

Dispensing Automation System

Fresenius Kabi Oncology Limited

Operational Qualification Protocol Document

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

BAR CODE INDIA, 145 Udyog Vihar Phase I, Gurugram, Haryana-122016, PH: 0124 4337555

**Protocol Approval**

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| Prepared By | | |
| **Name** | **Designation** | **Signature & Date** |
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| **Name** | **Designation** | **Signature & Date** |
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| **Approved By** | | | |
| **Department** | **Name** | **Designation** | **Signature & Date** |
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# Objective

The objective of this protocol is :

1. To define the Operation Qualification (OQ) requirements for the Dispensing Automation System at Fresenius Kabi Oncology Ltd.
2. To ensure that the Dispensing Automation System operates according to the specifications.
3. To establish documented evidence that the barcode application system functions as expected.

# Scope

The scope of this protocol includes operations qualification procedure of the Dispensing Automation System. This protocol defines the procedures, documentation, acceptance criteria & re-qualification criteria.

# Qualification Team

Responsible staff from:

1. I.T
2. Warehouse
3. QC
4. Quality Assurance

# Responsibilities

|  |  |
| --- | --- |
| **Department** | **Description** |
| Vendor | * Supporting \ in conducting qualification in accordance with the protocol requirements. |
| QA | * Checking of protocol. * Execution of studies in coordination with other departments, according to the protocol. * Review the data documented during operation qualification. * Final Approval of Protocol & Report. |
| I.T, Warehouse, QC | * Checking of protocol. * Documentation of data during the qualification study. * Establishing written procedures for the operation of the application system for routine use. |

# Procedure

5.1 Operation qualification of system shall be conducted in presence of representatives from operating/user department, IT and QA department.

5.2 Check for the availability of following documents and record in **test data sheet 1**.

1. IQ report
2. SOPs (at least as drat) identified during IQ.

5.3 Check and ensure that different functions for correct operation of the system are working as expected and record in **test data sheet 2**.

5.4 Perform power and recovery verification of the system and record in **test data sheet 3**.

5.5 Check the password authorization and software complexity and record the same in **test data sheet 4**.

5.6 Deviation Handling: During execution, if any deviation is observed, it shall be recorded in **test data sheet 5**.

The deviation will be assessed whether it has any GMP criticality. GMP non-critical deviations can be justified whereas GMP critical deviation may require investigation and corrective action.

Analyze the deviations, whether they can affect the Operational or Performance qualification test or not. If not, performance qualification can be initiated before the deviations are closed.

# Acceptance Criteria

6.1 All operating inputs provided to the equipment as per the procedure of operation qualification, when checked, shall successfully comply with their intended use.

6.2 The equipment when operated shall not produce any abnormal sound or show any discrepancy in its smooth operation.

# Re-Qualification Criteria

7.1 Change in location of the system.

7.2 In case of any major maintenance, up gradation or modification, this affects performance of the system.

**Test Data Sheet # 1**

**AVAILABILITY OF DOCUMENTS**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Sr. No.** | **Document Title** | **Available**  **(Yes / No / NA)** | **Document No.** | **Checked By (Q.A)** | **Verified By (Q.A)** |
|  | IQ Report |  |  |  |  |
|  | Draft SOPs |  |  |  |  |

**Test Data Sheet # 2**

**FUNCTIONAL CHECKS**

**Part [ A ] : Functional Checks of Hardware**

|  |  |  |  |
| --- | --- | --- | --- |
| **Sr.**  **No** | **Procedure** | **Acceptance Criteria** | **Observation** |
| **a)** | **For Printer (ZT411/ZT230)** | | |
|  | Turn the printer power switch ON position. | Power should get supplied to the printer and status indicator should glow green. |  |
|  | Load the media in tear off mode. | Media (label roll) should get loaded in to the printer with proper position. |  |
|  | Load the ribbon. | Ribbon should get loaded in to the printer & no any error of “Ribbon Out” |  |
|  | Ensure that roll label is inside the printer and press the Feed functional key of the key pad. | Printer should feed one blank label. |  |
|  | When printing is ongoing, press the Pause functional key of the key pad. | Printing process should stop and pause indicator should glow with yellow light. |  |
|  | Press the Pause functional key again. | Printing process should resume. |  |
|  | When printing is ongoing, press the Cancel functional key of the key pad. | Current printing jobs should get cancelled. |  |

**Test Data Sheet # 2**

**FUNCTIONAL CHECKS**

**Part [A]: Functional Checks of Hardware**

|  |  |  |  |
| --- | --- | --- | --- |
| **Sr.**  **No** | **Procedure** | **Acceptance Criteria** | **Observation** |
| **a)** | **For Printer (ZT411/ZT230)** | | |
|  | Press the Arrow (Right) functional key of the key pad. | Navigation towards right should happen on the display. |  |
|  | Press the Arrow (Up) functional key of the key pad. | There should be increase in the value on the display. |  |
|  | Press the Arrow (Left) functional key of the key pad. | Navigation towards left should happen on the display. |  |
|  | Press the Arrow (Down) functional key of the key pad. | There should be decrease in the value on the display. |  |
|  | Give printout of labels from the barcode application system. | Data indicator should glow green while printing. |  |
|  | Press Right Select Button | Navigation on the display should happen for the command shown directly above the button. |  |
|  | Press Left Select Button | Navigation on the display should happen for the command shown directly above the button. |  |
|  | Connect the printer with network supply | Network indicator should glow red indication while connected to network |  |

**Test Data Sheet # 2**

**FUNCTIONAL CHECKS**

**Part [ A ] : Functional Checks of Hardware**

|  |  |  |  |
| --- | --- | --- | --- |
| **Sr.**  **No** | **Procedure** | **Acceptance Criteria** | **Observation** |
| **a)** | **For Printer (ZT411)** | | |
|  | Start the printer and print the label. | Label should get printed smoothly and contents on the printed label should be legible. |  |
| There should be no wear and tear of the label during the trial run. |  |
| No abnormal noise should be produced during the trial run. |  |
| No abnormal vibration should be produced during the trial run. |  |

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| **Department** |  |  |
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**Test Data Sheet # 2**

**FUNCTIONAL CHECKS**

**Part [ A ] : Functional Checks of Software**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Step: User Master** | | | | |
| **Sr.**  **No.** | **Test** | **Test Procedure** | **Acceptance Criteria** | **Observation** |
| 1. | Login of the user | Login with correct username and correct Password | The system should allow to login to the system if correct login credentials are entered | Complies  Does not comply |
| 2 | User Master Screen display | Go to user masters under Masters Screen | Only authorized personnel should be able to view the User Master Page | Complies  Does not comply |
| 3 | User creation | Create a new user using proper credentials | System should allow to create a new user with unique user credentials and specified user level assignment | Complies  Does not comply |
| 4 | Edit User | Try to edit created user | System should allow to edit the user details using authorized credentials like user level and password. | Complies  Does not comply |
| 5 | Duplicate User Code | Try to create a new User master with the existing User code | System should not allow to create duplicate User code | Complies  Does not comply |
| 6 | Assigning Rights to user | In the user master screen go to the rights tab under Master screen | System should allow the user select User ID, Plant ID and Role. Only authorized person can assign roles to user. | Complies  Does not comply |
| 7 | View Details | Click on view all details button | System will display all the details of user master.  User can perform search criteria using fields. | Complies  Does not comply |

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| **Step: User Role** | | | | |
| **Sr.**  **No.** | **Test** | **Test Procedure** | **Acceptance Criteria** | **Observation** |
| 1 | View Details | Click on view all details button after successful login. | System will display all the details of Role master.  User can perform search criteria using fields. | Complies  Does not comply |

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| **Step: Plant Master** | | | | |
| **Sr.**  **No.** | **Test** | **Test Procedure** | **Acceptance Criteria** | **Observation** |
| 1 | Login of the user | Login with correct username and correct Password | The system should allow to login to the system if correct login credentials are entered | Complies  Does not comply |
| 2 | Plant Master Screen display | Go to Plant masters under Masters Screen | Only authorised personnel should be able to view the Plant Master Page | Complies  Does not comply |
| 3 | Plant creation | Create a new Plant using proper credentials | System should allow to create a new Plant | Complies  Does not comply |
| 4 | Edit Plant Created | Try to edit created plant | System should allow to edit the Plant Created | Complies  Does not comply |
| 5 | Duplicate Plant Code | Try to create a new plant master with the existing plant code | System should not allow to create duplicate plant code | Complies  Does not comply |
| 6 | View Details | Click on view all details button | System will display all the details of Plant master.  User can perform search criteria using fields. | Complies  Does not comply |

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| **Step: Bin Master** | | | | |
| **Sr.**  **No.** | **Test** | **Test Procedure** | **Acceptance Criteria** | **Observation** |
| 1 | Bin Master screen display | Go to Bin masters under Masters Screen after successful login. | Only authorised personnel should be able to view the Bin Master Page | Complies  Does not comply |
| 2 | Bin creation | Select the plant code, enter the bin Code and Click on ‘Get SAP Data’ Button | System will gets data from SAP and display the details of Bin | Complies  Does not comply |
| 3 | Edit Bin Created | Try to edit created Bin | System should allow to only activate / de-activate the Bin. | Complies  Does not comply |
| 4 | Deactivate Bin | Try to deactivate Created Bin | System should allow to deactivate the created Bin | Complies  Does not comply |
| 5 | Duplicate Bin Code | Try to create a new Bin master with the existing plant code | System should not allow to create duplicate Bin code | Complies  Does not comply |
| 6 | View Details | Click on view all details button | System will display all the details of Bin master.  User can perform search criteria using fields. | Complies  Does not comply |

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| **Step: Booth Master** | | | | |
| **Sr.**  **No.** | **Test** | **Test Procedure** | **Acceptance Criteria** | **Observation** |
| 1 | Booth Master Screen display | Go to Booth masters under Masters Screen after successful login. | Only authorised personnel should be able to access the Booth Master Page | Complies  Does not comply |
| 2 | New Booth master creation | Create a new Booth master using proper credentials | System should allow to create a new Booth master with proper printer code, printer IP, printer port and cubicle code | Complies  Does not comply |
| 3 | Edit created Booth master | Try to edit created Booth master | System should allow to edit created Booth master | Complies  Does not comply |
| 4 | Duplicate Booth Master | Try to create new Booth master with the existing Booth code | System should not allow to create duplicate Booth code | Complies  Does not comply |
| 5 | View Details | Click on view all details button | System will display all the details of Booth master.  User can perform search criteria using fields | Complies  Does not comply |

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| **Step: Weighing Master** | | | | |
| **Sr.**  **No.** | **Test** | **Test Procedure** | **Acceptance Criteria** | **Observation** |
| 1 | Weighing Master  Screen display. | Go to weighing masters under Masters Screen after successful login. | Only authorised personnel should be able to view the Weighing Master Page | Complies  Does not comply |
| 2 | Data Entry. | All the required fields should be filled | System should allow to fill the mandatory fields with the proper data. | Complies  Does not comply |
| 3 | Weighing Master Creation | After filling all the details click on save button | System should allow to save the created weighing master | Complies  Does not comply |
| 4 | Edit created Weighing Master | Select the required weighing master and edit the details | System should allow to edit the weighing master details using authorized credentials. | Complies  Does not comply |
| 5 | Duplicate Master | Try creating a duplicate weighing master with already used weighing code. | System should not allow creation of duplicate weighing master | Complies  Does not comply |
| 6 | View Details | Click on view all details button | System will display all the details of Weighing master. User can perform search criteria using fields. | Complies  Does not comply |

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| **Step: Standard Weight Master** | | | | |
| **Sr.**  **No.** | **Test** | **Test Procedure** | **Acceptance Criteria** | **Observation** |
| 1 | Standard Weight  Master Screen  display | Go to Standard Weight masters under Masters Screen after successful login. | Only authorized personnel should be able to view the Standard weight Master Page | Complies  Does not comply |
| 2 | Data Entry | All the required fields should be filled | System should allow to fill the mandatory fields with the desired values | Complies  Does not comply |
| 3 | Standard Weight creation | After Filling all the mandatory fields click on save button | System should allow to save the standard weight | Complies  Does not comply |
| 4 | Edit Created Standard Weight master | Select the created standard weight try to edit the details in the master edit the details | System should allow to edit the standard weight details using authorized credentials. Master details using authorized credentials. | Complies  Does not comply |
| 5 | Duplicate Master | Try creating a duplicate master | System should not allow creation of duplicate standard weight master | Complies  Does not comply |
| 6 | View Details | Click on view all details button | System will display all the details of Weighing master. User can perform search criteria using fields. | Complies  Does not comply |

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| **Step: Printer Master** | | | | |
| **Sr.**  **No.** | **Test** | **Test Procedure** | **Acceptance Criteria** | **Observation** |
| 1 | Printer Master Screen display | Go to Printer masters under Masters Screen after successful login. | Only authorized personnel should be able to access the Printer Master Page | Complies  Does not comply |
| 2 | New Printer master creation | Create a new printer master using proper credentials | System should allow to create a new printer  master with proper printer code, printer IP, printer port and cubicle code | Complies  Does not comply |
| 3 | Edit created printer master | Try to edit created printer master | System should allow to edit created printer master | Complies  Does not comply |
| 4 | Duplicate Printer Master | Try to create new printer master with the existing printer code | System should not allow to create duplicate printer code | Complies  Does not comply |
| 5 | View Details | Click on view all details button | System will display all the details of Printer master.  User can perform search criteria using fields. | Complies  Does not comply |

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| **Step: Master label Printing** | | | | |
| **Sr.**  **No**. | **Test** | **Test Procedure** | **Acceptance Criteria** | **Observation** |
| 1 | Master Barcode Print screen display | Go to Barcode Print Master under Masters Screen after successful login. | Only authorised personnel should be able to access the Barcode Print Master Page | Complies  Does not comply |
| 2 | Select Print Master Barcode or Re-Print Master Barcode | Select Module Bin Master or Weighing Master | On selection of module appropriate records will display below of Bin /Weighing Master. | Complies  Does not comply |
| 3 | Select all (checkbox) | Check the select all checkbox | System will select all the records | Complies  Does not comply |

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| **Step: Material Receiving** | | | | |
| **Sr.**  **No.** | **Test** | **Test Procedure** | **Acceptance Criteria** | **Observation** |
| 1 | Transaction screen display | In the Warehouse menu go to Purchase Order Screen after successful login. | Only authorized personnel should be able to view the Purchase Order Page under Warehouse Menu | Complies  Does not comply |
| 2 | General Details Entry | Click On “Enter General Details” Button and enter proper credentials and then Save the details by Pressing “Save” Button | Software should allow to enter the general details and also allow to Save the details | Complies  Does not comply |
| 3 | Material Details | After General Details Entry click on “Next” Button and enter the material details | System will allow to enter the proper material details and allow to save the details into System | Complies  Does not comply |

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| **Step: MAN No. Creation** | | | | |
| **Sr.**  **No.** | **Test** | **Test Procedure** | **Acceptance Criteria** | **Observation** |
| 1 | Transaction Screen display | In the Warehouse menu go to Material Posting (MAN No.) after successful login. | Only authorised personnel should be able to view the Material Posting (MAN No.) screen under Warehouse Page | Complies  Does not comply |
| 2 | Enter Purchase Order No. | Enter Purchase Order No. and click on ‘Get’ Button | System allow to enter the purchase order no. and display the details into list after clicking ‘Get’ Button. | Complies  Does not comply |
| 3 | Create MAN No | Enter the SAP user name and Password and Click on ‘Post Data To SAP’ Button | System allow to Post data to SAP and display MAN No. to user | Complies  Does not comply |

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| **Step: Sample Label Printing** | | | | |
| **Sr.**  **No.** | **Test** | **Test Procedure** | **Acceptance Criteria** | **Observation** |
| 1 | Transaction Screen display | In the Warehouse menu go to Status Label Printing after successful login. | Only authorised personnel should be able to view the Status Label Printing screen under Warehouse Page | Complies  Does not comply |
| 2 | MAN No entry | Enter the MAN No ,click on Get button  And after getting Details Press Print button after selecting Printer name To Print Label | Software should allow entry of MAN No. On clicking get button appropriate records will be displayed. And Label will get print after clicking print button. | Complies  Does not comply |
| 3 | Printer Name entry | Enter Printer Name | Select the printer name, otherwise error message will be displayed(Please select Printer) | Complies  Does not comply |

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| **Step: Status Label Re-Printing** | | | | |
| **Sr.**  **No.** | **Test** | **Test Procedure** | **Acceptance Criteria** | **Observation** |
| 1 | Transaction Screen display | In the Warehouse menu go to Status Label Printing after successful login. | Only authorised personnel should be able to view the Status Label Printing screen under Warehouse Page | Complies  Does not comply |
| 2 | MAN No entry | Enter the MAN No ,click on Get button  And after getting Details Press Print button after selecting Printer name To Print Label | Software should allow entry of MAN No. On clicking get button appropriate records will be displayed. And Label will get print after clicking print button. | Complies  Does not comply |

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| **Step: Sample withdrawn** | | | | |
| **Sr.**  **No.** | **Test** | **Test Procedure** | **Acceptance Criteria** | **Observation** |
| 1 | Transaction screen display | In the main menu go to Sample Withdrawn after successful login. | Only authorized personnel should be able to view Sample Withdrawn Screen | Complies  Does not comply |
| 2 | Status Label Barcode Scan | Scan Sample Barcode | Software should allow Scan Status Barcode and display MAN No., Material Code, description, Batch No., Accepted Qty.,UOM | Complies  Does not comply |
| 3 | Sample Quantity | Enter Sample Quantity and Save the Details | System should allow entering sample quantity and Save Details into System. | Complies  Does not comply |
| 4 | Duplicate Scan | Scan Status barcode which is already Sampled | System should display message as “Already Sampled” | Complies  Does not comply |

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| **Step: Allocation** | | | | |
| **Sr.**  **No.** | **Test** | **Test Procedure** | **Acceptance Criteria** | **Observation** |
| 1 | Transaction screen  display | In the Allocation menu go to Material Allocation screen after successful login. | Only authorized personnel should be able to view Material Allocation under Allocation Menu | Complies  Does not comply |
| 2 | Bin Scan | Scan Bin Barcode | Software should allow Scan Bin code , and allow to scan the material barcode and display Storage Type | Complies  Does not comply |
| 3 | Scan Status Label | Scan Status barcode label | System should allow Scan Status Barcode , and display the Material Code, Material Description, Batch no, Source Storage Bin and system will save the details and display Total count. | Complies  Does not comply |

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| **Step: Location Transfer** | | | | |
| **Sr.**  **No.** | **Test** | **Test Procedure** | **Acceptance Criteria** | **Observation** |
| 1 | Transaction screen  display | In the Allocation menu go to Material Allocation screen after successful login. | Only authorized personnel should be able to view Material Allocation under Allocation Menu | Complies  Does not comply |
| 2 | Bin Scan | Scan To Bin Barcode | Software should allow Scan To Bin code , and allow to scan the material barcode and display Storage Type | Complies  Does not comply |
| 3 | Scan Status Label | Scan Status barcode label | System should allow Scan Status Label, and display the Material Code, Material Description, Batch no, Source Storage Bin and system will save the details and display Total count | Complies  Does not comply |
| 4 | Check Material Allocation | Scan the material which is not allocated | System should not allow to material transfer which is not allocated | Complies  Does not comply |

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| **Step: Material Allocation Posting** | | | | |
| **Sr.**  **No.** | **Test** | **Test Procedure** | **Acceptance Criteria** | **Observation** |
| 1 | Transaction screen  Display | In the Allocation menu go to Material Allocation Posting screen after successful login. | Only authorized personnel should be able to view Material Allocation Posting under Allocation Menu | Complies  Does not comply |
| 2 | Allocation Details Display | After accessing the screen system wil show the pending allocation details which are remaining for Posting To SAP. | System should show the records which are pending for posting Only | Complies  Does not comply |
| 3 | Posting Allocation  Data To SAP | Enter SAP User ID and SAP Password and then click on post button | System will Post the data to SAP and successful posted message will display on the screen. | Complies  Does not comply |

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| **Step: Weighing Calibration** | | | | |
| **Sr.**  **No.** | **Test** | **Test Procedure** | **Acceptance Criteria** | **Observation** |
| 1 | Transaction screen  Display | In the Main menu go to Weighing Calibration screen after successful login. | Only authorized personnel should be able to view Weighing Calibration screen in Main Menu | Complies  Does not comply |
| 2 | 4 Point Calibration | Perform 4 Point Calibration using Weighing calibration screen | System should allow to perform 4 Point calibration | Complies  Does not comply |
| 3 | Corner Calibration | Perform Corner Calibration using Weighing calibration screen | System should allow to perform Corner Calibration | Complies  Does not comply |
| 4 | Reproducibility  Calibration | Perform Reproducibility Calibration using Weighing calibration screen | System should allow to perform Reproducibility Calibration | Complies  Does not comply |
| 4 | Daily Calibration | Perform Daily Calibration using Weighing calibration screen | System should allow to perform Daily Calibration | Complies  Does not comply |
| 5 | Yearly Calibration | Perform Yearly Calibration using Weighing calibration screen (Done by Vendor) | System should allow to perform Yearly Calibration | Complies  Does not comply |

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| **Step: Picking (Process Order)** | | | | |
| **Sr.**  **No.** | **Test** | **Test Procedure** | **Acceptance Criteria** | **Observation** |
| 1 | Transaction screen  display | In the Main menu go to Picking screen after successful login. | Only authorized personnel should be able to view Picking screen under Main Menu | Complies  Does not comply |
| 2 | PO Number  Details | Select the PO no. Check Box and enter PO no. and Click on ‘Get SAP Data’ Button | System will allow checking the PO No. and displaying the PO No Details in the list after Clicking the Get SAP Data Button. | Complies  Does not comply |
| 3 | Material Picking  Screen | After getting the details Select the Material from list and Click on Next Button. | System should allow to select the material and On Next button click system will show the details of selected material on the screen. | Complies  Does not comply |
| 4 | Scan Bin | Select the Bin from suggest bin drop down list and Scan the Bin Barcode | System allow to select the bin from drop down list and after the scanning of Bin code system should allow to scan the material. | Complies  Does not comply |
| 5 | Scan Material  Barcode | Scan Material Status label Barcode and Press SAVE button | System will allow to scan Material Status label Barcode and after pressing Save  Button details should Save the details. | Complies  Does not comply |
| 6 | Invalid Bin Scan | Scan the bin which is not in suggested list / Invalid list | System will show invalid bin scanned message | Complies  Does not comply |
| 7 | Invalid Material  Scan | Scan any other material | System will show invalid material scanned message | Complies  Does not comply |

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| **Step: Dispensing (Process Order)** | | | | |
| **Sr.**  **No.** | **Test** | **Test Procedure** | **Acceptance Criteria** | **Observation** |
| 1 | Transaction screen  display | In the Main menu go to Dispensing screen after successful login. | View dispensing screen under Main Menu | Complies  Does not comply |
| 2 | PO Number  Details | Select the PO no. Check Box and enter PO no. and Click on ‘Get Data’ Button | System will allow checking the PO No. and displaying the PO No Details in the list after Clicking the Get Data Button. | Complies  Does not comply |
| 3 | Material  Dispensing Screen | After getting the details Select the Material from list and Click on Next Button. | System should allow selecting the material and On Next button click system will show the details of selected material on the screen. | Complies  Does not comply |
| 4 | Scan Material | Select the booth and scan the status label | System should allow to select the booth and allow to scan status label. | Complies  Does not comply |
| 5 | Weight Capture | Scan the weighing balance code and capture the Tare and Net weight | System should allow to capture weight by scanning the weighing balance code. | Complies  Does not comply |
| 6 | Dispensing Label  Print | After capturing weight, Select the Printer and click on Print Button. | System should print dispensed label from selected printer. | Complies  Does not comply |
| 7 | Invalid Material | Scan any other material barcode | System will show Invalid material scan message. | Complies  Does not comply |

**Checked By (Sign/Date): Verified By (Sign/Date):**

**(Warehouse) (QA)**

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| **Step: Picking (Reservation)** | | | | |
| **Sr.**  **No.** | **Test** | **Test Procedure** | **Acceptance Criteria** | **Observation** |
| 1 | Transaction screen  display | In the Main menu go to Picking screen after successful login. | View Picking screen under Main Menu | Complies  Does not comply |
| 2 | Reservation  Number Details | Select the Reservation no. Check Box and enter Reservation no. and Click on ‘Get SAP Data’ Button | System will allow checking the Reservation No. and displaying the Reservation No Details in the list after Clicking the Get SAP Data Button. | Complies  Does not comply |
| 3 | Material Picking  Screen | After getting the details Select the Material from list and Click on Next Button. | System should allow to select the material and On Next button click system will show the details of selected material on the screen. | Complies  Does not comply |
| 4 | Scan Bin | Select the Bin from suggest bin drop down list and Scan the Bin Barcode | System allows selecting the bin from drop down list and after the scanning of Bin code system should allow to scan the material. | Complies  Does not comply |
| 5 | Scan Material  Barcode | Scan Material Status label Barcode and Press SAVE button | System will allow to scan Material Status label Barcode and after pressing Save  Button details should Save the details. | Complies  Does not comply |

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| **Step: Dispensing (Reservation)** | | | | |
| **Sr.**  **No.** | **Test** | **Test Procedure** | **Acceptance Criteria** | **Observation** |
| 1 | Transaction screen  display | In the Main menu go to Dispensing screen after successful login. | View dispensing screen under Main Menu | Complies  Does not comply |
| 2 | Reservation No.  Details | Select the Reservation no. Check Box and enter Reservation no. and Click on ‘Get Data’ Button | System will allow checking the Reservation No. and displaying the Reservation No Details in the list after Clicking the Get Data Button. | Complies  Does not comply |
| 3 | Material  Dispensing Screen | After getting the details Select the Material from list and Click on Next Button. | System should allow selecting the material and On Next button click system will show the details of selected material on the screen. | Complies  Does not comply |
| 4 | Scan Material | Select the booth and scan the status label | System should allow to select the booth and allow to scan status label. | Complies  Does not comply |
| 5 | Weight Capture | Scan the weighing balance code and capture the Tare and Net weight | System should allow to capture weight by scanning the weighing balance code. | Complies  Does not comply |
| 6 | Dispensing Label  Print | After capturing weight, Select the Printer and click on Print Button. | System should print dispensed label from selected printer. | Complies  Does not comply |

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**(Warehouse) (QA)**

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| **Step: Dispensing Data Posting (Process Order)** | | | | |
| **Sr.**  **No.** | **Test** | **Test Procedure** | **Acceptance Criteria** | **Observation** |
| 1 | Transaction screen  display | In the warehouse menu go to Dispensing Posting screen after successful login. | View Dispensing Posting under warehouse menu | Complies  Does not comply |
| 2 | PO no entry | Select PO No. check box and enter the PO no | Software should allow entry PO No and appropriate records will be displayed below. | Complies  Does not comply |
| 3 | Dispense Data  Posting | Enter the SAP user ID and Password quantity and click on Post Button | System will allow to enter the details and system will Post data to SAP and Posted Document No will display on screen | Complies  Does not comply |

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**(Warehouse) (QA)**

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| --- | --- | --- | --- | --- |
| **Step: Dispensing Data Posting (Reservation)** | | | | |
| **Sr.**  **No.** | **Test** | **Test Procedure** | **Acceptance Criteria** | **Observation** |
| 1 | Transaction screen  display | In the warehouse menu go to Dispensing Posting screen after successful login. | View Dispensing Posting under warehouse menu | Complies  Does not comply |
| 2 | Reservation No entry | Select Reservation No. check box and enter the Reservation no | Software should allow entry Reservation No and appropriate records will be displayed below. | Complies  Does not comply |
| 3 | Dispense Data  Posting | Enter the SAP user ID and Password quantity and click on Post Button | System will allow to enter the details and system will Post data to SAP and Posted Document No will display on screen | Complies  Does not comply |

**Checked By (Sign/Date): Verified By (Sign/Date):**

**(Warehouse) (QA)**

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| **Step: Re-Print Dispensing Label** | | | | |
| **Sr.**  **No.** | **Test** | **Test Procedure** | **Acceptance Criteria** | **Observation** |
| 1 | Transaction Screen display | In the Warehouse menu go to Dispensing label Reprinting screen after successful login. | View the Dispensing Label Re –printing under Warehouse Menu | Complies  Does not comply |
| 2 | PO / Reservation no entry | Enter the PO / Reservation no | Software should allow entry of PO / Reservation no. On clicking get button appropriate records will be displayed. | Complies  Does not comply |
| 3 | Printer Name, Reason entry | Select the Printer Name, and enter Reason and Click On Print Button | Label get Printed | Complies  Does not comply |

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**(Warehouse) (QA)**

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| --- | --- | --- | --- | --- |
| **Step: MRN Label Printing** | | | | |
| **Sr.**  **No.** | **Test** | **Test Procedure** | **Acceptance Criteria** | **Observation** |
| 1 | Transaction screen  display | In the Warehouse menu go to MRN Label Printing Screen after successful login. | View MRN Label Printing Screen | Complies  Does not comply |
| 2 | Enter Material  Doc. No | Enter Material Doc. No Click on GET Data From SAP  button | System will allow to enter Material Doc. No. and display the details after pressing GET Data From SAP | Complies  Does not comply |
| 3 | Enter the details | Select the material and Batch no and enter the no. of container and the Quantity of the container and then select the Printer for Printing MRN Label | System will allow to enter the details | Complies  Does not comply |
| 4 | Print MRN Label | Click on Print Button | System will Print MRN Label | Complies  Does not comply |

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**(Production) (QA)**

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| **Step: Re-Print MRN Label** | | | | |
| **Sr.**  **No.** | **Test** | **Test Procedure** | **Acceptance Criteria** | **Observation** |
| 1 | Transaction Screen display | In the Warehouse menu go to MRN label Reprinting screen after successful login. | View the MRN Label Re –printing under Warehouse Menu | Complies  Does not comply |
| 2 | Material Doc. no entry | Enter the Material Doc. no | Software should allow entry of Material Doc.no. On clicking get button appropriate records will be displayed. | Complies  Does not comply |
| 3 | Printer Name, Reason entry | Select the Printer Name, and enter Reason and Click On Print Button | Label get Printed | Complies  Does not comply |

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**(Warehouse) (QA)**

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| **Step: Intermediate Label Printing** | | | | |
| **Sr.**  **No.** | **Test** | **Test Procedure** | **Acceptance Criteria** | **Observation** |
| 1 | Transaction screen  display | In the Warehouse menu go to Intermediate Label Printing Screen after successful login. | View Intermediate Label Printing Screen | Complies  Does not comply |
| 2 | Enter the details | Enter all details  required to print the  intermediate labels | System will allow to enter the details to print the intermediate labels | Complies  Does not comply |
| 3 | Print Intermediate  Label | Select the Printer in dropdown list and click on Print button | System will Print MRN Label | Complies  Does not comply |

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| **Step: Re-Print Intermediate Label** | | | | |
| **Sr.**  **No.** | **Test** | **Test Procedure** | **Acceptance Criteria** | **Observation** |
| 1 | Transaction Screen display | In the Warehouse menu go to Intermediate label Reprinting screen after successful login. | View the Intermediate Label Re –printing under Warehouse Menu | Complies  Does not comply |
| 2 | Product Code entry | Enter the Product code and press Get button. | Software should allow enter the Product Code. On clicking get button appropriate records will be displayed. | Complies  Does not comply |
| 3 | Printer Name, Reason entry | Select the Printer Name, and enter Reason and Click On Print Button | Label get Printed | Complies  Does not comply |

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**(Warehouse) (QA)**

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| **Step: Code To Code Transfer** | | | | |
| **Sr.**  **No.** | **Test** | **Test Procedure** | **Acceptance Criteria** | **Observation** |
| 1 | Transaction screen  display | In the Warehouse menu go to Code To Code Transfer Screen after successful login. | View Code To Code Transfer Screen | Complies  Does not comply |
| 2 | Enter the details | Enter all details  required to Code To  Code Transfer | System will allow to enter the details to Code To Code Transfer | Complies  Does not comply |
| 3 | Print Code To Code Transfer | Select the Printer in dropdown list and click on Print button | System will Print MRN Label | Complies  Does not comply |

**Checked By (Sign/Date): Verified By (Sign/Date):**

**(Warehouse) (QA)**

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| **Step: Status Display** | | | | |
| **Sr.**  **No.** | **Test** | **Test Procedure** | **Acceptance Criteria** | **Observation** |
| 1 | Transaction screen  display | In the Main menu go to Status Display Screen after successful login. | Only authorized personnel should be able to view Status Display Screen | Complies  Does not comply |
| 2 | Scan Material  Status Label | Scan Status barcode Label | System will allow to scan Status Label and display the Status details | Complies  Does not comply |

**Checked By (Sign/Date): Verified By (Sign/Date):**

**(Warehouse) (QA)**

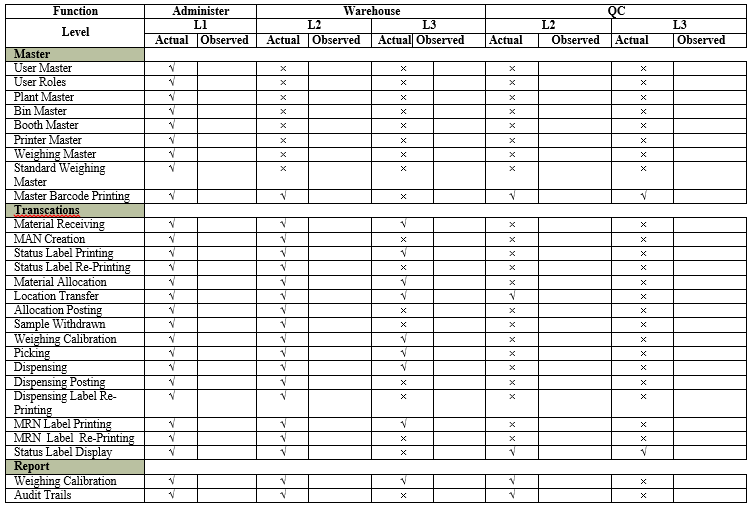
**Test Data Sheet # 3**

**POWER FAILURE & RECOVERY VERIFICATION**

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| --- | --- | --- | --- | --- | --- |
| **Sr. No.** | **Procedure** | | **Acceptance Criteria** | | **Observation** |
| 1 | Switch off the Power supply of Printer (ZT411/ZT230) | | Printer should stop in normal mode. | |  |
| 2 | Restore the power supply of printer (ZT411/ZT230)  (Operator intervention required to restart the system) | | Printer should starts automatically & prints remaining labels as well as reprints the label which is under printing head during power failure. | |  |
| **Signature** | |  | |  | |
| **Date** | |  | |  | |
| **Name** | |  | |  | |
| **Department** | |  | |  | |
|  | | **Checked By** | | **Verified By** | |

**Test Data Sheet # 4**

**VERIFICATION OF PASSWORD AUTHORIZATION & SOFTWARE COMPLEXITY**



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| --- | --- | --- |
| **Checked By(IT):** | **Checked By (WH):** | **Checked By(QC):** |
| **Verified By(QA):** | **Verified By(QA):** | **Verified By(QA):** |

**Verification of Password Requirement**

Objective: To verify the complexity of password of the computerized system.

Procedure: Login with user credentials and checks the password complexity requirements

Acceptance Criteria: The password of the software system should be complex and meet the expected results

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| --- | --- | --- | --- |
| **Sr. No.** | **As Expected** | **As observed** | **Meet Acceptance Criteria** |
| 1 | The system must have password complexity |  | Complies  Does not comply |
| 2 | Password aging must be enabled on the system. |  | Complies  Does not comply |
| 3 | The entered password must be masked |  | Complies  Does not comply |
| 4 | The system should auto logout after a certain period of inactivity. 15 minutes |  | Complies  Does not comply |
| 5 | System should not allow creation of already created user ID. |  | Complies  Does not comply |

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| **Signature** |  |  |
| **Date** |  |  |
| **Name** |  |  |
| **Department** |  |  |
|  | **Checked By** | **Verified By** |

**Test Data Sheet # 5**

**Deviation/ Discrepancy Sheet**

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| **Sr. No.** | **Description of Deviation/ Discrepancy** | **GMP Criticality** | **Corrective Action** | **Need to be closed before PQ** |
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| --- | --- | --- | --- | --- |
| **Signature** |  |  |  |  |
| **Date** |  |  |  |  |
| **Name** |  |  |  |  |
| **Department** | **Warehouse** | **Q.C** | **QA** | **QA** |
| **Prepared By** | **Checked By** | **Checked By** | **Authorized By** |

# Preparation of Report

A separate Operation Qualification report shall be prepared recording the summary of observations with regard to the execution of the tests as mentioned in various test data sheets of the protocol.

# List of Abbreviations

|  |  |
| --- | --- |
| OQ | Operational qualification |
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# Identification of Participants

In the list below all persons having participated in the execution of OQ and having signed on any of the tests are identified with their full name, department and function and their signature.

With this signature the test participant confirms awareness of procedures to be followed in qualification tests and completion of associated documentation.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Name** | **Department** | **Function** | **Full Signature** | **Initials** |
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