



Designation: D8282 – 19

Standard Practice for Laboratory Test Method Validation and Method Development¹

This standard is issued under the fixed designation D8282; 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 The quality, efficacy, and safety of cannabis and products containing cannabis extracts shall be evaluated by validated testing methodologies used by trained staffed utilizing qualified instruments and/or materials.

1.2 This practice provides the cannabis industry with guidance for the development and validation of testing methods that adequately evaluate cannabis and products containing cannabis extracts for quality, efficacy, and consumer health safety in the absence of validated methods from agencies. This includes, but is not limited to, the potency of active substances and adulteration, including impurities stemming from potential adulteration during agricultural or manufacturing processes or both (for example, pesticides, residual solvents, and the presence of fungus and microorganisms) before product approval and release for use. Depending on the methodology and precision and accuracy required, these methods may be both qualitative or quantitative.

1.3 This practice shall define the procedures for test method characterization (TMC), test method validation (TMV), and test method transfer/transfer of analytical procedures (TMT/TAP) of biological, chemical spectroscopic, and physical-based laboratory test methods.

1.4 Depending on the nature of the test in question (chemical, microbiological, etc.) different variables will need to be considered for validation. The particular variables subject to consideration are beyond the scope of this document. Refer to Guide [E2857](#) for more guidance.

1.5 This standard does not consider the specifics of acceptable test method limits and users should consult relevant standard literature to determine the appropriate test parameters.

1.6 *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 This practice is under the jurisdiction of ASTM Committee [D37](#) on Cannabis and is the direct responsibility of Subcommittee [D37.03](#) on Laboratory.

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1.7 *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

[E2857 Guide for Validating Analytical Methods](#)

2.2 *Other Documents:*

[United States 40 CFR Appendix B to Part 136 Definition and Procedure for the Determination of the Method Detection Limit](#)³

[USP 1224 Transfer of Analytical Procedures](#)

[USP 1225 Validation of Compendial Procedures](#)

[ICH Q2\(R1\) – Validation of Analytical Procedures: Text and Methodology](#)

3. Terminology

3.1 *Definitions:*

3.1.1 *acceptance criteria, AC, n*—specification(s) that shall be met by a test sample or matrix specific method to be considered suitable or validated for use, respectively.

3.1.1.1 *Discussion*—State-specific criteria shall be met as applicable.

3.1.2 *accuracy, n*—the closeness of agreement between a test result and an accepted reference value.

3.1.2.1 *Discussion*—The term accuracy, when applied to a set of test results, involves a combination of a random component and of a common systematic error or bias component.

3.1.3 *addendum, n*—document written to make minor updates to an existing completed protocol or report.

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 U.S. Government Printing Office, Superintendent of Documents, 732 N. Capitol St., NW, Washington, DC 20401-0001, <http://www.access.gpo.gov>.