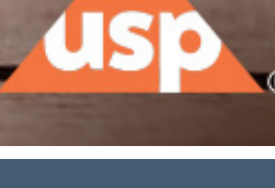


The Supplement Summer Newsletter 2021



Upcoming Events

USP Stakeholder Forum
→ Dietary Supplements & Herbal Medicines
September 14-15, 2021 | 10:00am - 1:00pm ET
Virtual Meeting

USP Dietary Supplements & Herbal Medicines Stakeholder Forum September 14-15, 2021

Stakeholder input is essential to developing USP's quality standards, maintaining public trust and protecting patient health. Join us on September 14 and 15 for a dietary Supplements & Herbal Medicines Stakeholder Forum. Organizations, manufacturers, service providers, and others are encouraged to attend and share their perspectives on priority standards and dietary supplements quality issues. [Click here to learn more or register](#) for this free, virtual event.

The 6th International qNMR Summit October 5-7, 2021

A definitive international event concerning every aspect of qNMR theory and practice, its compendial and industrial implementation, and future development perspectives. Now, virtual and free! Please [register here](#), and alert your colleagues. For further details, please consult [qNMRsummit.com](#), or send an email to Anton.Bzhelevsky@usp.org.

Dietary Supplements Compendium



What is a Dietary Ingredient Admission Evaluation and why should you care?

The Dietary Supplements Compendium (DSC) contains over 100 Admission Evaluation summaries in the "Supplementary Information" section for dietary ingredients that have been admitted for monograph development. Admission Evaluations are comprehensive literature reviews that illustrate a dietary ingredient's known public health and safety profile, including the ingredient's chemistry, typical intake levels, potential adulterants or contaminants, clinical trial and toxicological data, and potential adverse interactions. This information is compiled by USP to help determine whether a dietary ingredient should be admitted for monograph development and potential publication in USP compendia.

DSC's Admission Evaluations can serve as a unique resource for health care practitioners and retailers, providing a thorough review of common use, identification, and potential risks. Exclusively available to DSC subscribers, each Admission Evaluation is paired with at least one corresponding USP monograph or family of botanical monographs, some of which are in development.

The 2021 edition of the DSC Online went live in June 2021. New monographs, general chapters, admission evaluations, chromatograms, chemical structures and photomicrographs have been added to further enhance this comprehensive resource for in-depth background, specifications and assays to help support quality and safe use of dietary ingredients.

[Click here for more information and to subscribe](#) to the Dietary Supplements Compendium for only \$150 per year.

USP in the News

Publications in Peer-reviewed Journals

Open Access:

United States Pharmacopeia (USP) Safety Review of Gamma-Aminobutyric Acid (GABA)
Hellen A. Oketch-Rabah, Emily F. Madden, Amy L. Roe and Joseph M Betz

Nutrients, 2021, 12(8), 2742

[View this publication in Nutrients here](#) **An Effective Workflow for Differentiating the Same Genus Herbs of *Chrysanthemum morifolium* Flower and *Chrysanthemum indicum* Flower**
Jiao He, Qian Zhang, Cuiying Ma, Gabriel I. Giancaspro, Kaishun Bi and Qing Li

Published on 22 April 2021

[View this publication in Frontiers in Pharmacology](#)

Improving and Comparing Probiotic Plate Count Methods by Analytical Procedure Lifecycle Management
M. L. Jane Weitzel, Christina S. Vegge, Marco Pane, Virginia S. Goldman, Binu Koshy, Cisse Hedegaard Porsby, Pierre Burguère and Jean L. Schoen*

Published on 12 July 2021

[View this publication in Frontiers in Microbiology](#)

Essential Terminology Connects NMR and qNMR Spectroscopy to its Theoretical Foundation

Guido Pauli, G. Joseph Ray, Anton Bzhelevsky, Birgit Jaki, Charlotte Corbett, Christina Szabo, Christoph Seimbeck, Dan Sarason, Damien Jeanrenaud, Daniel Ferreira, David Lanlin, James McAipine, Jean-Nicholas Dumez, Jonathan Bisson, Krish Krishnamurthy, Matthias Niemitz, Michael Nelson, Patrick Giraudéau, Samuli-Petrus Korhonen, Stefan Kuhn, Toru Miura and Lucy Botros

Preprint

[View this publication in Analytical Chemistry](#)

Safety of Cranberry: Evaluation of Evidence of Kidney Stone Formation and Botanical Drug-Interactions

Emily Madden, Caleb McLachlan, Hellen Oketch-Rabah, Angela I. Calderón

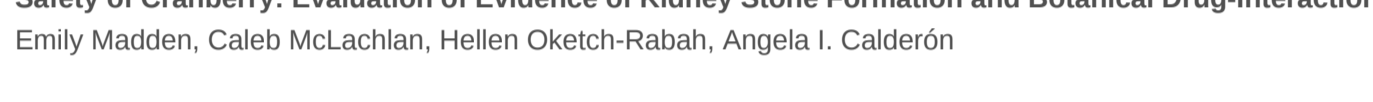
Preprint

View this publication in *Planta Medica*

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:



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 DietaryStdStaff@usp.org.

USP Admission Evaluations of Articles Prior to Monograph Development

The USP Dietary Supplements Admission Evaluations and Labeling Expert Committee (DSAEL EC) held a virtual working meeting on Monday, July 12, 2021. Members deliberated on and admitted *Lactiplantibacillus plantarum* LP-115, *Ligilactobacillus salivarius* LS-33, *Streptococcus thermophilus* ST-21, and *Bacillus coagulans* Unique 52 for monograph development. The DSAEL EC will meet via WebEx in November 2021 (exact date to be determined), to deliberate on Bitter Orange Young Fruit, Neem Leaf, and Bromelain. Comments on the safety of these ingredients are welcome. For more information, please contact [Hellen Oketch-Rabah, Ph.D.](mailto:Hellen.Oketch-Rabah.Ph.D.), or [Emily Madden, Ph.D., DABT](mailto:Emily.Madden.Ph.D.@DABT).

Nomenclature of Dietary Supplements

The Dietary Supplements and Herbal Medicines Nomenclature Joint Subcommittee (DSHM Nom JSC) met in March, May and July 2021 and recommended the following monograph titles to the USP Nomenclature and Labeling Expert Committee for approval:

- American Elder Berry
- Bergamot Orange Fruit Dry Extract
- Blood Orange Fruit Dry Extract
- Bitter Orange Young Fruit
- Bitter Orange Young Fruit Powder
- Bitter Orange Immature Fruit
- Bitter Orange Immature Fruit Powder
- Black Cumin Seed Thymoquinone Oil Capsules
- Coptis chinensis Rhizome Aqueous Dry Extract
- Cumin Fruit
- Cumin Fruit Powder
- Cumin Fruit Dry Extract
- European Elder Berry
- Pacific Salmon Oil
- Pea Protein
- Phosphatidylserine
- Red Yeast Rice Powder
- Streptococcus salivarius*

DSHM Nom JSC revised the [Guideline for Assigning Titles to USP Dietary Supplement Monographs](#) available [here](#). For more information on dietary supplements nomenclature, please contact [Hellen Oketch-Rabah, Ph.D.](mailto:Hellen.Oketch-Rabah.Ph.D.)

Products & Services

New Dietary Supplements Reference Standards

Herbal Medicines/ Botanical Dietary Supplements

- [Chrysanthemum indicum Flower Dry Extract](#)
- [Chrysanthemum x morifolium Flower Dry Extract](#)
- [Isobutylphthalic Acid A](#)
- [Linalin](#)

Non-Botanicals

- Choline Citrate (Coming soon)
- [Choline Related Compounds A](#)
- [N-Acetylserine](#)

Reference Standards in development:

Botanicals

- Aegle marmelos Fruit Dry Extract
- Angelica sinensis Root Powder
- Ankafavin
- Azadirachta indica Seed Oil
- Azadirachta indica Leaf Dry Extract
- Broccoli Seed Dry Extract
- Black Cumin Seed Thymoquinone Oil
- Carvacrol
- Cranberry Fruit Juice Dry Extract
- 4-cymene
- Ginger Rhizome Carbon Dioxide Soft Extract
- Glucorapharin
- Ligustrum chinensis Rhizome Powder
- Chrysanthemum indicum Flower Dry Extract
- Chrysanthemum x morifolium Flower Dry Extract
- Cranberry Fruit Juice Dry Extract
- 4-cymene
- Ginger Rhizome Carbon Dioxide Soft Extract
- Glucorapharin
- Monascin
- Portogalactate Fruit Dry Extract
- Procyanidin A2
- Punicagin
- Red Yeast Dry Extract
- Senkyanolide A
- Z-Ligustilide
- Cimifugin
- 5-O-Methylvisaminoside
- Saposhnikovia divaricata Root Dry Extract
- Alloeverose
- Alom B

Non-Botanicals

- Diosmetin
- Hydroxycobalamin Citrate
- Inositol Naachate
- L-Ornithine Hydrochloride
- Lysine
- Nalingerin
- Palm Oil Tocotrienols and Tocopherols
- Phosphatidylserine

Monographs

Standards Open for Public Comment until Sep. 30, 2021

The standards below were published in PF 47 (4) for public comment on July 1, 2021. USP will accept public feedback until Sep. 30, 2021. To comment, please visit [Pharmacopeial Forum](#).

Revised Monographs/General Chapters

- Calcium Ascorbate
- Menthol

Standards Open for Public Comment until Nov. 30, 2021

The standards below were published in PF 47 (5) on Sept. 1, 2021 and public feedback will be accepted until Nov. 30, 2021. To comment, please visit [Pharmacopeial Forum](#).

New Monographs/General Chapters

- Bitter Orange Young Fruit
- Bitter Orange Young Fruit Powder
- GC <2900> Multi-Ingredient Dietary Supplement Products - Development of Quality Tests

Revised Monographs/General Chapters

- Curcuminoids Capsules
- Curcuminoids Tablets
- Bifidobacterium animalis* subsp. lactis

Standards to be published in PF 47 (6)

The standards below will be published in PF 47 (6) for public comment on Nov. 1, 2021. USP will accept public feedback until Jan. 31, 2022. To comment, please visit [Pharmacopeial Forum](#).

New Monographs/General Chapters

- Bromelain
- GC <1567> Pyrrolizidine Alkaloids as Contaminants

Revised Monographs/General Chapters

- Feverfew
- Feverfew leaf
- Sodium Ascorbate

New Monographs under Development

- Black Cumin Seed Oil
- Black Cumin Seed Oil Thymoquinone Capsules
- Cinnamomum cassia Bark
- Cinnamomum cassia Bark Powder
- Cinnamomum verum Bark
- Cinnamomum verum Bark Powder
- Coptis chinensis Rhizome Aqueous Dry Extract (American and European)
- Cranberry Fruit Powder
- Cranberry Fruit Gummies
- Elder Berry Juice (American and European)
- Elder Berry Juice Concentrate (American and European)
- Elder Berry Dry Juice (American and European)
- Elder Berry Liquid Extract (American and European)
- Elder Berry Aqueous Dry Extract (American and European)
- Elder Berry Fruit Powder (American and European)
- Feverfew Leaf Dry Extract
- Gastrodia rhizome
- Gastrodia rhizome Powder
- Gastrodia rhizome Dry Extract
- Green Tea Leaf Dry Extract
- Indian Elecampare Root
- Indian Elecampare Root Powder
- Indian Elecampare Root Dry Extract
- Maca root powder
- Maca root gelatinized powder
- Maca root extract
- Maqui berry
- Maqui berry powder
- Maqui berry dry juice
- Mate leaf
- Mate leaf dry extract
- Moring Leaf
- Moringa Leaf Dry Extract
- Penella Fruit
- Penella Fruit Powder Purple corn dry extract
- Red Clover Tablets
- Red Yeast Dry Extract
- Red Yeast Rice Powder
- Shatavari Root
- Shatavari Root Powder

Non-Botanicals

- Apigenin
- beta-Hydroxy-beta-methylbutyric acid (HMB)
- Basilus subtilis
- Bromelain
- Calcium beta-hydroxy-beta-methylbutyrate (Ca-HMB)
- GABA
- Hematococcus pluvialis powder
- Hydrolyzed Collagen
- Hydrolyzed Keratin
- Inositol Naachate
- Levocarnitine Tartrate
- Lactin Esters
- Lysine
- Mineral Ascorbates
- Mineral Bisglycinate
- Native Collagen
- Oil-soluble Vitamins Preparation
- Phosphatidylserine
- Phytosterol Esters
- Plant sterols
- Rice protein
- Pacific salmon oil
- Pea Protein
- Soy Protein
- Streptococcus thermophilus

New General Chapters Under Development

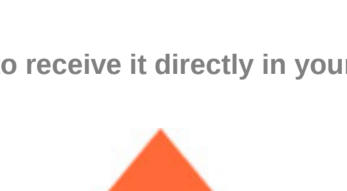
- <582> Water-Soluble Vitamins Assay by Liquid Chromatography—Mass Spectrometry
- <587> Analysis of Contaminant Pyrrolizidine Alkaloids
- <2760> Impurities in Dietary Ingredients and Dietary supplements

Find a USP Reference Standard

Suggest a Reference Standard

Download the free USP Reference Standards and Resources App from the [Apple Store](#) or [Google Play](#), and easily access, track and receive information and alerts on the USP Reference Standards of interest to you from your device.

If you received this newsletter as a forward and wish to receive it directly in your inbox, [please sign up here](#).



Empowering a healthy tomorrow

usp.org

[Forward to a Colleague or Friend](#)

Copyright © 2021. All rights reserved.

Our mailing address is:

© The United States Pharmacopeial Convention
12001 Twinbrook Parkway | Rockville, MD 20852-7790
Phone: +1-301-891-0666 or 00-800-4875-5555 (select Europe)

[USP.org](#) | [Contact Us](#) | [Privacy Statement](#)

[Manage Your USP email Subscription Preferences](#)

[Unsubscribe from @USP emails](#)