



Designation: D8557 – 24

Standard Guide for Good Manufacturing Practices (GMPs) for Cannabis/Hemp- Containing Edibles, Dietary Supplements, Topicals, and Inhaled Products¹

This standard is issued under the fixed designation D8557; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This guide describes Good Manufacturing Practices (GMPs) for use by facilities that produce cannabis/hemp-containing edibles, dietary supplements, topicals, and inhaled products for human use. It applies to facilities that operate in jurisdictions without actionable regulatory GMP requirements, to all aspects of manufacturing, including the use of non-cannabis/hemp ingredients, additives, or components, and regardless of which plant part or derivative is used.

1.2 Other guides will address GMPs for facilities that operate in jurisdictions with specific requirements for manufacturing these products or other types of cannabis/hemp-containing products such as for veterinary use.

1.3 This guide does not apply to cultivation, harvesting, or immediate post-harvest activities such as trimming, cleaning undesired plant parts, drying, and curing. Guidance on Good Cultivation Practices will be provided in a separate standard.

1.4 This guide does not apply to products or ingredients that have been approved by a regulatory authority for use as food ingredients, dietary ingredients, or drug substances (for example, hemp seeds as a food ingredient), and are produced within the scope of that approval.

1.5 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.6 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

¹ This guide is under the jurisdiction of ASTM Committee D37 on Cannabis and is the direct responsibility of Subcommittee D37.02 on Quality Management Systems.

Current edition approved July 1, 2024. Published July 2024. DOI: 10.1520/D8557-24.

2. Referenced Documents

2.1 ASTM Standards:²

D8220 Guide for Conducting Recall/Removal Procedures for Products in the Cannabis Industry

D8222 Guide for Establishing a Quality Management System (QMS) for Consumer Use of Cannabis/Hemp Products

D8250 Practice for Applying a Hazard Analysis Critical Control Points (HACCP) System for Cannabis Consumable Products

D8270 Terminology Relating to Cannabis

D8286 Guide for Processing Cannabis Product Complaints

D8477 Practice for Cannabis or Hemp Supplier Lifecycle Management

2.2 Other Documents:

Health Canada Good Production Practices Guide for Cannabis Requirements under Part 5 of the Cannabis Regulations³

Code of Federal Regulations Title 21 Part 111 Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, Or Holding Operations For Dietary Supplements⁴

Code of Federal Regulations Title 21 Part 117 Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food (21 CFR 117) Subpart B Good Manufacturing Practice⁵

Code of Federal Regulations Title 21 Part 211 Current Good Manufacturing Practice for Finished Pharmaceuticals⁶
Regulation (EC) No 852/2004 of the European Parliament

² For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at www.astm.org/contact. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

³ Available from Government of Canada, <https://www.canada.ca/en/health-canada/services/cannabis-regulations-licensed-producers/good-production-practices-guide/guidance-document.html>.

⁴ Available from U.S. Food and Drug Administration, <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?cfrpart=111>.

⁵ Available from U.S. Food and Drug Administration, <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=117>.

⁶ Available from U.S. Food and Drug Administration, <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=211>.

and of the Council of 29 April 2004 on the Hygiene of Foodstuffs, Annex II⁷

3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*

3.1.1 *allergen, n*—a substance, usually a protein, that can trigger an IgE-mediated immune system reaction in sensitive individuals.

3.1.2 *allergen cross-contact, n*—the unintentional incorporation of an allergen into a product.

3.1.3 *contaminant, n*—any undesirable or harmful microorganism, chemical, allergen, or physical material.

3.1.4 *contamination, n*—the presence of a contaminant in or on inputs, ingredients, products, packaging material, or product contact surfaces.

3.1.5 *environmental monitoring, v*—the collection and testing of environmental samples from surfaces within the facility (for example, walls, floors, and equipment) to verify that GMPs, including sanitation controls, are effective.

3.1.5.1 *Discussion*—Air sampling can be used to verify the effectiveness of GMPs related to airborne hazards.

3.1.6 *facility, n*—the building or structure, or parts thereof, used for manufacturing.

3.1.7 *manufacturing, v*—all activities carried out at a facility leading to the creation of a final product including receiving, processing, packaging, storage, and shipping.

3.1.8 *microorganisms, n*—yeasts, molds, bacteria, viruses, protozoa, and microscopic parasites.

3.1.9 *non-product contact surfaces, n*—those surfaces that do not contact inputs, ingredients, products, or packaging materials and from which drainage or transfer onto product contact surfaces does not ordinarily occur during the course of operation.

3.1.10 *product contact surface, n*—those surfaces of equipment and utensils that contact inputs, ingredients, products, packaging materials, and those surfaces from which drainage or transfer of contaminants onto inputs, ingredients, products, or packaging material, or onto other surfaces that contact inputs, ingredients, products, and packaging materials may occur during the normal course of operation.

3.1.11 *undesirable microorganisms, n*—microorganisms that are pathogens, that cause decomposition or spoilage, that indicate unsanitary conditions, or that otherwise may cause a product to be hazardous or of unacceptable quality.

3.2 General definitions are in accordance with Terminology D8270.

4. Summary of Guide

4.1 Good Manufacturing Practices (GMPs) are the facility-specific practices and controls that are necessary to provide an environment for the manufacturing of cannabis/hemp-derived

edibles, dietary supplements, topicals, and inhaled products for human use that are safe and of high quality.

4.2 GMP principles include controls for:

- 4.2.1 Buildings and Grounds,
- 4.2.2 Personnel,
- 4.2.3 Operations,
- 4.2.4 Equipment and Utensils,
- 4.2.5 Processes,
- 4.2.6 Suppliers,
- 4.2.7 Hazards,
- 4.2.8 Complaints and Recalls, and
- 4.2.9 Documentation.

5. Significance and Use

5.1 This guide provides guidance for the development and implementation of Good Manufacturing Practices (GMPs) for the manufacture of cannabis/hemp-containing edibles, dietary supplements, topicals, and inhaled products for human use. These GMPs create and maintain conditions that support product safety and quality.

5.2 This guide applies to facilities that operate in jurisdictions where actionable regulatory GMP requirements do not exist.

5.2.1 In jurisdictions where actionable regulatory GMP requirements do exist, this guide may be used to provide additional information and guidance.

5.3 This guide is consistent with internationally recognized practices. However, local laws and regulations take precedence.

5.4 Note that the specific terminology used to describe the various components of GMPs in some jurisdictions may differ from those used in this guide.

6. Procedure

6.1 *Buildings and Grounds:*

6.1.1 All grounds should be maintained in good condition, protected from the accumulation of trash, dirt, and debris, kept clear of standing water, and free from pest harborages.

6.1.2 Equipment used to maintain the grounds should be stored properly.

6.1.3 Litter and waste should be removed, and weeds or grass within the immediate vicinity of the facility should be cut to avoid creating attractants, breeding places, or pest harborages.

6.1.4 Roads, yards, and parking lots should be maintained so that they do not become a source of dust, debris, or other hazards.

6.1.5 Areas that may be sources of seepage, foot-borne filth, or pests should be eliminated.

6.1.6 The construction, maintenance, and placement of outdoor bulk vessels should protect them from damage and contamination.

6.1.7 The facility should be of suitable size, construction, and design. There should be enough space for equipment and storage including room for access for cleaning, maintenance, safe operation, and to protect against contact with employee clothing and personal contact.

⁷ Available from European Union Law, <https://eur-lex.europa.eu/eli/reg/2004/852/oj>.