Validation Report SIMCA®-online 18.0.1 2025-03-24 09:28

	Role	Name	Date
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Content

1 Introduction

The purpose of the **Validation report** is to summarize and document the found differences that require corrective actions from the validation activities performed.

This partial validation complements the full validation of SIMCA®-online 18 (version 18.0.0.226).

2 Validation Report Summary

The Validation plan defines the validation tasks to perform. The results from the validation tasks are included in the validation package and summarized under paragraph 3.

2.1 Validation Package Content

The validation package includes files and folders as follows:

- Validation Report - This document
- Validation Plan – Scope of the validation
- Risk Assessment – Risks and mitigations
- Defects folder – Lists details for defects fixed in the release.
- Regression and numerical validation folder – Holding the results from the automated regression and numerical comparisons.

3 Validation Task Results

The numerical validation of SIMCA®-online 18.0.1 was done versus current specification using TestComplete under Windows 10. The outcome is included in the validation package.

No differences that require a corrective action were found. Differences due to rounding are not included.

Regression tests were completed as listed in the table in paragraph 3 in the Risk assessment document.

4 Verification of Installed Software

To verify that your license of the software has been correctly installed follow the instruction here:

1. In SIMCA®-online, click **File | Help** and under About SIMCA®-online, verify that the version is SIMCA®-online 18.0.1.339.
2. Open one of the .pdfs in the Graphical validation folder in the full validation of SIMCA®-online (18.0.0.226).
3. In the Verification of installed software folder, find folders:
    - Sovring for continuous and
    - Lubrizolow for batch.
4. Upload the selected project in the software, and configure using the .bcg-file.
5. Import the DBMaker-files as database and let it provide data
6. Create and compare one of the plots. The plots should content wise be identical.

5 Validation Conclusion

All defects found during this development life cycle that remain unsolved were considered noncritical to the user of the system and therefore remain open.

All deviations compared to specifications are stored in the defect database. There are no known serious deviations.

The performed quality activities throughout the life cycle of the software development, in accordance with the outlined testing and validation strategy in the Quality Management System (QMS), secures that the requirements perform according to specification and that SIMCA®-online 18.0.1 gives correct results and is reliable.

6 Approval of Validation and Release to Customer

When all activities have passed according to acceptance criteria for the final build/package, the Product Owner issues the release approval. The Product Manager, RTE and a quality representative from Quality Assurance sign the Release and Validation approval document to approve the release to customer and to approve the validation report via validation conclusion.