



# The Supplement Summer Newsletter 2019



## Dietary Supplements Compendium 2019 Edition

In response to customer feedback, coupled with the evolving information needs in our digital world, we have moved the USP *Dietary Supplements Compendium (DSC)* to an online platform for the 2019 edition. It continues to provide in-depth, comprehensive information for all phases of development and manufacturing of quality dietary supplements including quality control, quality assurance, and regulatory/compendial affairs.

Some of the advantages that come with the new, online platform include:

- More frequent updates to ensure that you have access to the most current information
- Customizable alerts to notify you when selected documents are changed
- An intuitive interface to quickly and easily navigate to the information you need
- A customizable workspace with bookmarks, alerts and a viewing history to help streamline your online experience
- Convenient, anytime, anywhere access with most, commonly used browsers

In addition to selected new and revised monographs and General Chapters from the *USP-NF* and *Food Chemicals Codex* issued over the last three years, the *DSC 2019* features:

- 24 new General Chapters
- 72 new dietary ingredient and dietary supplement monographs
- 27 sets of supplementary information for botanical and nonbotanical dietary supplements
- 59 updated botanical HPTLC plates
- Revised and updated dietary intake comparison tables
- Updated Dietary Supplement Verification Program manual

[View this page for more information or to subscribe to the 2019 online DSC.](#)

## Upcoming Events and Meetings

### Activity on Probiotics

The probiotics Expert Panel, which reports to the Non-Botanicals Dietary Supplement Expert Committee, published an article entitled "[Improving end-user trust in the quality of commercial probiotic products](#)" in *Frontiers in Microbiology* in April.

## Products and Services

### New Dietary Supplements Reference Standards

Below is a list of newly released Reference Standards.

### Herbal Medicines/ Botanical Dietary Supplements

- [Negundoside](#)
- [Vitex negundo Leaf Dry Extract](#)
- [Baicalein](#)
- [Baicalein 7-O-Glucuronide](#)
- [Scutellaria Baicalensis Root Dry Extract](#)

### Non-Botanicals

- [Conjugated Linoleic Acids – Triglycerides \(100 mg\)](#)
- [Docosahexaenoic Acid](#)
- [Eicosapentaenoic Acid](#)
- [Omega-3 Free Fatty Acids](#)
- [L-alpha-Glycerophosphorylethanolamine](#)
- [L-alpha-Glycerolphosphorylcholine](#)
- [beta-Glycerolphosphorylcholine](#)
- [Creatine](#)
- [Creatinine](#)

### Reference Standards in development:

#### Botanicals

- Bitter Orange Fruit Flavonoid Dry Extract
- *Coptis chinensis* Rhizome Dry Extract
- Coptisine Chloride
- Epicatechin
- Guarana Seed Dry Extract
- Procyanidin B2

#### Non-Botanicals

- Annatto Seed Tocotrienols Extract
- Hydroxocobalamin Chloride
- Pyrroloquinoline quinone

### Monographs

### Standards Open for Public Comment until September 30, 2019

The standards below were

## qNMR Summit Returns to Rockville



Please join us on October 2-3 as the Fifth International Quantitative NMR Summit is returning to USP in Rockville, MD, three years after the highly acclaimed inaugural 2016 event. This summit will be open to everyone so that you can prepare for the paradigm-shifting update to compendial analysis. The summit will assemble the leading-edge qNMR practitioners from around the world. In the tradition of the original event, this summit will be co-organized with Center for Natural Product Technologies (CeNaPT) from the University of Illinois in Chicago (UIC). Further details will appear shortly at the USP [Research and Innovation](#) and the [UIC/CeNaPT](#) websites. A free NMR Validation Workshop will be held at the conclusion of the qNMR Summit on October 4, hosted by [Steelyard Analytics](#).

USP offers discounted pricing for governmental and academic attendees. Registration is now open. [Register Today!](#)

For questions related to the qNMR Summit, please contact Anton Bzhelyansky, [anb@usp.org](mailto:anb@usp.org).

## Past Events

### CPhI-China and HNC 2019 June 2019 | Shanghai, China

In June 2019, staff from USP participated in the Convention on Pharmaceutical Ingredients (CPhI) in China exhibiting, speaking and hosting workshops, namely the Sino-US Symposium on Natural Health Products cohosted with ChP. Presentations and discussions centered on dietary supplement, health food and herbal medicine regulations, standards and quality requirements.



In this same month, USP also exhibited at the Healthplex Expo and Natural & Nutraceutical Products China 2019 (HNC) where staff members were able to meet with stakeholders in the nutraceutical, health food, and dietary supplement industry providing information and education on relevant standards and quality verification programs.

### 2019 Dietary Supplements Stakeholder Forum May 15, 2019 | Rockville, MD

Over 200 stakeholders participated in the USP Dietary Supplements Stakeholder Forum at the USP Headquarters in Rockville, MD. Gisele Atkinson, B.S., and Jim Griffiths, Ph.D., Council for Responsible Nutrition chaired the meeting on behalf of the stakeholder panel. Participants representing manufacturers, trade associations, service providers, and other interested parties who work with dietary supplements shared perspectives and provided direct feedback on priority standards issues. USP staff provided updates about recently proposed new monographs, revisions and omissions in Pharmacopeial Forum.

Several high-impact topics including label claim and overages, standards for hemp, limits for pesticide residues, testing for food allergens, and probiotics were discussed. Stakeholders provided feedback on the role USP public standards in the light of the FDA initiatives to modernize the dietary supplement regulations.

Stakeholders were also encouraged to apply as expert volunteers through USP's Call for Candidates process for the 2020-2025 cycle of [USP Council of Experts](#). Detailed notes from the meeting and the speaker presentations are available [here](#).

published in PF 45(4) for public comment on July 1, 2019 and will accept public feedback until September 30, 2019. To comment, please visit:

To comment, please visit: [USP-NF Pharmacopeial Forum](#)

### New Monographs/General Chapters

- Calcium Magnesium Citrate
- D-chiro-Inositol
- Fish Oil Omega-3 Acid Ethyl Esters Concentrate
- Pummelo Peel
- Pummelo Peel Powder
- Pummelo Peel Flavonoids Dry Extract

### Revised Monographs/General Chapters

- Asian Ginseng Root and Rhizome
- Asian Ginseng Root and Rhizome Powder
- Asian Ginseng Root and Rhizome Dry Extract
- American Ginseng Root and Rhizome
- American Ginseng Root and Rhizome Powder
- American Ginseng Root and Rhizome Dry Extract
- [L-alpha-Glycerylphosphorylcholine](#)
- Cod Liver Oil
- Cod Liver Oil Capsules

### Standards Open for Public Comment until November 30, 2019

The standards below will be published in PF 45(5) for public comment on September 1, 2019 and will accept public feedback until November 30, 2019. To comment, please visit:

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

### New Monographs/General Chapters

- *Bifidobacterium bifidum*
- *Bifidobacterium longum subsp longum*
- *Lactobacillus reuteri*
- Water-Soluble Vitamins Preparation

### Revised Monographs/General Chapters

- Aztec Marigold Zeaxanthin Extract
- *Lactobacillus rhamnosus* HN001

### Standards Open for Public Comment until January 31, 2020

The standards below will be published in PF 45(6) for public comment on November 1, 2019 and will accept public feedback



Image 1: Gabriel Giancaspro, Vice President, Science-DS & Herbal Medicines, presenting a gift to thank Gisele Atkinson, B.S., and Jim Griffiths, Ph.D., with Council for Responsible Nutrition for their role as chairs of the 2019 DS Stakeholder Forum



Image 2: Panel discussion held during the DS Stakeholder Forum

### Participation in the International Conference on the Science of Botanicals (ICSB) 2019 April 8-11, 2019 | Oxford, MS

Staff from the Dietary Supplements and Herbal Medicines at USP participated in the International Conference on the Science of Botanicals (ICSB) held in Oxford, Mississippi. The discussion at the conference focused on 25th Anniversary of DSHFA (The Dietary Supplement Health and Education Act of 1994) including reviewing the history, confronting the issues, and discussing future aspects

Our staff participated in the following sessions:

#### Expert Panel

##### ***Pharmacopeial Standards as Tools to Assure Botanical Quality***

- Nandu Sarma, Ph.D. and Gabriel Giancaspro, PhD, US Pharmacopeia (USP)
- Ulrich Rose, PhD, European Pharmacopeia (EP)
- Roy Upton, RH, American Herbal Pharmacopeia (AHP)
- G N Singh, PhD, and Vivekanandan Kalaiselvan, PhD, Indian Pharmacopeia (IP)
- De-an Guo, PhD, member, Chinese Pharmacopeia (ChP)

The global supply chain and the adoption of several botanicals that were traditionally used as medicine, foods or dietary supplements around the world present challenges in ensuring the quality of the ingredients and products. USP recognizes the importance that the harmonization of national standards plays on promoting public health and global commerce. This session, coordinated and chaired by USP, focused on past, present and future pharmacopeial approaches to botanical standard-setting, as well as new areas where the pharmacopeial standards can play an important role. Topics included: Scientific basis for pharmacopeial standard-setting, transparency in methods to meet regulatory needs, potential for prospective harmonization, global supply chain and commerce – implications for pharmacopeial standards, current industry needs and priorities, and new technologies in pharmacopeial standards. Through this session, USP provided a forum for the industry and regulators to share their experience in using the pharmacopeial standards to help to identify some industry needs and priorities.

#### Scientific Session:

until January 31, 2020. To comment, please visit:  
<http://www.usp.org/usp-nf/pharmacopeial-forum>

#### **New Monographs/General Chapters**

- Sour Jujube Seed
- Sour Jujube Seed Powder
- Sour Jujube Seed Dry Extract
- Cranberry Fruit Juice Dry Extract
- Cranberry Fruit Juice Concentrate
- Pomegranate Fruit Dry Extract
- Broccoli Seed Dry Extract

#### **Revised Monographs/General Chapters**

- Cranberry Liquid Preparation
- <2750> MANUFACTURING PRACTICES FOR DIETARY SUPPLEMENTS

#### **New Monographs under Development**

##### **Botanicals**

- Ajowan Fruit
- Ajowan Fruit Powder
- Ajowan Fruit Dry Extract
- Cranberry Fruit Dry Juice
- Feverfew Leaf Extract
- Red Clover Tablets
- White Peony Root
- White Peony Root Powder
- White Peony Root Dry Extract
- *Gastrodia elata* Rhizome
- *Gastrodia elata* Rhizome Powder
- *Gastrodia elata* Rhizome Dry extract
- *Saposhnikovia divaricata* Root
- *Saposhnikovia divaricata* Root Powder
- *Saposhnikovia divaricata* Root Dry Extract

##### **Non-Botanicals**

- Astaxanthin ester capsules
- beta-hydroxy-beta-methylbutyric acid (HMB)
- Calcium 3-hydroxy-3-methylbutyrate
- Choline Citrate
- Hydrolyzed Collagen
- Inositol Niacinate
- Lutein Esters
- Lysine
- Native Collagen
- Oil- and water-soluble Vitamins Premixes
- Oil-soluble Vitamins Premixes
- Oil- and water-soluble



## [HPLC and HPTLC To Identify Plant Products and Distinguish Closely Related Species](#)

Cuiying Ma, Gabriel I. Giancaspro

[Read the full scientific session here.](#)

### Poster presentations:

#### 1. *USP Cranberry Monograph: Progress Report*

Maria Monagas, Joshua Bhattacharya, Jennifer Fedorowski, Hellen Oketch, Débora Frommenwiler, Eike Reich, Paula N. Brown, Kit Goldman, and Gabriel Giancaspro

View [poster summary](#) and [poster presentation](#) for USP Cranberry Monograph

#### 2. *United States Pharmacopeia Safety Review of Chinese Skullcap Root*

Adam Hussain, Hellen Oketch-Rabah, Gabriel Giancaspro, and Tieraona Low Dog

View [poster summary](#) and [poster presentation](#) of USP Safety Review of Chinese Skullcap Root.

#### 3. *Flavonoid Characterization in USP Botanical Reference Standards by High Resolution Mass Spectrometry*

Amanda Guiraldelli, Rafael Maranhão, Maria Monagas, Cuiying Ma, Kalyani Gude, and Gabriel Giancaspro

View [poster summary](#) and [poster presentation](#) here.

### 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 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)

Vitamins with Minerals  
Chewable Gel

- Phytosterol Esters
- Plant sterols
- S-Adenosyl-L-Methionine 1,4-Butanedisulfonate
- Tocotrienols
- Water Soluble Vitamins Premixes
- Zeaxanthin Preparation

### 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
- *Chrysanthemum indicum* Flower Dry Extract
- *Chrysanthemum x morifolium* Flower Dry Extract
- *Citrus maxima* Peel Flavonoids Dry Extract
- Cranberry Fruit Juice Dry Extract
- *Cullen corylifolium* Fruit Dry Extract
- Ginger Rhizome Carbon Dioxide Soft Extract
- Ginsenoside Rb1
- 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
- Rhoifolin
- *Terminalia chebula* Fruit Dry Extract
- Z-Ligustilide
- *Sophora japonica* Flower Dry Extract
- Jujuboside A
- Spinosin
- *Ziziphus jujuba* var. *spinosa* Seed Dry Extract

### Non-Botanicals

- Calcium Magnesium Citrate
- Choline Citrate
- Conjugated Linoleic Acids--Triglycerides
- D-chiro-Inositol
- Pinitol
- L-Ornithine Hydrochloride
- Lysine
- S-Adenosyl-L-Methionine

- Plant Sterol tablets
- S-Adenosyl-L-Methionine Disulfate Tosylate tablets

1,4-Butanedisulfonate

[Click here to Find a Reference Standard](#)

To Suggest a Reference Standard, [click here](#).

For more information on how to donate and a complete list of requested monographs, please visit: [USP Dietary Supplements and Herbal Medicines Standards Development Process](#) or contact [DietarySciStaff@USP.org](mailto:DietarySciStaff@USP.org).

### **USP Admission Evaluations of Articles Prior to Monograph Development**

Before development of a quality standard for a dietary ingredient is considered, 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 a serious health risk when used as a dietary supplement.

[Continue learning more about the USP admission evaluations of articles prior to monograph development.](#)

### ***Nomenclature of Dietary Supplements***

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

DSHM Nom JSC met on February 26th, 2019 and recommended the following monograph titles for approval:

- $\beta$ -Hydroxy- $\beta$ -methylbutyric acid
- Calcium  $\beta$ -hydroxy- $\beta$ -methylbutyrate
- Levocarnitine Tartrate

DSHM Nom JSC revised the **Guideline for Assigning Titles to USP Dietary Supplement Monographs** available at <http://www.usp.org/sites/default/files/usp/document/get-involved/submission-guidelines/guideline-for-assigning-titles-to-usp-dietary-supplement-monograph.pdf>. The revised guideline will be available at the above link after review and approval by the Nomenclature and Labeling Expert Committee in September 2019.

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

### **USP Answers Your Questions**

**Q.** How are various **Temperature and Storage** conditions defined by USP?

**A. Freezer:** A place in which the temperature is controlled between  $-25^{\circ}$  and  $-10^{\circ}$  ( $-13^{\circ}$  and  $14^{\circ}$  F). It is noted that, in some instances, articles may have a recommended storage condition below  $-20^{\circ}$  ( $-4^{\circ}$  F). In such cases, the temperature of the storage location should be controlled to  $\pm 10^{\circ}$ .

**Refrigerator:** A cold place in which the temperature is controlled between  $2^{\circ}$  and  $8^{\circ}$  ( $36^{\circ}$  and  $46^{\circ}$  F).

**Cold:** Any temperature not exceeding  $8^{\circ}$  ( $46^{\circ}$  F).

**Cool:** Any temperature between  $8^{\circ}$  and  $15^{\circ}$  ( $46^{\circ}$  and  $59^{\circ}$  F). [Note—An article for which storage in a cool place is directed may, alternatively, be stored and shipped as refrigerated, unless otherwise specified by the individual monograph.]

**Room temperature** (also referred to as *Ambient temperature*): The temperature prevailing in a working environment.

**Controlled room temperature:** The temperature maintained thermostatically that encompasses the usual and customary working environment of  $20^{\circ}$ – $25^{\circ}$  ( $68^{\circ}$ – $77^{\circ}$  F). The following conditions also apply:

- Mean kinetic temperature not to exceed  $25^{\circ}$ . Excursions between  $15^{\circ}$  and  $30^{\circ}$  ( $59^{\circ}$  and  $86^{\circ}$  F) that are experienced in pharmacies, hospitals, and warehouses, and during shipping are allowed. Provided the mean kinetic temperature does not exceed  $25^{\circ}$ , transient spikes up to  $40^{\circ}$  are permitted if they do not exceed 24 h. Spikes above  $40^{\circ}$  may be permitted only if the manufacturer so instructs.
- Articles may be labeled for storage at "controlled room temperature" or at " $20^{\circ}$ – $25^{\circ}$ ", or other wording based on the same mean kinetic temperature [see also [Good Storage and Distribution Practices for Drug Products <1079>](#), [Quality Management System, Environmental Management System, Mean Kinetic Temperature \(MKT\) Calculation](#)].

- An article for which storage at *Controlled room temperature* is directed may, alternatively, be stored and shipped in a cool place or refrigerated, unless otherwise specified in the individual monograph or on the label.

*Warm:* Any temperature between 30° and 40° (86° and 104° F).

*Excessive heat:* Any temperature above 40° (104° F).

*Dry place:* A place that does not exceed 40% average relative humidity at 20° (68° F) or the equivalent water vapor pressure at other temperatures. The determination may be made by direct measurement at the place. Determination is based on NLT 12 equally spaced measurements that encompass either a season, a year, or, where recorded data demonstrate, the storage period of the article. There may be values of up to 45% relative humidity provided that the average value does not exceed 40% relative humidity. Storage in a *Container* validated to protect the article from moisture vapor, including storage in bulk, is considered a *Dry place*.

*Protect from freezing:* The *Container* label will bear an appropriate instruction to protect the article from freezing in cases where freezing exposes an article to loss of strength or potency or to destructive alteration of its characteristics. These risks are present in addition to the risk that the *Container* may break if exposed to freezing temperatures.

*Protect from light:* Where light subjects an article to loss of strength or potency or to destructive alteration of its characteristics, the *Container* label bears an appropriate instruction to protect the article from light. The article must be packaged in a light-resistant *Container*.

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