Draft Jamaican Standard

Practice

for

Laboratory test method validation and method development



BUREAU OF STANDARDS JAMAICA

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PUBLIC COMMENTS PERIOD OCTOBER 31 TO DECEMBER 1, 2020

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The general policies of the JBS Certification Mark Programme are as follows:

- The JBS provides certification services for manufacturers participating in the programme and licensed to use the gazetted JBS Certification Marks to indicate conformity with Jamaican Standards.
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Participants in the programme should note that in the event of failure to resolve an issue arising from interpretation of requirements, there is a formal appeal procedure.

Further information concerning the details of the JBS Certification Mark Programme may be obtained from the Bureau of Standards, 6 Winchester Road, Kingston 10.

CERTIFICATION MARKS





Product Certification Marks



Plant Certification Mark



Certification of Agricultural Produce (CAP) Mark



Jamaica-Made Mark

Jamaican Standard

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Month 201x

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ISBN XXXXXXXXXX

Declared by the Bureau of Standards to be a standard practice pursuant to section 7 of the Standards Act 1969.

First published Month 201x

This standard was circulated in draft form for thirty (30) days non-objection under the reference DJS ASTM D8282-19:

Jamaican Standards establish requirements in relation to commodities, processes and practices, but do not purport to include all the necessary provisions of a contract.

The attention of those using this specification is called to the necessity of complying with any relevant legislation.

Amendments

No.	Date of Issue	Remarks	Entered by and date

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National foreword

This standard is an adoption and is identical to ASTM D8282-19 Standard Practice for Laboratory Test Method validation and Method Development published by ASTM International.

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.
- 1.7 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.

Where the words 'International Standard' appear, referring to this standard, they should be read as 'Jamaican Standard'.

Where reference is made to informative and normative annexes the following definitions should be noted:

- Informative Annex gives additional information intended to assist in the understanding or use of the document. They do not contain requirements.
- Normative Annex gives provisions additional to those in the body of a document. They contain requirements.

Users should note that all standards undergo revision from time to time and that any reference made herein to any standard implies its latest edition, unless otherwise stated.

This standard is voluntary

Committee Representation

The adoption of this standard for the Standards Council, established under the Standards Act, 1969 was carried out under the supervision of the Cannabis Technical Committee, which at the time comprised the following members:

Acknowledgment

Acknowledgement is made to the ASTM International for permission to adopt ASTM D8282-19.