

**April 2010****Email Notice**

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[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 March 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that have been discontinued/have a new price and/or have a new package size; items with lots that are (or soon will be) no longer valid; and items with new lots since the last email notice.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)
1013512	Almotriptan Malate	200 mg	F0J054	\$199
1013523	Almotriptan Related Compound A	20 mg	F0J055	\$620
1065695	Betaine	1 g	F0I379	\$199
1224992	Donepezil Related Compound A	25 mg	F0J070	\$620
1231717	Powdered Echinacea Pallida Extract	1 g	F0I285	\$199
1235933	Entacapone	150 mg	F0I395	\$380
1235944	Entacapone Related Compound A	25 mg	F0I396	\$620
1269152	Famciclovir	200 mg	F0J072	\$199
1297205	Goserelin Acetate	100 mg	F0H104	\$545
1297216	Goserelin Related Compound A	2 mg	F0H105	\$620
1370156	Lopinavir System Suitability Mixture	10 mg	F0J049	\$620
1443704	Midodrine Hydrochloride	200 mg	F0J068	\$199
1478403	Olopatadine Hydrochloride	150 mg	F0J014	\$274
1478425	Olopatadine Related Compound B	35 mg	F0J016	\$620
1478436	Olopatadine Related Compound C	35 mg	F0J022	\$620
1534209	Phenyl Salicylate Melting Point Standard	500 mg	F0I349	\$116
1546285	Polydextrose	200 mg	F0J052	\$199
1605216	Ropinirole Related Compound A	50 mg	F0J034	\$620
1614909	Sodium Tartrate Dihydrate	500 mg	F0I052	\$95
1643601	Tenofovir	15 mg	F0J005	\$199
1724951	Zolpidem Impurities Mixture CIV	15 mg	F0J040	\$620
1725036	Zonisamide Related Compound C	20 mg	F0J031	\$620

Previously Out-of-Stock Items Now Available

None

Backorder Availability Estimates, April 12, 2010

Catalog #	Description	Expected Availability*
1561507	Primaquine Phosphate (200 mg)	Q2/10

*Dates are targets and may change at any time. Q2/10=April-June 2010

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Items with New Package Size or New Description

Catalog	Description	Old Size	Size	Lot	Price (USD)
1048630	Benazepril Related Compound B*	15 mg	15 mg	H0I343	\$620
1082504	Butorphanol Tartrate CIV	500 mg	350 mg	K0I267	\$296
1097400	Cefamandole Nafate	200 mg	250 mg	I0J092	\$199
1287358	Gabapentin Related Compound D	20 mg	10 mg	F1I249	\$620
1342321	Insulin Lispro	5.97 mg (172 Units/Vial)	5.76 mg (166 Units/Vial)	G0I388	\$199
1344666	Iohexol Related Compound C	100 mg	50 mg	G0J013	\$620
1674004	Tretinoin	30 mg/vial; 5 vials	30 mg/ ampule; 5 ampules	K0H371	\$199

*The chemical name has changed to Mixture of (1R, 3S) and (1S, 3R) (3-(1-ethoxycarbonyl-3-phenyl-propyl)amino-2,3,4,5-tetrahydro-2-oxo-1H-1-benzazepine)-1-acetic acid, monohydrochloride

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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 March 31, 2010					
Catalog #	Description	Previous Lot/ Valid Use Date	Current Lot	Price (USD)	
1012939	Allantoin (200 mg)	F0C169 (03/10)	G0H207	\$199	
1044651	Atovaquone (200 mg)	F0B190 (03/10)	G0H328	\$199	
1110020	Chlordiazepoxide Related Compound A (25 mg)	G (03/10)	G1H228	\$620	
1134018	Ciclopirox (50 mg)	F0E086 (03/10)	G0G398	\$199	
1137005	Clindamycin Palmitate Hydrochloride (500 mg)	G0D334 (03/10)	H0I037	\$545	
1152009	Cyanocobalamin (1.5 g of mixture with mannitol) (Vitamin B12)	N (03/10)	O0H288	\$199	
1173235	Desogestrel (50 mg)	G1F145 (03/10)	H0H041	\$199	
1287030	Furosemide Related Compound B (100 mg)	J0E326 (03/10)	K0H287	\$620	
1292336	Glimepiride Related Compound C (20 mg) (Glimepiride urethane)	F0E234 (03/10)	F1H423	\$620	
1304005	Heparin Sodium (10 x 1 mL) (COLD SHIPMENT REQUIRED)	L0G091 (03/10)	L1I033	\$199	
1356971	Letrozole (200 mg)	F0B170 (03/10)	G0H299	\$199	
1370360	Lorazepam Related Compound E (25 mg)	H0D254 (03/10)	I0H446	\$620	
1424007	Methyclothiazide (200 mg)	G (03/10)	G1H341	\$199	
1430509	3-O-Methylmethyldopa (50 mg)	G-1 (03/10)	H0H391	\$620	
1431002	Methyl 5-methyl-3-isoxazolecarboxylate (25 mg) DISCONTINUED	F-1 (03/10)		\$620	
1449530	Nabumetone Related Compound A (15 mg)	F0D165 (03/10)	G0I062	\$620	
1499414	Paricalcitol Solution (3 mL) (COLD SHIPMENT REQUIRED)	G0H292 (03/10)	H0I227	\$372	
1546922	Polyethylene Terephthalate G (PETG) (3 Strips)	F (03/10)	F1H430	\$199	
1621008	Stearic Acid (500 mg)	J1D360 (03/10)	J2G054	\$199	
1632004	Sulfanilamide (5 g)	O0B047 (03/10)	O1H320	\$199	
1700501	L-Tryptophan (200 mg)	G2E237 (03/10)	H0H122	\$199	

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No Longer Valid as of April 30, 2010				
Catalog #	Description	Previous Lot/ Valid Use Date	Current Lot	Price (USD)
1031503	Amoxicillin (200 mg)	J0C043 (04/10)	K0H332	\$199
1048200	Baclofen (350 mg)	I (04/10)	J0H297	\$199
1149004	Corticotropin (5.6 Units/vial; 5 vials) (COLD SHIPMENT REQUIRED)	M (04/10)	M11180	\$158
1292507	Glipizide (125 mg)	G1C174 (04/10)	H0H396	\$158
1430349	Methyl Linolenate (5 x 50 mg)	G0D320 (04/10)	H0I008	\$199
1464001	Nitrofurantoin (500 mg)	J (04/10)	K0I060	\$199
1501108	Penicillamine Disulfide (200 mg)	I0F234 (04/10)	J0I007	\$620
1538006	Phytonadione (500 mg) (Vitamin K1)	N0B303 (04/10)	O0H310	\$199
1559505	Prednisone Tablets (30 tablets)	P0E203 (04/10)	P11300	\$230
1642212	Sumatriptan Succinate Related Compound A (15mg)	H0H253 (04/10)	H1H418	\$794
1683606	Triethyl Citrate (500 mg)	G0C393 (04/10)	G1G390	\$199
1708773	Valsartan Related Compound A (10 mg)	H1H329 (04/10)	H2I040	\$794

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) DISCONTINUED	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) DISCONTINUED	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) DISCONTINUED	F (05/10)		\$263
1651009	Tetracycline Hydrochloride (200 mg)	L0C216 (05/10)	L1H374	\$199
1656308	Thiamylal CIII (200 mg) DISCONTINUED	F (05/10)		\$263

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Items with New Lots

Catalog #	Description	Previous Lot/ Valid Use Date	Current Lot	Price (USD)
1006801	Acetone (1.5 mL/ampule; 3 ampules)	F0D028 (04/11)	G0I176	\$199
1013035	Allopurinol Related Compound C (25 mg)	F0G057 (03/11)	G0J066	\$620
1048630	Benazepril Related Compound B (15 mg)	G0G206 (03/11)	H0I343	\$620
1075757	Bisoprolol Fumarate (200 mg)	G0D316 (03/11)	H0J057	\$199
1082504	Butorphanol Tartrate CIV (350 mg)	J (03/11)	K0I267	\$296
1086301	Calcitriol (10 mg) (COLD SHIPMENT REQUIRED)	H0H053 (03/11)	I0H427	\$1,945
1090728	Capecitabine Related Compound B (20 mg)	F0G026 (04/11)	F1I333	\$620
1090739	Capecitabine Related Compound C (20 mg) (COLD SHIPMENT REQUIRED)	F0G023 (04/11)	G0I370	\$620
1097400	Cefamandole Nafate (250 mg)	H (03/11)	I0J092	\$199
1122700	Chloroxylenol (125 mg)	F2C259 (03/11)	G0I218	\$158
1147009	Colistimethate Sodium (200 mg)	H1D234 (02/11)	H2J047	\$199
1260012	Ethinyl Estradiol Related Compound A (20 mg)	H0G051 (03/11)	I0J071	\$620
1287358	Gabapentin Related Compound D (10 mg)	F0F246 (03/11)	F1I249	\$620
1291559	Ginkgo Terpene Lactones (50 mg)	G0I051 (04/11)	H0I309	\$409
1292347	Glimepiride Related Compound D (20 mg)	F1G258 (02/11)	F2J056	\$620
1342321	Insulin Lispro (5.76 mg) (COLD SHIPMENT REQUIRED)	F0E140 (12/10)	G0I388	\$199
1344666	Iohexol Related Compound C (50 mg)	F-1 (03/11)	G0J013	\$620
1347711	Irbesartan Related Compound A (25 mg)	F0F209 (03/11)	F1I362	\$620
1349014	Isoflurane Related Compound A (0.1 mL)	F0C232 (03/11)	G0I117	\$620
1356654	Labetalol Hydrochloride (200 mg)	G1F090 (03/11)	H0I313	\$199
1370305	Lorazepam CIV (200 mg)	I1D404 (03/11)	J0I304	\$263
1396003	Metaraminol Bitartrate (200 mg)	F-3 (03/11)	G0I354	\$199
1443500	Miconazole Nitrate (200 mg)	J0D011 (02/11)	J1I153	\$199
1458009	Neomycin Sulfate (200 mg)	L3E135 (03/11)	M0I253	\$199
1674004	Tretinoin (30 mg/ampule; 5 ampules)	J1F266 (03/11)	K0H371	\$199

Correction: Item 1323000 Hydromorphone Hydrochloride Lot J0C372 has a Valid Use Date of 02/11. The March 2010 Email Notice incorrectly listed the Valid Use Date of this Lot as 02/10.

USP Prednisone Tablets (item # 1559505) Lot P0E203


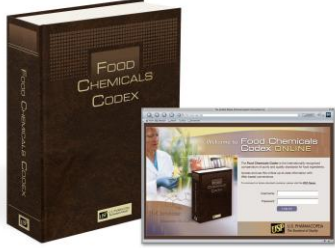
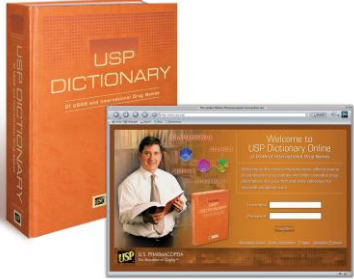
- USP has released [Prednisone Tablets continuation Lot P1I300](#).
- On April 30, 2010, Lot P0E203 will no longer be official.
- A Calculation Tool for the Performance Verification Test (PVT) of Dissolution Assemblies is available [here](#)
- Version 2.0 of the Dissolution Toolkit is available [here](#)

More details can be found at www.usp.org/goto/pvt

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USP Publication Highlights

	<p>USP 33–NF 28 Reissue Is Available <i>USP 33–NF 28 Reissue</i>, the replacement publication for <i>USP 33–NF 28</i> that was recalled on January 8, 2010—has published. Customers who previously ordered <i>USP 33–NF 28</i> should receive their replacement product by the end of this week. 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. Click here for additional details. If you have questions, 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> <p>New customers may order <i>USP 33–NF 28 Reissue</i> online at www.usp.org/products/ or contact USP Customer Service at the numbers above.</p>
	<p>Food Chemicals Codex (FCC), Seventh Edition, Is now Available The new <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 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>2010 USP Dictionary—Order Today for Important Drug Name Updates The 2010 <i>USP Dictionary of USAN and International Drug Names</i> is now available. It includes new and updated 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>

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Event Highlights

USP Customer Days—Coming to a City Near You!

- **May 12, 2010 in Chicago, IL**

Register now to ensure your place for an informative, interactive day with the USP Account Management team! These free seminars cover USP publications, Reference Standards, USP Verified Services, Pharmacopeial Education, new USP initiatives, and scientific hot topics. There's also plenty of time for Q&A with USP team members on specific topics of interest to you.

There is no cost to attend, but registration is limited. More information and electronic registration are available at: <http://www.usp.org/goto/USPCustomerDays>.

Or, contact us at: uspcustomerday@usp.org.

Visit USP at Excipient Fest booth # 12, May 5—May 6, 2010 in San Juan, Puerto Rico

Visit USP at GPhA/FDA Quality by Design Workshop for ANDAs, May 4-5, 2010, North Bethesda, MD to learn about the latest USP Reference Standards, publications, and other tools to help ensure quality in your work.

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

The [Nomenclature Workshop](#) will be held July 27 and 28, 2010 at USP 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.

[Provide early input to the Visual Inspection of Parenterals Advisory Panel](#)

May 13, 2010, online Interactive webcast presented through WebEx
8:00 am, Eastern Daylight Time (New York, GMT-04:00)

This Free interactive, online discussion is being convened to discuss and clarify several comments received in response to the *PF Stimuli Article 35(5)* [Sept.–Oct. 2009]

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Pharmacopeial Education

Featured Courses

Good Storage and Transportation Practices: Update on Proposed Revisions to General Chapter <1079>

The FDA definition of “adulterated drug” addresses “holding of a drug” including storage, distribution, transportation and warehousing activities. In this webinar, gain up-to-date information on revisions to USP General Chapter <1079>--Good Storage and Transportation, reflecting the globalization of the drug supply chain and the increase in biotechnology-derived drugs requiring refrigerated storage.

Live Webinar: \$150

May 4, 2010 (90 minutes)

[Click here](#) to register.

Essentials of Microbiological Testing

This course provides a practical understanding of microbiological practices in the pharmaceutical industry and gives an overview of the USP General Chapters that address microbiological testing.

Classroom Lecture: \$695 (Register by May 3 and save \$200)

May 17, 2010; Raleigh, NC

[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.

Offered in cooperation with SGS–Life Sciences Services and A&C American Chemicals Ltd.

Classroom Lecture: CDN \$595 (Register early and save CDN \$145)

May 26, 2010; Toronto, Canada

June 9, 2010; Montreal, Canada

[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

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](#)

[New Official Text](#)

Revision Bulletins:

[Methotrexate](#) (posted 26-Mar-2010; official 1 May 2010)

IRAs (*Pharmacopeial Forum* 36(2) March–April 2010)

None

Errata

[Vol. 36, No. 2](#) (35KB) [March–April 2010] (03/01/10)

[Compendial Notices](#)

New: [Glacial Acetic Acid: Notice of Intent to Revise](#) (posted 26-Mar-2010)

General Announcements: Nothing New

Intent to Revise: See New above

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

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Stimuli Articles

Featured in *PF 36(2)*, March–April 2010

There are no Stimuli Articles in this issue of *PF*.

Tip of the Month

USP provides Pending Monographs for certain drug products and their drug substances that have been submitted or are intended to be submitted to the U.S. Food and Drug Administration (FDA) for approval to be marketed in the United States, but have not yet received such approval. Under this approach, sponsors of Requests for Revision such as manufacturers of generic or over-the-counter (OTC) products and others can work with USP to create a Pending Monograph as authorized text. Once FDA approval is granted, USP then works with the sponsor to move that monograph into official USP–NF status, along with an official USP Reference Standard where appropriate. Details of the approach are described in the [Pending Monographs Guideline](#) Version 2.4

As new and revised Pending Monographs become available, they will be posted on the USP Web site on a monthly basis on the last Friday of each month. Monographs posted in draft for comment will also indicate the deadline for submitting comments and the e-mail address of the USP staff person to whom comments should be directed. Following review of comments and approval by the relevant Expert Committee, the Authorized Pending Standard will be posted at www.usp.org/standards/pending/

Question of the Month

What is the Official date of *USP 33–NF 28 Reissue New and Revised Official Text Since the Second Supplement to USP 32–NF 27*?

October 1, 2010

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