



The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
Bureau of Health Care Safety and Quality
Medical Use of Marijuana Program
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Title: Protocol for Sampling and Analysis of Finished Medical Marijuana Products and Marijuana-Infused Products for Massachusetts Registered Medical Marijuana Dispensaries

The Protocol contains the following sections:

- 1.0 Purpose and Applicability
- 2.0 Definitions and Acronyms
- 3.0 Applicable Regulations
- 4.0 Sampling and Analysis Requirements
- 5.0 Sampling Program Design
- 6.0 Sample Collection Procedures
- 7.0 Sample Analysis
- 8.0 Data Evaluation
- 9.0 References

1.0 Purpose and Applicability

1.1 Purpose

The purpose of this Protocol is to provide Massachusetts Registered Marijuana Dispensaries (RMDs) with required and recommended best practices for the collection and analysis of plant material and other finished medical marijuana products and marijuana-infused products (MIPs) to comply with Massachusetts regulation 105 CMR 725.000, Implementation of an Act for the Humanitarian Medical Use of Marijuana.

This protocol is subject to revision based on evolving best practices, updated scientific information or standards/guidelines, or other information relevant to the contents of the protocol.

1.2 Applicability

This protocol applies only to Massachusetts RMD operations, and not hardship cultivation operations. Testing requirements in the protocol apply only to the medical marijuana products dispensed by Massachusetts RMDs, including finished medical marijuana (i.e., plant material,

Because target cannabinoid contents and ratios may vary depending on the desired dosage, medical condition, and other use considerations, minimum profile standards are not mandated. However, the cannabinoid profile must be included in product labeling as an aid to patients and caregivers. Analytical procedures for determining cannabinoid profiles are available in AHP (2013).

7.2 Metals

Finished medical marijuana products must be tested for the four metals listed in Exhibit 4. Quantification of metals must be performed with a validated method such as those provided by USP (Chapter <233>) or FDA (2011). A production batch of finished medical marijuana products (e.g., finished plant material, cannabis resin, or cannabis concentrate) may only be dispensed to patients if all four of the metals are below the upper limits for the respective product and intended use specified in Exhibit 4 (e.g., ingestion only or all other uses). These limits are in micrograms (μg) of contaminant per kilogram (kg) of product.

Once a production batch of finished medical marijuana has been determined to meet the limits in Exhibit 4, it must bear the following label:

This product has been evaluated for environmental contamination (impurities) assuming that no more than 10 grams (0.35 ounces) of finished plant material (or the equivalent amount of concentrate) will be consumed per day.

In addition to the above labeling requirement for all production batches of finished medical marijuana, if the quantification of metals is below the upper limits specified for "Ingestion Use Only", as described in Exhibit 4 (b), the production batch of finished medical marijuana must bear the additional label:

**This product has been evaluated for impurities based on oral consumption only.
DO NOT INHALE THIS PRODUCT.**

7.3 Pesticides Residues and Plant Growth Regulators

Non-organic pesticides may not be used to cultivate medical marijuana in Massachusetts (105 CMR 725.105(B)(1)(d)). As discussed in Section 5, all production batches of finished plant material must be tested for residues of prohibited pesticides. At a minimum, samples of finished plant material must be tested for the pesticides, including plant growth regulators, listed in Exhibit 5. These pesticides were identified by AHP (2013) as commonly used in cannabis cultivation. Exhibit 5 identifies appropriate analytical methods for each of the listed pesticides.

Exhibit 5 includes only a small number of the many prohibited non-organic pesticides registered for use in the U.S. To test medical marijuana for pesticides beyond the minimum list in Exhibit 5, Massachusetts recommends additional testing based on the approach USDA Certifying Agents use to analyze prohibited pesticides in organic food. Acknowledging that no method currently exists that analyzes all registered pesticides efficiently (USDA, 2012a), USDA developed a