SARTORIUS

Validation Report SIMCA®-online 17.0.2   2022-11-21 15:42

	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.

The scope of the validation tasks performed are described in paragraph 2.1 in the Validation plan.

This patch validation complements the full validation of SIMCA-online 17 (version 17.0.0.55175), and the numerical validation of SIMCA-online 17.0.1 (version 17.0.1.27).

1.1 Notation and Notes

'US' followed by a number refers to a User Story in Azure DevOps.

'WI' followed by a number refers to a Work Item in Azure DevOps. May be Bug, User Story, Feature etc.

Note: Approving this document includes approval of all subdocuments and results referred to in this document.

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 all found difference requiring a corrective action are listed under paragraph 3.

2.1 Validation Package Content

The validation package includes files and folders as follows:

- SIMCA-online 17.0.2 validation documentation pdf, a compilation of validation documents including this document, SIMCA-online 17.0.2 Validation Report.

- Bugs document – Lists details for the bugs fixed in the patch.

- Numerical validation folder – Holding the results from the numerical comparisons.

- Automatic regression folder – Holding the results from the automated workflows validated

3 Validation Task Results

The numerical validation of SIMCA-online 17.0.2 was done versus SIMCA-online 17.0.1, and thus the current specification, using TestComplete and CompareSimcaData under Windows 10. The outcome is included in the validation package. Differences due to rounding are not listed.

3.1 Data Analytics Correctness – Desktop Numerical

In the numerical comparison versus SIMCA-online 17.0.1, no differences were found.

3.2 Automated Regression

In the automated regression covering group permissions, audit trail, Python preprocessing plugin and reset alarm in the web client, no differences requiring a corrective action were found.

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 17.0.2.41.

2. Open one of the .pdfs in the Graphical validation folder in the full validation of SIMCA-online.

3. Request validation project and DBMaker files from Sartorius and use DBMaker as database and let it provide data. Use for instance Sovring for continuous and Lubrizolow for batch.

4. Create and compare one of the plots. The plots should content wise be identical.

For SIMCA-online Web Client:

1. In the desktop client, with the project used for the above verification, click Web Client on the Home tab.

2. Using one of the supported browsers (Chrome, Edge, Safari), log in using your SIMCA-online user credentials.

3. Click the main menu, About, and verify that the version is SIMCA-online Web Client version 17.0.0 (build 52356).

4. Open one of the trend plots. The plots should content wise be identical.

5   Source Code

All source code for the final version of a full release is transferred to electronic media and kept in a safe storage externally.

6   Routines

The relevant routines are stored in Azure DevOps in the QualityManual and QualityManagementSystem folders.

7   Bug Handling

Work items describing bugs/defects found are stored electronically in Azure DevOps. Bug reports that require a corrective action are listed in the tables in paragraph 3.

8   Validation Conclusion

The defects listed in Bugs Fixed document were verified fixed and closed. Test cases were added for future verification of the functionality.

No differences that require a corrective action were found, and none of the remaining differences are serious.

The used routines together with the validation ensure that SIMCA-online 17.0.2 gives correct results and is reliable.