

### **Background**

Cannabis is available for medical use in parts of the U.S. and other countries. However, the lack of consistency in the quality of cannabis for medical use makes it difficult for regulators, prescribers, manufacturers, distributors, and patients/consumers to maintain confidence in the products on the market. One potentially serious health risk is the cannabis plant's ability to absorb heavy metals, many of which are known human carcinogens. A lack of consistent quality assurance can expose patients to the risk of substandard, super-potent, contaminated, or adulterated cannabis products.

# **Opportunity to strengthen quality**

Defined quality attributes can help mitigate public health risks associated with poor quality cannabis products and support reproducible research. Scientifically established tests, analytical procedures, and acceptance criteria to verify the identity, content of constituents, and limits on contaminants can help manufacturers and other stakeholders ensure the quality of cannabis products for medical use.

### **USP** solutions

- Six USP Reference Standards
  - Delta-9-Tetrahydrocannabinol
  - Exo-Tetrahydrocannabinol
  - Cannabinoid Acids Mixture
  - Cannabinoids Mixture
  - Cannabidiol Solution
  - Cannabidiol
- USP General Chapter <11> USP Reference Standards
  - Describes the types, applications and proper use of standards and the applications for which they are used, as well as packaging, labeling and storage.
- USP General Chapter <561> Articles of Botanical Origin
  - Describes sampling and analytical methods to test for substances that may be present in botanical materials.



- USP General Chapter <621> Chromatography
  - Contains general procedures, definitions, and calculations of common parameters and describes general requirements for system suitability.
- Proposed Cannabidiol USP active pharmaceutical ingredient monograph
  - Published in *Pharmacopeial Forum (PF)* in January 2022. Proposes identity and impurity assays and limits for impurities for CBD as a pharmaceutical drug substance.
- <u>Cannabis Inflorescence for Medical Purposes—USP Considerations for Quality</u> Attributes *J. Nat. Prod.* 2020, 83, 4, 1334–1351.

## Why it's important

The active and growing interest in cannabis for medical use means that more and more people are relying on these products as a component of their health regimen. Solutions that guide the quality attributes and testing protocols of cannabis products give manufacturers science-based tools to verify the quality of products on the market.

#### Web resources

- <a href="https://www.usp.org/cannabis">https://www.usp.org/cannabis</a>
- <a href="https://www.usp.org/dietary-supplements/reference-standards/cannabis-reference-standards">https://www.usp.org/dietary-supplements/reference-standards/cannabis-reference-standards</a>
- <a href="https://www.usp.org/sites/default/files/usp/document/our-work/DS/Cannabis">https://www.usp.org/sites/default/files/usp/document/our-work/DS/Cannabis</a> FAQ.pdf
- https://store.usp.org/home

