



August 2011

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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 2011; 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that have been discontinued/have a new price and/or have a new package size; items with lots that are (or soon will be) no longer valid; and items with new lots since the last email notice.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.

The Reference Standards Notification Program can be used to notify you when a new never-before-released Reference Standard becomes available. The Notification Program does not communicate the release of back-ordered items or lot changeovers. To participate in the New Reference Standards Release Notification Program, please fill out the form online at www.usp.org/referenceStandards/notificationProgram.html.

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New Reference Standards Now Available

Catalog #	Description	Size	Lot	Price (USD)
1012595	rAlbumin Human	4.92 mg	F0J199	\$199
1065491	Beta Carotene for System Suitability	200 mg	F0K128	\$199
1255850	Eszopiclone	100 mg	F0K158	\$263
1314960	Hydrocodone CII	125 mg	F0K177	\$263
1335417	Ibandronate Sodium	100 mg	F0K079	\$199
1711031	Vasicine	20 mg	F0K182	\$231

Previously Out-of-Stock Items Now Available

Catalog #	Description	Size	Lot	Price (USD)
1265402	Ethyl Acetate	1.2 mL / ampule; 3 ampules	G0I239	\$199
1491300	Oxytocin	5 vials, 46 USP units per vial	F2K133	\$199
1604905	Rocuronium Bromide	250 mg	G0K211	\$199

Backorder Availability Estimates, July 8, 2011

Catalog #	Description	Expected Availability*
1187207	Dichloralphenazone CIV (200 mg)	Q3/11
1342300	Insulin (Pork) (100 mg) (Cold Shipment Required)	Q4/11
1374000	Magaldrate (200 mg)	Q4/11
1377009	Meclizine Hydrochloride (500 mg)	Q3/11
1478630	Ondansetron Resolution Mixture (50 mg)	Q4/11
1686309	Trifluridine (200 mg)	Q3/11
1714007	Vincristine Sulfate (50 mg)	Q4/11

*Dates are targets and may change at any time. Q3/11=July-September 2011;
Q4/11=October-December 2011

Items with New Package Size or New Description

Catalog #	Description	Old Size	Size	Lot	Price (USD)
1090739	Capecitabine Related Compound C	20 mg	10 mg	G1J413	\$620
1098220	Cefuroxime Axetil	500 mg	350 mg	H0K039	\$199
1098231	Cefuroxime Axetil Delta-3 Isomers	15 mg	10 mg	J0K016	\$620
1478516	Omeprazole Related Compound A*	15 mg	15 mg	G0J410	\$620
1643394	Tazobactam Related Compound A**	20 mg	20 mg	G0K022	\$620
1716002	Retinyl Acetate (Vitamin A)***	10 ampules x 0.5 g	10 ampules x 0.5 g	X1K125	\$199

* This item has changed from an Authentic Substance to a reference standard and the chemical name has changed.

** The chemical name has changed from 2-amino-3-methyl-3-sulfinyl-4-(1H-1,2,3-triazol-1-yl)butyric acid to (2S,3S)-2-Amino-3-methyl-3-sulfinyl-4-(1H-1,2,3-triazol-1-yl)butyric acid.

***The Description has changed from Vitamin A to Retinyl Acetate (Vitamin A)

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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 July 31, 2011				
Catalog #	Description	Previous Lot/ Valid Use Date	Current Lot	Price (USD)
1003009	Acetaminophen (400 mg)	J2C423 (07/11)	K0I244	\$199
1046409	Open Ring Aztreonam (15 mg)	G0D071 (07/11)	H0J067	\$620
1162308	Dacarbazine (125 mg)	H (07/11)	I0J135	\$158
1166003	Deferoxamine Mesylate (300 mg)	J0G233 (07/11)	K0K196	\$199
1356836	Lamivudine (200 mg)	G0F114 (07/11)	H0I378	\$199
1377009	Meclizine Hydrochloride (500 mg)	J0G107 (07/11)		\$199
1379401	Meloxicam (400 mg)	G0I026 (07/11)	H0J100	\$331
1440003	Methysergide Maleate (350 mg)	H1F038 (07/11)	I0J203	\$306
1446804	Monostearyl Maleate (100 mg)	G1I191 (07/11)	H0J012	\$620
1457083	Naphthalene (200 mg)	F0H077 (07/11)	G0I219	\$199
1487007	Oxymetholone CIII (200 mg)	G1B247 (07/11)	H0J381	\$263
1491332	Paclitaxel (200 mg)	H0G193 (07/11)	I0I393	\$1,921
1547368	Polyoxyl 20 Stearyl Ether (1 g)	F0D355 (07/11)	G0J118	\$199
1604905	Rocuronium Bromide (250 mg)	F0H078 (07/11)		\$199
1686309	Trifluridine (200 mg)	G0I041 (07/11)		\$230

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Email Notice

No Longer Valid as of August 31, 2011					
Catalog #	Description	Previous Lot/ Valid Use Date	Current Lot	Price (USD)	
1009923	Acetyltriethyl Citrate (500 mg)	G0E085 (08/11)	H0I339	\$199	
1013079	Allopurinol Related Compound F (25 mg)	F0G130 (08/11)	G0J148	\$620	
1075203	Bis(2-ethylhexyl)maleate (2 mL)	G0E308 (08/11)	H0J224	\$620	
1082300	Butoconazole Nitrate (200 mg)	F1B097 (08/11)	G0J131	\$199	
1096407	Carboplatin (100 mg)	H1F175 (08/11)	I0J009	\$203	
1097909	Cefotaxime Sodium (350 mg)	J0C189 (08/11)	K0I356	\$199	
1098118	Cefpiramide (300 mg)	F0C203 (08/11)	G0J266	\$199	
1118000	Chloroquine Phosphate (500 mg)	I (08/11)	J0J212	\$199	
1123102	Chlorpheniramine Maleate Extended-Release Tablets (Drug Release Calibrator, Single Unit) (60 Tablets)	G0B259 (08/11)	G1J218	\$199	
1134380	Clarithromycin Related Compound A (50 mg)	G1E310 (08/11)	H0H381	\$620	
1135021	Clidinium Bromide Related Compound A (250 mg)	I (08/11)	J0J154	\$620	
1175004	Desoxycorticosterone Pivalate (125 mg)	H0C276 (08/11)	H1J119	\$158	
1226014	Doxycycline Related Compound A (10 mg)	F0H365 (08/11)	G0J058	\$620	
1249202	Escin (350 mg)	F0F088 (08/11)	G0J158	\$218	
1287303	Gabapentin (250 mg)	G0E005 (08/11)	H0J020	\$199	
1344509	Iodoquinol (100 mg)	I0D285 (08/11)	I1H317	\$199	
1347609	Irinotecan Hydrochloride (100 mg)	F0I245 (08/11)	G0J233	\$315	
1370291	Loratadine Related Compound B (15 mg)	F0D230 (08/11)	G0I358	\$620	
1375706	Mebrofenin (100 mg)	F (08/11)	F1I392	\$199	
1442009	Metronidazole (100 mg)	J0C316 (08/11)	J1I272	\$199	
1460736	Nevirapine Related Compound B (15 mg)	G0G271 (08/11)	H0J192	\$620	
1463508	Nifedipine (125 mg)	K0D401 (08/11)	L0J059	\$158	
1598008	3-Quinuclidinyl Benzilate (25 mg) DISCONTINUED	H (08/11)		\$657	
1601521	Residual Solvent Class 2 - 1,4-Dioxane (1.2 mL/ampule; 3 ampules)	F0D050 (08/11)	G0I251	\$199	
1623626	Sucralose (400 mg)	G1E317 (08/11)		\$199	
1623670	Sulbactam (250 mg) (COLD SHIPMENT REQUIRED)	I0G133 (08/11)	J0J117	\$199	
1661002	Thiopental CIII (250 mg)	I1D198 (08/11)	I2J217	\$263	

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No Longer Valid as of September 30, 2011

Catalog #	Description	Previous Lot/ Valid Use Date	Current Lot	Price (USD)
1012509	L-Alanine (200 mg)	G0E002 (09/11)	G1J091	\$199
1012906	Alfentanil Hydrochloride CII (500 mg)	F0B016 (09/11)	G0J037	\$263
1044527	Atorvastatin Related Compound A (20 mg)	F0I170 (09/11)	G0J255	\$620
1044550	Atorvastatin Related Compound D (20 mg)	F0I174 (09/11)	G0J257	\$620
1086312	Calcitriol Solution (5 mL) (COLD SHIPMENT REQUIRED)	F0D330 (09/11)	F1J229	\$244
1103003	Cetyl Alcohol (100 mg)	I1E065 (09/11)	I2I289	\$199
1121005	Chlorothiazide (200 mg)	H1E231 (09/11)	H2J042	\$199
1151006	Crotamiton (200 mg)	H-1 (09/11)	I0J073	\$199
1333058	Hydroxyzine Related Compound A (25 mg)	H1E248 (09/11)	I0I223	\$620
1340009	Indocyanine Green (250 mg)	I0B045 (09/11)	J0J241	\$217
1342106	Insulin Human (100 mg) (COLD SHIPMENT REQUIRED)	I1F270 (09/11)	J0J250	\$199
1359404	Levetiracetam (200 mg)	F0H295 (09/11)	G0J159	\$270
1535020	Phenytoin Related Compound B (50 mg)	F0C157 (09/11)	G0J173	\$620
1554206	Pravastatin Sodium (50 mg)	F0G003 (09/11)	F1I288	\$213
1604654	Risperidone (200 mg)	F0G288 (09/11)	G0J122	\$199
1612506	L-Serine (200 mg)	G (09/11)	H0J185	\$199
1642802	Tacrolimus (150 mg)	F0H135 (09/11)	G0J161	\$663
1708795	Valsartan Related Compound C (10 mg)	H0I005 (09/11)	H1J021	\$794

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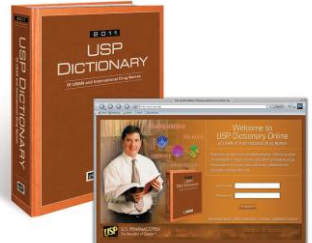

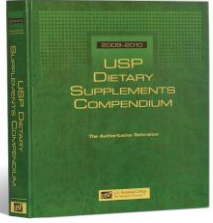
Items with New Lots

Catalog #	Description	Previous Lot/ Valid Use Date	Current Lot	Price (USD)
1090739	Capecitabine Related Compound C (10 mg) (COLD SHIPMENT REQUIRED)	G0I370 (07/12)	G1J413	\$620
1098184	Ceftriaxone Sodium (350 mg)	G1D265 (07/12)	H0J296	\$199
1098220	Cefuroxime Axetil (350 mg)	G (07/12)	H0K039	\$199
1098231	Cefuroxime Axetil Delta-3-Isomers (10 mg)	I0H005 (08/12)	J0K016	\$620
1104006	Cetylpyridinium Chloride (500 mg)	J0D299 (07/12)	J1K032	\$199
1133004	Cholestyramine Resin (500 mg)	I (07/12)	J0J386	\$158
1134018	Ciclopirox (50 mg)	G0G398 (08/12)	G1K115	\$199
1193505	Diethyl Phthalate (200 mg)	G (07/12)	G1J427	\$199
1224992	Donepezil Related Compound A (25 mg)	F0J070 (05/12)	G0K187	\$620
1229001	Droperidol (250 mg)	I1G375 (07/12)	J0K154	\$199
1265402	Ethyl Acetate (1.2 mL/ampule; 3 ampules)	F0E282 (04/12)	G0I239	\$199
1270800	Flecainide Acetate (200 mg)	F2A022 (07/12)	G0K124	\$199
1287358	Gabapentin Related Compound D (10 mg)	F1I249 (06/12)	G0K189	\$620
1292325	Glimepiride Related Compound B (20 mg)	F1H420 (08/12)	G0K200	\$620
1337004	Iminodibenzyl (25 mg)	I0C253 (07/12)	I1K213	\$620
1392002	Mercaptopurine (500 mg)	J0G300 (07/12)	K0K074	\$199
1431556	Methyl Oleate (500 mg)	G0C148 (08/12)	H0J393	\$199
1478516	Omeprazole Related Compound A (15 mg)	F0D363 (06/12)	G0J410	\$620
1491300	Oxytocin (5 vials, 46 USP units per vial) (COLD SHIPMENT REQUIRED)	F1G134 (06/12)	F2K133	\$199
1499403	Paricalcitol (10 mg) (COLD SHIPMENT REQUIRED)	H0H426 (07/12)	I0J338	\$1,945
1499414	Paricalcitol Solution (3 mL) (COLD SHIPMENT REQUIRED)	H0I227 (07/12)	I0J286	\$372
1502701	Penicillin G Sodium (150 mg)	L4C366 (07/12)	M0J423	\$199
1576708	Propylene Glycol (1 mL)	K0H231 (07/12)	L0J287	\$199
1604905	Rocuronium Bromide (250 mg)	F0H078 (07/11)	G0K211	\$199
1612641	Silydianin (20 mg)	G0F200 (07/12)	H0K052	\$199
1623626	Sucralose (400 mg)	G1E317 (08/11)	G2K179	\$199
1643394	Tazobactam Related Compound A (20 mg)	F0G123 (06/12)	G0K022	\$620
1716002	Retinyl Acetate (Vitamin A) (10 ampuls x 0.5 g)	X0I156 (07/12)	X1K125	\$199

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USP Publication Highlights

	<p>USP 34–NF 29 Standards Are Official and FDA-enforceable—Order Now!</p> <p>The 2011 edition of <i>USP–NF</i> features more than 4,500 monographs and more than 230 General Chapters, including important new and revised standards. Available in print, online, and CD formats, <i>USP 34–NF 29</i> became official May 1, 2011. (Please note: the print format is a 3-volume set with two separate <i>Supplements</i>. <i>Second Supplement</i> recently published June 1, 2011.) Subscribe today at www.usp.org/products/USPNF 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>Get the Latest Drug Name Updates in the 2011 <i>USP Dictionary</i></p> <p>The 2011 <i>USP Dictionary of USAN and International Drug Names</i> features more than 4,200 new and revised entries and includes 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>
	<p>FCC, <i>Seventh Edition</i>, through <i>Second Supplement</i> Available now!</p> <p>Rely on the latest <i>FCC</i> for important standards updates and helpful information for your work with colorings, flavorings, nutrients, and other food ingredients. Two-year print and online subscriptions are available. Subscription includes a main book and all <i>Supplements</i> that publish during the subscription period; <i>Second Supplement</i> published February 2011. 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>USP Dietary Supplements Compendium—Comprehensive Information Under One Cover!</p> <p>Only the <i>USP Dietary Supplements Compendium</i> combines <i>USP–NF</i> standards with information from the <i>FCC</i>, regulatory and industry documents, and helpful resources into one convenient reference! Published every two years in hardcover print. Order now at www.usp.org/products/dietarySupplementsCompendium/ 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>

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Event Highlights

USP User Forums Coming to a City Near You!

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

A User Forum is scheduled for October 11, 2011 in Minneapolis, Minnesota. More information is available [here](#) or contact: USPUserForum@usp.org

Science & Standards Symposium on Biologics & Biotechnology: Advancing Quality Standards through Analytics and Assays

Westin Seattle, Seattle, WA
October 3–6, 2011

The event will bring together an international panel of experts to speak on regulatory challenges across the globe associated with the development of regulation and characterization of pancrelipase/therapeutic enzymes, monoclonal antibodies, tissue and cell therapy products, and much more.

Click [here](#) for more information.

Workshops

Save the Date—Although still in the planning stages, the following workshops are scheduled. Call +1-301-816-8130 for additional information.

Workshop	Date
OTC	September 8–9, 2011
Bioassay Workshop as part of the USP Science & Standards Symposium	October 3–6, 2011
Intentional and Unintentional Adulteration of Foods and Dietary Supplements	November 16–17, 2011
Aerosols–Inhalation and Nasal Drug Products	December 12–13, 2011
Dissolution Methods for Liquid Filled Capsules	October 1–4, 2012
Probiotics Workshop	May 9–10, 2012
Extractables and Leachables Workshop	TBD 2012

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Pharmacopeial Education

Featured Courses*

Understanding the USP Compendial Process: Monographs, General Chapters and General Notices

This course is designed to give a better understanding on how monographs and general chapters are developed. Furthermore, the process for proposal of compendial improvements, public review & comment and approval & adoption are also discussed.

Classroom Lecture: \$495 (Special discount for combined registration with OTC Drug Substances and Drug Products Workshop)

September 7, 2011; Rockville, MD

[Click here](#) to learn more.

New Updates on Good Storage & Shipping Practices <1079>

Webinar: \$150

August 18, 2011; 1:00—2:00 (ET)

[Click here](#) to learn more.

Safely Compounding Quality Medications—A Review of USP General Chapter <795>

Webinar: \$25.00

August 23, 2011; 1:00—2:30 (ET)

[Click here](#) to learn more.

USP General Chapters <1224>, <1225>, and <1226>— How They Work Together for Analytical Procedures

Webinar: \$150

August 25, 2011; 1:00—2:30 (ET)

[Click here](#) to learn more.

Understanding the USP Compendial Process: Monographs, General Chapters and General Notices

Webinar: \$300.00

August 31, 2011; 1:00—4:00 (ET)

[Click here](#) to learn more.

Dietary Supplement GMPs from the FDA and USP Perspectives

Webinar: \$150.00

September 15, 2011; 1:00—2:30 (ET)

[Click here](#) to learn more.

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Courses in Conjunction with AAPS Annual Meeting in Washington, DC

In honor of the AAPS 25th Year Anniversary being held in Washington, DC, the USP Pharmacopeial Education department will be offering a series of six courses at USP headquarters on October 27–28. . Registration and additional information available at <http://www.usp.org/education/twoDaySpecialEducation.html>

Special Offer! Register for both days for a special discounted price. Sign-up for a course on October 27 and a half-day course on October 28 for \$695 or two full-day courses on October 27 & 28 for \$795. Contact PharmEd@usp.org for the discount code.

Determining Particulate Matter in Parenterals

This course will provide a solid foundation of knowledge on the subject as well as equip the student with the ability to extend their learning beyond formulaic application of concepts covered in the course. Two specific methods for determination of particulate matter in solution will be discussed in great detail: Light Obscuration and Membrane Microscopy. These methodologies are most widely associated with Chapter <788> Particulate Matter in Injections, but they also apply to Chapter <789> Particulate Matter in Ophthalmic Solutions. Additionally, this course will address recent changes to Chapter <788> Particulate Matter in Injections that came about due to harmonization efforts.

Classroom Lecture: \$495

October 27, 2011; Rockville, MD

Dissolution: Theory and Best Practices

This one-day course provides focused, relevant instruction on the fundamentals of pharmaceutical dissolution testing as described in USP General Chapter <711>. Gain an overview of the theory, practice, and history of dissolution. Learn the practical aspects of conducting dissolution tests, best practices, and performance verification testing. The newly revised course covers recent changes to the PVT test, its acceptance criteria and General Chapter <711>.

Classroom Lecture: \$495

October 27, 2011; Rockville, MD

Validation and Verification of Compendial Procedures

A recurring area of confusion encountered by many in the industry is the understanding of the distinction between Chapter <1225> Validation of Compendial Procedures and Chapter <1226> Verification of Compendial Procedures. This one-day course will help you distinguish between the two, and will cover procedures for validating traditional analytical methods found in the current *USP* General Chapters <1225>.

Classroom Lecture: \$495

October 27, 2011; Rockville MD

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Method Transfer

The one-day analytical procedure-transfer process is critical to qualify a laboratory to perform an analytical procedure that was developed and validated in another laboratory. The new chapter <1224> provides guidance on the basic steps of this process. It summarizes the types of transfers that may occur, including the possibility of waiver, and outline the components of a transfer process. All these general information chapters are part of a family of chapters devoted to providing guidance for the quality of the data-acquisition process. This course also gives an overview of each chapter focusing on the purpose of each of these activities as well as how a transfer report is structured.

Classroom Lecture: \$495

October 28, 2011; Rockville, MD

Practical Applications of General Chapter <467> Residual Solvents

This half-day program will move beyond an overview of the new requirements focusing on implementation issues in the lab. Analytical procedures contained in Chapter <467> and alternative testing protocols will be covered, as well as common points of confusion and concerns encountered by the industry. A question and answer period is included to address the specific inquires of attendees.

Classroom Lecture: \$295

October 28, 2011; Rockville, MD

Analysis of Elemental Impurities

This half-day program will cover new methodologies and testing strategies proposed in draft Chapter <233> Elemental Impurities – Procedures and draft General Chapter Elemental Impurities – Limits. Participants can expect to learn about the new features, as well as method development and method validation when analyzing impurities in materials that are currently tested using Chapter <231> Heavy Metals.

Classroom Lecture: \$295

October 28, 2011; Rockville, MD

***Note: Early registration and group discounts may apply see course listings www.usp.org/education/pe/courses.html for details.**

[Subscribe](#) to the Pharmacopeial Education Email Bulletin

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Compendial Highlights

New Official Text

Revision Bulletins:

[Alprazolam Extended-Release Tablets](#) (posted 29-Jul-2011; official 01-Aug-2011)


[Divalproex Sodium Delayed-Release Capsules](#) (posted 29-Jul-2011; official 01-Aug-2011)

[Donepezil Hydrochloride Tablets](#) (posted 29-Jul-2011; official 01-Aug-2011)

[Levofloxacin](#) (posted 29-Jul-2011; official 01-Aug-2011)

[Mefloquine Hydrochloride Tablets](#) (posted 29-Jul-2011; official 01-Aug-2011)

IRAs

[Modafinil](#)  (144KB) (posted 29-Jul-2011; official 01-Sep-2011)

Errata

USP 34–NF 29

[June 2011 Errata Posting](#)  (118KB) (posted 06/30/11)

[April 2011 Errata Posting](#)  (379KB) (posted 04/29/11)

[February 2011 Errata Posting](#)  (128KB) (posted 02/28/11)

[December 2010 Errata Posting](#)  (743KB) (posted 12/30/10)

Compendial Notices

New:

[Copovidone: Notice of Intent to Revise](#) (posted 09-Aug-2011)

[Call for Candidates: USP Expert Panel on Validation, Verification and Transfer of Analytical Procedures](#)
(posted 01-Aug-2011)

[Levalbuterol Hydrochloride: Notice of Intent to Revise](#) (posted 29-Jul-2011)

[Levalbuterol Inhalation Solution: Notice of Intent to Revise](#) (posted 29-Jul-2011)

[Mirtazapine Tablets: Notice of Intent to Revise](#) (posted 29-Jul-2011)

Sign up to receive updates electronically at

www.usp.org/support/products/uspNewslettersRequest.html?promo=compendial

Stimuli Articles

Featured in *PF 37(4)*, July–August 2011

In Vitro Assessment of Spacers and Valved Holding Chambers Used with Pressurized Metered-dose Inhalers: The Need for a USP Chapter with Clinically Relevant Test Methods

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Your opinion counts!

USP is interested in the **Identification Testing Methods that you use**. Your participation in this [survey](#) will help improve the *USP-NF* General Chapter <191> and help in the development of a new USP Spectral Library.

Your participation should take no longer than 15 minutes and as a thank you for your input, you will be offered the chance to enter a drawing for **one of three \$50 Amazon gift certificates**. Please click on the link below or paste it into your browser to take the survey: <https://deploy.ztelligence.com/start/index.jsp?PIN=163TLPFWW4CJC>

Tip of the Month

USP has been busy redesigning its website. Check www.usp.org frequently over the next month to learn more about the expanded content areas and enhanced features!

Question of the Month

What is an *Interim Revision Announcement (IRA)*?

IRAs are an expedited mechanism for making revisions official. An *IRA* appears in *PF* first as a *Proposed Interim Revision Announcement* with a 90-day comment period (prior to *PF 37(1)*, *IRAs* were available for comment for 60 days). If there are no significant comments, the *IRA* becomes official in the “Official Text” section of the USP web site (see *IRAs* [here](#)), with the official date indicated. *IRAs* replace the entire published monograph including the specified change and are incorporated into the next available *USP–NF* or *Supplement*.

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