

E-Track Application (BCIL)

Kusum Healthcare

Operational Qualification Document

This user’s guide includes the operational qualification protocols defined for the application.

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| Revision Number | Date | Prepared By | Reviewed By | Comment |
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# Protocol Approval

**By BCI Team**

|  |  |  |  |  |  |  |
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**By Kusum Team**

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# Objective

The objective of this document is to provide written procedure and/or guidelines and respective acceptance criteria for the Operation Qualification of E-Track Application (BCIL) with documented evidence that system is working as per design and will perform & control the process in operating mode, so as to protect the integrity & quality of the system.

# Scope

The scope of this document is limited to outline procedure / provide methodology for the operational qualification of equipment / system within the following boundaries.

* Verification of the Functional Keys, Sequential operation
* Verification of relevant SOPs for their operational accuracy (such as operation, etc).

# Software OQ

# Web Application

## Login

|  |  |  |  |
| --- | --- | --- | --- |
| **Test Parameter** | **Test Procedure** | **Expected Result** | **Test (Yes/No)** |
|  |  |  |  |

## Company Master

|  |  |  |  |
| --- | --- | --- | --- |
| **Test Parameter** | **Test Procedure** | **Expected Result** | **Test (Yes/No)** |
|  |  |  |  |

## Plant Master

|  |  |  |  |
| --- | --- | --- | --- |
| **Test Parameter** | **Test Procedure** | **Expected Result** | **Test (Yes/No)** |
|  |  |  |  |

## User Master

|  |  |  |  |
| --- | --- | --- | --- |
| **Test Parameter** | **Test Procedure** | **Expected Result** | **Test (Yes/No)** |
|  |  |  |  |

## GTIN Master

|  |  |  |  |
| --- | --- | --- | --- |
| **Test Parameter** | **Test Procedure** | **Expected Result** | **Test (Yes/No)** |
|  |  |  |  |

## Line Master

|  |  |  |  |
| --- | --- | --- | --- |
| **Test Parameter** | **Test Procedure** | **Expected Result** | **Test (Yes/No)** |
|  |  |  |  |

## Consignee Master

|  |  |  |  |
| --- | --- | --- | --- |
| **Test Parameter** | **Test Procedure** | **Expected Result** | **Test (Yes/No)** |
|  |  |  |  |

## Printer Master

|  |  |  |  |
| --- | --- | --- | --- |
| **Test Parameter** | **Test Procedure** | **Expected Result** | **Test (Yes/No)** |
|  |  |  |  |

## Label Design Master

|  |  |  |  |
| --- | --- | --- | --- |
| **Test Parameter** | **Test Procedure** | **Expected Result** | **Test (Yes/No)** |
|  |  |  |  |

## Reports

|  |  |  |  |
| --- | --- | --- | --- |
| **Test Parameter** | **Test Procedure** | **Expected Result** | **Test (Yes/No)** |
|  |  |  |  |

## Generation report

|  |  |  |  |
| --- | --- | --- | --- |
| **Test Parameter** | **Test Procedure** | **Expected Result** | **Test (Yes/No)** |
|  |  |  |  |

## Secondary Printing Report

|  |  |  |  |
| --- | --- | --- | --- |
| **Test Parameter** | **Test Procedure** | **Expected Result** | **Test (Yes/No)** |
|  |  |  |  |

## Tertiary Printing Report

|  |  |  |  |
| --- | --- | --- | --- |
| **Test Parameter** | **Test Procedure** | **Expected Result** | **Test (Yes/No)** |
|  |  |  |  |

## Outward Report

|  |  |  |  |
| --- | --- | --- | --- |
| **Test Parameter** | **Test Procedure** | **Expected Result** | **Test (Yes/No)** |
|  |  |  |  |

## Mapping Report

|  |  |  |  |
| --- | --- | --- | --- |
| **Test Parameter** | **Test Procedure** | **Expected Result** | **Test (Yes/No)** |
|  |  |  |  |

## Secondary Rejection/Sample Report

|  |  |  |  |
| --- | --- | --- | --- |
| **Test Parameter** | **Test Procedure** | **Expected Result** | **Test (Yes/No)** |
|  |  |  |  |

## Tertiary Rejection/sample Report

|  |  |  |  |
| --- | --- | --- | --- |
| **Test Parameter** | **Test Procedure** | **Expected Result** | **Test (Yes/No)** |
|  |  |  |  |

## Secondary Un-utilization Report

|  |  |  |  |
| --- | --- | --- | --- |
| **Test Parameter** | **Test Procedure** | **Expected Result** | **Test (Yes/No)** |
|  |  |  |  |

## Tertiary Un-utilization Report

|  |  |  |  |
| --- | --- | --- | --- |
| **Test Parameter** | **Test Procedure** | **Expected Result** | **Test (Yes/No)** |
|  |  |  |  |

## Audit Trail report

|  |  |  |  |
| --- | --- | --- | --- |
| **Test Parameter** | **Test Procedure** | **Expected Result** | **Test (Yes/No)** |
|  |  |  |  |

## batch report

|  |  |  |  |
| --- | --- | --- | --- |
| **Test Parameter** | **Test Procedure** | **Expected Result** | **Test (Yes/No)** |
|  |  |  |  |

## Client Application- Login

|  |  |  |  |
| --- | --- | --- | --- |
| **Test Parameter** | **Test Procedure** | **Expected Result** | **Test (Yes/No)** |
|  |  |  |  |

## Batch Creation

|  |  |  |  |
| --- | --- | --- | --- |
| **Test Parameter** | **Test Procedure** | **Expected Result** | **Test (Yes/No)** |
|  |  |  |  |

## Serial No Generation

|  |  |  |  |
| --- | --- | --- | --- |
| **Test Parameter** | **Test Procedure** | **Expected Result** | **Test (Yes/No)** |
|  |  |  |  |

## Barcode Printing

|  |  |  |  |
| --- | --- | --- | --- |
| **Test Parameter** | **Test Procedure** | **Expected Result** | **Test (Yes/No)** |
|  |  |  |  |

## Rejection of Generation Report

|  |  |  |  |
| --- | --- | --- | --- |
| **Test Parameter** | **Test Procedure** | **Expected Result** | **Test (Yes/No)** |
|  |  |  |  |

## Serial No. Rejection

|  |  |  |  |
| --- | --- | --- | --- |
| **Test Parameter** | **Test Procedure** | **Expected Result** | **Test (Yes/No)** |
|  |  |  |  |

## Job Creation

|  |  |  |  |
| --- | --- | --- | --- |
| **Test Parameter** | **Test Procedure** | **Expected Result** | **Test (Yes/No)** |
|  |  |  |  |

## Online Scanning

|  |  |  |  |
| --- | --- | --- | --- |
| **Test Parameter** | **Test Procedure** | **Expected Result** | **Test (Yes/No)** |
|  |  |  |  |

# Deviation Report

|  |  |  |
| --- | --- | --- |
| **Deviation if any** | **Available (Yes/No)** | **Remarks** |
|  |  |  |

# Conclusion

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

# Protocol Post Approval

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| Checked By | | |
| Name | Designation | Signature & Date |
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| Department | Name | Designation | Signature & Date |
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