



Designation: D8309 – 21

Standard Guide for Stability Testing of Cannabis-Based Products¹

This standard is issued under the fixed designation D8309; 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 is applicable to commercial processors and manufacturers engaged in the processing, testing, packaging, labeling, and storage of cannabis products intended for human consumption, including those derived from hemp. Hemp seed and products derived from hemp seed are excluded from the scope of this guide. This guide describes the minimum requirements for conducting stability testing of new cannabis products with the purpose of determining appropriate storage conditions and shelf-life.

1.2 This guide applies to all cannabis-derived products commercially manufactured and distributed for consumer use, regardless of the type of cannabis plant from which they were derived.

1.3 *Units*—The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

1.4 *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.*

1.5 *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.*

2. Referenced Documents

2.1 *ASTM Standards*:²

D8270 Terminology Relating to Cannabis

D8282 Practice for Laboratory Test Method Validation and Method Development

2.2 *ICH Documents*:³

Q1A(R2) Harmonised Tripartite Guideline – Stability Testing of New Drug Substances and Products

Q1B Harmonised Tripartite Guideline – Stability Testing: Photostability Testing of New Drug Substances and Products

3. Terminology

3.1 *Definitions*:

3.1.1 For definitions of terms, see Terminology D8270.

3.2 *Definitions of Terms Specific to This Standard*:

3.2.1 *accelerated testing, n*—studies designed to increase the rate of chemical degradation or physical change of a product by using exaggerated storage conditions as part of the formal stability studies.

3.2.1.1 *Discussion*—Data from these studies, in addition to long term stability studies, can be used to assess longer term chemical effects at non-accelerated conditions and to evaluate the effect of short-term excursions outside the label storage conditions (for example, during shipping). Results from accelerated testing studies are not always predictive of physical changes.

3.2.2 *cannabis product, n*—products derived from the cannabis plant (flowers or resins) that are intended for human consumption and are packaged and labeled in their final form for marketing.

3.2.3 *climatic zones, n*—the four zones in the world that are distinguished by their characteristic prevalent annual climatic conditions.

3.2.3.1 *Discussion*—Zone I is temperate, Zone II is subtropical, Zone III is hot dry, and Zone IV is hot humid/tropical. This is based on the concept described by Grimm, 1985 and 1986.⁴

3.2.4 *D65/ID65, n*—an illuminant standard used to represent daylight as defined by the International Commission on Illumination.

¹ This guide is under the jurisdiction of ASTM Committee D37 on Cannabis and is the direct responsibility of Subcommittee D37.03 on Laboratory.

Current edition approved June 1, 2021. Published July 2021. DOI: 10.1520/D8309-21.

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

³ Available from International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), ICH Secretariat, Route de Pré-Bois, 20, P.O. Box 1894, 1215 Geneva, Switzerland, <https://www.ich.org>.

⁴ Grimm, W., *Drugs Made in Germany*, Vol 28, pp. 196–202, 1985, and Vol 29, pp. 39–47, 1986.

3.2.4.1 *Discussion*—ID65 is the indoor equivalent of the D65 standard.⁵

3.2.5 *expiration date, n*—the date placed on the packaging or label, or both, that displays the time period during which the product is known to remain stable, which means it retains its strength, quality, and purity when it is stored according to its labeled storage conditions.

3.2.6 *extrapolation, n*—the practice of using a known data set to estimate information about future data.

3.2.7 *long-term testing, n*—stability studies under the recommended storage condition for the re-test period or shelf-life proposed (or approved) for labeling.

3.2.8 *mass balance, n*—the process of adding together the assay value and levels of degradation products to see how closely these add up to 100 % of the initial value, with due consideration of the margin of analytical error.

3.2.9 *shelf-life, n*—(also referred to as *expiration dating period*)—the time period during which a cannabis product is known to remain within the final product specifications, provided that it is stored under the conditions defined on the container packaging or label, or both.

3.2.10 *storage condition tolerances, n*—the acceptable variations in temperature and relative humidity of storage facilities for formal stability studies.

3.2.10.1 *Discussion*—The equipment should be capable of controlling the storage condition within the ranges defined in this guideline. The actual temperature and humidity must be monitored, documented, and controlled throughout the stability study. Short term temperature/humidity excursions that occur due to opening doors of the storage chamber are accepted as unavoidable. The effect of excursions due to equipment failure should be addressed and reported if judged to affect stability results. Excursions that exceed the defined tolerances for more than 24 hours should be described in the study report and their effect assessed.

3.2.11 *stress testing, n*—studies undertaken to elucidate the intrinsic stability of the cannabis products.

3.2.11.1 *Discussion*—Such testing is part of the development strategy and is normally carried out under more severe conditions than those used for accelerated testing.

3.2.12 *supporting data, n*—data, other than those from formal stability studies, that support the analytical procedures, the proposed re-test period or shelf-life, and the label storage statements.

3.2.12.1 *Discussion*—Such data include (1) stability data on early small-scale batches of materials, investigational formulations not proposed for marketing, related formulations, and product presented in containers and closures other than those proposed for marketing; (2) information regarding test results on containers; and (3) other scientific rationales.

4. Significance and Use

4.1 Stability testing provides evidence on how the quality and safety of cannabis-based product varies with time under the influence of a variety of environmental factors such as temperature, humidity, and light. The stability testing will also establish a re-test period for the cannabis product or a shelf-life for the cannabis product under recommended storage conditions. Recommended test conditions are based on ICH Q1A.

4.2 The choice of test conditions defined in this guideline is based on an analysis of the effects of climatic conditions in the three regions of the European Commission (EC), Japan and the United States. The mean kinetic temperature in any part of the world can be derived from climatic data, and the world can be divided into four climatic zones, I-IV.

4.3 Requirements of regulatory bodies or governmental departments supersede the recommendations in this guide.

5. Stability of Cannabis-Based Products

5.1 Information on the stability of the analyte(s) in cannabis products is an integral part of the systematic approach to stability evaluation.

5.2 Stress Testing:

5.2.1 Stress testing of the cannabis-based products can help identify the likely degradation products of analytes contained in the cannabis products, which can in turn help establish the degradation pathways and the intrinsic stability of the analytes and validate the stability indicating power of the analytical procedures used. The nature of the stress testing will depend on the individual analyte(s) and the type of cannabis product involved.

5.2.2 Photostability testing should be an integral part of stress testing. The standard conditions for photostability testing are described in ICH Q1B.

5.2.3 Examining degradation products under stress conditions is useful in establishing degradation pathways and developing and validating suitable analytical procedures. However, it may not be necessary to examine specifically for certain degradation products if it has been demonstrated that they are not formed under accelerated or long-term storage conditions.

5.3 Evaluation:

5.3.1 The purpose of the stability study is to establish a stability timeline, based on the recommendation to test a minimum of three batches of the cannabis product, and to evaluate the stability information (including, as appropriate, results of the physical, chemical, biological, and microbiological tests). A statistical approach should be used to determine the sample size for each batch.

6. Stability Study Design

6.1 The design of the formal stability studies for the cannabis product should be based on knowledge of the behavior, properties of the cannabis product analytes, and from stability studies on those chemicals and on experience gained from formulation studies. The likely changes on storage and the rationale for the selection of attributes to be tested in the formal stability studies should be stated.

⁵ International Commission on Illumination (CIE) and International Organization for Standardization (ISO) joint standard, *Colorimetry – Part 2: CIE Standard Illuminants for Colorimetry*, CIE S 014-2/E:2006/ISO 11664-2:2007(E).