



EMAIL NOTICE

September, 2017

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For all the latest information, visit www.usp.org

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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in the last month; backordered items with estimated availability dates; items with lots that are (or soon will be) no longer valid; and items with new lots since the last email notice. USP strongly suggest downloading the FREE Reference Standards and Resources APP to easily track and receive notifications and alerts for the reference standards of interest to you.

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 <http://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, fill out the form online at <http://www.usp.org/new-reference-standards-notification>.

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**New Reference Standards Now Available**

Catalog #	Description and Package Size	Lot	Price (USD)
1133922	Cinacalcet Related Compound C (50 mg)	F060G0	\$790
1350352	Isopropyl Isostearate (3 x 1 mL)	F069K0	\$275

Items with New Lots

Catalog #	Description and Package Size	Current Lot	Previous Lot (Valid Use Date)	Price (USD)
1000500	Abacavir System Suitability Mixture (15 mg)	R066P0	F0J097 (30-Apr-18)	\$730
1012101	Adenine (200 mg)	R068R0	I0M090 (31-Aug-18)	\$200
1019767	Aminobenzoate Sodium (200 mg)	R069S0	F (30-Apr-18)	\$230
1025602	Amino Methacrylate Copolymer (1.5 g)	R076U0	F0G005 (30-Jun-18)	\$230
1029013	Amitriptyline Related Compound A (25 mg)	R072Q0	G0K409 (31-Aug-18)	\$730
1046012	Azithromycin Identification Mixture (75 mg)	R07410	F0J232 (30-Sep-18)	\$730
1087009	Calcium Pantothenate (200 mg) (Vitamin B5)	R029P0	P0L523 (30-Jun-18)	\$230
1097192	Cefadroxil Related Compound I (25 mg)	R06810	F0M169 (31-Aug-18)	\$730
1111908	P-Chloroaniline (200 mg)	R07220	H0M240 (31-Jul-18)	\$235
1140247	Clomipramine Hydrochloride (200 mg)	R07670	R026G0 (30-Sep-18)	\$230
1141909	Cloxacillin Benzathine (200 mg)	G1M102	G0M102 (31-Aug-18)	\$230.
1143008	Cocaine Hydrochloride CII (250 mg)	R067U0	I1I294 (31-Aug-18)	\$305
1154558	Alpha Cyclodextrin (500 mg)	R073D0	G0H079 (31-Jul-18)	\$230
1191000	Dicyclomine Hydrochloride (125 mg)	R07540	I1M524 (30-Sep-18)	\$230
1213329	Diosmin for System Suitability (15 mg)	R071E0	F0K325 (31-Aug-18)	\$730
1225317	Dorzolamide Related Compound B (15 mg)	R083M0	F0L205 (31-May-18)	\$730
1231750	Echinacoside (15 mg)	R075A0	F0M214 (30-Jun-18)	\$200
1235853	Enoxaparin Sodium Molecular Weight Calibrant (mg)	R06720	G0L138 (30-Sep-18)	\$805
1255850	Eszopiclone CIV (100 mg)	R068G0	F0K158 (30-Jun-18)	\$305
1270311	Ferulic Acid (25 mg)	F1J193	F0J193 (30-Sep-18)	\$225
1334006	Hydroxyzine Pamoate (500 mg)	R060P0	H0C016 (31-Dec-17)	\$230
1357475	Latanoprost (50 mg)	R079T0	R05080 (30-Jun-18)	\$1,800
1362114	Levofloxacin Related Compound A (25 mg)	R069C0	G0M101 (31-Jul-18)	\$730



1424233	Methyl Caprate (100 mg)	R07360	G0D087 (30-Sep-18)	\$200
1445506	Monobenzene (200 mg)	R082Q0	F (30-Jun-18)	\$230
1471506	Norfloxacin (200 mg)	R061R0	I0M497 (30-Sep-18)	\$230
1478629	Ondansetron Related Compound D (30 mg)	R065P0	H0I048 (31-Aug-18)	\$730
1492244	Palonosetron Related Compound C (15 mg)	R08550	F02780 (30-Apr-18)	\$730
1546106	Poloxalene (500 mg)	R075W0	F0C009 (30-Sep-18)	\$230
1553815	Pramipexole Related Compound D (25 mg)	R073C0	R02030 (30-Sep-18)	\$730
1554669	Praziquantel Related Compound B (50 mg)	R079Q0	R04950 (30-Sep-18)	\$730
1601146	Residual Solvent Class 1 - Benzene (1.2 mL/amp 3 ampules)	R07930	G0H452 (30-Sep-18)	\$230
1601408	Residual Solvent Class 2 - Cyclohexane	R047N0	G0M072 (30-Jun-18)	\$230

Previously Out-of-Stock Items Now Available

Catalog #	Description and Package Size	Lot	Price (USD)
1025602	Amino Methacrylate Copolymer (1.5 g)	R076U0	\$230
1029013	Amitriptyline Related Compound A (25 mg)	R072Q0	\$730
1087009	Calcium Pantothenate (200 mg)	R029P0	\$230
1097192	Cefadroxil Related Compound I (25 mg)	R06810	\$730
1111908	P-Chloroaniline (200 mg)	R07220	\$235
1141909	Cloxacillin Benzathine (200 mg)	G1M102	\$230
1143008	Cocaine Hydrochloride CII (250 mg)	R067U0	\$305
1154558	Alpha Cyclodextrin (500 mg)	R073D0	\$230
1213329	Diosmin for System Suitability (15 mg)	R071E0	\$730
1225317	Dorzolamide Related Compound B (15 mg)	R083M0	\$730
1231750	Echinacoside (15 mg)	R075A0	\$200
1235853	Enoxaparin Sodium Molecular Weight Calibrant A (8.0 mg)	R06720	\$805
1255850	Eszopiclone CIV (100 mg)	R068G0	\$305
1334006	Hydroxyzine Pamoate (500 mg)	R060P0	\$230
1362114	Levofloxacin Related Compound A (25 mg)	R069C0	\$730
1445506	Monobenzene (200 mg)	R082Q0	\$230
1492244	Palonosetron Related Compound C (15 mg)	R08550	\$730
1554669	Praziquantel Related Compound B (50 mg)	R079Q0	\$730
1572503	Propofol (200 mg)	R046S0	\$230
1601146	Residual Solvent Class 1 - Benzene (1.2 mL/ampule; 3 ampules)	R07930	\$230
1601408	Residual Solvent Class 2 - Cyclohexane (1.2 mL/ampule; 3 ampules)	R047N0	\$230

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Backorder Availability Estimates, September 28, 2017

Catalog #	Description	Expected Availability*
1013727	Aloin (25 mg)	Q4/2017
1046205	Aztreonam (200 mg)	Q4/2017
1056504	1,4-Benzquinone (200 mg)	Q4/2017
1096407	Carboplatin (100 mg)	Q4/2017
1138507	Clocortolone Pivalate (200 mg)	Q4/2017
1148806	Corn Oil (1 g)	Q4/2017
1151935	Cyanidin-3-O-glucoside Chloride (15 mg)	Q4/2017
1161000	Cyproheptadine Hydrochloride (500 mg)	Q4/2017
1225306	Dorzolamide Related Compound D (30 mg)	Q4/2017
1225601	Doxercalciferol (2 x 20 mg)	Q4/2017
1356789	Lamotrigine Related Compound C (10 mg)	Q4/2017
1467950	Nonoxynol 9 (0.5 mL)	Q4/2017
1524806	Phenol (500 mg)	Q4/2017
1535733	Phosphatidylcholine (2 x 100 mg)	Q4/2017
1535802	Phosphoric Acid (1.5 mL/ampule; 3 ampules) (AS)	Q4/2017
1548134	Potassium Bicarbonate (1 g)	Q4/2017
1601281	Residual Solvents Class 2 - Mixture A (1.2 mL/ampule; 3 ampules)	Q4/2017
1601340	Residual Solvent Class 2 - Acetonitrile (1.2 mL/ampule; 3 ampules)	Q4/2017
1612594	Sevoflurane Related Compound C (0.2 mL)	Q4/2017
1612914	Sitagliptin System Suitability Mixture (20 mg)	TBD
1673012	Travoprost Related Compound A (1.5 mL)	Q4/2017
1685000	Trifluoperazine Hydrochloride (200 mg)	Q4/2017

*Dates are targets and may change at any time. Q1/ 2017 January—March 2017, Q2/ 2017 April – June 2017, Q3- July –September, Q4- October -December

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 Store online [here](#), and by downloading the free Reference Standards and Resources App.

No Longer Valid as of October 2017				
Catalog #	Description	Current Lot	Previous Lot/ Valid Use Date	Price (USD)
1042634	Aripiprazole (200 mg)	R045S0	R01490 (31-Oct-17)	\$230
1043819	Aspartic Acid (100 mg)	R05750	F0B087 (31-Oct-17)	\$230
1044210	Astaxanthin Esters from Haematococcus pluvialis (100 mg)	R034E0	F0J415 (31-Oct-17)	\$225
1051500	Benzethonium Chloride (500 mg)	R026T0	G1M022 (31-Oct-17)	\$230
1076385	Brinzolamide Related Compound B (50 mg)	R068J0	F0C035 (31-Oct-17)	\$730
1130006	Chlorthalidone (200 mg)	R05140	I1L127 (31-Oct-17)	\$230
1140000	Clomiphene Citrate (500 mg)	R052A0	I1J350 (31-Oct-17)	\$230
1171207	23-EPI-26-Deoxyactein (20 mg)	R03180	F0H262 (31-Oct-17)	\$965
1213318	Diosmin (300 mg)	R05500	R02090 (31-Oct-17)	\$230
1218005	Diphenhydramine Hydrochloride (200 mg)	R04070	K0K041 (31-Oct-17)	\$230
1235900	Enrofloxacin (200 mg)	R04690	G1H417 (31-Oct-17)	\$230
1251000	Estradiol Benzoate (250 mg)	H2L542	H1L542 (31-Oct-17)	\$230
1265424	Ethyl Acrylate and Methyl Methacrylate Copolymer Dispersion (1.5 g)	R054Y0	F0F189 (31-Oct-17)	\$230
1270355	Ferrous Sulfate (2 x 1 g)	R05970	F1K388 (31-Oct-17)	\$230
1287700	Galactose (200 mg)	R047C0	G0F252 (31-Oct-17)	\$750
1356945	Lauroyl Arginine (100 mg)	F1K155	F0K155 (31-Oct-17)	\$225
1359404	Levetiracetam (200 mg)	R039L0	H0K337 (31-Oct-17)	\$315
1378012	Medroxyprogesterone Acetate Related Compound (25 mg)	F1C427	F0C427 (31-Oct-17)	\$750
1380513	Memantine Related Compound A (50 mg)	R04470	R022D0 (31-Oct-17)	\$730
1396604	Methacrylic Acid and Ethyl Acrylate Copolymer (200 mg)	R050D0	G2E288 (31-Oct-17)	\$230
1431556	Methyl Oleate (5 x 100 mg)	R041K0	H0J393 (31-Oct-17)	\$200
1434022	Methylphenidate Related Compound A (50 mg)	R041J0	G (31-Oct-17)	\$730
1444707	Mitomycin (50 mg)	R07240	L0L428 (31-Oct-17)	\$705
1460736	Nevirapine Related Compound B (10 mg)	R046B0	I0L362 (31-Oct-17)	\$730
1478800	Orlistat (200 mg)	R03230	G0L008 (31-Oct-17)	\$510
1488000	Oxymorphone CII (300 mg)	R050C0	R016E0 (31-Oct-17)	\$305
1492007	Palmitic Acid (500 mg)	R029M1	R029M0 (31-Oct-17)	\$230
1494931	Pantoprazole Related Compounds D and F Mixture (20 mg)	R05000	G1L326 (31-Oct-17)	\$730
1500240	Paroxetine Related Compound C (30 mg)	R044W0	I0M277 (31-Oct-17)	\$730



1500284	Paroxetine Related Compound G (10 mg)	R05240	H1I332 (31-Oct-17)	\$730
1505506	Pentetic Acid (100 mg)	R05280	F2M478 (31-Oct-17)	\$230
1546467	Polyethylene Glycol 600 (1 g)	R052V0	F0E345 (31-Oct-17)	\$230
1546569	Polyethylene Glycol 4000 (1 g)	R05020	F0F040 (31-Oct-17)	\$230
1546809	Low-Density Polyethylene (3 strips)	R063J0	I0G312 (31-Oct-17)	\$230
1617000	Sorbitol (125 mg)	R055R0	H2F247 (31-Oct-17)	\$185
1643260	Tamsulosin Hydrochloride (200 mg)	R041N0	G0M310 (31-Oct-17)	\$2,215
1672712	Trandolapril Related Compound D (25 mg)	F1H163	F0H163 (31-Oct-17)	\$730
1672723	Trandolapril Related Compound E (25 mg)	F1M204	F0M204 (31-Oct-17)	\$730
1673012	Travoprost Related Compound A (1.5 mL)		G0J307 (31-Oct-17)	\$730
1705800	Uracil Arabinoside (50 mg)	I1J418	I0J418 (31-Oct-17)	\$235
1714007	Vincristine Sulfate (50 mg)	Y06331	Y06330 (31-Oct-17)	\$705

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Now Official!

USP 40–NF 35 is official as of May, 2017

The latest version of the USP-NF was released on November 1, 2016. The USP 40–NF 35 features more than 4,900 monographs and over 300 general chapters. Changes include:

- 17 new or revised general chapters and more than 120 new and revised Reagents
- 154 new or revised monographs, including the first Global Health monograph for Chlorhexidine Gluconate Topical Gel
- Plus important changes to General Notices and Requirements



Visit <http://www.usp.org/products> and select “buy now” under the icon of the USP–NF that you wish to order.



USP–NF Flash Drive Product

USP would like to inform you of some upcoming changes to the USP–NF Flash Drive product. These changes will become effective with the release of the USP41-NF36 Flash Drive product on November 1st, 2017.

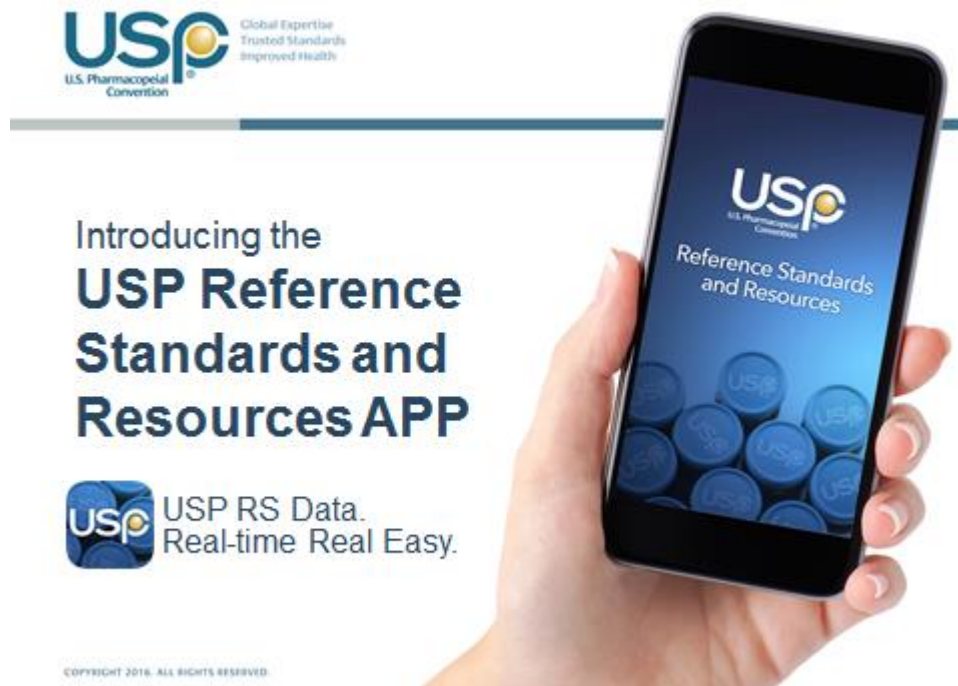
New product features will include:

- Left-hand navigation panel with detailed bookmarks
- Search tool that works across the entire publication including Supplements
- No internet connection necessary to view or access PDF content

If you have any questions or concerns, please contact Trey White III, PhD, Senior Director, Documentary Standards faw@usp.org.

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Showcasing...



The advertisement features the USP logo at the top left, with the tagline "Global Expertise Trusted Standards Improved Health". Below this, the text reads "Introducing the USP Reference Standards and Resources APP". To the right, a hand holds a smartphone displaying the app's interface, which includes the USP logo and the text "Reference Standards and Resources" above a grid of blue pill icons. At the bottom left of the ad, it says "USP RS Data. Real-time Real Easy." and "COPYRIGHT 2016. ALL RIGHTS RESERVED."

To download and learn more go to
<http://www.usp.org/reference-standards-app>

Event Highlights

USP User Forums Coming to a city near you!

The USP Strategic Customer Development 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.

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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](#).

Registration Now Open for:

[Computer Modeling - In vitro and In vivo Studies](#)

October 23, 2017 - October 25, 2017

[International Probiotics Association \(IPA\) Workshop co-sponsored by USP](#)

October 26, 2017

[4th USP Workshop on Synthetic Therapeutic Peptides: Regulations, Standards and Quality](#)

November 6, 2017 - November 7, 2017

[Stakeholder Forums](#)

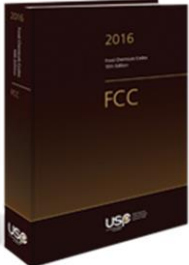
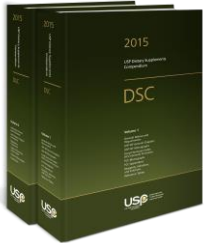
Stakeholder Forums are your opportunity to hear about USP's plans for future standards and to get involved in the process. Attendance is free, and you can participate via WebEx, for more details click [here](#).

USP Education

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

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USP Publication Highlights

	<p>Be Prepared for Compliance—Order <i>USP40–NF 35</i> Today! The latest edition of <i>USP–NF</i> was published on November 1, 2016. Order today for access to important updates, including:</p> <ul style="list-style-type: none"> • 17 new or revised general chapters, and more than 120 new and revised Reagents • 154 new or revised monographs for drug substances, drug products, excipients, and dietary supplements! <p>Available in print, online, and USB flash drive formats. Visit http://www.usp.org/products and select “buy now” under the icon of the <i>USP–NF</i> that you wish to order 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) Online Platform</i> The <i>FCC</i> is a collection of internationally recognized standards, methods and information that enables manufacturers and suppliers to verify the identity, quality, and purity of food ingredients including probiotics, prebiotics, sweeteners, colorants, flavors, and more. On September 1, USP launched a new enhanced <i>FCC</i> Online platform, featuring:</p> <ul style="list-style-type: none"> • Improved global search functionality • Simplified navigation • Personalized workspace • New individual accounts <p>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). For a limited time, purchase the <i>FCC</i> and receive 20% off the Food Fraud Database. Discount cannot be combined with other offers or enterprise subscriptions</p>
	<p>2015 <i>Dietary Supplements Compendium (DSC)</i>: The 2015 <i>DSC</i> 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/store/products/dietary-supplements-compendium or by calling USP Customer Service 1-800-227-8772 (U.S. / Canada), +1-301-881-0666, or 00-800-4875-5555 (Select Europe).</p>
	<p><i>USP38–NF33 Archive Available Now!</i> Complete content of previously-official <i>USP38–NF33</i> on one flash drive. 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.uspnf.com/purchase-usp-nf/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).</p>

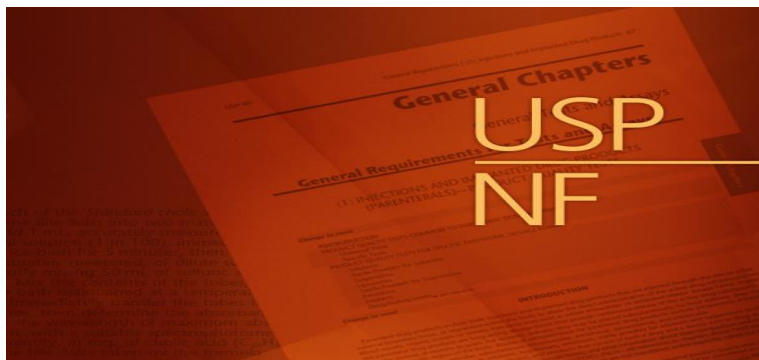
Champion for Quality—Partner with USP

To ensure effective and high quality medicines, we are working hard to update and increase the number of new monographs in the *USP–NF*. But we can't do it alone. **We need partners like you.**

By partnering with us, you are helping to ensure greater availability of quality assured medicines, meeting FDA regulatory needs, and creating efficiencies in testing and compliance.

To learn more, contact Mike Goede at myg@usp.org.

Compendial Highlights



USP creates and continuously revises USP–NF standards through a unique public–private collaborative process, which involves pharmaceutical scientists in industry, academia, and government as well as other interested parties from anywhere in the world. Go to [New Official Text](#) to access all information related to Revision Bulletins, Errata, IRAs, Stage 6 Notices, Compendial Notices and more.

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Call for Candidates:

[USP Volunteer Online Recruitment Form Now Available](#)

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[Stimuli Articles](#)

Stimuli Articles can be accessed for free at www.usppf.com

Tip of the Month

The RS App is here to help!!

“USP Reference Standards valid date of use could change any given day. Which means that in order to stay in compliance you, every day before using the Reference Standard, will have to check its valid date of use”.

Now, USP makes it easier by sending you alerts at the precise moment a Reference Standard you use changed or you can use the barcode reader in the App to obtain the updated information of the Reference Standard straight out of the barcode on the vial label.

Download the Reference Standard and Resources App in your phone or tablet and get updated information and alerts on the reference standards you select.

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Question of the Month

How is the USP Reference Standard Labeled Value Calculated?

The method of choice in computing the assigned value of a USP Reference Standard is a mass balance analysis using independently determined components such as moisture, solvent residues, inorganic residues, chromatographic impurities and ion content. The values used in a mass balance equation used are confidential and cannot be shared due to legal and scientific reasons. The assay results against a previous lot or against another validated standard and the results of the functional group analysis are done for confirmatory purposes only. More importantly, **the use of a value obtained against another lot or standard would make the item a secondary standard.** USP's Reference Standards are considered primary standards, except for certain biological USP Reference Standards with units of activity that are established against and traceable to the World Health Organization International Standards.

USP uses the mass balance approach as this provides a more precise determination of the assigned value than assaying versus a previous lot. The assaying versus a previous lot approach inherently causes greater variability and less precision due to the variability of the previous lot being incorporated into the overall variability of the lot under evaluation. The mass balance approach also results in higher accuracy.

Note that values are not assigned to Reference Standards having only qualitative USP compendial uses.

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