

CHECKLIST: MASTER MANUFACTURING PROTOCOL

MANUFACTURED CANNABIS SAFETY BRANCH



The Master Manufacturing Protocol is a written document that describes the type and amount of each ingredient to be used and each step that must be followed to safely and consistently produce the product. This protocol helps reduce the risk of adulteration by preventing incorrect or unintended ingredients from being incorporated, includes any necessary steps to mitigate the hazards identified in the Product Quality Plan, and it ensures uniformity among all batches produced.

Manufacturers must have a Master Manufacturing Protocol for each unique formulation and batch size of cannabis product manufactured. The steps outlined in the Master Manufacturing Protocol are documented in a Batch Production Record when performed. Master Manufacturing Protocols must be disclosed, upon request, to MCSB inspectors.

The checklist below will assist in verifying that your Master Manufacturing Protocols capture the minimum required information. A complete list of requirements can be found in [section 40255](#) of the regulations.

CHECKLIST FOR MASTER MANUFACTURING PROTOCOL

OVERALL 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. This includes, but is not limited to, ingredients and any chemicals or substances used during extraction or post-processing (ex: ethanol, butane, carbon dioxide, propane etc.)

Weight or measure of each component to be used – The Master Manufacturing Protocol may include any steps needed to adjust cannabis ingredients to account for variability of cannabinoid content in harvest batches

Identity and expected weight or measure of finished product ingredients – 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 – This includes the step to be performed and timeframes, temperatures, equipment settings or other specific parameters. For example, extraction parameters, homogenization processes, mixing times, temperature ranges, oven time, target weights or volumes, equipment operating steps, etc.

Instructions for any actions taken to mitigate risks identified in the Product Quality Plan

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. This is also a good place to specify an acceptable range (e.g., minimum and maximum percentage of the expected yield), so there is clarity on when an investigation may be needed to determine the source of unusual excess or loss.

PACKAGING AND LABELING

Description of packaging to be used

Copy of the label (or a reference to the physical location of the label)

If you have any questions about these regulatory requirements, please email us: MCSB@cdph.ca.gov.