Laboratory Testing and Sampling Guidance for Adult-Use Processor Licensees and Registered Organizations

Introduction

The New York State Office of Cannabis Management (Office) is issuing updated guidance to entities authorized by the Office to cultivate or process any cannabis or cannabis products (licensees) clarifying cannabis product testing requirements. Specifically, this guidance details:

1. **Guidelines to address cannabis product types that can be tested by permitted laboratories**
2. **A summary of all tests required under the Office's final product testing requirements**
3. **Updated guidance for the requirement of homogeneity for cannabis products**
4. **Cannabis Lot Testing Guidance**

Licensees should refer to this guidance, as well as any other regulations and guidance issued by the Office when preparing for final product testing of their adult-use cannabis products. If you have any questions about the guidance, please contact compliance@ocm.ny.gov.

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Priority of Testing

Pursuant to Section 130.7 (g) of Part 130 laboratory regulations, laboratories are required to dedicate a percentage of their testing capacity to licensees that are businesses with limited resources as determined by the Office, and to Registered Organizations for medical cannabis product testing pursuant to the requirements set forth in Subchapter B of Title 9. As such, laboratories will reserve 60% of their daily capacity for individual lot testing for adult-use cannabis products licensees, 35% of their daily capacity for individual lot testing for medical cannabis products, and 5% for research and development. Should a laboratory's reserved capacity not be utilized for each of these categories, they may re-allocate testing slots to fill vacant testing slots.

Cannabis Product Testing -Types of Products for Testing

As required by Section 82 of Cannabis Law, every processor of cannabis products must contract with an independent cannabis laboratory, permitted pursuant to Section 129 of the Cannabis Law, to test the cannabis products it produces.

Table 1. Various Cannabis Product Types or Forms that can be Tested

Category	Type or Form	Description
Cannabis Flower Products	**Cannabis Flower Products**	All cannabis flower products, including whole flower, ground flower, or manufactured flower products (such as a pre-roll or tobacco-free blunt. This also includes pre-rolls dipped in kief).
Concentrated Cannabis	**Oil for Vaporization**	Oil to be used in a vaporizer.
	Topicals	All products intended for topical use containing >3% THC. Some examples are balms, lotions, and body oils.
	Wax or Shatter	Concentrated cannabis extracted using a solvent. Some examples are budder, sauce, shatter, crystals, and crumble.
	Resin	Concentrated cannabis extracted using a solventless method. Some examples are kief, hash, and rosin.
Cannabis Edible Products	**Gel-based foods**	Any cannabis edible product that is intended to be chewed and relies upon a gelling agent such as, but not limited to, gelatin, agar, or pectin to maintain its shape or texture. Some examples are fruit chews, gummies, and chewable gel capsules.
	Tablets, Capsules, and Lozenges	Includes all tablets, capsules, and lozenges.
	Oral Liquids	Homogeneous oral liquids including tinctures, oral solutions, syrups, and oral emulsions.
	Water-Soluble Edibles	Edible products which are intended to be dissolved in water before consumption. Some examples are dissolving powders and effervescent tablets.
	Solid Chocolates	Includes all solid chocolates.

	Other Foods	Any food that is not a gel-based food or a solid chocolate. Some examples are baked goods, and coffee grounds.
	Beverages	All beverages.

* Shelf stable baked goods are allowed. However, the licensee must work with the laboratory to ensure they have the capability to test the food product being proposed. It is often helpful to send a laboratory a "blank" food product so they can make any adjustments to their methods to prepare and test this form of edible. Note that with cannabis baked goods, food safety, allergens and potential contaminants pose a risk and can become prevalent much faster than other cannabis products.

Guidance for Required Laboratory Testing of Cannabis Products

Please note, that not all permitted laboratories have a full scope of required testing. Check the Office's website for the scope of testing offered by each permitted laboratory. The table below summarizes the type of testing that is currently required based on product type.

Table 2. Required Testing

Type of Testing	Required	Product Type Test is Required for
Cannabinoid Profile	X	All product types
Pesticides	X	All product types
Metals	X	All product types
Mycotoxins	X	All product types
Microbiology	X	All product types
Moisture Content	X	Flower
Filth/Foreign Material	X	Flower
Water Activity	X	Flower and solid, edible infused products
Residual Solvents	X	Enhanced flower, concentrates and edibles
Terpenes	X	All product types
Total Aerobic Bacteria Count+	X	All product types
Total Yeast and Mold+	X	All product types

+There is not a defined limit for Total Aerobic Bacteria Count and Total Yeast and Mold in unextracted products (e.g. cannabis flower products) in the adult-use program. Total Yeast and Mold should be used as a general quality indicator. Yeast and Mold growth is a common occurrence in our environment and more prevalent on outdoor grown cannabis. Total yeast and mold tests do not necessarily correlate

with the presence or absence of a harmful mold. Molds can potentially be a cause of allergic hypersensitivity reactions in consumers, can be harmful to consumers who are immunocompromised, and affect a cannabis product's shelf stability. It is the responsibility of the licensee to consider these test results and any impact to stability and expiration dating of the product, as well as any risks to the health of consumers. The Office will monitor these laboratory testing results and licensees may be required to conduct further testing where results indicate concerns with product quality or safety.

Homogeneity Testing for Adult-Use and Medical Cannabis Products

Except for cannabis flower products, a final cannabis product must be homogenous, with phytocannabinoid content evenly distributed throughout the cannabis product. Unless otherwise approved by the Office, a cannabis product shall be considered homogenous if the concentration of total THC and CBD is within 25% of the mean concentration of total THC and CBD in milligrams per single serving for that submitted lot with the exception that, for products with a specified total THC and CBD concentration less than two (2) milligrams per single serving, the concentration of each sample for that low concentration phytocannabinoid shall be within 0.5 milligrams per serving of the mean concentration.

Laboratories must test five (5) samples of cannabis product for homogeneity, regardless of batch or lot size, when products submitted for testing are new offerings from a licensee. Once initial homogeneity testing is completed on three (3) consecutive lot/batches and the results demonstrate the product is homogeneous, all subsequent lots/batches may forego homogeneity unless:

- There is a significant change to the standard operating procedures affecting the manufacturing of a previously produced cannabis product including but not limited to batch/lot size or volume, mixing or handling methods, change in ingredients, change in equipment; or
- Any other instance that may significantly affect homogeneity.

It is the licensee's responsibility to retain homogeneity records for five (5) years and make such records readily available to the Office upon request, to justify foregoing homogeneity testing. Homogeneity testing is not required for cannabis flower products.

Cannabis Lot Testing Guidance

Each batch/lot of cannabis product must be tested by an OCM Permitted Laboratory. A representative sample must be used to conduct this testing. Effective July 1, 2023, licensees must utilize approved cannabis sampling firms for the sampling and transportation of their final cannabis product samples for laboratory testing. A list of approved cannabis sampling firms can be found on the Office's website: Sampling Firms | Office of Cannabis Management (ny.gov).

A representative sample is defined in the Office's published guidance as a sample of cannabis product of the same size and composition that is required for cannabis product testing by a cannabis laboratory that represents a unique lot of cannabis product that is processed. Licensees are required to retain representative sample(s), and they must be stored on-site at the licensee's facilities to allow for testing in the future if requested by the Office.

Full lot processing completion, in ready-to-consume final product form, is mandatory prior to submitting samples for final product testing. This ensures that random sampling is performed and that the samples are representative of the lot produced.

Ready-to-consume final product form is a cannabis product that requires no further processing and ready for final packaging. Examples of final product form include but are not limited to: flower ready to be jarred; tablets, capsules, and chewable gels ready to be bottled; concentrates or oils ready to be placed in a device or cartridge; tinctures or other oral liquids ready to be bottled; or beverages ready to be bottled/canned.

The samples collected from a lot must be placed in the final packaging before they can be sent to the laboratory for testing. This can be done at the time of sample collection.

Please note that the entire lot does not have to be packaged in final packaging prior to sample collection provided that the licensee complies with the following:

- Certificates of analysis on ingredients/excipients indicating:
  - For all products (except vaporization products): ingredients/excipients are appropriate for the cannabis product type manufactured and are, at a minimum, food grade or considered generally recognized as safe;
  - For vaporization products: except for cannabis or botanically derived terpenes, excipients and ingredients must be pharmaceutical grade and appropriate for an inhaled cannabis product; and
- Documentation that indicates that the containers are food-grade, or of a similar standard approved by the Office, for the storage of cannabis and cannabis products. Containers must be clean, in good repair, suitable for the established use, and must be compliant with Part 128 Packaging and Labeling regulations.
- Quarantined product awaiting testing and packaging must be segregated in a designated area for storage and must be clearly labeled as to include but not limited to product name, product type, total quantity, lot/batch number, date of production, and date of expiration.

- Quarantined product that has passed all compliance testing must be packaged in a timely manner to ensure quality of the product in accordance with individual standard operating procedures using good manufacturing practice for each product type.
- The bulk storage of final product prior to packaging must not exceed six (6) months form the date of testing. Any final product that is in bulk storage exceeding 6 months must be resampled and have a full panel of required testing performed.
- Following GMP standards and to the satisfaction of the Office, a licensee must be able to provide documentation that ensures that products meet legal prerequisites for safety and quality during the time final product remains in bulk storage between receiving final product testing results and the conclusion of completely packaging the final product lot within a concurrent timeframe. Documentation must include but not limited to specifications of sanitary containers used, environmental controls, stability information, and any other pertinent information that ensures the final product remains unadulterated.

Once the licensee receives passing compliance testing results from the permitted laboratory, the licensee must package the entire lot prior to releasing for retail sale.

Acceptable final packaging, for testing purposes, is the layer of packaging in which the product comes in contact. Examples:

- Sealed Vaporization Cartridge /disposable pen
- Gummies in mylar bags
- Whole Flower in jars
- Pre-rolls in tubes
- Bottles of tincture

Final packaging, for testing purposes, does not require complete regulatory labeling, but at minimum must include the product name and form, specific unique lot number, net contents and target potencies.

Table 3. Cannabis Product Types

Product Type	Description	Lot and Sample
Cannabis Flower	Loose cannabis flower whole or ground.	Samples must be in packaging/containers as it would be sold to the consumer. (Jar, bag, etc.) Remainder of the lot must be stored in manner to ensure general sanitary practices and product stability. Remainder of the lot can be packaged after passing compliance testing results.

Pre-Rolled Cannabis Flower	Cannabis flower loaded, rolled and ready for consumption.	Samples must be packed in final packaging (Bag, doob tube, other compliant containers). Pre-roll lots in their entirety must be rolled prior to testing and can be stored in a manner to ensure general sanitary practices and product stability. Remainder of the lot can be packaged after receiving passing compliance testing results.
Oil for Vaporization	Pre-filled vape cartridges and prefilled disposable pens.	Samples must be in the layer of packaging in which the product comes in contact (Prefilled cartridge or disposable pen). Remainder of the lot must be stored in manner to ensure general sanitary practices and product stability. Remainder of the lot can be packaged after passing compliance testing results.
Topicals	All products intended for topical use containing >3% THC. Some examples are balms, lotions, and body oils.	Samples must be in packaging/containers as it would be sold to the consumer. Remainder of the lot must be stored in manner to ensure general sanitary practices and product stability. Remainder of the lot can be packaged after passing compliance testing results.
Wax, Shatter, Resin	Concentrated cannabis extracted using a solvent. Some examples are budder, sauce, shatter, crystals, and crumble.	Samples must be in packaging/containers as it would be sold to the consumer. Remainder of the lot must be stored in manner to ensure general sanitary practices and product stability. Remainder of the lot can be packaged after passing compliance testing results.
Gel-based foods, Water-Soluble Edibles, Tablets,	Includes: • Any cannabis edible product that is intended to be chewed and relies upon a gelling agent such as, but not limited to, gelatin, agar, or	Samples must be in packaging / containers as it would be sold to the consumer (bottles, mylar bags, jars, vials, etc).

Capsules, Solid Chocolates, and Lozenges	pectin to maintain its shape or texture. Some examples are fruit chews, gummies, and chewable gel capsules. • Tablets, capsules, and lozenges. • Edible products which are intended to be dissolved in water before consumption. Some examples are dissolving powders and effervescent tablets. • Edible products which are intended to be dissolved in water before consumption. Some examples are dissolving powders and effervescent tablets.	Remainder of the lot must be stored in a manner to ensure general sanitary practices and product stability. Remainder of the lot can be packaged after receiving compliance testing results.
Oral Liquids	Homogeneous oral liquids including tinctures, oral solutions, syrups, and oral emulsions.	Samples must be in the layer of packaging in which the product comes in contact (bottle, vial, dropper, etc). Remainder of the lot must be stored in manner to ensure general sanitary practices and product stability. Remainder of the lot can be packaged after passing compliance testing results.
Beverages	All beverages.	Samples must be sent in the bottled/canned form ready for consumption. Remainder of the lot must be stored in manner to ensure general sanitary practices and product stability. Remainder of the lot can be packaged after passing compliance testing results.

A random statistically significant sample of products from each lot of cannabis products produced must be tested. "How much" or the representative sample of products depends on the lot size. Refer to the Sampling Quality System Standard on this webpage: Sampling Firms | Office of Cannabis Management (ny.gov). Sampling Quality System Standard

All cannabis products must include a lot-unique identifier. The Office Sampling Quality System Standard for final product testing defines a lot-unique identifier as any distinctive combination of letters,

numbers, or symbols, or any combination of them, from which the complete history of production, manufacturing, testing, holding, distribution, or recall of a lot of adult-use cannabis product can be determined.

A cannabis product batch, or lot, is defined in Part 130 laboratory regulations as a uniquely defined quantity of cannabis product; including pre-rolls, that is uniform in processing, manufacture, and packaging within a concurrent time frame. The time frame may extend to more than one shift over a few workdays, provided that the prior criteria is met.

Revision Record

Date	Revisions Made
November 2022	Original Publication
June 2023	Line testing was removed from the guidance.
November 2023	Homogeneity criteria was updated from greater than +/- one (1) standard deviation to within 25% of the mean concentration of total THC and CBD.
June 2024	Updated table formatting and added clarification regarding timeframe limitation for packaging of product that is in bulk storage. Removed reference to conditional licensees and adding full licensees and registered organizations.