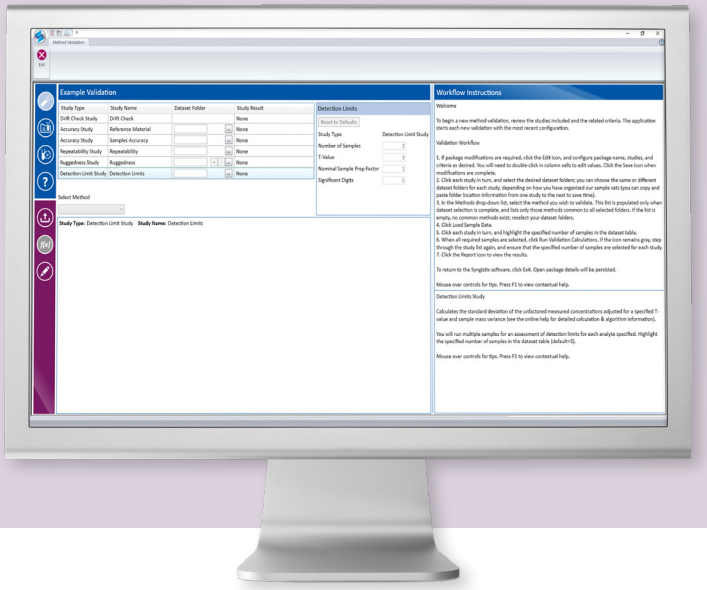
PRODUCT NOTE

## ICP - Mass Spectrometry



**Key Features:**

- Automated analysis and summarization of method validation data
- Consolidated validation report
- Enhanced Security with electronic data review for 21 CFR Part 11 compliance

# Syngistix for ICP-MS Automated Method Validation Application Module

Validation of analytical methods is a requirement for many types of laboratories. Analytical methods are often revised and optimized to improve the performance of critical attributes such as precision, accuracy or drift. Any changes to analytical methods require revalidation to ensure that they perform as intended and meet the required acceptance criteria. Method validation is a critical step in many types of laboratories as they seek to obtain national or international accreditation. The challenge is in satisfying regulatory compliance while significantly improving data traceability. Manual processes of validating methods are time-consuming and prone to errors, which negatively impacts productivity.

One prominent example of such a regulatory need for method validation is highlighted in United States Pharmacopeia Chapter 233, which specifies the various tests that a laboratory should be conducting to validate an ICP-MS method for the analysis of elemental impurities in pharmaceutical products.

The Syngistix™ Automated Method Validation application module in Syngistix for ICP-MS software is designed to eliminate process inefficiencies by streamlining the workflow and avoiding potential human error faced in traditional ICP-MS method validation.

| Challenges of Traditional Paper-based Validation | Advantages of Automated Method Validation Solution |
|---|---|
| Lack of automated transfer of validation data, therefore prone to human error | Eliminates manual steps in your current method validation process |
| Data from instruments are not centralized | Satisfies compliance requirements more easily, while significantly improving data integrity |
| Data integrity is compromised when exporting data from instrument software | Eliminates the use of separate software applications during method validation |
| Lack of visibility to validation status of analytical methods at the instrument level | Automates, streamlines, and simplifies the method validation workflow |
| Paper-based execution creates delays and errors | Quickly and easily determines if your data adhere to your quality<br>Stores your method validation data securely |

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The Automated Method Validation application module replaces the traditional paper-based analytical method validation process where technical data reside in protocols, notebooks, forms, unprotected spreadsheets, and technical reports. By centralizing all of the instrument validation data, this improves data traceability and integrity. If the module is installed along with Syngistix for ICP-MS Enhanced Security™ software, the User Access Control, Audit Trail, and Electronic Signatures functions are provided, helping the lab comply with 21 CFR Part 11. Permission Sets allow only permitted users to setup the study parameters and all actions are recorded in the audit trail. Electronic Signatures allow reviewers and approvers to digitally sign the validation reports.

The Automated Method Validation application module successfully streamlines your method validation practices and improves compliance by eliminating transcription errors, providing data traceability and reducing process inefficiencies.

## Accuracy

Accuracy is defined as the closeness of the agreement between the result of a measurement and a true value of the measurand. (Ref IUPAC: https://goldbook.iupac.org/html/A/A00060.html).

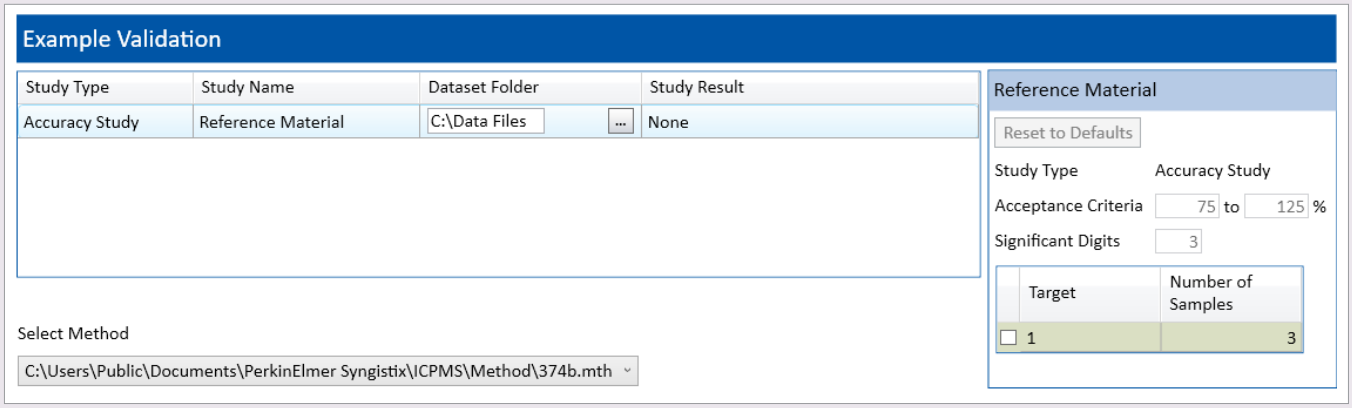


*Figure 1.* Screen capture of the Accuracy study showing test setup and criteria.

## Detection Limit

IUPAC defines the detection limit as the smallest amount of material detectable (3σ-criterion) in a matrix relative to the amount of material analyzed — given in atomic, mole or weight fractions. (Ref IUPAC: https://goldbook.iupac.org/html/R/R05263.html).

There are variances of detection limits used in analytical laboratories such as instrument detection limit (IDL), method detection limit (MDL), and practical quantitation limit or limit of quantification (PQL/LOQ). Through customizing the number of samples and the T-Value, the Automated Method Validation application module allows the user to specify the type of detection limit they wish to determine. This can be done either in solution or in original sample by adjusting the nominal sample preparation factor.

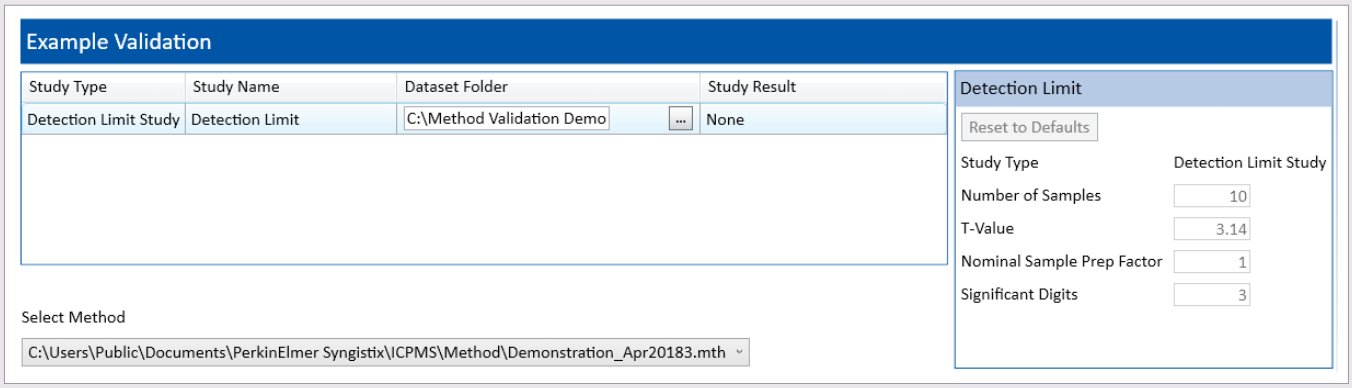


*Figure 2.* Screen capture of the Detection Limit study showing test setup and criteria.

## Drift

Drift is defined as a slow non-random change in signal with time. (Ref IUPAC: https://goldbook.iupac.org/html/D/D01859.html).

The Automated Method Validation application module offers the capability of measuring the percentage drift over two check samples and compares it to preset acceptance criteria. Multiple drift check studies can be used if there are multiple drift check samples in the validation dataset.

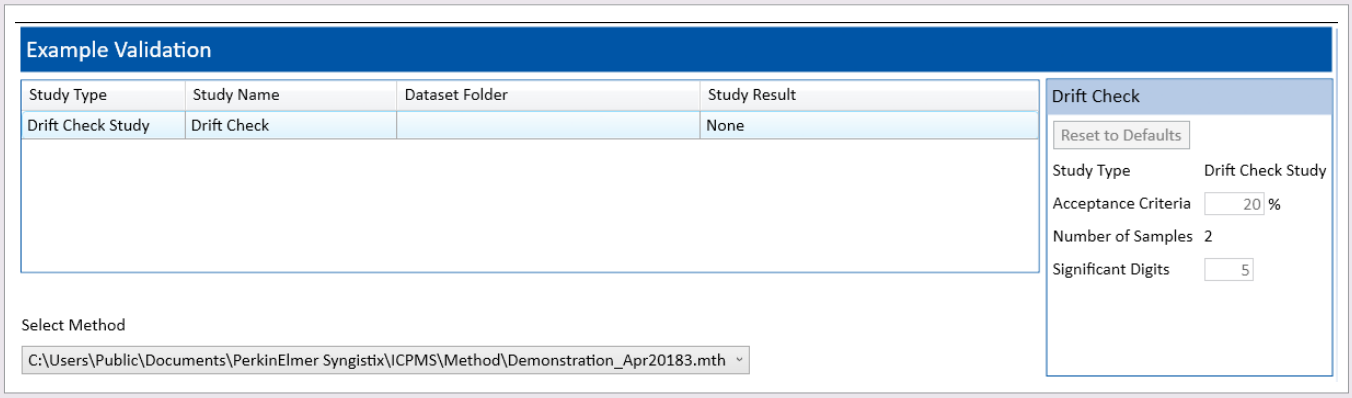


*Figure 3.* Screen capture of the Drift Check study showing test setup and criteria.

## Repeatability

Repeatability is defined as the closeness of agreement between independent results obtained with the same method on identical test material, under the same conditions (same operator, same apparatus, same laboratory and after short intervals of time). (Ref IUPAC: https://goldbook.iupac.org/html/R/R05293.html).

The Automated Method Validation application module offers the capability to run multiple repeatability studies to handle different test materials.

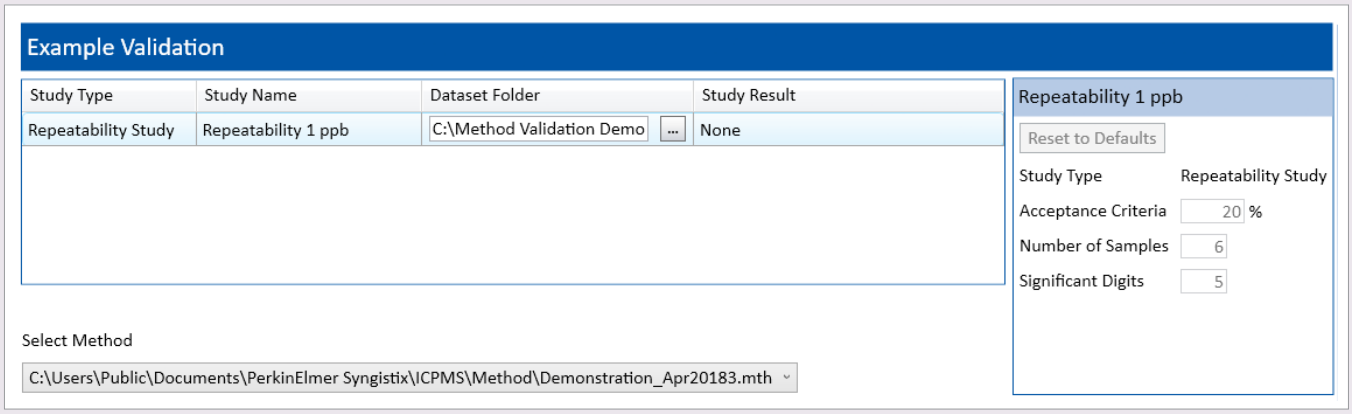


*Figure 4.* Screen capture of the Repeatability study showing test setup and criteria.

## Ruggedness

Ruggedness (or intermediate precision) is an extension to the repeatability test that accounts for analyses being done either on a different day, with a different instrumentation, with a different analyst, or a combination thereof.

The Automated Method Validation tool allows for 2-3 repeatability components to be summarized for the ruggedness study.

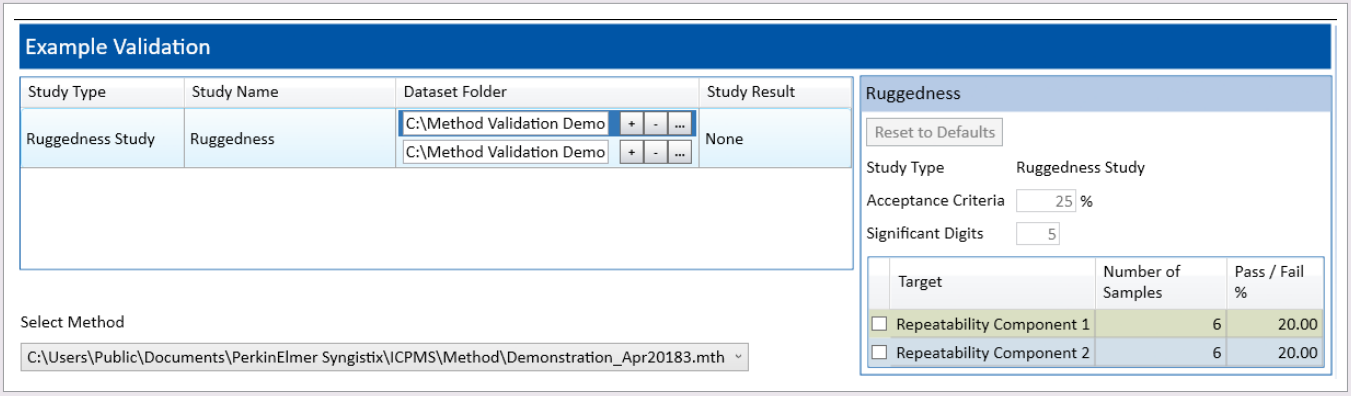


*Figure 5.* Screen capture of the Ruggedness study showing test setup and criteria.

Whether the user is following the required tests preset by USP 233 or generating a sequence from a combination of the various test types listed above, the Syngistix Automated Method Validation application module provides a full report that summarizes the analytical performance of the method and assigns a pass or fail. In the case of the latter, the report highlights the failures to help the user refine the methodology. If using the Enhanced Security version of Syngistix for ICP-MS, the Automated Method Validation report is subject to review and approval, thereby providing the user with a safe, traceable and auditable assurance that their methods have passed the relevant performance criteria related to their field of application.

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