Control Study Certification Form

Form Instructions

What is this form?

The purpose of a control study is to determine if a manufacturer is using standard operating procedures (SOP) that result in a finished cannabinoid concentrate, extract or product that is homogeneous, and for cannabinoid products meets the potency target identified in the SOPs.

This is the form a manufacturer submits to obtain a certified control study. Manufacturers who may use this form include recreational marijuana processors, micro-tier producers with the concentrate processing endorsement, producers making kief, and hemp handler certificate holders requesting testing on products that are tracked in Metrc. Wholesalers may arrange testing on behalf of other licensees, but this form must be completed by the product manufacturer.

INSTRUCTIONS for completing this form:

- The product manufacturer completes and signs pages 1 and 2 and provide them to the laboratory when requesting compliance testing for the batch.
- After performing compliance testing, the primary laboratory completes page 3, then submits the form to OLCC.Labs@oregon.gov. Do not provide a copy of test results or SOP unless requested. Associated test results or other documentation may be requested by the Commission to verify the responses contained in this form.
- Every section of this form must be completed legibly. Incomplete or illegible forms will be returned to the licensee and will not be reviewed by OLCC until deficiencies are corrected.
- No blanks should be left in the form. The manufacturer or laboratory representative completing this form should write “Not Applicable” or “NA” in any section they believe is not applicable to the testing of the particular product. If blank spaces are left in the form, or the Commission determines that a “Not Applicable” or “NA” response is not appropriate for a particular section, the form will be returned to the licensee and will not be reviewed by OLCC until the deficiencies are corrected.
- The control study is invalidated and the product manufacturer must undergo a control study for a product again or must have batches sampled and tested as if the product had not undergone a control study if:
    - There are any changes to the standard operating procedures for that product;
    - There are any changes in the type of ingredient in the product, except for a difference in the strain of usable marijuana, or the purity of an ingredient; or
    - A batch tested under the control study fails a THC or CBD test as described in OAR 333-007-0440(10)(b).
- If a control study is invalidated for any reason listed in 333-007-0440(10) then a manufacturer must notify the OLCC.

This form and OAR 333-007-0440 refer to standard operating procedures (SOPs). The certification of a control study is based on the SOP and is invalidated if the manufacturer makes and changes to the SOP other than as allowed under OAR 333-007-0440(11). Note that OLCC rules (OAR 845-025-3230) require processors to maintain written policies and procedures that include:

- Instructions for making each cannabinoid concentrate, extract or product;
- The ingredients and the amount of each ingredient for each process lot;
- The process for making each product;
- The number of servings in a process lot;
- The intended amount of THC per serving and in a unit of sale of the product; and
- The process for making each process lot homogeneous.

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OAR 333-007-0440

Section 1 – Business Information

Manufacturer Name:			
License or Certificate Number:		**Email:**	
Name of Manufacturer Representative Who Completed This Form:			

Section 2 – Product Information

Commercial Name of Item:				
Item Category:	☐ Concentrate (Skip Section 4)	☐ Extract (Skip Section 4)	☐ Cannabinoid Product (Skip Section 3)	
SOP Name or Reference:				
SOP Version:		**SOP Date** (Created or Revised)**:**		
Item is Intended to be "Medical Grade" Potency? (OAR 333-007-0220)**:**	☐ Yes	☐ No	☐ N/A	
Does This Item Contain Marijuana? (For hemp-only items, see OAR 845-025-2760)**:**	☐ Yes	☐ No		
Item Texture:	☐ Solid	☐ Liquid	☐ Gas	☐ Other:

Section 3 – Concentrate or Extract Item Information

If the item is a cannabinoid product, skip this section.

Process Lot (Batch) Weight:	grams	**Item is Intended for:** (Check any that apply)	☐ For sale to consumer ☐ For further processing
Compliance Tests Performed:	☐ Pesticides	☐ Solvents	☐ Potency
If item is not intended for sale to consumers, skip the following line			
Unit of Sale Weight:	grams	**Number of Servings per Unit:**	

Section 4 – Cannabinoid Product Item Information

If the item is a concentrate or extract, skip this section.

Process Lot (Batch) Size:	units	**Target THC per Unit of Sale:**	mg	
Unit of Sale Weight:	grams	**Number of Servings per Unit:**		
Metrc Category: (Select one)	☐ Edible ☐ Infused Pre-roll ☐ Combined Category	☐ Tincture ☐ Topical ☐ Hemp Cannabinoid Product	☐ Capsule ☐ Suppository	

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Section 5 –Variations

Use this section to describe any variation of the item that would be permitted under OAR 333-007-0440(11) that you intend to qualify for reduced sampling and testing once the control study is certified.

Item variations cannot result from changes in the SOP. Making changes to the SOP invalidates the certification of a control study.

Cannabinoid Products only **Will you make variations that use different flavors or colors that do not have an effect on the potency of the finished cannabinoid product?:**				☐ Yes ☐ No ☐ N/A
Will you make item variations that vary in the size of the unit of sale?: (If Yes, use the following lines to list each variation in the unit of sale)				☐ Yes ☐ No ☐ N/A
Variation #1	**Unit of Sale Weight:**	grams	**Number of Servings per Unit:**	
Variation #2	**Unit of Sale Weight:**	grams	**Number of Servings per Unit:**	
Variation #3	**Unit of Sale Weight:**	grams	**Number of Servings per Unit:**	
Variation #4	**Unit of Sale Weight:**	grams	**Number of Servings per Unit:**	
Variation #5	**Unit of Sale Weight:**	grams	**Number of Servings per Unit:**	
Will you make any other kinds of variations allowed under OAR 333-007-0440(11): (If Yes, describe the variations in the space below)				☐ Yes ☐ No

Section 6 – Manufacturer Attestation

I have reviewed all information submitted in Sections 1 through 6 of this form. All information submitted is true and correct to the best of my knowledge. I attest that every variation listed is permitted under OAR 333-007-0440(11) and does not involve a change in the standard operating procedures. I understand that the products listed under this control study must continue to meet these standards for the duration of the Control Study certification and that failure to comply with any of the applicable rule requirements may result in an administrative sanction.

By signing my name below, I affirm that this form has been evaluated by myself or by an employee, agent, or other representative acting on my behalf. I understand that submitting false or misleading information to a laboratory is a violation of administrative rule. I understand I must notify OLCC if any condition occurs that invalidates the certification of this control study.

Signature: _____ **Date:** _____

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Section 7 – Laboratory Information

Laboratory Name:			
License Number:		**Email:**	
Name of Laboratory Representative Who Completed This Form:			

Section 8 – Potency Results

If the item is a concentrate or extract that did not undergo compliance testing for potency, skip this section.

Detected THC Range:	**Highest Sample Concentration**	**Lowest Sample Concentration**	**RSD**
	mg/g	mg/g	%
Detected CBD Range:	**Highest Sample Concentration**	**Lowest Sample Concentration**	**RSD**
	mg/g	mg/g	%

For cannabinoid products intended to contain at least 10 mg THC per unit of sale **What is the threshold where a sample exceeds the target THC potency by 20%?**	= 1.2 × THC_{unit} ÷ $Weight_{unit}$ mg/g ☐ N/A
Did any sample exceed the manufacturer's target THC potency by 20% or more?	☐ Yes ☐ No ☐ N/A
For items subject to the potency limits specified in OAR 333-007-0210 or 333-007-0220 **What is the threshold where a sample exceeds the THC concentration limit by 10%?**	= 1.1 × THC_{limit} ÷ $Weight_{unit}$ mg/g ☐ N/A
Did any sample exceed the THC concentration permitted in a package by 10% or more?	☐ Yes ☐ No ☐ N/A

Section 9 – Laboratory Attestations

OLCC will not certify the control study unless all of the following boxes are checked. If any of the following statements are not true, this item has not met all of the conditions for passing a control study.

By checking the boxes below, I certify that:

☐	The number of sample increments taken meet the requirements of OAR 333-007-0360, Exhibit B.
☐	Pesticide testing results for each sample were below the action limits set in Exhibit A, Table 3 to OAR 333-007-0400; or Pesticide testing was not required and was not conducted.
☐	The Limit of Quantification ("LOQ") for each pesticide tested for was below the action limits set in Exhibit A, Table 3 to OAR 333-007-0400; or Pesticide testing was not required and was not conducted.
☐	All solvents listed in Exhibit A, Table 4 of OAR 333-007-0410 were tested for; or Solvent testing was not required and was not conducted.
☐	All solvents test results for each sample were below the action limits set in Exhibit A, Table 4 of OAR 333-007-0410; or Solvent testing was not required and was not conducted.
☐	The Limit of Quantification ("LOQ") for each solvent was below the action limits set in Exhibit A, Table 4 to OAR 333-007-0410; or Solvent testing was not required and was not conducted.
☐	The Relative Standard Deviation (RSD") among total THC results and among total CBD results is below 20%; or Potency testing was not required and was not conducted.

For official OLCC use only

OLCC's certification of this form is entirely conditioned on the accuracy of the information provided by the manufacturer and the laboratory who completed this form. Submitting false or misleading information to the Commission is a violation of Oregon Administrative Rules.

Certification #:		**Control Study Expires On*:**	
Processed by:			

**Unless invalidated prior to this date*