



TRACEABILITY MATRIX FOR COMPUTER SYSTEM

System Name: QC Documentation

System ID:

**TRACEABILITY MATRIX
FOR
COMPUTER SYSTEM
OF
QC DOCUMENTATION**

| | |
|-----------------------|-------------------------|
| System Name | QC DOCUMENTATION |
| System ID | |
| Location | Instrument Lab |
| Effective Date | |



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1. PREPARATION AND APPROVALS:

The signature listed below indicates the preparation and approval of this Traceability Matrix. This approval is joint responsibility of listed functional areas.



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| PROTOCOL DEVELOPMENT | SIGN / DATE |
|---|--------------------|
| Name : _____ Designation : _____ | |

| PROTOCOL REVIEW AND APPROVAL (M/S.....) | |
|---|--|
| Sign / Date : _____ Name : _____ Designation : _____ Engineering | |
| Sign / Date : _____ Name : _____ Designation : _____ IT | |
| Sign / Date : _____ Name : _____ Designation : _____ Quality Control | |

| PROTOCOL APPROVAL (M/S.....) | |
|---|--|
| Sign / Date : _____ Name : _____ Designation : _____ Quality Assurance | |

2. REVISION HISTORY:

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



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3. OBJECTIVE AND SCOPE:

The traceability matrix is prepared for the Computer system Based of QC_DOC. Project planned at The traceability matrix contains all the traceability mentioned in system requirement specifications.

This document is dynamic in nature and can be changed during the course of the project with suitable revision number.

4. INTRODUCTION:

To provide the relation between system requirement specifications and installation & operational qualification documents to ensure that all the requirement as per the system requirement specifications.

5. TRACEABILITY COLUMN DETAILS:

- SRS Test Reference No.
System Requirement Specifications requirement should be listed.
- SRS Test Description
System Requirement Specifications description should be listed.
- GxP Impact ? (Y/N)
If Y, then there must be a test reference in column 5, or a reference showing that this requirement is verified in some other way.
- Other Impact (Y/N)
The system may require some formal verification or testing for reasons other than GxP, and for which it would be good practice to trace from requirement through design to testing. It is recommended this column notes the reason for other impact.
- Verification Test Reference No.
A reference must be present where GxP impact Y.
- Remarks
Mentioned any remark that add information particularly where reference needs to be made to additional testing or requirements that have arisen as part of the exercise.



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6. REFERENCES:

The publication listed below form part of this protocol's reference documents. Each publication shall be the latest revision in effect on the date this protocol 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 protocol 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 | - |



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7. 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 (.....) | <ul style="list-style-type: none">➤ To collect data necessary for the generation, execution of this protocol from M/s.➤ To prepare the traceability matrix.➤ To identify the system inventory and document the traceability matrix.➤ Comply with regulatory/Guidelines/Standards/validation plan requirements throughout the validation life cycle.➤ To submit validation documents for approval. |
| Engineering (M/s.) | <ul style="list-style-type: none">➤ Project Management and Planning.➤ To provide the necessary data for qualification activities.➤ To co-ordinate during execution of qualification activities.➤ To review the validation documents. |
| IT (M/s.) | <ul style="list-style-type: none">➤ To provide the necessary data for qualification activities.➤ To co-ordinate during execution of qualification activities.➤ To review the validation documents. |
| Quality Control (M/s.) | <ul style="list-style-type: none">➤ To provide the necessary data for qualification activities.➤ To co-ordinate during execution of qualification activities.➤ To review the validation documents. |
| Quality Assurance (M/s.) | <ul style="list-style-type: none">➤ To approve and authorize the validation documents. |



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8. TRACEABILITY MATRIX:

| SRS Reference No. | SRS Test Description | GxP Impact? (Y/N) | Other Impact? (Y/N) | Verification of Test Reference (IQ & OQ) | Remarks |
|-------------------|--|-------------------|---------------------|--|----------|
| 10.1 | Hardware Components | Y | N | IQ12.4 | Found Ok |
| 10.2 | Software Components | Y | N | IQ12.5 | Found Ok |
| 10.3 | Capacity Requirement | Y | N | IQ12.3 | Found Ok |
| 10.4 | Power Utility | Y | N | IQ12.8 | Found Ok |
| 10.5 | Environmental Condition | Y | N | IQ12.9 | Found Ok |
| 10.6 | Communication Link Between Server to Computer System | Y | N | IQ12.10 | Found Ok |
| 10.7 | Window Security | Y | N | OQ12.1 | Found Ok |
| 10.8 | System Response Failure | Y | N | OQ12.3 | Found Ok |
| 10.9 | Electronic Data Security | Y | N | OQ12.4 | Found Ok |
| 10.10 | Data Back Up | Y | N | OQ12.6 | Found Ok |
| 10.11 | User Prevented from Alternating Date and Time | Y | N | OQ12.5 | Found Ok |
| 10.12 | Excel sheet verification | Y | N | OQ12.7 | Found Ok |

