



The Supplement Winter Newsletter 2019



New Online Dietary Supplements Compendium Coming Soon!

[Dietary Supplements Compendium 2019 Edition](#)

To align with user needs and expectations, the Dietary Supplements Compendium (DSC) 2019 Edition will be an online platform, similar to the *USP-NF Online*. The redesigned, intuitive interface will give users access to the most comprehensive collection of quality standards for dietary supplements. Click [here](#) for more details.

The new edition of the DSC will be available in the second half of 2019. **Please [check back](#) and [sign up](#) for the latest information about upcoming enhancements and availability!**

In addition to selected new and revised monographs and General Chapters from the *USP-NF* and *Food*

New Dietary Supplements Reference Standards:

Below is a list of recently released Reference Standards:

Botanicals

- [Ashwagandha Aerial Parts Dry Extract](#)
- [Kaempferol-3-O-Robinoside-7-O-Glucoside](#)

Non-Botanicals

- [Carotenes](#)

Monographs

Chemicals Codex issued over the last three years, the DSC 2019 will feature:

- **72 new monographs**
- **24 additional General Chapters**
- A total of **59 new, updated and supplementary sets** of High-Performance Thin-Layer Chromatographic (**HPLC**) **data** for the botanical monographs in full color and high resolution
- **24 new** and 45 revised **Admission Evaluations documents**
- 21 new and 12 revised sets of data in support of the dietary supplement monographs with **dozens of new chromatograms and color photomicrographs**
- A new edition of the USP Dietary Supplements Verification Program (DSVP) manual
- Revised and updated Dietary Intake comparison tables
- New and updated guidance documents contributed by DS industry associations
- An extensive collection of FDA documents relevant to the dietary supplement industry

USP is working with an Advisory Board of 14 USP volunteer experts, chaired by Dr. Craig Hopp, to understand the needs of our customers and stakeholders to develop a comprehensive and user-friendly standards resource. The new edition reflects our commitment to high-quality public standards for dietary supplements, and ongoing efforts keep our monographs and general chapters up to date. For questions or more information, please contact DietarySciStaff@USP.org.

Be Part of the Standards Development Process!

Help shape standards specifications and test methods by sponsoring monographs or general chapters and their supporting Reference Standards. USP doesn't charge fees to develop monographs – all you need is a willingness to collaborate with us to help safeguard the supply chain for supplements and ingredients.

USP standards for dietary ingredients and dietary supplements are a resource for public specifications and scientifically valid methods that can help in GMP

Standards Open for Public Comment until January 31, 2019

The standards below were published in PF 44(6) for public comment on November 1, 2018 and will receive and consider feedback until January 31, 2019. To comment, please visit:

<http://www.usp.org/usp-nf/pharmacoepial-forum>

New Monographs/General Chapters

- Japanese Sophora Flower
- Japanese Sophora Flower Dry Extract
- Japanese Sophora Flower Powder

Revised Monographs/General Chapters

- Calcium with Vitamin D Tablets
- Calcium and Vitamin D with Minerals Tablets
- Oil-Soluble Vitamins Tablets
- Oil-Soluble Vitamins with Minerals Tablets
- Oil- and Water-Soluble Vitamins Tablets
- Oil- and Water-Soluble Vitamins with Minerals Tablets
- Water-Soluble Vitamins Tablets
- Water-Soluble Vitamins with Minerals Tablets

Standards Open for Public Comment until March 31, 2019

The standards below were published in PF 45(1) for public

compliance and in safeguarding the supply chain for supplements and ingredients. USP is seeking donations for the following monographs:

Non-Botanical Dietary Supplement Ingredients:

- Undenatured Collagen Type II
- Glucoronolactone
- Gamma amino butyric acid (GABA)
- Keratin
- *Bifidobacterium Infantis*
- *Lactobacillus plantarum 299v*
- Lutein esters
- L-Ornithine
- Pantethine
- Rice protein isolate
- Salmon Oil
- Zeaxanthin preparation

Non-Botanical Dosage Forms (Finished Dietary Supplements)

- Cyanocobalamin capsules
- Glucosamine, Chondroitin Sulfate Sodium capsules
- Magnesium Citrate capsules
- Menaquinone 4 tablets or capsules
- Methylcobalamin orally disintegrating tablets
- Omega-3-Triglyceride chewable gels (gummies)
- Plant Sterol tablets
- S-Adenosyl-L-Methionine Disulfate Tosylate tablets

For more information on how to donate and a complete list of requested monographs, please visit:

<http://www.usp.org/dietary-supplements-herbal-medicines/development-process> or contact DietarySciStaff@USP.org.

Upcoming Events and Meetings

comment on January 1, 2019 and will receive and consider feedback until March 31, 2019. To comment, please visit:

<http://www.usp.org/usp-nf/pharmacopeial-forum>

Revised Monographs/General Chapters

- Chrysanthemum Flower
- Chrysanthemum Flower Powder
- Chrysanthemum Flower Dry Extract
- Wild Chrysanthemum Flower
- Wild Chrysanthemum Flower Powder
- Wild Chrysanthemum Flower Dry Extract

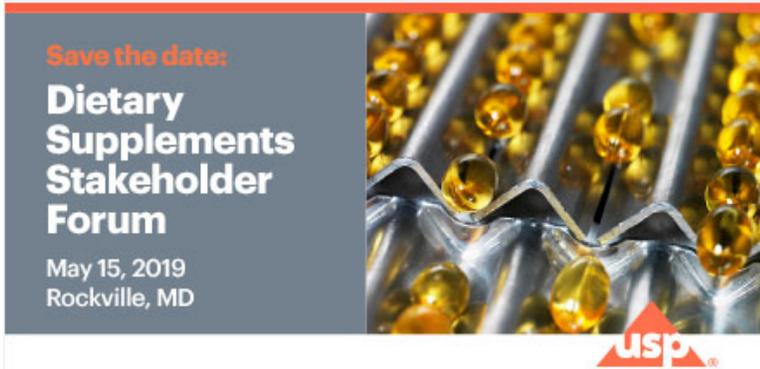
Reference Standards Coming Soon:

Botanicals

- Baicalein
- Baicalein 7-O-Glucuronide
- Bitter Orange Fruit Flavonoid Dry Extract
- *Coptis chinensis* Rhizome Dry Extract
- Coptisine Chloride
- Epicatechin
- Guarana Seed Dry Extract
- Procyanidin B2
- *Scutellaria baicalensis* Root Dry Extract

Non-Botanicals

- Annatto Seed Tocotrienols Extract
- beta-Glycerylphosphorylcholine



Save the date for the Dietary Supplements Stakeholder Forum to be held on May 15, 2019 at USP headquarters in Rockville, Maryland. More details will be available soon. [Click here](#) to register and [check back](#) for updates!

Past Events

SupplySide West

November 6-10, 2018

USP exhibited at SupplySide West in November in Las Vegas where, in addition to many discussions at the USP booth, we met with potential and current monograph sponsors, participated in UNPA and AHPA events, and learned about ingredients and products coming to the marketplace. Visitors to the USP booth learned about new monographs, Reference Standards, verification programs, and upcoming events.

IPA Probiotic Workshop in DC

October 25, 2018

In October, the International Probiotics Association (IPA) and USP co-hosted a Probiotics Regulatory Workshop in Bethesda, MD. Attendees included regulators, IPA industry members, academics and government researchers. The regulatory status of probiotics in Brazil, Canada and the U.S. was among the topics discussed. Other speakers presented on the taxonomic reclassification of the Lactobacillus genus, which may be split into numerous separate genera; next generation analytical tools such as whole genome sequencing, an update on the USP probiotic monographs and general chapters, and the FDA Food Safety Modernization Act (FSMA). There was also a

- L-alpha-Glycerophosphoryl-ethanolamine
- L-alpha-Glycerolphosphorylcholine
- L-alpha-Glycerolphosphorylcholine Solution

Standards Open for Public Comment until May 31, 2019

The standards below will be published in PF 45(2) for public comment on March 1, 2019 and will receive and consider feedback until May 31, 2019. To comment, please visit:

<http://www.usp.org/usp-nf/pharmacopeial-forum>

New Monographs/General Chapters

- Oil-and water soluble vitamins with minerals Chewable Gels

Revised Monographs/General Chapters

- Saw Palmetto Capsules
- Saw Palmetto Extract
- Lactase

Reference Standards in Development

Botanicals

- *Aegle marmelos* Fruit Dry Extract
- *Angelica sinensis* Root Powder
- *Berberis aristata* Stem Dry Extract
- Broccoli Seed Dry Extract
- Chebulagic Acid

discussion about potential impacts of the Nagoya protocol.

USP Admission Evaluations of Articles Prior to Monograph Development

Before a dietary ingredient is considered for 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 and whether the article poses any serious risk to health when used as a dietary supplement.

If the article does not pose a serious risk to health, 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 serious risk to health, it is placed in Class B and is not admitted for monograph development.

The DSAE JS3 held a working a meeting on Friday, November 30, 2018 where members considered and admitted Chinese Skullcap Root, Guarana Seed, and PQQ Disodium Salt for monograph development. The committee recommended that the USP monographs for both Chinese Skullcap Root and Guarana Seed include cautionary labeling stating that "If you are pregnant or nursing a baby, seek the advice of a healthcare practitioner before using this product." The committee also recommended cautionary labeling language for Chinese Skullcap Root stating "Discontinue use and consult a healthcare practitioner if you develop symptoms of liver trouble, such as abdominal pain, dark urine, or jaundice (yellowing of the eyes or skin)." The committee admitted PQQ Disodium Salt produced by fermentation but deferred action on PQQ Disodium Salt produced by chemical synthesis until there are more data on the impurities that are present in synthetic PQQ Disodium Salt.

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

- *Chrysanthemum indicum* Flower Dry Extract
- *Chrysanthemum x morifolium* Flower Dry Extract
- Cranberry Fruit Juice Dry Extract
- *Cullen corylifolium* Fruit Dry Extract
- Ginger Rhizome Carbon Dioxide Soft Extract
- Glucoraphanin
- Isochlorogenic Acid A
- Isorhamnetin-3-O-Rutinoside
- *Ligusticum chuanxiong* Rhizome Powder
- Linarin
- Maca root
- Maca root extract
- Marmelosin
- Palmatine Chloride
- Pomegranate Fruit Dry Extract
- Procyanidin A2
- Punicalagin
- Senkyunolide A
- *Sophora japonica* Flower Dry Extract
- *Terminalia chebula* Fruit Dry Extract
- Z-Ligustilide

Non-Botanicals:

- Choline Citrate
- Citicoline
- Conjugated Linoleic Acids--Triglycerides
- Docosahexaenoic Acid
- Eicosapentaenoic Acid
- Omega-3 Free Fatty Acids
- Pyrroloquinoline quinone
- L-Ornithine Hydrochloride

[Find a Reference Standard](#)

[Suggest a Reference Standard](#)

Nomenclature of Dietary Supplements

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

The Dietary Supplements and Herbal Medicines Nomenclature Joint Subcommittee (DSHM Nom JSC) held a working meeting on October 9th, 2018, and recommended to the USP Nomenclature and Labeling EC the following monograph titles for approval:

- Arabinose
- Picrorhiza Species Root and Rhizome
- Picrorhiza Species Root and Rhizome Powder
- Picrorhiza Species Root and Rhizome Dry Extract
- Sandalwood Oil
- Velvet Bean Seed
- Velvet Bean Seed Powder
- Velvet Bean Seed Dry extract
- Maca Root Glucosinolates Dry Extract
- Maca Root Macamides Dry Extract
- Maca Root
- Maca Root Powder
- Maca Root Gelatinized Powder

The following monograph titles were changed:

- Feverfew changed to Feverfew Leaf
- Powdered Feverfew changed to Feverfew Leaf Powder

DSHM Nom JSC held a working meeting on November 16th, 2018, and recommended to the USP Nomenclature and Labeling EC the following monograph title for approval:

- Fish Oil Omega-3 Acid Ethyl Esters Concentrate

DSHM Nom JSC also held a working meeting on December 3rd, 2018, and recommended to the USP Nomenclature and Labeling EC the following monograph titles for approval:

- Inositol Niacinate
- Oil Soluble Vitamins Preparation

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New Monographs under Development

Botanicals:

- Ajowan Fruit
- Ajowan Fruit Powder
- Ajowan Fruit Dry Extract
- Broccoli Seed Dry Extract
- Cranberry Fruit Juice Dry Extract
- Cranberry Fruit Juice Concentrate
- Cranberry Fruit Dry Juice
- Feverfew leaf extract
- Pomegranate Fruit Dry Extract
- Pummelo Peel
- Pummelo Peel Powder
- Pummelo Peel Flavonoids Dry Extract
- Red Clover Tablets
- Sour Jujube Seed
- Sour Jujube Seed Dry Extract
- Sour Jujube Seed Powder
- White Peony Root
- White Peony Root Powder
- White Peony Root Dry Extract

Non-Botanicals:

- 3-hydroxy-3-methylbutyric acid (HMB)
- *Bifidobacterium bifidum*
- *Bifidobacterium longum subsp longum*
- Calcium 3-hydroxy-3-methylbutyrate
- Calcium Magnesium Citrate
- Choline Citrate

- Water Soluble Vitamins Preparation
- Black Cumin Seed Oil
- White Peony Root Dry Extract

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

- D-*chiro*-Inositol
- Hydrolyzed Collagen
- *Lactobacillus reuteri*
- *Lactobacillus rhamnosus*
- Lutein Esters
- Native Collagen
- Oil- and Water Soluble Vitamins Premixes
- Oil Soluble Vitamins Premixes
- Oil-and Water-Soluble Vitamins with Minerals Chewable Gel
- Phytosterol Esters
- Plant sterols
- S-Adenosyl-L-Methionine 1,4-Butanedisulfonate
- Tocotrienols
- Water Soluble Vitamins Premixes
- Zeaxanthin Preparation

USP Answers Your Questions

Q. Can I use a different HPLC chromatographic column to run a USP analytical procedure?

A. USP provides some flexibility to change the chromatographic column without revalidation of the method. The USP General Chapter <621>, *Chromatography, System suitability*, describes in detail the range of adjustments allowed in the system when the suitability test fails. These adjustments in the operating conditions, when needed, are the maximum variations that can be made without the need for validation, rather than verification of method performance under the new conditions. Below, are the adjustments that can be made:

Column length: See Particle size (HPLC) below.

Column inner diameter: Can be adjusted if the linear velocity is kept constant. See Flow rate (HPLC).

Particle size (HPLC): For isocratic separations, the particle size and/or the length of the column may be modified, provided that the ratio of the column length (L) to the particle size (dp) remains constant or into the range between -25% and 50% of the prescribed L/dp ratio. Alternatively (as for the application of particle-size adjustment to superficially porous particles), other combinations of L and dp can be used, provided that the number of theoretical plates (N) is within -25% to 50%, relative to the prescribed column. Caution should be used when the adjustment results in a higher number of theoretical plates that generate smaller peak volumes, which may require adjustments to minimize extra-column band broadening by factors such as instrument plumbing, detector cell volume and sampling rate, and injection volume. For gradient separations, changes in length, column inner diameter, and particle size are not allowed.

Flow rate (HPLC): When the particle size is changed, the flow rate may require adjustment, because smaller-particle columns will require higher linear velocities for the same performance (as measured by reduced plate height). Flow rate changes for both a change in column diameter and particle size can be made by:

$$F_2 = F_1 \times [(dc_2^2 \times dp_1) / (dc_1^2 \times dp_2)]$$

where F_1 and F_2 are the flow rates for the original and modified conditions, respectively, dc_1 and dc_2 are the respective column diameters, and dp_1 and dp_2 are the particle sizes.

When a change is made from $\geq 3\text{-}\mu\text{m}$ to $< 3\text{-}\mu\text{m}$ particles in isocratic separations, an additional increase in linear velocity (by adjusting flow rate) may be justified, provided that the column efficiency does not drop by $>20\%$. Similarly, a change from $< 3\text{-}\mu\text{m}$ to $\geq 3\text{-}\mu\text{m}$ particles may require additional reduction of linear velocity (flow rate) to avoid reduction in column efficiency by $>20\%$. Changes in F , dc , and dp are not allowed for gradient separations.

For isocratic only, the flow rate can be adjusted by $\pm 50\%$.

For further information, please see USP General Chapter $\langle 621 \rangle$ *Chromatography, System suitability*, USP 41, page 6363.

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