



January 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 December 2007; 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that have been discontinued/have a new price and/or have a new package size; items with lots that are (or soon will be) no longer valid; and items with new lots since the last email notice.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 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

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Catalog #	Description	Size	Lot	Price (USD)
1000408	Abacavir Sulfate	200 mg	F0G247	\$176
1000419	Abacavir Sulfate Racemic	20 mg	F0G248	\$549
1135600	Climbazole	400 mg	F0G338	\$176
1265424	Ethyl Acrylate and Methyl Methacrylate Copolymer Dispersion	1.5 g	F0F189	\$176
1287755	Galantamine Hydrobromide	200 mg	F0G339	\$260
1287766	Galantamine Hydrobromide Racemic	15 mg	F0G344	\$549
1356960	Leflunomide	200 mg	F0G328	\$218
1357045	Leflunomide Related Compound A	50 mg	F0G330	\$549
1357056	Leflunomide Related Compound B	10 mg	F0G342	\$549
1357067	Leflunomide Related Compound C	10 mg	F0G341	\$549
1362307	Levomendol	100 mg	F0D302	\$176
1576683	Propylene Glycol Dicaprylate/ Dicaprate	1 mL	F0G287	\$176
1576785	Propylene Glycol Monolaurate, Type I	500 mg	F0E202	\$176



Previously Out-of-Stock Items Now Available

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Catalog #	Description	Size	Lot	Price (USD)
1027302	Amiodarone Hydrochloride	200 mg	G0G340	\$176
1078711	Buprenorphine Related Compound A	25 mg	G0G353	\$549
1282004	Fluphenazine Hydrochloride	125 mg	I0G294	\$140
1433008	Methylphenidate HCl CII	125 mg	J0G307	\$187
1623637	Sucrose	100 mg	H2G263	\$176
1677002	Triamcinolone Acetonide	500 mg	L0G322	\$176

Backorder Availability Estimates, December 17, 2007

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Catalog #	Description	Expected Availability*
1078700	Buprenorphine Hydrochloride CIII (50 mg)	Q4/07
1254508	Estriol (100 mg)	Q3/08
1320001	Hydrocortisone Phosphate Triethylamine	Q2/08
1341001	Indomethacin (200 mg)	Q1/08
1375058	Mandelic Acid (500 mg)	Q1/08
1392002	Mercaptopurine (500 mg)	Q1/08
1477003	Nystatin (200 mg)	Q1/08
1494079	Pancreatin Lipase (2 g)	Q1/08
1642212	Sumatriptan Succinate Rel Cpd A	Q2/08
1646009	Testosterone CIII (125 mg)	Q1/08
1670207	Tolcapone (200 mg)	Q1/08

*Dates are targets and may change at any time. Q4/07 = October–December 2007, Q1/08 = January–March 2008, Q2/08 = April–June 2008, Q3/08 = July–September 2008

Items with New Package Size

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Catalog #	Description	Old Size	New Size	Lot	Price (USD)
1078711	Buprenorphine Related Compound A	50 mg	25 mg	G0G353	\$549
1303013	Haloperidol Related Compound A	15 mg	10 mg	L0G226	\$549



RS Lots That Are No Longer Valid

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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 and online at www.usp.org; click on the USP Products link and look up the RS of interest.

No Longer Valid as of December 31, 2007					
Catalog #	Description	Previous Lot/ Valid Use Date	Current Lot	Price (USD)	
1041609	Apraclonidine Hydrochloride (100 mg)	H0B112 (12/07)	I0G001	\$567	
1081002	Butalbital CIII (200 mg)	H0C054 (12/07)	I0F204	\$245	
1091221	Captopril Disulfide (100 mg)	G1B066 (12/07)	H0F251	\$576	
1096757	Carteolol Hydrochloride (200 mg)	F-1 (12/07)	G0F326	\$185	
1096917	Cefaclor, Delta-3 Isomer (30 mg)	G (12/07)	H0G136	\$576	
1098231	Cefuroxime Axetil Delta-3-Isomers (10 mg)	H1E186 (12/07)	H2G014	\$576	
1107300	Chloramphenicol Palmitate (200 mg)	G-1 (12/07)	H0G266	\$185	
1138507	Clocortolone Pivalate (200 mg)	G (12/07)	H0G097	\$185	
1140597	Clopidogrel Related Compound B (20 mg)	F0E119 (12/07)	G0F319	\$700	
1140509	Clorazepate Dipotassium CIV (125 mg)	G0B027 (12/07)	G1F159	\$245	
1158504	Cyclosporine (50 mg)	H-1 (12/07)	I0F343	\$567	
1185020	Diazepam Related Compound A (25 mg)	I (12/07)	I1F077	\$576	
1271733	Fluconazole Related Compound C (10 mg)	F0D082 (12/07)	G0F202	\$576	
1336205	Ifosfamide (500 mg)	G1C371 (12/07)	H0F233	\$185	
1392705	Mesalamine (200 mg)	H0C341 (12/07)	I0F121	\$185	
1498706	Parbendazole (200 mg)	F (12/07)	G0F331	\$185	
1576708	Propylene Glycol (1 mL)	I0C022 (12/07)	J0F211	\$185	
1609002	Salicylic Acid (125 mg)	J3C400 (12/07)	K0F112	\$147	



No Longer Valid as of January 31, 2008

Catalog #	Description	Previous Lot/ Valid Use Date	Current Lot	Price (USD)
1131009	Cholecalciferol (30 mg/ampule; 5 ampules) (Vitamin D3)	M0B157 (01/08)	N0G038	\$189
1138008	Clindamycin Phosphate (125 mg)	I0C165 (01/08)	I1F315	\$253
1140600	Clopidogrel Related Compound C (20 mg)	F0E118 (01/08)	F1F333	\$700
1150353	Creatinine (100 mg)	F (01/08)	F1F318	\$185
1236801	Epilactose (200 mg)	H0E049 (01/08)	I0F194	\$576
1241506	Ergotamine Tartrate (150 mg) (List Chemical)	I0B174 (01/08)	J0F349	\$185
1269390	Felodipine Related Compound A (25 mg)	F0B207 (01/08)	F1F260	\$576
1287700	Galactose (200 mg)	F-4 (01/08)	G0F252	\$576
1343007	Iodipamide (200 mg)	G (01/08)	H0F334	\$185
1366002	Lidocaine (250 mg)	L (01/08)	M0F220	\$185
1448005	Morphine Sulfate CII (500 mg)	N0E161 (01/08)	O0F186	\$393
1500262	Paroxetine Related Compound E Mixture (25 mg)	F1F028 (01/08)	F2G002	\$576
1525707	Phenothiazine (500 mg)	F0D231 (01/08)	F1F267	\$185
1578500	Prostaglandin A1 (25 mg)	H0B108 (01/08)	I0F103	\$1,481
1643452	Terazosin Hydrochloride (200 mg)	F0C244 (01/08)	G0F290	\$185
1650006	Tetracaine Hydrochloride (200 mg)	J (01/08)	K0F307	\$185
1719000	Warfarin (200 mg)	I0B305 (01/08)	I1G072	\$185

Items with New Lots

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Catalog #	Description	Previous Lot/ Valid Use Date	Current Lot	Price (USD)
1019701	Amiloride Hydrochloride (500 mg)	H (11/08)	H1G197	\$185
1027302	Amiodarone Hydrochloride (200 mg)	F0D257 (10/08)	G0G340	\$185
1067001	Betamethasone Acetate (500 mg)	J0B079 (08/08)	K0G274	\$185
1134029	Ciclopirox Related Compound A (25 mg)	F0E087 (11/08)	G0G212	\$576
1140429	Clonidine Related Compound B (25 mg)	F0C403 (12/08)	G0G323	\$576
1166003	Deferoxamine Mesylate (500 mg)	I (09/08)	J0G233	\$185
1225292	Dorzolamide Hydrochloride Related Compound A (20 mg)	G0E029 (12/08)	H0G052	\$576
1268604	Etidronic Acid Monohydrate (1 g)	G (10/08)	G1G218	\$185
1282004	Fluphenazine Hydrochloride (125 mg)	H (09/08)	I0G294	\$147
1292347	Glimepiride Related Compound D (20 mg) (Glimepiride-3-isomer)	F0E235 (09/08)	F1G258	\$576
1327000	Hydroxychloroquine Sulfate (200 mg)	J0B297 (10/08)	K0G211	\$185
1433008	Methylphenidate Hydrochloride CII (125 mg)	I1C241 (12/08)	J0G307	\$196
1466007	Nitrofurazone Related Compound A (500 mg)	H0B100 (08/08)	I0G265	\$576
1485103	Oxybutynin Chloride (200 mg)	H0E080 (12/08)	I0G281	\$185
1491354	Paclitaxel Related Compound B (20 mg)	G0E019 (12/08)	H0G196	\$893
1535700	Phosphated Riboflavin (100 mg)	G1B286 (12/08)	H0G253	\$147
1570304	Propafenone Hydrochloride (200 mg)	G1C184 (11/08)	H0F302	\$185
1571001	Proparacaine Hydrochloride (200 mg)	G (12/08)	H0G228	\$185
1580002	Protriptyline Hydrochloride (200 mg)	G0E034 (09/08)	H0G267	\$185
1623637	Sucrose (100 mg)	H1C223 (12/08)	H2G263	\$185
1677002	Triamcinolone Acetonide (500 mg)	K (12/08)	L0G322	\$185



USP Publication Highlights

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Pharmacopeial Forum (PF), Volume 34 (1) Publishes this Week—Order Today!

Published six times a year, *PF* lets you review and submit both comments and proposals for standards revisions. Plus, *PF* gives you 2 to 12 months' advance notice of changes, allowing you to prepare early for revisions. Order *PF* 34 today to receive the first 2008 issue! Print and online formats, English only. Visit 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).

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USP 31–NF 26 Now Available. Subscribe Now for the Latest Standards.

The new *USP–NF* is available now in English (print, online, and CD formats). An annual subscription includes a main edition and two *Supplements*. The *USP 31–NF 26 Spanish Edition* (print only) publishes in January 2008. Subscribe now 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).

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New Food Chemicals Codex Coming Soon—Reserve Your Copy Now.

USP will be publishing the *Food Chemicals Codex (FCC)*, 6th edition, in spring 2008. The *FCC* provides internationally recognized standards of purity and quality for food ingredients. It will be published every two years with a supplement provided in interim years. Print and online subscriptions are available in English only. Reserve your copy today! Visit 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).

Publications Scheduled Ship Dates

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

Publication	Scheduled Ship/Post Date
<i>PF34(1) Print</i>	January 8, 2008
<i>First Supplement to USP31–NF26 Print</i>	February 1, 2008
<i>First Supplement to USP31–NF26 Online</i>	February 1, 2008
<i>First Supplement to USP31–NF26 CD</i>	February 1, 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.



Events

USP Customer Days—Coming to a City Near You!

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The USP Account Management Team will be traveling across the U.S. and Canada and select locations outside the U.S. holding free seminars to discuss USP publications, Reference Standards, USP Verified Services, Professional Education, new initiatives, and hot topics.

Meetings are scheduled for Irvine, CA (February 28, 2008); San Juan, Puerto Rico (April 1, 2008)*, St. Louis, MO (May 15, 2008); and Montreal, Canada (June 4, 2008). Registration and more information are available at: <http://www.usp.org/goto/USPCustomerDays> or contact: uspcustomerday@usp.org.

*Intercontinental San Juan Resort & Casino 5961 Isla Verde Avenue Carolina, Puerto Rico 00979
Tel:+1-787-791-6100

Exhibitions—Come Visit Us!

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Booth #6833 at Pittcon 2008 in New Orleans, LA March 3-6, 2008.

USP will have a booth at the **PABME**, Pharmaceutical Manufacturing and Biotechnology Middle East, at the International Exhibition Center in Dubai, UAE, 27–29 April 2008.

Survey

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USP is currently seeking the input of individuals involved in immunological test methods. The input will help us to create General Information Chapters for this area in the USP-NF and associated Reference Standards.

If you are working with immunoassays, please respond to our survey at <http://www.usp.org/survey/DSD/Immunological08.html> by January 18, 2008.

It should take no longer than 15 to 20 minutes of your time. To thank you for your participation, you will have the opportunity to enter a drawing for one of three \$50 Amazon.Com Gift Certificates. Upon completion of the survey, please include your contact information to be entered into the drawing.



Professional Education

New Open Forum Workshop

Residual Solvents: Results in Practice Seminar

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The Residual Solvents: Results in Practice Seminar will take place on February 27, 2008. This will be an additional, informal opportunity to gain and share insight with colleagues in the industry on implementation issues stemming from revision to General Chapter <467>. You will draw upon lessons learned in labs, USP's educational programs, and experience at the FDA.

INTENDED FOR: Laboratory scientists, lab managers, and compliance staff in the pharmaceutical and allied industries.

FORMAT(S)/DURATION: Traditional Classroom, 1 day of presentations with breakout sessions for open discussion in the afternoon. USP Headquarters, Rockville, MD, Cost US Early-Bird Registration \$895.00. Cost increases to US \$995.00 on January 21, 2008—*Register Now!*

For additional information on full course offerings for <467>, visit www.usp.org/education/pe/courses.html.

NEW Courses

Advanced Dissolution

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In-depth instruction on USP's dissolution and drug release tests. Upon completion of this course, you will be able to analyze dissolution data and ascertain compliance. In cases of non-compliance, the student will be able to identify root causes of the problems and provide correct actions. These tests include in-vitro performance tests that are applicable to many dosage forms such as tablets, capsules, suspensions, transdermal patches and suppositories. They are important components of the specifications that establish the quality and safety of the drug product for the end user.

INTENDED FOR: Scientists, chemists, and laboratory technicians who perform dissolution testing in the lab; quality control staff; and product development professionals who review dissolution data.

FORMAT(S)/DURATION: Traditional Classroom, 2 days. Cost US \$1,495.00

Validation of Compendial Procedures

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Validation of Compendial Procedures will comprehensively address USP's validation requirements. Focusing on the types and characteristics of the analytical procedures utilized to demonstrate compliance, the student will have an opportunity to define the characteristics of validation procedures, design experiments to consider those characteristics and interpret the results using a statistically-based methodology.



INTENDED FOR: Laboratory scientists and managers as well as compliance staff working for Pharmaceutical Manufacturers, API Manufacturers, Excipient Manufacturers, Contract Labs, and Regulators.

FORMAT(S)/DURATION: Traditional Classroom; 1 day, Cost US \$695.00 or Online; 10 hours over two week period. Cost US \$299.00

Subscribe to New Professional Education Email Bulletin

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USP Professional Education is developing several new courses for introduction in early 2008. If you would like stay informed of our new curriculum and upcoming schedule, subscribe now to the new Professional Education Email Bulletin. Simply contact us at professionaleducation@usp.org and type “email bulletin” in the subject field. Upcoming courses include:

- “Validation of Compendial Procedures”
- “Particulate Matter in Parenterals
- “GMP: A Quality Systems Approach for APIs”

For the USP Education Course List please go to <http://www.usp.org/education>

USP–NF Notices (<http://www.usp.org/USPNF/notices/?h>)

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Revision Bulletin: Lidocaine and Prilocaine Cream—Revision to Related Compounds Test —11/30/07
General Chapter <797> Pharmaceutical Compounding – Sterile Preparations Revised and Finalized—
12/03/07

Explanatory Notes/Announcements: *USP-NF General Notices: Revision Proposal* and Comment Period. To view the proposed changes and to find out how to comment please go to www.usp.org/USPNF/generalNotices.html. The proposed changes will appear in PF 33(1) and will be open for public comment until April 15, 2008.

Intent to Revise: Intent to Revise General Chapter <671> Containers—Performance Testing

Errata: Nothing New

Postponements: Nothing New



Stimuli Articles

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Featured in *PF* 33 (6), November–December 2007

The Application of Uncertainty to USP's Compendial Reference Standards Program: Certified Reference Materials <http://www.usp.org/pdf/EN/USPNF/Vol33No6Stimuli.pdf>

Proposed New USP General Information Chapter, Excipient Performance <1059>
<http://www.usp.org/pdf/EN/USPNF/Vol33No7Stimuli.pdf>

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Tip of the Month

Dissolution Toolkit— Check it out at
www.usp.org/pdf/EN/dissolutionProcedureToolkit2007-10-04.pdf

The USP released a document entitled *Dissolution Procedure: Mechanical Calibration and Performance Verification Test Toolkit*. The new toolkit provides laboratories with a set of best practices for qualifying dissolution apparatuses through mechanical calibration and periodically conducting performance verification testing. The toolkit is not intended as a standard requiring compliance but is offered as an aid in the effort to ensure accurate dissolution test results.

Question of the Month

In *Pharmacopeial Forum*, what does it mean when the chromatographic column is listed as L##?

Answer:

It means there is no Chromatographic Reagent packing in the list in <621> for the type of column used in the method. When (and if) the method becomes official, then a new L number will be designated for the column and it will appear in both the official method and in the list in <621>.