Cannabis for medical use FAQ

Why is USP working on standards for cannabis for medical purposes and for hemp?

Interest in cannabis inflorescence (*Cannabis sativa* L., Family *Cannabaceae*) for medical purposes is active and growing. USP is concerned about the safety and quality of cannabis products that do not comply with a science-based standard. To address quality and patient safety concerns about cannabis, cannabis-derived products, and cannabis-related compounds, USP recommends standardizing quality attributes and methods for testing as a necessary step in protecting public health and promoting good research by establishing a framework for the consistent characterization of products. USP will leverage its scientific expertise and convening power to collaborate with stakeholders and develop fit-for-purpose scientific resources and solutions and advocate for additional scientific research.

Is the Cannabis plant unique from other botanicals?

Like other botanicals, the cannabis plant is impacted by the growing and processing conditions with potential for contamination with pesticide residues, microbials and their metabolites such as aflatoxins, and others. Some varieties of the cannabis plant are reported to accumulate heavy metals from the soil[1]. Also, cultivation practices may result in plant varieties (chemotypes) that produce varying content of certain cannabinoid components, e.g., THC, CBD, or other minor cannabinoids[2].

What is FDA doing about cannabis and cannabis-derived products?

Please refer to the FDA website for information on FDA's regulatory approach and policies related to cannabis. https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd#whatare

What is USP doing about cannabis for medical purposes?

There is increased manufacturing, distribution and use of medical cannabis in over 30 states, without consistent quality validation methods to ensure patient safety. The Association for Public Health Laboratories reported that the absence of federal guidance has led states to develop their own cannabis testing protocols[3]; however, regulatory guidelines vary widely between states.

USP supports the importance of product quality, rooted in science-based standards, to reduce the risk of adverse events in patients using cannabis for medical purposes. USP has published validated test methods for identity, purity and contaminants in cannabis inflorescence (commonly known as "bud," medical cannabis or cannabis for medical use) to help ensure prescribers and patients are receiving consistent quality products. These science-based standards will also support robust clinical and laboratory studies. Consistent, transparent quality parameters will provide regulators, policy makers, manufacturers, distributors and patients a set of common expectations related to appropriate product quality.

How can USP help researchers, manufacturers/distributors or regulators?

With the growing use of cannabis and cannabis-derived products by millions of patients in the United States and globally, there is a need for rigorous clinical research and data to reduce the risk of harm. USP recommends standardizing quality attributes and methods for testing as a necessary step in protecting public health and promoting good research by establishing a framework for the consistent characterization of products. With expertise in botanical product characterization and quality, USP has responded to a variety of stakeholder requests for scientific input in cannabis quality discussions and responded to inquiries from Congressional staff related to hemp-derived products.

USP has developed a paper that focuses on the public health need for quality standards for cannabis products and the benefits of additional research into those products to help protect patients and consumers from harm.

USP collaborated with industry and scientific leaders and formed a Cannabis Expert Panel to provide scientifically valid methods for the analysis of cannabis inflorescence. The panel developed fit-for-purpose quality attributes and specifications that establish reproducible processes to guide manufacturers and regulators and facilitate scientific research for cannabis products for medical purposes.

Labs may report variable test results for the same material if the analytical methods are not harmonized and validated. The availability of science-based analytical methods can improve consistency and scientific validity of the results. Specifications for quality attributes are fundamental to address the challenges and to conduct the tests at each interval across the supply chain – plant sampling, identification testing, assay for cannabinoids and terpenes, and limits on contaminants.

How can USP help the medical community and patients?

With the growing use of cannabis and cannabis-derived products by millions of patients in the United States and globally, there is a need to protect public health and conduct rigorous clinical research to advance scientific understanding of these products and reduce the risk of harm. USP standards for quality attributes and testing methods establish a framework for the consistent characterization of cannabis and cannabis-derived products so medical professionals and patients can be confident in product quality.

What is USP doing to support FDA, manufacturers, medical community and patients regarding the quality of cannabidiol (CBD)?

There is one FDA approved CBD drug. To ensure the quality of new drugs, manufacturers need precise characterization to test the identity, strength and purity of materials with the absence of contaminants.

USP is interested in developing monographs for any cannabis or cannabis-derived ingredients or finished drug products that receive drug approvals from FDA.

What is USP doing about hemp standards?

There are no public standards for widely distributed foods and dietary supplements containing hemp. In a rapidly growing[4] product category such as hemp, public quality standards can help protect public health by providing scientifically validated tests to ensure the identity, content of components and limits of contaminants of a product. FDA has completed its review of Generally Recognized as Safe (GRAS) Notices for hemp ingredients – hemp seeds, hemp seed protein and hemp seed oil – and has no questions regarding the GRAS status of these products for the intended uses specified in FDA's response letters. USP is actively working on food ingredient standards for hemp seed protein and hemp seed oil, as these products meet admission requirements for the *Food Chemicals Codex (FCC)*.

What standards are available for dietary supplements containing CBD?

FDA has indicated that there is no legal basis to market CBD in the US as a dietary supplement or as food, and USP is not pursuing development of a dietary supplement or dietary ingredient monograph for CBD. USP does not admit articles into the compendial development process for dietary supplements when the FDA has indicated that there is no legal basis to market that substance in the US as a food or supplement.[5]

What is USP doing about recreational or adult marijuana?

In publishing science-based standards for cannabis used medically under state law, USP seeks to address quality issues and to help minimize public health risks associated with the use of cannabis for therapeutic purposes.

Federal law makes the use, sale, cultivation and distribution of marijuana in the U.S. illegal and FDA does not currently recognize cannabis for any medical uses.

What material standards are available from USP?

FDA has approved some products containing cannabinoids for medical use. The current edition of *USP–NF* contains monographs for Dronabinol and Dronabinol Tablets (Marinol), and USP is actively seeking to work with stakeholders to develop monographs for the synthetic cannabinoid, nabilone and nabilone capsules (Cesamet).

Reference standards (RS) are an integral part of analytical procedures used in assuring the identity and the determination for the content of constituents. For the purpose of establishing identity of a botanical ingredient, RS may be used for qualitative applications such as identification tests, system suitability tests, or chromatographic peak markers.

How can stakeholders collaborate with USP?

USP is continuing to collaborate with stakeholders – manufacturers, academia, scientific government liaisons, and organizations such as ASTM International, AOAC International, and the American Herbal Pharmacopeia to identify gaps in consistent quality standards for cannabis-related products.

USP invites scientific industry leaders and medical professionals to volunteer their time and expertise to help create public quality standards.

Contact **Nandakumara Sarma** to join our efforts to develop quality standards to help address public health concerns about cannabis, cannabis-derived products, and cannabis-related compounds.

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1 Girdhar, M.; Sharma, N. R.; Rehman, H.; Kumar, A.; Mohan, A. 3 Biotech 2014, 4, 579–589. https://pubmed.ncbi.nlm.nih.gov/28324308/

2 Small, E. Evolution and classification of Cannabis sativa (marijuana, hemp) in relation to human utilization. Bot. Rev. 2015, 81, 189–284. https://www.semanticscholar.org/paper/Evolution-and-Classification-of-Cannabis-sativa-in-Small/99b935bb9bdaa89b8fcbd0f48215d057a94c249b

3 Association of Public Health Laboratories. Guidance for State Medical Cannabis Testing Programs, 2016. https://www.aphl.org/aboutAPHL/publications/Documents/EH-Guide-State-Med-Cannabis-052016.pdf

4 https://cannabisindustryjournal.com/feature_article/hemp-a-growing-market-ripe-for-protection/

5 https://www.usp.org/sites/default/files/usp/document/get-involved/submission-guidelines/guideline-for-the-admission-of-dietary-supplement-ingredients.pdf