

Dietary Supplements

Fall Newsletter



Discontinuation of USP Cyanocobalamin RS Catalog #1152009

The USP Cyanocobalamin RS catalog #1152009 is discontinued effective immediately. All existing orders for the USP Cyanocobalamin RS #1152009 will be canceled. For your compendial testing needs, USP offers [#1152011 USP Cyanocobalamin \(Crystalline\) RS](#). This reference standard is available for purchase now.

The USP Cyanocobalamin (Crystalline) RS catalog #1152011 does not include any added substances. It has undergone extensive testing in a collaborative study. The crystalline form is approved as suitable for use in all USP compendial applications requiring the use of "USP Cyanocobalamin RS".

It is important to note that USP Cyanocobalamin (Crystalline) RS catalog #1152011 is about 100 times more concentrated than USP Cyanocobalamin RS catalog #1152009. For this reason, it requires more dilutions or the use of larger volumetric flasks to obtain the concentration specified in USP compendial applications. It also has different handling instructions.

Upcoming Events and Meetings

Upcoming Verification 101 Classroom Courses in two locations:

January 30, 2018 in Rockville, MD
April 4, 2018 at Utah Valley University

USP will hold the Verification 101 Classroom course on January 30, 2018 at USP in Rockville, MD and on April 4, 2018 at Utah Valley University.

Details are being finalized and additional information along with registration will be posted here in the coming weeks: <http://www.usp.org/dietary-supplements-herbal-medicines>. Visit the site to learn more on upcoming dates and times.

Stay tuned and don't miss this exciting course!

Products & Services

New Dietary Supplements Reference Standards

Non-Botanicals

- [Citicoline Sodium](#)

Reference Standards Coming Soon

Botanicals

- Coffee Fruit Dry Extract
- Coix Seed Oil Extract
- European Elder Berry Dry Extract
- Gallic Acid

Non-Botanicals

- Annatto Seed Tocotrienols Extract
- Calcium Citrate Malate
- Carotenes
- Diglycine
- Menaquinone-4
- Triglycine

Reference Standards in Development

Botanicals

AOAC 131st Annual Meeting and Exposition (September 24-27, 2017, Atlanta, Georgia)

The AOAC 131st Annual Meeting and Exposition was held on September 24-27, 2017 in Atlanta, Georgia. USP staff participated in the AOAC Stakeholder Panels on Dietary Supplements (SPDS), a collaborative group dedicated to identifying and prioritizing ingredients, and developing standard method performance requirements (SMPR). USP also participated in the approval of SMPRs for Echinacea, Ginseng, and SAME, as well as in the launch of working groups for proposing new SMPRs for Scullcap, Kavalactones, and Resveratrol. Members of the Botanical Dietary Supplements and Herbal Medicines and Non-Botanical Dietary Supplements Expert Committees were also engaged in these meetings, which contributed to further interactions related to the prioritization of USP standards.

Numerous attendees visited USP's exhibit hall booth to learn about dietary supplements and ingredient verification services, reference materials and standards, the Dietary Supplements Compendium and the Adulteration Workshop to be held in February 27-28, 2018. A poster on the USP Adulterants Database dealing with the challenges in cheminformatics, co-authored by the FDA Substance Registration System scientists, was presented on September 24, and subsequently selected for an oral session on September 27. For more information, please contact [Anton Bzhelyansky](#).

Other important symposia also took place at the annual meeting. A symposium on vulnerability assessment and prevention of food products adulterated with food allergens was co-chaired by Steven Gendel, Senior Director of the USP Foods program. Another symposium on food fraud and the role of non-targeted methods in the European and the US infrastructure was co-chaired by Kenny Xie, Scientific Liaison with the USP Foods program, and moderated by Steven Gendel. Aniko Solyom, Ph.D. of GAAS Analytical and a member of the USP Non-Botanical Dietary Supplements Expert Committee co-chaired the Workshop entitled *Seed to Shelf--What is the Sweet Spot between Manufacturers/Testing Labs/Supply Chain for Dietary Supplements and Foods?* with Amit Chandra of Amway. Working groups on supply chains (Rupa Das, BI Nutraceuticals), contract labs (Richard Sanders, Covance) and manufacturers (Mary Murray, Amway) fostered valuable discussions. Participants expressed interest in submitting new and modernized monograph methods, and encouraged USP to actively communicate with stakeholders on the calls for monographs and updated analytical methods.

USP Engages Stakeholders at the 2017 SupplySide West. September 25-29, 2017

USP partners with experts from around the world to help ensure the quality, potency and purity of dietary supplements through its monograph and Reference Standards. Conferences offer opportunities for USP staff to engage with industry experts who are integral to the standards setting process. At the Supply Side West meeting on September 25-29, 2017 in Las Vegas, NV, USP staff met with researchers, regulatory professionals, trade associations and others to exchange ideas and better understand the needs and challenges to meet regulatory requirements. USP Expert Committees, which set Compendial public standards, took

- *Angelica sinensis* Root Powder
- Baicalein
- Baicalein 7-O-Glucuronide
- *Chrysanthemum indicum* Flower Dry Extract
- *Chrysanthemum x morifolium* Flower Dry Extract
- Isochlorogenic Acid A
- *Ligusticum chuanxiong* Rhizome Powder
- Linarin
- *Scutellaria baicalensis* Root Dry Extract
- Senkyunolide A
- Z-Ligustilide

Non-Botanicals

- beta-Glycerolphosphorylcholine
- Choline Citrate
- L-alpha-glycerophosphorylethanolamine
- L-alpha-Glycerolphosphorylcholine
- L-alpha-Glycerolphosphorylcholine solution
- Pyrroloquinoline quinone

[Find a Reference Standard](#)
[Suggest a Reference Standard](#)

[Purchase 2015 Dietary Supplements Compendium](#)

Monographs in Revision Bulletin

Posted July 28017
Official December 1, 2017

- Salix Species Bark
- Salix Species Bark Dry Extract
- Salix Species Bark Powder

Standards Open for Public Comment

advantage of the meeting to update their awareness of the state of current technology and gaps in standards to prioritize standards development and to update existing monographs.

Visitors to the USP booth learned about new monographs, Reference Standards, verification programs, and upcoming events. The following are highlights of USP's participation at the meeting:

- Scientific staff and industry representatives discussed topics including high-impact prioritized ingredients, including aloe juice concentrate and cranberry extract, as well as new technologies such as DNA-based botanical identification methods.
- USP Expert Committee members Josef Brinckmann and Edward Fletcher spoke on the topic of botanical quality and adulteration.
- Our staff attended trade association briefings such as the United Natural Products Alliance (UNPA), the American Botanical Council meeting on botanical adulteration as well as the Supplement Safety & Compliance Initiative (SSCI) meeting.
- Gabriel Giancaspro, Ph.D., vice-president, Dietary Supplements and Herbal Medicines at USP, updated members of the American Herbal Products Association (AHPA) Botanical Congress about new standards, revisions, upcoming prioritized standards, and new initiatives such as cannabis, labeling of USP Powdered Decaffeinated Green Tea Extract monograph, limits for residual solvents in botanical extracts, and DNA methods for botanical ID.
- Dr. John Atwater, USP's Senior Director of Verification service presented at the session on how to select a contract manufacturer.

Research and Innovation

USP Admission Evaluations of Articles Prior to Monograph Development

Before a dietary ingredient is considered for the development of quality standards, it must undergo a [USP Admission Evaluation](#), performed by the USP Dietary Supplements Admission Evaluations Joint Standard Setting Subcommittee (DSAE JS3). The DSAE JS3 reviews information related to the ingredient's safety, relevance in the market, regulatory status, and presence in other pharmacopeias. The committee also determines whether the article poses any significant safety concerns.

If the article does not pose a safety concern, or poses a minor safety concern that can be mitigated by a label caution statement in the monograph, the article is placed in class A, meaning that it is admitted for monograph development. If the article poses a significant safety concern, it is placed in class B and is not admitted for monograph development.

Between May 2017 and August 2017, the DSAE JS3 reviewed the safety information for Carotenes,, Conjugated Linoleic Acid Free Fatty Acids, *Bacillus coagulans* GBI-30 6086, Coix Seed and *Vitex negundo* Leaf (Chinese chastetree Leaf). All articles except *Vitex negundo* Leaf (Chinese chastetree Leaf) were categorized as Class A, thus admitted to the USP-NF monograph development process. *Vitex negundo* Leaf was classified as Class B and not admitted for

Published for public comment Sept. 1, 2017. Please click [here](#) to comment. Comments due November 30, 2017.

New Monographs

- L-apha-Glycerylphosphorylcholine
- Dong Quai Root
- Dong Quai Root Powder

Revised Monographs

- Cod Liver Oil
- Cod Liver Oil Capsules
- Phytonadione

Published for public comment Nov 13, 2017. Please click [here](#) to comment. Comments due January 31, 2018

New Monographs

- Beta carotenes Capsules
- Vitamins with Minerals Oral Powder

Revised Monographs

- Beta carotenes Capsules
- Eleuthero Root and Rhizome Dry Extract Capsules and Tablets, and Rhodiola rosea Capsules and Tablets
- Eleuthero Root and Rhizome Dry Extract Tablets
- Rhodiola rosea Capsules
- Rhodiola rosea Tablets

New Monographs under Development

Botanicals

- *Bacillus coagulans* 5856
- Bitter Orange Peel Flavonoids Dry Extract
- Chinese Skullcap Root
- Chinese Skullcap Root Dry Extract

monograph development. Admission evaluations are in progress for the following articles: Menaquinone-4, European Elder Berry Dry Extract, Dong Quai and Sichuan lovage (*Ligusticum chuanxiong*).

The JS3 considered whether a limit for **Trimethylamine-N-oxide** (TMAO) in the krill oil monograph would be justified based on safety concerns related to the association of TMAO plasma levels with increased risk of cardiovascular disease. The DSAE JS3 reviewed the available data about TMAO in krill oil and decided that from a safety perspective there is no justification for including a limit for TMAO in the Krill Oil monograph. Public information on the safety of the articles under consideration by the DSAE JS3 is welcome. For more information, please contact Hellen Oketch-Rabah, Ph.D., at hao@usp.org or Kristi Jacobs, Ph.D., at KLJ@usp.org.

Nomenclature of Dietary Supplements

Updates from the Dietary Supplements and Herbal Medicines (DSHM) Nomenclature Subcommittee

From May 20, 2017 to August 2017, the Dietary Supplements and Herbal Medicines Nomenclature Joint Subcommittee (DSHM Nom JS) held two working meetings where monograph titles were considered and recommended to the USP Nomenclature and Labeling EC for approval.

Titles approved for new monographs:

- Whey Protein Isolate
- Hydrolyzed Collagen
- Coptis Species Rhizome
- Coptis Species Rhizome Powder
- Coptis Species Rhizome Dry Extract
- Japanese sophora Flower
- Japanese sophora Flower Powder
- Japanese sophora Flower Dry Extract

For more information on nomenclature issues, please contact: Hellen Oketch-Rabah, Ph.D., at hao@usp.org.

USP Answers Your Questions

Q. The majority of our products consist of dried/powdered herbs that are processed into tablets. We do have some products that are herbal powders, which we would classify as "chopped or powdered botanicals", but we were wondering if tablets should also be classified as such, or whether USP has another set of microbial limits for this type of dosage form? In addition, some of our herbal tablets contain a mixture of dried/powdered herbs and powdered extracts. USP specifies different microbial limits for dried/powdered botanicals and botanical extracts. What limit should we use for a product that contains a combination of the two types of ingredients?

- Chinese Skullcap Root Powder
- Chrysanthemum Flower
- Chrysanthemum Flower Dry Extract
- Chrysanthemum Flower Powder
- Cranberry Juice-Derived Powder
- Guarana Seed
- Guarana Seed Dry Extract
- Guarana Seed Powder
- Pomegranate Extract
- Red Clover Tablets
- Wild Chrysanthemum Flower
- Wild Chrysanthemum Flower Dry Extract
- Wild Chrysanthemum Flower Powder

Non-Botanicals

- Calcium Magnesium Citrate
- Choline Citrate
- Cyanocobalamin Chewable Gels
- D-*chiro*-Inositol
- Oil-and Water-Soluble Vitamins with Minerals Chewable Gels
- Omega-3 Free Fatty Acids
- Plant Sterols
- Plant Sterols and Stanols Esters
- Pyrroloquinoline Quinoline Sodium
- Saccharomyces boulardii
- S-Adenosyl-L-methionine 1,4-Butanedisulfonate
- Tocotrienols
- Vitamins with Minerals Oral Powder

Published by:

Gabriel Giancaspro, Ph.D.
Vice President
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Herbal Medicines

A. The applicable limits for botanicals in tablet dosage forms are those for "Nutritional Supplements with Botanicals" as listed in general chapter <2023> Microbial Attributes of Nonsterile Nutritional and Dietary Supplements. The limits are: total aerobic microbial count not more than (NMT) 1000 cfu/g; total, combined yeast and mold count NMT 100 cfu/g; absence of Salmonella species and E. coli in 10 g. For combination products, the most stringent USP microbial limit applies.

Q. What are the factors that can affect the quality of herbal products when they are in storage and how they should be maintained?

A. Important factors regarding storage of herbal products and how they should be maintained include the following:

1. **Light:** Protection from light is important for botanical articles. Light accelerates numerous chemical processes that may lead to degradation or changes in the constituents of the articles.
2. **Temperature:** Storage temperatures in *USP-NF* are defined in the General Notices. Excessive heat may affect the content of volatile constituents (essential oils) and accelerate degradation processes. However, heat treatments are sometimes useful in the maintenance of the article's quality and can be used in drying, reducing microbial load, and inhibiting certain enzymes. Heat application during these processes must be carefully controlled to achieve the desired balance between degradation and quality conservation.
3. **Humidity:** Moisture in the articles may allow certain enzymes such as glycosidases to become active, hence degrading constituents. High humidity also increases the danger of microbial proliferation. As a rule, it is advisable to store botanical articles below 60% relative humidity. Although controlled humidity and temperature warehouses are now required in many good manufacturing practices for natural products, much of the world still lacks access to these facilities.
4. **Degree of Comminution:** The degree of comminution plays a role in determining the stability of the botanical articles during storage. The increased surface area in fine powders allows oxidation and other degradation processes to occur more extensively and rapidly than in the case of a whole article. Plants containing tannins, bitter substances, and essential oils are particularly sensitive to the degree of comminution. In general, dried crude botanicals should be stored in a minimally processed form.
5. **Containers:** Appropriate containers are defined in *USP-NF*'s General Notices.

[Contact Gabriel Giancaspro](#)

Questions?

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