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VALIDATION MASTER PLAN(VMP)		
ERP SYSTEM		
Name of the system	:	ERP System
Location	:	
Document No.	:	
Validation No.	:	
Document Type	:	Original
Effective Date	:	
Prepared For	:	
Prepared By	:	

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1.0 APPROVAL – VALIDATION MASTER PLAN:

The Validation Master Plan for installed ERP System has been approved for release by the management.

		Activity	Name & Designation		Sign.	Date
		Prepared by				
		Department	**Name**	**Designation**	**Sign.**	**Date**
	Reviewed by	Information Technology				
		Purchase				
		Warehouse				
		Quality Control				
		Production				
		Quality Assurance				
		Engineering				
	Approved by	Quality Assurance				

2.0 REVISION HISTORY:

Version / Revision Number	Revised Date	Reason for Revision
00		

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3.0 PURPOSE:

This validation plan gives the overview of control systems designed & procedures implemented in the organization to meet the cGMP requirements, latest International standards and guidelines such as Good Automated Manufacturing Practice, Version 5 (GAMP 5) & USFDA 21 CFR Part 11 (wherever applicable).

It describes the scope of activities, within which validation of control system is to be performed and provides an overview of the planning system.

This validation plan is generated under the Validation policy of the company.

4.0 OBJECTIVE:

The objective of this Validation Master Plan is:

- To define the company's philosophy and commitment to validation and the overall structure for validation activities.
- To identify which ERP process are subject to validation.
- To identify the roles and responsibilities of persons involved in validation activities.
- To describe brief descriptions of the validation strategies for ERP system.
- To define test strategy and methodology to meet the compliance requirement.
- To ensure that ERP system is fit for intended use and compliant with applicable regulations.
- To outline protocols and test procedures and to define reporting requirements to document ERP system validation exercise.

5.0 SCOPE:

ERP System is already implemented in …….. It is decided to validate ERP process related to GMP critical areas. This Plan applies to ERP system and is used in GxP regulated activities. ERP process manufacturing system modules which will affect the quality of products and the quality of the data generated to support their business activities shall be covered under the scope. Consequently, there should be modules or processes, whose operation, although important for the efficient and economic operation of the facility, cannot be considered critical to the quality of products and therefore will not be validated as part of this activity.

The scope of this validation exercise shall include:

ERP System Modules

- Purchase
- Manufacturing Inventory
- Quality Control
- Production
- Sales Inventory
- Set up
- Centralised System Administration
- Requisition

- Quality Assurance

6.0 SYSTEM DESCRIPTION:

6.1 ENTERPRISE RESOURCE PLANNING (ERP) SYSTEM:

ERP system is the enterprise resource planning system supplied and supported by .....

ERP is mainly developed for pharmaceutical industries and it meets all the requirements of the pharmaceutical industry. However it has been customized to meet the URS of M/s. **.....** A system for taking backup of data is available in ERP system, which will enable the user to avoid data loss. The system enables the user to restore the data in case the current data is lost or redundant data in the system.

..... has amended/added functions to ERP System to enhance its use in supporting the business. These additional functions are being done to upgrade as part of this remediation project.

ERP is an enterprise resource planning system covering all functional areas in an organization such as system administration, accounts, purchase, warehouse, QC, production, QA and distribution. ERP consists of different modules, each addressing the requirements of a functional area. All the master data and parameters that are common to all other modules can be defined and managed in the setup module. Operations in all the other modules of ERP depend upon the information that is entered in the setup module.

The installation of ERP system at **.....** covered by the scope of this project, comprises of the following software and hardware elements:

Minimum Hardware Requirements:

Server Configuration:–

- Intel Xeon 2.0 Ghz
- Intel Server Board, 8GB RAM, 500GB HDD,
- DVD Writer, RAID Controller, 2QD Server Chassis with

500W + 500W, Zippy RPS, Keyboard & Optical Mouse

Client Configuration:-

- PIV or above
- 512 MB RAM or above
- 160 GB of Hard Drive or above

Minimum Software Requirements:

Server Configuration:–

- Application Server Operating System – Windows 2008Server

Client Configuration:–

- Windows 7 or above Operating system

The list of module-wise processes and sub processes which are relevant for GMP considerations is attached in Annexure 1.

The applicable GxP modules and processes from above shall be part of validation activities. The applicability of GxP shall be decided based on risk assessment process.

7.0 VALIDATION RESPONSIBILITIES:

7.1 VALIDATION COMMITTEE:

Validation is a team effort and various departments must need to participate in the project. Successful validation projects rely on the support and expertise of diverse groups within and outside the organization.

All SOP's shall be written by M/s **…….**

7.2 DOCUMENT APPROVAL:

Designated department heads shall be responsible for the joint approval of qualification protocols, report and SOP's

7.3 VALIDATION CONSULTANTS:

The validation consultants (M/s .....)shall provide validation project management, write and execute protocols and reports.

Protocol and report execution work must be supported by M/s …… Production, Quality Control, Quality Assurance, Engineering, Warehouse, Distribution and Information Technology on as needed basis.

8.0 VALIDATION APPROACH:

8.1 CATEGORIZATION OF THE SYSTEM:

The validation strategy for the system shall be based on the different "Categories of Software"

System categories are defined below as per GAMP 5:

Category 1: Infrastructure software including operation systems, database engines, programming languages, network monitoring tools etc.

Category 3: Non configurable software including commercial off the shelf software (COTS), laboratory instruments/ software

Category 4: Configurable software including LIMS, Data acquisition system, computer system, ERP, DCS, BMS, spreadsheets, PLC with SCADA.

Category 5: Custom/Bespoke software. For example internally and externally developed IT applications, internally and externally developed process control applications

The ERP Process falls under the Category 4 Configurable Software Packages as defined by GAMP 5 guidelines. Hence, verification of version & configuration and testing of operation will be performed against system requirements.

Typical category of hardware and Software Systems

Component	Software Category	Hardware Category
PC Hardware	NA	1
Operating System	1	NA
ERP	4	NA

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8.2 LIFE CYCLE MODEL:

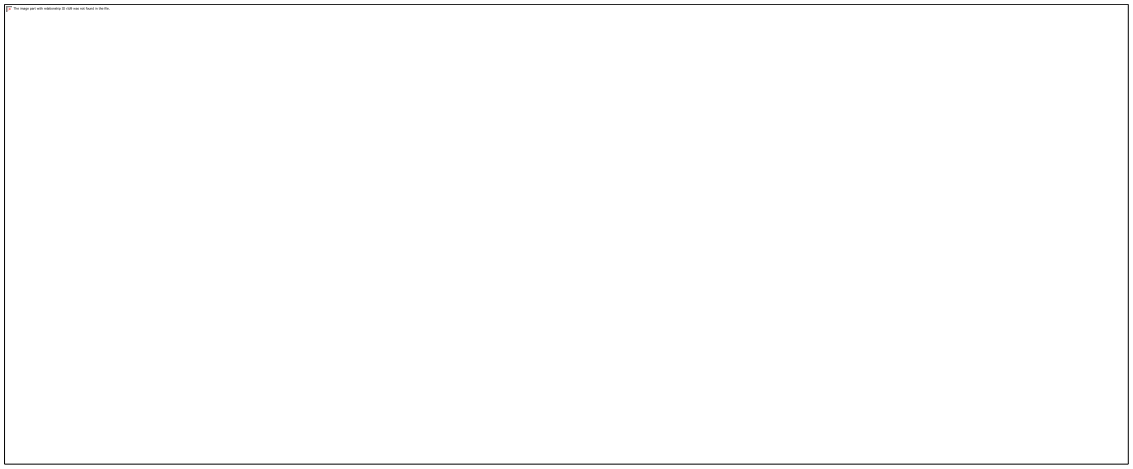
Validation shall be used as a tool for providing a high degree of assurance that ERP process consistently performs its business operations meeting its pre-determined specification and quality attributes.

The validation exercise shall follow the typical 'V' diagram approach as advocated by GAMP 5. The diagram is shown below as reference.

This model comprises of user requirement specifications (URS), functional Specifications (FS), configuration (or design) specifications (DS), installation qualification (IQ), operational qualification (OQ) and performance qualification (PQ). A typical life cycle management model is shown in diagram below.

8.3 APPROACH FOR ERP:

The validation exercise will follow the typical 'V' diagram approach for the ERP Processes advocated by GAMP 5 following Life Cycle Management model. The diagram is shown above in section.



The model suggests that after completion of first validation exercise, the ERP process will be governed by formal change control process during operation phase. All changes shall follow the 'V' model depending upon the impact assessment.

8.4 SPECIFICATIONS:

8.4.1 USER REQUIREMENT SPECIFICATIONS (URS):

A URS is an approved statement that outlines the basic requirements for ERP system and therefore contains a set of criteria or conditions that have to be met. The system requirement specification will cover the basic system requirements and functional requirements of the ERP system.

The URS will be prepared by validation agency.

8.4.2 DESIGN QUALIFICATION (DQ):

The document includes design details of the system. This documents links installation qualification. DQ shall be written by the vendor and shall be reviewed and approved by user.

8.5 GxP ASSESSMENT

The GxP assessment shall be done for the systems for the final decision whether the system has any GxP impact or not and further risks shall be assessed for the same.

8.6 RISK ASSESSMENT:

Risk assessment shall be carried out for ERP process in order to assess the GMP risks associated with systems in order to evaluate the need, scope and extent of validation, preventive maintenance and standard operating procedures.

The risk assessment process will follow the risk assessment protocol (Ref. no……..). The risk assessment process allows users to identify and minimize the impact of adverse events, while at the same time providing the necessary justification for the validation approach taken to support the system qualification. All risk identified during assessment process shall be challenged during the operational qualification

The GAMP 5 based Quality Risk Assessment process addresses the following five steps.

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All risk identified during assessment process shall be challenged during the operational qualification.

8.7 STANDARD VALIDATION FORMAT

The validation protocol shall cover the following key aspects:

- Installation Qualification (IQ)
- Operational Qualification (OQ)
- Performance Qualification (PQ)

8.7.1 INSTALLATION QUALIFICATION:

An installation qualification (IQ) is associated with the installation of the application software, its hardware systems and their interfaces. The IQ protocol shall be developed to verify and document that the system is installed. The installation qualification report will be submitted separately. Tests to be performed will be described in detail in the protocol of the system.

The installation qualification protocol and report shall be carried out by the Professional Consultancy Services.

8.7.2 OPERATIONAL QUALIFICATION:

The OQ protocol shall be developed to verify the ERP process functionality with functional testing throughout all critical (high risk) anticipated ranges and modes of operation. The operational tests will be designed to challenge and demonstrate the system's ability to operate and generate electronic records in accordance with the approved functional requirements. OQ activity shall be executed in test environment.

The operational qualification report shall be submitted subsequently. Tests to be performed will be described in detail in operational protocol of the system.

The operational qualification protocol and report shall be carried out by the Professional Consultancy Services.

Approval of this OQ report shall authorise the system for use in the ‘Live’ environment and signal that the Performance Qualification (Post Implementation Monitoring) exercise can commence.

8.7.3 PERFORMANCE QUALIFICATION:

The PQ protocol for the ERP processshall be developed to verify the ultimate performance of the ERP processin live environment in accordance with the system requirements.

The performance qualification report shall be submitted subsequently. Tests to be performed will be described in detail in the performance protocol of the system.

The performance qualification protocol and report shall be carried out by the **.....** after successful operational qualification.

8.7.4 EXECUTION OF PROTOCOLS - LINKAGE WITH TEST DATA AND TEST RESULTS:

All protocol documents shall be approved before the execution. Tests shall be executed by one or more persons and subsequently verified by someone other than the test executor. Actual test results shall be recorded using objective evidence (e.g. attached screen prints and reports) where practical. Each test result shall be signed and dated by the test executor and the reviewer. Discrepancies (e.g., cases where actual results do not match expected results) shall be identified in the summary section of the qualification document. After executing all tests in a qualification document, the results shall be reviewed and approved. The combined qualification document must be approved after all tests are successfully executed.

Any discrepancies or variations noted during the execution of the qualification shall be documented. The resolution of these tests and/or any test outstanding that require further effort to resolve shall be included. Only when all the tests are completed and approved (thus showing expected results), then the system shall be considered validated.

8.8 TEST STRATEGY:

8.8.1 TEST PHASES:

8.8.1.1 BLACK BOX TESTING (ALSO KNOWN AS PROCESS CHALLENGE TEST):

Black Box Testing shall be carried out for all the related ERP modules present at **……...**Black box testing takes an external perspective of the test object to derive test cases. The test designer selects Valid and Invalid input and determines the correct output. There is no knowledge of the test object's internal structure.

8.8.2 TEST ENVIRONMENT:

The operational qualification functionality and other challenge test shall be carried out on the test server with required configuration for necessary controls. The performance qualification testing shall be carried out on the live server.

8.9 TEST PRE-REQUISITES:

S.No.	Description	Pre-Requisites
1.	Tools/Tackles and Equipments	Test Server
		User ID.
		Computer system to compile test evidences
		Internet connection wherever required
		Digital/Mobile Camera
		Calibrated Thermo Hygrometer

S.No.	Description	Pre-Requisites
		Calibrated multi-meter
2.	Personnel	Availability of concern users.
3.	Time	Adequate time for carrying out the necessary testing for system
4.	Documentation	Approval of Protocols
		Test Tables with test data sets

8.9.1 TEST FOR QUALIFICATION:

INSTALLATION QUALIFICATION TEST

S.No.	Test Description
1.	Verification of environmental conditions
2.	Verification of installed server
3.	Verification of Antivirus Software for Server
4.	Verification of master documents
5.	Verification of installation procedure for server and ERP
6.	Verification of ERP access
7.	Verification of access control and security policies of servers
8.	Verification data backup and restoration
9.	Verification of module wise ERP users
10.	Verification of ERP date & time synchronization with server

OPERATIONAL QUALIFICATION TEST (OQ)

S.No.	Test Description
1.	Verification of Master Settings and Access Modules
	Annexure 1- Verification of Process Functionality
	Annexure 2- Verification of Process Challenges
	Annexure 3- Verification of Audit Trail
2.	Verification of Operational SOP

PERFORMANCE QUALIFICATION

S.No.	Test Description
1.	Verification of User Access Control and Authorizations (Ref. Annexure 1)
2.	Verification of Master and Module wise system Functionality
	Annexure 2- Verification of Process Functionality
	Annexure 3- Verification of Audit Trail
3.	Verification of Training Record

8.10 DISCREPANCY MANAGEMENT:

Discrepancies shall be observed in below cases:

- Results which fail to meet the acceptance criteria.
- Conflicts with specifications.
- Information which is unavailable.
- Discrepancy from protocol methodology.
- Documentation discrepancies (e.g. incorrect reference number, issue number, etc.).

All the discrepancies encountered during a validation activity shall be recorded in the appropriate section of the protocol / report / data sheet as per discrepancy report format. Recorded discrepancy shall be classified as Minor and Major based on the level of impact on the performance / outcome expected from the process / system. Observed discrepancy shall be evaluated by validation team and QA and shall be closed before completion of validation. Before completion of validation activity all discrepancies shall be corrected, tested and closed.

Following guideline shall be utilized to classify the observed discrepancy.

Minor: Those discrepancies which has minor/ no impact on the desired performance / outcome. Such discrepancies can be accepted and closed with justification.

Major: Those discrepancies which has Major impact on the desired performance / outcome. Such discrepancies can be conditionally accepted but must be corrected and closed within stipulated period.

All discrepancies must be resolved before post approval of the validation summary report. Protocols may be approved as interim if there are no outstanding "Major" discrepancies. All "Major" discrepancies must be resolved before proceeding to the next qualification protocol.

Critical: Those discrepancies which result in nonconformance with predefined specifications or acceptance criteria. These discrepancies require mandatory rectification before release of the system. The system shall kept on hold till the rectification of the critical discrepancy.

Discrepancy/Deviation/Management: If any of the above discrepancies observed at the time of validation are not resolved and are acceptable, they will be handled as per the Laboratory Incident Management SOP.

8.11 DATA INTEGRITY:

The various tests covered in installation and operational qualification shall ensure the compliance to international regulations and guidelines for electronic record and signature management (e.g. US FDA 21 CFR Part 11, Eudralex, EU GMP Volume IV Annexure 11, PIC/S Guidelines etc.). A separate traceability/verification shall be carried out for each software system to ensure that the data generated, stored, retrieved, archived is (ALCOA). This traceability/verification shall be created to give a reasonable assurance that the data handled by the computerized systems is meeting the expectation of the current data integrity requirements.

8.12 VALIDATION SUMMARY REPORT:

A consolidated validation summary report shall be developed at end of approvals of all protocol reports which shall summarize the results of the testing, the discrepancies, and provides a conclusion statement.

Once the validation summary report is reviewed and approved by management, the validation deliverables are assembled into binders and retained in a controlled location additionally; the raw data shall be securely stored and as true copy accessible in digital scanned format for local health authority inspections in the concerned countries. Approval of the validation summary report constitutes approval of the validation. After release of validation summary report, all the systems shall be governed by change control. Validation summary report shall be prepared by validation consultant and shall be reviewed and approved by……..

9.0 VALIDATION METHODOLOGY:

9.1 Data Collection for the Qualification

9.1.1 **Qualification Protocol/ Report**

The Installation, Operational and performance Qualification Protocol/Report will consist of the approved copy of this protocol completed as identification in clear handwriting and of appended documents (annotated where indicated in this protocol) listed in the section "List of annexure".

All sections in this protocol will be completed in English.

9.1.2 **Data Collection for the Qualification**

All people who enter data in this report will be identified in section "Signature Samples" of Validation Master Plan of the system. For those who are not employees of …….. abbreviated curriculum vitae shall be kept on file in the Validation Department.

9.1.3 **Corrections**

Any corrections to hand-written data will be made by crossing out the data with a single line, writing the correction and then signing abbreviated signature (initials) and dating the correction. Comments should be made where appropriate to explain the corrections and must be made when the correction impinges upon a specification.

9.1.4 **Appropriate Response**

The person executing the protocol must indicate the appropriate response by his/her abbreviated signature (initials). In case where the person executing the protocol must choose between a 'yes' or 'No' , the person must clearly write his initials in the proper box. Where an actual value is determined, the result must be written rather than 'meets specification', 'within limits' or 'pass'.

9.1.5 **Completion of Tables**

Certain tables included in this protocol are intended to document and detail present Installation. The person executing the protocol shall complete the tables as far as possible by writing in or correcting the manufacturer, model and other information that either not correct or not indicated in the table.

Writing 'N/Nv' or 'NA' will indicate that the information is not available and is no deemed essential. The person executing the protocol shall enter this information an date and initial in each entry.

9.2 Comments and / or Discrepancies

Refer section 8.10 in this document

9.3 Data

Originals data pages from the original, approved protocol shall be used to record test results and collect data. All data, including that which does not meets specifications, shall be included in the validation package. Supporting records and data are to be labeled and included or referenced in the final package.

9.4 Test Failure

Test failure shall be noted on test pages, where they occur. An explanation of the failure and description of permanent corrective action shall be noted on or attached to the test page.

The condition shall be corrected and the test repeated using a blank copy of the page (preferable) or by explain clearly that the second test results on the original test sheet complete with the new results. Both pages shall be included in the final package. If specifications cannot be met after adjustments or other changes have been made, an analysis of the impact of not meeting the specifications shall be made and included in the package summary.

9.5 Document Control

The approved protocol will be the final document. The original protocol will be made available for system executed by M/s …….. All the papers of the working copy will be initialized by QA and technical services personnel and will be issued for the execution.

10.0 VALIDATION DOCUMENTS:

Each document will be uniquely numbered for the project. All documentation created for this exercise shall be maintained with the respective department.

Following documents shall be created at end of overall validation exercise.

Type of Document	Document Number	Preparaed by	Executed by	Compiled by	Approved by
Validation Master Plan		PCS	NA	PCS	
User Requirement Specifications		PCS	NA	PCS	
Design Qualification	As per ERP System	ERP System	NA	ERP System	

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Type of Document	Document Number	Preparaed by	Executed by	Compiled by	Approved by
*GxP and Part 11 Evaluation		PCS	NA	PCS	
*Risk Assessment Protocol		PCS	NA	PCS	
*Risk Assessment Report		PCS	NA	PCS	
*Installation Qualification Protocol		PCS	PCS	PCS	
*Installation Qualification Report		PCS	PCS	PCS	
*Operational Qualification Protocol		PCS	PCS	PCS	
*Operational Qualification Report		PCS	PCS	PCS	
*Performance Qualification Protocol		PCS	PCS	PCS	
*Performance Qualification Report		PCS	PCS	PCS	
*Validation Summary Report		PCS	NA	PCS	

Asterisk (*) denoted document shall be prepared after preparation of Validation Master Plan.

11.0 SYSTEM OPERATION, MAINTENANCE AND SUPPORT:

Once the ERP process has been validated and released for use in operation, appropriate operational processes, procedures and plans shall be implemented during operational phase to maintain compliance and fitness for intended use throughout its life. This will be achieved by the use of upto date documented procedures and training that cover use, maintenance and management.

The system maintenance phase shall embody all maintenance and support activities necessary to ensure that the validated status of the system shall be maintained throughout its operational life and this shall be the responsibility of ……operating/ maintenance personnel.

11.1 CONTROLS & PROCEDURES / SUPPORT PROGRAMMES:

Controls and procedures relating to the ERP System will be prepared and approved before the validation summary report is approved. These procedures will be controlled and approved according to the local site procedure.

The responsibility for each control and procedure rests with the department responsible for that activity.

The following controls and procedures will be available:

- **Incident Management** – Describes the process to ensure that any unplanned issues that could impact patient safety, Product quality, and data integrity are addressed before any harm occurs. It ensures that operational events which are not part of the standard operation are identified, evaluated, resolved and closed in a timely manner.
- **Operational Change Control and Configuration Management**- Describes how changes to the ERP system hardware and software application shall be reviewed tested and approved to ensure the on-going validated state of the ERP system.
- **Data Backup and Restore –**Back-ups of the ERP System will be performed regularly and will be controlled by a local back-up procedure. A procedure will exist detailing how ERP System will be restored from back-ups.
- **Disaster Management and Business Continuity** – Describes what actions will be taken to recover and restore system functions in the event of a major disruption or disaster? It includes the process for Disaster management.
- **Security Management**- Describes how access rights to ERP systems are configured to prevent unauthorized system access.
- **System Administration**-Describes routine management and support of systems to ensure that the systems are running efficiently and effectively.
- **User Procedure**- End-user operating procedures, describing how the users are to use ERP System in their daily job, must be available along with operating procedures describing how technical personnel will operate the system.

11.2 CHANGE CONTROL:

The formal change control procedure is in place. Any kind of system's hardware/software changes shall be kept documented.

Change control procedure should be as per current approved site change control procedure.
Sample change control form is attached herewith. (Reference SOP No.: ……..)

11.3 TRAINING:

System users and technical staff supporting the system must be trained on relevant SOP prior to the performance qualification. The regulatory impact of using ERP systems must be covered in the training.

The training records shall be available to establish adequate training being imparted to operator to operate ERP System.

11.4 PERIODIC REVIEW:

In order to maintain the validation and GxP status of the ERP process, it should preferably be reviewed periodically; either internally or by an external contract based audit agency. An effective change control procedure should ensure that proposed changes are appropriately reviewed to assess impact and risk of implementing the change along with the evaluated, authorized, documented, tested and approved credentials before the implementation and subsequent closure of the change. Changes that can impact product quality may require full or partial revalidation of the ERP process which shall be controlled as per the existing change control procedure, in order to evaluate the trends in performance or changes in the operating environment in which the ERP Process operates. During the periodic review following aspects shall be reviewed:

1. Status of validation documentation and updates
2. Status of IT SOP and updates
3. Status of qualifications
4. Status of authorizations
5. Status of affected business/operational SOP for the changes.
6. Change control notes
7. Training records (as per the existing training SOP)
8. Problem (Incident) logs review

The results of the review are documented in a Periodic Review Report which will conclude either that the validation status is upheld or that revalidation is required.

12.0 SYSTEM ACCEPTANCE:

The following acceptance criteria are the basis of the certification of the ERP system as being validated:

- The validation master plan and all its revisions or supplements (if applicable) must be available, reviewed and approved.
- The different validation phases must be completed. All the documentation generated during these phases must be available, approved and correctly filed. This documentation must represent the current ERP system as used in daily operations at **…….**
- Controls and procedures required to maintain the ERP system in the validated state must be in place and approved and ready for application before going live with the ERP System.
- All test equipment's used during the qualification shall be calibrated and certified using standards traceable to the NPL, NIST or similar agency.
- All amendments and discrepancy shall be adequately resolved and approved by all individuals listed by title on the Qualification Completion and Approval

13.0 ACTIVITIES, DELIVERABLES AND RESPONSIBILITIES:

The following section details the deliverables that must be produced for this validation. Table1 below includes all the deliverables and a justification if the deliverable is not required for this project. Where the deliverable requirement will be met by inclusion within another deliverable this is also detailed.

Additional deliverables deemed necessary for this project are shown with the word "ADDITIONAL" included in the "Deliverable required" column. As far as possible the deliverables in Table 1 are listed in the sequence in which they will be developed.

TABLE 1 – REQUIRED DELIVERABLES FOR VALIDATED SYSTEMS:

Deliverable Required for Validated System	Deliverable Required (YES/ NO) and if NO a Justification	Primary Author	Approver(s)
Validation Master Plan	YES	Validation agency	Members of the ERP system validation approval team
User Requirement Specification	YES	Validation agency	Members of the ERP system validation approval team
Design Qualification (DQ)	YES	Supplier (ERP System Pvt. Ltd.)	Members of the ERP system validation approval team
IQ Protocol & Report	YES	Validation agency	Members of the ERP system validation approval team

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Deliverable Required for Validated System	Deliverable Required (YES/ NO) and if NO a Justification	Primary Author	Approver(s)
OQ Protocol& Report	YES	Validation agency	Members of the ERP system validation approval team
GxP and Part 11 Evaluation	YES	Validation agency	Members of the ERP system validation approval team
Risk Assessment	YES	Validation agency	Members of the ERP system validation approval team
SOP for Incident Management	YES	QA	Members of the ERP system validation approval team
SOP for Operational Change Control and Configuration Management	YES	IT Co-ordinator	Members of the ERP system validation approval team
SOP for Back Up & Restore	YES	IT Co-ordinator	Members of the ERP system validation approval team
SOP for Disaster Management and Business Continuity	YES	IT Coordinator	Members of the ERP system validation approval team
SOP for Security Management	YES	IT Co-ordinator	Members of the ERP system validation approval team
SOP for user procedure for ERP	YES	Concern Dept.	Members of the ERP system validation approval team
OQ Report	YES	Validation Agency	Members of the ERP system validation approval team
PQ Protocol & Report	YES	Validation Agency	Members of the ERP system validation approval team
Discrepancy Report	YES	Validation Agency	Members of the ERP system validation approval team
Training	YES	Supplier	Project Leader
List of Configuration Items	YES	IT Co-ordinator	Members of the ERP system validation approval team
Change Control	YES, the current site IT change control procedure will be used	N/A	N/A
Validation Summary Report	YES	Validation Agency	Members of the ERP system validation approval team
Certificate	YES	Validation Agency	Members of the ERP system validation approval team

Note: Any additional deliverables deemed necessary during the course of this project will be documented in a revision to this validation master plan or in the validation summary report.

Reference: Annexure-2 (Validation team member signing form)

14.0 REQUALIFICATION CRITERIA:

The re-qualification of the controlled system shall be carried out through change control procedure.

- The software is replaced / reinstalled / updated: or
- Any hardware component (critical) is replaced / reinstalled / updated: or
- Any regulatory requirements.

15.0 REVALIDATION CRITERIA:

The validated state of ERP system shall be checked periodically or after major changes to maintain the validation status during the entire life cycle of the system. Checking after major changes is done through revalidation. Revalidation proves that the ERP system remains in validated state as a whole.

Event driven revalidation is triggered through changes of hardware, software or accessories and system. Changes to validated systems must follow change procedure in accordance with the standard operating procedure. Every change shall follow the risk assessment process and criticality of that change is identified as minor or major. Based on that need for retesting of associated functions shall be determined. All those steps shall be documented as governed by this VMP.

16.0 ABBREVIATIONS

Abbreviation	Full form
GAMP	Good Automated Manufacturing Practices
GxP	Good ‘x’ Practice, where ‘x’ is one of: a. Clinical b. Distribution c. Laboratory d. Manufacturing e. Engineering
ERP	Enterprise Resource Planning
VMP	Validation Master Plan
DQ	Design Qualification
IQ	Installation Qualification
OQ	Operational Qualification
PQ	Performance Qualification

Abbreviation	Full form
NPL	National Physical Laboratories
NIST	National Institute of Standard and Technology
PIC/S	Pharmaceutical Inspection Co-operation/Scheme
URS	User Requirement Specifications
NA	Not Applicable
IT	Information Technology
PCS	Professional Consultancy Services
GMP	Good Manufacturing Practices
ERP	Enterprise Resource Planning
QC	Quality Control
QA	Quality Assurance
COTS	Commercial Off The Shelf Software
LIMS	Laboratory Information Management System
SCADA	Supervisory Control and Data Acquisition
DCS	Distributed Control System
BMS	Building Management System
PLC	Programmable Logic Controller
NA	Not applicable
RA	Risk Assessment
SOP	Standard Operating Procedure
ID	Identification
US FDA	United States Food and Drug Administration
CFR	Code of Federal Regulations
EU GMP	European Union's Good Manufacturing Practices
ALCOA	Attributable, Legible, Contemporaneous, Original, Accurate
VSR	Validation Summary Report
RTM	Requirement Traceability Matrix
VMP	Validation Master Plan
CAPA	Corrective and Preventive Action
RAP	Risk Assessment Protocol
RAR	Risk Assessment Report
IQP	Installation Qualification Protocol
IQR	Installation Qualification Report
OQP	Operational Qualification Protocol
OQR	Operational Qualification Report
PQP	Performance Qualification Protocol
PQR	Performance Qualification Report

17.0 ANNEXURE:

Annexure	Description
Annexure 1	ERP process inventory list
Annexure 2	Validation team member signing form

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Validation Master Plan for ERP System	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

18.0 TERMINOLOGIES:

Access security:
A protection mechanism that ensures system access only to authorized persons on their assigned access level.

Archiving:
The provision to ensure the long-term retention requirements for the type of data held and the expected life of the computerized system, system changes must provide for continued access to and retention of the raw data without integrity checks.

Audit trail:
For the purpose of computerized systems, audit trail means a secure, computer generated, time-stamped electronic record that allows reconstruction of the course of events relating to the creation, modification, and deletion of an electronic record. The data must be able to be interrogate, sorted by date, time, reason for change, person.

Back-up:
Provisions made for the recovery of data files or software, for restarting of processing, or for use of alternative computer equipment after a system failure or disaster.

Bug: A manifestation of an error in software (a fault).

Automated process:
A set of sequential activities in a production plant which is controlled by an automated system.

Automated system:
A system that automatically, without human intervention, controls or monitors a specific set of sequential activities; such as plant process, laboratory function, or data processing operation.

Critical components:
Components that affect the process parameters & thus the quality of product.

Modularity (Software):
The extent to which software is composed of discrete components such that as change to one component has minimal impact on other components.

Operating System:
A set of programs provided with a computer that function as the interface between the hardware and the application programs. Software that controls the execution of programs. An operating system may provide service, such as resource allocation, scheduling, Input/output control, and data management.

Utility Software:
Computer programs or routines designed perform some general support function required by other application software, by the operating system, or by system users.

I/O: Input and Output signals of the system.

NABL:
National Accreditation Board for Testing and Calibration laboratories according to ISO 17025.

Prospective validation:
Validation conducted prior to the distribution of either a new product, or product made under a revised manufacturing process, where the revisions may affect the product's characteristics.

Retrospective validation:
Validation of the process for a product already in distribution based upon accumulated production, testing and control data.

Validation:
Documented evidence that provide a high degree of assurance that a specific process will consistently produce a product meeting its predetermined specifications and quality attributes.

Validation protocol:
A written plan stating how validation will be conducted, including test parameters, product characteristics, production equipment, and decision points on what constitutes acceptable test results.

CSV:
Computer system validation checks the effectiveness and the efficiency with which the system is meeting the purpose for which it was designed.

User requirement specification (URS):
User Requirement Specification is a list of all requirements regarding the equipment. It defines the functions to be carried out, the data on which the system will operate and the operating environment.

GxP:
The first stage of whether a system requires a validation is to identify whether the system has a GxP impact.

Risk assessment (RA):
It is useful to a high level determination of the computerized system GxP impact identified to help support the decision processes for the level of validation and controls to be applied throughout the computer system lifecycle. This initial risk assessment should consider the impact to GMP and the complexity of the system.

User requirement specification (URS):
A URS is a document or set of documentation that describes the feature and behavior of a system or software application. It includes a variety of elements that attempts to define the intended functionality required by the customer to satisfy their different users.

In addition to specifying how the system should behave, the specification also defines at a high-level the main business processes that will be supported, what simplifying assumptions have been made and what key performance parameters will need to be met by system.

URS should include a description of the functional requirements, system requirements, technical requirements, constraints, assumptions and acceptance criteria.

Installation qualification (IQ):
Documented verification that all key aspects of hardware and software installation adhere to appropriate codes and approved design intentions and that the recommendations of the manufacture have been suitably considered.

Operational qualification (OQ):
Documented verification that the equipment-related system or subsystem operated as specified throughout representative or anticipated operating ranges.

Performance Qualification (PQ):
Documented verification that the equipment-related system or subsystem performed as intended to accordance with the manufacture and system developer.

Validation summary Report (VSR):
A Validation report must be prepared at the conclusion of the activities prescribed in the validation plan. Where there are deviations from the validation plan or unresolved incidents, these should be documented and justified where critical unresolved issues remain the computer system cannot be considered validated.

The validation report for a system must not be approved until all the relevant documents defined within its validation plan have been approved. Approval of the validation report marks the completion of the validation process.

The validation report must, therefore include a clear statement confirming whether or not the whole computer system is validated and authorized for use.

The concept of a validation summary report can be taken a step further in the form of validation certificate. This merely states that a computer system is validated, and it specifies a review date against this compliance status. While a validation certificate could be presented to a regulatory inspector as evidence of validation, we believe that this would prompt the inspector to request more detailed information. The effort to produce and maintain validating certificate must be carefully weighed

19.0 REFERENCE:

The publications listed below are referred while preparing this VMP. Each publication is the latest version. Latest guidelines shall be considered where ever applicable.

S.No.	Document Description
1.	GAMP-5, A Risk-Based approach to Compliant GxP Computerized Systems.
2.	US FDA 21 CFR Part11 (Rule for Electronic Records and signatures), [Title 21, Volume 1][Revised as of April 1, 2012]
3.	Eudralex Volume 4 GMP, Annexure-11 : Computerized Systems
4.	Guide to GMP for Medicinal Products-Annexure 11 for Computerized System Published by PIC/S.
5.	GAMP Good Practice Guide – A Risk-Based Approach to testing of GxP System , 2nd Edition, 2012
6.	MHRA GMP Data Integrity Definitions and Guidance for Industry, Jan.2015
7.	GAMP® Guide: Records and Data Integrity