

The Supplement Fall Newsletter 2020



Update to The Supplement Newsletter

Note that we did not publish an edition of The Supplement in Summer 2020. We've been busy behind the scenes preparing for upcoming improvements to this newsletter and to the USP Dietary Supplements & Herbal Medicines website. Stay tuned for exciting new changes to keep you better informed in 2021 and beyond!

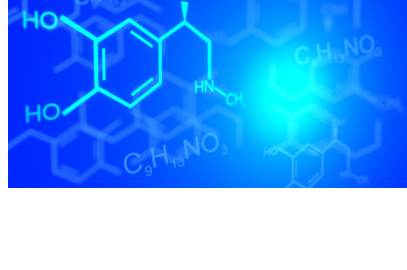
Dietary Supplements Compendium Online



The DS staff is busy assembling the next edition of the [USP Dietary Supplements Compendium \(DSC Online\)](#) to become available in summer 2021; the second annual update of this exceptional resource. A number of under-the hood enhancements will be implemented to improve the user experience, bringing this edition one step closer to the way it was envisioned when we switched from the print edition. As always, we invite you, our ultimate arbiters, to provide feedback and help us prioritize the work for the upcoming and the subsequent DSC Online editions. Please direct your comments to Anton Bzhelevsky (antb@usp.org). DSC Online 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. We will provide more details on the update in the upcoming DSC Newsletters.

For more information or to order the online DSC please click [here](#).

Publications in Peer-reviewed Journals



MINI-REVIEW: Quantitative NMR (qNMR) for pharmaceutical analysis: The pioneering work of George Hanna at the US FDA. Birgit U. Jaki, Anton Bzhelevsky and Guido F. Pauli. *Magnetic Resonance in Chemistry*. MRC, 2020 September 10. Full text [available here](#).



Open Access: Collaborative Study to Validate Purity Determination by 1H Quantitative NMR Spectroscopy by Using Internal Calibration Methodology. Toru Miura et al., *Chem. Pharm. Bull.* 68, 868–878 (2020) Full text [available here](#).

Past Events

2020 AOAC INTERNATIONAL Annual Meeting and Exposition

September 8-24, 2020

The staff of the Dietary Supplements and Herbal Medicines Department represented USP at the 2020 AOAC International Meeting and Exposition held virtually last September 8-24, 2020. Dr. Kit Goldman gave an oral presentation entitled "USP Probiotic Activities update", which included the following topics, among others: USP Probiotic Expert Panel Activities, Enumeration Concerns, DNA Sequencing, Safety of Probiotic Strains, Contaminants and Performance Testing. In addition, the following posters were presented: (1) "Development and Validation of an HPLC-IPC Method for the Analysis of Glucosinolates in Maca Root Dietary Ingredients" by Qun Xu, Zanema Kassymbek, Maria Monagas, Steven Wallich and Gabriel Giancaspro; (2) "Combination of RP-LC-FL-MS and HILIC-FL-MS for the characterization and detection of adulteration in Proanthocyanidin-derived Dietary Supplements" by Amanda Guiraldelli, Maria Monagas, Mark Han, Macy Ma, and Gabriel Giancaspro.

Virtual Workshop & Roundtable: Quantitative NMR and Digital Data Applications - Overview and Perspectives

November 17-19, 2020 | Virtual

A complimentary online three-day workshop and roundtable was held in November 2020, addressing immediate issues relevant to the use of qNMR in industrial and compendial applications was attended by over 200 online participants. Representatives of the major chemical companies, several key international regulatory and government bodies, as well as the instrument manufacturers and software developers, shared their perspectives on the current state of the art of qNMR. USP scientists provided updates on the status of the revision of the General Chapters <761> and <1761> as well as the thoughts on the strategies of qNMR method validation.

Workshop Agenda [available here](#)

Stimuli Article: Quantitative Nuclear Magnetic Resonance (qNMR), a Metrological Method—Proposed Revisions to the USP General Chapters on NMR, Nuclear Magnetic Resonance Spectroscopy <761> and Applications of Nuclear Magnetic Resonance Spectroscopy <1761>. View [stimuli article here](#).

Upcoming Events

USP Elderberry Standard Development Open Forum

January 22, 2021 | Virtual



USP is planning an open virtual discussion with stakeholders, industry and regulators to discuss the following topics concerning USP standard development for COVID-19 related Elderberry ingredients and Dietary Supplements: Adulteration concerns, different plant species used in DS applications, different types of DS ingredients and manufacturing processes, specifications and monograph requirements, and methodologies for anthocyanin analysis. Please keep an eye on the [USP Events Calendar](#) or contact [Maria Monagas](#) for further inquiries.

USP Pyrrolizidine Alkaloids Open Forum

January 29, 2021 | Virtual



Also in January, USP is planning a virtual open forum with stakeholders on Pyrrolizidine Alkaloids (PAs). In the first part of this open forum, USP would like to present the progress on informational General Chapter <1567>, Pyrrolizidine Alkaloids as Contaminants, and seek feedback for any improvements.

In the second part, USP would like to get input on General Chapter <567>. Analysis of Contaminant Pyrrolizidine Alkaloids on the following topics: analytical procedures, reference standards, limits, validation data, and associated challenges during testing.

Please keep an eye on the [USP Events Calendar](#) or contact [Sandeep Putty](#) for further inquiries.

The 6th International qNMR Summit

Preliminary Dates: October 5-7, 2021 | Virtual



A definitive, broadly international event concerning every aspect of qNMR theory and practice, its compendial and industrial implementation and future development perspectives. Further details to be announced. Please keep an eye on the [USP Events Calendar](#) or send an email to Anton.Bzhelevsky@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 compliance and in safeguarding the supply chain for supplements and ingredients. USP is seeking donations for the following monographs:

Botanical Dietary Supplement Ingredients

- Acai
- *Cuminum cyminum*
- Dandelion Root
- Hops
- Horehound
- *Melissa officinalis*
- Moringa Leaf
- Skullcap aerial parts
- Yarrow aerial parts

Non-Botanical Dietary Supplement Ingredients:

- Glucuronolactone
- Histidine
- *Lactobacillus plantarum* 299v
- Lutein esters
- L-Ornithine
- Pantethine
- Salmon Oil
- Soy Protein
- Zeaxanthin preparation

Non-Botanical Dosage Forms (Finished Dietary Supplements):

- Cyanocobalamin capsules
- Glucosamine, Chondroitin Sulfate Sodium capsules
- Magnesium Citrate capsules
- Menaquinone 4 tablets and capsules
- Methylcobalamin orally disintegrating tablets
- Omega-3 Triglyceride chewable gels (gummies)
- Plant Sterol tablets
- Plant Sterols and Stanols Ester Capsules
- S-Adenosyl-L-Methionine Disulfate Tosylate tablets
- Omega-3-Acid Triglycerides with Vitamin D capsules

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 DietaryStaff@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 and Labeling Expert Committee (DSAEL E.C). The DSAEL E.C reviews information related to the ingredient's safety, relevance in the market, regulatory status, presence in other pharmacopias and whether the article poses a serious health risk when used as a dietary supplement.

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

The DSAEL E.C held a working meeting via Webex on Monday November 2, 2020. Members deliberated on and admitted Pomegranate Fruit Peel Dry Extract for monograph development. The DSAEL E.C met via Webex on Monday December 7, 2020, to deliberate on Ajowan Fruit and Red Asian Ginseng. For more information, please contact [Helen Oketch-Rabah, Ph.D.](#), or [Emily Madden, Ph.D., DABT](#).

Nomenclature of Dietary Supplements

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

DSHM Nom JSC met in June 2020 and recommended the following monograph titles to USP Nomenclature and Labeling EC for approval:

- *Bacillus subtilis* subsp. inaquosorum
- *Haematooccus pluvialis* Powder
- Red Yeast Dry Extract

DSHM Nom JSC will be considering the following titles at future meetings. Any information on their nomenclature is welcome.

- Bitter Orange Young Fruit
- Bitter Orange Immature Fruit
- Phosphatidylserine
- Bergamot Orange Fruit Dry Extract
- Blood Orange Fruit Dry Extract
- Wild Salmon Oil
- Farmed Salmon Oil

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>. For more information on dietary supplement nomenclature, please contact [Helen Oketch-Rabah, Ph.D.](#)

Products & Services

New Dietary Supplements Reference Standards

Herbal Medicines/ Botanical Dietary Supplements

- [Ginsenoside Fb1](#)
- [Isorhamnetin-3-O-Rutinoside](#)
- [Sophora japonica Flower Dry Extract](#)
- [Santonin](#)
- [Syringhinin](#)
- [Ziziphus Ajaha japonica Seed Dry Extract](#)

Reference Standards in development:

Botanicals

- *Aegle marmelos* Fruit Dry Extract
- *Angelica sinensis* Root Powder
- *Azadirachta indica* Seed Oil
- *Azadirachta indica* Leaf Dry Extract
- Broccoli Seed Dry Extract
- *Chrysanthemum indicum* Flower Dry Extract
- *Chrysanthemum x morifolium* Flower Dry Extract
- *Cimifugin*
- *Cranberry Fruit Juice Dry Extract*
- *Cullen coriifolium* Fruit Dry Extract
- *Egeline*
- *Ginger Rhizome Carbon Dioxide Soft Extract*
- *Glucoraphanin*
- *Isochlorogenic Acid A*
- *Jujuboside A* (coming soon)
- *Ligusticum chuansiang* Rhizome Powder
- *Linarin*
- *Maca root extract*
- *Marmelosin*
- *S-O-Methylvisnaminoside*
- *Paeoniflorin*
- *Paeonia lactiflora* Peeled Root Dry Extract
- *Pomegranate Fruit Dry Extract*
- *Procyandiolin A2*
- *Punicicillin*
- *Senkyunolide A*
- *Trachyspermum arami* Fruit Oil
- *Z-Ligustilide*

Non-Botanicals

- *Choline Citrate*
- *Hydroxocobalamin Chloride*
- *Inositol Niacinate*
- *L-Ornithine Hydrochloride*
- *Lysine*
- *Palm Oil Tocotrienols and Tocopherols*

Monographs

Standards Open for Public Comment until July 31, 2021

The public comment period was closed for publications in PF 46 (4) and PF 46 (5). The standards below were published in PF 46 (6) for public comment on Nov. 1, 2020 and will accept public feedback until Jan. 31, 2021.

To comment, please visit: <http://www.usp.org/usp-nfbpharmacopeial-forum>

New Monographs/General Chapters

- *Astaxanthin Esters Capsules*
- <274D> Manufacturing Practices for Dietary Ingredients
- *Palm Oil Tocotrienols and Tocopherols*

Revised Monographs/General Chapters

- *Asian Ginseng Tablets*
- *American Ginseng Capsules*
- *American Ginseng Tablets*
- <401> Fats and Fixed oils
- *Bacillus coagulans*

Standards Open for Public Comment until March 31, 2021

The standards below will be published in PF 47 (1) for public comment on Jan 1, 2021 and will accept public feedback until March 31, 2021. To comment, please visit: <http://www.usp.org/usp-nfbpharmacopeial-forum>

New Monographs/General Chapters

- *Japanese Sophora Flower Bud*
- *Japanese Sophora Flower Bud Powder*

Revised Monographs/General Chapters

- *Calcium Pantothinate*
- *Choline chloride*
- *Choline bitartrate*

Standards to be published in PF 47 (2)

The standards below will be published in PF 47 (2) on March 1, 2021 and will accept public feedback until May 31, 2021. To comment, please visit: <http://www.usp.org/usp-nfbpharmacopeial-forum>

New Monographs/General Chapters

- *Cranberry Fruit Juice Dry Extract Capsules*
- *Sichuan Lovage Rhizome*
- *Sichuan Lovage Rhizome Powder*

New Monographs under Development

Botanicals

- *Ajowan Fruit*
- *Ajowan Fruit Powder*
- *Ajowan Fruit Oil*
- *Bitter Orange Young Fruit*
- *Bitter Orange Young Fruit Powder*
- *Black Cumin Seed Oil Thymoguanine Capsules*
- *Cinnamonum cassia Bark*
- *Cinnamonum cassia Bark Powder*
- *Cinnamonum verum Bark*
- *Cranberry Fruit Juice Dry Extract Capsules*
- *Elder berry Fruit Dry Juice*
- *Feverfew Leaf Extract*
- *Gastrodia rhizome*
- *Gastrodia rhizome Powder*
- *Gastrodia rhizome Dry Extract*
- *Green Tea Leaf Dry Extract*
- *Inula racemosa Root*
- *Inula racemosa Root Powder*
- *Inula racemosa Root Dry Extract*
- *Maca root gelatinized powder*
- *Maca root extract*
- *Neem Leaf*
- *Neem Leaf Powder*
- *Neem Leaf Dry Extract*
- *Red Clover Tablets*
- *Red Yeast Dry Extract*
- *Red Yeast Rice Powder*

Non-Botanicals

- *Apigenin*
- *Astaxanthin Biomass*
- *beta-Hydroxy-beta-methylbutyric acid (HMB)*
- *Calcium beta-hydroxy-beta-methylbutyrate (Ca-HMB)*
- *GABA*
- *Hydrolyzed Collagen*
- *Inositol Niacinate*
- *Lactobacillus plantarum*
- *Lactobacillus salivarius*
- *Levocarnitine Tartrate*
- *Lutein Esters*
- *Lysine*
- *Mineral Accretate*
- *Mineral Bisglycinate*
- *Naturo Collagen*
- *Oil-soluble Vitamins Preparation*
- *Phytosterol Esters*
- *Plant Sterols*
- *Rice protein*
- *Salmon oil (farmed and wild)*
- *Zeaxanthin Preparation*
- *Streptococcus thermophilus*

New General Chapter under Development

- <S2> Water-Soluble Vitamins Assay by Liquid Chromatography–Mass Spectrometry
- <290D> Multi-ingredient Dietary Supplement Products – Development of Quality Tests
- <1567> Pyrrolizidine Alkaloids as Contaminants
- <567> Analysis of Contaminant Pyrrolizidine Alkaloids

Find a Reference Standard

Suggest a Reference Standard

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Our mailing address is:

© The United States Pharmacopeial Convention
12601 Twinbrook Parkway | Rockville, MD 20852-1790
Phone: +1-301-591-0069 or 00-800-497-5555 (select Europe)

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