



Resolution

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 3 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 – The Cannabis Expert Panel of USP’s Botanical Dietary Supplements and Herbal Medicines (BDSHM) Expert Committee reviewed public comments on proposed quality specifications for cannabidiol (CBD) as a drug substance that were previously published for comment in *Pharmacopeial Forum (PF)*. USP verified new analytical methods to ensure quality and safety that were received after publication of the proposal in *PF*. A revised proposal for the monograph is planned for publication after incorporation of the inputs from public comments. The intent is for the proposal to include analytical methods and acceptance criteria for CBD identification, quantitative estimation, and contaminant limits.

Quality Considerations for Cannabis

Research – USP published for public comment in *PF* its proposed General Chapter <1568> *Quality Considerations for Cannabis and Cannabis-Derived Products for Clinical Research*. The proposal provides specifications for quality attributes fundamental to characterizing the materials for clinical research. It is intended to complement related FDA guidance and includes analytical methods, acceptance criteria, and reference standards for assessing quality.

Proposed Monograph for Cannabis

Inflorescence – USP proposed a monograph for cannabis inflorescence 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*. The Cannabis Expert Panel evaluated public comments on the proposal and suggested changes that would require republication of the proposal for additional public comment.

Addressing Impurities – In response to concerns about health hazards associated with consumption of delta-8-tetrahydrocannabinol (D8-THC) products highlighted in public health advisories, USP collaborated with an external lab to identify impurities in synthesized D8-THC products and develop analytical methods to separate the impurities using chromatographic methods. The methods were then used to analyze commercial D8-THC samples. In May 2023, an article on the topic was submitted for publication in *Cannabis and Cannabinoid Research*.

Certified Reference Materials for Cannabinoids – USP began developing certified reference materials for cannabinoids. The goal is to provide ISO 17034:2016 compliant reference materials for determination of cannabinoids in cannabis product samples in the ISO/IEC 17025:2017 environment, which is expected by regulators. The materials for non-compendial application include information about assigned values, uncertainty values, homogeneity, and stability.

Outreach and Engagement – USP engaged with regulators and other stakeholders on a range of cannabis quality-related issues.

- ▶ USP and ASTM International cosponsored the Global Workshop on Cannabis Quality in December 2022, gathering 500+ stakeholders from industry, testing laboratories, regulatory bodies, and academia across the Americas and Europe. The virtual event facilitated the sharing of perspectives on regulatory issues, standards development, potential harmonization among standards-setting bodies, and needs for future research. A similar June 2023 USP-ASTM webinar focused on Africa and Asia.
- ▶ USP continued to engage with the Cannabis Regulators Association

through a presentation about USP cannabis quality tools that gathered nearly 100 regulatory officials from over 30 states. USP also engaged FDA’s Cannabis Product Council to update the agency on USP’s scientific work related to cannabis and cannabis-derived compounds.

- ▶ USP submitted comments to the European Directorate for the Quality of Medicines & HealthCare (EDQM) and shared information to help inform the EDQM’s proposed Cannabis flos monograph.
- ▶ USP created cannabis toolkits in four volumes that provide scientists, manufacturers, and regulators with the resources needed to help protect public health by establishing a framework for the consistent characterization of cannabis for medical use. Though not standards, they are intended to facilitate stakeholder engagement and education.

Planned for Remainder of the Cycle

- ▶ USP will incorporate changes to its proposed specifications for CBD based on public comments and plans to publish a revised monograph proposal for CBD in *PF* for further public comment.
- ▶ Based on public comments received on proposed specifications for cannabis inflorescence outlined in General Chapter <1568> and the *Herbal Medicines Compendium*, USP plans to incorporate changes and repropose the standards.
- ▶ USP will continue to work with collaborating labs to study the phenomenon of “potency inflation/standards creep” related to the expression of cannabinoid content on a dry weight basis and will publish the findings.

- ▶ USP will continue to engage stakeholders to increase awareness about available cannabis quality resources.

Contact

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