

## **Cannabis Sampling Guide Updated 4/1/2022**

The Oregon Health Authority writes rules for testing cannabis that effect both the medical and recreational market. Newly adopted testing rules go into effect March 31, 2022, that make many changes to testing. This guide is a summary of the major changes and should not be relied on solely. You may review the testing rules, found in Division 7 and 64, in full at [healthoregon.org/ommprules](https://healthoregon.org/ommprules).

### **ORELAP sampling protocols updates**

- ORELAP-SOP-001 (usable marijuana) revision 4.1 effective July 1, 2022.
- ORELAP-SOP-002 (concentrates/extracts/products/hemp vapor items) revision 4.3 effective March 31, 2022.

Protocols may be found on [ORELAP's website](#).

### **Finished Inhalable Cannabinoid Products**

Finished inhalable cannabinoid products are a subcategory of cannabinoid products and ORELAP-SOP-002 should be followed for sampling these items. They should be sampled according to OAR 333-007-0360, Exhibit B, Table 7. Finished inhalable cannabinoid products will be required to be compliance tested once they are finished, but before they are packaged, for pesticides, solvents (if required), adult use cannabinoids and CBD concentration, mycotoxins if manufactured on or after July 1, 2022, heavy metals contaminants if manufactured on or after March 1, 2023, and microbiological contaminants if manufactured on or after March 1, 2023.

Examples of items that fit under this category are things like infused pre-rolls or inhalable cannabinoid products with non-cannabis additives. Rules specific to testing them can be found under OAR 333-007-0341.

### **Preparing Composite Samples**

Starting March 31, 2022, a batch of marijuana or usable marijuana may consist of a harvest lot of a specifically identified quantity that is cultivated utilizing the same growing practices, harvested within a seven calendar-day period at the same location and cured under uniform conditions. The batch size may not exceed 15 pounds and starting July 1, 2022, the batch size may not exceed 50.0 pounds. The batch submitted for testing does not need to be strain specific, though if multiple strains are being grouped into a batch together, potency must be tested separately.

For potency testing, multiple batches of the same strain and substantially similar material in terms of appearance and quality may be combined. This generally means that trim and flower should not be combined for potency testing. Each quantity of dissimilar material would need to have their own potency test if they will be sold separately.

Each sample taken shall be homogenized individually at the laboratory. When a composite sample is being prepared for testing, a proportionally representative amount of material is withdrawn from each homogenized sample using the laboratory's formal subsampling method, and then the material from each sample is combined to produce the composite testing sample.

## **Sampling – Concentrates, Extracts, Finished Inhalable Products and Industrial Hemp-Derived Vapor Items**

The whole batch of finished cannabinoid concentrates, extracts, inhalable products and industrial hemp-derived vapor item must be available for sampling. Concentrates, extracts, finished inhalable cannabinoid products, and industrial hemp-derived vapor items are to be sampled according to OAR 333-007-0360, Exhibit B, Table 7.

- If the weight of the finished item is 12.0 kilograms or under only a primary and duplicate sample will be needed for tests required. The number of increments required per sample changes depending on batch weight.
- If the weight of the batch of finished items is over 12.0 kilograms, then a replicate sample will need to be taken but only tested for potency and solvents. The number of additional replicate samples changes depending on the weight of the batch. The number of increments required per sample changes depending on batch weight. Each additional replicate sample consists of the same number of increments as the primary and duplicate and is sampled using the same sampling technique as the primary and duplicate sample.

### Sampling Examples

*Example 1:* A 3.5kg batch requires a primary and duplicate sample to be analyzed separately for all required compliance tests. Each of the samples is made from five increments.

*Example 2:* A 6.5kg batch requires a primary and duplicate sample to be analyzed separately for all needed compliance tests. Each sample for this batch is made from seven increments.

*Example 3:* A 12.5kg batch requires a primary, a duplicate and one additional replicate sample. Each of the three samples is made from seven increments and is tested separately for residual solvents (if required) and potency. Two of the three samples (randomly selected) are named the primary and duplicate and are analyzed for all of the other required compliance tests.

*Example 4:* A 60.5 kg batch requires a primary, a duplicate and three additional replicate samples. Each of the five samples is made from seven increments and is tested separately for residual solvents (if required) and potency. Two of the five samples (randomly selected) are named the primary and duplicate and are analyzed for all of the other required compliance tests.

For batches with weight that exceeds those listed in 333-007-0360, Exhibit B, Table 7, a formula for calculating the number of replicate samples is found at the bottom of the table. Replicate samples are in addition to the primary and duplicate sample and only tested for residual solvents (if required) and potency. The formula calculates the number of replicate samples, which are defined as *in addition to* the primary and duplicate sample. The primary and duplicate samples are tested for all required compliance tests and are randomly selected according to the laboratory's policy and procedures, such as by using a random number generator.

## **Sampling – Products**

The whole batch of finished cannabinoid product must be available for sampling. Only a primary and duplicate sample will be required to be taken. A batch may not consist of more than 35,000 units of sale.

The allowance of unbaked edible items to be sampled will be allowed. Prior to sampling, the processor or processing site must ensure that the entire batch is available to the laboratory and in a form where the only remaining step to complete the edible is baking. If anything is added to the edible after baking, the entire batch must be baked and finished prior to sampling. The sampler must select the unbaked samples per the sampling plan and the samples must be baked by the processor at the processing site while the sampler remains at the processing site in order to not break chain of custody of the sampled item.

Process lots must consist of items that are uniform in texture and weight but may vary in flavor or color. The processor must ensure that the flavor or color variation does not result in a change of potency. Despite different flavors or color items may be sampled and tested together. If should be noted that:

- Different flavors or colors – ok if substituted for one another at a 1:1 ratio
- Different ingredients – not ok

*Acceptable product variation example:*

- A processor makes a batch of two different flavored cake pops. The batter is made and split in two, one lemon flavored and one orange flavored. The flavorings are used in the same quantity and the end products are consistent in texture and weight. There is no expected change in potency since the only difference is the use of a different flavoring agent. In this case, the two different flavors may be considered one batch and sampled and tested together.

*Unacceptable product variation examples:*

- A processor makes a batch of cookies that are different flavors. Chocolate chip cookies and peanut butter cookies may not be presented as one batch for sampling and testing since there is a texture difference. Each would need to be sampled from individually and have their own potency testing performed.
- A processor makes a batch of cupcakes with frosting. A batch of frosted and unfrosted cupcakes could not be presented as one batch for sampling and testing since there is a weight difference. Each would need to be sampled from individually and have their own potency testing performed.

A sufficient sample size must be taken for analysis of all requested tests and the quality control performed by the testing laboratory for these tests. This may mean additional sample increments must be taken to provide enough material in each sample for analysis of all required tests and the quality control performed by the testing laboratory for these tests.

### **Homogenization**

The requirement around homogenization is not changing but is being clarified to state that the entire combined sample must be homogenized prior to testing. If the homogenization process would invalidate the analysis for a required test, the laboratory must utilize a subsampling procedure to withdraw a portion of the sample prior to homogenization for the required test. Testing that would be invalidated by the homogenization process includes but is not limited to, cryogenic sterilization of the sample prior to microbiological analysis. Potency analysis shall not be performed on material subsampled prior to homogenization steps.

### **Laboratory Control Standards (LCS)**

LCS recovery limits are specified in OAR 333-064-0100, Exhibit C, Table 1. Ensure your laboratory meets all the limits for the tests you are accredited to perform by March 31, 2022.

New LCS and QC limits also include:

- Microbiology and chemistry tests now have specified QC parameters.
- Positive and negative controls for microbiology.
- Blank and laboratory control standard (LCS) for chemistry.
- Potency LCS limits are changing from 70 – 130 percent recovery to 90 – 110 percent recovery.
- Precision (RPD for primary/duplicate or RSD for replicate analyses) tightens from 20 to 10%.
- Limits of quantitation (LOQs) for all matrices must now be less than or equal to half of the action level for pesticides, solvents, heavy metals, and mycotoxins. LOQs for Total delta-9 THC and delta-8 THC must be less than or equal to 0.15%.

The full rule text for these changes may be found under OAR 333-064-0100.

### **Reporting cannabis test results when they exceed 100%**

If a laboratory's calculated adult use cannabinoid or CBD result exceeds 100 percent and the difference between the result and 100 percent is within the laboratory's calculated analytical uncertainty, the laboratory may report the result as 100 percent with a qualifying statement on the certificate of analysis or the laboratory may report the calculated result with or without a qualifying statement. If the difference between the result and 100 percent is outside the calculated analytical uncertainty, the calculated result shall be reported without correction.

- The qualifying statement on the certificate of analysis shall clearly state the calculated value and the laboratory's analytical uncertainty.
- For the purposes of calculating RPD or RSD, a laboratory shall use the calculated result and not the adjusted result described in this rule.

### **Reporting when duplicates or replicates are required**

Testing fails if the laboratory calculates an RPD of more than 10% between the primary and the duplicate results if the mean result is greater than half the action level for any analyte or calculates an RSD of more than 10% between all sample results if the mean result is greater than half the action level for any analyte.

Potency value is reported as an averaged concentration from all required samples but the individual potency results in the primary, duplicate, or replicate samples may not exceed the maximum concentration limit permitted on the package by more than 10%.

### **Reporting Results and Subcontracting**

When subcontracting out required compliance tests, the primary laboratory shall issue the final report. Subcontract laboratories have 24 hours to report a failing result to the primary laboratory from the time the analytical run was completed. The primary laboratory has 24 hours from receiving the failing result from the subcontracted laboratory to report the failing test result to Metrc and the client.