



May 2016

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[USP Catalog](#)

## 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 the last month; 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dates; items that have a new price and/or have a new package size; items with lots that are (or soon will be) no longer valid; and items with new lots since the last email notice.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](http://www.usp.org/products).

An expanded list of [USP Reference Standards Under Development](#) has been posted to the USP website. The list includes new **USP Reference Standards that we expect to release within a year**. The list is updated four times per year; most recently in April 2016. The list can be sorted by calendar quarter, monograph name, compendium and more. The list can be sorted by Reference Standard category (impurity, small molecule, system suitability, etc).

**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, fill out the form online at [www.usp.org/reference-standards/find-reference-standard/notification-service](http://www.usp.org/reference-standards/find-reference-standard/notification-service).

USP has expanded its **Donor Recognition Program** to further recognize contributors who participate in the standards-setting process and help make an impact on global health. Visit the [donor recognition page](#) to learn more.

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## New Reference Standards Now Available

Catalog #	Description and Package Size	Lot	Price (USD)
1011889	Advantame (200 mg)	F034R0	\$222
1133853	Cidofovir (100 mg)	F042K0	\$303
1133864	Cidofovir Enantiomer (15 mg)	F042P0	\$692
1228552	Dronedarone Related Compound B (20 mg)	F029S0	\$692
1228574	Dronedarone Related Compound D (20 mg)	F029U0	\$692
1369055	Lithol Rubine BK (100 mg)	F015J0	\$222
1546194	Polydatin (20 mg)	F049G0	\$222
1614716	Anhydrous Sodium Succinate (250 mg)	F048D0	\$222
1615300	Solifenacin Succinate (100 mg)	F04890	\$662
1615311	Solifenacin Identification Mixture A (15 mg)	F048A0	\$692
1615322	Solifenacin Identification Mixture B (20 mg)	F048B0	\$692
1619039	Spirolactone Related Compound C (30 mg)	F050G0	\$692
1619040	Spirolactone Related Compound D (30 mg)	F050H0	\$692
1619051	Spirolactone Epimer Mixture (30 mg)	F050K0	\$692
1619094	Spirolactone Related Compound I (30 mg)	F050J0	\$692

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## Previously Out-of-Stock Items Now Available

Catalog #	Description and Package Size	Lot	Price (USD)
1134040	Ciclopirox Related Compound B (25 mg)	H1M545	\$692
1133933	Cinnamic Acid (100 mg)	R041T0	\$222
1226014	Doxycycline Related Compound A (10 mg)	R04660	\$692
1287722	Galactosamine Hydrochloride (50 mg)	G1L378	\$222
1478185	Oleyl Alcohol (5 x 50 mg)	R05550	\$222
1535744	Phosphatidylethanolamine (100 mg)	R04380	\$376
1601226	Residual Solvent Class 1 - 1,1,1-Trichloroethane (1.2 mL/ampule; 3 ampules)	R04900	\$222

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## Backorder Availability Estimates, May 9, 2016

Catalog #	Description	Expected Availability*
1224700	Docosate Calcium (500 mg)	Q3/2016
1095517	Carbidopa Related Compound A (25 mg) (3-O-Methylcarbidopa)	TBD
1396003	Metaraminol Bitartrate (200 mg)	TBD
1535733	Phosphatidylcholine (350 mg) (INTERNATIONAL COLD CHAIN SHIPMENT REQUIRED)	Q2/2016
1686310	Trifluridine Related Compound A (10 mg) (5-Carboxy-2'-deoxyuridine)	Q2/2016
1237509	Epitetracycline Hydrochloride (200 mg)	TBD
1720407	Xylazine (200 mg)	Q2/2016

\*Dates are targets and may change at any time. Q2/2016 April–June 2016; Q3/2016 July–September 2016

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## Items with New Package Size or New Description

Catalog #	Description	Old Size	New Size	Lot	Price (USD)
1584014	Pyrantel Related Compound A (25 mg) ((Z)-1-Methyl-2-(2-(thiophen-2-yl)vinyl)-1,4,5,6-tetrahydropyrimidine Pamoate)	25 mg	—	R044X0	\$692

Pyrantel Related Compound A (25 mg) (1-methyl-2-[(Z)-2-(thiophen-2-yl)ethenyl]-1,4,5,6-tetrahydropyrimidine Pamoate)

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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.

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No Longer Valid as of April, 2016				
Catalog #	Description	Current Lot	Previous Lot/ Valid Use Date	Price (USD)
1038003	Antazoline Phosphate (200 mg)	R019L0	H (30-Apr-16)	\$222
1044345	Atazanavir System Suitability Mixture (25 mg)	F015B1	F015B0 (30-Apr-16)	\$692
1076341	Boric Acid (1 g)	F1D036	F0D036 (30-Apr-16)	\$284
1090706	Capecitabine (200 mg)	R014M0	G0J205 (30-Apr-16)	\$222
1096000	Carbinoxamine Maleate (200 mg)	I1K403	I0K403 (30-Apr-16)	\$222
1117008	Chloroprocaine Hydrochloride (200 mg)	G1B285	G0B285 (30-Apr-16)	\$222
1133503	Cholic Acid (2 g)	R016D0	G0J404 (30-Apr-16)	\$222
1134266	Citalopram Related Compound C (25 mg)	R030U0	G0L177 (30-Apr-16)	\$692
1134357	Cisplatin (100 mg)	R00510	J0L420 (30-Apr-16)	\$222
1148001	Colistin Sulfate (200 mg)	R02022	G-1 (30-Apr-16)	\$222
1171003	Denatonium Benzoate (200 mg)	R020M0	I1F025 (30-Apr-16)	\$222
1191000	Dicyclomine Hydrochloride (125 mg)	I1M524	I0M524 (30-Apr-16)	\$222
1224981	Donepezil Hydrochloride (200 mg)	R020S0	G0K230 (30-Apr-16)	\$1,000
1225485	Doxazosin Related Compound F (15 mg)	R022Q0	F0H028 (30-Apr-16)	\$692
1234125	Efavirenz Related Compound A (20 mg)	R027V0	F1L237 (30-Apr-16)	\$692
1265504	Ethylcellulose (1 g)	R024J0	J0L385 (30-Apr-16)	\$222
1286060	Formononetin (50 mg)	R029F0	F0C196 (30-Apr-16)	\$740
1287030	Furosemide Related Compound B (100 mg)	R00750	K0H287 (30-Apr-16)	\$692
1321004	Hydrocortisone Valerate (200 mg)	R024Y0	F-1 (30-Apr-16)	\$222
1332000	Hydroxyurea (200 mg)	R010X0	H (30-Apr-16)	\$222
1337004	Iminodibenzyl (25 mg)	R028S0	I1K213 (30-Apr-16)	\$692
1347529	Ipratropium Bromide Related Compound B (10 mg)	R024T0	F0G242 (30-Apr-16)	\$692
1349014	Isoflurane Related Compound A (0.1 mL)	R019E0	H0M473 (30-Apr-16)	\$692
1370327	Lorazepam Related Compound A (25 mg)	R013M0	H0F195 (30-Apr-16)	\$692
1370600	Lovastatin (125 mg)	H5K027	H4K027 (30-Apr-16)	\$176



1430000	Methylergonovine Maleate (50 mg)	R007F0	K0H114 (30-Apr-16)	\$222
1446848	Montelukast Racemate (20 mg)	R031T0	G0M114 (30-Apr-16)	\$692
1463304	Nicotine Bitartrate Dihydrate (400 mg)	R02011	R02010 (30-Apr-16)	\$222
1477604	Octreotide Acetate (4.37 mg)	R021U0	G0M429 (30-Apr-16)	\$679
1478855	Orlistat Related Compound E (10 mg)	F11019	F0I019 (30-Apr-16)	\$692
1501108	Penicillamine Disulfide (200 mg)	R017T0	J0I007 (30-Apr-16)	\$692
1546707	High Density Polyethylene (3 strips)	K0M357	J0L476 (30-Apr-16)	\$222
1605205	Ropinirole Hydrochloride (200 mg)	R020T0	F0J036 (30-Apr-16)	\$718
1614669	Sodium Starch Glycolate Type A (400 mg)	H1L048	H0L048 (30-Apr-16)	\$222
1651009	Tetracycline Hydrochloride (200 mg)	R039W0	L1H374 (30-Apr-16)	\$222
1700501	L-Tryptophan (200 mg)	R001N0	H0H122 (30-Apr-16)	\$222
1724408	Ziprasidone Hydrochloride (200 mg)	F1J028	F0J028 (30-Apr-16)	\$222

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No Longer Valid as of May 2016				
Catalog #	Description	Current Lot	Previous Lot (Valid Use Date)	Price (USD)
1098195	Ceftriaxone Sodium E-Isomer (25 mg)	R011D0	I2K393 (31-May-16)	\$692
1133536	Choline Bitartrate (200 mg)	R028F0	F0C057 (31-May-16)	\$222
1134211	Cladribine Related Compound A (20 mg)	R009R0	F0F244 (31-May-16)	\$808
1140430	Clopidogrel Bisulfate (125 mg)	R018J0	G1K326 (31-May-16)	\$989
1140597	Clopidogrel Related Compound B (20 mg)	R014S0	G2J411 (31-May-16)	\$840
1147009	Colistimethate Sodium (200 mg)	H3J047	H2J047 (31-May-16)	\$222
1149004	Corticotropin (5.6 Units/vial; 2 vials)	M21180	M11180 (31-May-16)	\$176
1173257	Desogestrel Related Compound B (25 mg)	R024C0	H0K327 (31-May-16)	\$692
1241506	Ergotamine Tartrate (150 mg) (List Chemical)	R02200	J0F349 (31-May-16)	\$222
1248006	Erythromycin Stearate (200 mg)	R01900	H0B187 (31-May-16)	\$222
1269913	Fentanyl Related Compound A (100 mg)	R00620	F0H141 (31-May-16)	\$692
1294848	Gamma-Glutamyl-(S)-allyl-L-cysteine (30 mg)	R036Y0	G0J002 (31-May-16)	\$960
1295607	Glycerin (2 mL)	R007A0	I0I071 (31-May-16)	\$222
1365000	Levothyroxine (500 mg)	R016X1	L0D226 (31-May-2016)	\$222
1368609	Lisinopril (300 mg)	J1F043	J0F043 (31-May-16)	\$222
1370906	Lynestrenol (20 mg)	G0M147	F0B314 (31-May-16)	\$287
1380524	Memantine Related Compound B (15 mg)	R012N1	R012N0 (31-May-16)	\$692
1381709	Menthol (250 mg)	R00640	J0I189 (31-May-16)	\$222
1387002	Mepivacaine Hydrochloride (200 mg)	R00960	H (31-May-16)	\$222
1421009	Methscopolamine Bromide (200 mg)	R011A0	H0I222 (31-May-16)	\$222
1431625	Methyl Palmitoleate (3 x 100 mg)	R007X0	G0F330 (31-May-16)	\$222
1443602	Midazolam Hydrochloride CIV (200 mg)	F1G152	F0G152 (31-May-16)	\$314
1451000	Nalidixic Acid (200 mg)	H11155	H0I155 (31-May-16)	\$222
1526007	Phenoxybenzamine Hydrochloride (250 mg)	H0M461	G (31-May-16)	\$222
1539508	Pimozide (200 mg)	G2M338	G1H103 (31-May-16)	\$222
1577008	Propylparaben (200 mg)	R002F0	J1J025 (31-May-16)	\$222
1581005	Pseudoephedrine Hydrochloride (125 mg)	J3K305	J2K305 (31-May-16)	\$176
1626001	Sulfadimethoxine (200 mg)	H1K048	H0K048(31-May-16)	\$222
1639003	Sulfisoxazole Acetyl (200 mg)	I0L490	H-1(31-May-16)	\$222

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No Longer Valid as of June 2016				
Catalog #	Description	Current Lot	Previous Lot (Valid Use Date)	Price (USD)
1019712	Amiloride Related Compound A (30 mg)	F1E287	F0E287 (30-Jun-16)	\$692
1027302	Amiodarone Hydrochloride (200 mg)	H0M435	G0G340 (30-Jun-16)	\$222
1027346	Amiodarone Related Compound D (20 mg)	F1J007	F0J007 (30-Jun-16)	\$692
1027357	Amiodarone Related Compound E (25 mg)	F1I150	F0I150 (30-Jun-16)	\$692
1033203	Ampicillin Sodium (125 mg)	R019R0	H0I248 (30-Jun-16)	\$176
1044549	Atorvastatin Related Compound C (20 mg)	H1M148	H0M148 (30-Jun-16)	\$692
1048663	Benazepril Related Compound E (25 mg)	G0M421	F0F280 (30-Jun-16)	\$692
1065480	Beta Carotene (7 x 100 mg)	G0M537	F0J240 (30-Jun-16)	\$222
1096633	Carvedilol Related Compound A (15 mg)	R037U0	F0H146 (30-Jun-16)	\$692
1098526	Celecoxib Related Compound B (10 mg)	R018P0	F0L039 (30-Jun-16)	\$692
1134244	Citalopram Related Compound A (25 mg)	R015E0	G0L327 (30-Jun-16)	\$692
1136002	Clindamycin Hydrochloride (200 mg)	R011T0	H1K043 (30-Jun-16)	\$608
1140247	Clomipramine Hydrochloride (200 mg)	R026G0	G0H405 (30-Jun-16)	\$222
1150207	Cottonseed Oil (1 g)	G0L406	F0D173 (30-Jun-16)	\$222
1179887	Dextran 70 Calibration (100 mg)	G1J373	G0J373 (30-Jun-16)	\$222
1224959	Dolasetron Mesylate (125 mg)	R032Y0	F0C319 (30-Jun-16)	\$222
1314960	Hydrocodone CII (125 mg)	R023C0	F0K177 (30-Jun-16)	\$294
1339000	Indigotindisulfonate Sodium (750 mg)	R045L0	I0H368 (30-Jun-16)	\$222
1340009	Indocyanine Green (250 mg)	J1J241	J0J241 (30-Jun-16)	\$242
1349025	Isoflurane Related Compound B (0.1 mL)	R012K0	H0M326 (30-Jun-16)	\$692
1356326	Ketorolac Related Compound B (20 mg)	R021R0	G0M481 (30-Jun-16)	\$692
1356858	Lamivudine Resolution Mixture B (10 mg)	R013V0	I0K003 (30-Jun-16)	\$692
1357001	L-Leucine (200 mg)	I1J121	I0J121 (30-Jun-16)	\$222
1378001	Medroxyprogesterone Acetate (200 mg)	R032M0	I1K073 (30-Jun-16)	\$222
1449530	Nabumetone Related Compound A (15 mg)	R016N0	G0I062 (30-Jun-16)	\$692
1453526	Naltrexone Related Compound A CII (30 mg)	R02350	F1G035 (30-Jun-16)	\$692
1468400	Nordazepam CIV (50 mg)	R013P0	I0H001 (30-Jun-16)	\$795
1478254	Olive Oil (1 g)	G0L407	F0D175 (30-Jun-16)	\$222
1478334	Olanzapine Related Compound C (5 mg)	R016Q0	H0L545 (30-Jun-16)	\$692
1478378	Olmesartan Medoxomil Related Compound A (20 mg)	R017P0	F0J419 (30-Jun-16)	\$692
1478516	Omeprazole Related Compound A (15 mg)	R022U0	R003E0 (30-Jun-16)	\$692
1492040	Palm Oil (1 g)	G0L426	F0D179 (30-Jun-16)	\$222
1499006	Pargyline Hydrochloride (200 mg)	F-2	F-1 (30-Jun-16)	\$222
1522301	Pheniramine Maleate (150 mg)	R020N0	H0M087 (30-Jun-16)	\$222
1542003	Piperazine Phosphate (200 mg)	F-1	F (30-Jun-16)	\$222
1578500	Prostaglandin A1 (25 mg)	R01890	J0K053 (30-Jun-16)	\$1,778
1581504	Pseudoephedrine Sulfate (200 mg)	R00970	H0E285 (30-Jun-16)	\$222
1602502	Retinyl Palmitate (4 x 50 mg)	R020B0	F0J106 (30-Jun-16)	\$222
1604654	Risperidone (100 mg)	R019F0	H0L153 (30-Jun-16)	\$222
1604803	Ritonavir (200 mg)	H0M427	G0L143 (30-Jun-16)	\$222
1604870	Rivastigmine Related Compound B (15 mg)	R028R0	F0I126 (30-Jun-16)	\$692
1667585	Titanium Dioxide (2 g)	R038S0	F0D079 (30-Jun-16)	\$222
1669004	Tolazoline Hydrochloride (300 mg)	R012L0	F (30-Jun-16)	\$222
1711461	Verteporfin (200 mg)	R049D0	R004G0 (30-Jun-16)	\$665



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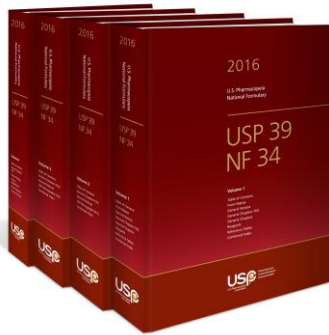
## Items with New Lots

Catalog #	Description and Package Size	Previous Lot (Valid Use Date)	Current Lot	Price (USD)
1043309	Powdered Ashwagandha Root Extract (1 g)	F0I273 (30-Apr-17)	F1I273	\$222
1098107	Cefoxitin (500 mg)	J0E038 (31-May-17)	J1E038	\$222
1115705	Chloromethyl Isopropyl Carbonate (100 mg)	R021D0 (30-Apr-17)	R043B0	\$692
1133580	Oversulfated Chondroitin Sulfate (10 mg)	H0M191 (30-Apr-17)	R037X0	\$743
1133933	Cinnamic Acid (100 mg)	F0L161 (30-Apr-17)	R041T0	\$222
1134040	Ciclopirox Related Compound B (25 mg)	H0M545 (1-Mar-16)	H1M545	\$692
1138405	Clobetasol Propionate (200 mg)	H0K292 (30-Apr-17)	H1K292	\$222
1156000	Cyclopentolate Hydrochloride (300 mg)	J0J112 (31-May-17)	R045B0	\$222
1181302	Dextrose (500 mg)	K0K311 (30-Apr-17)	R035J0	\$222
1226014	Doxycycline Related Compound A (10 mg)	G1M394 (30-Nov-16)	R04660	\$692
1237000	Epinephrine Bitartrate (200 mg)	P1L152 (30-Apr-17)	P2L152	\$222
1265515	Ethylene Glycol (0.5 mL)	G0K011 (30-Apr-17)	G1L121	\$222
1268900	Eucalyptol (200 mg)	F0K046 (30-Apr-17)	R017H0	\$222
1287507	Gadodiamide (500 mg)	G0M395 (31-May-17)	R04000	\$222
1287722	Galactosamine Hydrochloride (50 mg)	G0L378 (30-Apr-17)	G1L378	\$222
1304038	Heparin Sodium Identification (50 mg)	G1L413 (30-Apr-17)	G2L413	\$222
1356337	Ketorolac Related Compound C (20 mg)	R00050 (30-Apr-17)	R042H0	\$692
1356960	Leflunomide (200 mg)	F0G328 (31-May-17)	R043F0	\$275
1442009	Metronidazole (100 mg)	J1I272 (30-Apr-17)	J2I272	\$222
1457301	Naproxen (200 mg)	J0H044 (30-Apr-17)	R03550	\$222
1460703	Nevirapine Anhydrous (100 mg)	G0M270 (31-Mar-17)	R03560	\$222
1478119	Ofloxacin Related Compound A (25 mg)	G0K034 (30-Apr-17)	R039Q0	\$692
1478185	Oleyl Alcohol (5 x 50 mg)	F0M526 (28-Feb-17)	R05550	\$222
1496008	Papaverine Hydrochloride (200 mg)	H2M423 (30-Apr-17)	R031V0	\$222
1535744	Phosphatidylethanolamine (100 mg)	R00690 (30-Apr-17)	R04380	\$376
1535788	Phosphatidylinositol (Soy) Sodium (10 mg)	R043E0 (30-Apr-17)	R047X0	\$222
1548190	Potassium Chloride (1 g)	G0F268 (30-Apr-17)	R047P0	\$222
1584014	Pyrantel Related Compound A (25 mg)	F0I122 (30-Apr-17)	R044X0	\$692
1601226	Residual Solvent Class 1 - 1,1,1-Trichloroethane (1.2 mL/ampule; 3 ampules)	F0C410 (30-Apr-17)	R04900	\$222
1643576	Temozolomide Related Compound C (15 mg)	F0I323 (30-Apr-17)	F1I323	\$692
1652001	Tetrahydrozoline Hydrochloride (200 mg)	H0L538 (30-Apr-17)	R031X0	\$222
1700523	Tryptophan Related Compound B (25 mg)	F0H101 (30-Apr-17)	F1H101	\$692
1705753	Uracil (15 mg)	F0K302 (30-Apr-17)	F1K302	\$222
1727018	Zolmitriptan R-Isomer (20 mg)	F0K148 (30-Apr-17)	R027H0	\$692

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## USP Publication Highlights

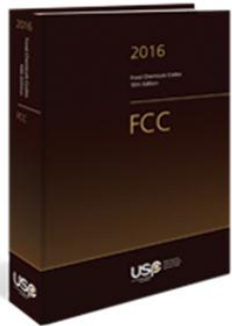


### Be Prepared for Compliance in 2016—Order **USP 39–NF 34** Today!

The 2016 edition of *USP–NF* became official May 1, 2016. Order today for access to important updates, including:

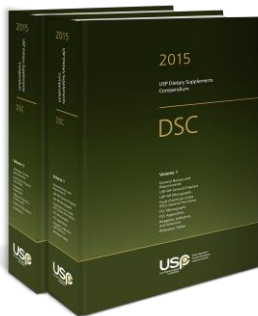
- 24 new or revised general chapters, including <661> Containers–Plastic, <711> Dissolution, <771> Ophthalmic Products—Quality Tests, and more!
- More than 180 new or revised monographs for drug substances, drug products, excipients, and dietary supplements!

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### Order the **Food Chemicals Codex (FCC), Tenth Edition!**

The *FCC, Tenth Edition* published March 1<sup>st</sup>, 2016. It features more than 45 additional monographs including 8 on probiotics. Plus two new appendices, including one on microbial food cultures; an identity standard on pomegranate juice; and new general tests and assays. Step-by-step methods and helpful information for manufacturers, suppliers, and users of food ingredients are included. Two-year subscription includes a main edition plus three supplements that publish with updates every six months. **Save \$100 with promotion code HWYEZZ25. Order now at [order 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).



### **2015 Dietary Supplements Compendium (DSC):**

The *2015 DSC* has about 100 more monographs; over 40 new or revised Admissions Evaluations; more than 20 additional General Chapters; plus 150 pages added of full-color illustrations and/or images have been added. **Save \$100 with promotion code HDWDZZ25. Order now at <http://www.usp.org/dsc-2015>** or by calling USP Customer Service 1-800-227-8772 (U.S. / Canada), +1-301-881-0666, or 00-800-4875-5555 (Select Europe).



### **USP37–NF32 Archive Available Now!** This new Archive complements the earlier Archive, which includes *USP28–NF23* through *USP36–NF31*.

This valuable reference tool designed for scientists and industry professionals is now available electronically. Both Archives are provided as PDF files on USB flash drives. **Order now at <http://www.usp.org/store/products-services/usp-nf-archive>** or by calling USP Customer Service 1-800-227-8772 (U.S. / Canada), +1-301-881-0666, or 00-800-4875-5555 (Select Europe).

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## Event Highlights

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### **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](mailto: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](#).

## USP Education

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USP's 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 [Education.usp.org](http://Education.usp.org)

### **New course!**

#### **GMP Compliance in Quality Operations for Dietary Supplements**

U.S. FDA recently released its 2015 list of cGMP inspection observations for dietary supplements. A total of 30% of major observations were observed in the area of quality control (QC). The FDA observations indicated that 21 Code of Federal Regulations §§ 111.70 and 111.75—GMP compliance requirements for manufacturers—remained challenging.

This course will focus on key aspects and approaches for QC operations to comply with the dietary supplement GMP requirements, and on the use and benefits of USP monographs, test procedures, Reference Standards, and general guidance chapters to help meet GMP compliance. The course will also cover GMP compliance for QC laboratory operations, covering a broad range of topics, including specifications for components and finished products, analytical instrument qualification and calibration, validation and verification of test procedures, and internal and third-party laboratory audits.

June 2, 2016, 8:30 am to 4:00 pm. Available simultaneously as a classroom course in Rockville, MD and via webcast

Sign up [here](#) to receive USP Education information.

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## Compendial Highlights

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### [New Official Text](#)

#### **RB** Revision Bulletins

- [Valine \(POSTPONEMENT\)](#) (posted 29–Apr–2016; official 01–May–2016)

#### **IRA** IRAs

- [Ketorolac Tromethamine](#) (posted 25–Mar–2016; official 01–May–2016)

#### **E** [Access USP–NF Errata](#) [Errata Table Updated March 25, 2016](#)

#### **H6** [Stage 6 Notices](#)

Nothing new this month

### [Compendial Notices](#)

#### General Announcements:

- [Pending Monographs Page Updated](#) (25-Mar-2016)

#### General Chapter Prospectus Notices:

- [<197> Spectroscopic Identification Tests](#) (posted 25-Mar-2016; deadline 25-Apr-2016)

#### Notices of Intent to Revise:

- [Trihexyphenidyl Hydrochloride Oral Solution](#) (posted 04-May-2016)
- [Trihexyphenidyl Hydrochloride Extended-Release Capsules](#) (posted 04-May-2016)

#### Call for Candidates:

- [Biologics Stability Expert Panel](#) (deadline: May 15, 2016)

Sign up to receive updates electronically at [www.usp.org/store/free-resources/newsletter-and-information](http://www.usp.org/store/free-resources/newsletter-and-information).

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## [Stimuli Articles](#)

- **Factors to Consider in Setting Adequate Overages of Vitamins and Minerals in Dietary Supplements Fitness for Use: Decision Rules and Target Measurement Uncertainty**

Stimuli Articles can be accessed for free at [www.usppf.com](http://www.usppf.com)

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## Tip of the Month

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### **USP General Chapter Prospectus—New way to impact future standards**

General Chapters have broad applications. We now will seek stakeholder input at the earliest development stages. Prior to publishing in *PF*, new and significantly revised chapters will be posted on our website for comment. For details and links to current postings, please visit: <http://www.usp.org/usp-nf/notices/usp-pilot-process-early-input-general-chapters>

## Question of the Month

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### **Question:**

With regard to general Chapter <61>, Microbial Examination of Nonsterile Products: Microbial Enumeration Tests, do we have to test systematically in parallel a previous and approved batch in order to compare with the new batch?

### **Answer:**

You do not have to test a previous batch in parallel. You can do the comparison 'on paper' if growth was clearly described.

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