



Material Tracking System

ACME Limited

Design Qualification Document

This user’s guide includes the design qualification document defined for the application.

Prepared By: Omkar G Version Number: 1.0.0

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| **DESIGN QUALIFICATION** | | | |
| System Name | Material Tracking System | System Id No | WH-MTS-01 |
| Document No. | ACME-MTS-Design-Qualification | Department | Warehouse |
| Version No. | 1.0 | Page No. | Page 1 of 9 |

# 1 PROTOCOL APPROVAL

|  |  |  |
| --- | --- | --- |
| **Prepared By** | | |
| **Name** | **Designation** | **Signature & Date** |
| Omkar Gaonkar | Technical Writer |  |
| **Checked By** | | |
| **Name** | **Designation** | **Signature & Date** |
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| --- | --- | --- | --- |
| **Approved By** | | | |
| **Department** | **Name** | **Designation** | **Signature & Date** |
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# 2 OBJECTIVE

The objective of this protocol is:

1. To define the Design Qualification (139) requirements for the Minimal Tracking System.
2. The details in this document describe the Installation and configuration of the implantation of the Material Tracking System from a Business Technical and functional perspective.

# 3 SCOPE

The scope of this protocol include design qualification procedure of the Material Tracking System for ACME GENERICS LLP.

This protocol defines the procedure alums. Documentation, acceptance criteria & re-qualification criteria.

# 4 QUALIFICATION TEAM

Responsible staff from:

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

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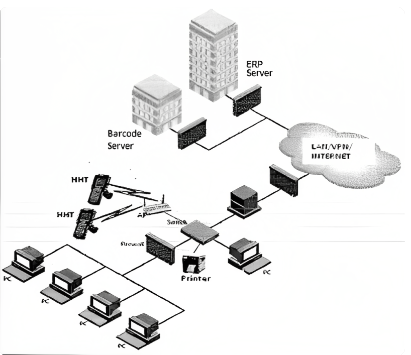
# 5 RESPONSIBILITIES

**Responsible persons for validation activity as following:**

|  |  |
| --- | --- |
| **Responsibilities** | **Details** |
| Vendor’s | Supplying drawings, manual, certificates and necessary documents for the generation and implementation of this protocol |
| QA | * Preparation of the document * Checking of documents * To verify the design activity as per document * Review the data documented during design qualification. * Final approval of protocol and report |
| I.T, Warehouse and QC | * Checking of document * To provide area for design and make related arrangements |

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# 6 HARDWARE ARCHITECTURE



The application architecture will be “Central Server Architecture”.

* + 1. All the plants will access the data from the Central Server.
    2. There will be a database server kept at ACME Generics LLP.
    3. The mobile data transfer will be through Wireless.
    4. The Server will be connected to SQL Database.
    5. The work station will be directly connected to SQL Database.

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# 7 LOGICAL ARCHITECTURE

Logical Architecture consist of Mobile Client and Server

**Mobile Client**

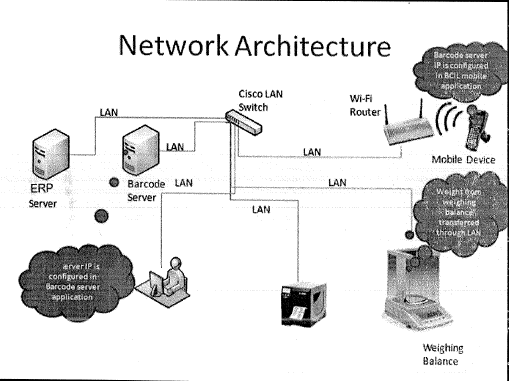
Mobile client will define the User Screens, Communication system with the mobile server and logs of the system in the mobile client

**Mobile Server**

Mobile server will consist of a barcode server and the barcode server will carry all the business logic, authentication, ERP Interfaces and updating data in SQL database.

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# 8 NETWORK ARCHITECTURE



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# 9 DEVIATION SHEET

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Sr.No** | **Description of Deviation** | **GMP Criticality** | **Corrective Action** | **Need to be closed before OQ** |
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| --- | --- | --- | --- |
| **Interferences** | | | |
| **Name** |  |  |  |
| **Sign** |  |  |  |
| **Date** |  |  |  |
| **Department** | **Prepared By** | **Checked By** | **Verified By** |

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# 10 IDENTIFICATION OF PARTICIPANTS

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

|  |  |  |  |
| --- | --- | --- | --- |
| **Review & Approval (Cipla Team)** | | | |
| **Department** | **Name** | **Designation** | **Signature & Date** |
| Warehouse |  |  |  |
| IT |  |  |  |
| QC |  |  |  |
| QA |  |  |  |
| Warehouse |  |  |  |

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 ACME Ltd

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