



Cannabis Final Form Packaging

Laboratory Testing Guidance

October 25, 2024

Testing cannabis in final packaging is intended to improve the accuracy of the information reported on a Certificate of Analysis (COA) by testing the product in the packaged form it will be received by the consumer. Testing cannabis in the final form and inside of its final packaging provides laboratory testing results that are the most representative of what an individual will actually consume, and it also reduces risks associated with:

1. Contamination, adulteration, degradation or mix-up during the packaging process;
2. Harmful interactions between the packaging and the cannabis in final form, such as heavy metal leaching from vape cartridges;
3. Additional manufacturing occurring after COA testing that may change the constitution or otherwise alter a batch; and
4. Reporting errors between Cannabis Establishments and cannabis testing laboratories.

The Department appreciates licensees' efforts to adjust their processes to comply with this new legal requirement and applauds their commitment to better protect consumers and patients.

What does “in final packaging” mean?

Final packaging is the inner-most layer of packaging that directly touches the product and preserves its integrity. If the licensee chooses to utilize an inner package and outer package in combination to meet the requirements of section 21a-421j-31(c) of the Adult Use Policies and Procedures, the cannabis does not need to be placed in the outer packaging until the licensee receives a passing COA for the batch. While waiting for the COA to be issued after collecting the representative samples, the remainder of the batch must be stored in a manner to prevent degradation, adulteration, contamination or mix-up until such time that the additional packaging can be applied.

Example: Oil in vape cartridges is considered to be in final packaging for the purpose of submitting for COA testing. The vape cartridge does not need to be placed in an exterior package that will only be used for the purpose of meeting the standard for light-resistance. Vape cartridges should be stored in a light-resistant, labeled bin while awaiting testing.

What does in a “timeframe and manner that ensures consistency and integrity between the batch and the samples taken from such batch” mean?

This language is meant to be flexible and allow packaging over multiple days, provided the process, environment and resources used all result in a consistent product. Licensees must comply with their internal policies and procedures related to safe and sanitary production, manufacturing, handling and storage of cannabis, which are submitted to the Department prior to final licensure and upon renewal each year. If

inconsistency is identified within a batch that was packaged over multiple days, it may indicate a need for changes to the licensee's internal policies and procedures.

How should my product in “final packaging” appear in the Cannabis Analytic Tracking System?

As soon as a cannabis product is in “final packaging” (not including any external packaging required to comply with section 21a-421j-31), the registrant should convert it in the Cannabis Analytic Tracking System (CATS) into units of finished product. It should not continue to be reflected as an intermediate product that is tracked by weight in CATS. Each unit must contain the same quantity of product as the sample selected by the laboratory for testing. If products tested as individual units are subsequently sold in multi-unit packages, those multi-unit packages must be entered into CATS as individual units.

Example: A vape product that is tested on an individual unit basis, and later sold as a 3-pack, shall be reflected as 3 vape cartridges, accounting for each individual vape cartridge included in the multi-pack.

How should test results be uploaded to CATS for each packaged unit?

The test results for any usable cannabis (flower, trim, grind, pre-rolls, and other raw cannabis products) should be entered as percent by weight. The test results for any extract products (i.e. concentrates, vapes, infused pre-rolls, edibles, topicals) should be entered as the total milligrams (mg) in the net weight of the sample provided.

Example: For a package of 10 gummies, the results entered into CATS should include the total mg for each active ingredient in the entire package of 10 gummies, not the single dose per gummy. However, the single dose per gummy may also be included on the official Certificate of Analysis.

What about Certificates of Analysis received after 9/15/2024 from samples pulled for testing prior to 9/15/24?

Certificates of Analysis received for tests performed on parent batches prior to 9/15/2024 may be applied to the derivative products, as evidenced in CATS, provided that the product has been stored and packaged in a manner to prevent degradation, adulteration, contamination or mix-up. All COAs received on products submitted for testing after 9/15/24 may only be applied to the final, packaged product batch sampled by the cannabis testing laboratory.

What if I pack my product and then subsequently fail testing?

In order to inform batch processing and avoid unsatisfactory test results after packaging, operators are encouraged to perform preliminary testing prior to packaging. Operators may create smaller batch sizes and test the packaging itself to address concerns with test failures in final packaging. Operators following GMP and 21 CFR 211 subparts B, C, D, and J, as required by the Adult Use Policies and Procedures, should have a high level of confidence in their ability to package cannabis in a way that prevents contamination and leads to satisfactory final package testing results. In the event packaged product does fail testing for a COA, the product may be remediated and/or retested in accordance with Public Act 24-76 Section 3(d). Remediation may or may not require the product to be removed from its final package, depending on the licensee's approved internal policies and procedures for remediation and equipment specifications.

How should batches be labeled and stored to prevent mix-ups while awaiting lab results?

This is ultimately a business decision, but the Department encourages operators to promptly and clearly label each unit that is in final packaging to distinguish it from other like products while awaiting test results. Such labeling might include useful information such as the corresponding batch unique identifier, or UID,

(automatically assigned in CATS) and date of packaging, along with other information to differentiate the product. All final packaged units in a batch should be stored together, in a secure storage location and segregated from all other batches. Your standard operating procedures and quality assurance programs should be updated considering the unique circumstances of your organization and your staff should be trained to ensure compliance.