TRACEABILITY MATRIX

FOR

COMPUTER SYSTEM

OF

STABILITY-PC

System Name	**STABILITY-PC**
System ID	
Location	**QUALITY ASSURANCE**
Effective Date	

TRACEABILITY MATRIX FOR COMPUTER SYSTEM

TABLE OF CONTENTS

TRACEABILITY MATRIX FOR COMPUTER SYSTEM

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.

PROTOCOL DEVELOPMENT	SIGN / DATE
Name : _____ **Designation : _____**	

PROTOCOL REVIEW AND APPROVAL
Sign / Date : _____ **Name : _____** **Designation : _____** **Engineering**
Sign / Date : _____ **Name : _____** **Designation : _____** **IT**
Sign / Date : _____ **Name : _____** **Designation : _____** **Quality Assurance**

PROTOCOL APPROVAL
Sign / Date : _____ **Name : _____** **Designation : _____** **Quality Assurance**

2. REVISION HISTORY

Date	Supersedes	Reason for Revision

TRACEABILITY MATRIX FOR COMPUTER SYSTEM

3. OBJECTIVE AND SCOPE

The traceability matrix is prepared for the Computer system Based of STABILITY-PC. 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 excerise.

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	ICS-18.063.13-VP-R0
SRS	ICS-18.063.13-SRS-R0
RA	ICS-18.063.13-RA-R0
IQ	ICS-18.063.13-IQ-R0
OQ	ICS-18.063.13-OQ-R0

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	➢ 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.

TRACEABILITY MATRIX FOR COMPUTER SYSTEM

Engineering (M/s…….)	➢ 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……)	➢ 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……)	➢ 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……..)	➢ To approve and authorize the validation documents.

TRACEABILITY MATRIX FOR COMPUTER SYSTEM

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	OQ12.2	Found Ok
10.8	Password Security	Y	N	OQ12.4	Found Ok
10.9	System Response Failure	Y	N	OQ12.5	Found Ok
10.10	Electronic Data Security	Y	N	OQ12.6	Found Ok
10.11	Audit Trail	Y	N	OQ12.7	Found Ok
10.12	Report Generation	Y	N	OQ12.8	Found Ok
10.13	Alarms & Interlocks	Y	N	OQ12.9	Found Ok
10.14	Data Back Up	Y	N	OQ12.10	Found Ok
10.15	User Prevented From Alternating Date and Time	Y	N	OQ12.11	Found Ok
10.16	21 CFR part 11 Clauses	Y	N	OQ12.12	Found Ok

TRACEABILITY MATRIX FOR COMPUTER SYSTEM

9. ABBREVIATION

Abbreviations	Description
GMP	Good Manufacturing Practices
IQ	Installation Qualification
OQ	Operation Qualification
QA	Quality Assurance
TM	Traceability Matrix
SOP	Standard Operating Procedure
SRS	System Requirement and Specification
QA	Quality Assurance
QC	Quality Control
WHO	World Health Organization

10. SUMMARY & CONCLUSION

Compiled by: _____ **Date:**_____