# VALIDATION SUMMARY REPORT

# FOR

# COMPUTER SYSTEM

# OF

# WAREHOUSE

| | |
|---|---|
| **System Name** | **WAREHOUSE** |
| **System ID** | |
| **Location** | **STORE OFFICE** |
| **Effective Date** | |

# VALIDATION SUMMARY REPORT FOR COMPUTER SYSTEM OF WAREHOUSE

**System Name:** Warehouse **System ID:**

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## VALIDATION SUMMARY REPORT FOR COMPUTER SYSTEM OF WAREHOUSE

**System Name:** Warehouse **System ID:**

### 1. PREPARATION AND APPROVALS:

The signature listed below indicates the preparation and approval of this Validation summary report. This approval is joint responsibility of listed functional areas.

| REPORT DEVELOPMENT | SIGN / DATE |
|---|---|
| **Name** : _____<br>**Designation** : _____ | |

| REPORT REVIEW AND APPROVAL (M/S……) |
|---|
| **Sign / Date** : _____<br>**Name** : _____<br>**Designation** : _____<br>**Engineering** |
| **Sign / Date** : _____<br>**Name** : _____<br>**Designation** : _____<br>**IT** |
| **Sign / Date** : _____<br>**Name** : _____<br>**Designation** : _____<br>**Warehouse** |

| REPORT AUTHORIZATION (M/S……) |
|---|
| **Sign / Date** : _____<br>**Name** : _____<br>**Designation** : _____<br>**Quality Assurance** |

**VALIDATION SUMMARY REPORT FOR COMPUTER SYSTEM OF WAREHOUSE**

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## 2. REVISION HISTORY:

| Date | Supersedes | Reason for Revision |
|---|---|---|
| | | |
| | | |

## 3. OBJECTIVE AND SCOPE:

The objective of this summary report is to collect sufficient data and the qualification executed pertaining to the Computer system of WAREHOUSE at ……..

Successful completion of this document will provide the successfully validated of the computer system of WAREHOUSE.

This document is applicable to environment monitoring systemat ……. This report describes the successful validation qualification for the control system.

## 4. REFERENCES:

The publication listed below form part of this report's reference documents. Each publication shall be the latest revision in effect on the date this report is approved for execution unless noted otherwise. Except as modified by the requirements specified herein or the details of the drawings, work included in this report shall conform to the applicable provisions of these publications.

| | |
|---|---|
| **GAMP 5** | Good Automated Manufacturing Practices, Version 5, Guideline document for Automated Systems from International Society of Pharmaceutical Engineering |
| **21 Code of Federal Regulations (CFR), Part 210** | Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding off Drugs; General |
| **21 Code of Federal Regulations (CFR), Part 211** | Current Good Manufacturing Practice for finished Pharmaceuticals |
| **WHO** | Appendix 5, validation of computerized systems. |
| **VP** | - |
| **SRS** | - |
| **RA** | - |
| **IQ** | - |
| **OQ** | - |
| **TM** | - |

## 5. ROLE AND RESPONSIBILITY:

The Validation team comprising of representative from each of the following departments should be responsible for overall compliance with this validation plan.

| Department | Responsibilities |
|---|---|
| **Validation Agency (……..)** | ➢ To collect data necessary for the generation, execution of this report from M/s. ……..<br>➢ To prepare the validation summary report.<br>➢ Comply with regulatory/Guidelines/Standards/validation plan requirements throughout the validation life cycle.<br>➢ To submit validation documents for approval. |
| **Engineering (M/s. ……..)** | ➢ Project Management and Planning.<br>➢ To provide the necessary data for qualification activities.<br>➢ To co-ordinate during execution of qualification activities.<br>➢ To review and approve the validation documents. |
| **IT (M/s. ……..)** | ➢ To provide the necessary data for qualification activities.<br>➢ To co-ordinate during execution of qualification activities.<br>➢ To review and approve the validation documents. |
| **Warehouse (M/s. ……..)** | ➢ To provide the necessary data for qualification activities.<br>➢ To co-ordinate during execution of qualification activities.<br>➢ To review the validation documents. |
| **Quality Assurance (M/s……)** | ➢ To approve and authorize the validation documents. |

## 6. DELIVERABLE DOCUMENTS:

- Validation Plan
- System Requirement Specification
- Gap and Risk Assessment
- Installation Qualification
- Operational Qualification
- Traceability Matrix
- Validation Summary Report

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## 7. INSTALLATION QUALIFICATION TEST STATUS:

| S.No. | Critical Feature | Pass/Fail | Discrepancy ( Y / N ) | Checked By / Date |
|---|---|---|---|---|
| 1. | Identification of System Details | | | |
| 2. | Verification of Master Documents | | | |
| 3. | Verification of Capacity Requirement | | | |
| 4. | Verification of Hardware Components | | | |
| 5. | Verification of Software Components | | | |
| 6. | Verification of Physical and Logical Security Control | | | |
| 7. | Verification of Test Instruments Calibration and Traceability | | | |
| 8. | Verification of Power Utility | | | |
| 9. | Verification of Environmental Condition | | | |
| 10. | Verification Of Communication Link Between Server to Computer System | | | |
| 11. | Verification of General System Installation | | | |

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## 8. OPERATION QUALIFICATION TEST STATUS:

| S.No. | Critical Feature | Pass / Fail | Discrepancy? (Y/N) | Checked By / Date |
|---|---|---|---|---|
| 1. | Verification of Windows Security | | | |
| 2. | Verification of System Start-up & Shutdown. | | | |
| 3. | Verification of System Response Failure. | | | |
| 4. | Verification of Electronic Data Security. | | | |
| 5. | Verification of Report Generation. | | | |
| 6. | Verification of User Prevented from Alternating Date and Time | | | |
| 7. | Verification of Data Back Up | | | |

## 9. ABBREVIATION:

| Abbreviations | Description |
|---|---|
| GMP | Good Manufacturing Practices |
| IS | Information Services |
| IQ | Installation Qualification |
| OQ | Operation Qualification |
| QA | Quality Assurance |
| TM | Traceability Matrix |
| SOP | Standard Operating Procedure |
| SRS | System Requirement and Specification |
| TS | Technical Services |
| WHO | World Health Organization |

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## 10. SUMMARY & CONCLUSION:

**Compiled by:** _____ **Date:**_____