



August 2008



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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 July 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that have been discontinued/have a new price and/or have a new package size; items with lots that are (or soon will be) no longer valid; and items with new lots since the last email notice.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)
1286129	Formoterol Fumarate Resolution Mixture	20 mg	F0H168	\$673
1535824	Bovine Acellular Dermal Matrix Reference Photomicrographs	CD	F0H106	\$287

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**Previously Out-of-Stock Items Now Available**

Catalog #	Description	Size	Lot	Price (USD)
1002505	Acesulfame Potassium	200 mg	G0H082	\$308
1086301	Calcitriol	10 mg	H0H053	\$1481
1091006	Capreomycin Sulfate	250 mg	H0H181	\$185
1288510	Gemfibrozil Related Compound A*	20 mg	H0H180	\$576
1320001	Hydrocortisone Phosphate Triethylamine	200 mg	G0H109	\$185
1330005	Hypromellose	250 mg	H1H066	\$185
1357001	L-Leucine	200 mg	H1H198	\$185
1443307	Mezlocillin Sodium	350 mg	H0H213	\$185
1601000	Reserpine	200 mg	P0H197	\$185
1612415	Sesame Oil Related Compound A	6 mg /vial; 3 vials	F1H059	\$576
1612550	Sevoflurane Related Compound A	0.2 mL	H0H072	\$576
1612630	Silybin	50 mg	G1H175	\$185
1623648	Sufentanil Citrate CII	25 mg	I0G358	\$260

*The chemical name has changed to (E,Z)-2,2-dimethyl-5-[2,5-dimethyl-4-(propene-1-yl)phenoxy]valeric acid.



Backorder Availability Estimates, July 21, 2008

Catalog #	Description	Expected Availability*
1032007	Amphotericin B (125 mg)	Q3/08
1044800	Atracurium Besylate (100 mg)	Q3/08
1046089	N-Demethylazithromycin (15 mg)	Q3/08
1047503	Bacitracin (1 g) (Susceptibility disk standard)	Q3/08
1068004	Betamethasone Sodium Phosphate (500 mg)	Q4/08
1086301	Calcitriol (10 mg)	Q3/08
1122722	Chloroxylenol Related Compound A (25 mg)	Q3/08
1140600	Clopidogrel Related Compound C (20 mg)	Q3/08
1173202	Desmopressin Acetate (1.91 mg)	Q4/08
1224802	Docusate Sodium (500 mg)	Q3/08
1254508	Estriol (100 mg)	Q3/08
1329800	Hydroxypropyl Cellulose (200 mg)	Q3/08
1358503	Leuprolide Acetate (200 mg)	Q4/08
1361009	Levodopa (200 mg)	Q3/08
1392002	Mercaptopurine (500 mg)	Q3/08
1410002	Methicillin Sodium (500 mg) (AS)	Q4/08
1457403	Naproxen Sodium (200 mg)	Q3/08
1471007	Norethynodrel (200 mg)	Q4/08
1499414	Paricalcitol Solution (3 mL)	Q3/08
1500808	Penbutolol Sulfate (200 mg)	Q3/08
1553000	Pralidoxime Chloride (200 mg)	Q3/08
1612630	Silybin (50 mg)	Q3/08
1642212	Sumatriptan Succinate Related Compound A (15 mg)	Q3/08
1651621	Delta-9-Tetrahydrocannabinol (1 mL)	Q3/08
1673828	Trenbolone Acetate CIII (200 mg)	Q4/08
1676000	Triamcinolone (250 mg)	Q3/08
1681000	Trichlormethiazide (200 mg)	Q3/08
1708784	Valsartan Related Compound B (10 mg)	Q3/08

*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)
1029909	Ammonio Methacrylate Copolymer Type A	100 mg	500 mg	G0G291	\$185



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.

No Longer Valid as of July 31, 2008					
Catalog #	Description	Previous Lot/ Valid Use Date	Current Lot	Price (USD)	
1068004	Betamethasone Sodium Phosphate (500 mg)	K0C358 (07/08)	LOG223	\$185	
1129007	Chlortetracycline Hydrochloride (200 mg)	K0C185 (07/08)	LOF198	\$185	
1224700	Docusate Calcium (500 mg)	H0B044 (07/08)	H1G144	\$185	
1302509	Halcinonide (200 mg)	F (07/08)	G0G239	\$185	
1349706	Isoniazid (200 mg)	H (07/08)	I0G205	\$185	
1356916	Lansoprazole (150 mg)	G0D307 (07/08)	H0G191	\$185	
1370338	Lorazepam Related Compound B (25 mg)	G (07/08)	G1G125	\$576	
1375105	Mannitol (200 mg)	I0B212 (07/08)	I1G090	\$185	
1396400	Methacrylic Acid Copolymer Type A (200 mg)	G0B140 (07/08)	G1F057	\$185	
1412008	Methocarbamol (200 mg)	H2B029 (07/08)	I0G112	\$185	
1431625	Methyl Palmitoleate (300 mg)	F (07/08)	G0F330	\$185	
1450007	Nafcillin Sodium (200 mg)	H (07/08)	I0G229	\$185	
1612641	Silydianin (20 mg)	F (07/08)	G0F200	\$185	
1614308	Sodium Lactate (200 mg)	J0E249 (07/08)	K0G115	\$185	
1623706	Sulfabenzamide (200 mg)	G (07/08)	G1A020	\$185	
1670207	Tolcapone (200 mg)	F0D280 (07/08)	F1G397	\$185	
1682206	Triclosan (200 mg)	G0D001 (07/08)	H0G147	\$185	
1724532	Zidovudine Related Compound C (100 mg)	F-1 (07/08)	G0G181	\$576	



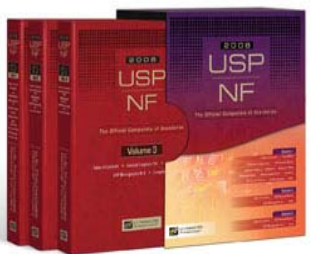
No Longer Valid as of August 31, 2008				
Catalog #	Description	Previous Lot/ Valid Use Date	Current Lot	Price (USD)
1045337	Avobenzene (500 mg)	G1E109 (08/08)	H0G220	\$185
1048630	Benazepril Related Compound B (15 mg)	F1E156 (08/08)	G0G206	\$576
1067001	Betamethasone Acetate (500 mg)	J0B079 (08/08)	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
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

Items with New Lots

Catalog #	Description	Previous Lot/ Valid Use Date	Current Lot	Price (USD)
1002505	Acesulfame Potassium (200 mg)	F0C136 (06/09)	G0H082	\$308
1029909	Ammonio Methacrylate Copolymer Type A (500 mg)	F-1 (06/09)	G0G291	\$185
1091006	Capreomycin Sulfate (250 mg)	G1F191 (05/09)	H0H181	\$185
1288510	Gemfibrozil Related Compound A (20 mg)	G0D369 (06/09)	H0H180	\$576
1320001	Hydrocortisone Phosphate Triethylamine (200 mg)	F-1 (12/08)	G0H109	\$185
1335541	Ibuprofen Related Compound C (0.2 mL/ampule; 3 ampules)	F0F011 (07/09)	F1H048	\$576
1357001	L-Leucine (200 mg)	H0B237 (06/09)	H1H198	\$185
1546809	Low-Density Polyethylene (3 strips)	H0E114 (07/09)	I0G312	\$185
1604701	Ritodrine Hydrochloride (200 mg)	G-1 (07/09)	H0G333	\$185
1612415	Sesame Oil Related Compound A (6 mg/vial; 3 vials)	F0E131 (02/08)	F1H059	\$576
1612550	Sevoflurane Related Compound A (0.2 mL)	G0F348 (06/09)	H0H072	\$576
1613509	Sodium Ascorbate (200 mg)	G2C067 (07/09)	H0G289	\$185
1623648	Sufentanil Citrate CII (25 mg)	H1E105 (06/09)	I0G358	\$260



USP Publication Highlights

	<p>Reserve Your New USP 32–NF 27 Today! Order the new <i>USP–NF</i> in English now and receive your copy once it publishes on November 1. You'll have extra time to prepare for important new and revised standards that become official in 2009. (Spanish edition publishes January 2009.) Visit www.usp.org/products/USPNF/ for details.</p>
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Publications Scheduled Ship Dates

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

Publication	Scheduled Ship/Post Date
<i>USP31–NF26 Second Supplement Spanish</i>	August 1, 2008
<i>PF 34(5) Highlights</i>	August 22, 2008
<i>PF 34(5) Online</i>	August 29, 2008
<i>PF 34(5) Print</i>	September 8, 2008
Pharmacists' Pharmacopeia Second Edition Supplement 2 Online	October 15, 2008
<i>PF 34(6) Highlights</i>	October 24, 2008
<i>PF 34(6) Online</i>	October 31, 2008
<i>USP32–NF27 Print</i>	November 3, 2008
<i>USP32–NF27 Online</i>	November 3, 2008
<i>USP32–NF27 CD</i>	November 3, 2008
<i>PF 34(6) Print</i>	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 Bioassay Workshop, August 13–14, 2008, USP Headquarters in Rockville, MD

Bioassays continue to play an essential role in drug development and in many phases of the pharmaceutical product lifecycle. This workshop will address USP General Chapters on the Design, Development, Analysis and Validation of Bioassays. The development, analysis, and validation of bioassays typically require teams of scientists, technicians and statisticians to move a bioassay from development to practice. The new USP chapters and this workshop will provide best-practice guidelines to facilitate this process. The workshop will also explore the role of bioassays in monographs, the transition from animal assays to cell based assays, and bioassays for potency and immunogenicity testing. This interactive event will not only provide guidance and information on bioassays, but will also provide an opportunity for vigorous discussion of the compendial proposals.

For more information or to register for this event please click on the following link:

<http://ems.intellor.com/?p=201821&do=register&t=12>

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

USP Pharmacopeial Education introduces on-demand courses.

In response to suggestions from students, USP will make selected online courses available on-demand starting late this summer. Selected courses will include but are not limited to the popular FCC and <797> webinar series.

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.

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Effectively Using *USP-NF*

Increase your productivity and save money by learning to derive the most important information from the *USP-NF*, *USP-NF Supplements*, and *Pharmacopeial Forum*. As an added benefit, you will have a tour of the new headquarters and labs where the trusted standards recognized and used in more than 130 countries are developed.

Intended For: Laboratory scientists, lab managers, and compliance staff in the pharmaceutical and allied industries

Format: Traditional Classroom, Full Day, Lecture

Classroom Cost: US \$695, click [here](#) to register. **Registrations will be accepted at the door.**

Date and Location: August 6, 2008; Rockville, MD

Navigating Chapter <467> Residual Solvents (online course)

Back by Popular Demand!

Changes to Chapter <467> became effective July 1, 2008. However, many companies are not yet in compliance with or are confused by the new changes to Chapter <467>. USP will offer this in-depth web based course on interpreting and applying the new USP standards for the control of residual solvents. Highlighting the analytical procedures contained in Chapter <467>, this course will also help you structure protocols for the tests and procedures necessary to demonstrate compliance.

Intended For: Lab managers, bench chemists, QA/QC personnel, those involved with method validation in the pharmaceutical and allied industries.

Format: Web based education, 10 hours of self paced learning over 10 days.

Classroom Cost: US \$399, click [here](#) to register.

Date and Location: September 4, 2008; available online! View on your PC at home or at the office.

Dissoluton: 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

Upcoming PE Courses

- [USP/ISMP Workshop: Using Data Effectively to Manage the Risks to Medication Safety](#)
- [Effectively Using USP-NF](#)
- [Navigating Chapter <467> Residual Solvents](#)
- [Dissolution: Theory and Best Practices](#)
- [Validation of Compendial Procedures](#)
- [Essentials of Microbiological Testing](#)

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.

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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: [Heparin Sodium and Heparin Calcium Monographs](#) (06/18/08)

Explanatory Notes/Announcements: [USP to Defer Decision on Green Tea Extract Cautionary Labeling](#) 
(49KB) (07/02/08)

Intent to Revise: Nothing New

Errata: [Erratum to Mannitol Injection Monograph](#) (07/02/08)

Postponements: Nothing New

General: [Electronic Second Supplement USP 31–NF 26 includes an incorrect version of General Chapter <55> Biological Indicators–Resistance Performance Tests. Download the corrected PDF.](#) (07/23/08)

Inorganic Impurities (Heavy Metals) Stimuli Article—04/23/08. To read the article before it is published in *PF34(5)* click [here](#)

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(4)*, July–August 2008

[The Inhalation Ad Hoc Advisory Panel for the USP Performance Tests of Inhalation Dosage Forms](#)
[Use of Scanning Electron Microscopy in the Authentication of Botanicals](#)



Tip of the Month

In an effort to improve drug product, drug substance, and excipient monographs to current scientific/regulatory standards, USP is seeking submission of proposals for improved methods for inclusion in the following *USP-NF* monographs. Click [here](#) for details and to see the list of monographs.

Question of the Month

Can USP-NF methods for tablets be assumed to be valid for capsules?

No, the tablet method was developed and validated for a specific product so a capsule method would have to be developed and validated. Even when using the official tablet method for your tablet, verification of the method is required <1226>.

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