



September 2008



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Click on links to go to sections.

For all the latest information, visit www.usp.org

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 2008; 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that have been discontinued/have a new price and/or have a new package size; items with lots that are (or soon will be) no longer valid; and items with new lots since the last email notice.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.

New Reference Standards Now Available

Catalog #	Description	Size	Lot	Price (USD)
1040683	Apigenin	30 mg	F0H245	\$250
1096622	Carvedilol	200 mg	F0G379	\$280
1270708	Flavoxate Hydrochloride	200 mg	F0H157	\$185
1356552	Ketoprofen Related Compound C	20 mg	F0H248	\$576
1478301	Olanzapine	200 mg	F0H200	\$185
1548032	Polyvinyl Acetate	1 g	F0H014	\$185
1672712	Trandolapril Related Compound D	25 mg	F0H163	\$576



Previously Out-of-Stock Items Now Available

Catalog #	Description	Size	Lot	Price (USD)
1046089	N-demethylazithromycin	15 mg	G0H164	\$576
1122722	Chloroxylenol Related Compound A	25 mg	H0H221	\$576
1140586	Clopidogrel Related Compound A	20 mg	G0H250	\$700
1176007	Dexamethasone	125 mg	K0H243	\$147
1329800	Hydroxypropyl Cellulose	500 mg	H0H051	\$185
1347700	Irbesartan	200 mg	G0H216	\$185
1361009	Levodopa	200 mg	J0H244	\$185
1432005	Methylparaben	125 mg	K1H071	\$147
1457403	Naproxen Sodium	200 mg	J1H092	\$185
1500808	Penbutolol Sulfate	200 mg	G0H272	\$185
1539508	Pimozide	200 mg	G1H103	\$185
1553000	Pralidoxime Chloride	200 mg	H0H050	\$185
1620220	Stavudine System Suitability Mixture	10 mg	F1G128	\$576
1642212	Sumatriptan Succinate Related Compound A	15 mg	H0H253	\$738
1676000	Triamcinolone	250 mg	J0H208	\$185
1681000	Trichlormethiazide	200 mg	I0H202	\$185
1706701	Urea C13	150 mg	I0H205	\$216





Backorder Availability Estimates, August 25, 2008

Catalog #	Description	Expected Availability*
1032007	Amphotericin B (125 mg)	Q4/08
1044800	Atracurium Besylate (100 mg)	Q4/08
1045009	Atropine Sulfate (500 mg)	Q4/08
1047503	Bacitracin (1 g) (Susceptibility disk standard)	Q4/08
1068004	Betamethasone Sodium Phosphate (500 mg)	Q4/08
1224802	Docusate Sodium (500 mg)	Q3/08
1254508	Estriol (100 mg)	Q4/08
1358503	Leuprolide Acetate (200 mg)	Q4/08
1381006	Menadione (200 mg) (Vitamin K3)	Q3/08
1392002	Mercaptopurine (500 mg)	Q4/08
1410002	Methicillin Sodium (500 mg) (AS)	Q4/08
1471007	Norethynodrel (200 mg)	Q4/08
1499414	Paricalcitol Solution (3 mL)	Q4/08
1500808	Penbutolol Sulfate (200 mg)	Q3/08
1598700	Ranitidine Related Compound C (50 mg)	Q3/08
1601623	Residual Solvent Class 2 - Methanol (1.2 mL/ampule; 3 ampules)	Q4/08
1620220	Stavudine System Suitability Mixture (20 mg)	Q3/08
1651621	Delta-9-Tetrahydrocannabinol (1 mL)	Q4/08
1673828	Trenbolone Acetate CIII (200 mg)	Q4/08

*Dates are targets and may change at any time. Q3/08=July–September 2008, Q4/08=October–December 2008

Items with New Package Size

Catalog #	Description	Old Size	New Size	Lot	Price (USD)
1329800	Hydroxypropyl Cellulose	200 mg	500 mg	H0H051	\$185
1620220	Stavudine System Suitability Mixture	20 mg	10 mg	F1G128	\$576
1706701	Urea C13	100 mg	150 mg	I0H205	\$216

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RS Lots That are No Longer Valid

This Table 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 Catalog online at www.usp.org: click on the USP Products link and look up the RS of interest.

Note: The Valid Use Date for Betamethasone Sodium Phosphate Lot L0G223 was changed to May 2008.

No Longer Valid as of August 31, 2008				
Catalog #	Description	Previous Lot/ Valid Use Date	Current Lot	Price (USD)
1045337	Avobenzene (500 mg)	G1E109 (08/08)	H0G220	\$185
1048630	Benazepril Related Compound B (15 mg)	F1E156 (08/08)	G0G206	\$576
1067001	Betamethasone Acetate (500 mg)	J0B079 (08/08)	K0G274	\$185
1134073	Cimetidine Hydrochloride (200 mg)	F (08/08)	G0G176	\$185
1183002	Diacetylmorphine Hydrochloride CI (25 mg) (AS) (Heroin Hydrochloride)	J (08/08)	J1G200	\$245
1218005	Diphenhydramine Hydrochloride (200 mg)	J0B013 (08/08)	J1G210	\$185
1236007	Ephedrine Sulfate (200 mg) (List Chemical)	H-2 (08/08)	I0G194	\$185
1286005	Folic Acid (500 mg) (Vitamin M or Vitamin Bc)	P (08/08)	Q0G151	\$185
1313006	Hydralazine Hydrochloride (200 mg)	K1E183 (08/08)	L0G068	\$185
1339000	Indigotindisulfonate Sodium (500 mg)	H1B153 (08/08)	H2G304	\$185
1349659	Isometheptene Mucate (200 mg)	F (08/08)	G0F338	\$185
1367005	Lincomycin Hydrochloride (200 mg)	H2B130 (08/08)	H3G186	\$185
1444279	Mirtazapine (350 mg)	F0D155 (08/08)	G0G145	\$947
1466007	Nitrofurazone Related Compound A (500 mg)	H0B100 (08/08)	I0G265	\$576
1531007	Phenylbutazone (250 mg)	J0A008 (08/08)	K0G199	\$185
1585006	Pyrazinamide (200 mg)	G (08/08)	H0G198	\$185
1598405	Ranitidine Hydrochloride (200 mg)	H0B268 (08/08)	H1G103	\$185
1613564	Sodium Benzoate (1 g)	F0E025 (08/08)	G0G183	\$185
1643408	Temazepam CIV (200 mg)	H0C205 (08/08)	H1G187	\$245
1711155	Vecuronium Bromide (50 mg)	F0C367 (08/08)	G0G252	\$185

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No Longer Valid as of September 30, 2008				
Catalog #	Description	Previous Lot/ Valid Use Date	Current Lot	Price (USD)
1043003	Ascorbic Acid (1 g) (Vitamin C)	Q0B012 (09/08)	Q1G135	\$185
1166003	Deferoxamine Mesylate (500 mg)	I (09/08)	J0G233	\$185
1194009	Diethylpropion Hydrochloride CIV (200 mg)	H (09/08)	I0G127	\$245
1213001	Dinoprost Tromethamine (50 mg)	F (09/08)	G0G082	\$1,805
1282004	Fluphenazine Hydrochloride (125 mg)	H (09/08)	I0G294	\$147
1292347	Glimepiride Related Compound D (20 mg)	F0E235 (09/08)	F1G258	\$576
1349502	L-Isoleucine (200 mg)	F-2 (09/08)	G0G167	\$185
1370462	Losartan Potassium (250 mg)	F0D287 (09/08)	G0G169	\$185
1441287	Metoprolol Fumarate (200 mg)	F (09/08)	G0G148	\$185
1445211	Mitoxantrone System Suitability Mixture (0.3 mg)	F0D010 (09/08)	G0F107	\$592
1511203	Perphenazine Sulfoxide (100 mg)	G-1 (09/08)	H0G202	\$576
1578000	Propylthiouracil (200 mg)	G (09/08)	H0G031	\$185
1580002	Protriptyline Hydrochloride (200 mg)	G0E034 (09/08)	H0G267	\$185
1602706	Ribavirin (200 mg)	H1C335 (09/08)	I0G153	\$342
1643500	Terbutaline Sulfate (125 mg)	H (09/08)	I0G250	\$147

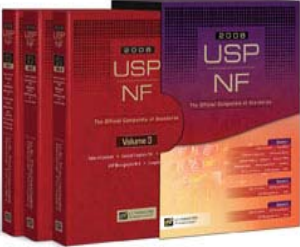

Items with New Lots

Catalog #	Description	Previous Lot/ Valid Use Date	Current Lot	Price (USD)
1012780	Alendronate Sodium (200 mg)	G0D288 (08/09)	H0H004	\$185
1046089	N-Demethylazithromycin (15 mg)	F0E068 (02/09)	G0H164	\$576
1048619	Benazepril Hydrochloride (125 mg)	G0E079 (08/09)	G1G280	\$185
1086301	Calcitriol (10 mg)	G0F104 (05/09)	H0H053	\$1,481
1122722	Chloroxylenol Related Compound A (25 mg)	F-1 (07/04)	H0H221	\$576
1140586	Clopidogrel Related Compound A (20 mg)	F1F332 (07/09)	G0H250	\$700
1140600	Clopidogrel Related Compound C (20 mg)	F1F333 (07/09)	F2H215	\$700
1176007	Dexamethasone (125 mg)	J (08/09)	K0H243	\$147
1271722	Fluconazole Related Compound B (10 mg)	G0F218 (08/09)	H0H123	\$576
1271733	Fluconazole Related Compound C (10 mg)	G0F202 (08/09)	H0H124	\$576
1329800	Hydroxypropyl Cellulose (500 mg)	G0F066 (07/09)	H0H051	\$185
1347700	Irbesartan (200 mg)	F0F293 (07/09)	G0H216	\$185
1361009	Levodopa (200 mg)	I (06/09)	J0H244	\$185
1432005	Methylparaben (125 mg)	K0C382 (07/09)	K1H071	\$147
1457403	Naproxen Sodium (200 mg)	J0C379 (07/09)	J1H092	\$185
1539508	Pimozide (200 mg)	G (07/09)	G1H103	\$185
1553000	Pralidoxime Chloride (200 mg)	G-2 (07/09)	H0H050	\$185
1612630	Silybin (50 mg)	G0D392 (07/09)	G1H175	\$185
1642212	Sumatriptan Succinate Related Compound A (15 mg)	G0F113 (06/08)	H0H253	\$738
1681000	Trichlormethiazide (200 mg)	H (06/09)	I0H202	\$185
1706701	Urea C 13 (150 mg)	H0E110 (08/09)	I0H205	\$216
1708784	Valsartan Related Compound B (10 mg)	F0G129 (07/09)	G0H058	\$738

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USP Publication Highlights

	<p>Be Prepared for 2009—Order USP 32–NF 27 Today! Available November 1 in English in print, online, and CD formats. An annual subscription includes a main edition and two Supplements. The <i>USP 32–NF 27</i> Spanish Edition will be published in print only in January. Subscribe today at www.usp.org 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>View the New Electronic USP Publications Catalog at www.usppublications.com You'll find complete details on current and upcoming USP publications and links to sample pages, Flash previews, and more! It allows you to "Click through" ordering to the USP Online Store. Published online twice a year –it's FREE!</p>

Publications Scheduled Ship Dates

The following table lists the scheduled ship dates for USP publications.

Publication	Scheduled Ship/Post Date
PF 34(5) Print	September 8, 2008
Pharmacists' Pharmacopeia Second Edition Supplement 2 Online	October 1, 2008
PF 34(6) Highlights	October 24, 2008
PF 34(6) Online	October 31, 2008
USP32–NF27 Print	November 3, 2008
USP32–NF27 Online	November 3, 2008
USP32–NF27 CD	November 3, 2008
PF 34(6) Print	November 7, 2008

Orders should arrive within two weeks of placement. If you do not receive your publication order when expected, please contact USP Customer Service at +1-301-881-0666 or email custsvc@usp.org



Event Highlights

USP Annual Scientific Meeting

A great way to get involved with USP, the 2008 USP Annual Scientific Meeting will be held September 24–26, 2008 at the Westin Crown Center in Kansas City, MO. For more information on the meeting, visit www.usp.org/meetings/asMeeting/.

Pharmacopeial Education

Featured Courses

On-Demand courses are now available!

USP's on-demand online courses are 60- to 90-minute web casts designed with your scheduling and budget needs in mind. These modules are available 24 hours a day, 7 days a week via a computer with broadband connection, and cover a wide range of standards-based courses critical to performing your job. You have the flexibility to subscribe to a series or a single web cast, allowing you to control the breadth and the topics you would like to learn about. USP experts are also available to answer your questions via email.

On demand courses available now for free include: (click course title for more information or click view to take the course):

[Introduction to the New FCC](#)

[View](#)

[Navigating the FCC](#)

[View](#)

[How to Use the FCC Forum—Making the FCC Your Own](#)

[View](#)

[How to Develop an FCC Monograph](#)

[View](#)

Dissolution: Theory and Best Practices

Receive a hands-on overview of the history, theory, and practice of pharmaceutical dosage form dissolution testing to support quality assurance as required by General Chapter <711>.

Intended For: Scientists, chemists, and laboratory technicians who perform dissolution testing in the laboratory; quality control staff; and product development professionals who review dissolution data

Format: Traditional Classroom, 2 Day, Lecture and Lab

Classroom Cost: US \$1,495, click [here](#) to register.

Date and Location: October 1-2, 2008; Distek, NJ

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Validation of Compendial Procedures

Gain insight into USP's perspective on validation methods required by General Chapter <1225>. Learn requirements of specific validation performance parameters and their relationships to other relevant General Chapters.

Classroom Cost: US \$695.00

Date and Location: October 16, 2008; Chicago, IL. Click [here](#) to register.

Date and Location: November 7, 2008, Rockville, MD. Click [here](#) to register.

TLC for Dietary Supplements: Botanicals

This course offers guidance in translating the information of Chapter <621> into a practical methodology and interpreting results obtained with compendial thin layer chromatography (TLC) methods within the realm of botanicals. We are offering a one-day lecture/demonstration course and a two-day lecture/lab course.

1-day offering – Date, Location, and Cost: October 30, 2008 – Salt Lake City, UT (Lecture and Demonstration), click [here](#) for registration information. \$495.00 for the first person, \$295 per each additional person

2-day offering – Date, Location, and Cost: November 5–6, 2008 – Irvine, CA (Lecture and Lab), click [here](#) to register. \$995.00 per person

Essentials of Microbiological Testing

Course establishes a practical understanding of microbiological practices in the pharmaceutical industry and provides an overview of the USP General Chapters which address microbiological testing.

Classroom Cost: \$ 495.00 for first, \$295 per each additional person.

1-day offering – Cost, Date and Location: \$695, November 3, 2008 – Raleigh, NC (Lecture and Demonstration), click [here](#) to register.

2-day offering – Cost, Date and Location: \$995, November 3–4, 2008 – Raleigh, NC (Lecture and Lab), click [here](#) to register.

Upcoming PE Courses

- [USP/ISMP Workshop: Using Data Effectively to Manage the Risks to Medication Safety](#)
- [Dissolution: Theory and Best Practices](#)
- [Validation of Compendial Procedures](#)
- [Essentials of Microbiological Testing](#)
- [Effectively Using USP-NF](#)

Subscribe to the Pharmacopeial Education Email Bulletin

USP Pharmacopeial Education is developing several new courses for introduction in 2008 and 2009. If you would like to stay informed of our new curriculum and upcoming schedule, [subscribe now](#) to the Pharmacopeial Education Bulletin.

For the complete USP Education course list, please go to <http://www.usp.org/education/pe/courses.html>



Compendial Highlights

[USP–NF Notices](#)

Sign up to receive Notices electronically at

<http://www.usp.org/support/products/uspNewslettersRequest.html?promo=compendial>

Revision Bulletins: [USP Postpones the Official Date of General Chapter <381> Elastomeric Closures for Injections – Implementation Date Delayed to May 2009](#) (08/07/08)

Explanatory Notes/Announcements: Nothing New

Intent to Revise: [Galantamine Tablets: Intent to Revise](#) (08/01/08)

Errata: [Erratum to Lidocaine and Prilocaine Cream Revision Bulletin](#) (08/22/08)

Postponements: [USP Postpones the Official Date of the General Chapter <1> Injections Labeling on Ferrules and Cap Overseals](#) (08/22/08)

General: [First Supplement USP 31-NF 26 included three errors in USP General Chapters <61> and <62>](#) (08/15/08)

Levothyroxine Sodium Tablets Monograph Revision- Based on the request received from the FDA, the Levothyroxine Sodium Tablets Monograph will be revised to narrow the assay range specification from the current "not less than 90.0 percent and not more than 110.0 percent of the labeled amount of levothyroxine sodium" to "not less than 95.0 percent and not more than 105.0 percent of the labeled amount of levothyroxine sodium." **The revised monograph will become official on October 3, 2009.** The current proposed change is available for public review in the *Pharmacopeial Forum 34(1) (January-February 2008)*. Please direct any comments or questions related to the revision to Dr. Elena Gonikberg, Senior Scientist, eg@usp.org

Stimuli Articles

Featured in *PF 34(5)*, September–October 2008

[General Chapter on Inorganic Impurities: Heavy Metals](#) (336KB)

[The Cadaver Skin Absorption Model and the Drug Development Process](#) (331KB)



Tip of the Month

Did you know that USP performs 3rd party certification for Dietary Supplements, Dietary Supplement Ingredients, and Pharmaceutical Ingredients including drug substances and excipients? Learn more about the [USP Verification Program](#) including which companies are participating, which items have been USP Verified, how USP does verification, and how you can participate by visiting <http://www.usp.org/USPVerified/> or by contacting Rob Tyler, 301-816-8233, rt@usp.org

Question of the Month

In a USP monograph test for Loss on Drying <731>, what is the acceptable temperature range for the temperature specified?

Per <731>, the temperature specified in the monograph is to be regarded as being within the range of $\pm 2^\circ$ of the stated figure.

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