RISK ASSESSMENT ANNEXURE-1 (BEFORE QUALIFICATION)

System Name: Stability-PC   **System ID:**

Risk ID No.	Identified Risk	Impact	Severity	Probability	Risk Class	Probability of Detection	Risk Priority	Proposed Mitigation Action
A. Unauthorized System Access								
1.	Unauthorized person tries to log into system	Unauthorized persons may damage the system	High	Medium	1	Medium	High	▪ System shall be password Protected. ▪ Shall be verified in Operational Qualification

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PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

RISK ASSESSMENT ANNEXURE-1 (BEFORE QUALIFICATION)

System Name: Stability-PC   **System ID:**

Risk ID No.	Identified Risk	Impact	Severity	Probability	Risk Class	Probability of Detection	Risk Priority	Proposed Mitigation Action
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	▪ UPS supply shall be conected with system for safely shutdown the system. ▪ Shall be verified in Operational Qualification

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RISK ASSESSMENT ANNEXURE-1 (BEFORE QUALIFICATION)

System Name: Stability-PC   **System ID:**

Risk ID No.	Identified Risk	Impact	Severity	Probability	Risk Class	Probability of Detection	Risk Priority	Proposed Mitigation Action
C. Window Security								
1.	Unauthorized person tries to log into Window	Unauthorized persons may damage the window	High	Medium	1	Medium	High	▪ Window shall be password Protected. ▪ Shall be verified in Operational Qualification

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RISK ASSESSMENT ANNEXURE-1 (BEFORE QUALIFICATION)

System Name: Stability-PC   **System ID:**

Risk ID No.	Identified Risk	Impact	Severity	Probability	Risk Class	Probability of Detection	Risk Priority	Proposed Mitigation Action
D. Communication Failure PC and Local area network								
1.	Communication fail between CPU and Monitor and Local area network	1. Data may be losses and system operation control is lost. 2. User cannot operate the operation.	High	Medium	1	Medium	High	▪ 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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PHARMA DEVILS
QUALITY ASSURANCE DEPARTMENT

RISK ASSESSMENT ANNEXURE-1 (BEFORE QUALIFICATION)

System Name: Stability-PC   **System ID:**

Risk ID No.	Identified Risk	Impact	Severity	Probability	Risk Class	Probability of Detection	Risk Priority	Proposed Mitigation Action
E. Hardware Failure								
1.	Failure of hardware (PC)	In case of hardware (PC) failure, all process shall be stopped.	High	Medium	1	Medium	High	▪ 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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RISK ASSESSMENT ANNEXURE-1 (BEFORE QUALIFICATION)

System Name: Stability-PC   **System ID:**

Risk ID No.	Identified Risk	Impact	Severity	Probability	Risk Class	Probability of Detection	Risk Priority	Proposed Mitigation Action
F. Physical security of system								
1.	Unauthorized person tries to operate system.	In case system not physical secure the electronic componets damage or loss	High	Medium	1	Medium	High	▪ System shall be physically secure ▪ Shall be verified in Installation Qualification

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RISK ASSESSMENT ANNEXURE-1 (BEFORE QUALIFICATION)

System Name: Stability-PC   **System ID:**

Risk ID No.	Identified Risk	Impact	Severity	Probability	Risk Class	Probability of Detection	Risk Priority	Proposed Mitigation Action
G. Improper Training and Procedure								
1.	Untrained operator tries to operate the system	System may get damage or lose	High	Medium	1	Medium	High	▪ 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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RISK ASSESSMENT ANNEXURE-1 (BEFORE QUALIFICATION)

System Name: Stability-PC   **System ID:**

Risk ID No.	Identified Risk	Impact	Severity	Probability	Risk Class	Probability of Detection	Risk Priority	Proposed Mitigation Action
2.	Operation SOP does not contain proper information	System may get damage or lose	Medium	Medium	2	Medium	Medium	▪ System operation SOP shall be review and verified for availability in IQ. ▪ Shall be verified in Operational Qualification

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RISK ASSESSMENT ANNEXURE-1 (BEFORE QUALIFICATION)

System Name: Stability-PC   **System ID:**

Risk ID No.	Identified Risk	Impact	Severity	Probability	Risk Class	Probability of Detection	Risk Priority	Proposed Mitigation Action
H. Audit Trial Failure								
1	Failure of Login, Logout and Login Fail entry into the report	May lead to Data integrity	High	Medium	1	Medium	High	▪ Failure of Login, Logout and Login Fail shall be update in the report ▪ Shall be verified in Operational Qualification
2.	Report Edition	May lead to Data integrity	High	Medium	1	Medium	High	▪ Users will not able to Edition in report ▪ Shall be verified in Operational Qualification

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RISK ASSESSMENT ANNEXURE-1 (BEFORE QUALIFICATION)

System Name: Stability-PC
System ID:

Risk ID No.	Identified Risk	Impact	Severity	Probability	Risk Class	Probability of Detection	Risk Priority	Proposed Mitigation Action
I. Authorized System Access								
1	Authorized person tries to change the date and time	Ambiguity of data may arise	High	Medium	1	Medium	High	▪ 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	▪ System shall have specific Path and limited access for Data Storage. ▪ Shall be verified in Operational Qualification

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