



ASTM–USP Global Workshop on Cannabis Quality

Part One – America and Europe

Standards Panel

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Opening Remarks

- Public standards can set specifications for identity, cannabinoid content, limits for contaminants and other quality attributes. Standards are fundamental to meet the challenges of test methods that are not validated, inaccurate label claims for cannabinoid content, varying limits for microbial and chemical contamination, and emerging concerns related to synthetic minor cannabinoids and impurities.
- **Documentary standards** (also known as pharmacopeial or compendial standards) articulate agreed-upon testing methods and acceptance criteria used in quality assurance and quality control protocols. They provide benchmarks to evaluate an article's identity, purity, strength and performance. They provide transparency on quality expectations for the article. They can be utilized by any stakeholder to help assess the quality of their products.
- **Reference standards** are physical samples consisting of a known quantity of a substance or ingredient, developed in alignment with the specifications outlined in the corresponding documentary standard. They undergo rigorous testing in a collaborative study and are subject to statistical analysis. These standards come in small vials, and enable manufacturers to test their product against the standards to ensure it meets published specifications.

Examples of Recent Cannabis Standards Work

- ASTM Committee D37 on Cannabis has > 40 documentary standards for cannabis, its products and processes, published in the *Annual Book of ASTM Standards*; 100+ are in development. Activities are focused on meeting the needs of the cannabis industry addressing quality and safety through the development of voluntary consensus standards and supplementary programs on proficiency testing, training and certification.
- USP BDSHM EC and the Cannabis EP published a very detailed open-access journal article *Cannabis Inflorescence for Medical Purposes: USP Considerations for Quality Attributes* with extensive supplementary information, in *J. Nat. Prod.* 2020, 83, 1334–1351 (<https://dx.doi.org/10.1021/acs.jnatprod.9b01200>); a prospectus for *General Chapter <1568> Quality Considerations for Cannabis and Cannabis-derived Products for Clinical Research* (<https://www.uspnf.com/notices/gc-1568-prospectus-20220527>) now in development; a draft monograph on CBD published for comment (Jan. 03–Mar. 31, 2022) in PF 48(1) (<https://www.uspnf.com/pharmacopeial-forum>); a *Herbal Medicines Compendium* monograph on *Cannabis* Species Inflorescence posted Sept. 21, 2022 for comment until Dec. 20, 2022 (<https://hmc.usp.org/monographs/cannabis-species-inflorescence-0-1>); and a series of Reference Standards:
 - USP Cannabidiol RS, USP Cannabidiol-4 RS, USP Cannabidiol Hydroxyquinone RS, USP Cannabidiolic Acid RS, USP Cannabidivarin RS, USP Cannabinol RS, USP 4-Monobromo Cannabidiol RS, USP Olivetol RS, USP Δ^9 -Tetrahydrocannabinol RS, USP Δ^8 -Tetrahydrocannabinol RS, USP Tetrahydrocannabinolic Acid RS, USP Exo-Tetrahydrocannabinol RS, USP Cannabinoids Mixture RS (Δ^9 -THC, Δ^8 -THC, CBD, CBN, CBC, CBG, THCV, CBDV), USP Cannabinoid Acids Mixture RS (THCA, CBDA, THCVA, CBDVA, CBGA).
- The Netherlands Office of Medicinal Cannabis has an *Analytical Monograph: Cannabis Flos (flowers / granulated)* (2014) and standardized cannabis products are made available through pharmacies: Bedrobinol[®], Bedrocan[®], Bedica[®], Bediol[®], Bedrolite[®] (<https://english.cannabisbureau.nl/medicinal-cannabis/types-of-medicinal-cannabis>).
- The German (2017), Danish (2019), and Swiss (2019) Pharmacopoeias have a monograph on *Cannabis Flowers* (based on the Dutch monograph) and the German Pharmacopoeia (2020) added a monograph on *Cannabis Standardized Extract*.
- EDQM published a draft Ph. Eur. Cannabis flos draft monograph on Oct. 13, 2022 in *Pharmeuropa 34.4* for comment until Dec. 31, 2022.
- American Herbal Pharmacopoeia: *Cannabis Inflorescence – Cannabis spp.: Standards of Identity, Analysis, and Quality Control* (Rev. 2014).

The Panel's Charge

- **Objectives of the Workshop:**

- Obtain awareness of the existing data, regulatory framework, and public policy for cannabis quality, public quality standards, and policy guidance documents on defining cannabis product quality attributes globally;
 - Understand the scientific basis for standards to explore potential harmonization amongst the standards groups;
 - Facilitate discussions between stakeholders to identify needs and challenges related to cannabis quality;
 - Identify areas of global data gaps to inform future standards and research needs.
- Diverse and complementary standards are needed but clear lines of communication must be maintained to prevent duplication or wasting of precious resources.
 - This *Standards Panel for the ASTM–USP Global Workshop on Cannabis Quality* is a step in the right direction as a forum for conversations toward promoting regulatory convergence or harmonization to the extent possible given our different legislative/regulatory frameworks and areas of expertise.

