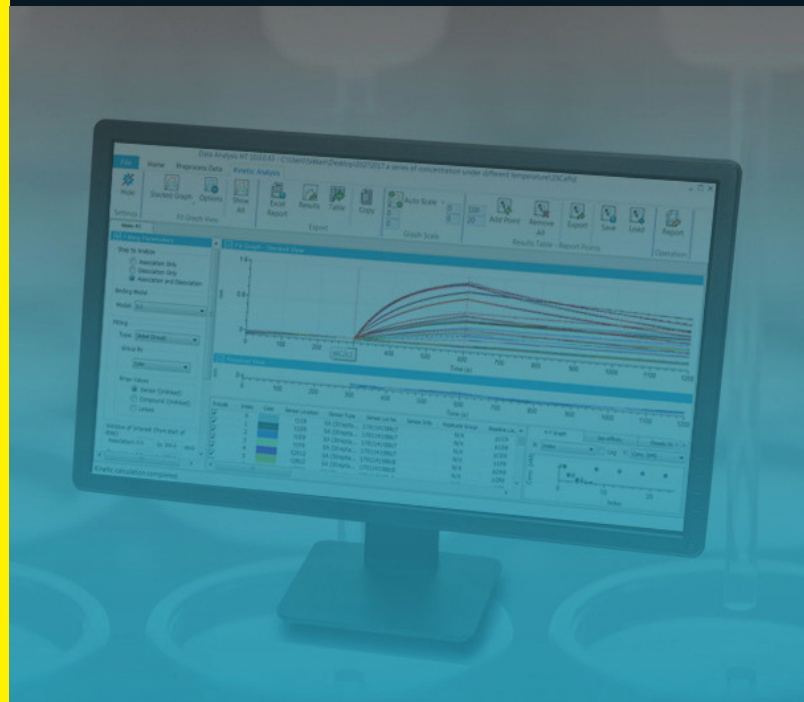


Software Validation Package

For Octet® Version 14
Compliance Suite



Product Information

The Octet® Software Validation Package is designed for laboratories using Octet® Software Version 14 with the Octet® Compliance Suite and Compliance Hub and operates in a regulated environment where they are responsible for software validation within their own quality system. Validation activities are performed by the end user (non-Sartorius personnel) to reflect the lab's intended use, workflows, and quality procedures.

Confidence in Every Workflow

The workflow offered by the validation package is intended for:

- Laboratories operating under GxP requirements, such as GLP or GMP, that require documented evidence of software fitness for intended use
- QC, QA, and regulated development teams establishing controlled electronic records and workflows
- Organizations subject to regulations such as FDA 21 CFR Part 11, when configured and validated by the customer
- Validation, quality, and IT teams that are responsible for executing and documenting software qualification activities
- Customers deploying Octet® Software v14 for the first time or following significant configuration or version changes

Simplify Your Octet® Software Validation

The user executed Octet® Software Validation Package is designed to provide labs with all the essential materials needed to validate Octet® Software in regulated environments.

Octet® Software Validation Package

Central foundation for regulated software validation. Provides all essential materials for user-executed validation activities.

Validation Guide

Defines scope, framework, and clarifies customer responsibilities. Ensures alignment with regulatory requirements.

Software Validation Tests

Includes security, access controls, and audit trail behavior tests. Supports robust validation of software features.

Calculation Verification

Workflows for confirming kinetics and quantitation fits. Ensures accuracy in analytical calculations.

Example Datasets & Files

Provides Octet® data files and analysis settings. Enables result confirmation and reproducibility.

Validation Templates

Supplies worksheets and audit-ready records. Facilitates evidence capture and reporting for compliance.

What is Included

The Octet® Software Validation Package includes structured, reusable materials intended to support customer-executed software validation and result confirmation. The package provides documentation, test scripts, templates, and example datasets; it does not include Sartorius personnel performing the validation, and it is not a substitute for instrument installation qualification (IQ), operational qualification (OQ), or performance qualification (PQ).

Component	What is it used for?	Examples of what you receive
Validation User Guide	Provides a structured framework for customer-executed software validation aligned to your quality system and intended use.	Scope, assumptions, and prerequisites; mapping of software features to regulated use cases; step-by-step test guidance; validation boundaries and customer responsibilities.
Software Validation Test Scripts	Supports verification of governance and security behaviors in your configured environment.	Tests for user role permissions; controlled access and authentication; audit trail generation and filtering; electronic signature behavior; password rules, idle timeout, and account lockout; controlled data actions.
Analysis & Calculation Verification Tests	Helps confirm calculation and analysis outputs against expected results (including optional third-party comparison workflows).	Kinetics curve fits; quantitation curve fits; data pre-processing checks (alignment, subtraction, filtering).
Example Datasets & Test Files	Reduces setup time by providing reusable datasets and configuration assets used within validation workflows.	Octet® software data files; analysis settings files; test folders; optional third-party comparison outputs where applicable.
Reusable Validation Artifacts	Supports consistent documentation and evidence capture for internal review and audit readiness.	Templates and worksheets for evidence capture, result documentation, deviations approvals, and standardized validation reporting.

Authenticating Calculations with Third Party Software

The Validation Package supports independent confirmation of Octet® software calculations by providing workflows that compare Octet® outputs with commonly used third-party tools, such as spreadsheet software or curve-fitting applications.

Users can use the provided templates to export pre-processed data from the Octet® software to third-party software to compute and compare values generated by the Octet® Software with predefined criteria for pass | fail outcomes. This supports algorithm verification and confidence in results for regulated workflows where an independent calculation review is required.

System Requirements

The Validation Package does not establish or install system requirements. Instead, it assumes that:

- Octet® Software 14 and Octet® Compliance Hub have already been installed and configured in the lab environment
- System installation qualification (IQ) and operation qualification (OQ) activities have been completed
- The software environment reflects the lab's intended use, IT policies, and security configurations
- The validation documentation may reference:
 - Controlled Windows environments
 - Microsoft Excel (required), GraphPad Prism (optional) for result confirmation

Regulatory Note

The Octet® Software Validation Package provides resources to support customer validation activities. Validation planning, execution, and approval are performed by the end user (non-Sartorius personnel). Regulatory compliance remains the customer's responsibility and depends on configuration, validation execution, and ongoing governance within the lab's quality system.

Ordering Information

Part No	Description
50-0301	Octet® Compliance Suite Validation Package. Includes the Validation User Guide; software validation test scripts; calculation and analysis verification workflows (kinetics, quantitation, and preprocessing); example datasets and test files

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