



# PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

## RISK ASSESSMENT ANNEXURE-1 (BEFORE QUALIFICATION)

**System Name:** GAS CHROMATOGRAPHY (PC)

**System ID:**

Risk ID No.	Identified Risk	Impact	Severity	Probability	Risk Class	Probability of Detection	Risk Priority	Proposed Mitigation Action
<b>A. Unauthorized System Access</b>								
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"> <li>System shall be password Protected.</li> <li>Shall be verified in Operational Qualification</li> </ul>

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<b>B. Power Failure</b>								
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"> <li>▪ UPS supply shall be connected with system for safely shutdown the system.</li> <li>▪ Shall be verified in Operational Qualification</li> </ul>

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<b>C. Window Security</b>								
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"> <li>Window shall be password Protected.</li> <li>Shall be verified in Operational Qualification</li> </ul>

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<b>D. Communication Failure PC and Local area network</b>								
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	<ul style="list-style-type: none"> <li>▪ Monitor should display error message or monitor should not response.</li> <li>▪ Printing command should not reached to printer.</li> <li>▪ Shall be verified in Operational Qualification</li> </ul>

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<b>E. Hardware Failure</b>								
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"><li>Hardware accessories make should be standard and designed.</li><li>Spare parts of hardware and accessories should be available and it will be one to one replaceable or AMC with vendor.</li><li>Shall be verified in Operational Qualification</li></ul>

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<b>F. Physical security of system</b>								
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"> <li>▪ System shall be physically secure</li> <li>▪ Shall be verified in Installation Qualification</li> </ul>

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<b>G. Improper Training and Procedure</b>								
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"> <li>▪ System is password Protected.</li> <li>▪ Only authorized persons access the system.</li> <li>▪ Operator are trained for operation of system.</li> <li>▪ Shall be verified in Operational Qualification</li> </ul>

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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"> <li>System operation SOP shall be review and verified for availability in IQ.</li> <li>Shall be verified in Operational Qualification</li> </ul>

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<b>H. Audit Trial Failure</b>								
1	Failure of Login, Logout and Login Fail entry into the report	May lead to Data integrity	High	Medium	1	Medium	High	<ul style="list-style-type: none"> <li>Failure of Login, Logout and Login Fail shall be update in the report</li> <li>Shall be verified in Operational Qualification</li> </ul>
2.	Report Edition	May lead to Data integrity	High	Medium	1	Medium	High	<ul style="list-style-type: none"> <li>Users will not able to Edition in report</li> <li>Shall be verified in Operational Qualification</li> </ul>

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<b>I. Authorized System Access</b>								
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"> <li>Date and time shall be password protected.</li> <li>Shall be verified in Operational Qualification</li> </ul>
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"> <li>System shall have specific Path and limited access for Data Storage.</li> <li>Shall be verified in Operational Qualification</li> </ul>

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