THE NATALIE M. LAPRADE MARYLAND MEDICAL CANNABIS COMMISSION'S (MMCC) TECHNICAL AUTHORITY FOR MEDICAL CANNABIS TESTING

REVISION 2.0

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The MMCC has provided this report to define contaminants and corresponding action limits associated with those contaminants in medical cannabis. This information is intended for the independent testing laboratories registered by the MMCC.

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INTRODUCTION

Analytical testing of medical cannabis for safety and potency is increasingly recognized as a critical and necessary component of the industry for several reasons (Freeman et al. 2016):

- Laboratory testing minimizes the risk of pesticides, microbes, heavy metals, toxins, and residual solvents from being consumed by an immunocompromised population;
- Quantification of cannabinoid profiles and potency becomes available for the consumer and aids in determining appropriate dosing for individual use; and
- Laboratory testing provides a sense of public safety and product quality for the medical cannabis tested.

The Maryland Medical Cannabis Commission (MMCC), with the help of a scientific work group, has established this guidance to serve as a reference for the Independent Testing Laboratories (ITL) to follow when analyzing medical cannabis. Medical cannabis safety and potency is to be analyzed based on the most current version of the cannabis inflorescence monograph published by the American Herbal Pharmacopeia (AHP), or a scientifically valid methodology that is equal or superior to that of the AHP monograph. The Code of Maryland Regulations (COMAR) 10.62.15.05 and 10.62.23.04 list the quality control testing requirements for medical cannabis. This guidance provides the lists of contaminants and the acceptable tolerances that the ITL is required to report as stated in COMAR 10.62.15.05 and 10.62.23.04. The tolerances were established following a review of available literature in the cannabis industry as well as references from the International Conference for Harmonisation (ICH) Guideline Q3C on Impurities and the ICH Guideline Q3D on Elemental Impurities Guidance for Industry.

The four categories of contaminants identified in the Code of Maryland Regulations (COMAR) 10.62.15.05 and 10.62.23.04 include:

- Pesticides;
- Residual Solvents;
- Microbiological Impurities; and
- Heavy Metals.

In an effective testing program, standardized sampling procedures are an integral component to quality laboratory testing. The data generated from all analytical methods must be consistently reliable and legally defensible. To achieve this, method precision and accuracy measurements should be performed during the sample testing process. This guidance will provide some best practices for the sample collection by the ITL.

All sampling and analysis described in this guidance shall be conducted by an independent testing laboratory registered with MMCC and in good standing with a third-party accrediting body accredited to International Organization for Standardization (ISO) 17025.

The MMCC is committed to evidence-based decision making when implementing technical guidance for the registered ITL. As research into cannabis use and safety advances, this report will be revised and updated to reflect the state of science as it pertains to the medical cannabis industry.

SAMPLING

The objective of a sampling procedure is to ensure the proper collection, clear labeling, proper preservation, careful transportation, and storage of samples by trained personnel for laboratory analyses. Collection of the sample is critical as it must be truly representative of the material being analyzed or the results will not be meaningful. Independent testing laboratories (ITL) are required to develop a statistically valid sampling method and collect a representative sample from each batch or lot of final product that is adequate to perform the required testing (COMAR 10.62.15.04B). The amount of sample required for cannabinoid or contaminant testing may vary due to sample matrix, analytical method, and laboratory-specific procedures, but a minimum sample volume of 0.5% of the batch mass of usable cannabis is required by MMCC in order to achieve a representative sample for analysis. For concentrates, extracts, and medical cannabis infused product, the sample volume will be determined by each ITL. In all cases, the amount of sample collected by the laboratory should be large enough and sufficiently homogenized to provide a representative sample of the batch but not in excess to raise issues with possible diversion or waste disposal.

Medical Cannabis sampling procedures play an important role in identifying and/or confirming the integrity of a sample, as well as the completeness of request and chain of custody forms.

To reliably provide the laboratory with a representative sample, standard sampling methods with descriptive steps must be applied with quality and consistency. All sampling must be consistently performed using accepted methodologies. It is the responsibility of the ITL to define a standard operating procedure that minimizes both imprecision and bias, and lists chronological steps that ensure a consistent and repeatable method.

The following are sampling guidelines the ITL shall use when developing a sampling protocol:

- The use of appropriate sampling equipment to avoid contamination;
- The documentation of observations and procedures used during sample collection;
- The use of an aseptic collection technique is required for antimicrobial testing;
- The importance of personal hygiene and use of person protective equipment; and
- The method used by personnel to consistently obtain samples throughout the batch.
- Additional parameters affecting sample preparation, documentation, and transport may include:
    - ❖ Accepted test sample types;
    - ❖ Minimum test sample size;
    - ❖ Test sample labeling;
    - ❖ Transport and storage conditions; and
    - ❖ The documentation of sample chain of custody.

An example collection procedure is included as a baseline reference (USP 36 2014). For detailed information regarding sample collection, please refer to "Good Samples: Guidance on Obtaining Defensible Samples" (Thiex 2015), or "Sampling Cannabis for Analytical Purposes (Sexton 2013).

(See Appendix A for information regarding required testing for each sample matrix).

EXAMPLE COLLECTION PROCEDURE FOR LABORATORY SAMPLES

Equipment:

Disposable Gloves
Calibrated Scale
Sampling Tongs
Appropriate Sample Collection Vessel
70% Ethanol or Bleach Wipes

Procedure:

1) Put on disposable gloves to mitigate the risk for contamination of the sample during the collection process.
2) Ensure the work surface and scale are clean and decontaminated.
3) Label a collection vessel with the appropriate METRC identifier, and the batch or lot mass. Do not sample if pertinent information is not available.
4) Retrieve the container you will be collecting the sample from and wipe off the lid of the container.
5) For usable cannabis: Withdraw samples from the upper, middle and lower sections of each container. With the upper section sample being taken from a depth of not less than 10 centimeters. In circumstances where there are 1-10 containers in a batch, collect a sample from all containers. Record the time the sample was collected, any inconsistencies with the sampling plan, or other remarks that might be relevant to data analysis or quality assurance.

   For concentrates, extracts, and products (Solid and Semi Solid): Each sample increment should be taken from a randomly chosen position in the lot. A sample increment should be taken from each container if possible.

   For concentrates, extracts, and products (Liquid): The sample should be chosen from a bulk container, ensure homogenization prior to product sampling by mixing the container thoroughly.

NOTE: The minimum sample volume to be collected from each batch of usable cannabis is 0.5% of the batch mass. The ITL must collect equal weights from each domain (upper, middle, and lower sections of the batch container) until the target sample weight is achieved.
If this does not supply sufficient mass for required analysis, the mass of the sample increments can be increased or decreased as long as they are equivalent to each other.

6) Place the sample in the appropriate collection vessel, seal and place to the side.
7) Return bulk product container to its appropriate place.
8) Wipe down the scale and work surface using either a 70% ethanol solution or bleach wipes.
9) Dispose of gloves.
10) Document the appropriate chain of custody information in METRC.

**The following sample collection procedure is based U.S. Pharmacopeia Convention Chemical Tests / 561 Articles of Botanical Origin. 2014 July.*

PESTICIDES

COMAR 10.62.11.03G states pesticide applicators and applications shall follow state and federal pesticide requirements for any pesticide applied. MMCC's current list of pesticide targets are documented in Table 1. The MMCC created the current list of pesticide targets by initially comparing lists from other states performing pesticide screens with the compounds named in the American Herbal Pharmacopoeia as commonly used in cannabis cultivation. Please note these compounds will be continually evaluated and updated based on available scientific and industry information. Action levels will be developed based on limits of quantitation (LOQ) achievable by the ITL. Cannabis samples with pesticide active ingredients detected above the action level listed below fail and the product must be destroyed.

Table 1: List of Target Pesticides and Plant Growth Regulators in Parts Per Million (PPM)

Pesticide/PGR	USE	LOQ
Acetamiprid	Insecticide	0.2
Abamectin	Insecticide	0.5
Aldicarb	Insecticide	0.4
Ancymidol	PGR	0.2
Azoxystrobin	Fungicide	0.2
Bifenazate	Insecticide	0.2
Bifenthrin	Fungicide	0.2
Boscalid	Fungicide	0.4
Carbaryl	PGR	0.2
Carbofuran	Insecticide	0.2
Chlorantraniliprole	Insecticide	0.2
Chlorpyrifos	Insecticide	0.2
Clofentezine	Acaricide	0.2
Cyfluthrin	Insecticide	1.0
Daminozide (Alar)	PGR	1.0
DDVP (Dichlorvos)	Insecticide	0.1
Diazinon	Insecticide	0.2
Dimethoate	Insecticide	0.2
Ethephon	PGR	1.0
Etoxazole	Acaricide	0.2
Fenpyroximate	Insecticide	0.5
Fipronil	Insecticide	0.4
Flonicamid	Insecticide	1.0
Fludioxonil	Fungicide	0.4

Pesticide/PGR	USE	LOQ
Flurprimidol	PGR	0.2
Hexythiazol	Ovicide	1.0
Imazalil	Fungicide	0.2
Imidacloprid	Insecticide	0.4
Kresoxim-methyl	Fungicide	0.4
Malathion	Insecticide	0.2
Metalaxyl	Fungicide	0.2
Methiocarb	Insecticide	0.2
Methomyl	Insecticide	0.4
Myclobutanil	Fungicide	0.2
Naled	Insecticide	0.5
Oxamyl	Insecticide	1.0
Paclobutrazol	PGR	0.4
Permethrin	Insecticide	0.5
Phosmet	Insecticide	0.2
Piperonyl butoxide	Insecticide	1.0
Propiconazole	Fungicide	0.4
Pyrethrins	Insecticide	1.0
Spinosad	Insecticide	0.2
Spiromesifen	Insecticide	0.2
Spirotetramat	Insecticide	0.2
Thiacloprid	Insecticide	0.2
Thiamethoxam	Insecticide	0.2
Trifloxystrobin	Fungicide	0.2

RESIDUAL SOLVENTS

Some producers of cannabis products use solvents to extract and/or concentrate the active ingredients from cannabis. The MMCC has adopted a list of target residual solvents based on common extraction and concentration techniques in the industry. Concentration limits are based on the "International Conference for Harmonisation (ICH) Guideline Q3C (R5) on Impurities: Guidelines for residual solvents". The concentration limits listed in ICH Q3C are based on the toxicity of the individual solvent and on the magnitude of exposure to occur from consuming 10 grams of the pharmaceutical. It is unlikely that a medical cannabis user would consume >10 grams of cannabis extract or concentrate in a single day.

Note: No health-based solvent residual limits have been established specifically for cannabis extract or concentrate products. We are uncertain whether the selected action levels for solvents in cannabis products sufficiently protect persons who smoke cannabis. However, the ICH Q3C does assume 100% absorption by any exposure route.

Table 2: Concentration Limits for Residual Solvents in Parts Per Million (PPM)

Solvent	PPM
Heptanes	<5000
Hexanes	<290
Butanes	<5000
Benzene	<2
Toluene	<890
Total Xylenes	<2170
Propanes	<5000
Ethanol	<5000

MICROBIOLOGICAL IMPURITIES

The presence of microbes is common in all natural products. It is important to distinguish between organisms ubiquitous in nature and those that are known pathogens. "Indicator tests" don't directly test for pathogens, but serve as quality tests or indications that follow-up pathogen testing should be performed (Holmes et al. 2015). Additionally, microbial and fungal limits are not typically reported as "pass/fail", the MMCC has established acceptable limits of detection based on the literature available. The MMCC requires microbiological impurities to be tested according to COMAR 10.62.15.05 and COMAR 10.62.23.04. The criteria for acceptability in Table 3 (below) lists the microbiological impurities and the detection limits associated with each organism to be tested.

Water activity (Aw) is a measure of the available water that can be utilized for microbiological growth. Aw ranges from 0 to 1 with microbial growth unlikely below Aw 0.6. Most cannabis is dried and cured to a final water activity level of Aw 0.3-0.6, most pathogens cannot grow below Aw 0.9 (Holmes et al. 2015). Water activity, or the moisture of the cannabis flower in units, measured below Aw 0.65 will safeguard cannabis products against microbial growth during storage and before sale.

Table 3: Microbiological Impurities and Accepted Detection Limits in Colony Forming Units (CFU/g) and Parts Per Billion (PPB)

Microbiological Impurity	**CFU/g**
Total Aerobic Microbial Count (TAMC)	<100,000 CFU/g
Total Yeast and Mold Count (TYMC)	<10,000 CFU/g
E. coli	<100 CFU/g
Salmonella spp.	"none detected"/g
Water Activity (Aw)	<0.65

Mycotoxin	**PPB**
Aflatoxin B1	<20ppb
Alflatoxin B2	<20ppb
Alflatoxin G1	<20ppb
Alflatoxin G2	<20ppb
Ochratoxin A	<20ppb

HEAVY METALS

Elemental impurities do not provide any therapeutic benefit to the medical cannabis patient. Because of their high degree of toxicity, arsenic, cadmium, chromium, lead, and mercury rank among the priority metals that are of public health significance (Tchounwou P et al. 2012). The MMCC requires an ITL to test for heavy metal presence in medical cannabis (COMAR 10.62.15.05 and COMAR 10.62.23.04). Table 4 lists the eight heavy metals required in contaminant testing and their associated concentration limits based on a 5 gram/day consumption of medical cannabis.

Note: The permitted daily exposure (PDE) for heavy metals is based on the Q3D Elemental Impurities Guidance for Industry.

Table 4: Heavy Metals and Associated Concentration Limits in Parts Per Million (PPM)

Heavy Metal	PPM
Lead	<1.0
Arsenic	<0.4
Mercury	<0.2
Cadmium	<0.4
Chromium	<0.6
Barium	<60.0
Silver	<1.4
Selenium	<26.0

STABILITY TESTING

COMAR (10.62.15.07 and 10.62.23.06) states that stability testing is to be performed at 6 month intervals. The purpose of stability testing is to provide evidence on how the quality of a drug substance varies with time under the influence of a variety of environmental factors (ICH 2003).

The ITL must have policies and procedures established for the collection of stability and retention samples and the analysis of stability testing samples.

The stability testing required at 6 month intervals will include:

- Cannabinoid content;
- Microbiological impurities.

Findings of the stability studies will be reported to MMCC through the METRC tracking system to ensure medical cannabis purity and potency are maintained throughout the storage process without significant change. *Significant change* for medical cannabis is defined as failure to meet the tolerances listed in this technical guidance for purity.

Stability testing protocol for MMCC licensed growers is available in Appendix C.

Stability testing protocol for MMCC licensed processors is available in Appendix D.

APPENDIX A- Medical Cannabis Compliance Testing Requirements

	Usable Cannabis	Medical Cannabis Concentrate (non-solvent)	Medical Cannabis Concentrate (solvent based) made with CO2 Extractor	Medical Cannabis Concentrate (solvent based)	Medical Cannabis-Infused Product	Medical Cannabis Vape Cartridges
Moisture Content	√					
Potency Analysis	√	√	√	√	√	√
Terpene Analysis	√	√	√	√	√	√
Foreign Matter Inspection	√	√	√	√	√	√
Microbial Screen	√	√	√	√	√	√
Mycotoxin Screen	√	√	√	√	√	√
Water Activity	√					
Heavy Metal Screen	√	√	√	√	√	√
Residual Solvent Test		√	√	√	√	√
Pesticide Residue Analysis	√	√	√	√	√	√
Vitamin E Acetate						√

Note:

Vitamin E Acetate was added as a compliance test required for vape cartridges and disposable vape pens effective 11-15-2019. The U.S. Centers for Disease Control and Prevention have identified vitamin E acetate as a chemical of concern among people with e-cigarette, or vaping product use associated with lung injury (EVALI). CDC recommends that "until the relationship of vitamin E acetate and lung health is better understood, vitamin E acetate should not be added to e-cigarette or vaping products.

APPENDIX B-DEFINITIONS

Batch-

(a) Means all of the plants of the same variety of medical cannabis that have been:

(i) Grown, harvested, and processed together; and
(ii) Exposed to substantially similar conditions throughout cultivation and processing.

(b) "Batch" includes all of the processed materials produced from those plants.

Chain of Custody- The chronological documentation showing the collection, custody, control, transfer, analysis, and disposition of a sample.

Commission- The Natalie M. LaPrade Medical Cannabis Commission.

CFU/g- Colony forming units per gram. Refers to a measure of the amount of living bacteria per given amount (1 gram) of a sample.

Independent Testing Laboratory- A facility, entity, or site that offers or performs tests of medical cannabis and products containing medical cannabis:

(a) Accredited as operating to ISO standard 17025 by an accreditation body:

(i) Operating in accordance with the International Organization for Standardization (ISO) standard ISO/IEC 17011; and

(ii) A signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA); and

(iii) That is independent from all other persons involved in the Maryland cannabis industry; and

(b) Registered with the Commission.

Limit of Quantification (LOQ)- The lowest concentration at which the analyte can not only be reliably detected but at which some predefined goals for bias and imprecision are met.

Lot- All of a medical cannabis finished product that is uniform, that is intended to meet specifications, and that is manufactured, packaged, or labeled together during a specified time period according to a single lot record.

METRC- Marijuana Enforcement Tracking Regulation and Compliance system.

Medical Cannabis- Any product containing usable cannabis or medical cannabis finished product.

Medical Cannabis Concentrate- A product derived from medical cannabis that is kief, hashish, bubble hash, oil, wax, or other product, derived from cannabis or that includes cannabinoids extracted from the plant through the use of:

(a) Solvents;
(b) Carbon dioxide; or
(c) Heat, screens, presses or steam distillation.

Medical Cannabis-Infused Product-

(a) Any oil, wax, ointment, salve, tincture, capsule, suppository, dermal patch, cartridge or other product containing medical cannabis concentrate or usable cannabis that has been processed so that the dried leaves and flowers are integrated into other material.
(b) Medical cannabis infused product does not include a food.

Representative Sample- A sample obtained according to a sampling procedure designed to ensure that the different parts of a batch or lot or the different properties of a batch or lot are proportionally represented.

Sample- An amount of medical cannabis collected by laboratory personnel from a licensee and provided to an independent testing laboratory for testing.

Solvent- A substance that can dissolve another substance, or in which another substance is dissolved, forming a solution.

Target Analyte- A chemical the lab must test for to see if it is present in medical cannabis.

Usable Cannabis-

(a) The dried leaves and flowers of the cannabis plant.
(b) Does not include seedlings, seeds, stems, stalks or roots of the plant or the weight of any non-cannabis ingredients combined with cannabis, such as ingredients added to prepare a topical administration.

Water Activity- The partial vapor pressure of water in a substance divided by the standard state partial vapor pressure of water.

APPENDIX C- STABILITY TESTING PROTOCOL (GROWER)

COMAR 10.62.15.07 requires stability testing to be performed for each released batch of usable medical cannabis. This document outlines the required protocol to be followed by MMCC licensed growers and the MMCC registered independent testing laboratories performing the stability studies.

Definitions:

Batch – All of the plants of the same variety of medical cannabis that have been: a) Grown, harvested, and processed together; and b) Exposed to substantially similar conditions throughout cultivation and processing. This includes all of the processed materials produced from those plants (flower, trim, kief, etc).

Testing Panel - Each sample is to be tested for a) micro-organisms and b) potency to ensure product potency and purity and provide support for expiration dating per COMAR 10.62.15.07.

Stability Sample – 12 grams of material stored in routine conditions by the licensed grower to allow for collection of testing samples at all time-points.

Testing Sample – 3 grams collected from the stability sample to be collected by, homogenized and analyzed by the independent testing laboratory for each time-point.

Time-Point – 6 month interval when testing should occur per COMAR 10.62.15.07 (0, 6, 12 and 18 months)

Homogenization – Manipulation of a product by mixing, and/or grinding, to obtain equal distribution of all components or ingredients with the goal of reducing variability

Stability Testing Goals:

The design will assess:

1. Decay of cannabinoids and terpenes in usable medical cannabis products over an 18 month period when held at routine storage conditions at a licensed cultivation facility.
2. Levels of bacterial/fungal growth in usable medical cannabis products over an 18 month period when held at routine storage conditions at a licensed cultivation facility.

Stability Testing Protocol Requirements:

1. Stability testing shall be performed for each unique batch of cannabis as defined by COMAR 10.62.01.01(B)(2). If material produced is to be distributed/sold as unique products (flower, trim, kief) each of these products shall constitute a batch and must be tested individually as potency, microbiological activity and environmental impact on stability may vary between product forms.
2. Stability testing shall be repeated annually or whenever there is a change in grow protocols, processing methods or storage conditions that have the potential to impact product stability.
3. The licensed grower shall be responsible for stability sample storage, and selection of the independent testing laboratory to perform stability testing
4. The independent testing laboratory shall be responsible for the collection of the stability and testing samples, analysis and submission of stability testing data into METRC.
5. Each stability sample shall contain 12 grams of material to allow the independent testing laboratory to collect a 3 gram testing sample at each of the four time-points. Failure to generate sufficient data for analysis may require repeating the missing time-point/testing and potentially the full protocol. In cases where insufficient material to complete full testing is available (kief, trim) from a single batch a modified protocol to assess the stability of these products shall be proposed by the licensed grower for approval by the MMCC.
6. Stability samples shall be uniquely identified, clearly labeled "For Stability Testing Only" and stored in the same environmental conditions as product intended for sale. Care shall be taken to keep the sample segregated from other product to avoid potential contamination of study samples.
5. The independent testing laboratory shall collect a testing sample of 3 grams from the stability sample at each time-point. In cases where the product is packaged in volumes lower than what is required by the laboratory for testing multiple packages of a product from the same batch may be used to produce a single, homogenized sample for testing. These packages shall be collected by the independent testing laboratory and combined into a single sample at the time of testing.
6. Testing samples are to be collected and analyzed by the independent testing laboratory at 0, 6, 12 and 18 months per COMAR 10.62.15.07.
7. Testing results for each all time-points shall be generated within 5 calendar days of the date of the time-point to be measured.

8. Each testing sample is to be ground at the time of testing by the laboratory to achieve homogeneity.
9. Each testing sample shall be analyzed by the independent testing laboratory for a) micro-organisms and b) potency per COMAR 10.62.15.07.
10. Laboratory methodology shall be consistent throughout the study. No changes to technology or protocols shall occur. Any changes may require repeating the full protocol.
11. Independent testing laboratory shall provide all data electronically to the MMCC within 30 calendar days of the measured time-point.
12. Data shall include:
    - Date of batch harvest
    - Unique sample ID's for each sample traceable to all data
    - Lab certified testing results/CoA by sample ID
    - All records or notes detailing anomalies, discrepancies or other factors which may have impacted testing results either at the storage location or testing laboratory

APPENDIX D- STABILITY TESTING PROTOCOL (PROCESSOR)

Licensed Processor Stability Testing Protocol

COMAR 10.62.23.06 requires stability testing to be performed for each released lot of processed medical cannabis. This document outlines the required protocol to be followed by MMCC licensed processors and the MMCC registered independent testing laboratories performing the stability studies.

Definitions:

Medical Cannabis-Infused Product – Oil, wax, ointment, salve, tincture, capsule, suppository, dermal patch, cartridge or other product containing medical cannabis concentrate or usable cannabis that has been processed so that the dried leaves and flowers are integrated into other material.
Lot – All of a medical cannabis finished product that is uniform, that is intended to meet specifications, and that is manufactured, packaged or labeled together during a specified time period according to a single lot record.
Testing Panel - Each testing sample is to be tested for a) micro-organisms and b) potency per COMAR 10.62.23.06
Stability Sample – Sufficient material stored in routine conditions by the licensed processor to generate testing samples at all time-points.
Testing Sample – Sample to be collected from the stability sample by the independent testing laboratory sufficient to complete the testing panel for each time-point.
Time-Point –6 month interval when testing should occur per COMAR 10.62.23.06 (0, 6, 12 and 18 months)
Homogenization – Manipulation of a product by mixing, to obtain equal distribution of all components or ingredients with the goal of reducing sample variability

Stability Testing Goals:

The design will assess:

3. Decay of cannabinoids and terpenes in medical cannabis processed products over an 18 month period when held at routine storage conditions at a licensed processing facility.
4. Levels of bacterial/fungal growth in medical cannabis processed products over an 18 month period when held at routine storage conditions at a licensed processing facility.

Stability Testing Protocol Requirements:

7. Stability testing shall be performed for each unique medical cannabis-infused product. Each product with a unique strain, terpene/cannabinoid profile or delivery method shall be tested independently as potency, microbiological activity and environmental impact on stability may vary between product forms.
8. Stability testing shall be repeated annually or whenever there is a change in strain/starting material, processing methods or storage conditions that have the potential to impact product stability.
9. The licensed processor shall be responsible for stability sample storage and selection of the independent testing laboratory to perform stability testing.
10. The independent testing laboratory shall be responsible for the collection of the stability and testing samples, analysis and submission of stability testing data into METRC.
11. Each stability sample shall contain sufficient material to allow the independent testing laboratory to collect a testing sample at each of the four time-points sufficient to complete the testing panel. Failure to generate sufficient data for analysis may require repeating the missing time-point/testing and potentially the full protocol.
12. Stability samples shall be uniquely identified, clearly labeled "For Stability Testing Only" and stored in the same environmental conditions as product intended for sale. Care shall be taken to keep the sample segregated from other product to avoid potential contamination of study samples.
13. The independent testing laboratory shall collect a testing sample from the stability sample at each time-point sufficient to complete the full testing panel. In cases where the product is packaged in volumes lower than what is required by the laboratory for testing multiple packages of a product from the same batch may be used to produce a single, homogenized sample for testing. These packages shall be collected by the independent testing laboratory and combined into a single sample at the time of testing.
14. Testing samples are to be collected and analyzed by the independent testing laboratory at 0, 6, 12 and 18 per COMAR 10.62.23.06.
15. Testing results for each all time-points shall be generated within 5 calendar days of the date of the time-point to be measured.

16. Each testing sample shall be analyzed by the independent testing laboratory for a) micro-organisms and b) potency per COMAR 10.62.23.06.
17. Laboratory methodology shall be consistent throughout the study. No changes to technology or protocols should occur within a study. Any changes may require repeating the full protocol.
18. When possible each sample is to be homogenized at the time of testing by the independent testing laboratory.
19. Independent testing laboratories shall provide all data electronically to the MMCC within 30 calendar days of the measured time-point.
20. Data shall include:
    - Unique sample ID's for each sample traceable to all data
    - Lab certified testing results/CoA by sample ID
    - All records or notes detailing anomalies, discrepancies or other factors which may have impacted testing results either at the storage location or testing laboratory

HOLD FOR EDIBLES STABILITY PROTOCOL

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