



Method Validation Process for Cannabis Products

INTRODUCTION

Health Canada requires that laboratories use “Validated Methods” for testing cannabis. An accepted validation protocol is the International Conference on Harmonization (ICH) Guideline: *Validation of Analytical Procedures: Text and Methodology*; Q2(R1) or ICH Q2(R1) for short. The guideline provides details on the validation process. Validating a quantitative analytical method in accordance with the protocol is a significant undertaking.

The validation process will quantify numerous characteristics of the method, such as accuracy, precision, specificity and detection limit. The validation data is obtained by using a specific method to analyze a specific product or material. For this reason, the data only applies to that method and material.

Therefore, revalidation is necessary when there are changes to the composition of the product or changes to the analytical procedure. The extent of revalidation required will depend on the nature of the changes, but in general, changes in the formulation of a product will require additional validation.

This document provides a general outline of what is involved with method validation for cannabis products, including how validation is carried out at SRC Environmental Analytical Laboratories on cannabis products and what can be expected from the laboratory during the validation process.

CLIENT RELATIONSHIPS

With the legalization of cannabis for use in edibles, topicals and other personal care products, there is an opportunity to develop new products for consumers. These products are regulated by Health Canada and require analysis for various components and contaminants under the *Cannabis Act* and associated regulations.

As such, the methods used to analyze these cannabis products must be validated. Since method validation must be carried out on the appropriate sample matrix, it is best to work closely with your laboratory.

A strong working relationship with your laboratory helps ensure the laboratory gains the necessary experience with your products and has appropriate validated methods in place that are suited to your products. This also helps facilitate revalidation when changes are made to product formulations.

METHOD VALIDATION AT SRC

SRC Environmental Analytical Laboratories has worked with clients to validate a variety of methods on various matrices. The method validation process can be expected to take at least several weeks.

The process is carried out at SRC Environmental Analytical Laboratories as follows:

- The client approaches SRC to discuss their needs and potential product validation. An agreement with the laboratory is established to begin the validation process.

- Information disclosed by the client is always held in strict confidence by laboratory personnel as prescribed by the laboratory's policies and the ISO 17025 standard adhered to by the lab.
- A plan for the necessary method validation, including a timeline, is developed.
- Method validation is carried out and a formal validation report is prepared and delivered to the client.

METHOD VALIDATION COSTS

The laboratory incurs a significant cost to conduct a method validation study. There are direct costs, such as standards, supplies and labour of technical staff. There are also indirect costs, such as instrument downtime, in which an instrument could be running samples and is instead being used for the validation study.

A method validation report is useful for the client as it provides documented evidence for regulators that validated methods are being used for product testing.

For these reasons, there is a cost associated with a method validation study. The exact cost will depend on the type of matrix, the methods used and the specific parameters that need validating.

A specific quotation for your needs can be determined through discussions with your laboratory. As SRC Environmental Analytical Laboratories is committed to establishing good client relationships for the benefits outlined earlier, there are usually a variety of ways to help clients offset some of the method validation costs.

Please contact our laboratory to discuss your specific needs.

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