

IMMACULE LIFESCIENCES PVT. LTD.			
OPERATION QUALIFICATION PROTOCOL FOR MATERIAL TRACKING SYSTEM			
System Name	Material Tracking System	System ID No.	WH-MTS-01
Protocol Number		Area	Warehouse
Effective Date		Page No.	Page 1 of 51

**PROTOCOL FOR
OPERATION QUALIFICATION
OF
MATERIAL TRACKING SYSTEM**

Name of the Department	Warehouse
System Identification No.	WH-BCA-01
Location of Installation	Warehouse, QC
Issue Date	
Number of Pages	52

BAR CODE INDIA LIMITED

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IMMACULE LIFESCIENCES PVT. LTD.			
OPERATION QUALIFICATION PROTOCOL FOR MATERIAL TRACKING SYSTEM			
System Name	Material Tracking System	System ID No.	WH-MTS-01
Protocol Number		Area	Warehouse
Page No.	Page 2 of 51		

1.0 TABLE OF CONTENTS

Sr. No.	Title	Page No.
1.0	Table of contents	2
2.0	Protocol approval	3
3.0	Objective	4
4.0	Scope	4
5.0	Qualification team	4
6.0	Responsibilities	5
7.0	Procedure	6
8.0	Acceptance criteria	7
9.0	Re-qualification criteria	7
	TDS 1: Availability of <i>documents</i>	8
	TDS 2: Functional checks of the equipment Part [A] for Hardware Part [B] for Software	9
	TDS 3: Power failure & recovery verification	48
	TDS 4: Verification of password authorization & software complexity	49
10.0	Deviation/ Discrepancy Sheet	50
11.0	Preparation of Report	51
12.0	List of Abbreviations	51
13.0	Identification of Participants	51



IMMACULE LIFESCIENCES PVT. LTD.			
OPERATION QUALIFICATION PROTOCOL FOR MATERIAL TRACKING SYSTEM			
System Name	Material Tracking System	System ID No.	WH-MTS-01
Protocol Number		Area	Warehouse
Page No.	Page 3 of 51		

2.0 Protocol Approval

Prepared By			
Department	Name	Designation	Signature & Date
QA			

Reviewed By			
Department	Name	Designation	Signature & Date
IT			
Production			
Warehouse			
QC			
QA			

Approved By			
Department	Name	Designation	Signature & Date
QA			



IMMACULE LIFESCIENCES PVT. LTD.			
OPERATION QUALIFICATION PROTOCOL FOR MATERIAL TRACKING SYSTEM			
System Name	Material Tracking System	System ID No.	WH-MTS-01
Protocol Number		Area	Warehouse
Page No.	Page 4 of 51		

3.0 Objectives:

The objective of this protocol is :

- i. To define the Operation Qualification (OQ) requirements for the Material Tracking System.
- ii. To ensure that the Material Tracking System operates according to the specifications.
- iii. To establish documented evidence that the barcode application system functions as expected.

4.0 Scope:

The scope of this protocol includes operations qualification procedure of the Material Tracking System.

This protocol defines the procedures, documentation, acceptance criteria & re-qualification criteria.

5.0 Qualification Team:

Responsible staff from:

- i) I. T
- ii) Warehouse
- iii) QC
- iv) Production
- v) Quality Assurance



IMMACULE LIFESCIENCES PVT. LTD.			
OPERATION QUALIFICATION PROTOCOL FOR MATERIAL TRACKING SYSTEM			
System Name	Material Tracking System	System ID No.	WH-MTS-01
Protocol Number		Area	Warehouse
Page No.	Page 5 of 51		

6.0 Responsibilities:

Department	Description
Vendor	➤ Supporting in conducting qualification in accordance with the protocol requirements.
QA	<ul style="list-style-type: none"> ➤ Preparation of protocol and report. ➤ 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, Production	<ul style="list-style-type: none"> ➤ Checking of protocol. ➤ Documentation of data during the qualification study. ➤ Establishing written procedures for the operation of the application system for routine use.



IMMACULE LIFESCIENCES PVT. LTD.			
OPERATION QUALIFICATION PROTOCOL FOR MATERIAL TRACKING SYSTEM			
System Name	Material Tracking System	System ID No.	WH-MTS-01
Protocol Number		Area	Warehouse
Page No.	Page 6 of 51		

7.0 Procedure:

- 7.1 Operation qualification of system shall be conducted in presence of representatives from operating/user department, IT and QA department.
- 7.2 Check for the availability of following documents and record in **test data sheet 1**.
 - IQ report
 - SOPs (at least as drat) identified during IQ.
- 7.3 Check and ensure that different functions for correct operation of the system are working as expected and record in **test data sheet 2**.
- 7.4 Perform power and recovery verification of the system and record in **test data sheet 3**.
- 7.5 Check the password authorization and software complexity and record the same in **test data sheet 4**.
- 7.6 Deviation Handling: During execution, if any deviation is observed, it shall be recorded in deviation sheet.

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.



IMMACULE LIFESCIENCES PVT. LTD.			
OPERATION QUALIFICATION PROTOCOL FOR MATERIAL TRACKING SYSTEM			
System Name	Material Tracking System	System ID No.	WH-MTS-01
Protocol Number		Area	Warehouse
Page No.	Page 7 of 51		

8.0 ACCEPTANCE CRITERIA:

- 8.1 All operating inputs provided to the equipment as per the procedure of operation qualification, when checked, shall successfully comply with their intended use.
- 8.2 The equipment when operated shall not produce any abnormal sound or show any discrepancy in its smooth operation.

9.0 RE-QUALIFICATION CRITERIA:

- 9.1 Change in location of the system.
- 9.2 In case of any major maintenance, up gradation or modification, this affects performance of the system.



IMMACULE LIFESCIENCES PVT. LTD.			
OPERATION QUALIFICATION PROTOCOL FOR MATERIAL TRACKING SYSTEM			
System Name	Material Tracking System	System ID No.	WH-MTS-01
Protocol Number		Area	Warehouse
Page No.	Page 8 of 51		

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)
1.	IQ Report				
2.	Draft SOPs				



IMMACULE LIFESCIENCES PVT. LTD.

OPERATION QUALIFICATION PROTOCOL FOR MATERIAL TRACKING SYSTEM

System Name	Material Tracking System	System ID No.	WH-MTS-01
Protocol Number		Area	Warehouse
Page No.	Page 9 of 51		

Test Data Sheet # 2

FUNCTIONAL CHECKS

Part [A] : Functional Checks of Hardware

Sr. No	Procedure	Acceptance Criteria	Observation
a)	For Printer (ZT230)		
1.	Turn the printer power switch ON position.	Power should get supplied to the printer and status indicator should glow green.	
2.	Load the media in tear off mode.	Media (label roll) should get loaded in to the printer with proper position.	
3.	Load the ribbon.	Ribbon should get loaded in to the printer & no any error of "Ribbon Out"	
4.	Ensure that roll label is inside the printer and press the Feed functional key of the key pad.	Printer should feed one blank label.	
5.	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.	
6.	Press the Pause functional key again.	Printing process should resume.	
7.	When printing is ongoing, press the Cancel functional key of the key pad.	Current printing jobs should get cancelled.	



IMMACULE LIFESCIENCES PVT. LTD.

OPERATION QUALIFICATION PROTOCOL FOR MATERIAL TRACKING SYSTEM

System Name	Material Tracking System	System ID No.	WH-MTS-01
Protocol Number		Area	Warehouse
Page No.	Page 10 of 51		

Test Data Sheet # 2

FUNCTIONAL CHECKS

Part [A] : Functional Checks of Hardware

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



IMMACULE LIFESCIENCES PVT. LTD.			
OPERATION QUALIFICATION PROTOCOL FOR MATERIAL TRACKING SYSTEM			
System Name	Material Tracking System	System ID No.	WH-MTS-01
Protocol Number		Area	Warehouse
Page No.	Page 11 of 51		

Test Data Sheet # 2

FUNCTIONAL CHECKS

Part [A] : Functional Checks of Hardware

Sr. No	Procedure	Acceptance Criteria	Observation
a)	For Printer (ZT230)		
16.	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.	

Signature		
Date		
Name		
Department		
	Checked By	Verified By



IMMACULE LIFESCIENCES PVT. LTD.			
OPERATION QUALIFICATION PROTOCOL FOR			
MATERIAL TRACKING SYSTEM			
System Name	Material Tracking System	System ID No.	WH-MTS-01
Protocol Number		Area	Warehouse
Page No.	Page 12 of 51		

Test Data Sheet # 2

FUNCTIONAL CHECKS

Part [A] : Functional Checks of Hardware

b)	Printer (GT800)		
Sr. No.	Procedure	Acceptance Criteria	Observation
1.	Release the latches on the printer and load the media (label roll).	Media (label roll) should get loaded in to the printer.	
2.	Press the Feed functional key of the key pad.	Printer should force the printer to feed one blank label.	
3.	Press the power switch	Power should get supplied to the printer and 'status light' indicator should glow green.	
4.	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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Date		
Name		
Department		
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IMMACULE LIFESCIENCES PVT. LTD.			
OPERATION QUALIFICATION PROTOCOL FOR MATERIAL TRACKING SYSTEM			
System Name	Material Tracking System	System ID No.	WH-MTS-01
Protocol Number		Area	Warehouse
Page No.	Page 13 of 51		

Test Data Sheet # 2

FUNCTIONAL CHECKS

Part [A] : Functional Checks of Hardware

c)	Hand Held Terminal (TC20)		
Sr. No.	Procedure	Acceptance Criteria	Observation
1.	Power up the hand held terminal.	Display should get on and Main screen should appear	
2.	Press the Trigger key of the hand held terminal (HHT).	Red Horizontal beam should appear.	
3.	Scan a barcode label using the trigger key of the HHT.	The barcode label should get scanned successfully displaying the correct details on the screen of HHT.	
4.	Start Wireless Connection.	Device should configure through wireless connection and wireless connected icon should be indicated on the display at the bottom left corner of the screen.	
5.	Put the HHT in the cradle (charger) and turn the power switch ON.	Charging of HHT should get started with Orange light indication in the center of the screen.	



IMMACULE LIFESCIENCES PVT. LTD.			
OPERATION QUALIFICATION PROTOCOL FOR MATERIAL TRACKING SYSTEM			
System Name	Material Tracking System	System ID No.	WH-MTS-01
Protocol Number		Area	Warehouse
Page No.	Page 14 of 51		

Test Data Sheet # 2

FUNCTIONAL CHECKS

Part [A] : Functional Checks of Hardware

c)	Hand Held Terminal (TC20)		
Sr. No.	Procedure	Acceptance Criteria	Observation
6.	Check wireless connectivity, by ping the access point and sever which are in network with it.	HHT should connect through wireless to access point and server.	

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Date		
Name		
Department		
	Checked By	Verified By



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OPERATION QUALIFICATION PROTOCOL FOR MATERIAL TRACKING SYSTEM

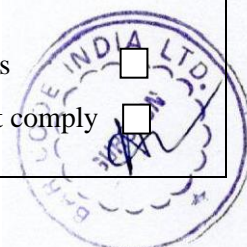
System Name	Material Tracking System	System ID No.	WH-MTS-01
Protocol Number		Area	Warehouse
Page No.	Page 15 of 51		

Test Data Sheet # 2

FUNCTIONAL CHECKS

Part [B] : 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 <input type="checkbox"/> Does not comply <input type="checkbox"/>
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 <input type="checkbox"/> Does not comply <input type="checkbox"/>
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 <input type="checkbox"/> Does not comply <input type="checkbox"/>
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 <input type="checkbox"/> Does not comply <input type="checkbox"/>
5	Deactivate User	Try to deactivate Created user	System allow to deactivate the created user	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
6	Mandatory fields	Try saving the created user(details) by keeping mandatory field blank	System should not allow to save the user detail if all mandatory fields are not entered.	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
7	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 <input type="checkbox"/> Does not comply <input type="checkbox"/>
8	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	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>



IMMACULE LIFESCIENCES PVT. LTD.

**OPERATION QUALIFICATION PROTOCOL FOR
MATERIAL TRACKING SYSTEM**

System Name	Material Tracking System	System ID No.	WH-MTS-01
Protocol Number		Area	Warehouse
Page No.	Page 16 of 51		

			person can assign roles to user.	
9	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 <input type="checkbox"/> Does not comply <input type="checkbox"/>

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(QA)



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**OPERATION QUALIFICATION PROTOCOL FOR
MATERIAL TRACKING SYSTEM**

System Name	Material Tracking System	System ID No.	WH-MTS-01
Protocol Number		Area	Warehouse
Page No.	Page 17 of 51		

Step: User Role				
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 <input type="checkbox"/> Does not comply <input type="checkbox"/>
2	User Role Screen display	Go to User Roles under Masters Screen	Only authorised personnel should be able to view the User Roles Page	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
3	User Role creation	Create a new user role using proper credentials	System should allow to create a new user role and assign access rights to user	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
4	Edit User Role	Try to edit created user role	System should allow to edit the user role details like user access rights and user type, transaction type	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
5	Mandatory fields	Try to save the user role by keeping mandatory field blank	System should not allow to save the user role if all mandatory fields are kept blank.	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
6	View Details	Click on view all details button	System will display all the details of Role master. User can perform search criteria using fields.	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>

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(QA)



IMMACULE LIFESCIENCES PVT. LTD.

OPERATION QUALIFICATION PROTOCOL FOR MATERIAL TRACKING SYSTEM

System Name	Material Tracking System	System ID No.	WH-MTS-01
Protocol Number		Area	Warehouse
Page No.	Page 18 of 51		

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 <input type="checkbox"/> Does not comply <input type="checkbox"/>
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 <input type="checkbox"/> Does not comply <input type="checkbox"/>
3	Plant creation	Create a new Plant using proper credentials	System should allow to create a new Plant	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
4	Edit Plant Created	Try to edit created plant	System should allow to edit the Plant Created	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
5	Deactivate Plant	Try to deactivate Created Plant	System allow to deactivate the created Plant	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
6	Mandatory fields	Try saving the Plant by keeping mandatory field blank	System should not allow saving the Plant if all mandatory fields are kept blank.	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
7	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 <input type="checkbox"/> Does not comply <input type="checkbox"/>
8	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 <input type="checkbox"/> Does not comply <input type="checkbox"/>

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IMMACULE LIFESCIENCES PVT. LTD.

OPERATION QUALIFICATION PROTOCOL FOR MATERIAL TRACKING SYSTEM

System Name	Material Tracking System	System ID No.	WH-MTS-01
Protocol Number		Area	Warehouse
Page No.	Page 19 of 51		

Step: Bin 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 <input type="checkbox"/> Does not comply <input type="checkbox"/>
2	Bin Master screen display	Go to Bin masters under Masters Screen	Only authorised personnel should be able to view the Bin Master Page	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
3	Bin creation	Create a Bin using proper credentials	System should allow to create a new Bin	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
4	Edit Bin Created	Try to edit created Bin	System should allow to edit the Bin Created	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
5	Deactivate Bin	Try to deactivate Created Bin	System should allow to deactivate the created Bin	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
6	Mandatory fields	Try to save the Bin by keeping mandatory filed blank	System should not allow saving the Bin if all mandatory fields are kept blank.	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
7	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 <input type="checkbox"/> Does not comply <input type="checkbox"/>
8	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 <input type="checkbox"/> Does not comply <input type="checkbox"/>

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OPERATION QUALIFICATION PROTOCOL FOR MATERIAL TRACKING SYSTEM

System Name	Material Tracking System	System ID No.	WH-MTS-01
Protocol Number		Area	Warehouse
Page No.	Page 20 of 51		

Step: Booth 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 <input type="checkbox"/> Does not comply <input type="checkbox"/>
2	Booth Master Screen display	Go to Booth masters under Masters Screen	Only authorised personnel should be able to access the Booth Master Page	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
3	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 <input type="checkbox"/> Does not comply <input type="checkbox"/>
4	Edit created Booth master	Try to edit created Booth master	System should allow to edit created Booth master	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
5	Deactivate Booth Master	Try to deactivate Created Booth Master	System allow to deactivate the created Booth master	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
6	Mandatory fields	Try saving the Booth master by keeping mandatory field blank	System should not allow to save the Booth master if all mandatory fields are kept blank.	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
7	Duplicate Booth Master	Try to create new Booth master with the existing Booth code	System should not allow to create duplicate Booth code	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
8	View Details	Click on view all details button	System will display all the details of	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>



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**OPERATION QUALIFICATION PROTOCOL FOR
MATERIAL TRACKING SYSTEM**

System Name	Material Tracking System	System ID No.	WH-MTS-01
Protocol Number		Area	Warehouse
Page No.	Page 21 of 51		

			Booth master. User can perform search criteria using fields.	
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OPERATION QUALIFICATION PROTOCOL FOR MATERIAL TRACKING SYSTEM

System Name	Material Tracking System	System ID No.	WH-MTS-01
Protocol Number		Area	Warehouse
Page No.	Page 22 of 51		

Step: Weighing 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 <input type="checkbox"/> Does not comply <input type="checkbox"/>
2	Weighing Master Screen display.	Go to weighing masters under Masters Screen	Only authorised personnel should be able to view the Weighing Master Page	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
3	Data Entry.	All the required fields should be filled	System should allow to fill the mandatory fields with the proper data.	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
4	Weighing Master Creation	After filling all the details click on save button	System should allow to save the created weighing master	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
5	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 <input type="checkbox"/> Does not comply <input type="checkbox"/>
6	Duplicate Master	Try creating a duplicate weighing master with already used weighing code.	System should not allow creation of duplicate weighing master	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
7	Mandatory fields	Try saving the Weighing master by keeping mandatory field blank	System should not allow to save the Weighing master if all mandatory fields are kept blank.	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>



IMMACULE LIFESCIENCES PVT. LTD.			
OPERATION QUALIFICATION PROTOCOL FOR MATERIAL TRACKING SYSTEM			
System Name	Material Tracking System	System ID No.	WH-MTS-01
Protocol Number		Area	Warehouse
Page No.	Page 23 of 51		

8	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 <input type="checkbox"/> Does not comply <input type="checkbox"/>
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OPERATION QUALIFICATION PROTOCOL FOR
MATERIAL TRACKING SYSTEM

System Name	Material Tracking System	System ID No.	WH-MTS-01
Protocol Number		Area	Warehouse
Page No.	Page 24 of 51		

Step: Printer 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 <input type="checkbox"/> Does not comply <input type="checkbox"/>
2	Printer Master Screen display	Go to Printer masters under Masters Screen	Only authorized personnel should be able to access the Printer Master Page	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
3	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 <input type="checkbox"/> Does not comply <input type="checkbox"/>
4	Edit created printer master	Try to edit created printer master	System should allow to edit created printer master	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
5	Deactivate Printer Master	Try to deactivate Created Printer Master	System allow to deactivate the created printer master	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
6	Mandatory fields	Try saving the printer master by keeping mandatory field blank	System should not allow to save the printer master if all mandatory fields are kept blank.	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
7	Duplicate Printer Master	Try to create new printer master with the existing printer code	System should not allow to create duplicate printer code	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>



IMMACULE LIFESCIENCES PVT. LTD.			
OPERATION QUALIFICATION PROTOCOL FOR MATERIAL TRACKING SYSTEM			
System Name	Material Tracking System	System ID No.	WH-MTS-01
Protocol Number		Area	Warehouse
Page No.	Page 25 of 51		

8	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 <input type="checkbox"/> Does not comply <input type="checkbox"/>
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Verified By (Sign/Date):
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OPERATION QUALIFICATION PROTOCOL FOR MATERIAL TRACKING SYSTEM

System Name	Material Tracking System	System ID No.	WH-MTS-01
Protocol Number		Area	Warehouse
Page No.	Page 26 of 51		

Step: Barcode Print 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 <input type="checkbox"/> Does not comply <input type="checkbox"/>
2	Master Barcode Print screen display	Go to Barcode Print Master under Masters Screen	Only authorised personnel should be able to access the Barcode Print Master Page	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
3	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 <input type="checkbox"/> Does not comply <input type="checkbox"/>
4	Select all (checkbox)	Check the select all checkbox	System will select all the records	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
5	Mandatory fields	Try print master by keeping mandatory field blank	System should not allow to print Barcode master if all the mandatory are not filled	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>

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OPERATION QUALIFICATION PROTOCOL FOR MATERIAL TRACKING SYSTEM

System Name	Material Tracking System	System ID No.	WH-MTS-01
Protocol Number		Area	Warehouse
Page No.	Page 27 of 51		

Step: SU Label Printing

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 <input type="checkbox"/> Does not comply <input type="checkbox"/>
2	Transaction screen display	In the Warehouse menu go to SU Label printing screen	Only authorized personnel should be able to view the SU Label Printing Page under Transaction	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
3	Document no entry	Enter the document no from ERP ,click on get	Software should allow entry of document no from ERP. On clicking get button appropriate records will be displayed. If not entered then system should prompt to enter the document no	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
4	Mandatory fields	Try to print Label by keeping mandatory field blank	System should not allow to print SU Label if all mandatory fields are kept blank.	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
5	Printer Name entry	Enter the Printer Name	Select the printer name ,otherwise error message will be displayed(Please select Printer name)	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>

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OPERATION QUALIFICATION PROTOCOL FOR MATERIAL TRACKING SYSTEM

System Name	Material Tracking System	System ID No.	WH-MTS-01
Protocol Number		Area	Warehouse
Page No.	Page 28 of 51		

Step: SU Label Re-Printing

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 <input type="checkbox"/> Does not comply <input type="checkbox"/>
2	Transaction Screen display	In the Warehouse menu go to Label Reprinting screen	Only authorised personnel should be able to view the SU Label Re-printing under Transaction Page	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
3	Document no entry	Enter the document no from ERP	Software should allow entry of document no from ERP. On clicking get button appropriate records will be displayed. If not entered then system should prompt to enter the document no	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
4	Mandatory fields	Try to print Label by keeping mandatory field blank	System should not allow re-printing label if all mandatory fields are kept blank.	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
5	Printer Name, Reason entry	Enter the Printer Name, Reason and Click On Print Button	Select the printer, reason name, otherwise error message will be displayed(Please select Printer and reason)	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>

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OPERATION QUALIFICATION PROTOCOL FOR MATERIAL TRACKING SYSTEM

System Name	Material Tracking System	System ID No.	WH-MTS-01
Protocol Number		Area	Warehouse
Page No.	Page 29 of 51		

Step: Sample Label Printing

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 <input type="checkbox"/> Does not comply <input type="checkbox"/>
2	Transaction screen display	In the Warehouse menu go to Sampling printing screen	Only authorised personnel should be able to view Sampling printing under Transaction Page	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
3	ARNO entry	Enter the Arno from SAP	Software should allow entry of ARNO from ERP. Details like Material code, material name, batch name, GRNO, GRN date will be displayed below after entering ARNO. If not entered error message will be displayed(Please enter document ARNO)	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
4	Mandatory fields	Try to print Label by keeping mandatory field blank	System should not allow printing label if all mandatory fields are kept blank.	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
5	Printer Name entry	Enter Printer Name	Select the printer name, otherwise error message will be displayed(Please select Printer)	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>

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OPERATION QUALIFICATION PROTOCOL FOR MATERIAL TRACKING SYSTEM

System Name	Material Tracking System	System ID No.	WH-MTS-01
Protocol Number		Area	Warehouse
Page No.	Page 30 of 51		

Step: Sample Label Re-Printing

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 <input type="checkbox"/> Does not comply <input type="checkbox"/>
2	Transaction screen display	In the transaction menu go to Sampling Label Reprinting screen	Only authorised personnel should be able to view Sampling Label Re- printing under Transaction Page	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
3	ARNO entry	Enter the Arno from SAP	Software should allow entry of ARNO from SAP and appropriate records will be displayed below. . If not entered error message will be displayed(Please enter document ARNO)	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
4	Mandatory fields	Try to print Label by keeping mandatory field blank	System should not allow printing label if all mandatory fields are kept blank.	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
5	Printer Name, Reason entry	Enter the Printer Name, Reason	Select the printer, reason name, otherwise error message will be displayed(Please select Printer Name and Select reason)	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>

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OPERATION QUALIFICATION PROTOCOL FOR MATERIAL TRACKING SYSTEM

System Name	Material Tracking System	System ID No.	WH-MTS-01
Protocol Number		Area	Warehouse
Page No.	Page 31 of 51		

Step: Sampling

Sr. No.	Test	Test Procedure	Acceptance Criteria	Observation
1.	Login of the user.	Login with correct username and correct Password in Device Application	The system should allow to login to the system if correct login credentials are entered	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
2	Transaction screen display	In the QC menu go to Sampling screen	Only authorized personnel should be able to view Sampling under QC Menu	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
3	Sample Barcode Scan	Scan Sample Barcode	Software should allow Scan Sample Barcode and display Material Code, description, Batch No., GRN No., GRN Date and Total No. Of Sample barcode	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
4	Scan Material SU barcode	Scan Material SU barcode label	System should allow to Scan code , and display the total count	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
5	Sample Quantity	Enter Sample Quantity	System should allow to enter sample quantity and UOM	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
6	Save Record	Click on Save Button	System will save the records	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
7	Invalid Location	Scan any other barcode	System should display message as "Invalid Location"	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>



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**OPERATION QUALIFICATION PROTOCOL FOR
MATERIAL TRACKING SYSTEM**

System Name	Material Tracking System	System ID No.	WH-MTS-01
Protocol Number		Area	Warehouse
Page No.	Page 32 of 51		

8	Invalid Material	Scan any other barcode which is not a SU barcode	System should display message as “Invalid Material Scan” and total scan remain same as previous	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
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OPERATION QUALIFICATION PROTOCOL FOR MATERIAL TRACKING SYSTEM

System Name	Material Tracking System	System ID No.	WH-MTS-01
Protocol Number		Area	Warehouse
Page No.	Page 33 of 51		

Step: Allocation

Sr. No.	Test	Test Procedure	Acceptance Criteria	Observation
1.	Login of the user.	Login with correct username and correct Password in Device Application	The system should allow to login to the system if correct login credentials are entered	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
2	Transaction screen display	In the Allocation menu go to Allocation screen	Only authorized personnel should be able to view Allocation under Transaction Page	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
3	Location Scan	Scan location code Barcode	Software should allow Scan location code , and allow to scan the material barcode	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
4	Scan Material	Scan Material SU barcode label	System should allow Scan location code , and display the total count	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
5	Invalid Location	Scan any other barcode	System should display message as "Invalid Location"	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
6	Invalid Material	Scan any other barcode which is not a SU barcode	System should display message as "Invalid Material Scan" and total scan remain same as previous	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>

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OPERATION QUALIFICATION PROTOCOL FOR MATERIAL TRACKING SYSTEM

System Name	Material Tracking System	System ID No.	WH-MTS-01
Protocol Number		Area	Warehouse
Page No.	Page 34 of 51		

Step: Location Transfer

Sr. No.	Test	Test Procedure	Acceptance Criteria	Observation
1.	Login of the user.	Login with correct username and correct Password in Device Application	The system should allow to login to the system if correct login credentials are entered	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
2	Transaction screen display	In the allocation menu go to Location transfer screen	Only authorized personnel should be able to view Location transfer under Transaction Page	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
3	Location Scan	Scan To Location	Software should allow Scan location code , and allow to scan the material barcode	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
4	Scan Material	Scan Material SU barcode label	System should allow Scan location code , and display the total count	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
5	Invalid Location	Scan any other barcode	System should display message as "Invalid Location"	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
6	Invalid Material	Scan any other barcode which is not a SU barcode	System should display message as "Invalid Material Scan" and total scan remain same as previous	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
7	Check Material Allocation	Scan the material which is not allocated	System should not allow to material transfer which is not allocated	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>

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OPERATION QUALIFICATION PROTOCOL FOR MATERIAL TRACKING SYSTEM

System Name	Material Tracking System	System ID No.	WH-MTS-01
Protocol Number		Area	Warehouse
Page No.	Page 35 of 51		

Step: Picklist Generation

Sr. No.	Test	Test Procedure	Acceptance Criteria	Observation
1.	Login of the user.	Login with correct username and correct Password in PC Application	The system should allow to login to the system if correct login credentials are entered	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
2	Transaction screen display	In the warehouse menu go to Picklist Generation screen	Only authorized personnel should be able to view Picklist Generation under warehouse menu	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
3	Data entry	Select the Date range i.e. from date and to date or Batch. Click on Get button	System allows to select the date range and / or allow to enter the batch. After Pressing Get button the details should display into list.	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
4	Generate Picklist	Select the Batch record from list and click on Picklist	System will generate picklist and display the picklist no. on screen.	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
5	Campaign Batch Picklist	Select the Date range i.e. from date and to date and add multiple Batches and Click on Get button after entering the batch one by one.	System will Allow to add multiple batches and display the records in the list	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
6	Generate Picklist	Select the multiple Batches from list and click on Picklist	System will generate picklist of multiple batches and display the picklist no. on screen.	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>

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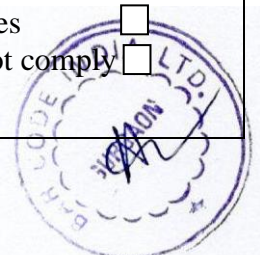
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OPERATION QUALIFICATION PROTOCOL FOR MATERIAL TRACKING SYSTEM

System Name	Material Tracking System	System ID No.	WH-MTS-01
Protocol Number		Area	Warehouse
Page No.	Page 36 of 51		

Step: Picking

Sr. No.	Test	Test Procedure	Acceptance Criteria	Observation
1.	Login of the user.	Login with correct username and correct Password in Device Application	The system should allow to login to the system if correct login credentials are entered	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
2	Transaction screen display	In the Picking menu go to Picking screen	Only authorized personnel should be able to view Picking screen under Picking Menu	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
3	Enter Picklist No	Enter Picklist no and Press Go Button	System will allow to enter Picklist No and allow User to select the Material From Drop down List	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
4	Select AR No,	After selecting the Material from Drop done	System should allow to select the AR No from drop down list and system will display Material description, Total quantity , Scan quantity and suggested bin	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
5	Scan Bin Barcode	Scan the Bin Code	System will allow to scan Bin Code	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
6	Scan Material Barcode	Scan Material SU Barcode and Press SAVE button	System will allow to scan Material SU barcode and after pressing button total scan qty. and increase No. Of container	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
7	Invalid Bin Scan	Scan the bin which is not in suggested list / Invalid list	System will show invalid bin scanned message	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>



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**OPERATION QUALIFICATION PROTOCOL FOR
MATERIAL TRACKING SYSTEM**

System Name	Material Tracking System	System ID No.	WH-MTS-01
Protocol Number		Area	Warehouse
Page No.	Page 37 of 51		

8	Invalid Material Scan	Scan any other material	System will show invalid material scanned message	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
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**OPERATION QUALIFICATION PROTOCOL FOR
MATERIAL TRACKING SYSTEM**

System Name	Material Tracking System	System ID No.	WH-MTS-01
Protocol Number		Area	Warehouse
Page No.	Page 38 of 51		

Step: Reverse Picking

Sr. No.	Test	Test Procedure	Acceptance Criteria	Observation
1.	Login of the user.	Login with correct username and correct Password in Device Application	The system should allow to login to the system if correct login credentials are entered	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
2	Transaction screen display	In the Picking menu go to Reverse Picking screen	Only authorized personnel should be able to view Reverse Picking screen under Picking Menu	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
3	Scan Material Barcode	Scan Material SU Barcode which has to reverse	System will allow to scan Material SU barcode and display the remaining quantity	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
4	Scan Bin Barcode	Scan the Bin Code	System will allow to scan Bin Code	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
5	Invalid Bin Scan	Scan the bin which is not in suggested list / Invalid list	System will show invalid bin scanned message	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
6	Invalid Material Scan	Scan any other material	System will show invalid material scanned message	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>

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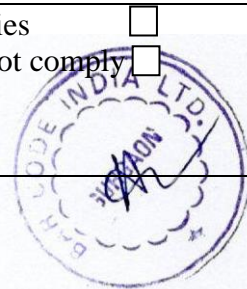
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OPERATION QUALIFICATION PROTOCOL FOR MATERIAL TRACKING SYSTEM

System Name	Material Tracking System	System ID No.	WH-MTS-01
Protocol Number		Area	Warehouse
Page No.	Page 39 of 51		

Step: Dispensing

Sr. No.	Test	Test Procedure	Acceptance Criteria	Observation
1.	Login of the user.	Login with correct username and correct Password in Device Application	The system should allow to login to the system if correct login credentials are entered	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
2	Transaction screen display	In the Main menu go to dispensing screen	Only authorized personnel should be able to view dispensing screen	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
3	Batch Details	Enter Batch No. and click on "Get" Button	System will allow to enter the batch and display the batch details into list box	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
4	Select Material	Select the material from List and click on Next button	System will allow to select the material and on next button click the next screen should display with the selected material details for dispensing	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
5	Enter Details	Select the details i.e. Select booth, Lot, Select UOM , and enter the no. of containers	System allows selecting the LOT, UOM and entering No. Of containers	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
6	Scan Material Barcode	Scan Material SU Barcode	System will allow to scan Material SU barcode and display the quantity	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
7	Scan Balance Barcode	Scan Balance Code to capture the tare weight and Gross weight	System will allow to scan the balance and capture Tare and Gross weight and system should display NET weight	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
8	Add quantity from multiple container	Click on Add button to add material from another container	System will allow to take material from other container	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>



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OPERATION QUALIFICATION PROTOCOL FOR MATERIAL TRACKING SYSTEM

System Name	Material Tracking System	System ID No.	WH-MTS-01
Protocol Number		Area	Warehouse
Page No.	Page 40 of 51		

9	Print Dispense Label	Click on Print Button	System should Print dispensed label	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
Bulk Dispensing				
10	Batch Details	Enter Batch No. and click on "Get" Button	System will allow to enter the batch and display the batch details into list box	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
11	Select Material	Select the material from List and click on Bulk Dispensing button	System will allow to select the material and on Bulk Dispensing button click the next screen should display with the selected material details for dispensing	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
12	Enter Details	Select the details i.e. Select booth, Lot, Select UOM , and enter the no. of containers	System allows selecting the LOT, UOM and entering No. Of containers	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
13	Scan Material Barcode	Scan Material SU Barcode	System will allow to scan Material SU barcode and display the quantity	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
14	Add quantity from multiple container	Click on Add button to add material from another container	System will allow to take material from other container	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
15	Print Dispense Label	Click on Print Button	System should Print dispensed label	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
16	Invalid Material Scan	Scan any other material	System will show invalid material scanned message	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>



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**OPERATION QUALIFICATION PROTOCOL FOR
MATERIAL TRACKING SYSTEM**

System Name	Material Tracking System	System ID No.	WH-MTS-01
Protocol Number		Area	Warehouse
Page No.	Page 41 of 51		

17	Invalid Balance Scan	Scan any other balance code	System will show invalid balance scanned message	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
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**OPERATION QUALIFICATION PROTOCOL FOR
MATERIAL TRACKING SYSTEM**

System Name	Material Tracking System	System ID No.	WH-MTS-01
Protocol Number		Area	Warehouse
Page No.	Page 42 of 51		

Step: Dispensing Confirmation

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 <input type="checkbox"/> Does not comply <input type="checkbox"/>
2	Transaction screen display	In the warehouse menu go to Dispensing Confirmation screen	Only authorised personnel should be able to view Dispensing Confirmation under Transaction Page	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
3	Batch no entry	Enter the Batch no	Software should allow entry batch no and appropriate records will be displayed below. If not entered error message will be displayed (Please enter document Batch no)	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
4	Dispense Confirmation	Enter the reason, adjust quantity and click on Adjust Stock	System will allow to enter the details and system should save the adjusted quantity	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>

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**OPERATION QUALIFICATION PROTOCOL FOR
MATERIAL TRACKING SYSTEM**

System Name	Material Tracking System	System ID No.	WH-MTS-01
Protocol Number		Area	Warehouse
Page No.	Page 43 of 51		

Step: Re-Print Dispensing Label

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 <input type="checkbox"/> Does not comply <input type="checkbox"/>
2	Transaction Screen display	In the Warehouse menu go to Label Reprinting screen	Only authorised personnel should be able to view the SU Label Re –printing under Transaction Page	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
3	Batch no entry	Enter the Batch no	Software should allow entry of Batch no. On clicking get button appropriate records will be displayed. If not entered then system should prompt to enter the document no	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
4	Mandatory fields	Try to print Label by keeping mandatory field blank	System should not allow re-printing label if all mandatory fields are kept blank.	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
5	Printer Name, Reason entry	Enter the Printer Name, Reason and Click On Print Button	Select the printer, reason name, otherwise error message will be displayed(Please select Printer and reason)	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>

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OPERATION QUALIFICATION PROTOCOL FOR MATERIAL TRACKING SYSTEM

System Name	Material Tracking System	System ID No.	WH-MTS-01
Protocol Number		Area	Warehouse
Page No.	Page 44 of 51		

Step: Stock Adjustment

Sr. No.	Test	Test Procedure	Acceptance Criteria	Observation
1.	Login of the user.	Login with correct username and correct Password in Device Application	The system should allow to login to the system if correct login credentials are entered	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
2	Transaction screen display	In the main menu go to Stock Adjustment screen	Only authorized personnel should be able to view Stock Adjustment	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
3	Scan Material Barcode	Scan Material SU Barcode which has to reverse	System will allow to scan Material SU barcode and display the available quantity	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
4	Enter the details	Enter the reason, adjust quantity and click on Adjust Stock	System will allow to enter the details and system should save the adjusted quantity	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
5	Invalid Material Scan	Scan any other material	System will show invalid material scanned message	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>

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**OPERATION QUALIFICATION PROTOCOL FOR
MATERIAL TRACKING SYSTEM**

System Name	Material Tracking System	System ID No.	WH-MTS-01
Protocol Number		Area	Warehouse
Page No.	Page 45 of 51		

Step: MRN Label Printing

Sr. No.	Test	Test Procedure	Acceptance Criteria	Observation
1.	Login of the user.	Login with correct username and correct Password in web Application	The system should allow to login to the system if correct login credentials are entered	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
2	Transaction screen display	In the production menu go to MRN Label Printing Screen	Only authorized personnel should be able to view MRN Label Printing Screen	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
3	Enter Batch No	Enter Batch Details and Click on GET button	System will allow to enter Batch No. and display the details after pressing Get Button	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
4	Enter the details	Select the material and AR 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 <input type="checkbox"/> Does not comply <input type="checkbox"/>
5	Print MRN Label	Click on Print Button	System will Print MRN Label	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
6	Invalid batch	Enter the Batch which is not dispatch	System will give message as Invalid Batch / Data not found message	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>

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OPERATION QUALIFICATION PROTOCOL FOR MATERIAL TRACKING SYSTEM

System Name	Material Tracking System	System ID No.	WH-MTS-01
Protocol Number		Area	Warehouse
Page No.	Page 46 of 51		

Step: MRN Label Verification

Sr. No.	Test	Test Procedure	Acceptance Criteria	Observation
1.	Login of the user.	Login with correct username and correct Password in device Application	The system should allow to login to the system if correct login credentials are entered	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
2	Transaction screen display	In the Main menu go to MRN Label Verification Screen	Only authorized personnel should be able to view MRN Label Verification Screen	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
3	Scan MRN Label	Scan MRN Label	System will allow to scan MRN Label and display the MRN details	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
4	Verify Details	Verify the details of scanned MRN barcode details and press verify button	System will allow to verify the MRN details	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
5	Invalid MRN Material	Scan any other material which is not MRN	System will display Invalid material scanned	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>

Checked By (Sign/Date):
(Warehouse)

Verified By (Sign/Date):
(QA)



IMMACULE LIFESCIENCES PVT. LTD.			
OPERATION QUALIFICATION PROTOCOL FOR			
MATERIAL TRACKING SYSTEM			
System Name	Material Tracking System	System ID No.	WH-MTS-01
Protocol Number		Area	Warehouse
Page No.	Page 47 of 51		

Step: Status Display				
Sr. No.	Test	Test Procedure	Acceptance Criteria	Observation
1.	Login of the user.	Login with correct username and correct Password in device Application	The system should allow to login to the system if correct login credentials are entered	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
2	Transaction screen display	In the Main menu go to Status Display Screen	Only authorized personnel should be able to view Status Display Screen	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
3	Scan Material SU Label	Scan SU barcode Label	System will allow to scan SU Label and display the SU details	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>
4	Invalid SU Material	Scan any other material which is not RM// PM	System will display Invalid material scanned	Complies <input type="checkbox"/> Does not comply <input type="checkbox"/>

Checked By (Sign/Date):
(Warehouse)

Verified By (Sign/Date):
(QA)



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OPERATION QUALIFICATION PROTOCOL FOR MATERIAL TRACKING SYSTEM			
System Name	Material Tracking System	System ID No.	WH-MTS-01
Protocol Number		Area	Warehouse
Page No.	Page 48 of 51		

Test Data Sheet # 3

POWER FAILURE & RECOVERY VERIFICATION

Sr. No.	Procedure	Acceptance Criteria	Observation
1	Switch off the Power supply of Printer (ZT230)	Printer should stop in normal mode.	
2	Restore the power supply of printer (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.	
3	Switch off the Power supply of Printer (GT800)	Printer should stop in normal mode.	
4	Restore the power supply of printer (GT800) (Operator intervention required to restart the system)	In case of Printer connected to PC: Printer should starts automatically & prints remaining labels as well as reprints the label which is under printing head during power failure.	
		In case of Printer connected through "wifi" Label should not get print.	
5	Switch off the power switch of HHT	HHT should stop in normal mode.	
6	Restore the power supply to HHT device (Operator intervention required to restart the system)	HHT should restart in normal condition.	
Signature			
Date			
Name			
Department			
	Checked By		Verified By



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OPERATION QUALIFICATION PROTOCOL FOR MATERIAL TRACKING SYSTEM

System Name	Material Tracking System	System ID No.	WH-MTS-01
Protocol Number		Area	Warehouse
Page No.	Page 49 of 51		

Test Data Sheet # 4

VERIFICATION OF PASSWORD AUTHORIZATION & SOFTWARE COMPLEXITY

Function	Administer		Warehouse				QC				Production			
Level	L1		L2		L3		L2		L3		L2		L3	
	Actual	Observed	Actual	Observed	Actual	Observed	Actual	Observed	Actual	Observed	Actual	Observed	Actual	Observed
Desktop application														
User creation	√		x		x		x		x		x		x	
User deletion	√		x		x		x		x		x		x	
User rights edition	√		x		x		x		x		x		x	
Print														
SU Label Printing	√		√		√		x		x		x		x	
Sample printing	√		x		x		√		√		x		x	
Pick List Generation	√		x		x		√		√		x		x	
Dispensing Confirmation	√		x		x		x		x		√		√	
Material return	√		x		x		x		x		x		x	
Label Reprint	√		√		x		√		x		√		x	
Report														
Dispensing Report	√		√		√		√		√		√		√	
Location Chart	√		√		√		√		√		√		√	
HHT														
Material allocation	√		√		√		x		x		x		x	
QC sampling	√		x		x		√		√		x		x	
Picking	√		√		√		x		x		x		x	
Dispensing	√		√		√		x		x		x		x	
Material return	√		√		√		x		x		x		x	
Stock Adjustment	√		√		√		x		x		x		x	

Checked By(IT):	Checked By (WH):	Checked By(QC):	Checked By(Prod):
Verified By(QA):	Verified By(QA):	Verified By(QA):	Verified By(QA):



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OPERATION QUALIFICATION PROTOCOL FOR MATERIAL TRACKING SYSTEM			
System Name	Material Tracking System	System ID No.	WH-MTS-01
Protocol Number		Area	Warehouse
Page No.	Page 50 of 51		

10. Deviation/ Discrepancy Sheet:

Sr. No.	Description of Deviation/ Discrepancy	GMP Criticality	Corrective Action	Need to be closed before PQ

Signature					
Date					
Name					
Department	Warehouse	Q.C	Production	QA	QA
	Prepared By	Checked By	Checked By	Checked By	Authorized By



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OPERATION QUALIFICATION PROTOCOL FOR MATERIAL TRACKING SYSTEM			
System Name	Material Tracking System	System ID No.	WH-MTS-01
Protocol Number		Area	Warehouse
Page No.	Page 51 of 51		

11.0 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.

12.0 List of Abbreviations:

OQ	Operational qualification
HHT	Hand held terminal
SU	Single Unit

13.0 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

