**Operational Qualification Report**

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| **Project title:** | A two-part, Phase 1b/2a study to investigate the safety and efficacy of topical Medi‑Solfen for wound analgesia and antisepsis, when used prior to Standard of Care (SOC) (including suture repair) of small to medium, simple skin lacerations in adults |
| **Project code:** | MEDISOLFEN\_H\_06 |
| **Sponsor:** | Medi-Solfen Pty Ltd |
| **Version:** | 1.0 |
| **Date:** | 30.01.2025 |

# **Purpose**

The purpose of this document is to verify and document that RStudio operates as intended and meets the defined operational requirements under actual conditions of use on Windows and macOS.

# **Scope**

This OQ report applies to the installation of RStudio on Windows and macOS.

# **Responsibilities**

**Tester:** Responsible for executing the test scripts and documenting results.

**Validator:** Responsible for reviewing test results and ensuring compliance with acceptance criteria.

**Approver:** Responsible for approving the OQ report

# **Prerequisites**

* Installation Qualification (IQ) completed and approved.
* Test environment prepared and validated.
* Required dependencies installed (e.g., R version).

# **Test plan**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **ID** | **Test Objective** | **Test result** | |  | | --- | |  |   **Pass** | **Comments** |
| 1 | RStudio libraries loaded successfully. | All libraries loaded successfully. |  |  |
| 2 | Data is simulated correctly | Header is displayed |  |  |
| 3 | Data is manipulated correctly | Header is displayed |  |  |
| 4.1 | T test is performed correctly | Test result is displayed |  |  |
| 4.2 | Linear regression is performed correctly | Test result is displayed |  |  |
| 4.3 | ANOVA is performed correctly | Test result is displayed |  |  |
| 5 | Graphical representation is executed correctly | Scatter plot is displayed |  |  |
| 6. | Saving and displaying as .png is performed correctly | Scatter plot is saved as a .png and displayed |  |  |
| 7. | Saving as .xlsx is performed correctly | The file 'manipulated\_data.xlsx' exists in the working directory |  |  |
| 8. | Results are the same as in SAS | Results are the same as in SAS |  |  |

# **Exceptions and Deviations**

Document any exceptions or deviations encountered during the operational process and their resolutions.

|  |  |  |
| --- | --- | --- |
| **Deviation** | **Resolution** | **Date Resolved** |
|  |  |  |

# **Attachments**

Output file generated during testing – OQ-sym-report-OS.

# **Conclusions**

## Summary of Results

The Operational Qualification (OQ) tests were conducted as outlined in the test plan, simulating typical operational conditions to evaluate system performance. All critical functions and workflows were tested against predefined acceptance criteria.

## Validation Status

* Successful Validation: If all acceptance criteria are met, the Operational Qualification stage is deemed successful, demonstrating that the system operates as intended under expected conditions. The system is ready to proceed to the Performance Qualification (PQ) stage.
* Unsuccessful Validation: If any tests fail to meet the acceptance criteria, the OQ stage is considered incomplete until all deviations are resolved and retested successfully.

## Actions for Non-Compliance

If validation is unsuccessful, the following steps should be taken:

* Record the details of the failure or deviation, including affected functionality, observed behavior, and potential root causes.
* Identify the root cause of the failure.
* Perform corrective actions, such as system reconfiguration, workflow adjustments, or patch installation.
* Verify that corrective actions align with predefined specifications.
* Re-execute the affected OQ tests to confirm that the issue has been resolved.
* Ensure all retests meet the acceptance criteria before proceeding to the next qualification stage.

## Recommendations

Revalidation of the OQ stage is recommended under the following conditions:

* Significant modifications to workflows or system configurations.
* Major software updates, such as new features or system patches.
* Prolonged system downtime or disruptions in operational performance.

## Next Steps

Upon successful completion of the Operational Qualification, the system is ready to progress to the Performance Qualification (PQ) stage. The PQ stage will test the system's performance under actual production conditions, ensuring it meets end-user and regulatory requirements.

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| --- | --- |
| Validation status | Successful Validation |

# **Approval**

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| --- | --- | --- | --- |
| Role | Name | Signature | Date |
| Prepared By | Oleksandr Savuliak |  | 30.01.2025 |
| Reviewed By | Anna Zaremba |  | 30.01.2025 |
| Approved By | Marius Ardelean |  | 30.01.2025 |