## DRAFT AOAC SMPR 2020.XXX; Version 6 February 11, 2020.

### Method Name: Determination of Moisture in Hemp and Cannabis Plant Matter

### Intended Use: Consensus-based Reference method.

1. Purpose: AOAC SMPRs describe the minimum recommended performance characteristics to be used during the evaluation of a method. The evaluation may be an on-site verification, a single-laboratory validation, or a multi-site collaborative study. SMPRs are written and adopted by AOAC Stakeholder Panels composed of representatives from the industry, regulatory organizations, contract laboratories, test kit manufacturers, and academic institutions. AOAC SMPRs are used by AOAC Expert Review Panels in their evaluation of validation study data for methods being considered for Performance Tested Methods or AOAC Official Methods of Analysis, and can be used as acceptance criteria for verification at user laboratories.

#### **2.** Applicability:

Determination of less than 15% moisture in dried, ground hemp and cannabis plant material.

### **3.** Analytical Technique:

Any analytical technique(s) that meets the following method performance requirements is/are acceptable.

#### **4.** Definitions:

## Quantitative method

Method of analysis which response is the amount of the analyte measured either directly
 (enumeration in a mass or a volume), or indirectly (color, absorbance, impedance, etc.) in a certain
 amount of sample.

### 33 Repeatability

Variation arising when all efforts are made to keep conditions constant by using the same
 instrument and operator and repeating during a short time period. Expressed as the repeatability
 standard deviation (SD<sub>r</sub>); or % repeatability relative standard deviation (%RSD<sub>r</sub>).

### 38 Reproducibility

The standard deviation or relative standard deviation calculated from among-laboratory data.
 Expressed as the reproducibility standard deviation (SD<sub>R</sub>); or % reproducibility relative standard
 deviation (% RSD<sub>R</sub>).

## Hemp Plant Materials

Fresh or dried, whole or milled plant material of low-THC cultivars of Cannabis spp.

## **5.** Method Performance Requirements:

- 50 See table 1.

- 6. System suitability tests and/or analytical quality control: Suitable methods will include control samples, as appropriate for the method platform.
  7. Reference Material(s): Refer to Annex F: Development and Use of In-House Reference Materials in Appendix F: Guidelines for Standard Method Performance Requirements, 19<sup>th</sup> Edition of the AOAC INTERNATIONAL Official Methods of Analysis (2012). Available at: <u>http://www.eoma.aoac.org/app\_f.pdf</u>
  8. Validation Guidance:
- Precision data are critical to this SMPR, special attention should be given to study design power and
   acquiring robust precision data. See section 3.4.1 of Appendix K (referenced below) for
   instructions to determine accuracy.
- No criteria for accuracy are specified in this SMPR because no reference methods or reference
   materials for moisture in hemp are available at the time of the development of this SMPR.
   However, method developers must provide an estimate of the method accuracy and explain in
   detail the procedure used to estimate accuracy, such as comparison with an alternate method. See
   section 3.4.1 of Appendix K (referenced below) for instructions to determine accuracy.
- An initial and important stage in cannabis testing is preparation of a homogeneous sample of the
   plant material. Detailed and complete procedures for reproducible preparation of test samples
   from the plant material must be addressed during method validation and those data must be
   included in the method validation submission.
- Validation should include data demonstrating performance for various samples with moisture levels
  at different points within the method range, with some samples falling in the lower part of the range
  and some in the higher part of the NMT 15% range. Most dried hemp samples are expected to
  contain 4-12% moisture.

- <u>Appendix D</u>: Guidelines for Collaborative Study Procedures To Validate Characteristics of a Method of Analysis; 19<sup>th</sup> Edition of the AOAC INTERNATIONAL Official Methods of Analysis (2012). Available at: http://www.eoma.aoac.org/app\_d.pdf
- Appendix F: Guidelines for Standard Method Performance Requirements; 19<sup>th</sup> Edition of the AOAC
   INTERNATIONAL Official Methods of Analysis (2012). Available at:
   http://www.eoma.aoac.org/app f.pdf
- 94 <u>Appendix K</u>: Guidelines for Dietary Supplements and Botanicals; 19<sup>th</sup> Edition of the AOAC
   95 INTERNATIONAL Official Methods of Analysis (2012). Available on line at:
   96 <u>http://www.eoma.aoac.org/app\_k.pdf</u>
- 99 9. Maximum Time-To-Result: None

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# Table 1: Method performance requirements

Parameters	Ranges (%)
	< 15
% RSDr	≤ 2
% RSD <sub>R</sub>	≤ 6