MINNESOTA
OFFICE OF CANNABIS MANAGEMENT

Cannabis Technical Authority: Standards for Sampling and Testing Cannabis Products

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Purpose of the Technical Standard

This document contains details of compliance testing requirements for cannabis and hemp products manufactured or sold by businesses licensed by the Office of Cannabis Management (OCM).

Analytical testing of cannabis for safety and potency is increasingly recognized as a critical and necessary component of the industry for several reasons:

1. Laboratory testing minimizes the risk of pesticides, microbes, heavy metals, toxins, and residual solvents from being consumed.
2. Quantification of cannabinoid profiles and potency becomes available for the consumer and aids in determining appropriate consumption for individual use.
3. Laboratory testing provides a sense of public safety and product quality for the cannabis tested.

To comply with Minnesota Statutes, section 342.61, subd. 2, testing for potency and homogeneity is required. Stability must be tested to determine the expiration date for each product. To comply with Minnesota Statutes, section 342.61, subd. 4, testing for contaminants must include testing for residual solvents, foreign material, microbiological contaminants, heavy metals, pesticide residue, mycotoxins, and any items identified pursuant to paragraph (b) which mandates that a business must disclose all known information regarding pesticides, fertilizers, solvents, or other foreign materials, including but not limited to catalysts used in creating artificially derived cannabinoids, applied or added to the batch.

Roles and Responsibilities

The testing requirements in this document apply to all cannabis or hemp products produced or sold by operators licensed by the Minnesota Office of Cannabis Management. Cultivators and manufacturers are required to comply with the sampling requirements described in rule and this document and are required to contract with a laboratory licensed by OCM to perform the required testing. The laboratories licensed by OCM are required to test the products to the levels described in this document, to communicate the results through the statewide monitoring system, to report the results in compliance with this document, and to use methods meeting performance criteria specified in this document. Pursuant to Minnesota Statutes, section 342.37, ISO 17025, and Minnesota Rules Part 9810.3000, which require that testing facilities ensure the impartiality of testing results, in order to maintain the independence of the Minnesota cannabis marketplace, a person, cooperative or business holding a cannabis testing facility license must maintain a conflict of interest policy.

Applicability

These standards apply to all cultivators, manufacturers, and laboratories licensed by OCM for operation in the cannabis and lower potency hemp marketplace and to any cannabis or hemp products imported to be sold in retail locations licensed by OCM.

Definitions

For the purposes of this standard, the terms defined in Minnesota Statutes, Chapter 342, or Minnesota Rules 9810 have the meanings given them.

Artificially derived cannabinoid (ADC) refers to a cannabinoid extracted from a cannabis plant, cannabis flower, hemp plant, or hemp plant parts with a chemical makeup that is changed after extraction to create a different cannabinoid or other chemical compound by applying a catalyst other than heat or light. Artificially derived cannabinoid includes but is not limited to any tetrahydrocannabinol created from cannabidiol but does not include cannabis concentrate, cannabis products, hemp concentrate, lower-potency hemp edibles, or hemp-derived consumer products. See Minnesota Statutes, section 342.01, subd. 6.

CFU/g is an abbreviation for colony forming units per gram. It is the unit used to measure the number of viable microorganisms per given amount of a sample.

Compliance sample refers to the representative sample taken from each batch of cannabis or hemp product for the required compliance analysis.

Confirmatory methods refer to microbial analysis methods that are used to confirm the presence of pathogenic organisms.

Continuing calibration refers to an analytical standard prepared from the same source as the calibration standards that is analyzed periodically prior to, during, and after analysis of samples to verify continued accuracy of an instrument calibration.

Corrective and preventive action (CAPA) is a systematic approach implemented to collect information, analyze information, identify and investigate quality problems, and take appropriate and effective corrective and preventive actions to prevent their recurrence.

Enumeration methods refer to methods used to estimate the number of viable microorganisms in a sample.

Flower (cannabis) means the harvested flower, bud, leaves, and stems of a cannabis plant. Cannabis flower includes adult-use cannabis flower and medical cannabis flower. Cannabis flower does not include cannabis seed, hemp plant parts, or hemp-derived consumer products. See Minnesota Statutes, section 342.01, subd. 16.

Flower (hemp) means the harvested flower, bud, leaves, and stems of a hemp plant, but does not include the stalk, derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers that are separated from the plant. See Minnesota Statutes, section 342.01, subd. 42.

Full panel testing means final product testing whereby analysis is done as defined in this document for all the requirements for microbiological testing in Section I, mycotoxin testing in Section II, heavy metals testing in Section III, screened for all pesticides listed in Section IV, screened for all solvents listed in Section V, foreign matter in Section VI, potency in Section VII, homogeneity if applicable in Section VIII, stability in Section IX, and terpenes if applicable in Section X.

Initial calibration verification refers to an analytical standard that is prepared separately from the calibration standards and is used to verify the calibration for each analysis.

Internal standard refers to a standard used to compensate for sensitivity changes due to matrix suppression and signal drift in standards and sample solutions.

Laboratory reagent blank refers to a sample without matrix, prepared identically to a laboratory sample (i.e., same glassware, solvents, reagents, etc.). The purpose of a reagent blank is to identify any possible sources of contamination in the reagents, equipment, glassware or laboratory environment.

Laboratory control sample (LCS) refers to a portion of appropriate clean matrix that is spiked with known quantities of target analytes and carried through the entire sample preparation process, and treated exactly as a sample, including exposure to the same glassware, equipment, solvents, and reagents that are used with other laboratory samples.

Limit of detection (LOD) is defined as the lowest concentration or mass of analyte in a test sample that can be distinguished from a true blank sample at a specified probability level.

Limit of quantitation (LOQ) is the minimum concentration or mass of analyte in a given matrix that can be reported as a quantitative result.

Manufactured final products includes any product made by a licensed manufacturer by combining a cannabis or hemp rosin, a cannabis or hemp resin, or artificially derived cannabinoid product with other substances. Examples include but are not limited to: infused pre-roll, lower potency hemp edibles (Minnesota Rules, part 9810.2100, subp. 2), hemp-derived consumer products (Minnesota Rules, part 9810.2100, subp. 3), ingestible cannabis products (Minnesota Rules, part 9810.2100, subp. 1 B), topical and transdermal cannabis and hemp products (Minnesota Rules, part 9810.2100, subp. 1C), and products containing artificially derived cannabinoids.

Negative control refers to a laboratory sample that is treated the same as all other samples but is not expected to produce any response.

Percent variance and percent difference refers to a mathematical assessment of a result by the following equation:

$$\text{Percent Variance} = \frac{\text{Actual Value-Target value}}{\text{Target value}} \times 100$$

Positive control refers to a laboratory sample that is treated the same as all other samples to produce an expected result, confirming that experimental procedure is functioning as expected.

Purity refers to the degree to which a substance is made up of the intended chemical form with minimal impurities.

Reanalysis refers to testing performed after a failed batch testing result that is performed by the same lab that performed the original analysis and performed using the same representative sample of the batch.

Resins refer to hemp or cannabis concentrates (Minnesota Statutes, section 342.01, subd. 15 and subd. 35) prepared using solvents in the extraction or refining process.

Retention sample refers to a portion of the representative sample taken from each batch that is held by the licensee until six months after the product expiration date.

Retest refers to testing performed after a failed batch testing result that is performed by a separate lab than the original analysis and is performed on a separate representative sample of the batch.

Rosins refer to hemp or cannabis concentrates (Minnesota Statutes, section 342.01, subd. 15 and subd. 35) prepared without using solvents in the extraction or refining process.

Sample duplicate refers to a sample that is analyzed twice. This must represent two separate preparations. The sample should be chosen at random and run together on the same analytical run.

Sterility control refers to an exposed plate that will act as an environmental negative control to account for environmental contamination during the preparation of plated microbiological samples.

Testing Required by Product Type

Overview

To protect public health and ensure products meet consumer expectations, each batch of product must be sampled and analyzed to ensure that harmful contaminants are not present in the product above the specified limits prior to entering the retail market. The contaminants to be evaluated include microbial, mycotoxins, heavy metals, pesticides, residual solvents, and foreign matter. Each product must also be tested to ensure that the reported concentration of cannabinoids is accurate. This risk-based testing scheme ensures that contaminants are tested for each product while minimizing testing on the final product.

How to Navigate the Required Testing Flow Chart

In the product testing flow chart on page 6, the risk-based testing scheme is diagramed. There are three main product categories that will reach the market in this testing scheme: dried flower, concentrates, and manufactured finished products. Refer to the definitions listed above to understand how each category is used in the flow diagram. Each of the test categories listed for the products is further explained in the corresponding sections (I – X) that follow the diagram. For a text description of the flow chart, refer to Appendix A.

Cannabis or Hemp Flower

When a cultivator has dried flower intended to be packaged for retail sales, they will prepare a representative sample of the batch and send that sample to a state licensed lab to perform the required testing as listed for each category: microbial, mycotoxins, heavy metals, pesticides, foreign matter, potency, and stability. Each batch of flower tested must meet the requirements delineated in this document. Once testing is complete and the flower has been demonstrated to meet the criteria, the product can enter the retail market.

If flower is intended to be further processed into concentrate, no batch testing is required under this testing standard. However, it is recommended that microbial, heavy metals, pesticides, and potency are tested. Microbial, heavy metal, and pesticide contaminants can be carried through and concentrated when cannabinoid concentrates are prepared. Testing that these contaminants meet criteria prior to the extraction can help to ensure the concentrate will also meet the criteria after extraction.

Concentrate

Once a manufacturer has produced a cannabis concentrate intended to be packaged for retail sales or to use the product to manufacture finished products, they will prepare a representative sample of the batch and send that sample to the state licensed lab to perform the required testing as listed for each category: microbial, mycotoxins, heavy metals, pesticides, residual solvents, potency, and stability. Each batch of concentrate tested must meet the requirements delineated in this document. Once testing is complete and the product is demonstrated to meet the criteria, the product can enter the retail market or be utilized to manufacture finished products.

Manufactured Final Products

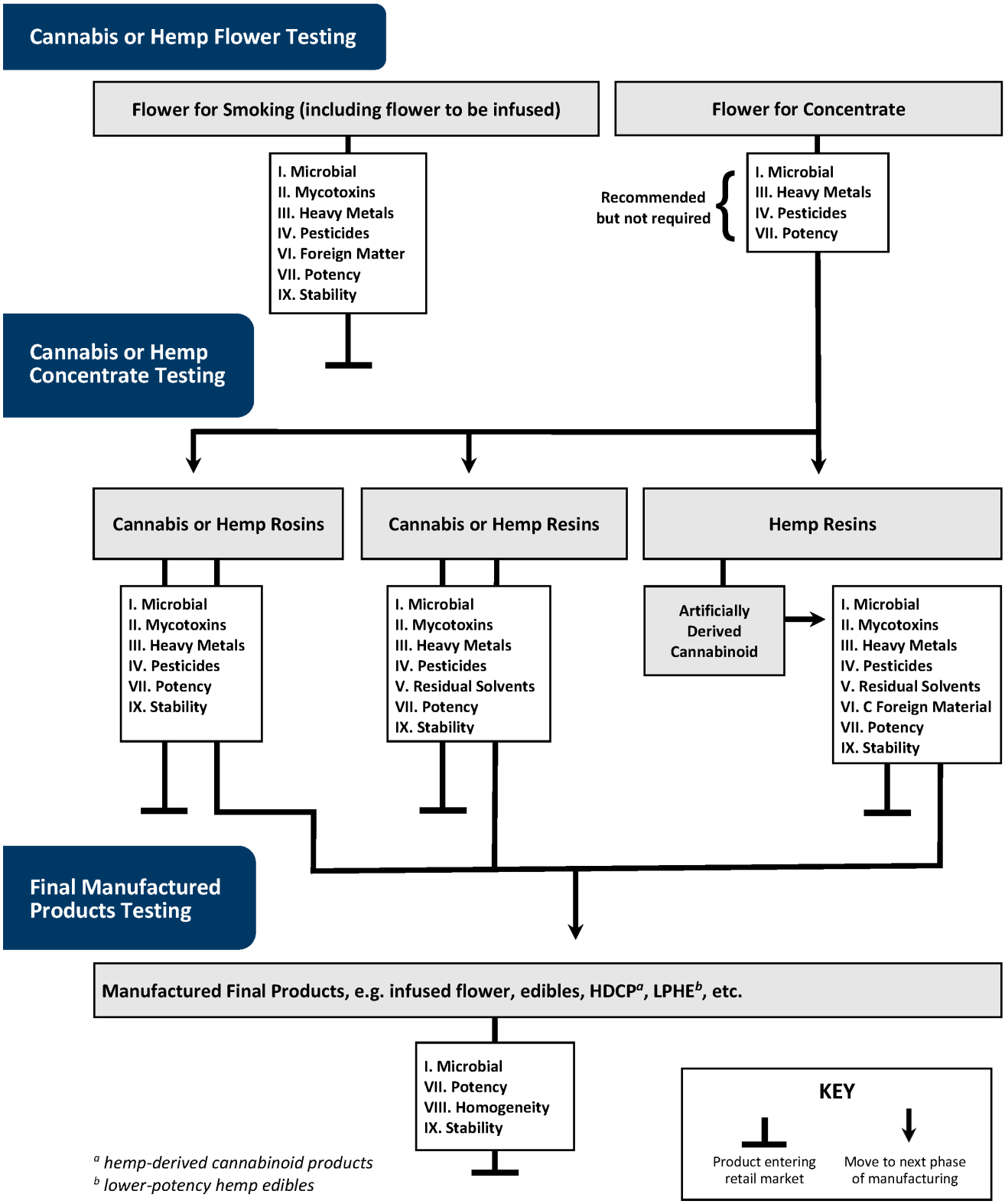
When a manufacturer uses cannabis flower or concentrate that has been tested for the relevant contaminants and the flower or concentrate meet the criteria specified in this document, then the product does not need to be tested for those same contaminants again, as long as the production or packaging process does not introduce or enhance the potential for the contaminant category in the regulated product. The manufacturer must conduct a risk assessment for each contaminant to document that the testing regime is appropriate, and no contaminant risk potentials are overlooked. For example, vape cartridges may leach heavy metals into the finished product, therefore heavy metals contamination should be evaluated in the final product for vape devices.

When a manufacturer has a finished product intended to enter the retail market, they will prepare a representative sample of the batch and send that sample to the state licensed lab to perform the required testing as listed for each category: microbial, potency, homogeneity, and stability. Each batch of manufactured final products tested must meet the requirements delineated in this document. Once testing is complete and the product is demonstrated to meet the criteria, the product can enter the retail market.

Products entering the Minnesota market from Tribal entities or other states

When a cultivator or manufacturer has a cannabis or hemp product to import into the Minnesota market, the product must have full panel testing performed on the finished product. The cultivator or manufacturer will prepare a representative sample of the batch and send that sample to a state licensed lab to perform the required testing as listed for each category: microbial, mycotoxins, heavy metals, pesticides, residual solvents, foreign matter, potency, homogeneity and stability. Each batch tested must be tested in accordance with the testing instructions and meet the requirements delineated in this document. Once testing is complete and the product is demonstrated to meet the criteria, the product can enter the retail market.

Required Testing Flow Chart



[a] *hemp-derived cannabinoid products*
[b] *lower-potency hemp edibles*

Testing Analytes and Limits

This technical standard provides the lists of contaminants and the acceptable tolerances that the licensed laboratories are required to report. The tolerances were established following a review of available literature in the cannabis industry as well as references from the International Conference for Harmonization (ICH) Guideline Q3C on Impurities and the ICH Guideline Q3D on Elemental Impurities Guidance for Industry.

I. Microbiological Testing

A. Microbial Analysis

A representative sample from each batch of flower, concentrate, and final products must be tested for microbiological contaminants using appropriate aseptic techniques. A sample passes the microbiological contaminant test if it meets the following standards for microbial and fungal limits in colony forming units per gram (CFU/g):

Microbial Target	Dried Raw Flower[a]	Concentrate	Infused Non-Edibles	Infused Edibles
Total aerobic microbial	< 10^5 CFU/g	Not applicable	Not applicable	Not applicable
Total yeast and mold	< 10^5 CFU/g	Not applicable	Not applicable	Not applicable
Enterobacteriaceae	< 10^3 CFU/g	150 CFU/g	150 CFU/g	150 CFU/g
Salmonella species[b]	Not detected in 10 g	Not detected in 5 g	Not detected in 10 g	Not detected in 25 g
Shiga toxin-producing E. coli[b]	Not detected in 10 g	Not detected in 5 g	Not detected in 10 g	Not detected in 25 g
L. monocytogenes[b]	Not applicable	Not detected in 5 g	Not detected in 10 g	Not detected in 25 g
Aspergillus spp. [b,c]	Not detected in 10 g	Not detected in 5 g	Not detected in 10 g	Not detected in 25 g

[a]Including combination products

[b]Sample enrichment/pre-enrichment is required prior to screening for pathogens. If a pathogen is detected during a screening method, a confirmatory test is required to verify the pathogen.

[c]Pathogenic *Aspergillus* spp. include *Aspergillus niger, Aspergillus flavus, Aspergillus fumigatus, Aspergillus terreus*

Detection of total aerobic microbial or total yeast and mold analysis above the specified limit for medical cannabis will result in a failed batch. Detection of total aerobic microbial or total yeast and mold analysis above the specified limit for adult use cannabis or hemp flower will alert OCM of the result and require that the licensee perform an investigation as to what led to the high total aerobic microbial and total yeast and mold result. The licensee must document and implement a corrective action and preventive action (CAPA) plan to address the specific conditions which led to the high results and identify the changes that will be made such as improving sanitation, before the flower can be released to the market or further processing. Further evaluation of pathogens will inform whether the product can be remediated or if it should be destroyed.

Cannabis or hemp flower that did not meet the criteria for microbial load may be allowed to undergo remediation.

B. Water Activity

Water activity (A_W) is a measure of the available water that is available for microbiological growth.

Acceptable water activity limits for cannabis and hemp flower and edible products. Liquid edible products are excluded from water activity testing.

Water Activity	(A_W)
Flower products	< 0.65
Edible products	< 0.85

Note: The calculation for percent content for any tested component including cannabinoid profile should not be adjusted based on the water content.

II. Mycotoxin Testing

Mycotoxin	Limit for flower product (ppb)	Limit for Concentrate (ppb)
Aflatoxin B1	< 5	< 20
Aflatoxin B2	< 20	< 20
Aflatoxin G1	< 20	< 20
Aflatoxin G2	< 20	< 20
Ochratoxin A	< 20	< 20

A product fails for mycotoxin testing if any of the compounds are detected above the limit, or if the combined total of mycotoxins is > 20 ppb.

III. Heavy Metals Testing

Element	Limit for inhalation products (ppm)	Limit for non-inhalation products (ppm)
Arsenic	0.2	1.5
Cadmium	0.2	0.5
Lead	0.5	0.5
Mercury	0.1	3

A product fails for heavy metals if any of the tested metals are detected above the specified limit. Note: inorganic arsenic, not total arsenic, is the species of concern. If a product fails for total arsenic, a confirmatory test may be run to determine if the amount of inorganic arsenic is below the specified limit.

IV. Pesticide Residuals Testing

All crop-inputs must be tracked in the statewide monitoring system per Minnesota Rules, part 9810.1302, subp. 5B and Minnesota Rules, part 9810.2000, subp. 13D. The following list does not indicate that the following compounds are legally approved for application to cannabis plants in Minnesota, nor is it meant to limit which products are allowed to be used on cannabis plants. The following list was assembled based on current assessment of substances found in cannabis products in the U.S. market. The compound levels identified are those at which the OCM will take regulatory action against products and associated responsible parties, up to and including product destruction.

A batch fails pesticide testing if the presence of one of the following is above the following listed limit.

List of Pesticide Analytes for Compliance Testing

This table does not constitute a list of compounds approved for application to cannabis or hemp plants. This table lists compounds for which cannabis will be tested. It includes both high risk compounds and compounds that might be suitable for use on cannabis and/or hemp. Prior to use, refer to a pesticide's label to determine if it may be used on cannabis or hemp.

Substance	Chemical Abstract Services (CAS) Registry number	Limit (ppm)
Abamectin	71751-41-2	0.5
Acephate	30560-19-1	0.4
Acequinocyl	57960-19-7	2
Acetamiprid	135410-20-7	0.2
Azadirachtin	11141-17-6	1
Azoxystrobin	131860-33-8	0.2
Bifenazate	149877-41-8	0.2
Bifenthrin	82657-04-3	0.2
Boscalid	188425-85-6	0.4
Carbaryl	63-25-2	0.2
Chlorantraniliprole	500008-45-7	0.2
Chlorfenapyr	122453-73-0	1
Chlormequat Chloride	999-81-5	0.2
Chlorpyrifos (Dursban)	2921-88-2	0.2
Clofentezine	74115-24-5	0.2
Cyfluthrin	68359-37-5	1
Cypermethrin	52315-07-8	1
Daminozide	1596-84-5	1
DDVP (Dichlorvos)	62-73-7	0.1
Diazinon	333-41-5	0.2
Dimethoate	60-51-5	0.2
Etofenprox	80844-07-1	0.4
Etoxazole	153233-91-1	0.2
Fenoxycarb	72490-01-8	0.2
Fenpyroximate	134098-61-6	0.4

Substance	Chemical Abstract Services (CAS) Registry number	Limit (ppm)
Fipronil	120068-37-3	0.4
Flonicamid	158062-67-0	1
Fludioxonil	131341-86-1	0.4
Hexythiazox	78587-05-0	1
Imazalil	35554-44-0	0.2
Imidacloprid	138261-41-3	0.4
Kresoxim-methyl	143390-89-0	0.4
Malathion	121-75-5	0.2
Metalaxyl	57837-19-1	0.2
Methiocarb	2032-65-7	0.2
Methomyl	16752-77-5	0.4
Myclobutanil	88671-89-0	0.2
Naled	300-76-5	0.5
Oxamyl	23135-22-0	1
Paclobutrazol	76738-62-0	0.4
Permethrins[a]	52645-53-1	0.3
Phosmet	732-11-6	0.2
Piperonyl Butoxide	51-03-6	2
Prallethrin	23031-36-9	0.2
Propiconazole	60207-90-1	0.4
Propoxur	114-26-1	0.2
Pyrethrins[b]	8003-34-7	1
Pyridaben	96489-71-3	0.2
Spinosad	168316-95-8	0.2
Spiromesifen	283594-90-1	0.2
Spirotetramat	203313-25-1	0.2
Tebuconazole	80443-41-0	0.4
Thiamethoxam	153719-23-4	0.2
Trifloxystrobin	141517-21-7	0.2

[a]Permethrins should be measured as cumulative residue of cis- and trans-permethrin isomers (CAS numbers 54774-45-7 and 51877-74-8).

[b]Pyrethrins should be measured as the cumulative residues of Cinerin I (CAS # 25402-06-6), Jasmolin I (CAS # 4466-14-2), Pyrethrin I (CAS # 121-21-1), Cinerin II (CAS # 121-20-0), Jasmolin II (CAS # 1172-63-0), and Pyrethrin II (CAS # 121-29-9).

V. Residual Solvent Testing

All solvents and foreign materials used in the production of products regulated by OCM must be disclosed to the office per Minnesota Statutes, section 342.61, subd. 4b.

The following list was assembled based on current assessment of substances used in cannabis product manufacturing in the U.S. market. The compound levels identified are those at which the OCM will take regulatory action against products and associated responsible parties, up to and including product destruction.

A batch fails residual solvent testing if the presence of one of the following is above the following listed limit. Products produced using solvents that do not have established limits will be assessed individually as part of the manufacturing approval process.

List of Solvent Analytes for Compliance Testing

Substance	Edible Product Limit (ppm)[a]	Inhalable Product Limit (ppm)[b]
Acetone	5000	750
Benzene	2	1
Butane	5000	800
Chloroform	2	1
Cyclohexane	3880	300
Dichloromethane	600	125
Ethanol	5000	1000
Ethyl Acetate	5000	400
Heptane	5000	500
Hexane	290	50
Isopropanol (2-Propanol)	5000	500
Methanol	3000	250
Pentane	3000	750
Propane	5000	2100
Toluene	890	150
Trichloroethene (Trichloroethylene)	80	25
Total Xylenes	2170	150

[a]Including concentrates used to produce edible products

[b]Including concentrates used to produce inhalable products

VI. Foreign Material Testing

A. Gross Foreign Matter

The presence of any foreign material including but not limited to hair, insects, organic particulates, natural fibers, filth, or any plant-based adulterant on any cannabis or hemp products primarily consisting of plant parts results in failure for foreign matter when they are detected above 5% by mass after inspection and dissection as described below in the portion of the sample analyzed for foreign matter.

The presence of any foreign material that is sharp, hard, or can puncture (including but not limited to glass, metal, plastics) or any synthetic adulterant (including but not limited to plastics) on any cannabis or hemp products primarily consisting of plant parts results in failure for foreign matter when they are detected above 1% by mass in the product.

If a sample fails for foreign matter testing, then the laboratory must include a note in the statewide tracking system listing the contaminants identified.

A magnification of up to 10x is suitable for routine examination, and higher magnifications may be employed where necessary.

1. The laboratory should perform foreign material testing of not less than 30% of the total representative sample of intact buds and flower material prior to sample grinding or milling.
2. The buds should be separated into no less than 10 increments, the results from which can be averaged together as total foreign matter contamination.
3. Dissection of nodes should be done whenever physically possible.
4. If dissection of distinct nodes is deemed unnecessary due to the small and compact nature of the buds, then the buds should be examined in their entirety and additionally cut in half to observe the inside portion.
5. Quantitation of filth should be done by mass.
6. Calculations should be included in standard operating procedures.

B. Restrictions on Products for Vaporization or Inhalation

Solutions prepared for vaporization or inhalation must not contain the following:

1. Medium-chain triglycerides (MCT)
2. Polyethylene glycol (PEG)
3. Vegetable glycerin (VG)
4. Vitamin E acetate
5. Diacetyl
6. Squalene

C. Restrictions on Residual Foreign Material in Artificially Derived Cannabinoids

The presence of any foreign material including but not limited to solvents or catalysts used in the derivation of cannabinoids must not be detected at a harmful level in the derived cannabinoid product. It is the responsibility of the manufacturer of artificially derived cannabinoid products to disclose any solvents or catalysts used and to demonstrate that the solvents or catalysts are sufficiently removed from the final product.

VII. Potency Testing – Cannabinoid Content

A. Cannabinoid Screening

A representative sample from each batch must be tested to establish the concentration of the following cannabinoid analytes, reported as the percentage content by weight or mg/serving. Each cannabinoid should be reported if it is detected above the LOD established by the licensed laboratory following the standard method performance requirements listed in this document. The percent content should not be adjusted based on the water content of the product.

1. delta-9-tetrahydrocannabinol (THC)
2. delta-9-tetrahydrocannabinolic acid (THCA)
3. cannabidiol (CBD)
4. cannabidiolic acid (CBDA)
5. cannabinol (CBN)
6. cannabigerol (CBG)
7. cannabigerolic acid (CBGA)
8. delta-8 tetrahydrocannabinol (delta-8 THC)
9. tetrahydrocannabivarin (THCV)
10. cannabichromene (CBC)

B. Total THC and Total CBD

In addition, the testing laboratory must calculate and report the total THC content and total CBD content:

1. total THC content is defined in Minnesota Statutes, section 342.01, subd. 69.b, and it is calculated:

   Total THC = %THC + (%THCA x 0.877)

2. total CBD content is calculated:

   Total CBD = %CBD + (%CBDA x 0.877)

C. Cannabinoid Purity

In addition to the cannabinoid profile required for all products (listed in A above), any product that contains or that may contain artificially derived cannabinoids, including but not limited to lower-potency hemp edible products and hemp-derived consumer products, must be tested for purity. If detected, compounds that are not among the target analytes and are unknown, unidentified, tentatively identified, or that are known, should have their estimated concentration determined based on peak area comparison to the CBD calibration curve. The ratio by weight of delta-9-THC to all other artificially derived cannabinoids must be no less than 20 to 1 (at least 95% delta-9-THC) [Minnesota Statutes, section 342.01, subd. 50 (b)(1)(iii)].

D. Restrictions for Other Artificially Derived Cannabinoids

A batch of any product containing artificially derived cannabinoids fails if it contains more than a combined total of 0.5 milligrams of all other cannabinoids per serving other than delta-9 THC, CBD, CBG, CBN, and CBC [Minnesota Statutes, section 342.01, subd. 50 (b)(1)(ii)].

E. Testing Variance

The measured percent cannabinoid content for any product with a label claim for cannabinoid content must be within 15% of the label amount for each compound listed. For non-intoxicating cannabinoids present at low levels (< 5%) in products with more than 70% THC, the allowed variance is 25% of the label amount.

VIII. Homogeneity Testing

Homogeneity testing is required to be demonstrated for all products with serving units. Homogeneity must be evaluated on the final packaged form of the product. This includes but is not limited to edibles (including gummies and beverages), lozenges, and patches. Homogeneity must be demonstrated on the first batch for each manufacturing process. If the manufacturing process changes, homogeneity must be demonstrated for the new manufacturing process.

To perform homogeneity testing, each unit shall be treated as a separate individual sample and a total of 10 units shall be sampled at random. If there are multiple units in a single package (for example multiple units marked on a chocolate bar or multiple gummies in one package) the random sample units tested should represent both different units within the same package and units from different packages. The weight of the unit and concentration of the cannabinoid present in the highest amount according to the product label must be recorded.

The variability of the weight of the unit and the concentration of the cannabinoid present in the highest amount in the tested portions may not exceed ± 15% difference as compared to the claim on the label.

IX. Stability Testing

Stability testing is required for all products. Product stability must be evaluated in the final packaged form to establish an expiration date for the product. Product stability must be established on the first batch for each cultivation or manufacturing process. If the cultivation or manufacturing process changes, stability must be demonstrated for the new cultivation or manufacturing process.

For each stability test timepoint, the cultivator, producer, or lab will document storage of a portion of sample from one batch in the final packaged form. The sample must be stored at the conditions specified on the product label or, if none is indicated, at room temperature and not in direct sunlight until the stability test timepoint. The manufacturer must provide the licensed testing laboratory with an adequate sample volume in the final packaged form to generate a sufficiently sized composite of the samples at each stability test timepoint. The manufacturer may test at whatever time increments are appropriate for the material.

At the stability test timepoint the sample will be analyzed for microbial content (as specified in Section I), cannabinoid profile (as specified in Section VII), and any contaminant category that could leach from the packaging. For example, solutions stored in vape devices should be tested for heavy metals.

To meet the stability requirements for each timepoint, the microbial content must meet those specified in Section I and the concentration of the cannabinoid present at the highest concentration must vary by less than 15% of the label claim as compared to the potency determined at T=0 or, if there is no label claim, from the amount determined at T = 0.

Until data has been collected establishing evidence-based expiration dates, a cannabis product will have a six-month expiration date. If a licensee has data to support a longer expiration date on the first batch, they can submit that data to the office for evaluation on a case-by-case basis. Stability testing must be initiated within three months for any new products. Failure to demonstrate six-month stability will result in an assigned expiration date as the last demonstrated passing results for that product.

X. Terpene Analysis

Terpene analysis is required for all products with added terpenes or a label claim for terpene content (Minnesota Rules, part 9810.1401). The label claim for terpene content must be supported on the certificate of analysis (COA) by lab testing for terpenes that are added as an ingredient or for which a label claim amount is listed. For terpenes with a label claim of quantity, the test results may not exceed ± 15% difference as compared to the claim on the label. Terpene content may also be tested and included on the COA at the request of the product manufacturer or cultivator.

The testing laboratory must report the result of the terpene testing on the COA both as a percentage and in either milligrams per gram (mg/g) if by weight, milligrams per milliliter (mg/mL) if by volume, or mg/serving for label potency reporting.

Testing Instructions

Test Scheduling and Reporting

A. Batch Testing

All regulatory batch testing must be scheduled through the statewide monitoring system within two business days of sampling the batch. For each product type, testing should follow the flow chart on Page 6.

1. It is the responsibility of the cultivator or manufacturer to ensure that all necessary testing is performed for each batch.
2. It is the responsibility of the cultivator to provide an accurate and complete list of pesticides applied to the batch to the state licensed lab through the statewide monitoring system when pesticide testing is requested.
3. It is the responsibility of the manufacturer to provide an accurate and complete list of solvents or catalysts used in extraction or conversion to the state licensed labs through the statewide monitoring system when residual solvent or foreign material testing is requested.

Additional tests may be performed per the licensees' request. If the primary licensed laboratory is unable to perform all necessary testing, the tests may be subcontracted to other state licensed laboratories for testing. Testing results must be uploaded directly into the statewide monitoring network by the state licensed laboratory.

All required testing must be complete, demonstrated to meet the requirements of this document, and reported in the statewide monitoring system before any product can be moved to retail sales or used for manufacturing other products. All test results must be reported in the statewide monitoring system within two business days of test completion. Through this reporting system, the test lab will notify OCM and the licensed producer of the test results simultaneously through upload to the statewide monitoring system. After test results are entered in the statewide monitoring system, the product will be released for sale or further processing.

B. Testing for Research and Development

Any cultivator or manufacturer may submit samples of cannabis or hemp flower and cannabis or hemp products for research and development purposes. Such testing may not satisfy the mandatory compliance testing requirements of these regulations. Any sample transferred to a testing facility for these purposes must be deemed a sample for research and development purposes in the statewide monitoring system prior to being transferred. All samples for research and development purposes must be transferred to a testing facility in accordance with regulations. The test results of the research and development samples will be labeled as such in the statewide monitoring system and cannot be used for batch release analysis.

C. Failed Test Samples

1. Reanalysis: If a licensee is notified of a failed testing result, they may request a reanalysis of the same sample from the same laboratory within seven days of being notified of the failure. The laboratory may only conduct reanalysis for the compliance test that initially failed. The licensee must notify the office if a reanalysis is requested for a failed sample.
    a. If the reanalysis results in another fail, the associated batch must be held for destruction or remediation per Minnesota Rules, part 9810.3100, subp. 9.
    b. If the reanalysis results in a pass, then the associated batch must be resampled, and a different licensed lab must retest the sample to determine if the product meets the testing criteria.
2. Retesting: Retesting must be completed by a second laboratory within 30 days from the date the retesting was requested. Retesting may not be performed at a laboratory under the same ownership as the original laboratory that performed the original testing and may not be done by a laboratory that was subcontracted to do the original testing.
    a. If the retesting results in another fail, the associated batch must be held for destruction or remediation per Minnesota Rules, part 9810.3100, subp 9.
    b. If the retesting results in a pass, then the associated batch is considered to have passed that test.
3. Limitations for failed batches
    a. A sample may only be reanalyzed once, and a batch may only be retested once.
    b. If reanalysis or retesting is performed, then the batch must remain in its original quantity as it was initially submitted to the laboratory for testing and may not be subdivided or combined with other batches as part of remediation or further processing.
    c. Each state licensed lab must have a policy stating the laboratory analysis conditions that must be met to allow a reanalysis or retest of the sample if there is no failed test result.
    d. The COA for the batch must indicate that the results are from a reanalyzed or retested sample.

Sampling

Overview:

Proper sampling procedures are essential to ensure that representative samples are being analyzed and therefore testing results are accurate for the whole batch of product or material. Sampling procedures must include proper collection, labeling, preservation, transportation, and storage by trained personnel to ensure sample integrity and chain of custody are maintained. The steps in the sampling procedure must be followed exactly every time to reliably and consistently provide the laboratory with a representative sample.

Licensed cannabis/hemp manufacturers and cultivators must follow a statistically valid sampling method by developing their own validated method or by following the method as detailed below. It is the responsibility of the licensee to adopt a sampling standard operating procedure (SOP) that minimizes imprecision and bias and lists chronological steps to ensure a consistent and repeatable method. All staff collecting samples for testing must be trained on proper procedures and periodically monitored by the manager or owner to ensure the procedures are consistently followed. Sampling must also be done in areas that are under video surveillance.

The amount of sample required for testing may vary due to sample matrix, analytical method, and laboratory-specific procedures. The amount sampled per this procedure will take into account the compliance sample size required for laboratory testing, and the retention sample size, which must be retained and stored by the business for six months after the expiration date.

A. Equipment

1. Personal protective equipment (PPE) – Nitrile gloves, at a minimum. Evaluate the need for other specific PPE depending on the materials being handled (example: dust mask for handling flower material).
2. Calibrated balance
3. Two sterile sample collection vessels (more vessels will be needed for samples required for stability and homogeneity testing) – note: sample collection vessels should be made of inert material that does not leach substances that may skew results, such as heavy metals or foreign material, or alter the sample in anyway.
4. Isopropyl alcohol/ethanol or other sanitizer
5. Required Metrc tags

B. Procedure

1. Wash hands, then put on nitrile gloves to mitigate the risk of contamination of the sample during the collection process.
2. Ensure the work surface and balance are clean and sterilized.
3. Any sampling device required such as a probe, dipper, or scoop must be sterilized prior to use.
4. Label a sterile collection vessel with the appropriate batch number from the statewide monitoring system and confirm the batch or lot mass. Do not sample if pertinent information is not available. Refer to Minnesota Rules, part 9810.3100, subp.7b(6) for the required labeling information.
5. Collect the sample:
    a. The minimum sample volume to be collected from each batch is 0.5% of the batch mass and not less than 60 g of flower, 32 g of concentrate, 60 g of infused non-edible, 60 g of infused edible, or 200 mL of a beverage. The sample volume must meet or exceed minimum volume requirements for all compliance testing performed. The minimum number of sample increments listed below must be collected for the gross sample (this includes both compliance and retain sample).
    b. Withdraw samples from the upper, middle, and lower sections of each container. Do not sample within 6 inches of any outer surface of the batch, when possible.
    c. In circumstances where there are from one to 10 containers in a batch, collect a sample from each container, take the samples from the top, middle, or bottom of the containers at random.
    d. Record the time the sample was collected, any inconsistencies with the sampling plan, and any other remarks that may be relevant to data analysis or quality assurance.

e. For processed products: Each sample must be taken in final product form from randomly chosen positions in the lot. The sample may be taken before or after final packaging. The sample volume must meet or exceed minimum volume requirements for all compliance testing performed. If an agitator or mixer is required to keep the liquid properly mixed, then it must be in use during sampling. Note: homogeneity and stability must be evaluated on the final packaged form of the product.

6. Once you have collected the sample, remove the retention sample amount, weigh using calibrated balance, and place into a labeled, sterile sample collection vessel. The retention sample must be retained and stored by the business until six months after the expiration date.
7. Place the remainder of the sample after removing retention sample in a second collection vessel, label, and seal. If stability or homogeneity are being tested, the sample mass and quantity of individual collection vessels must reflect the amount required for the necessary tests.
8. Document the appropriate chain of custody information to be recorded in the statewide monitoring system and on the laboratory chain of custody form.
9. Samples should be securely stored as appropriate for the specific matrix until they are submitted to the laboratory, i.e., perishable items must be refrigerated or cold-packed during transit.

Batch Mass	Compliance Sample Size*	Minimum Laboratory Analysis Sample Size	Retention Sample Size
≤10 lbs	10 sample increments totaling 0.5 % of the batch mass	• Flower: 40 g • Concentrate: 22 g • Infused non-edible: 40 g • Infused edible: 40 g or 200 mL	• Flower: 20 g • Concentrate: 10 g • Infused non-edible: 20 g • Infused edible: 20 g or 100 mL
>10 lbs	12 sample increments totaling 0.5 % of the batch mass	• Flower: 40 g • Concentrate: 22 g • Infused non-edible: 40 g • Infused edible: 40 g or 200 mL	• Flower: 20 g • Concentrate: 10 g • Infused non-edible: 20 g • Infused edible: 20 g or 100 mL

*Sample size must meet the minimum amount required for laboratory analysis.

Requirements for State Licensed Labs

The state licensed labs must meet the requirements listed in Minnesota Statutes, section 342.38, and Minnesota Rules, part 9810.3000. As well as:

A. Impartiality of Testing Facility

Pursuant to Minnesota Statutes, section 342.37, ISO 17025, and Minnesota Rules Part 9810.3000, testing facilities are responsible for ensuring the impartiality of testing results in order to maintain the independence of the Minnesota cannabis marketplace, a person, cooperative or business holding a cannabis testing facility license must maintain a conflict of interest policy. The policy must demonstrate that a testing facility:

1. Does not employ anyone who owns any portion of another cannabis business;
2. Does not employ anyone who receives financial compensation from another cannabis business;
3. Prohibits the testing of products that were cultivated or manufactured by another cannabis business that has any shared ownership, equity, or investment interest with the testing facility; and
4. Identifies and prohibits other potential conflicts of interest that would result in the perception of conflicts of interest that threaten the impartiality of the testing facility; this includes but is not limited to:

- Any shared cannabis business ownership or investment interest amongst the immediate family the testing facility's owners, investors, or employees; or
- Any testing of products that were cultivated or manufactured by another cannabis business that employees the immediate family of the testing facility's owners, investors, or employees.

Test results from a lab in violation of the testing standards, including the impartiality of testing facility requirement, are invalid. To meet the testing requirements of this document, the sample must be tested by an impartial testing facility.

B. Statewide Monitoring System

Per Minnesota Rules, part 9810.3000, subp. 9, the state licensed labs must use the statewide monitoring system to track the samples sent for testing and to upload the results for customers.

C. Required Sample Amount

Each state licensed lab must clearly state a minimum test sample amount required for batch testing so that the customers can easily determine the sample quantity required for each set of required tests.

D. Testing Timeline

Each state licensed lab must initiate testing any sample received for microbial analysis within five days to maintain the integrity of the samples. All sample testing should be completed within 10 days. Licensed testing laboratories must notify OCM if the timeline for reporting results will not be met due to an equipment failure and the estimated timeframe for the report to be filed in the statewide monitoring system. The notification must be made prior to the deadline for reporting results.

E. Proficiency Testing

Per Minnesota Rules, part 9810.3000, subp.4b (3), each state licensed lab must participate in proficiency testing programs to demonstrate that the results generated by the lab meet the testing criteria. Each state licensed laboratory must have a proficiency testing plan that meets the criteria below:

1. The proficiency testing provider must be ISO 17043 accredited.
2. All state licensed labs must report the results of all proficiency testing to OCM.
3. A state licensed lab must participate in a proficiency testing program for each approved test category in which it seeks certification.
4. To maintain continued certification, a state licensed lab must participate in the designated proficiency testing program with continued satisfactory performance.
5. The state licensed lab must participate in proficiency testing twice annually for each testing category in which they are certified. When proficiency tests are available in multiple matrices for the same analytes, the laboratory is not expected to test all matrices twice annually. However, the laboratory should participate in proficiency testing for all relevant matrices within the calendar year.
6. A state licensed lab must analyze the proficiency testing samples using the same procedures with the same number of replicate analyses, standards, testing analysts, and equipment as used in its standard operating procedures.
7. A state licensed lab must meet the criteria set by the proficiency testing provider to positively identify 80% of the target analytes tested to be considered satisfactory. A positive identification must include accurate quantitative and qualitative results as applicable. Failing to identify 80% of the target compounds or any false positive results reported will be considered an unsatisfactory score for the proficiency testing event.

8. A state licensed lab must take and document corrective action and preventive action if any of the proficiency testing results are outside of the acceptable range set by the proficiency testing provider. Corrective action and preventive documentation must include a review of samples tested and results reported since the last successful proficiency testing event.
9. Consecutive unsatisfactory proficiency testing scores may result in limitation, suspension, or revocation of the license.

F. Quality Control Requirements

Each licensed lab must demonstrate testing validity for each set of samples analyzed. The state licensed laboratories must have criteria for each of the following in the SOP for each method. The method SOP must also include steps to be taken if any of the following criteria are not met for an analysis. The quality control (QC) must simulate the samples during each phase. If the sample tested is going through an incubation at a specific temperature, then the QC must mirror it on the same medium. The quality control measures that must be demonstrated for each analysis include but are not limited to:

1. Chemistry tests
    a. Initial calibration verification to demonstrate accuracy and precision
    b. Laboratory reagent blank free from background contamination
    c. Limit of quantification demonstrated
    d. Laboratory control sample
    e. One sample duplicate analyzed per set of 20 samples
    f. Continuing calibration confirmed after no more than 10 samples
2. Microbiological tests: Microbial QC must mimic the sample analysis and needs to run through every incubation period during every run (i.e., a broth base analysis must include a broth-based QC, and a plate-based analysis must include a plate-based QC).
    a. Sterility control and/or negative control as appropriate
    b. Positive control
    c. Molecular based tests must include an internal standard for amplification

Certificates of Analysis

A. Certificate of Analysis Reports

A state licensed laboratory shall issue to the licensed processor a certificate of analysis (COA) for each lot, with supporting data, to report:

1. Sample-identifying information, including matrix type and unique sample identifiers and descriptions (e.g., composite sample, dried plant material, remediated batch, etc.).
2. Sample history, including date collected, date received by the testing laboratory, and whether the sample was tested as received or sampled by the testing laboratory.
3. Dates of sample preparations and analyses.
4. Identities of test methods used to perform analyses.
5. Measurement uncertainty and limits of detection and/or limits of quantitation with the results of each sample.
6. The total primary sample weight in grams, reported to three significant figures, that was analyzed in each individual analysis.

7. Pass or fail indication that the presence of contaminants tested does not exceed the levels provided in Sections I through VI, and a disclaimer that not all potential/existing hazards were tested.
8. The concentration of each cannabinoid specified in Section VII.
9. Amounts of any terpenes listed as ingredients or added to any products.
10. Any compounds detected during the analyses of the sample that are not among the targeted analytes and are unknown, unidentified, tentatively identified or known.
11. The COA must indicate if the results represent a reanalysis or retest of a sample.

B. Quality Assurance

The testing laboratory must validate the accuracy of the information contained in the COA, and the facility director or other employee responsible for quality assurance must sign and date the COA.

C. COA Corrections

If an error is discovered following the issuance of the COA, the testing laboratory must correct the error through reissuance of a corrected COA. If the client requests an updated COA for any other reason, the lab can reissue a corrected COA. The corrected COA must state that it is a reissued version of a previous COA and must include the original sample identifiers as well as the reason for reissuance.

D. COA Accessibility

COAs for the cannabinoid profile of products offered for sale in retail establishments must be made available to customers upon request and be available in the statewide monitoring system.

Performance Tested Methods and Method Performance Requirements

Per Minnesota Rules, part 9810.3000, subp. 6B, a testing facility must use analytical testing methodologies for the required safety tests prescribed by Minnesota Statutes, section 342.61, subd. 2, and Minnesota Rules, part 9810.3100, subp. 4, that are based upon published peer-reviewed methods, have been validated for cannabis testing by an independent third party, and have been internally verified by the licensed laboratory according to Appendix J or K of the AOAC International's Official Methods of Analysis, 22nd Edition, with guidance from published cannabis standard method performance requirements where available. Method verification results must demonstrate sufficient specificity and sensitivity to meet the reporting limit requirements for each analyte for which the lab is approved. Method validation procedures for testing methods that are based on independently developed and validated methods must meet AOAC International validation guidelines, AOAC Standard Method Performance Requirements (SMPRs) if any exist, and the limits set in this document.

Recommended Methods and Method Validation Standards

For each set of analytes evaluated in parts I through VII above, the following methods are recommended by OCM.

1. Microbial Contaminants

Enumeration Methods

DRBC via method/matrix extension of BAM Chapter 18 for total yeast and mold

CompactDry YMR AOAC PTM 092002

Petrifilm Rapid Yeast and Mold (RYM) Count Plate AOAC PTM 121301

TEMPO YM (Yeasts/Molds) AOAC PTM 041001

TEMPO AC (Aerobic Count) AOAC PTM 121204

TEMPO EB (Enterobacteriaceae) AOAC PTM 050801

USP Chapter <61> Microbiological Examination of Nonsterile Products: Microbial Enumeration Tests

AOAC Official Method 997.02 3M Petrifilm Yeast and Mold Count Plate for the Enumeration of Yeasts and Molds in Dried Cannabis Flower

AOAC Official Method 990.12 Aerobic Plate count in Foods: Dry Rehydratable Film Method

AOAC Official Method 2003.01 Enumeration of Enterobacteriaceae in Selected Foods

Soleris Direct Yeast & Mold Test AOAC PTM 051301

Soleris Enterobacteriaceae Vial AOAC PTM 121901

EnviroX-F AOAC PTM 092001

PathogenDx QuantX Fungal One Step AOAC PTM 072105

PathogenDx DetectX Combined with Optional Live/Dead AOAC PTM 012201

BAM Chapter 3: Aerobic Plate Count

PathoSEEK Total Yeast & Mold Detection Assay AOAC PTM 062401

Pathogen Methods

GENE-UP PRO STEC/Salmonella Assay AOAC PTM 092101

GENE-UP Salmonella 2 (SLM2) AOAC PTM 121802

GENE-UP Listeria species (LIS) AOAC PTM 121803

GENE-UP Listeria monocytogenes (LMO) AOAC PTM 121804

GENE-UP Aspergillus PRO AOAC PTM 022103

GENE-UP PRO STEC/Salmonella Assay AOAC PTM 092101

GENE-UP EHEC Series AOAC PTM 121806

iQ-Check Salmonella II Real-Time PCR AOAC PTM 010803

iQ-Check STEC VirX/SerO/SerO II Real-Time PCR AOAC PTM 121203

Molecular Detection Assay 2 – Salmonella (MDA2 – SAL) AOAC PTM 091501

Molecular Detection Assay 2 – STEC Gene Screen (MDA2-STXEAE) AOAC PTM 071902

Molecular Detection Assay 2 – STEC Gene Screen (MDA2-STX) AOAC PTM 071903

PathoSEEK Salmonella and STEC E.coli Multiplex Assay with SenSATIVAx Extraction AOAC PTM 022202

PathoSEEK Salmonella and STEC E.coli Multiplex Assay with SenSATIVAx Extraction AOAC PTM 022202

BAX System Real-Time PCR Assay Suite for STEC AOAC PTM 091301

BAX System Real-Time PCR Assay for E.coli 0157:H7 Exact AOAC PTM 102003

Clear Micro SalSTEC Mplex AOAC PTM 082301

BAM Chapter 4A: Diarrheagenic Escherichia coli

BAM Chapter 5: Salmonella

BAM Chapter 10: Detection of Listeria monocytogenes in Foods and Environmental Samples, and Enumeration of Listeria monocytogenes in Foods

Method Performance Parameters

AOAC SMPR 2021.009 Standard Method Performance Requirements (SMPRs) for Viable Yeast and Mold Count Enumeration in Cannabis and Cannabis Products

AOAC SMPR 2020.002 Standard Method Performance Requirements (SMPRs) for Detection of Salmonella species in Cannabis and Cannabis Products

AOAC SMPR 2020.012 Standard Method Performance Requirements (SMPRs) for Detection of Shiga Toxin-Producing Escherichia coli in Cannabis and Cannabis Products

AOAC SMPR 2019.001 Standard Method Performance Requirements (SMPRs) for Detection of Aspergillus in Cannabis and Cannabis Products

2. Water Activity

Method

ASTM D8196-22 Standard Practice for Determination of Water Activity in Cannabis Flower

3. Mycotoxins

Method Performance Parameters

AOAC SMPR 2020.013 Standard Method Performance Requirements (SMPRs) for Mycotoxin Screening Technique in Cannabis Plant Material and Cannabis Derivatives

4. Heavy Metals

Methods

AOAC Official Method 2021.03 Heavy Metals in a Variety of Cannabis and Cannabis-Derived Products Inductively Coupled Plasma–Mass Spectrometry (First Action 2021)

EPA 6010D ICP-OES

EPA 6020B ICP-MS

USP General Chapter <233>

Method Performance Parameters

AOAC SMPR 2020.001 Standard Method Performance Requirements (SMPRs) for Determination of Heavy Metals in a Variety of Cannabis and Cannabis-Derived Products

AOAC SMPR 2023.005 Standard Method Performance Requirements (SMPRs) for Determination of Heavy Metals in Cannabis-Containing Beverages

5. Pesticides

Methods

ASTM D8399-23 Standard Test Method for Multi-residue Analysis of Pesticides in Dried Cannabis and Hemp Raw Materials Using Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS)

Method Performance Parameters

AOAC SMPR 2018.011 Standard Method Performance Requirements (SMPRs) for Identification and Quantitation of Selected Pesticide Residues in Dried Cannabis Materials

AOAC SMPR 2023.001 Standard Method Performance Requirements (SMPRs) for Determination of Pesticides in Cannabis-Containing Beverages

6. Residual Solvents

Methods

USP Chapter <467> Residual Solvents

EPA Methods 5021A (Headspace Sampling), 8015D (GC-FID) and 8260D (GC-MS)

Method Performance Parameters

AOAC SMPR 2019.002 Standard Method Performance Requirements (SMPRs) for Identification and Quantitation of Selected Residual Solvents in Cannabis-Derived Materials

7. Potency

Methods

AOAC Official Method 2018.10 Cannabinoids in Cannabis sativa Dried Flowers and Oils Liquid Chromatography with UV Detection

AOAC Official Method 2018.11 Quantitation of Cannabinoids in Cannabis Dried Plant Materials, Concentrates, and Oils: Liquid Chromatography-Diode Array Detection Technique with Optional Mass Spectrometric Detection

Method Performance Parameters

AOAC SMPR 2017.002 for Quantitation of Cannabinoids in Dried Plant Materials

AOAC SMPR 2017.019 for Quantitation of Cannabinoids in Edible Chocolate

AOAC SMPR 2017.001 Quantitation of Cannabinoids in Cannabis Concentrates

AOAC SMPR 2022.001 for Quantitation of Cannabinoids in Beverages

AOAC SMPR 2019.003 for Quantitation of Cannabinoids in Plant Materials of Hemp

8. Homogeneity

Method

USP Chapter <905> Uniformity of Dosage Units

Appendix A – Text Details for Required Testing Flow Chart

Cannabis or Hemp Flower Testing

Flower for Smoking (including flower to be infused)

All cannabis or hemp flower for smoking, including flower to be infused, must be evaluated for and meet the requirements for the following tests:

- I. Microbial
- II. Mycotoxins
- III. Heavy Metals
- IV. Pesticides
- VI. Foreign Matter
- VII. Potency
- IX. Stability

Once testing is complete and the flower has been demonstrated to meet the criteria outlined in this document, the product can enter the retail market.

Flower for Concentrate

The following tests are recommended but not required for flower for concentrate:

- I. Microbial
- III. Heavy Metals
- IV. Pesticides
- VII. Potency

All relevant contaminants will be evaluated under cannabis or hemp concentrate testing.

Cannabis or Hemp Concentrate Testing

Cannabis or Hemp Rosin

If the cannabis or hemp concentrate was extracted without solvent, it is considered a cannabis or hemp rosin. The cannabis or hemp rosin must be evaluated and meet the requirements for the following tests:

- I. Microbial
- II. Mycotoxins
- III. Heavy Metals
- IV. Pesticides
- VII. Potency
- IX. Stability

Once testing is complete and the product has been demonstrated to meet the criteria outlined in this document, the product can enter the retail market or be utilized to manufacture finished products.

Cannabis or Hemp Resins

If the cannabis or hemp concentrate was extracted with a solvent, it is considered a cannabis or hemp resin. The refined cannabis or hemp resin must be evaluated for and meet the requirements for the following tests:

- I. Microbial
- II. Mycotoxins
- III. Heavy Metals
- IV. Pesticides
- V. Residual Solvents
- VII. Potency
- IX. Stability

Once testing is complete and the product has been demonstrated to meet the criteria outlined in this document, the product can enter the retail market or be utilized to manufacture finished products.

Hemp Resins: Artificially Derived Cannabinoid

If the cannabis or hemp concentrate is used to make artificially derived cannabinoids, the resulting concentrate must be evaluated for and meet the requirements for the following tests:

- I. Microbial
- II. Mycotoxins
- III. Heavy Metals
- IV. Pesticides
- V. Residual Solvents
- VI. Foreign Material, specifically part C for catalysts
- VII. Potency
- IX. Stability

Once testing is complete and the product has been demonstrated to meet the criteria outlined in this document, the product can enter the retail market or be utilized to manufacture finished products.

Final Manufactured Products Testing

Manufactured final products, e.g. infused flower, edibles, hemp-derived cannabinoid products (HDCP), lower-potency hemp edibles (LPHE), etc. produced using cannabis or hemp rosin, resin or artificially derived cannabinoid concentrate that met all contaminant testing requirements at a minimum must be evaluated for the following:

- I. Microbial
- VII. Potency
- VIII. Homogeneity
- IX. Stability

Once testing is complete and the product has been demonstrated to meet the criteria outlined in this document, the product can enter the retail market.

Revision Log

Document version	Date of revision	Summary of revision
1.2	August 21, 2025	Disclaimer added to “List of Pesticide Analytes for Compliance Testing” table on page 9.
1.1	June 13, 2025	Document name updated. Corrections and clarifications made to content on pages 1, 5, 7, 21, and 22. Alterations to requirements made on pages 7, 14, and 18.
1.0	April 10, 2025	Document published.