



September 2012

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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 August 2012; 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dates; items that have a new price and/or have a new package size; items with lots that are (or soon will be) no longer valid; and items with new lots since the last email notice.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.

The Reference Standards Release Notification Service can be used to notify you when a new never-before-released Reference Standard becomes available. The Notification Service 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/reference-standards/find-reference-standard/notification-service.

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Shutdown of USP's Order Management System for Upgrade

USP will be upgrading our ordering system to better serve you. **As a result, all ordering systems will be unavailable during the following times:**

- **Thursday, September 20, 2012, 5:00 pm EST through Tuesday, September 25, 2012, 10:00 am EST.**
- **USP will make every effort to process orders received prior to the scheduled down time.**
- **USP will start to process orders again after 10:00 am EST on September 25, 2012**

We encourage you to place orders by September 19, 2012 for any USP Reference Standards you might need through the remainder of September 2012 to minimize impact on your work.

We apologize in advance for any inconvenience this may cause.

New Reference Standards Now Available

Catalog #	Description	Size	Lot	Price (USD)
1019494	Amikacin Sulfate	100 mg	FOL324	\$204
1045520	Azacitidine	150 mg	FOL296	\$204
1045574	Azacitidine Related Compound C	15 mg	FOL319	\$636
1076148	Bosentan Related Compound C	15 mg	FOL304	\$636
1076159	Bosentan Related Compound D	15 mg	FOL300	\$636
1076160	Bosentan Related Compound E	15 mg	FOL301	\$636
1082639	Butyl Stearate	500 mg	FOL302	\$204
1084215	Allyl Butyrate	0.5 mL x 5	FOL017	\$204
1154514	Cyclobenzaprine Related Compound A	10 mg	FOL193	\$636
1154525	Cyclobenzaprine Related Compound B	10 mg	FOL194	\$636
1171819	Desbenzyl Donepezil Hydrochloride	20 mg	FOL339	\$636
1255861	Eszopiclone Related Compound A	10 mg	FOL285	\$636
1268874	Etoricoxib Related Compound A	50 mg	F0K430	\$636
1268885	Etoricoxib Related Compound B	50 mg	F0K431	\$636
1268896	Etoricoxib Related Compound C	50 mg	FOL323	\$636
1379456	(Z)-N'-Methylmeloxicam	30 mg	FOL249	\$636
1604811	Rivastigmine Related Compound C	15 mg	FOL287	\$636
1612685	Sildenafil Related Compound A	10 mg	F0K413	\$636
1636800	Allyl Sulfide	5 x 0.5 mL	FOL018	\$204

Previously Out-of-Stock Items Now Available

Catalog #	Description	Size	Lot	Price (USD)
1044538	Atorvastatin Related Compound B	20 mg	HOL297	\$636
1570009	Promethazine Hydrochloride	500 mg	MOL315	\$204

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Backorder Availability Estimates, September 10, 2012

Catalog #	Description	Expected Availability*
1090739	Capecitabine Related Compound C (10 mg) (COLD SHIPMENT REQUIRED)	Q3/12
1381742	Menthyl Anthranilate (500 mg/ampule) (Meradimate)	Q1/13
1478844	Orlistat Related Compound D (10 mg)	Q4/12
1643543	Temozolomide (200 mg)	Q1/13
1700002	Trypsin Crystallized (300 mg) (COLD SHIPMENT REQUIRED)	Q3/12

*Dates are targets and may change at any time. Q3/12=July–September 2012; Q4/12=October–December 2012; Q1/13 January–March 2013

Items with New Package Size or New Description

Catalog #	Description	Old Size	Size	Lot	Price (USD)
1078755	Bupropion Hydrochloride Related Compound B	15 mg	10 mg	G0L045	\$691
1097603	Cefazolin	400 mg	200 mg	L1K284	\$204
1164008	Dapsone	125 mg	200 mg	I0L013	\$204
1231808	Econazole Nitrate	200 mg	100 mg	H0K380	\$204
1347653	Irinotecan Related Compound D*	15 mg	15 mg	G0L060	\$636
1379445	4-Methoxymeloxicam**	30 mg	30 mg	G0L252	\$636
1481237	Oxaliplatin Related Compound C***	20 mg	20 mg	H0L353	\$636
1554217	Pravastatin Related Compound A	15 mg	10 mg	G0L198	\$636
1708795	Valsartan Related Compound C****	10 mg	10 mg	I0L225	\$814

*The chemical name changed for this lot from ([1,4'-Bipiperidine]-1'-carboxylic acid, 4,11-diethyl-3,4,12,14-tetrahydro-4-hydroxy-3,14-dioxo-1H-pyrano[3',4':6,7]indolizino [1,2-b]quinolin-9-yl ester, monohydrochloride, trihydrate, (R)-) to ((R)-9-[(1,4'-Bipiperidine)-1'-carboxyl]-4,11-diethyl-3,4,12,14-tetrahydro-4-hydroxy-3,14-dioxo-1H-pyrano[3',4':6,7]indolizino[1,2-b]quinolin hydrochloride, trihydrate).

* *Reference Standard Name changed from Meloxicam Related Compound D to 4-Methoxymeloxicam. Chemical Name changed from 4-Methoxy-2-methyl-(5-methyl-1,3-thiazol-2-yl)-2H-1,2-benzothiazine-3-carboxamide-1,1-dioxide to 4-Methoxy-2-methyl-N-(5-methyl-1,3-thiazol-2-yl)-2H-1,2-benzothiazine-3-carboxamide 1,1-dioxide.

***The chemical name changed for this lot from ([1R-trans-(1,2-cyclohexanediamine-N,N')]-trans-dihydroxido-[oxalate(2-)-O,O']platinum(IV)) to ([1R-trans-(1,2-cyclohexanediamine-N,N')]-trans-dihydroxido-[oxalato(2-)-O,O']platinum(IV)).

****The chemical name changed for this lot from N-valeryl-N-[[2'-(1H-tetrazole-5-yl)biphenyl-4-yl]methyl]-L-valine benzyl ester (for propose lot I0L225) to (S)-N-valeryl-N-([2'-(1-H-tetrazole-5-yl)biphenyl-4-yl]methyl)valine benzyl ester (for lot H1J021)

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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 Longer Valid as of August 31, 2012					
Catalog #	Description	Previous Lot/ Valid Use Date	Current Lot	Price (USD)	
1021000	Aminocaproic Acid (200 mg)	G0D101 (08/12)	H0K201	\$204	
1076308	Bleomycin Sulfate (15 mg)	J1G042 (08/12)	K0K126	\$401	
1085003	Caffeine (200 mg)	J1D241 (08/12)	K0K210	\$204	
1098231	Cefuroxime Axetil Delta-3-Isomers (10 mg)	I0H005 (08/12)	J0K016	\$636	
1134018	Ciclopirox (50 mg)	G0G398 (08/12)	G1K115	\$204	
1134266*	Citalopram Related Compound C (25 mg)	F0G048 (08/12)	G0L17	\$63	
1140586	Clopidogrel Related Compound A (20 mg)	G0H250 (08/12)	G1K001	\$772	
1187091	Dibutyl Sebacate (1 mL)	F0D128 (08/12)	F1K138	\$204	
1200804	Dihydrocodeine Bitartrate CII (200 mg)	I0D205 (08/12)	J0K044	\$270	
1220506	Dipyridamole (200 mg)	H1F120 (08/12)	I0K205	\$204	
1254508	Estriol (100 mg)	K0H209 (08/12)	L0K175	\$204	
1265504	Ethylcellulose (1 g)	I0H084 (08/12)	I1K174	\$204	
1287609	Gadopentetate Monomeglumine (500 mg)	G0G222 (08/12)	H0K203	\$204	
1288816	Genistein (15 mg)	F0H252 (08/12)	F1K131	\$204	
1292325	Glimepiride Related Compound B (20 mg)	F1H420 (08/12)	G0K200	\$636	
1344600	Iohexol (200 mg)	G0F254 (08/12)	H0J211	\$213	
1362103	Levofloxacin (200 mg)	F0H194 (08/12)	G0J406	\$204	
1370600	Lovastatin (125 mg)	H3F071 (08/12)	H4K027	\$162	
1431556	Methyl Oleate (500 mg)	G0C148 (08/12)	H0J393	\$204	
1465004	Nitrofurazone (200 mg)	I0E149 (08/12)	J0J292	\$204	
1481237	Oxaliplatin Related Compound C (20 mg)	F0H348 (08/12)	G0K194	\$636	
1504503	Penicillin V Potassium (200 mg)	H0C213 (08/12)	I0J242	\$204	
1514008	Phenacetin Melting Point Standard (500 mg) (Approximately 135 degrees)	I0H080 (08/12)	J0J346	\$122	
1570304	Propafenone Hydrochloride (200 mg)	H0F302 (08/12)	I0K184	\$204	
1612550	Sevoflurane Related Compound A (0.2 mL)	H0H072 (08/12)	I0J319	\$636	
1667803	Alpha Tocopheryl Acid Succinate (250 mg) (Vitamin E Succinate)	G0D077 (08/12)	H0J288	\$204	
1692709	Trimipramine Maleate (100 mg)	F0G146 (08/12)	G0I372	\$204	

*Item Added

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No Longer Valid as of September 30, 2012				
Catalog #	Description	Previous Lot/ Valid Use Date	Current Lot	Price (USD)
1076363	Brinzolamide (200 mg)	F0C034 (09/12)	G0K216	\$204
1078700	Buprenorphine Hydrochloride CIII (50 mg)	H0G362 (09/12)	I0K247	\$270
1111908	P-Chloroaniline (200 mg)	F0H281 (09/12)	G0K206	\$204
1140600	Clopidogrel Related Compound C (20 mg)	F2H215 (09/12)	F3K088	\$772
1188800	Diclofenac Sodium (200 mg)	H1F335 (09/12)	H2K051	\$204
1287303	Gabapentin (250 mg)	H0J020 (09/12)	I0K190	\$204
1356701	Lactose Monohydrate (500 mg)	H0C151 (09/12)	H1K036	\$204
1379183	Melamine (250 mg) (2,4,6-Triamino-1,3,5-triazine)	F0G025 (09/12)	F1K021	\$204
1379423	Meloxicam Related Compound B (25 mg)	G0I108 (09/12)	H0K353	\$636
1444285	Mirtazapine Related Compound A (15 mg)	F0G396 (09/12)	F1K156	\$814
1478334	Olanzapine Related Compound C (5 mg)	F0I261 (09/12)	G0K178	\$636
1547925	Polysorbate 20 (2 g)	F0D130 (09/12)	F1K233	\$204
1607040	Saccharin Sodium (100 mg)	F0F006 (09/12)	F1K245	\$204
1706698	Urea (200 mg)	F0D331 (09/12)	G0J383	\$204

No Longer Valid as of October 31, 2012				
Catalog #	Description	Previous Lot/ Valid Use Date	Current Lot	Price (USD)
1012076	Acyclovir Related Compound A (50 mg)	F0F010 (10/12)	G0K243	\$646
1013024	Allopurinol Related Compound A (25 mg)	G (10/12)	H0K282	\$636
1078799	Bupropion Hydrochloride Related Compound F (30 mg) (COLD SHIPMENT REQUIRED)	H0H224 (10/12)	I0J331	\$691
1134390	Clarithromycin Identity (20 mg)	F1I262 (10/12)	F2K141	\$636
1138507	Clocortolone Pivalate (200 mg)	H0G097 (10/12)	I0K296	\$204
1242010	Erythromycin B (100 mg)	G2F259 (10/12)	G3J304	\$204
1270377	Fexofenadine Hydrochloride (200 mg)	F1E289 (10/12)	G0K308	\$204
1272204	Fludarabine Phosphate (300 mg)	G0E247 (10/12)	H0K220	\$204
1275009	Fluocinolone Acetonide (100 mg)	J2I027 (10/12)	K0K185	\$204
1333003	Hydroxyzine Hydrochloride (500 mg)	J0F024 (10/12)	K0J364	\$204
1353000	Diluted Isosorbide Dinitrate (500 mg of 25% mixture with lactose)	I2E153 (10/12)	J0K330	\$204
1356789	Lamotrigine Related Compound C (10 mg)	F0H280 (10/12)	F1K157	\$636
1359302	Levamisole Hydrochloride (125 mg)	F2C122 (10/12)	F3K315	\$162
1389008	Meprobamate CIV (200 mg)	G2G065 (10/12)	H0K339	\$270
1441243	Metoprolol Related Compound B (100 mg)	G0E189 (10/12)	H0J254	\$680
1463869	Nimodipine Related Compound B (50 mg)	F0F206 (10/12)	G0K355	\$636
1492007	Palmitic Acid (500 mg)	K0F048 (10/12)	L0K054	\$204
1563502	Procainamide Hydrochloride (200 mg)	H1B117 (10/12)	I0I286	\$204
1708784	Valsartan Related Compound B (10 mg)	H0K089 (10/12)	H1K270	\$814

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Items with New Lots

Catalog #	Description	Previous Lot/ Valid Use Date	Current Lot	Price (USD)
1000452	Abacavir Related Compound C (20 mg)	F0H285 (09/13)	F1L322	\$636
1044538	Atorvastatin Related Compound B (20 mg)	G0J256 (08/13)	H0L297	\$636
1069007	Betamethasone Valerate (200 mg)	K0C330 (08/13)	L0K350	\$204
1086312	Calcitriol Solution (5 mL) (COLD SHIPMENT REQUIRED)	F1J229 (08/13)	F2L073	\$250
1134313	Ciprofloxacin (200 mg)	H0E306 (09/13)	I0L049	\$162
1141024	Clotrimazole Related Compound A (25 mg)	J0I329 (08/13)	J1K352	\$636
1164008	Dapsone (200 mg)	H0D260 (08/13)	I0L013	\$204
1231808	Econazole Nitrate (100 mg)	G1C346 (08/13)	H0K380	\$204
1267000	Ethylparaben (200 mg)	I1F039 (09/13)	I2L094	\$204
1294207	Glucosamine Hydrochloride (200 mg)	F0C363 (07/13)	F1L072	\$204
1295800	Glycine (200 mg)	G1H369 (08/13)	H0L015	\$204
1350400	Isopropyl Myristate (500 mg)	J0D247 (08/13)	K0K143	\$204
1370350	Lorazepam Related Compound D (25 mg)	I0J083 (09/13)	J0L024	\$636
1379445	4-Methoxymeloxicam (30 mg)	F0E160 (N/A)	G0L252	\$636
1414025	Methotrexate Related Compound B (75 mg)	F0H350 (07/13)	G0L331	\$711
1431603	Methyl Palmitate (300 mg)	G0E329 (08/13)	H0K274	\$204
1443307	Mezlocillin Sodium (350 mg)	H0H213 (08/13)	H1L027	\$204
1446859	Montelukast Sodium (50 mg)	F0J082 (05/13)	G0L231	\$204
1448923	Mupirocin Lithium (100 mg)	I0H095 (09/13)	J0J376	\$204
1453005	Naloxone (125 mg)	M1I123 (08/13)	M2L247	\$162
1477003	Nystatin (200 mg) (COLD SHIPMENT REQUIRED)	O1G308 (08/13)	O2K402	\$204
1481237	Oxaliplatin Related Compound C (20 mg)	G0K194 (08/13)	H0L353	\$636
1482207	Oxaprozin (200 mg)	F0C115 (09/13)	G0L342	\$204
1494942	Pantoprazole Related Compound E (20 mg)	F0H271 (09/13)	G0L292	\$636
1498706	Parbendazole (200 mg)	G0F331 (08/13)	H0L293	\$204
1546900	Polyethylene Terephthalate (PET) (3 Strips)	G0G240 (08/13)	H0L135	\$204
1554217	Pravastatin Related Compound A (10 mg)	F0G024 (07/13)	G0L198	\$636
1570009	Promethazine Hydrochloride (500 mg)	L0F056 (08/13)	M0L315	\$204
1612652	Simethicone (50 g)	K0I213 (08/13)	L0J395	\$204
1614396	Sodium Metabisulfite (1 g)	F0D111 (07/13)	F1L076	\$204
1700512	Tryptophan Related Compound A (15 mg)	F0I189 (09/13)	F1L273	\$636
1705323	Ubidecarenone Related Compound A (15 mg) (COLD SHIPMENT REQUIRED)	G0I163 (08/13)	H0K297	\$636
1708762	Valsartan (350 mg)	K1K224 (08/13)	L0L195	\$204

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USP Publication Highlights

ATTENTION: *USP–NF* Subscribers—Important Renewal Information

It's time to renew *USP–NF* for 2013! Subscribers with USP Online Store accounts can log into their accounts and view subscription information by clicking “Yes” under the “Renewal Alert”; customers without USP Online Store accounts will receive their renewal information by email, mail, or fax.

Should you have any questions or would like to renew at anytime by phone, contact USP Customer Service at 1-800-227-8772 (U.S. and Canada), +1-301-881-0666, or 00-800- 4875-5555 (Select Europe).

	<p>Be Prepared for Compliance in 2013—Pre-order <i>USP 36–NF 31</i> Today! The 2013 edition of <i>USP–NF</i> publishes on November 1. Pre-order today for access to important updates, including:</p> <ul style="list-style-type: none">• 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 <p>Available in print, online, and USB flash drive formats. Subscribe today at http://uspgo.to/USPNF-2013 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>New <i>Food Chemicals Codex (FCC), Eighth Edition</i>. Save \$100 with Promotion Code HW2BZZ11! The <i>FCC, Eighth Edition</i>, features more than 1,100 monographs, appendices with step-by-step methods, and helpful information for manufacturers, suppliers, and users of food ingredients—including data from the new USP Food Fraud Database. Subscription includes the main edition plus three supplements (the first supplement published on Sept. 1, 2012 and becomes effective Dec. 1, 2012), which publish at six-month intervals during the subscription period. Print and online formats. Order at 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>New 2012 <i>Dietary Supplements Compendium (DSC)</i>—Two-Volume Set Available Now! Volume Two may be purchased separately and contains information not found in either the <i>USP–NF</i> or <i>FCC</i> including: Reference Tables; USP Admission Criteria Safety Reviews; USP Dietary Supplement and Ingredient Verification Programs; Dietary Supplements Regulatory Framework; Table of Tolerable Upper Intake Levels (UL) of Vitamins, Minerals, and Electrolytes; Guidance Documents; plus ~ 300 full-color illustrations. Order at www.usp.org/store/products-services/dietary-supplements-compedium 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). Save 20% on the purchase of Volume Two only with Promotion Code HYQBZZ25.</p>



COMPOUNDING

USP on Compounding: A Guide for the Compounding Practitioner

New electronic publication that offers convenient access to complete, up-to-date text of the five essential compounding-related general chapter from the *USP–NF*, plus more than 40 supporting general chapters and General Notices and Requirements. Delivered electronically in PDF format. Updated with the release of each new *USP–NF* edition and supplement. 12-month subscription, English only. Order at www.usp.org/store/products-services/usp-compounding or call USP Customer Service at 1-800-227-8772 (U.S. and Canada), +1-301-881-0666, or 00-800-4875-5555 (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](#).

Shows

- Visit USP at Booth #3224 at AAPS October 15–17, 2012. in Chicago, IL
- Visit USP at Booth #100 at EAS November 12–14, 2012. in Somerset, NJ

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

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Compendial Highlights

[New Official Text](#)

Revision Bulletins:

[Cetirizine Hydrochloride Tablets](#) (posted 27–Jul–2012; official 01–Aug–2012)

[Famciclovir](#) (posted 27–Jul–2012; official 01–Feb–2013)

[Isosorbide Mononitrate Extended-Release Tablets](#) (posted 27–Jul–2012; official 01–Aug–2012)

[Metoprolol Succinate Extended-Release Tablets](#) (posted 27–Jul–2012; official 01–Aug–2012)

[Mycophenolate Mofetil Capsules](#) (posted 27–Jul–2012; official 01–Aug–2012)

IRAs

[Benzalkonium Chloride](#) (posted 27–Jul–2012; official 01–Sep–2012)

[Benzalkonium Chloride Solution](#) (posted 27–Jul–2012; official 01–Sep–2012)

Errata

[July 2012 Errata Posting](#) (posted 29–Jun–2012)

[May 2012 Errata Posting](#) (posted 27–Apr–2012)

[March 2012 Errata Posting](#) (posted 24–Feb–2012)

[January 2012 Errata Posting](#) (posted 29–Dec–2011)*

[October 2011 Errata Posting](#) (posted 28–Oct–2011)

[August 2011 Errata Posting](#) (posted 30–Aug–2011)

[June 2011 Errata Posting](#) (posted 30–Jun–2011)

[April 2011 Errata Posting](#) (posted 29–Apr–2011)

[February 2011 Errata Posting](#) (posted 28–Feb–2011)

[December 2010 Errata Posting](#) (posted 30–Dec–2010)

*Beginning with the December 29, 2011 posting, Errata postings will be named with the month in which they become official.

[Compendial Notices](#)

New

[Revision Bulletins to be Posted Bimonthly](#) (posted 31–Aug–2012)

[Citalopram Hydrobromide Notice of Intent to Revise](#) (posted 31–Aug–2012)

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

[Stimuli Articles](#)

Featured in *PF 38(5)*, September–October 2012

None

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Tip of the Month

Effective immediately, USP will post Revision Bulletins on a bimonthly basis rather than on a monthly basis. With this change, Revision Bulletins routinely will be posted every other month (July, September, etc.) unless a need arises for an urgent revision, such as one related to patient safety. This change also applies to *FCC's* Immediate Standards. For more information, please go to <http://www.usp.org/usp-nf/notices/revision-bulletins-be-posted-bimonthly>

Question of the Month

For an Identification test by HPLC retention time, how much variation is acceptable between the standard and sample retention time?

USP does not offer any guidance with regards to retention times. *USP* General Chapter <621> does make a reference to Relative Retention times, however:

"Relative retention times may be provided in monographs for informational purposes only to aid in peak identification. There are no acceptance criteria applied to relative retention times."

You will have to develop your own criteria for acceptable variation in retention times. You may want to consult your internal SOPs and/or your QA department.

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