

**IMMACULE LIFESCIENCES PVT. LTD.**

**INSTALLATION QUALIFICATION PROTOCOL**

System Name	Material Tracking System	System ID No.	WH-MTS-01
Document No		Department	Warehouse
Effective Date		Page No.	1 of 20

**INSTALLATION QUALIFICATION**  
**OF**  
**MATERIAL TRACKING SYSTEM**

**BAR CODE INDIA LIMITED**

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## 2.0 Protocol Approval: -

Prepared By		
Name	Designation	Signature & Date
Checked By		
Name	Designation	Signature & Date

Approved By			
Department	Name	Designation	Signature & Date

## 3.0 Objective:

The objective of this protocol is:

- To define the Installation Qualification (IQ) requirements for the Material Tracking System.
- To ensure that the Material Tracking System is in accordance with the requirements and conforms to the purchase specifications.
- The Material Tracking System is installed correctly and in accordance with installation plan and as per the manufacturer's installation instructions.
- To establish documented evidence that the installation qualification of Barcode application system is carried out as per the specified requirements.

## 4.0 Scope:

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

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

## 5.0 Qualification Team:

Responsible staff from:

- i) I.T
- ii) Stores
- iii) QC
- iv) Quality assurance

## 6.0 Responsibilities:

Responsibilities	Details
Vendor	<ul style="list-style-type: none"> <li>➤ Supplying drawings, manual, certificates, and necessary documents for the generation and implementation of this protocol.</li> </ul>
QA	<ul style="list-style-type: none"> <li>➤ Preparation of the protocol and report.</li> <li>➤ Checking of protocol and report.</li> <li>➤ To verify the installation activity as per protocol.</li> <li>➤ Review the data documented during installation qualification.</li> <li>➤ Final approval of protocol &amp; report.</li> </ul>
I.T, Warehouse and QC	<ul style="list-style-type: none"> <li>➤ Checking of protocol and report.</li> <li>➤ To provide area for installation and make related arrangements.</li> <li>➤ To check the installation activity.</li> </ul>

## 7.0 System Description

Bar Code Application system is a server-based system with purpose of tracking the material from receiving to dispensing area.

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#### a. Hand Held terminal TC20

Hand held terminal is designed specifically to read the barcodes and perform data entry while operating barcode application system.

Hand held terminal of TC20 is ZEBRA make, which features a 1280 x 720 resolution, a standard 1D-2D imager scanner, watt-hours smart Lithium-ion battery 4300 mah

#### b. Zebra Thermal Transfer Printer ZT230

ZT230, Thermal transfer printing, 203 dpi, 4" print width, ZPL, 128MB Flash, 128MB DRAM, RS-232 serial, Lan , USB interface, US Power cord

### 8.0 Installation Procedure:

8.1 Instructions for execution of the qualification activity:

8.1.1 Read the contents of the document thoroughly before proceeding for execution of the activity (In case of doubts / contradictions / contact the approvers of the document for clarifications). All the details are to be verified jointly by the validation team members with assistance of supplier's representative as applicable.

8.1.2 All the columns in the following pages are to be filled by the concerned persons.

If a particular detail is not applicable, indicate the same by putting NA in the column.

8.1.3 Follow the specific instructions as mentioned in the particular test for verifying the parameters & recording the observations

8.2 Compare equipment, as received, with purchase order and write system detail in **test data sheet # 1**. Attach a copy of purchase order as **Annexure I**.

8.3 Check for the availability of following documents as Pre-requisite to initiate the qualification activity  
– User requirement specifications (URS), Design Qualification (DQ) or SRS (system requirement

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specification), Change Control, authentication letter for the engineer performing the qualification of the equipment, from the manufacturer / supplier of the equipment and record in **test data sheet # 2**.

- 8.4 Check the installation verification of the system as per checklist and record the details in **test data sheet # 3**.
- 8.5 Check the verification of system as per installation checklist and record the details in **test data sheet # 4**.
- 8.6 Verification of the major components of the system and records the details in **test data sheet # 5**.
- 8.7 Verify the document in **test data sheet # 6**.
- 8.9 Identify the SOPs to be prepared, related to the system (if required) and record in **test data sheet # 7**.
- 8.10 Deviation Handling: During execution, if any deviation is observed, it shall be recorded in **test data sheet # 8**.
- 8.11 A summary report of the qualification activities conducted shall be prepared. Report shall be checked by warehouse and QC department and approved by QA
- 8.12 Upon successful completion of installation qualification activity, operation qualification shall be initiated.

## 9.0 Acceptance Criteria

- 9.1 System and its accessories shall be as per the purchase order and free from any physical damage.
- 9.2 The installation of system shall be checked in accordance with this protocol and it should be found satisfactory.

## 10. Requalification Criteria

Re-qualification of the equipment is applicable when,

- Change in location of the equipment.

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- In case of any major maintenance or modification, this affects performance of the equipment.

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**Test Data Sheet 1**

**DETAILS OF SYSTEM**

Purchase order No.	
Name of the system	Material Tracking System
Identification No.	
Manufacturer's name & Address	
Model name & number	i) ii) iii) iv)
Location for installation	
Purpose	



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**Test Data Sheet 2**

**PRE-REQUISITE TO INITIATE THE QUALIFICATION**

Sr. No.	Document	Status (Available / Unavailable)
1.	User Requirement Specifications (URS)	
2	Change Control	

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### Test Data Sheet 3

#### INSTALLATION VERIFICATION

Parameter / Description	Specification	Observed
Physical Condition	No Physical damage to the system after locating on the final site of installation.	
Physical installation	All components are installed.	
Cleanliness	All access ports are examined and cleared of any debris.	

Sr. No.	Description	Observation
1	System is installed as per manufacturers recommendations	
2	All electrical connections have been done	
3	Sufficient room for servicing provided	
4	All utilities are connected properly	

<b>Inference:</b>			
<b>Name</b>			
<b>Sign</b>			
<b>Date</b>			
<b>Department</b>	<b>Done By</b>	<b>Checked By</b>	<b>Verified By</b>

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### Test Data Sheet 4

### VERIFICATION OF SYSTEM

( A ) Zebra Thermal Transfer Printer :

Sr. No.	Parameter/ Description	Specification	Observation
1	Name	Should be clearly visible	
2	Name	Zebra printer	
3	Make	Zebra technologies	
4	Model	ZT230	
5	Locations	To be recorded	
6	Mounting details	Portable	
7	Total Nos.	07 nos.	
8.	Serial no.	To be recorded	

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**( B ) Zebra Thermal Transfer Printer :**

Sr. No.	Parameter/Description	Specification	Observation
1	Name plate	Should be clearly visible	
2	Name	Zebra printer	
3	Make	Zebra technologies	
4	Model	GT800	
5	Locations	To be recorded	
6	Mounting details	Portable	
7	Total Nos.	04 nos.	
8.	Serial no.		

**(C) Hand Held Terminal (TC20)**

Sr. No.	Parameter/Description	Specification	Observation
1	Nameplate	Should be clearly visible	
2	Name	TC20 HHT	

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3	Make	Zebra	
4	Model	TC200J	
5	Locations	To be recorded	
6	Mounting details	Portable	
7.	Total Nos		
8.	Serial no.		

### Inference:

<b>Name</b>			
<b>Sign</b>			
<b>Date</b>			
<b>Department</b>	<b>Done By</b>	<b>Checked By</b>	<b>Verified By</b>

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### Test Data Sheet 5

#### Verification of major components/accessories

#### 1. Component / Accessory Name: Printer

Parameter	Specification	Observation
Width:	10.9" (H) x 9.5" (W) x 17" (D)	
Electrical	100-240 VAC; 47-63 Hz	
Supply	3 Amp (100W)	

#### 2. Component / Accessory Name: Printing specification

##### ZT230 PRINTER

Parameter	Specification	Observation
Ribbon width	51 mm to 110 mm	
Standard length	300 m	
Ribbon core inside diameter	25.4 mm	

##### GT800 PRINTER

Parameter	Specification	Observation
Length	12.27 inch	
Width	8.50 inch	
Height	7.24 inch	

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**3. Component / Accessory Name: TC20 (Hand Handle Terminal)**

Parameter	Specification	Observation
Size	6.1 in. L x 2.9 in. W x 0.73 in. D	
Electrical	90-265 VAC, 48 – 62 Hz, 5 Amps	
Memory	2GB RAM /16GB FLAS	

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**Test Data Sheet 6**

**DOCUMENT VERIFICATION**

Sr. No	Manual	Received / Not received	Checked By (QA)	Verified By (QA)
1.	Manual			
2	Others			

**Test Data Sheet 7**

**IDENTIFICATION OF STANDARD OPERATING PROCEDURES**

Sr. No.	SOP Title	Tentative SOP No.	Checked By	Verified By
1.				
2.				
3.				



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Test Data Sheet 8

DEVIATION SHEET

Sr. No.	Description of Deviation	GMP Criticality	Corrective Action	Need to be closed before OQ

Inference:			
Name			
Sign			
Date			
Department	Prepared By	Checked By	Verified By

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## 11.0 Preparation of Report

A separate Installation 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

MTS	Material Tracking System
GMP	Good manufacturing practice
V	volt
Hz	Hertz
Amp	Amperes
IQ	Installation qualification

## 13.0 Identification of Participants

In the list below all persons having participated in the execution of IQ 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.

Department	Name	Designation	Full Signature	Initials

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