July 2013

Table of Contents

Reference Standards Highlights

- Reference Standards under Development
- **New Reference Standards** Now Available
- Previously Out-of-Stock Items Now Available
- **Backorder Availability** Estimates, July 8, 2013
- Items with New Package Size or Description
- RS Lots That Are No Longer Valid
- Items with New Lots

USP Publication Highlights

- USP 36-NF 31 is Now Official
- FCC, Eighth Edition
- 2012 Dietary Supplements Compendium
- Order the New 2013 USP Dictionary for the Latest Drug Name Updates!

Pharmacopeial Education

- **Find Courses**
- Sign up for Pharmacopeial **Education Information**

Compendial Highlights

- **New Official Text**
- **Compendial Notices**
- Stimuli Articles

Tip of the Month

Question of the Month

Event Highlights

- **USP User Forums**
- Workshops

Click on links to go to sections.

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 June 2013; backordered items with estimated availability dates; items that have a new price and/or have a new package size; items with lots that are (or soon will be) no longer valid; and items with new lots since the last email notice.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.

An expanded list of **USP Reference Standards Under Development** has been recently posted to the USP website. The expanded list now includes new USP Reference Standards that we expect to release within a year. The list will continue to be updated four times per year. The list is organized by calendar quarter, and can be downloaded as an MS Excel (xls) spreadsheet.

The Reference Standards Release Notification Service can be used to notify you when a new never-beforereleased Reference Standard becomes available. The Notification Service does not communicate the release of backordered items or lot changeovers. To participate, fill out the form online at www.usp.org/reference-standards/findreference-standard/notification-service.



New Reference Standards Now Available

Catalog #	Description	Size	Lot	Price (USD)
1000532	Acarbose System Suitability Mixture	2 mg	F0L204	\$655
1003064	Acetaminophen Related Compound F	50 mg	F0M236	\$655
1013206	Almond Oil	1 g	F0L399	\$210
1013727	Aloin	25 mg	F0M265	\$210
1034501	alpha-Amylcinnamyl Acetate	500 mg	F0L288	\$210
1034512	alpha-Amylcinnamyl Alcohol	500 mg	F0L262	\$210
1050949	Benzaldehyde Propylene Glycol Acetal	5 x 0.5 mL	F0L333	\$210
1082628	Butyl Heptanoate	5 x 0.5 mL	F0L520	\$210
1090150	Canola Oil	1 g	F0L366	\$210
1123135	Chlorpheniramine Related Compound B	25 mg	F0M273	\$655
1123146	Chlorpheniramine Related Compound C	10 mg	F0M275	\$1000
1231229	Ebastine Related Compound B	100 mg	F0L522	\$655
1231262	Ebastine Related Compound F	15 mg	F0M271	\$655
1231750	Echinacoside	15 mg	F0M214	\$210
1279054	Fluorouracil Related Compound E	25 mg	F0M276	\$655
1311714	rHuman Interleukin 4	51µg	F0M173	\$1329
1356599	Krill Oil	2 g	F0K345	\$210
1372061	Lysophosphatidylcholine (Soy)	40 mg	F0L268	\$655
1448628	Moxifloxacin Related Compound B	25 mg	F0M232	\$655
1448639	Moxifloxacin Related Compound C	25 mg	F0M233	\$655
1448655	Moxifloxacin Related Compound E	25 mg	F0M234	\$655
1478083	R-Ofloxacin	25 mg	F1M266	\$655
1510051	Pepsin for Assay	5 X 1 g	F0M228	\$210
1535755	Phosphatidylcholine (Soy)	50 mg	F0L265	\$210
1535766	Phosphatidylethanolamine (Soy)	50 mg	F0L270	\$210
1598031	Rabeprazole Related Compound B	15 mg	F0M252	\$655
1598075	Rabeprazole Related Compound F	15 mg	F0M256	\$655
1607200	Safflower Oil	1 g	F0L365	\$210
1617500	Soybean Oil	1 g	F0L405	\$210
1642347	Sunflower Oil	1 g	F0L364	\$210
1643645	Tenofovir Disoproxil Related Compound E	15 mg	F0M259	\$655
1643678	Tenofovir Disoproxil Related Compound G	15 mg	F0M263	\$655

Previously Out-of-Stock Items Now Available

Catalog #	Description	Size	Lot	Price (USD)
1288000	Gallamine Triethiodide	200 mg	G0M284	\$210
1350002	Isopropamide lodide	200 mg	G0M260	\$210

Backorder Availability Estimates, July 8, 2013

Catalog #	Description	Expected Availability*
1012595	rAlbumin Human (4.92 mg) (Recombinant Human Albumin) (COLD SHIPMENT REQUIRED)	Q3/13
1044549	Atorvastatin Related Compound C (20 mg)	Q3/13
1048652	Benazepril Related Compound D (15 mg)	Q3/13
1061005	Benztropine Mesylate (200 mg)	Q3/13
1096509	Carboprost Tromethamine (25 mg)	Q4/13
1096804	Cathinone Hydrochloride CI (50 mg) (alpha-Aminopropiophenone Hydrochloride)	Q1/14
1161586	Cystine (200 mg)	Q3/13
1177000	Dexamethasone Phosphate (200 mg)	Q1/14
1260023	Ethinyl Estradiol Related Compound B (10 mg)	Q3/13
1438001	Methyltestosterone CIII (200 mg)	Q1/14
1547925	Polysorbate 20 (2 g)	Q3/13
1601770	Residual Solvent Class 2 - Tetrahydrofuran (1.71 mg)	Q3/13
1613859	Sodium Citrate (1 g) (AS)	Q3/13
1643543	Temozolomide (200 mg)	Q3/13
1643554	Temozolomide Related Compound A (15 mg) (4-diazo-4H-imidazole-5-carboxamide)	Q3/13
1643656	Tenofovir Disoproxil Fumarate (200 mg)	Q1/14
1711100	Vasopressin (1.71 mg) (8-L-arginine vasopressin) (COLD SHIPMENT REQUIRED)	Q3/13

^{*}Dates are targets and may change at any time. Q3/13 July–September 2013; Q4/13 October–December 2013; Q1/14 January-March 2014

Items with New Package Size or New Description

Catalog #	Description	Old Size	Size	Lot	Price (USD)
1315012	Hydrocodone Related Compound A *	70 mg	70 mg	G0M030	\$690
1343550	Iodixanol Related Compound D**	50 mg	50 mg	F0B231	\$655
1347755	Amiloxate***	750 mg	750 mg	G0L414	\$210
1448617	Moxifloxacin Related Compound A****	25 mg	25 mg	F1M238	\$655
1598507	Ranitidine Related Compound A*****	50 mg	50 mg	I0L576	\$655

^{*}The Reference Standard name changed from Hydrocodone Bitartrate Related Compound A to Hydrocodone Related Compound A and the chemical name changed from Morphinan-6-one, 4-hydroxy-3-methoxy-17-methyl to 4-hydroxy-3-methoxy-17-methylmorphinan-6-one.

**** The chemical name in the item description was changed to (1-cyclopropyl-6,8-difluoro-1,4-dihydro-7-[(4aS,7aS)-octahydro-6H-pyrrolo[3,4-b]pyridin-6-yl]-4-oxo-3-quinolinecarboxylic acid).

*****The chemical name in the item description was changed to

 $(5\hbox{-}[[(2\hbox{-}aminoethyl)thio]methyl]\hbox{-}N,N-dimethyl-2-furanmethanamine, hemifumarate salt)}.$

^{**}This is not a new Lot. The chemical name has been corrected to (5-[acetyl(2-hydroxy-3-methoxypropyl)amino]-N,N'-bis(2,3-dihydroxypropyl)-2,4,6-triiodo-1,3-benzenedicarboxamide).

^{***} The Reference Standard name of this Item has changed to Amiloxate (formerly Isoamyl Methoxycinnamate).



RS Lots That are No Longer Valid

These Tables list 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 Longe	No Longer Valid as of June 30, 2013							
Catalog	Description	Previous	Lot/	Current	Price			
#	•	Valid Use	Date	Lot	(USD)			
1029013	Amitriptyline Related Compound A (25 mg)	F0F310	(06/13)	G0K409	\$655			
1029512	Amlodipine Related Compound A (15 mg)	F0I143	(06/13)	G0L172	\$655			
1062008	Benzyl Benzoate (5 g)	J0C060	(06/13)	K0K392	\$210			
1096600	Carisoprodol CIV (1 g)	H0J375	(06/13)	H1L295	\$278			
1130006	Chlorthalidone (200 mg)	I0C255	(06/13)	I1L127	\$210			
1173257	Desogestrel Related Compound B (15 mg)	G0F144	(06/13)	H0K327	\$655			
1234125	Efavirenz Related Compound A (20 mg)	F0l384	(06/13)	F1L237	\$655			
1234136	Efavirenz Related Compound C (20 mg)	F0I394	(06/13)	F1L211	\$655			
1234147	Efavirenz Related Compound B (10 mg)	F0J183	(06/13)	G0L438	\$655			
1317007	Hydrocortisone Acetate (200 mg)	K	(06/13)	L0L246	\$210			
1359404	Levetiracetam (200 mg)	G0J159	(06/13)	H0K337	\$285			
1424211	Methylbenzethonium Chloride (500 mg)	F0E101	(06/13)	G0K435	\$210			
1457505	Natamycin (200 mg)	J0D180	(06/13)	K0K368	\$210			
1477502	Octoxynol 9 (200 mg)	G	(06/13)	G1L235	\$210			
1494895	Pantoprazole Sodium (250 mg)	G0J258	(06/13)	H0L207	\$210			
1547936	Polysorbate 40 (2 g)	F0D204	(06/13)	F1K235	\$210			
1548407	Potassium Sorbate (1 g)	F0D264	(06/13)	G0K358	\$210			
1600824	Repaglinide Related Compound A (10 mg)	G0J300	(06/13)	H0L007	\$655			
1607007	Saccharin (200 mg)	G4C375	(06/13)	H0L091	\$210			
1642201	Sumatriptan Succinate (200 mg)	F1E256	(06/13)	G0L156	\$279			
1643496	Terbinafine Hydrochloride (200 mg)	F0G310	(06/13)	G0K287	\$210			
1651621	Delta-9-Tetrahydrocannabinol (1 mL)	G0H324	(06/13)	H0K404	\$245			
1672210	Topiramate Related Compound A (25 mg)	F0F279	(06/13)	G0L154	\$655			
1700002	Trypsin Crystallized (300 mg) (COLD SHIPMENT REQUIRED)	I0E055	(06/13)	J0L380	\$210			
1705301	Ubidecarenone (200 mg) (COLD SHIPMENT REQUIRED)	G0E154	(06/13)	H0L006	\$336			
1707839	Valacyclovir Hydrochloride (200 mg)	F0I084	(06/13)	G0K421	\$210			

No Longe	No Longer Valid as of July 31, 2013						
Catalog	Description	Previous	Previous Lot/		Price		
#		Valid Us	e Date	Lot	(USD)		
1040708	Apigenin-7-glucoside (30 mg)	G0H057	(07/13)	H0L150	\$655		
1083100	3-tert-Butyl-4-hydroxyanisole (200 mg)	M0G066	(07/13)	N0L032	\$210		
1097647	Cefepime Hydrochloride System Suitability (25 mg)	G0J374	(07/13)		\$655		
	(DISCONTINUED)						
1125006	Chlorpromazine Hydrochloride (200 mg)	J	(07/13)	J1K257	\$210		
1132001	Cholesteryl Caprylate (200 mg)	F	(07/13)	F1L277	\$210		
1287358	Gabapentin Related Compound D (10 mg)	G0K189	(07/13)	G1K279	\$655		
1294207	Glucosamine Hydrochloride (200 mg)	F0C363	(07/13)	F1L072	\$210		
1414025	Methotrexate Related Compound B (75 mg)	F0H350	(07/13)	G0L331	\$732		
1478844	Orlistat Related Compound D (10 mg)	F0I120	(07/13)	G0L570	\$684		
1554217	Pravastatin Related Compound A (10 mg)	F0G024	(07/13)	G0L198	\$655		
1570428	2-Propanol (1.2 mL/ampule; 3 ampules)	G0H068	(07/13)	H0J176	\$210		
1572558	Propofol Related Compound C (25 mg)	G0H165	(07/13)	G1K251	\$655		
1613564	Sodium Benzoate (1 g)	G0G183	(07/13)	H0L216	\$210		
1614396	Sodium Metabisulfite (1 g)	F0D111	(07/13)	F1L076	\$210		
1711508	Vidarabine (200 mg)	G-2	(07/13)	H0L212	\$210		

No Longe	No Longer Valid as of August 31, 2013						
Catalog	Description	Previous	s Lot/	Current	Price		
#	•	Valid Us	e Date	Lot	(USD)		
1005706	Glacial Acetic Acid (1.5 mL/ampule; 3 ampules)	G0E279	(08/13)	H0K218	\$210		
1044538	Atorvastatin Related Compound B (20 mg)	G0J256	(08/13)	H0L297	\$655		
1069007	Betamethasone Valerate (200 mg)	K0C330	(08/13)	L0K350	\$210		
1078755	Bupropion Hydrochloride Related Compound B (10 mg)	F0E011	(08/13)	G0L045	\$712		
1086312	Calcitriol Solution (5 mL) (COLD SHIPMENT REQUIRED)	F1J229	(08/13)	F2L073	\$258		
1090739	Capecitabine Related Compound C (10 mg) (COLD SHIPMENT REQUIRED)	H0L147	(08/13)	I0L372	\$655		
1097603	Cefazolin (200 mg)	L0C345	(08/13)	L1K284	\$210		
1141024	Clotrimazole Related Compound A (25 mg)	J0l329	(08/13)	J1K352	\$655		
1164008	Dapsone (200 mg)	H0D260	(08/13)	I0L013	\$210		
1231808	Econazole Nitrate (100 mg)	G1C346	(08/13)	H0K380	\$210		
1295800	Glycine (200 mg)	G1H369	(08/13)	H0L015	\$210		
1301801	Guanethidine Monosulfate (200 mg)	F1F192	(08/13)	G0L530	\$210		
1347653	Irinotecan Related Compound D (15 mg)	F0I246	(08/13)	G0L060	\$655		
1350400	Isopropyl Myristate (500 mg)	J0D247	(08/13)	K0K143	\$210		
1381742	Meradimate (500 mg/ampule) (Menthyl Anthranilate)	F0B103	(08/13)	G0L306	\$210		
1431603	Methyl Palmitate (300 mg)	G0E329	(08/13)	H0K274	\$210		
1443307	Mezlocillin Sodium (350 mg)	H0H213	(08/13)	H1L027	\$210		
1453005	Naloxone (125 mg)	M1I123	(08/13)	M2L247	\$167		
1477003	Nystatin (200 mg) (COLD SHIPMENT REQUIRED)	O1G308	(08/13)	O2K402	\$210		
1481204	Oxaliplatin (125 mg)	F0H306	(08/13)	G0L253	\$1,080		
1481237	Oxaliplatin Related Compound C (20 mg)	G0K194	(08/13)	H0L353	\$655		
1498706	Parbendazole (200 mg)	G0F331	(08/13)	H0L293	\$210		
1546900	Polyethylene Terephthalate (PET) (3 Strips)	G0G240	(08/13)	H0L135	\$210		
1570009	Promethazine Hydrochloride (500 mg)	L0F056	(08/13)	M0L315	\$210		
1612652	Simethicone (50 g)	K0I213	(08/13))	L0J395	\$210		
1643543	Temozolomide (200 mg)	F0J088	(08/13)		\$491		
1705323	Ubidecarenone Related Compound A (15 mg) (Coenzyme Q9) (COLD SHIPMENT REQUIRED)	G0I163	(08/13)	H0K297	\$655		
1708762	Valsartan (350 mg)	K1K224	(08/13)	L0L195	\$210		
1724521	Zidovudine Related Compound B (25 mg)	101363	(08/13)	J0K278	\$655		



Items with New Lots

Catalog	Description	Previous	Lot/	Current	Price
#		Valid Use	Date	Lot	(USD)
1003027	Acetaminophen Related Compound B (50 mg)	F0L217	(06/14)	F1M245	\$655
1012076	Acyclovir Related Compound A (50 mg)	G0K243	(06/14)	H0L558	\$665
1013068	Allopurinol Related Compound E (25 mg)	F0G094	(06/14)	G0M120	\$655
1134030	Ciclopirox Olamine (125 mg)	I0F067	(06/14)	J0L408	\$167
1232006	Edetate Calcium Disodium (200 mg)	H0B272	(06/14)	H1L565	\$210
1265402	Ethyl Acetate (1.2 mL/ampule; 3 ampules)	G0I239	(06/14)	H0K396	\$210
1279804	Fluoxetine Hydrochloride (200 mg)	G0F085	(06/14)	H0L518	\$210
1288317	Ganciclovir Related Compound A (15 mg)	G0J294	(06/14)	G1L421	\$838
1315012	Hydrocodone Related Compound A CII (70 mg)	F0C214	(06/14)	G0M030	\$690
1350002	Isopropamide Iodide (200 mg)	F-2	(05/14)	G0M260	\$210
1396331	Metformin Related Compound B (25 mg)	F0F019	(06/14)	G0M116	\$655
1440808	Metoclopramide Hydrochloride (500 mg)	H0D121	(06/14)	I0M065	\$210
1477943	Octisalate (400 mg) (Octyl Salicylate)	G0D278	(06/14)	H0L453	\$210
1494895	Pantoprazole Sodium (250 mg)	H0L207	(06/14)	H1M239	\$210
1494942	Pantoprazole Related Compound E (20 mg)	G0L292	(06/14)	G1M243	\$655
1522301	Pheniramine Maleate (150 mg)	G0H038	(06/14)	H0M087	\$210
1598507	Ranitidine Related Compound A (50 mg)	H2G343	(06/14)	I0L576	\$655
1624006	Sulfacetamide Sodium (500 mg)	I1B318	(06/14)	J0L478	\$210

USP Publication Highlights



USP 36-NF 31 is Now Official—Order Today for Compliance!

The 2013 edition of *USP-NF* became official and FDA-enforceable on May 1. Order today for access to important updates, including:

- New General Chapters: <17> Prescription Container Labeling. <1197> Good Distribution Practices for Bulk Pharmaceutical Excipients, and <1761> Applications of Nuclear Magnetic Resonance Spectroscopy
- Revised General Chapters: <788> Particulate Matter in Injections. <921> Water Determination, and <1136> Packaging—Unit of Use
- 89 new and revised monographs

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The 2012 DSC has 64 new dietary supplement monographs, 23 Admissions Criteria Safety Reviews, Guidance Documents, ~330 pages of full-color illustrations/images, and more. Order at www.usp.org/store/productsservices/dietary-supplements-compendium 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).



Order the New 2013 USP Dictionary for the Latest Drug Name Updates! The 2013 USP Dictionary of USAN and International Drug Names published

April 1 and features important updates to generic and brand drug names. pronunciations, chemical structures, UNII codes, and more! Available in print and online formats. Order now at http://www.usp.org/store/productsservices/usp-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).



Event Highlights

USP User Forums Coming to a City Near You!

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

More information including locations and dates is available here, or contact USPUserForum@usp.org.

Workshops

USP web forums and workshops encourage discussion of a wide range of current scientific findings and regulatory trends. Participants discuss hot topics that concern the public and exchange practical advice.

Information on workshops is available here.

Pharmacopeial Education

USP's Pharmacopeial Education division is dedicated to providing quality education for chemists, scientists, and healthcare practitioners in the United States and around the world. We seek to improve the effective implementation of standards that affect best practices for the development, manufacture, regulation, compounding, storage, and dispensing of pharmaceuticals, dietary supplements, food additives, and other therapeutics.

To find a course, please visit www.usp.org/education/pe/courses.html

Sign up here to receive Pharmacopeial Education information.



Compendial Highlights

New Official Text



Revision Bulletins:

Anagrelide Hydrochloride (posted 31-May-2013; official 01-Jun-2013)

Atorvastatin Calcium (posted 31-May-2013; official 01-Jun-2013; updated 05-Jun-2013)

Cefdinir for Oral Suspension (posted 31–May–2013; official 01–Jun–2013)

Griseofulvin Tablets (posted 31–May–2013; official 01–Jun–2013)

Saw P almetto Extract (posted 31–May–2013; official 01–Jun–2013)

Temozolomide (posted 31–May–2013; official 01–Jun–2013)

Verapamil Hydrochloride Extended-Release Capsules (posted 31-May-2013; official 01-Jun-2013; updated 05-Jun-2013)



Escitalopram Oxalate (posted 31–May–2013; official 01–Jul–2013)

High Fructose Corn Syrup (posted 31–May–2013; official 01–Jul–2013)

Tamsulosin Hydrochloride Capsules (posted 31-May-2013; official 01-Jul-2013)

Access new USP-NF Errata



Mew Stage 6 Notices

Next posting date: September 27, 2013

Hypromellose (posted 26-Apr-2013; official 01-May-2014)

Methylcellulose (posted 26–Apr–2013; official 01–May–2014)

Corn Starch (posted 26–Apr–2013; official 01–May–2014)

Compendial Notices

New

List of Revised Titles in the Description and Solubility Reference Table of USP 36-NF 31 2S (posted 03-Jun-2013)

Reagent PDFs and Errata PDFs Online for USP 36-NF 31 2S (posted 31-May-2013)

Implementation Deferred for General Chapters <232> Elemental Impurities—Limits and <233>

Elemental Impurities—Procedures (posted 24–May–2013)

General Announcements:

Elemental Impurities Key Issue Page Updated: Elemental Impurities Advisory Group: Meeting #1

Summary (posted 28-Jun-2013)

FCC 8, Third Supplement Revisions (posted 28–Jun–2013)

Pending Monographs Update (posted 28-Jun-2013)

Monograph Modernization List Updated (posted 28-Jun-2013)

Sign up to receive updates electronically at www.usp.org/support-home/opt-information-service.



Stimuli Articles

Featured in PF 39(4), July-August 2013

- A New General Chapter on Tablet Splitting
- Metal Packaging Systems and Their Materials of Construction for Pharmaceutical **Products**
- Overarching USP General Chapters on Good Distribution Practices
- Solubility Criteria for Veterinary Drugs—Workshop Report
- USP Melting Point Reference Standards: Evaluation of Parameters That Affect the Melting Point
- Vibrational Circular Dichroism as a New Technology for Determining the Absolute Configuration, Conformation, and Enantiomeric Purity of Chiral Pharmaceutical Ingredients

Tip of the Month

In our efforts to simplify customer login into USP's Products, USP Information Technology has implemented a Single Sign-On solution. Please note the following:

When you log into any of the following products:

1. http://www.usppf.com Pharmacopeial Forum 2. http://www.uspchromcolumns.com Chromatographic Columns 3. https://mc.usp.org/ Medicines Compendium 4. http://hmc.usp.org Herbal Medicines Compendium 5. http://fccforum.usp.org FCC Forum 6. http://www.foodfraud.org Food Fraud Database

A message and link to reset your password will pop up. Please follow the directions to reset your password. Once logged-in to one of the above listed products, you will be able to traverse between any of them.



Question of the Month

USP has deferred the proposed General Notices provision 5.60.30 Elemental Impurities. What is a "deferral" and what are the possible outcomes?

USP's standards-setting process requires that a standard be balloted by the responsible Expert Committee before it is published and becomes official. Under certain circumstances, e.g., when public comments indicate the need for a standard or part of a standard to be reconsidered, the Expert Committee may choose to defer the balloting of the text in question to allow time for additional review. Following a deferral, the standard may be balloted at a future date in its original or slightly modified form. Typically if the Expert Committee decides to significantly modify the original proposal, it would be reproposed for public comment, or canceled altogether.