



Pharma Devils

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

RISK ASSESSMENT ANNEXURE-1 (BEFORE QUALIFICATION)

System Name: Warehouse

System ID:

Risk ID No.	Identified Risk	Impact	Severity	Probability	Risk Class	Probability of Detection	Risk Priority	Proposed Mitigation Action
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A. Unauthorized System Access

1.	Unauthorized person tries to log into system	Unauthorized persons may damage the system	High	Medium	1	Medium	High	<ul style="list-style-type: none"> System shall be password Protected. Shall be verified in Installation Qualification
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B. Power Failure								
1.	Power failure during operation	Data may be lost and system may get damaged which may lead to affect Product quality	High	Medium	1	Medium	High	<ul style="list-style-type: none"> ▪ UPS supply shall be connected with system for safely shutdown the system. ▪ Shall be verified in Operational Qualification

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C. Window Security								
1.	Unauthorized person tries to log into Window	Unauthorized persons may damage the window	High	Medium	1	Medium	High	<ul style="list-style-type: none"> Window shall be password Protected. Shall be verified in Operational Qualification

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D. Communication Failure PC and Local area network

1.	Communication fail between CPU and Monitor and Local area network	<p>1. Data may be losses and system operation control is lost.</p> <p>2. User cannot operate the operation.</p>	High	Medium	1	Medium	High	<ul style="list-style-type: none"> ▪ Monitor should display error message or monitor should not response. ▪ Printing command should not reached to printer. ▪ Shall be verified in Operational Qualification
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E. Hardware Failure								
1.	Failure of hardware (PC)	In case of hardware (PC) failure, all process shall be stopped.	High	Medium	1	Medium	High	<ul style="list-style-type: none"> ▪ Hardware accessories make should be standard and designed. ▪ Spare parts of hardware and accessories should be available and it will be one to one replaceable or AMC with vendor. ▪ Shall be verified in Operational Qualification

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F. Physical security of system								
1.	Unauthorized person tries to operate the system.	In case system not physical secure the electronic componets damage or loss	High	Medium	1	Medium	High	<ul style="list-style-type: none"> System shall be physically secure Shall be verified in Installation Qualification

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G. Improper Training and Procedure

1.	Untrained operator tries to operate the system	System may get damage or lose	High	Medium	1	Medium	High	<ul style="list-style-type: none"> ▪ System is password Protected. ▪ Only authorized persons access the system. ▪ Operator are trained for operation of system. ▪ Shall be verified in Operational Qualification
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2.	Operation SOP does not contain proper information	System may get damage or lose	Medium	Medium	2	Medium	Medium	<ul style="list-style-type: none">System operation SOP shall be review and verified for availability in IQ.Shall be verified in Operational Qualification

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H. Authorized System Access								
1	Authorized person tries to change the date and time	Ambiguity of data may arise	High	Medium	1	Medium	High	<ul style="list-style-type: none"> Date and time shall be password protected. Shall be verified in Operational Qualification
2.	Authorized person tries to access to data storage folder	Ambiguity of data may arise	High	Medium	1	Medium	High	<ul style="list-style-type: none"> System shall have specific Path and limited access for Data Storage. Shall be verified in Operational Qualification

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