

## Standard Method Performance Requirements (SMPRs®) for Determination of Heavy Metals in Cannabis-Containing Beverages

Intended Use: Surveillance Methods for Routine Monitoring

### 1 Purpose:

*What:* AOAC Standard Method Performance Requirements (SMPRs®) are voluntary consensus standards developed in accordance with the AOAC policy, “AOAC Due Process for Development of AOAC Non-Method Consensus Standards and Documents.” SMPRs describe the scientific community’s recommended minimum method performance characteristics and analytical requirements for a specific method-related intended use.

*Who:* Drafted by AOAC working groups, SMPRs are adopted by AOAC by a consensus of stakeholders affiliated with its integrated science programs and projects, which are composed of volunteer subject matter experts representing academia, government, industry, and nonprofit sectors from around the world.

*Use:* AOAC SMPRs are used in AOAC core science programs as a resource for AOAC method experts, including expert review panels, in the evaluation of validation study data for methods submitted to the AOAC *Official Methods of Analysis*<sup>SM</sup> and AOAC *Performance Tested Methods*<sup>SM</sup> programs. AOAC SMPRs also may be used to provide acceptance criteria for the verification of methods and serve as a resource to guide method development and optimization.

### 2 Applicability

Determination of total cadmium (CAS No. 7440-43-9), total arsenic (CAS No. 7440-38-2), total lead (CAS No. 7439-92-1), and total mercury (CAS No. 7439-97-6) in cannabis-containing beverages. Additional elements in Table 1 may be included. Beverage categories are listed in Table 2.

### 3 Analytical Technique

Inductively coupled plasma-based instrumentation or alternative methodology that meets the performance requirements.

**Table 1. Optional elements not frequently required**

Optional element	CAS No.
Antimony	744-36-0
Barium	744-39-3
Chromium	18540-29-9
Copper	744-50-8
Nickel	7440-02-0
Silver	7440-22-4
Selenium	7782-49-2
Zinc	7440-66-6

## 4 Definitions

*Limit of quantitation (LOQ).*—Minimum concentration or mass of analyte in a given matrix that can be reported as a quantitative result.

*Optional.*—Additional elements listed in Table 1 can be added to the method’s scope, provided that sufficient validation data is submitted. Additional elements will be evaluated by the expert review panel on an ad hoc basis to determine if they meet the general requirements in Table 3 (repeatability, reproducibility, and recovery), while limits of quantitation for optional elements will be determined based on data provided. For consideration of First Action status, priority will be given to methods, including As, Pb, Cd, and Hg; and then any optional elements from Table 1 may be included.

*Recovery.*—Fraction or percentage of spiked analyte that is recovered when test sample is analyzed using entire method.

*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>).

*Reproducibility.*—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>).

## 5 Method Performance Requirements

See Table 3.

## 6 System Suitability Tests and/or Analytical Quality Control

Suitable methods will include blank check samples and check standards at the lowest point and midrange point of the analytical range.

## 7 Reference Material(s)

A certified reference material should be used when available. Internally produced reference materials may be used for a variety of cannabis-containing beverages until reference materials are made available by an internationally recognized organization, such as Institute for Reference Materials and Measurements (IRMM) or U.S. National Institute of Standards and Technology (NIST).

## 8 Validation Guidance

Detailed and complete procedures for reproducible preparation of test samples of each beverage matrix category must be addressed

**Table 2. Cannabis-containing beverage matrix categories<sup>a</sup>**

Beverage/matrix category	Sample
Carbonated beverages	Sodas, sparkling water
Coffees	With and without dairy/fats
Teas and multiherb blends	Kombucha, green tea, ginger-turmeric
Other	Fruit juices, smoothies/shakes, sports drinks, dry powder mixes, wine, beer

<sup>a</sup> Manufactured as cannabis-containing, manufacturer-containing, or commercially available cannabis beverages.

**Table 3. Method performance requirements**

Limit of quantitation (LOQ) Range	$\leq 10 \mu\text{g/kg}^a$		
	Repeatability (RSD <sub>r</sub> ), %	Reproducibility (RSD <sub>R</sub> ), %	Recovery, %
$\geq 10$ to 100 $\mu\text{g/kg}$	15	32	60–115
>100 to 1000 $\mu\text{g/kg}$	11	16	80–115
>1 to 10 $\text{mg/kg}$	7.3	8	80–115

<sup>a</sup> LOQ applies to product as consumed.

during method validation and those data must be included in the method validation submission. Required matrix categories are listed in Table 2; method developers must include validation data and detailed sample preparation procedures for at least one sample from each matrix category.

LOQ applies to product as consumed.

AOAC guidance on single-laboratory validations: [https://members.aoac.org/AOAC\\_Docs/StandardsDevelopment/SLV\\_Guidelines\\_Dietary\\_Supplements.pdf](https://members.aoac.org/AOAC_Docs/StandardsDevelopment/SLV_Guidelines_Dietary_Supplements.pdf)

FDA guidance: <https://www.fda.gov/food/laboratory-methods-food/elemental-analysis-manual-eam-food-and-related-products>

USP <233>: <https://www.usp.org/sites/default/files/usp/document/our-work/chemical-medicines/key-issues/c233.pdf>

#### **9 Maximum Time-to-Result**

None.

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