPONEMENT\)](#)
(posted 27-May-2011; official 01-Jun-2011)

[Vitamin A Oral Liquid Preparation](#) (posted 30-Jul-2010; official 01-Oct-2010; updated 27-May-2011)

IRAs

May 2011 IRAs—No posting due to the switch to the 90-day Comment Period
(posted 27-May-2011)

Errata

USP 34–NF 29

[April 2011 Errata Posting](#)  (379KB) (posted 04/29/11)

[February 2011 Errata Posting](#)  (128KB) (posted 02/28/11)

[December 2010 Errata Posting](#)  (743KB) (posted 12/30/10)

Compendial Notices

New:

[Call for Candidates: USP Expert Panel on Containers - Moisture Vapor Transmission Rate Testing](#)
(posted 1-June-2011)

[Olanzapine Tablets: Notice of Intent to Revise](#) (posted 27-May-2011)

Sign up to receive updates electronically at

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

Stimuli Articles

Featured in *PF 37(3)*, May–June 2011

USP Responses to Comments on Stimuli Article: Co-processed Excipients

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Tip of the Month

Reference Standards Daily Catalog Now Available as an Excel Spreadsheet

In response to several user inquiries, we now offer a downloadable, Excel spreadsheet version of our Daily Catalog on our website. Updated each evening, this spreadsheet is searchable, may be uploaded into your ordering system, and can be used as a quick reference with the latest Reference Standard availability information. To access the new catalog, please go to:

<http://www.usp.org/referenceStandards/> and click on the "Daily Catalog (xls)" link under the "Catalogs" tab at the top center of the page.

Question of the Month

What is the deadline to submit comments on items in the in-process revision section of *Pharmacopeial Forum 37(3) May-June 2011*?

There is a 90 day comment period of *PF* items so the deadline is July 31, 2011. You can find the publication and comment schedule at

<http://www.usp.org/USPNF/publication.html>

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