SYSTEM REQUIREMENT SPECIFICATION

FOR

COMPUTER SYSTEM OF

WAREHOUSE

System Name	**Warehouse**
System ID	
Location	**STORE OFFICE**
Effective Date	

SYSTEM REQUIREMENT SPECIFICATION FOR COMPUTER SYSTEM OF WAREHOUSE

System Name: Warehouse **System ID:**

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1. PREPARATION AND APPROVALS:

The signature listed below indicates the preparation and approval of this system requirement specification. This approval is joint responsibility of listed functional areas.

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

DOCUMENT REVIEW AND APPROVAL (M/S ……..)
Sign / Date : _____ **Name** : _____ **Designation** : _____ **Engineering**
Sign / Date : _____ **Name** : _____ **Designation** : _____ **IT**
Sign / Date : _____ **Name** : _____ **Designation** : _____ **Warehouse**

DOCUMENT APPROVAL (M/S ……)
Sign / Date : _____ **Name** : _____ **Designation** : _____ **Quality Assurance**

2. OBJECTIVE:

The objective of the system requirement specification defines the requirements of hardware software, functions and documentation for the Computer System (Warehouse) installed at M/s. …….. This document will be cross-referenced with the relevant system specification to ensure that the system specifications have been met according to M/s. ……. requirements.

3. SCOPE

This document is applicable to validation of Hardware and Software of computer system installed at M/s. …….. Quality control department. This system requirement specification shall define the documentation, references and acceptance criteria to establish that the validation of Hardware and Software of Computer system after modification is installed in accordance with the guidelines laid down by the manufacturer of the system.

4. SYSTEM DESCRIPTION:

Computer system of Warehouse defines to the system is use for Analyzing Warehouse data. Perform an array of functions that may include receiving and processing incoming stock and materials, picking and filling orders from stock, packing and shipping orders, or managing, organizing and retrieving stock in the Warehouse. This system is also use to Mailing for document per pass, ERP (Enterprise resource planning) for management information system integrates areas. Control panel and other external device disable for this system to protect data and piracy and Data store within the system.

6. 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 system requirement specification activities. ➢ To prepare the system requirement specification in coordination with engineering, validation and quality assurance team. ➢ Comply with regulatory / Guidelines / Standards / validation plan requirements throughout the validation life cycle. ➢ To submit system requirement specification for approval.
Engineering (M/s. …….)	➢ To provide the necessary data for system requirement specification activities. ➢ To review system requirement specification.
IT (M/s. ……..)	➢ To provide the necessary data for system requirement specification activities. ➢ To review system requirement specification.
Quality Control (M/s. ……..)	➢ To provide the necessary data for system requirement specification activities. ➢ To review system requirement specification.
Quality Assurance (M/s. ……)	➢ To approve and authorized the system requirement specification.

7. 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 11 Electronic 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.

8. 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.

9. 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 Based system (WAREHOUSE) have been reviewed and found to be acceptable, sign the corresponding block in the qualification completion and approval form.

10. ACCEPTANCE CRITERIA:

- Installation completion as per manufacturer's recommendations & cGMP requirements.
- Installation of major components as per the design specifications.
- The supply of all necessary documentation from manufacturer.
- The system is operating as intended and is under state of control.
- Operational features meet system requirements and system specifications.

11. SYSTEM REQUIREMENTS:

11.1 Hardware Components:

S.No.	Name	Make/ Assemble By	Model No./Specification	Quantity
1.	Monitor	Acer	V206HQL	01
2.	CPU	Acer	Veriton-IC6404	01
3.	Keyboard	Acer	NA	01
4.	Mouse	Acer	NA	01
5.	UPS	Emerson Network System	20 kVA	01
6.	RAM	Acer	4 GB	01
7.	Processor	Intel	I5 2.70GHz	01
8.	Printer	HP	HP Laser Jet M1005 MFP	01

Communication Port

S.No.	Port Type	Quantity
1.	USB	2
2.	Ethernet	1

11.2 Software Components:

S.No.	Name	Version no.	Quantity
1.	Adobe Reader	18.011.20063	01
2.	Google Chrome	69.0.3497	01
4.	Mozilla Firefox	59.0	01
5.	Windows 10 Pro	1803	01
6.	SAP GUI for windows 7.30	7.30 Compilation 1	01
7.	WinRAR 5.20 (64-bit)	5.20.0	01

11.3 Capacity Requirement:

Processing Power	No more than 50% of the processing capacity of system components should be required to provide normal processing and display functionality with satisfactory performance.
Memory	No more than 50% of the installed physical memory in system components should be required to provide normal processing and display functionality.
Local Electronic Storage	No more than 50% of the installed hard disk capacity in PCS components should be consumed by installed software.

11.4 Power Utility:

S.No.	DESCRIPTION	SPECIFIED
1.	Computer System Power Supply	230 VAC

11.5 Environmental Condition:

S.No.	DESCRIPTION	TEMPERATURE	RELATIVE HUMIDITY
1.	Computer System Environmental Condition	NMT 25 °C	NA

11.6 Communication Link Between Server To Computer System:

S.No.	DESCRIPTION	Ping with	Pinged Ip
1.	Computer system	File Server	192.168.2.3

11.7 Window Security:

S.No.	DESCRIPTION	SPECIFIED
1.	Login to PC with blank User ID & Blank password.	Access Denied &Error message displayed.
2.	Login to PC with Correct User ID & Blank password.	Access Denied & Error message displayed.
3.	Login to PC with Correct User ID & incorrect password.	Access Denied & Error message displayed.
4.	Login to PC with Incorrect user ID and correct password.	Access Denied & Error message displayed.
5.	Login to PC with correct password.	Access granted

11.8 System Response Failure:

S.No.	DESCRIPTION	SPECIFIED
1.	CPU Failure	CPU should be off and monitor cannot be response.
2.	Monitor Failure	Monitor should be off and CPU should be on.
3.	UPS Failure	UPS should be off and CPU and Monitor cannot response.
4.	Communication failure between CPU and Monitor	Monitor should not be response.
5.	Communication failure with Local area network	Printing should be stop
6.	Power Failure	UPS supply connected with system to safe shutdown.

11.9 Electronic Data Security:

S.No.	DESCRIPTION	SPECIFIED
1.	Electronic Record Storage	All the electronic should be store in a correct manner and specified location.
2.	Electronic Data Storage Path Accessbility	Only authorised user shall be access the elecronic storage data.

11.10 Data Back Up:

S.No.	DESCRIPTION	SPECIFIED
1.	Access to Data Storage Path	System shall have specific Path and limited access for Data Storage

11.11 User Prevented From Alternating Date and Time:

S.No.	DESCRIPTION	SPECIFIED
1.	User Prevented From Alternating Date and Time	User cannot change or alter the date and time of system.

12. 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 production, engineering 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, IT, QC and QA will decide whether discrepancy is acceptable or not.
- If discrepancy is acceptable, provide conclusion and recommendation if any into respective column.

13. 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

14. ABBREVIATION:

Abbreviations	Description
GMP	Good Manufacturing Practices
CPU	Central Processing Unit
RA	Risk Assessment
SRS	System Requirement and Specification
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
UPS	Uninterruptible Power Supply
CS	Computer System
NMT	Not More Than