

CHECKLIST: BATCH PRODUCTION RECORDS

MANUFACTURED CANNABIS SAFETY BRANCH



A Batch Production Record is a detailed documentation of the work performed to manufacture or remediate a batch of cannabis product. Batch production records include information about the cannabis and non-cannabis ingredients used, the staff member(s) who completed each step, verifications that the Master Manufacturing Protocol was followed, and information about the quality control processes used to ensure safety.

The checklist below will assist in verifying that your batch production records capture the minimum required information. A complete list of requirements can be found in [section 40258](#) of the regulations.

CHECKLIST FOR BATCH PRODUCTION RECORDS

OVERALL INFORMATION

The manufacturing premises where activity occurred - Including the name, license number and location of the premises

The identity of the product being manufactured

INGREDIENTS

The unique identifiers (UIDs) of the cannabis and cannabis products used in the batch

The identity, identification numbers and weight or measure of all cannabis and non-cannabis ingredients used – Records of which raw ingredients were used in which production batches are important when tracing is needed, such as when a supplier issues a recall. A common way of tracking ingredients is by using the lot numbers assigned by the ingredients' manufacturer.

EQUIPMENT AND PROCESSING LINES

Identification numbers of equipment and processing lines used - Major equipment and processing lines that play a crucial role in the production of the batch should be given identification numbers, and those numbers should be recorded in the batch production record. The intent of this requirement is to identify equipment that plays a crucial role in manufacturing of a cannabis product, where if the equipment malfunctioned, the cannabis product would not meet quality or safety standards.

Maintenance, cleaning and sanitizing logs (*or a reference to where these logs can be found*) – These should include the date the activity was performed and the name of the staff member who completed the cleaning or maintenance.

PRODUCTION STEPS

The date on which each step of the Master Manufacturing Protocol was performed

The signature or initials of the person who performed each step. This includes the person who weighed or measured each component, who added each component to the batch, and who verified the addition of components

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PRODUCTION STEPS (CONTINUED)

Expected yield and actual yield – These values should be recorded at key stages of processing, such as after extraction, post-processing or refinement, after producing infused product, and/or when cannabis product is packaged in retail-ready form.

PACKAGING AND LABELING

A copy of the label and package (or a reference to label and package documented in the Master Manufacturing Protocol)

Expected number of packages and labels to be used

Actual number of packages and labels used

QUALITY CONTROL STEPS

Results of monitoring, testing or verification activities – These are activities performed to ensure product safety or quality and may include monitoring of temperature, time of activity, or volume or weight; homogenization; operating parameters for extraction equipment; quality assurance testing; etc.

Quality control review – Documentation that quality control personnel reviewed the batch production record, monitoring operations, tests and examinations

Quality control approval – Documentation that quality control personnel approved/released or rejected the finished cannabis product and the batch for distribution

Documentation of any material review and disposition

FINISHED PRODUCT

The UID of the finished product

The batch or lot number of the finished product

The Certificate of Analysis for finished product – This is added to the Batch Production Record after regulatory compliance testing is completed

KEY POINTS TO REMEMBER

- Records must be accurate and legible
- The documentation captured in a batch production record occurs when the activity is performed.
- Batch production records contain the actual values and observations obtained during the production, monitoring and verification processes.

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