VALIDATION PLAN

FOR

COMPUTER SYSTEM OF

STABILITY-PC

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

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1. PREPARATION AND APPROVALS

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

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

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

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

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2. SIGNATURE OF EXECUTOR

All the executer involved in these documents have to sign within prescribed format given below.

M/s ……

Name	Designation	Signature	Initial	Date

M/s …….

Name	Designation	Signature	Initial	Date

3. REVISION HISTORY

Date	Supersedes	Reason for Revision

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4. OBJECTIVE

The objective of Validation Plan is to provide an organization approach towards the validation activities for the Computer System hardware and software of QA Department STABILITY-PC. This document will define the requirement and standards that must be followed for all the validation activities as apply to the Computer System of STABILITY-PC

5. SCOPE

This document is applicable to validation of Hardware and Software system of Computer System (STABILITY-PC). This document shall define the test procedures, documentation, references and acceptance criteria in accordance with the guidelines laid down by the manufacturer of the system.

6. SYSTEM DESCRIPTION

Computer system of STABILITY-PC defines the controlling of Stability chamber connected to the system. The CS software of stability chamber is a communication software for data management. The operator interface is carried out by CS screen. The CS is used to feed required parameters and set points in the system during operation. The system is connected to data server for printing and data backup. The system is secured by IT through password only within the system.

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 the necessary data for qualification activities. ➢ To prepare the Validation Plan, Risk Assessment, Installation Qualification, Operational Qualification, Traceability Matrix and Validation Summary Report. ➢ To execute the qualification in coordination with engineering, validation and quality assurance team. ➢ Comply with regulatory / Guidelines / Standards / validation plan requirements throughout the validation life cycle. ➢ To submit qualification for approval.
Engineering (M/s. ……..)	➢ To provide the necessary data for system requirement specification activities. ➢ To review Validation Plan.
IT (M/s. ……..)	➢ To provide the necessary data for system requirement specification activities. ➢ To review Validation Plan.
Quality Assurance (M/s. ……..)	➢ To provide the necessary data for system requirement specification activities. ➢ To review Validation Plan.
Quality Assurance (M/s……..)	➢ To approve and authorized the Validation Plan.

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8. REFERENCES

The publication listed below form part of this reference documents. Each publication shall have latest revision in effect on the date of this document is approved for execution.

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
21 Code of Federal Regulations (CFR), Part 11	21 Code of Federal Regulations (CFR), Part 11Electronic Records, Electronic Signatures, Final Rule Electronic Submissions; Establishment of Public Docket, Notice
ICH Q9	International Conference of Harmonization (ICH) quality risk assessment Q9
EU GMP	Laying down the principles and guidelines of GMP in respect of medicinal products for human use.
WHO	Appendix 5, validation of computerized systems.

9. DOCUMENTATION PROCEDURE

- Qualification activities will be performed as defined in the approved document.
- All documentation will be completed during the execution of the qualification.
- Recording of information will be made in permanent ink.
- Fill out complete information in the verification table provided.
- Do not keep any space blank. Mark blank space with a single line throughout the appropriate space with mentioning NA (Not Applicable) and put initial and date.
- Correct the mistakes by drawing a single line through the incorrect data, recording the correct information and then initialing and dating the change.

10. QUALIFICATION COMPLETION AND APPROVAL

- Verify that all tests required by qualification are completed and attached.
- Verify that all amendments and discrepancies are documented, approved and attached.
- If all items in the qualification for the Computer System of STABILITY-PC have been reviewed and found to be acceptable, sign the corresponding block in the qualification completion and approval form.

11. ACCEPTANCE CRITERIA

- Installation completion as per manufacturers recommendations & cGMP requirements.
- The supply of all necessary documentation from manufacturer/Installer.
- The system is operating as intended and is under state of control.
- Operational features meet system requirements and system specifications.

12. DOCUMENTATION MANAGEMENT

All quality and project relevant documents delivered by ……are handled through ……. document management system. Each document has a unique ID and is version. The identification number of a document has the following structure:

<…..>-<Project No.>-<Document Name>-Version

The author's name, the file name, the document number (document code and Revision No.) and the total pages number are included in the document footer in order to clearly assign each page to a certain document.

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13. REFERENCE DOCUMENTS

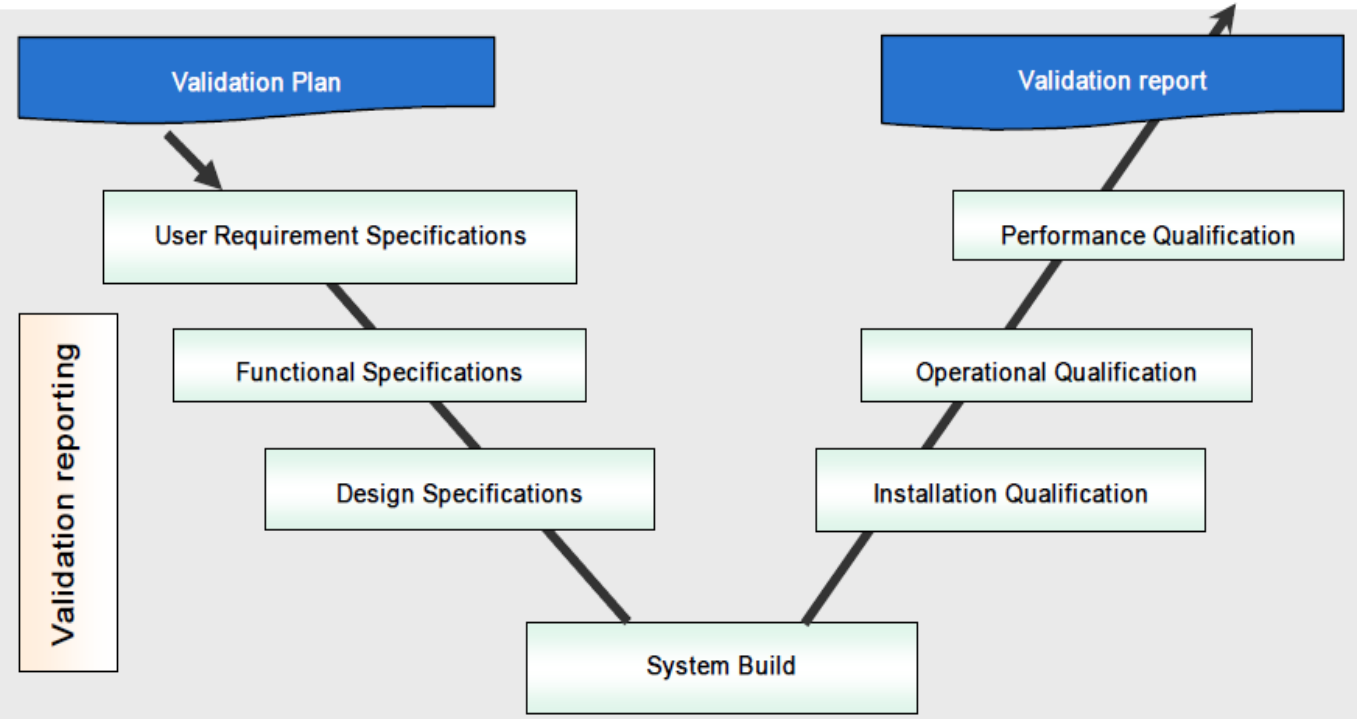
a. Standard operating procedures

b. User requirement specifications

- System operation manual
- System bill of material

14. V-MODEL OF GAMP

The system development life cycle is based on the GAMP-5 development life cycle and the ISPE baseline for validation.



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15. VALIDATION APPROACH

For the validation, GAMP 5 guidelines have been considered. As per GAMP Software Life Cycle approach is considered for all automated control systems. The following table depicts categorization of various software systems as per GAMP 5.

The system categorization is intended to evaluate and determine appropriate validation activities and deliverables. Once a system is evaluated as a whole, the functionality of individual components can be assessed for potential risk to data integrity and tested accordingly.

In determining the system categorization, functionality and intended use of the system are to be considered.

Category	Software Type	Validation Approach
3	Non-configured Software e.g. Firmware based application COTS software Instruments	• Abbreviated Lifecycle approach • Risk based approach to supplier assessment • Record version (and configuration of environment) and verify correct installation. • Risk based tests against requirements. (calibrations for instruments) • Procedures in place for maintaining compliance and fitness for intended use.
4	Configurable Software Packages, e.g. DAS IPC ERP DCS BMS LIMS HMI	• Life Cycle approach • Risk based approach to supplier assessment. • Record version number, verify correct installation • Risk based testing to demonstrate applicable works as designed in a test environment and within the business process. • Procedure in place for maintaining compliance and fitness for intended use. • Procedures in place for managing data.
5	Custom Software e.g. internally or externally developed IT applications. Custom ladder logic Spreadsheets (macro)	Same as configurable, plus: • More rigorous supplier assessment. • Possession of full life cycle documentation • Design and source code review

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16. CATEGORIZATION OF THE CONTROL SYSTEM

16.1 Computer System

The Computer control system falls under the **category-3** Non-configurable software package as defined by **GAMP-5** guidlines. hence, verification & configuration and testing of operation against user requirement will be performed.

16.2 Hardware CategoryAnd Software Category

- Hardware Category 1 - Standard hardware component
- Hardware Category 2 - Custom built hardware component

Category	GAMP-4	GAMP-5
1	Operating Software	Infrastructure Software
2	Firmware	No longer used
3	Standard Software	Non configured Software
4	Configurable Software	Configured Software
5	Custom Software	Custom Software

17. DOCUMENT SCOPE

The documents scope of this validation plan is to establish the project framework for carrying out quality assurance and project management measures impacting …. and M/s …….for the project as described. The documents scope should define the activities to be performed, which will perform them, the control mechanisms to be used and the deliverables

- Validation Plan
- System Requirement Specification
- Risk Assessment Protocol
- Installation Qualification
- Operation Qualification
- Traceability Matrix
- Validation Summary Report

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17.1 Risk Assessment

Definition	This document is to provide the analyses the risk of utilization of the Computer System of STABILITY-PC as per the cGMP and GxP and to identify the possible areas of risk , where the existing laid down appropriate controls or measures requires further strengthening. To suggest suitable solutions (action plan) to mitigate or minimize the risk.
Phase	Designing
Control	Review
Executor	Validation Team
Prerequisites	SRS is approved
Acceptance	M/s ……
Outcomes	Risk Assessment

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17.2Installation Qualification

Definition	The objective of the installation qualification test is to verify the Computer System of STABILITY-PC installed at the M/s …….. This includes the following tests: • Identification of System Details • Verification of Master Documents for computer system • Verification of capacity Requirement of computer system • Verification of Hardware Components • Verification of Software Components • Verification of Physical and Logical Security Control • Verification of Test Instruments Calibration and it's Traceability • Verification of Power Supply • Verification of Environmental Condition • Verification of Communication Link Between Server To Computer System • Verification of General System Installation • Verification of Standard Operating Procedures
Phase	Commissioning
Control	Review
Executor	Validation Team
Prerequisites	Risk Assessment is Pre approved
Acceptance	M/s ……..
Outcomes	Installation Qualification

17.3 Operational Qualification

Definition	The objective of the operational qualification test is to verify the function of Computer System of STABILITY-PC installed at the M/s …….. This includes the following tests: • Verification of Field Instrument Calibration • Verification of Windows Security • Verification of System Start-up & Shutdown • Verification of Password Security • Verification of Application software Screens. • Verification of System Response Failure. • Verification of Electronic Data Security. • Verification of Audit Trail. • Verification of Report Generation. • Verification of Alarms and Interlocks. • Verification of Data Back Up • Verification of User Prevented From Alternating Date and Time • Verification of system software as per 21 CFR part 11 Clauses.
Phase	Commissioning
Control	Review
Executor	Validation Team
Prerequisites	Installation Qualification is approved
Acceptance	M/s …….
Outcomes	Operational Qualification

17.4Traceability Matrix

Definition	The traceability matrix is to provide the assurance that mapped between IQ and OQ. The traceability matrix contains all the traceability mentioned in system requirement specifications.
Phase	Commissioning
Control	Review
Executor	Validation Team
Prerequisites	SRS, IQ and OQ is approved
Acceptance	M/s ……
Outcomes	Traceability Matrix

17.5Validation Summary Report

Definition	This validation summary report is to collect sufficient data and the qualification executed pertaining to the Computer System of STABILITY-PC. Successful completion of this document will provide the successfully validated of the Computer System of STABILITY-PC This report describes the successful validation qualification for the Computer System of STABILITY-PC.
Phase	Commissioning
Control	Review
Executor	Validation Team
Prerequisites	IQ and OQ is approved
Acceptance	M/s ……
Outcomes	Validation Summary Report

18. CHANGE CONTROL

All changes in the control system during the validation activities shall be handled as per the change control SOP.

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19. MAINTENANCE AND SUPPORT

The Computer System of STABILITY-PC and its associated components shall be incorporated into the planned preventive maintenance activities. Any software changes, which shall be required and any upgrades in hardware and operating system software shall be carefully controlled and all documentation maintained as per prevailing change control procedures.

20. STANDARD OPERATING PROCEDURE

A number of SOPs will be developed for the operations that support the control systems during this validation exercise. Each SOP is listed below.

- System Security
- Change Control
- Data Backup, Archiving and Retrieval
- User Administration Policy
- Preventive Maintenance & System operation

21. DISCREPANCIES HANDLING DURING COMPUTER SYSTEM QUALIFICATION

- In case of discrepancy observed during qualification, document in the defined column in each table and document the details of the observation in the discrepancy log sheet.
- Inform to engineering, IT, QA and quality assurance about discrepancy.
- Investigate the discrepancy and ensure the possible impact.
- If discrepancy does not have potential to impact on operation as well as performance of the system, close the discrepancy with proper justification.
- The engineering, User, IT and QA will decide whether discrepancy is acceptable or not.
- If discrepancy is acceptable, provide conclusion and recommendation if any into respective column.

22. DISCREPANCY AND CORRECTIVE ACTION FORM

Protocol Reference	
Discrepancy Number	

DISCREPANCY

Describe the Discrepancy	
Reported by	Date

CORRECTIVE ACTION

Describe corrective action taken (Attach additional sheets if necessary)	
Reported by	Date

DISPOSITION ACTION

Acceptable?	Yes	No	
Discussion			
Approved by			Date

COMPLETION

Completed by	Date

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23. APPROVAL AND DELIVERABLES

The complete validation is governed by a series of quality assurance measures. The following table lists the validation deliverables. It is assumed that all documents are submitted by ……as required.

Deliverable	Original Location	Validation Agency (Developer)	M/S (Reviewer)	M/S (Reviewer)	M/S (Reviewer)	M/S (Approver)
Validation Plan	Validation Dept.	…….	Engineering	IT	Quality Assurance	Quality Assurance
System Requirement Specfication						
Risk Assessment Protocol						
Installation Qualification						
Operational Qualification						
Traceability Matrix						
Validation Summary Report						

24. ABBREVIATION

Abbreviations	Description
GMP	Good Manufacturing Practices
SRS	SystemRequirement Specification
RA	Risk Assessment
IQ	Installation Qualification
OQ	Operation Qualification
QA	Quality Assurance
TM	Traceability Matrix
VSR	Validation Summary Report
SOP	Standard Operating Procedure
NA	Not Applicable
IO	Input Output
ICH	International Conference of Harmonization
CS	Computer System
ID	Identification
WHO	World Health Organisation