## **Validation Plan (VP)**

**Project Title:** Computer System Validation of ERPNext for Pharmaceutical Operations  
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 **Date:** DD-MM-YYYY

### **1. Objective**

This Validation Plan defines the strategy, responsibilities, and activities required to validate the ERPNext application used in pharmaceutical operations. The goal is to ensure that ERPNext meets all regulatory and user requirements when configured for GxP processes like inventory, production, quality, and procurement.

### **2. Scope**

This plan applies to the ERPNext system instance configured for the pharmaceutical industry M/S………………... The validation scope includes:

* Inventory Management
* Production Planning & Execution
* Quality Management System
* Procurement & Supplier Qualification
* Document Management

### **3. GAMP 5 Category**

ERPNext is categorized as a **Category 4 - Configured Product** as per GAMP 5 guidelines because it is an open-source platform that can be configured to meet specific pharma requirements.

### **4. Validation Strategy**

A risk-based approach will be applied following the **V-model** lifecycle. Validation will include:

* User Requirements Specification (URS)
* Functional Specification (FS)
* Risk Assessment
* Traceability Matrix
* Installation Qualification (IQ)
* Operational Qualification (OQ)
* Performance Qualification (PQ)
* Final Validation Summary Report

### **5. Roles and Responsibilities**

| **Role** | **Responsibility** |
| --- | --- |
| Validation Lead | Planning, execution, and documentation |
| QA | Review & approval of validation documents |
| Business Owner | Approve URS and ensure business needs |
| IT Support | Support installation and issue handling |

### **6. Risk-Based Approach**

A qualitative risk assessment will be conducted to identify critical GxP functions. Based on risk, testing effort will be prioritized to ensure compliance without over-validation.

### **7. Assumptions**

* ERPNext will be hosted and accessed via a secure web interface.
* No custom code will be developed, only standard configuration.
* All documentation will be maintained in Google Docs/Sheets.
* JIRA will be used for test tracking and defect logging.

### **8. Deliverables**

| **Phase** | **Deliverable** |
| --- | --- |
| Planning | Validation Plan |
| Requirements | URS, Risk Assessment |
| Design | Functional Spec, Traceability Matrix |
| Testing | IQ, OQ, PQ Protocols and Execution |
| Issue Handling | Defect Log, Deviation Reports |
| Completion | Validation Summary Report |

### **9. Acceptance Criteria**

* All planned validation activities completed
* No open critical defects
* QA-approved deliverables
* Signed summary report

### **10. References**

* GAMP 5 Guide
* 21 CFR Part 11
* EU Annex 11
* Company CSV SOPs

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| **Name** | **Role** | **Signature** | **Date** |
| --- | --- | --- | --- |
| Dudekula Manila Saleem | CSV Trainee |  |  |
| [Insert QA Name] | Quality Assurance |  |  |
| [Insert Manager Name] | Business Owner |  |  |