

Master Manufacturing Protocol Checklist

The Master Manufacturing Protocol is a written document that describes how to make a cannabis product. It lists the type and amount of each ingredient to use and each step that must be followed to safely and consistently produce the product. This protocol helps reduce adulteration risk by preventing incorrect or unintended ingredients from being incorporated into a batch. It includes steps to mitigate the hazards identified in the manufacturing licensee's Product Quality Plan. It also ensures uniformity among all batches produced by the licensed manufacturer.

Licensed manufacturers must have a Master Manufacturing Protocol for each unique formula and batch size manufactured. The steps of the Master Manufacturing Protocol are documented in a Batch Production Record when they are performed. Master Manufacturing Protocols must be disclosed, upon request, to the Department of Cannabis Control (Department).

The checklist below will help verify that your Master Manufacturing Protocols include the required information. A complete list of requirements can be found in section 17215 of the Department of Cannabis Control's regulations. (Cal. Code Regs., tit. 4, § 17215.)

Information

- Product name
- Intended cannabinoid concentration

Ingredients/components

- A complete list of each component to be used
This includes all substances used in the production of a cannabis product, whether it remains in the finished product or not (e.g., ethanol, butane, carbon dioxide, propane).
- Weight or measure of each component to be used
The Master Manufacturing Protocol may include any steps needed to adjust the weight or measure of cannabinoid-containing ingredients to account for variability of cannabinoid content in harvest batches.
- Identity and weight or measure of ingredients in the finished product
This includes all ingredients that will be declared on the labeled ingredients list



Production steps

- Instructions for each point, step, or stage in the manufacturing process
Include any actions taken to mitigate against risks identified in the Product Quality Plan – For example, the step to be performed and any timeframes, temperatures, equipment settings, or other specific parameters (e.g., extraction parameters, homogenization processes, mixing times, temperature ranges, oven temperatures, cook time, target weights or volumes, and equipment operating steps).
- Expected yield
This value is based on the amount of ingredients or packaging to be used, before accounting for any loss or errors during production. The Manufacturing Master Protocol must also identify the maximum and minimum percentages of expected yield beyond which a deviation investigation of a batch will be necessary, material review will be conducted, and a decision on the disposition of the product will be made.

Packaging and labeling

- Description of packaging to be used
- Copy of the label
You can also use a reference to the physical location of the label
- Expected number of packages and labels to be used
If the cannabis product will leave the manufacturing premises in final form and packaged and labeled as it will be sold at retail.

The Department of Cannabis Control (DCC) licenses and regulates commercial cannabis activity within California. To learn more about the California cannabis market, state licenses or laws, visit cannabis.ca.gov. Email questions to info@cannabis.ca.gov or call 1-844-61-CA-DCC (1-844-612-2322).

