

**STANDARD FOR  
MANUFACTURING LOZENGE, TOPICAL FORMULATIONS AND EDIBLE FORM PRODUCTS BY AN  
ALTERNATIVE TREATMENT CENTER**

**PURPOSE AND SCOPE**

This document shall serve as the minimum standard for Alternative Treatment Centers (ATC) in establishing protocols for the manufacturing of lozenge, topical formulations, and edible forms of medicinal marijuana permitted under the Compassionate Use Medical Marijuana Act (Act) (P.L. 2009, c.307) and its adjoining regulation (Rule) (N.J.A.C. 8:64-1 et seq.).

This document establishes standards for the quality and control of processes, components, and environments associated with manufacturing lozenge, topical formulations, and edible forms, and for the skill and knowledge of ATC personnel who prepare manufactured products. This document establishes minimum good manufacturing practices that will enhance an ATC's ability to manufacture products that are of acceptable and consistent strength, quality, and purity.

The ATC shall follow all requirements of N.J.A.C. 8:64-1, et al., in addition to the minimum standard outlined in this standard.

**DEFINITIONS**

The following words and terms used in this standard shall have the following meanings:

“Alternative Treatment Center” or “ATC” means the permitted alternative treatment center authorized to grow and provide registered qualifying patients with usable marijuana and related paraphernalia in accordance with the provisions of the Act. This term shall include the organization's officers, directors, board members, and employees. (N.J.A.C. 8:64-1.2).

“Certification” means a statement signed by a physician with whom a qualifying patient has a bona fide physician-patient relationship, which attests to the physician's authorization for the patient to apply for registration for the medical use of marijuana and meets the requirements of N.J.A.C. 13:35-7A. (N.J.A.C. 8:64-1.2).

“Dispensable Product” means lozenge, topical formulation, and edible forms of medical marijuana.

“Dispensable Package” means a manufactured dispensable product, packaged for distribution, equivalent to ¼ ounce (7.1 gm) of packaged dispensable medical marijuana. A dispensable package shall contain no more than 700 mg of THC.

“Dosage Unit” means the measured quantity of a therapeutic agent to be taken at one time. A dosage unit shall have a cannabinoid concentration that is within 95% to 105% of the specified milligram dose. A dosage unit shall contain no more than 10mg of THC.

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“Edible Forms” or “edible form” means an oral administered formulation of marijuana extract. Edible form shall include tablets, capsules, drops, or syrups and any other form as authorized by the Commissioner of Health. (p.l. 2013, C.160).

“Lozenge” means a solid oral dosage form that is designed to dissolve or disintegrate slowly in the mouth. Lozenges contain one or more active pharmaceutical ingredients that are slowly released from the flavored and sweetened base. Lozenges can be prepared by molding (gelatin and/or fused sucrose or sorbitol base) or by compression of sugar-based tablets. (N.J.A.C. 8:64-1.2).

"Manufacturing" means the preparation, mixing, assembling, packaging, and labeling of a dispensable product.

“Manufacturing Record” means documentation of each unique manufacturing event and shall include the name and strength of the manufactured dispensable product, the master formulation record reference for the preparation, and the sources and lot numbers of ingredients. The manufacturing record shall also include: the total number of dosage units manufactured, the name of the person or persons who prepared the manufactured dispensable product, the name of the manufacturing supervisor who approved the preparation, the date of preparation, and an assigned beyond-use date. For all manufactured dispensable products, results of quality control procedures shall be recorded in the manufacturing record.

“Manufacturing Supervisor” means a qualified individual who, by possession of a recognized degree, certificate, or professional standing, or by extensive knowledge, training and experience, will be responsible for ensuring compliance with this standard. Examples of a “qualified individual” include, but are not limited to, someone who possesses a recognized degree, certificate, or professional standing, or extensive knowledge, training and experience in general, in: organic and pharmaceutical chemistry; analytical chemistry, including analysis of medicinal products; pharmacology; pharmaceutical technology; or pharmacognosy.

“Master Formulation Record” means the unique formulation record of individually manufactured dispensable products. This record must list the name, strength, and dosage form of the manufactured dispensable product, all ingredients, their quantities, the equipment needed, and mixing instructions. Mixing instructions should include the order of mixing, mixing temperatures or other environmental controls, such as the duration of mixing, and other factors pertinent to the replication of the manufactured dispensable product. The master formulation record must include an assigned beyond-

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use date, the container used in dispensing, the storage requirements, and any quality control procedures.

“Oral administered” means enteral (swallowed), buccal (dissolved inside the cheek), sublabial (dissolved under the lip) and sublingual (dissolved under the tongue) administration.

“Qualifying patient” or “patient” means a resident of the State of New Jersey who has been provided with a certification by a physician pursuant to a bona fide physician-patient relationship. (N.J.A.C. 8:64-1.2).

“Quality control” means a planned and systematic operation or procedure for ensuring the strength, quality, and purity of a dispensable product.

“THC” means delta-9-tetrahydrocannabinol. (N.J.A.C. 8:64-1.2).

“Topical formulation” means a transcutaneous therapeutic marijuana extract formulation comprising of water, short carbon chains, alcohol, dimethylsulfoxide, polyethylene glycol, polypropylene glycol, glycerin, mineral, and mixtures thereof. (N.J.A.C. 8:64-1.2).

“Unusable marijuana” means marijuana seedlings, seeds, stems, stalks, or roots. (N.J.A.C. 8:64-1.2).

“Usable marijuana” means the dried leaves and flowers of the female marijuana plant, and any mixture or preparation thereof, and does not include the seedlings, seeds, stems, stalks, or roots of the plant. (N.J.A.C. 8:64-1.2).

**PERSONNEL REQUIREMENTS**

- a) The ATC shall designate a manufacturing supervisor who will be responsible for ensuring compliance with this standard.
- b) Personnel employed by the ATC shall have appropriate education and/or experience to assume responsibility for positions that would affect compliance with this standard.
- c) The ATC shall maintain personnel files of individuals involved in the manufacture of dispensable products. This file shall contain at a minimum:
  - 1. Job descriptions and responsibilities;
  - 2. Evidence of the education/experience of personnel;
  - 3. Training records of personnel involved in the manufacture of dispensable products; and,
  - 4. Other records as required by N.J.A.C. 8:64-9.4, Personnel records

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**PROHIBITED MANUFACTURING**

An ATC shall not manufacture dispensable products that contain drug products that appear on the Federal Food and Drug Administration's list of Drug Products Withdrawn or Removed from the Market for Reasons of Safety or Effectiveness, codified at 21 C.F.R. 216.24.

**MANUFACTURE OF INVENTORY**

An ATC may manufacture dispensable products in a quantity that reflects current patient needs by possessing an inventory of dispensable products in accordance with N.J.A.C. 8:64-11.6, Inventory.

**MANUFACTURING AREA**

- a) An ATC that engages in manufacturing shall have an area specifically designated for the safe and orderly manufacturing of dispensable products. Such area shall allow for the orderly placement of equipment and materials in order to minimize the potential for errors.
- b) An ATC engaged in manufacturing shall ensure that:
  - 1. All manufacturing areas are well-lighted and ventilated and are maintained in a clean and sanitary condition;
  - 2. Heating and air conditioning systems are controlled to avoid decomposition of chemicals;
  - 3. Sewage, trash, and other refuse in and from the ATC and immediate product manufacturing area are maintained, and disposed of, in a timely, safe, and sanitary manner; and,
  - 4. The manufacturing area is easily accessible to hot and cold running water, exclusive of the bathroom sink; soap or detergent; and air dryers or single-source towels.

**EQUIPMENT**

- a) An ATC shall possess equipment appropriate to the type of manufacturing performed.
- b) Equipment used in manufacturing dispensable products shall be of appropriate design and capacity, and shall be suitably located to facilitate operations for the intended use, cleaning, and maintenance of the equipment.
- c) Equipment used in manufacturing dispensable products shall be of suitable composition.
- d) Equipment surfaces that contact ingredients shall not be reactive, additive, or adsorptive such that those surfaces could alter the safety, identity, strength, quality, and purity of the manufactured product.

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- e) Equipment used in manufacturing dispensable products shall be thoroughly cleaned and sanitized after each use, and when necessary, prior to use, in order to prevent cross-contamination of ingredients and preparations.
- f) Equipment used in manufacturing dispensable products shall be stored in a manner to prevent cross-contamination of ingredients and preparations.
- g) Automated, mechanical, or electronic equipment may be used in manufacturing dispensable products. All equipment utilized in manufacturing dispensable products shall be inspected, maintained, and validated at appropriate intervals, consistent with manufacturer's recommendations, to ensure the accuracy and reliability of equipment performance.

**QUALITY CONTROL**

- a) The ATC shall establish dispensable product specifications to ensure the identity, strength, quality, and purity of the dispensable product, and to ensure that the dispensable product has been manufactured, packaged, labeled, and stored under conditions to prevent adulteration.
- b) The ATC shall establish procedures to ensure quality control over its manufacturing process.
- c) The ATC may establish laboratory testing to ensure quality control over its manufacturing process.

**RESPONSIBILITIES OF THE MANUFACTURING SUPERVISOR; REPORTING REQUIREMENT**

- a) The manufacturing supervisor shall be responsible for ensuring that:
  - 1. Dispensable products have been properly prepared, labeled, controlled, stored, dispensed, and distributed in accordance with the provisions of this standard;
  - 2. All aspects of the manufacturing process are documented and that accurate manufacturing records for all dispensable products prepared by the ATC are maintained;
  - 3. Manufacturing personnel are capable of and qualified to perform their assigned duties;
  - 4. Ingredients used in manufacturing have their expected identity, strength, quality, and purity consistent with the requirements in this standard;
  - 5. Dispensable products are manufactured with acceptable strength, quality, and purity, are packaged with appropriate packaging and labeling, and are prepared in accordance with good manufacturing practices;

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6. Critical processes are recorded and validated to ensure that procedures will consistently result in the expected strength, quality, and purity in the finished dispensable products;
  7. The manufacturing environment is suitable for its intended purpose;
  8. Appropriate stability evaluation is performed or is determined from literature for establishing reliable beyond-use dating to ensure that the finished dispensable products have their expected strength, quality, and purity, at least until the labeled beyond-use date;
  9. Manufacturing conditions and procedures are in place to minimize the potential for errors; and.
  10. Adequate procedures and records exist for investigating and correcting failures or problems in manufacturing, quality control, or in the dispensable product itself.
- b) The manufacturing supervisor shall report any confirmed failure of a dispensable product to meet the standard of acceptable strength, quality, purity, packaging, and labeling to the New Jersey Department of Health Medicinal Marijuana Program within 24 hours of incident confirmation.

**BEYOND-USE DATES**

- a) The beyond-use date is the date after which a dispensable product shall not be dispensed. The beyond-use date shall be determined from the date the preparation is manufactured.
- b) In the absence of stability information that is applicable to a specific dispensable product, the following are the maximum beyond-use dates for dispensable products that are packaged in tight, light-resistant containers and stored at controlled room temperature, unless otherwise indicated in (c) of this section:
  1. For water-containing formulations (prepared from ingredients in solid form), the beyond-use date shall not be later than 14 days for liquid preparations when stored at cold temperatures between two degrees and eight degrees Celsius (36 degrees and 46 degrees Fahrenheit); and,
  2. For all other formulations, the beyond-use date shall not be later than the intended duration of therapy or 30 days, whichever is earlier.
- c) The beyond-use date limits established in this section may be exceeded only when there is supporting valid scientific stability information that is directly applicable to the specific preparation (that is, the same drug concentration range, pH, excipients, vehicle, water content, etc.).

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**INGREDIENT SELECTION**

- a) An ATC shall use only useable marijuana in the manufacture of dispensable products.
- b) All ingredients used to manufacture dispensable products shall be United States Pharmacopeia–National Formulary (USP–NF), analytical reagent (AR), certified American Chemical Society (ACS), or Food Chemicals Codex (FCC) grade substances. If a USP-NF, AR, ACS, or FCC grade substance ingredient is not available, the ATC shall establish the purity and safety of the ingredient by reasonable means, which may include lot analysis, manufacturer reputation, or reliability of source study.
- c) Components used in the manufacturing of dispensable products such as aliquots, triturates, stock solutions, buffering agents, or isotonic solutions may be prepared in advance and stored as ATC stock. The preparation of such products shall be documented in accordance with the requirements outlined in this standard.

**MANUFACTURING TECHNICIANS; REQUIRED SUPERVISION**

- a) The manufacturing supervisor shall provide immediate personal supervision to manufacturing technicians who are manufacturing dispensable products.
- b) The manufacturing supervisor may delegate to manufacturing technicians the manufacturing of dispensable products. The manufacturing supervisor shall ensure that each task has been performed correctly.

**DISPENSIBLE PRODUCT PACKAGING AND INGREDIENT CONTENT**

- a) Packaging of dispensable products shall meet the requirements of 16 C.F.R. 1700.15, Poison prevention packaging standards.
- b) A dispensable product shall be packaged in containers meeting United States Pharmacopeia standards (see Containers under Preservation, Packaging, Storage, and Labeling in the General Notices and Requirements, Containers 661, and Containers—Permeation 671).
- c) The container used shall depend on the physical and chemical properties of the dispensable product. Container–drug interaction is to be considered with substances such as phenolic compounds and sorptive materials (e.g., polypeptides and proteins).
- d) A dispensable package shall not exceed 700 mg of THC.
- e) A dosage unit of dispensable product shall contain no more than 10 mg of THC. For example:
  - 1. A dispensable package of lozenge shall contain no more than 70 lozenges at 10 mg of THC per lozenge.
  - 2. A dispensable package of a sublingual drops shall contain no more than 70 ml at 10 mg of THC per ml.

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- f) Other active ingredients of the lozenge, topical formulation, or edible form shall be present in ratios determined by the ATC.
- g) A dosage unit shall have a cannabinoid concentration that is within 95% to 105% of the specified milligram dose for that dispensable product.
- h) The ATC shall follow all processing and packaging requirements outlined in N.J.A.C. 8:64-10.8.

**INFORMATION REQUIRED TO APPEAR ON DISPENSABLE PRODUCT LABEL**

- a) The dispensing container for all dispensable products shall bear a permanently affixed label with the following information:
  - 1. Manufacturing batch or lot number associated with the dispensable product;
  - 2. The name, address, and telephone number of the ATC;
  - 3. The name of all active ingredients;
  - 4. A profile, in milligrams, of all active ingredients contained in a single dosage unit;
  - 5. The name of all excipient ingredients;
  - 6. Directions for administration (oral or topical);
  - 7. The beyond-use date, consistent with the requirements outlined in this standard;
  - 8. The number of dosage units contained within the dispensable package; and,
  - 9. The requirements for proper storage.
- b) The ATC shall provide to the qualified patient or their caregiver a supplemental information sheet that:
  - 1. Identifies the Product Name;
  - 2. Identifies all ingredients used in the active ingredient extraction process and manufacturing of the dispensable product, regardless of whether those ingredients are present in the final product;
  - 3. Bears the New Jersey Poison Control Center emergency telephone number;
  - 4. Provides for an anticipated onset of the dispensable products effect when used as directed;
  - 5. Identifies drugs to avoid because of the potential for interactions, and advises the patient to discuss those drugs with their physician;
  - 6. Instructs against the use of alcohol with the product and advises the patient to discuss any use with their physician;
  - 7. Identifies activities the patient should avoid while taking the product, such as driving a motor vehicle or operating dangerous machinery;
  - 8. Instructs that the product is not intended for children, unless authorized by a physician;



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9. Advises the patient to talk to their physician before taking the product if the patient is pregnant or breast-feeding; and,
  10. Instructs that the product should be used only by the patient whose name is listed on the product label and should not be given to other people.
- c) The ATC shall follow all labeling requirements as outlined in N.J.A.C. 8:64-10.6.

**PACKAGING PROHIBITIONS**

- a) Dispensable product or dispensable package may not bear any:
1. Resemblance to a trademarked, characteristic, or product-specialized packaging of any commercially-available candy, snack, baked good, or beverage;
  2. Statement, artwork, or design that could reasonably mislead any person to believe that the dispensable product or dispensable package contains anything other than finished medicinal marijuana product;
  3. Seal, flag, crest, coat of arms, or other insignia that could reasonably mislead any person to believe that the dispensable product or dispensable package has been endorsed, manufactured, or used by any State, county, or municipality, or any agency thereof; or,
  4. Cartoon, color scheme, image, graphic, or feature that might make the dispensable product or dispensable package attractive to children.

**AUDIT TRAIL; MANUFACTURING RECORD DOCUMENTATION**

- a) The ATC shall maintain a manufacturing record for each dispensable product that contains the following information:
1. Selection of all ingredients and documentation of source, lot/batch numbers, and expiration dates of all ingredients used;
  2. Verification that ingredients comply with the master formulation record;
  3. Verification that the dispensable product label complies with the requirements outlined in this standard;
  4. Verification that the dispensable product is complete and ready to be dispensed;
  5. Strength of dispensable products;
  6. Date of preparation;
  7. Name or personal identifier of the person(s) who performed each step of the manufacturing process and the manufacturing supervisor who verified the preparation of the dispensable products;
  8. Reference(s) for formulation, if available;
  9. Total quantity of dispensable product manufactured in each lot/batch;

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10. Detailed steps of the manufacturing process to ensure that the exact same dispensable product can be duplicated at a future date;
  11. Type of dispensing container used when the dispensable product has specific storage requirements;
  12. Beyond-use date of the dispensable products consistent with the requirements outlined in this standard;
  13. Instructions for use, storage, and handling of the dispensable product.
- b) The ATC shall follow all recordkeeping requirements as outlined in N.J.A.C. 8:64-10.3.

**REPRESENTATIVE SAMPLES; COLLECTION AND RETENTION**

- a) The ATC shall establish and follow written procedures to fulfill the requirements of this section.
- b) The manufacturing supervisor shall collect representative samples of in-process materials for each manufactured batch at certain points, steps, or stages in the manufacturing process. The master manufacturing record must identify those particular points, steps, or stages in the manufacturing process where quality control is necessary to ensure the identity, strength, quality, and purity of dispensable products.
- c) The manufacturing supervisor shall collect representative samples of a subset of finished batches of each dispensable product that is manufactured before releasing for distribution to verify that the finished batch of dispensable products meet product specifications.
- d) The ATC shall retain the representative samples referenced in (a), (b), and (c) in this section using a container-closure system that is identical to the package and label used when the dispensable product is distributed. The container-closure system must identify the batch, lot, or control number.
- e) The ATC shall retain the representative samples referenced in (a), (b), (c), and (d) in this section for one year after the beyond-use date, or for one year from the date of distribution of the last batch of dispensable product associated with the reserve sample.

**RETURNED DISPENSABLE PRODUCTS; PRODUCT COMPLAINTS; ACTION AND RECORD KEEPING**

- a) The ATC shall establish and follow written procedures to fulfill the requirements of this section.
- b) The ATC shall identify and quarantine returned dispensable product until the manufacturing supervisor conducts a material review and makes a disposition decision.
- c) The manufacturing supervisor shall:
  1. Review all product complaints and returned dispensable product to determine whether the product complaint or return is related to the possible failure of a

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- dispensable product to meet any of its specifications, including those specifications and other requirements that, if not met, may result in a risk of illness or injury;
2. Investigate any product complaints and returned dispensable product that involve a possible failure of a dispensable product to meet any of its specifications, including those specifications and other requirements that, if not met, may result in a risk of illness or injury;
  3. Review and approve decisions about whether to investigate a product complaint or returned dispensable product; and,
  4. Review and approve the findings and follow-up action of any investigation performed regarding a product complaint or returned dispensable product.
- d) If the reason for a product complaint or returned dispensable product implicates other batches, the manufacturing supervisor shall conduct an investigation of the manufacturing process in each of those implicated batches to determine compliance with specifications of the master formulation record.
- e) An ATC shall recall and destroy all dispensable products associated with the product complaint or returned dispensable product unless the outcome of a review and disposition decision is that the manufacturing supervisor deems the remaining batch to be in compliance with specifications of the master formulation record and approves the remaining batch of dispensable product for distribution.
- f) The ATC shall make and keep the following records:
1. A written record of every dispensable product complaint that is related to manufacturing practice;
  2. A written record of every returned dispensable product that is related to manufacturing practice;
  3. Any review and disposition decision on a returned dispensable product or complaint;
  4. The results of any testing or investigation conducted to determine compliance with product specifications established under the master formulation record; and,
  5. Documentation of the evaluation by the manufacturing supervisor of any dispensable product in question.
- g) The written record on returned dispensable product or product complaint must include the following:
1. The name and description of the dispensable product;
  2. The batch, lot, or control number of the dispensable product, if available;
  3. The date the complaint was received and the name, address, or telephone number of the complainant, if available;
  4. The nature of the complaint including, if known, how the product was used and the effects on the complainant;
  5. The reply to the complainant, if any; and
  6. Findings of the investigation and follow-up action taken when an investigation is performed.

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**RECALL PROCEDURES**

- a) The ATC shall establish and follow written recall procedures consistent with the requirements of this section.
- b) This recall procedure shall include at a minimum:
  - 1. Factors which necessitate a dispensable product recall;
  - 2. Personnel responsible for a dispensable product recall;
  - 3. Notification protocols;
  - 4. A mechanism to contact all patients that have, or could have, obtained the dispensable product from the ATC;
  - 5. Instructions for the return or destruction of any recalled dispensable product by customers; and
  - 6. Communication and outreach via media, as necessary and appropriate.
- c) Any confirmed incidents of dispensable product discrepancy necessitating a recall shall be reported by the manufacturing supervisor to the New Jersey Department of Health Medicinal Marijuana Program immediately upon becoming aware of any such incidents.

**HEALTH AND SAFETY STANDARDS**

- a) The ATC shall:
  - 1. Enter into an on-site consultation agreement with the New Jersey Department of Labor and Workforce Development, Division of Public Safety and Occupational Safety and Health, Occupational Safety and Health On-Site Consultation Program (“Consultation Program”) established pursuant to 29 C.F.R. Part 1908 and in accordance with the Consultation Program’s procedures identified on its website at [http://lwd.dol.state.nj.us/labor/lsse/employer/Occupational\\_Safety\\_and\\_Health\\_Onsite\\_Consultation\\_Program.html](http://lwd.dol.state.nj.us/labor/lsse/employer/Occupational_Safety_and_Health_Onsite_Consultation_Program.html);
  - 2. Cooperate fully with the Consultation Program in the consultation process;
  - 3. Permit the Consultation Program full access to evaluate the ATC premises and operations and to interview the ATC staff on an ongoing basis;
  - 4. Correct, to the satisfaction of the Consultation Program, health and safety hazards that the Consultation Program may find and identify in its written report; and
  - 5. Maintain ongoing cooperation with the Consultation Program and continue to correct, to the satisfaction of the Consultation Program, health and safety hazards that the Consultation Program may find and identify in subsequent written reports.
- b) The Department shall not authorize the commencement of manufacturing by an ATC unless and until the ATC:
  - 1. Corrects, to the satisfaction of the Consultation Program, imminent dangers and serious hazards that the Consultation Program identifies; and
  - 2. Demonstrates ongoing progress and cooperation, to the satisfaction of the Consultation Program, in the correction of other-than-serious hazards in accordance with a schedule and action plan of correction accepted by the Consultation Program.