Cannabis

USP will leverage its scientific expertise and convening power to collaborate with stakeholders and develop fit-for-purpose scientific resources and solutions that will help address quality-related concerns as well as support additional scientific research on cannabis, cannabis-derived products, and cannabis-related compounds.

Year 2 Update

To help protect patient safety and public health, USP provides scientific and technical guidance for the evaluation of the quality of cannabis and cannabis-derived products, including for research purposes.

Key areas of progress over the past fiscal year include:

Quality Specifications for CBD – USP’s Botanical Dietary Supplements and Herbal Medicines Expert Committee and Cannabis Expert Panel continued to develop quality specifications for cannabidiol (CBD) as a drug substance. The monograph proposal for CBD, which was published for public comment in *Pharmacopeial Forum (PF)*, includes analytical methods and acceptance criteria for CBD identification, quantitative estimation, and contaminant limits.

Quality of Cannabis and Cannabis-Derived Products – USP published a General Chapter Prospectus in May to solicit public comments on plans to develop informational General Chapter <1568>.

Addressing Adulteration and Impurities – In response to reports of products marketed as cannabis/hemp plant material being adulterated with an intoxicating cannabinoid (synthetic delta-8-tetrahydrocannabinol) or potentially containing high levels of other synthetic impurities with an unknown safety profile, USP published related perspectives on its website. USP’s commentary highlighted the need for scientifically valid analytical methods to address potential adulteration and impurities, and the need for systematic clinical investigations using quality research materials and methods consistent with FDA draft guidance.
Outreach and Engagement – USP developed and shared comments and perspectives on cannabis quality-related issues with regulators and other stakeholders.

- USP submitted comments on a discussion draft of the Cannabis Administration and Opportunity Act, emphasizing the need for requirements for public quality standards for legally marketed cannabis-derived products.
- USP presented pharmacopoeial perspectives on quality considerations for cannabis-derived compounds at a botanical science seminar held by FDA’s Center for Drug Evaluation and Research.
- USP provided public comments on FDA’s draft guidance on cannabis quality considerations for clinical research, and comments to state regulators in New York and California on a proposed rule and state bill, respectively, related to cannabis quality.
- USP submitted comments about cannabis quality attributes to Health Canada, the National Conference on Weights and Measures, and the American Council of Independent Laboratories.
- USP shared cannabis quality perspectives with the Cannabis Regulators Association and trade groups.

Planned for Year 3

- USP will continue to consider approaches to provide stakeholders with information on cannabis product consistency and quality, including development of the proposed informational General Chapter <1568>.
- USP will evaluate comments on a proposed monograph for cannabis inflorescence published in the non-official *Herbal Medicines Compendium*, building on its 2020 publication of quality considerations for cannabis inflorescence for medical use in the *Journal of Natural Products*.
- USP is in dialogue with quantitative nuclear magnetic resonance (qNMR) device manufacturers, and particularly benchtop NMR manufacturers, about the possibility of developing a digital toolkit for identification and quantitation of cannabis-derived and synthetic compounds.
- USP will evaluate public comments on proposed specifications for CBD, continue to work on providing appropriate methods and Reference Standards to limit impurities, and publish a revised monograph proposal for CBD in *PF* for further public comments.
- USP will continue to develop chromatographic methods to identify and quantify impurities and contaminants in cannabinoids to help regulators, industry, and public health professionals address related public health concerns.

Contact

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