Designation: D8439 – 22

Standard Specification for Medicinal-use Cannabis Inflorescence[1]

This standard is issued under the fixed designation D8439; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This standard defines the specifications (appropriate tests, their analytical methods and acceptance criteria) for the identification, strength (for example, cannabinoid content), and purity (for example, limits for contaminants) for medicinal-use cannabis inflorescence.

1.2 This specification references approved analytical methods used to verify the specifications, and in the absence of approved analytical methods, a suggested method for validating such specifications.

1.3 *Units*—The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

1.4 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.5 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

D8196 Practice for Determination of Water Activity (a_w) in Cannabis Flower

D8197 Specification for Maintaining Acceptable Water Activity (a_w) Range (0.55 to 0.65) for Dry Cannabis Flower Intended for Human/Animal Use

D8219 Guide for Cleaning and Disinfection at a Cannabis Cultivation Center

D8244 Guide for Analytical Laboratory Operations Supporting the Cannabis/Hemp Industry

D8270 Terminology Relating to Cannabis

D8282 Practice for Laboratory Test Method Validation and Method Development

D8334 Practice for Sampling of Cannabis/Hemp Post-Harvest Batches for Laboratory Analyses

3. Terminology

3.1 Definitions are in accordance with Terminology D8270 unless otherwise indicated.

3.2 *Definitions:*

3.2.1 *cannabis inflorescence, n*—fruiting tops of a cannabis plant (excluding the seeds and leaves when not accompanied by the tops) from which the resin has not been extracted, by whatever name they may be designated by the authority having jurisdiction.

3.2.2 *total CBD, n*—the amount of CBD that considers the potential of CBDA to convert quantitatively to CBD with no further degradation, using the following formula:

$$\text{Total CBD} = \text{CBD} + 0.877 \times \text{CBDA}$$

3.2.3 *total THC, n*—the amount of THC that considers the potential of Δ9-THCA to convert quantitatively to THC with no further degradation, using the following formula:

$$\text{Total THC} = \text{THC} + 0.877 \times \text{THCA}$$

3.3 *Acronyms:*

3.3.1 *ADI, n*—acceptable daily intake

3.3.2 *AHJ, n*—authority having jurisdiction

3.3.3 *CBD, n*—cannabidiol (CAS #: 13956-29-1)

3.3.4 *CBDA, n*—cannabidiolic acid (CAS #: 1244-58-2)

3.3.5 *CBN, n*—cannabinol (CAS #: 521-35-7)

3.3.6 *CBNA, n*—cannabinolic acid (CAS #: 2808-39-1)

3.3.7 *PDE, n*—permitted daily exposure

3.3.8 *THC or Δ-9-THC, n*—delta-9-tetrahydrocannabinol (CAS #: 1972-08-3)

3.3.9 *THCA or Δ-9-THC-A, n*—delta-9-tetrahydrocannabinolic acid (CAS #: 23978-85-0)

3.3.10 *USP, n*—United States Pharmacopeia

3.3.11 *WHO, n*—World Health Organization

[1] This specification is under the jurisdiction of ASTM Committee D37 on Cannabis and is the direct responsibility of Subcommittee D37.04 on Processing and Handling.

Current edition approved Sept. 1, 2022. Published October 2022. DOI: 10.1520/D8439-22.

[2] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

4. Significance and Use

4.1 *Significance:*

4.1.1 This specification defines the metrics for identification, cannabinoid specifications, and limits for contaminants for medicinal-use cannabis inflorescence.

4.1.2 The specifications cited in this specification are reported from multiple global standards as referenced in the text and supported by both the U.S. Pharmacopeia's Cannabis Expert Panel recommendations as published (**1**)[3] and the American Herbal Pharmacopeia (**2**). As coming from standards that are global and currently utilized, the specifications cited herein are considered attainable.

4.2 *Use:*

4.2.1 All measurements shall be reported based on the weight of the product that is stored under conditions meeting the specification of water activity in Specification D8197.

4.2.2 Businesses engaged in the cultivation, processing, buying, and selling of medicinal-use cannabis inflorescence utilize this specification for the creation of contract stipulations, and a basis for ensuring that products meet producer claims of cannabinoid dominance and ratio as well as minimum safety and consistency profiles.

4.2.3 Testing laboratories use this standard to verify that medicinal use cannabis inflorescence meets the specification claims within contracts and to verify that unknown samples fall into the appropriate cannabinoid dominance type.

4.2.4 Testing laboratories engaged in the providing methodology must be using validated test methods referenced within this specification or equivalent. For guidance on acceptable validation methodology, refer to Practice D8282, AOAC Single Laboratory Validation of Chemical Methods for Dietary Supplements and Botanicals (**3**), USP General Chapter <1225> Validation of Compendial Methods (**4**), or Guidelines for the Validation of Chemical Methods in Food, Feed, Cosmetics, and Veterinary Products 3rd Edition-U.S. Food and Drug Administration Foods Program (**5**).

4.2.5 Where these specifications differ from those of governing regulatory, local, or regional jurisdictions, the governing body's requirements shall hold precedence.

5. Types of Medicinal-use Cannabis Inflorescence

5.1 For purposes of specification delineation, medicinal-use cannabis inflorescence has been divided into three dominant Types as follows:

5.1.1 *Type I*—THC-dominant medicinal-use cannabis inflorescence.

5.1.2 *Type II*—THC/CBD intermediate medicinal-use cannabis inflorescence.

5.1.3 *Type III*—CBD-dominant medicinal-use cannabis inflorescence.

5.2 Specifications common to all types of medicinal-use cannabis inflorescence are provided in the subsequent sections and summarized in Table X1.1 except where explicitly stated.

6. Cultivation and Storage Practices

6.1 Medicinal-use cannabis inflorescence shall be cultivated under defined protocols following sanitation practices as articulated in Guide D8219 and cultivated in accordance with an appropriate quality management system such as Good Agricultural and Collection Practices (GACP) or Global Gap (**6, 7**).

6.2 Medicinal-use cannabis inflorescence shall be stored in conditions that maintain the water activity (a_w) at 0.60 ± 0.05 as per Specification D8197.

7. Sampling

7.1 Samples for analysis should be taken from medicinal-use cannabis inflorescence batches following Practice D8334.

8. Methods and Specifications Information

8.1 The methods and specifications described in this document provide:

8.1.1 Fit-for-purpose analytical methods for the identification of medicinal-use cannabis inflorescence using macroscopic, microscopic, chromatographic, and spectroscopic procedures.

8.1.2 Methods to determine the strength and chemical composition of cannabis inflorescence, specifically the cannabinoids and terpenes, using quantitative tests should be scientifically valid according to 4.2.4 and fit-for-purpose to resolve major and minor cannabinoids, including Δ-8-THC and Δ-9-THC; and appropriate terpene determinations.

8.1.3 Quality specifications addressing the purity are provided to limit the content of common contaminants of herbal materials. Multiple test methods are included to complement each other and thereby provide an appropriate quality characterization. These include:

8.1.3.1 Pesticides as described in USP General Chapter <561> Articles of Botanical Origin (**8**);

8.1.3.2 Elemental impurities;

8.1.3.3 Microbials;

8.1.3.4 Mycotoxins; and

8.1.3.5 Foreign organic material.

8.1.4 This specification addresses additional quality attributes such as:

8.1.4.1 Water activity; and

8.1.4.2 Total ash and insoluble ash.

9. Verification of Identity

9.1 Visual confirmation against standardized visual reference chart via macroscopic and microscopic analysis criteria are found in Appendix 1 of Cannabis Inflorescence for Medical Purposes: USP Considerations for Quality Attributes (**9**); and

9.2 Verification of cannabinoid presence via TLC, HPLC, or GC Chromatographic Analysis (for example, **10, 11, 12**) or by means of a validated test method as described in 4.2.4.

10. Cannabinoid Concentration

10.1 Medicinal-use cannabis inflorescence is categorized by the ratio of Total THC to Total CBD present in the inflorescence and portioned into Type I, Type II, or Type III, as determined by chromatographic test methods (**10, 12**).

[3] The boldface numbers in parentheses refer to a list of references at the end of this standard.

10.2 *Type I*—THC-dominant medicinal-use cannabis inflorescence with a ratio of Total THC to Total CBD content not less than (NLT) 5:1, with not more than (NMT) 10 mg/g of Total CBD and NLT 10 mg/g Total THC.

10.2.1 The content of CBN is NMT 2 % of the content of Total THC.

10.2.2 No unidentified peak in the sample solution chromatogram shall exceed the area of the CBN peak.

10.3 *Type II*—THC/CBD intermediate medicinal-use cannabis inflorescence with a ratio of Total THC content to Total CBD content is NLT 0.2:1 and NMT 5:1, with NLT 10 mg/g Total CBD and NLT 10 mg/g Total THC.

10.3.1 The content of CBN is NMT 2 % of the content of Total THC.

10.3.2 No unidentified peak in the sample solution chromatogram shall exceed the area of the CBN peak.

10.4 *Type III*—CBD-dominant medicinal-use cannabis inflorescence with a ratio of Total THC content to Total CBD content is NMT 1:5 and contains NMT 10 mg/g total THC and NLT 10 mg/g total CBD.

10.5 *All Types:*

10.5.1 All cannabinoids present in an amount of 10 mg/g or more shall be identified with the name and amount.

10.5.2 All Types shall contain NLT 80 % and NMT 120 % of the labeled amount of cannabinoids measured in mg/g.

11. Terpene Identity

11.1 The following terpenes shall be tested for and reported when present above 10 mg/g:

11.1.1 β-caryophyllene (CAS 87-44-5)

11.1.2 D-limonene (CAS 5989-27-5)

11.1.3 β-myrcene (CAS 123-35-3)

11.1.4 α-pinene (CAS 7785-26-4), and

11.1.5 γ-terpinolene (CAS 586-62-9)

11.2 Validated test methods for quantifying terpene content include Sarma et al. 2020 Appendix 4 and others (**13**, **14**). Other analytical methods may be used and should be scientifically valid according to 4.2.4.

11.3 Reported amounts of terpenes shall be NLT 80 % and NMT 120 % of the labeled amount of terpenes that were measured in mg/g.

12. Limits for Contaminants

12.1 *Pesticides:*

12.1.1 The user of this specification is responsible for referring to their authority having jurisdiction (AHJ) for limits of allowable pesticides.

12.1.2 For pesticides without established limits by an AHJ, the following formula shall be used to calculate the maximum acceptable pesticide residue (**15**):

$$\text{Residue Limit (ppm)} = AM/1000B \quad (1)$$

where:

A = the ADI from (**8**) in mg/kg;
M = the body weight (for example, 60 kg); and
B = the daily dose of the article (with a 1000× safety factor).

12.1.3 Multiple test methods have been published, many of which are vendor-specific. AOAC publishes a standard test method: Multiresidue Method of Analysis of Pesticides in Medical Cannabis (**16**). The European Commission also provides non-cannabis specific guidance for consideration (**17**).

12.1.4 Other analytical test methods may be used and should be scientifically valid according to 4.2.4.

12.2 *Elemental Impurities:*

12.2.1 The user of this specification is responsible for referring to their authority having jurisdiction (AHJ) for limits of allowable elements.

12.2.2 In the absence of established limits from the AHJ, the following list should be followed, and is summarized in Table X1.2.

12.2.2.1 Cadmium (Cd) – NMT 0.2 µg/g
12.2.2.2 Lead (Pb) – NMT 0.5 µg/g
12.2.2.3 Arsenic (As) – NMT 0.2 µg/g
12.2.2.4 Mercury (Hg) – NMT 0.1 µg/g
12.2.2.5 Cobalt (Co) – NMT 0.3 µg/g
12.2.2.6 Vanadium (V) – NMT 0.1 µg/g
12.2.2.7 Nickel (Ni) – NMT 0.5 µg/g
12.2.2.8 Lithium (Li) – NMT 2.5 µg/g
12.2.2.9 Antimony (Sb) – NMT 2 µg/g
12.2.2.10 Barium (Ba) – NMT 30 µg/g
12.2.2.11 Molybdenum (Mo) – NMT 1 µg/g
12.2.2.12 Copper (Cu) – NMT 3 µg/g
12.2.2.13 Tin (Sn) – NMT 6 µg/g
12.2.2.14 Chromium (Cr) – NMT 0.3 µg/g
12.2.2.15 When additional elemental impurities are known to be present or have the potential for introduction, established limits shall be defined by the user of this specification, tested for, and adhered to.

12.2.3 Test methods for determining the level of elemental impurities are provided in USP, General Chapter <233> (**18**).

12.3 *Microbial Contaminants:*

12.3.1 Specifications for the microbial quality of cannabis inflorescence shall be as follows:

12.3.2 The total aerobic bacterial count: NMT 100 000 cfu/g;

12.3.3 The total combined molds and yeast count: NMT 10 000 cfu/g;

12.3.4 Meets the tests' requirements for the absence of bile-tolerant Gram-negative bacteria, *Staphylococcus aureus* and *Pseudomonas aeruginosa*.

12.3.5 Aspergillus Species: Tests negative for all four species of *Aspergillus*, *A. niger*, *A. flavus*, *A. fumigatus*, and *A. terreus*.

12.4 When an acceptance criterion for microbiological quality is prescribed, it is interpreted as follows (**19**, **20**):

12.4.1 10^1 cfu: maximum acceptable count = 20;
12.4.2 10^2 cfu: maximum acceptable count = 200;
12.4.3 10^3 cfu: maximum acceptable count = 2000; and so forth.

12.5 Testing methodologies and specifications can be found in the European Pharmacopeia (**21**, **22**), and USP General Chapters <61>, <62>, and <1223> (**19**, **23**, **24**).

12.6 *Mycotoxins:*